



# USER'S GUIDE

*Mark 5 Nuvo Family*  
**NUVO, NUVO 8 & NUVO 10**  
**OXYGEN CONCENTRATOR**

[Original language is English]



NUVO 8 shown for reference.



Federal Law (US) restricts this device to sale by, or on the order of, a licensed physician. This oxygen concentrator should be used only under the supervision of a licensed physician.



**DANGER: Do not smoke when using oxygen or when near this device.**

**CONTENTS**

**GLOSSARY OF SYMBOLS**

<b>GLOSSARY OF SYMBOLS</b>	1
<b>1. GENERAL SAFETY GUIDELINES</b>	2
1.1. Method for Waste Disposal	3
1.2. Method for Disposing of Device	3
<b>2. Description</b>	3
2.1. Front panel (Fig. 2. 1)	3
2.2. Rear panel (Fig. 2. 2)	3
<b>3. STARTING-UP / INSTALLATION</b>	3
3.1. Use in direct oxygen therapy	3
<b>4. CLEANING-MAINTENANCE</b>	4
4.1. Cleaning	4
4.2. Everyday disinfection	4
4.3. Maintenance	4
<b>5. USEFUL INFORMATION</b>	4
5.1. Accessories and spare parts	4
5.2. Materials in direct/indirect contact with patient	5
5.3. Operating principles	5
5.4. Alarms - Safety devices	5
5.5. Indicators	5
5.6. Expected Life	6
5.7. Technical characteristics	6
5.8. Standards	7
5.9. Preventative Maintenance	7
5.10. Troubleshooting	8
<b>6. EMC, Electromagnetic statements</b>	9

	: ON (Power Switched on)
	: OFF (Power Switched off)
	: Type B Device
	: Class II Protection
	: DO NOT EXPOSE TO OPEN FIRE
	: DO NOT USE OIL OR GREASE
	: Technical Information
	: Consult the accompanying documents
	: Keep in vertical position
	: Fragile - Handle with care
	: Oxygen concentration warning light
	<b>0413</b> Complies with the 93/42/EEC directive certified by the approved organization 0413.

## GENERAL SAFETY GUIDELINES

Only persons who have read and understood this entire manual should be allowed to operate the *device*.

**The WARNINGS below indicate a potentially hazardous situation. If conditions are not avoided a situation could occur that results in serious injury or death.**



- Oxygen is not a flammable gas, but it accelerates the combustion of materials. Do not use in explosive atmosphere. To avoid risk of fire and explosion the concentrator should be kept away from Flames, Heat sources, Incandescent sources, Smoking Materials, Matches, Oil, Grease, Solvents, Aerosols, etc. Do not allow oxygen to accumulate on upholstery or other fabric such as bedding or personal clothing. If concentrator is operating while not connected to patient, position cannula so that the gas flow is diluted in the ambient air.
- Improper patient connection to and use of the cannula may result in injury including strangulation. Avoid situations that might cause the cannula or hose to become entangled about the patients neck.
- Use of other accessories not described in this User's Guide are not recommended. Patient benefit may be diminished.
- No modification to the equipment is allowed. To do so may affect patient benefit.
- Contraindications; those who continue to smoke (because of the increased fire risk and the probability that the poorer prognosis by smoking will offset the treatment benefit).
- Device must have power to operate. In the event of power loss and for continued operation a backup source is recommended.
- DO NOT disassemble due to danger of electrical shock. Refer servicing to qualified service personnel.



**The CAUTIONS below indicate a potentially hazardous situation. If conditions are not avoided a situation could occur that results in property damage or minor injury or both.**



- Use the power cord provided, and check that the electrical characteristics of the power socket used match those indicated on the manufacturer's plate on the rear panel of the device.
- We recommend against the use of extension cords and adapters, as they are potential sources of sparks and fire.
- The *device* has an audible alarm to warn the user of problems. In order that the alarm may be heard, the maximum distance that the user can move away from it must be determined to suit the surrounding noise level.
- The *device* must only be used for oxygen therapy and only on a medical prescription. The indicated daily duration and flow must be followed, otherwise it may present a risk to the health of the patient.
- Do not use in a specifically magnetic environment (MRI, X-ray, etc.). May cause device malfunction.
- This unit may be equipped with a polarized plug. That is one blade wider than the other. If it does not fit into the outlet, reverse the plug. If it still does not fit, contact a qualified electrician. Do not defeat this safety feature.
- Note: Medical Device Regulations require users and service providers to report to the manufacturer any incident that could, if repeated, result in injury to any person.



## **CONFORMITY WITH IEC60601-1-2003**

(2ND EDITION)

“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, modifications 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 specifications, the manufacturer is not responsible in the event of an accident or non-performance.

This device complies with the requirements of the FDA Quality System Regulation and 93/42/EEC European directive but its operation may be affected by other devices being used near by, such as diathermy and high frequency electrosurgical equipment, mobile telephones, CB and other portable devices, microwave ovens, induction plates or even remote control toys or any other electromagnetic interferences which exceed the levels specified by the EN 60601-1-2 standard.

## **UNPACKING and PACKAGING**

The Oxygen Concentrator is packaged to protect the device from damage while being transported and stored. After the device is removed from the package, inspect for damage. If damage is detected, please contact your equipment provider. Operating environmental condition guidelines are discussed later in another section of this User's Guide.

## 1.1 METHOD FOR WASTE DISPOSAL

All waste from the device (Patient Circuit, Filters, Etc.) must be disposed of using methods appropriate to the civil authority of the location where disposed.

## 1.2 METHOD FOR DISPOSING OF THE DEVICE

This device has been supplied by an environmentally aware manufacturer. A majority of the parts in the device are recyclable.

Follow local governing ordinances and recycling plans regarding disposal of the device or components normally used in operation. Any accessories not original to the device must be disposed of in accordance with the individual product markings for disposal. Furthermore, as part of the marking directive 93/42/EEC, the serial number of the device disposed of must be sent to Nidek Medical if the unit has the **CE** marking.

## 2. DESCRIPTION

The device is intended to supply supplemental oxygen to persons requiring oxygen therapy. It is not intended to be life supporting or life sustaining. It produces an oxygen enriched product by concentrating the oxygen contained in room air. It can be used to administer oxygen with nasal cannulas or another type of device.

The device is easy to use, it has a power failure alarm and an operating fault alarm. A single flow adjustment knob allows:

- the device to be easily adjusted to the prescribed flow rate,
- the equipment supplier or medical staff to limit flows to a specific flow rate with a built in locking device.

Note: the performances described pertain to the use of the device with accessories recommended by Nidek Medical Products, Inc. Refer to section 5.

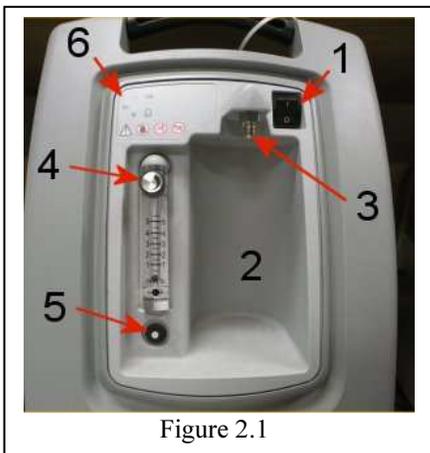


Figure 2.1

### 2.1. Front panel (Fig. 2.1)

- 1 - (I/O) On/Off Power Switch
- 2 - Humidifier (space reserved)
- 3 - Oxygen product outlet
- 4 - Flow adjustment knob (lpm)
- 5 - Circuit Breaker
- 6 - OCSI (Oxygen Concentration Status Indicator) Indicator Lights

### 2.2. Rear panel (Fig. 2.2)

- 7 - Cabinet Air Filter
- 8 - Manufacturer's Technical Label
- 9 - Power Cord

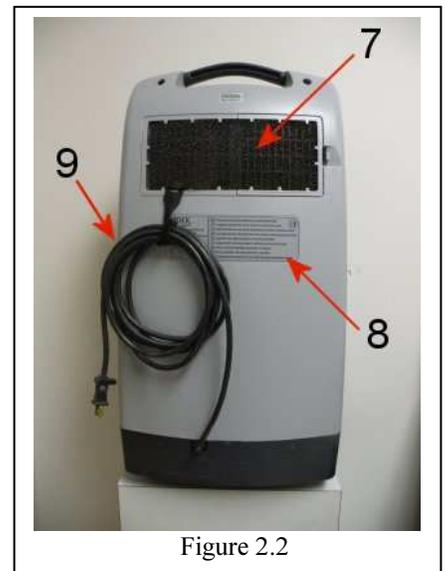


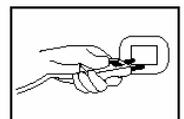
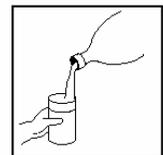
Figure 2.2

## 3. STARTING UP / INSTALLATION

### 3.1. Use in direct oxygen therapy

- Ensure that the switch I/O is in the "O" (OFF) position.
- If used with a humidifier:
  - Unscrew the flask and fill it with water up to the line (see humidifier instructions). Then screw the lid on the humidifier flask until there are no leaks.
  - Connect the oxygen tube to the humidifier outlet nozzle or to the concentrator outlet if a humidifier has not been prescribed. The tube between the cannula and the **device should be limited to 20 meters (60 feet) long**, in order to ensure that the oxygen flow rate remains within specification values.
  - Ensure that all of the parts are connected correctly so as to avoid leaks
- Plug the power cable into a power outlet of the correct voltage and frequency as defined on the manufacturer's technical label (8).
- Press the power switch (I/O) to the ON position (I). The green indicator will light when the oxygen concentration exceeds the set point (OCSI) or normal operating pressures.

**Note:** After turning the unit off, the user must wait 3-5 minutes before turning it back on. System pressure must dissipate before the unit will properly restart.



e. Turn the flow adjustment knob (4) to the prescribed value. This knob may have already been locked in the medically prescribed position. In this case, do not force it. Only the technician or medical personnel are authorized to release it.

**Note:** View the flowmeter from straight on for accurate settings.

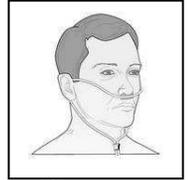
f. Check that the oxygen flows out of the administration device (nasal cannulas or other) by placing the orifice(s) on the surface of a glass of water. The flow should disturb the surface of the water.

g. Adjust the nasal cannula to suit your face.

**Note:** the required oxygen concentration is normally obtained within five minutes after the unit is started.

h. At the end of the treatment, press the **I/O** Switch to place it in the **O** (OFF) position to stop the device. The oxygen enriched air flow continues for approximately one minute after the device is stopped.

**Note: For the equipment supplier or medical staff:** The flow adjustment knob may be locked to limit it to a specific predetermined value.



## 4. CLEANING - MAINTENANCE

### 4.1. Cleaning

Only the outside of the *device* is to be cleaned, with a soft, dry cloth or, if necessary, a damp sponge, then thoroughly dried with wipes and an alcohol based solution. Acetone, solvents or any other inflammable products **must not be used**. Do not use abrasive powders.

The removable cabinet air filter (7) must be cleaned in warm water and household detergent weekly or after approximately 100 hours of use. More frequent cleaning is recommended in dusty environments. Dry before reinstalling.

### 4.2. Daily disinfection

Because there is a final product filter inside the device, daily disinfection concerns only the external oxygen therapy accessories: humidifier, nasal cannulas (refer to the respective instructions for use).

**The device must be switched off when alcohol based solutions are used.**

**a. The following minimum guidelines must be observed:**

Humidifier: (If prescribed by a physician)

Clean according to the manufacturer's instructions. If no instructions are provided, do the following:

*Daily:*

- Empty the water from the humidifier.
- Rinse the humidifier flask under running water.
- Fill humidifier up to the mark with distilled water.

*Regularly:*

- Disinfect the humidifier parts by immersing them in a disinfectant solution (In general, we recommend using a solution of 1 part vinegar diluted with 10 parts water).
- Rinse and dry.
- Check that the humidifier lid seal is in good condition.

Oxygen tubing and nasal cannula: Follow the manufacturer's instructions.

**b. For each new patient:**

Follow the instructions from the humidifier manufacturer. The *device* must be cleaned and disinfected as per the above instructions. The cabinet air filter (7) should be washed or replaced. The entire oxygen administration circuit (oxygen therapy nasal cannulas, etc.) must be changed.

### 4.3. Maintenance

**No special maintenance needs to be carried out by the patient.** Your equipment supplier performs periodic maintenance operations to assure continued reliable service from the *device*.

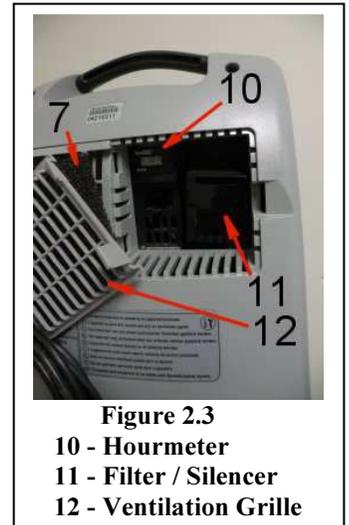
## 5. USEFUL INFORMATION

### 5.1. Accessories and spare parts

The accessories used with the *device* must:

- be oxygen compatible,
- be biocompatible,
- comply with the general requirements of the FDA Quality System Regulation or the 93/42/EEC European Directive as appropriate.

The connectors, tubes, nasal cannulas, or masks must be designed for oxygen therapy usage.



**Figure 2.3**

**10 - Hourmeter**

**11 - Filter / Silencer**

**12 - Ventilation Grille**

The accessories with a **Nidek Medical** part number reference, or included in the set of accessories supplied with the device, comply with these requirements. Contact your equipment supplier to obtain these accessories.

**Note:** The use of certain administration accessories which are not specified for use with this concentrator may reduce its performance and void the manufacturer's responsibility (ISO 8359).

#### AVAILABLE ACCESSORIES IF PRESCRIBED BY A PHYSICIAN

- |                                   |                              |                               |
|-----------------------------------|------------------------------|-------------------------------|
| • Humidifier:                     | Part Ref. 9012-8774 (1-5LPM) | Part Ref. 9251-8774 (2-10LPM) |
| • Cannula with 2 m (7 ft) tubing: | Part Ref. 9012-8780 (1-5LPM) | Part Ref. 9251-8780 (2-10LPM) |
| • Extension Tubing 7.7 m (25ft):  | Part Ref. 9012-8781          |                               |
| • Tubing Adapter:                 | Part Ref. 9012-8783          |                               |

The items listed above are available from Nidek Medical Products, Inc.

#### 5.2. Materials in direct or indirect contact with the patient

- |                              |   |
|------------------------------|---|
| • Concentrator enclosure     | ABS/Polycarbonate                           |
| • Mains cable                | PVC   |
| • Cabinet air filter         | Polyester                                   |
| • <b>I/O</b> (On/Off) switch | Nylon                                       |
| • Casters                    | Nylon                                       |
| • Flow adjustment knob       | ABS   |
| • Oxygen product outlet      | SS or Brass                                 |
| • Printed labels             | Polycarbonate                               |
| • Pipe/Tubing                | Aluminum, PVC, polyurethane and/or silicone |
| • Humidifier                 | Polypropylene                               |
| • Filter                     | Polypropylene                               |

#### 5.3. Operating principle

The compressor sends filtered ambient air to an electronic valving system, which allows compressed air to pass to the column in production. The columns contain a molecular sieve, whose function is to adsorb the nitrogen and thus allow oxygen to pass. The oxygen enriched product is then directed to a pressure reducing valve through the adjustable flow meter to the oxygen outlet fitting. During this time, the column which is being "regenerated" is connected to the ambient air and flow of oxygen enriched product is passed through it (from the column "in production"). In this way, when one column is in production, the other is in a nitrogen desorption or "regeneration" phase. The oxygen enriched product finally passes through a bacterial filter located prior to the oxygen outlet fitting.

#### 5.4. Alarms - Safety devices

##### 5.4.1. Alarms

- **No voltage detection:** In the event of a loss of mains power, an intermittent audible alarm is activated and the green light turns off. Test alarm by actuating the **I/O** (On/Off) switch when the power cord is not plugged into the wall receptacle.
- **Oxygen concentration:** The oxygen monitor measures the concentration and activates an audible and visual alarm if it falls below the alarm set point percentage.
- **Blocked cannula:** If supplied, the device Oxygen Concentrator has a No Flow Alarm. This device provides a continuous audible alarm and red light in the event the Oxygen Flow to patient becomes blocked.
- **Maintenance of the device alarms:** No special maintenance is required. The alarm set-point is factory set and the setting cannot be adjusted. All OCSI models are set at  $84\% \pm 2\%$ . The equipment supplier checks that the device is still operating correctly when the routine checks are performed on the *device*.

##### 5.4.2. Safety devices

###### Compressor motor:

- Thermal safety is ensured by a thermal switch situated in the stator winding ( $145 \pm 5^\circ \text{C}$ ).

**Electrical protection of the *device*:**

- A 5A circuit breaker is incorporated into the front cabinet of all 230V models
- A 10A circuit breaker is incorporated into the front cabinet of all 115V models
- Class II devices with insulated castings (EN60601-1 standard)

**Safety valve:**

- This is fitted on the compressor outlet and is calibrated to 3.4 bar (50 psig).

## 5.5 INDICATORS

### Oxygen Concentration Status Monitor

The oxygen concentration monitor (6) is an electronic module capable of checking the effective oxygen concentration supplied by the concentrator. The oxygen monitor measures the concentration and activates an audible and visual alarm if it falls below the alarm set point percentage. When the *device* is started, the indicator lights located on the front panel operate as described below.

#### 5.5.1. Green indicator

The green indicator light indicates that power is applied to the concentrator and that it is ready to provide oxygen enriched air to the patient. To be lighted, it is necessary that the concentrator power plug be inserted into the wall outlet, that the **I/O** (On/Off) switch be actuated and that the oxygen concentration has reached the alarm set-point. On initial power up it will flash green until the unit has reached normal operating conditions.

#### 5.5.2. Red indicator

The red indicator light is used to warn the patient of a system fault. The two events that can cause the red indicator to be lighted are low oxygen concentration or blockage of the cannula or hose (if equipped). The low oxygen concentration warning will light when the oxygen concentration level falls below the set point. When the red indicator light is lighted for 15 minutes ( $\pm 2$  minutes), a continuous audible alarm is activated. Call the equipment supplier to service the device.

### 5.6. Expected Service Life

- The expected service life of this device is 15,000 hrs or 3 years.

### 5.7. Technical characteristics

#### Physical Properties

- Dimensions: L x W x H: 394 x 396 x 706 mm (15.5 x 15.6x 27.8 in.)
- Caster diameter: 50 mm (2.0 in.)
- Tilt angle (transport with humidifier fitted): 70°
- Weight: 24 kg /54 lbs
- Noise level within ISO 8359 guidelines

#### Flow values:

- Continuously Adjustable Flowmeter: 1 to 5 lpm, 2 to 8 lpm, or 2 to 10 lpm (depending on model)

#### Accuracy of flow supplied:

- In compliance with the ISO 8359 standard, the flow supplied is equal to the flow set on the flowmeter, accurate to within  $\pm 10\%$  or 200 ml/min, whichever is the larger of the two.

#### Average oxygen content:

- 2 lpm:  $> 90\%$  (Values at 21°C and at one atmosphere pressure)
  - 5 lpm, 8 lpm, 10 lpm: from 87% to 95.5% (Values at 21°C and at one atmosphere pressure)
  - Minimum recommended flow: 1 lpm on Nuvo unit, 2 lpm on Nuvo 8 & 10 units
  - Maximum recommended flow: 5 lpm on Nuvo, 8 lpm on Nuvo 8 and 10 lpm on Nuvo 10 model specific
- The variation of the maximum recommended flow does not exceed  $\pm 10\%$  of the indicated value when a back pressure of 6.9 kPa (1 psig) is applied to the output of the device. The maximum outlet pressure is: 7psig for Nuvo 5 lpm, 15 psig for Nuvo 8 lpm, and 17 psig for Nuvo 10 lpm.

**Electrical power supply:**

Model	5lpm 115V	5LPM 230V	8LPM 115V	8LPM 230V	10LPM 115V	10LPM 230V
Frequency	60Hz	50/60Hz	60Hz	50Hz	60Hz	50Hz
Average Power	410 Watts	420 Watts	500 Watts	490 Watts	700 Watts	600 Watts
Protection Class	Class II	Class II				
Mains Protection	10A	5A	10A	5A	10A	5A

**Filters:**

- At the rear of the device: a cabinet air filter (7).
- At the compressor input: an inlet air filter (11), behind cabinet air filter.
- Before the oxygen outlet: a final product filter < 0.3 µm. (technician only)

**Air circulation:**

- One tubeaxial fan cools the compressor compartment and additional fans cool the heat exchanger coil on 8 & 10 lpm models.

**Environmental limit conditions:**

The performance of the device (especially the oxygen concentration) are quoted at 21°C (70°F) and one atmosphere. They may change with temperature and altitude. For further information, please consult the service manual. See Section 5.9.

- The device must be stored, transported and used in the vertical position only.
- Ambient temperature of between 10°C and 40°C (50°F to 105°F) operation.
- Storage temperature from -20°C to 60°C (0°F to 140°F).
- Relative humidity of between 15 % and 95 % operation and storage, both non-condensing.
- Altitude(21°C): Up to 1500m (5000ft) without degradation;

Consult your equipment provider for further information regarding 1500 m to 4000m (5000 to 13000ft).

Complies with EN60601-1:2003 standard; spilling of a glass of water.

**5. 8. Standards - Nuvo, Nuvo 8 & Nuvo 10**

ISO 8359:1996 Oxygen concentrators for medical use.

EN60601-1[UL60601-1:2003]

CAN/CSA-C22.2No.601.1-M90 w/A1&A2: Electrical Safety- Medical Devices.

EN60601-1-2:2001 Electromagnetic Compatibility

**Nuvo Serial No.** \_\_\_\_\_

**Date first used:** \_\_\_\_\_

**Maintained by:** \_\_\_\_\_

**Your equipment provider address:** \_\_\_\_\_

**Telephone :** \_\_\_\_\_

**5.9. PREVENTIVE MAINTENANCE:**

- Wash cabinet filter (7) weekly.
- Inspect inlet air filter (11) at each patient visit. Replace filter annually, or more often depending on environment.
- Check oxygen concentration every 15,000 hours or 3 years to verify the continuing OCSI function.

The manufacturer’s instructions for the preventive maintenance of the devices are defined in the service manual, part ref: 2010-2329 NUVO Family Service Manual. Check with your service provider for any updates to recommended schedules.

The work must be carried out by suitably trained technicians certified by the manufacturer. Use original spare parts only (see section 5.8 Maintenance). Upon request, the supplier can provide circuit diagrams, spare parts lists, technical details or any other information of use to qualified technical personnel for parts of the device which are designated as being the manufacturer’s responsibility or by the manufacturer as repairable.

Medical Device Regulations require users and service providers to report to the manufacturer any incident that could, if repeated, result in injury to any person.

## 5. 10. Troubleshooting.

Observations	Possible Causes	Solutions
The <b>I-O</b> (ON/OFF) button is in the “ <b>I</b> ” (ON) position but the device does not operate.	Power cable (9) is not correctly plugged into the wall outlet.	Check the cable connection.
Capacitor is not charged Internal electrical fault.	Capacitor is not charged Internal electrical fault.	Check the circuit breaker (5) on the front of the unit; Reset if necessary.
Capacitor is not charged Internal electrical fault.	Capacitor is not charged Internal electrical fault.	Contact your equipment supplier.
The alarm test does not work. See IV 4.1.	Capacitor is not charged Internal electrical fault.	Plug unit in for 10 minutes and retest Contact your equipment supplier.
The <b>I-O</b> (ON/OFF) button is in the “ <b>I</b> ” (ON) position, the compressor is operating and there is a flow but the green light is not lighted.	Faulty indicator.	Contact your equipment supplier.
The <b>I-O</b> (ON/OFF) button is in the “ <b>I</b> ” (ON) position but there is no flow. The audible alarm sounds continuously.	Pneumatic connection broken or other pressure problem.	Stop the device by pressing the <b>I-O</b> (ON/OFF) button and contact your equipment supplier.
The <b>I-O</b> (ON/OFF) button is in the “ <b>I</b> ” (ON) position, the compressor is operating and there is a flow but the audible alarm sounds continuously.	Internal electrical fault. Pneumatic circuit fault or low purity.	Stop the device and contact your equipment supplier.
The compressor stops in mid-cycle, then starts again after a few minutes.	Compressor thermal safety device has been activated. Dirty Filters. Fan is not working	Stop the device and wait for it to cool down. Clean cabinet filter. Restart. If the device does not start, contact your equipment supplier.
The oxygen enriched air flow is interrupted at the nasal cannula outlet.	Tube disconnected or humidifier cap is not tight.	Check that tubing connections are se-cure and that the humidifier is sealed.
The flow at the nasal cannula outlet is irregular.	Cannula tubing is kinked or restricted.	Straighten the tubing; contact your equipment supplier if damaged.

### Maintenance Items

Cabinet Air Filter: Part Ref: 9250-1025; Wash weekly; Replace as needed.

Inlet Air Filter: Part Ref: 9250-1180; Inspect at each patient visit; Replace annually.

Please record all maintenance activity in the Maintenance Log found in the service manual and online at [www.nidekmedical.com](http://www.nidekmedical.com) under the 'Maintenance Log' tab.



## 6. EMC, Electromagnetic Statements

### Appendix A: EMC Information

**Important:** Failure to follow these guidelines listed may result in increased emissions and/or decreased immunity of the subject device.

- Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
- The use of Accessories, transducers, and cables other than those specified by the manufacturer, may result in increased Emissions or decreased immunity of the device.
- The device should not be used adjacent to or stacked with other equipment and that adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- Use on Nidek Replacement electrical parts.

#### Guidance and Manufacturer's Declaration – Electromagnetic Emissions

**This device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.**

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3.2	Class B	
Voltage Fluctuations /Flicker Emissions	Complies	

#### Guidance and Manufacturer's Declaration - Electromagnetic Immunity

**This device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment**

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV Air	Complies	Floors should be wood, concrete, or ceramic tile. floors are covered with synthetic material, the relative humidity should be at least 30%.
Conducted RFIEC 61000- 4-6	3 Vrms 150 kHz to 80 Hz	Complies	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level ( 3 V/m ) in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the distance calculated from the equation applicable to the frequency of the transmitter. $d = 1.2 \sqrt{P}$ (80-800MHz) P=Transmitter power level in watts $d = 2.3 \sqrt{P}$ (800MHz-2.5GHz) d=distance in meters
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	Complies	
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 2 kV for power supply lines ± 1 kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of the typical location in a typical commercial or hospital environment
Voltage Dips, short interruptions and voltage variations on power supply input line. IEC 61000-4-8	<5% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycles	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continuous operation during power mains interruption, it is recommended that the device
	40% $U_T$ (60% dip in $U_T$ ) for 5 cycles	Complies	
	70% $U_T$ (30% dip in $U_T$ ) for 25 cycles	Complies	
	<5% $U_T$ (>95% dip in $U_T$ ) for 5 seconds	Complies	
<b>Note:</b> $U_T$ is the a.c. mains voltage prior to the application of the test levels			







**Nidek Medical Products, Inc.**  
3949 Valley East Industrial Drive  
Birmingham, Alabama 35217 U.S.A.  
Tel: 205-856-7200 Fax: 205-856-0533

**EU Representative**  
mdi Europa GmbH  
Langenhagener Str. 71  
30855 Hannover-Langenhagen  
Germany  
Tel: +49-511-39-08 95 30  
Fax: +49-511-39-08 95 39  
info@mdi-europa.com  
www.mdi-europa.com