USER'S GUIDE

Mark 5 Nuvo(OCSI)

Lite 3

OXYGEN CONCENTRATOR

[Original language is English]

WARNING

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

CE **0413** Complies with the 93/42/EEC directive certified by the approved organization no 0413.

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

Contents

GLOSSARY OF SYMBOLS

I : ON (power switched on)

O : OFF (power switched off)

: Type B device

: Class II protection

: Do not expose to open flames

: Do not use oil or grease

: Technical information

: Consult the accompanying documents

: Keep in the vertical position

: Fragile - handle with care

: Oxygen concentration warning light

GENERAL SAFETY GUIDELINES

Only persons who have read and understood this entire manual should be allowed to operate the *MARK 5 Nuvo Lite3*

.

The WARNINGS below indicate a potential 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.
- 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 ***Mark 5 Nuvo Lite3*** 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 ***Mark 5 Nuvo Lite3*** 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 (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.

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, defibrillators, short wave therapy 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.

1. UNPACKING and PACKAGING

The Oxygen Concentrator is packaged to protect the device from damage while being transported and stored. Check for damage to the packaging. After 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 Circut, Filters, Etc.) must be disposed of using methods appropriate to the civil authority of the location where disposed.

1.2 METHOD FOR DISPOSING OF 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 ***Mark 5 Nuvo Lite3*** is intended to supply supplemental oxygen to persons requiring low flow oxygen therapy. It is not intended to be life supporting or life sustaining. It produces 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 ***Mark 5 Nuvo Lite3*** is easy to use.
The single flow adjustment knob allows:

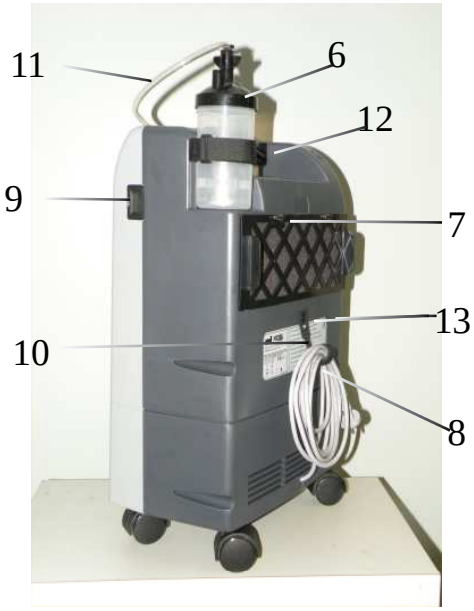
- The device to be easily adjusted to the prescribed flow rate,
- The equipment supplier or medical staff to limit flows to a specific flow rate with a built-in locking device.

It has a power failure alarm and an operating fault alarm.

Note: the performances described pertain to the use of the ***Mark 5 Nuvo Lite3*** with the accessories recommended by Nidek Medical Products, Inc. Refer to section 5.

2.1. Front panel (Fig. 2.1)

1 - I/O (ON/OFF) Switch
2 - Indicator Lights
3 - Oxygen product outlet
4 - Flow adjustment knob (l/min.)
5 - Circuit Breaker



2.2. Rear panel (Fig. 2.2)

6 - Humidifier
7 - Filter
8 - Power Cord
9 - Elapsed Time Meter
10 - Technical Label
11 - Humidifier Tube
12 - Humidifier Bottle Attachment Strap
13 - Power Cord Retainer

3. STARTING UP / INSTALLATION

3.1. Use in direct oxygen therapy

a. Ensure that the switch (Item1 in Fig.2.1) is in the O (OFF) position.

b. For use without Humidifier Bottle connect the cannula directly to the concentrator oxygen product outlet (Item 3 in Fig 2.1). Simply slide the cannula over the oxygen outlet (Fig 3.1).

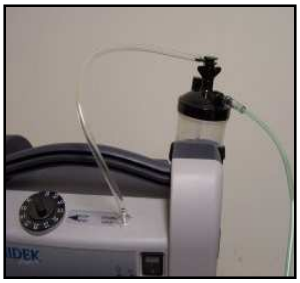
c. If a Humidifier Bottle is prescribed: Unscrew the lid from the bottle and fill with water, per the humidifier bottle manufacturer's recommendation. Re-attach the lid to the bottle and connect to the oxygen concentrator. Place the bottle on the concentrator and secure with the attachment straps as indicated in (Fig.2.2). Connect the clear plastic tube supplied to the Humidifier Bottle by use of the DISS fitting. Connect the other end of the tube to the oxygen outlet (Item 3 in Fig 2.1). Connect the cannula to the outlet on the Humidifier Lid (Fig. 3.2).

NOTE: The tube between the cannula and the *Mark 5 Nuvo Lite3* should be limited to 20 meters (60 feet) long.

d. Ensure that all of the parts are connected correctly to avoid leaks.

No Humidifier Bottle. This illustration shows the Cannula attached directly to the oxygen product outlet connection on the concentrator.

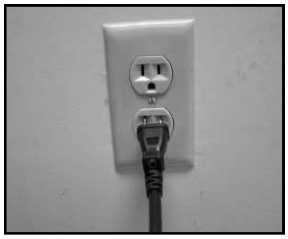
(Fig. 3.1)



This illustration shows the Humidifier Bottle in place. A tube is attached to the DISS fitting on the bottle lid and to the oxygen product outlet connection. The cannula is attached to the outlet on the bottle lid.

(Fig.3.2)

e. Plug the power cable into a power outlet (Fig. 3.3) of the correct voltage and frequency as defined on the manufacturer's technical label (Fig 2.2).




115V (Fig 3.3) 230V

f. Press the power switch **(I/O)** to the ON position **(I)**. The green indicator light flashes until concentration is achieved.

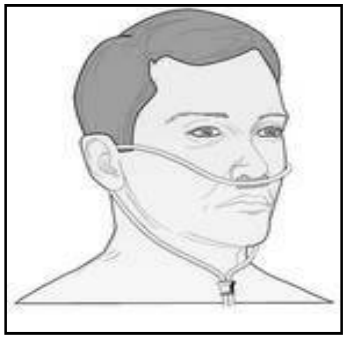
Note: the required oxygen concentration is normally obtained within five minutes after the unit is started.

g. Turn the flow adjustment knob (Item 4 Fig. 2.1) 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.

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

h. Check the oxygen flow out of the administration device (nasal cannula or other) by placing it near the surface of a glass of water. The flow should disturb the surface of the water.

i. Adjust the nasal cannula to suit your face, see (Fig. 3.4).



(Fig. 3.4)

3.2 Turning off device

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.

4. CLEANING - MAINTENANCE

4.1. Cleaning

Only the outside of the ***Mark 5 Nuvo Lite3*** is to be cleaned. Use a soft dry cloth, a damp sponge or wipes with alcohol based solution. The cabinet must then be thoroughly dried. Acetone, solvents or any other inflammable products **must not be used**. Do not use abrasive powders.

The removable cabinet air filter (Item 2 Fig.4.1) must be cleaned in warm water and household detergent weekly or after approximately 100 hours of use. Dry before reinstalling. More frequent cleaning is recommended in dusty environments.

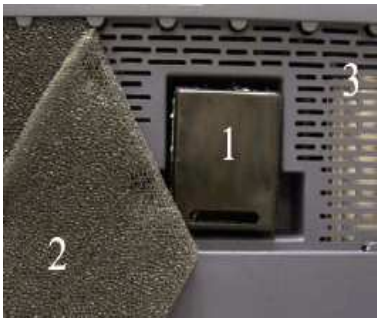


Fig. 4.1

1. Filter / Silencer
2. Cabinet filter
3. Ventilation grill
Note: Shown with grate removed

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 and disconnected from its power source 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 water per the manufacturer's recommendations.

Regularly
- Disinfect the humidifier parts by immersing them in a disinfection 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 ***Mark 5 Nuvo Lite3*** must be cleaned and disinfected as per the above instructions. The cabinet air filter should be washed or replaced. The entire oxygen administration circuit (oxygen therapy nasal cannula, 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 ***Mark 5 Nuvo Lite3***.

5. USEFUL INFORMATION

5.1. Accessories and spare parts

The accessories used with the ***Mark 5 Nuvo Lite3*** must:
- be oxygen compatible.
- be biocompatible.
- comply with the requirements of the FDA Quality System Regulations or the 93/42/EEC European Directive as appropriate.

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

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:	**Ref: 9012-8774**
Cannula with 2 m (7 ft) tubing:	**Ref: 9012-8780**
Extension Tubing 7.7 m (25ft):	**Ref: 9012-8781**
Tubing Adapter:	**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 casing	ABS
Power Cord	PVC
Cabinet Air Filter	Polyester
I/O (On/Off) switch	Nylon
Casters	Nylon
Flow adjustment knob	ABS
Oxygen product outlet	Aluminum
Printed labels	Polycarbonate
Pipe/Tubing	Aluminium,PVC, polyurethane or silicone
Humidifier	Polypropylene
Humidifier tube	PVC
Filter	Polypropylene

5.3. Operating principle

The compressor sends filtered room air to a solenoid valve, 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 through a pressure reducing valve to the adjustable flow valve and continuing to the oxygen product 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 final product filter located prior to the oxygen outlet fitting.

5.4. Alarms - Safety devices - Indications

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 outlet.

- **Process fault**

In the case of a process fault, a visible and audible alarm is activated (continuous red light or lighted alarm and audible alarm).

- **Oxygen Concentration**

If the oxygen concentration level falls below the required range the red light comes on and the green light goes out. After a 15 minute delay the audible alarm will sound.

- **Blocked Cannula**

If the oxygen flow is blocked within the cannula and remains so for 5 seconds the red indicator in addition to the green indicator will be illuminated. Also, an audible alarm will sound.

5.4.2. Safety devices

- **Compressor motor**

Thermal safety is ensured by a thermal switch situated in the motor winding (145 ± 5 °C).

- **Electrical protection**

A 5A circuit breaker is incorporated into the front cabinet of all models.

Class II devices with insulated casings (EN60601-1 standard)

- **Safety valve**

This is fitted on the compressor outlet and is calibrated to 2.7 bar (40 psig).

5.4.3 Indicators

- The green indicator light (Fig.5.1) indicates that power is applied to the device. When first turned on the indicator will flash until correct oxygen concentration is achieved. At that time the green indicator will remain illuminated and the device is ready to provide oxygen enriched air to the patient.

5.4.3 Indicators (continued)

- The red indicator warns of a process fault. One event that can cause the red indicator to be illuminated is low oxygen concentration. The low oxygen concentration red indicator will light when oxygen concentration falls below a predetermined set point. Another event that will cause the red indicator to light is a blocked cannula. In this case the green indicator and red indicator will be illuminated simultaneously.

5. 5. OCSI (oxygen concentration status indication module) **function**

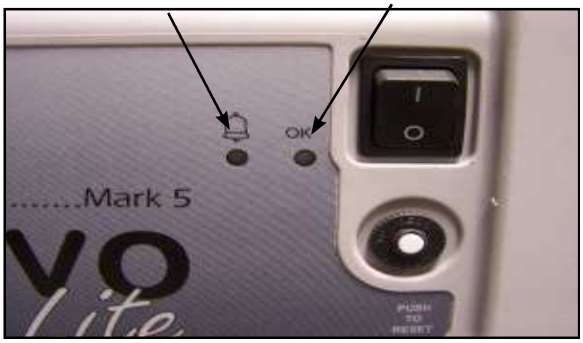
5.5.1. Operating principle

The oxygen monitor (Item 2 Fig 2.1) is an electronic module capable of checking the effective oxygen concentration supplied by the ***Mark 5 Nuvo Lite3*** concentrator.

The oxygen monitor measures the concentration and activates an audible and visual alarm if it falls below the alarm set point percentage.

(Refer to Section 5.4 for information on the operation of the indicators and alarms for the OCSI function)

Red Indicator Green Indicator



(Fig. 5.1)

5.5.4 Maintenance of the Device Alarms

No special maintenance is required. The alarm set-point is factory set and the setting cannot be adjusted. All models are set at 84%.

The equipment supplier verifies that the device is still operating correctly when the routine checks are performed.

5.6. Technical characteristics

Dimensions: L x W x H: 36x23x58.5 cm (14 x 9 x 23 in.)
Caster diameter: 3.8 cm (1.5 in.).
Tilt angle (transport with humidifier fitted) 30°.
Weight: 14.5 kg. (32 lbs) varies by model.
Noise level conforms to ISO 8359 Standards.

Flow values

8 position flow valve 0.125-3 liters/minute.
(Some models may have other values.)

Accuracy of flow supplied

In compliance with the ISO 8359 standard. The flow supplied is equal to the selected flow, accurate to within ± 10 % or 200 ml/min, whichever is the larger.

Oxygen Concentration

- at 2 l/min: >90%.
- at 3 l/min: 90%. (+6.5%/-3%)

(Values at 21°C and at one atmosphere pressure).

Maximum flow: 3 l/min.
The variation of the maximum flow does not exceed ± 10 % of the indicated value when a back pressure of 7 kPa (1 psig) is applied to the output of the device. The maximum outlet pressure is 50 kPa (7 psig).

Electrical power supply:

Rating:	230V 50Hz
Average Power:	180 W(avg)
Protection Class:	Class II
Mains Protection:	5A

Filters:
At the rear of the device: a cabinet air filter.
At the compressor input: an inlet air filter, 5 µm, located behind the cabinet air filter.
Before the oxygen outlet: a final product filter, < 0.3 µm. (technician only).

Air circulation
A tubeaxial fan cools the compressor compartment.

Environmental limit conditions
The performances 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 maintenance manual Ref # 2010-8405.

- The device must be stored, transported and used in the vertical position only.
- Ambient temperature of between 5°C and 40°C (40°F to 104°F) operation.
- Storage temperature from -20°C to 60°C (-4°F to 140°F).
- Relative humidity of between 15% and 95% operation and storage, both non-condensing.
- Altitude(21°C): Up to 2,286m (7,500ft) without degradation; Consult your equipment provider for further information regarding 2,286m to 4000m (7500 to 13000 ft)
- Complies with EN60601-1 standard; spilling a glass of water.

5.7. Standards

ISO 8359:1996 Oxygen concentrators for medical use.
EN 60601-1[UL60601-1:2003],CAN/CSA-C22.2 No.601.1-M90 w/A1&A2: Electrical Safety- Medical Devices.
EN60601-1-2:2001 Electromagnetic Compatibility

Mark 5 Nuvo Lite3 **Serial No. _____**
_____

Date first used : _____

Maintained by: _____
_____

Your distributor: _____

Address : _____
_____

Telephone : _____

PREVENTIVE MAINTENANCE

a. Wash cabinet filter weekly.
b. Inspect inlet air filter at each patient visit. Replace filter every 2 years, or more often depending on environment.
c. Check oxygen concentration every 15,000 hours or 3 years of operation to verify the continuing OCSI function.

The manufacturer's instructions for the **preventive maintenance** of the devices are defined in the maintenance manual. Check with your service provider for any updates to recommended schedules. The work must be carried out by suitably trained technicians.

Use original spare parts only (see Pg. 10)

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.

5.8. Troubleshooting.

Observations	Possible Causes	Solutions
The **I/O** (ON/OFF) button is in the **"I"** (ON) position but the device does not operate. The audible alarm sounds intermittently.	Power cord is not correctly plugged into the wall outlet. Power failure.	Check the cable connection. Check the circuit breaker (5) on the front of the unit; Reset if necessary.
Red light remains lighted.	Oxygen concentration is too low.	Contact your equipment supplier.
The alarm test does not work. See 5.4.1.	Capacitor is not charged Internal electrical fault.	Backup capacitor has discharged operate unit for approximately 10 minutes and retest Contact your equipment supplier.
The compressor operates and the **I/O** (ON/OFF) button is in the **"I"** (ON) position but the green indicator is not lighted.	Faulty indicator.	Contact your equipment supplier.
The **I/O** (ON/OFF) button is in the **"I"** (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 **I/O** (ON/OFF) button and contact your equipment supplier.
The **I/O** (ON/OFF) button is in the **"I"** (ON) position, the compressor is operating and there is a flow but the audible alarm sounds continuously.	Internal electrical fault. Pneumatic circuit fault.	Stop the device and contact your equipment supplier.
The compressor stops in mid-cycle, then starts again after a few minutes.	Dirty Filters, blockage Fan is not working.	Clean cabinet filter. Restart. Clear blockage. Restart Reset circuit breaker. 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 secure and that the humidifier is sealed.
The flow at the nasal cannula outlet is irregular.	Cannula tubing is restricted.	Straighten the tubing; contact your equipment supplier if damaged.

Maintenance Items

Cabinet Air Filter:	Ref: 8400-1025;	Wash weekly; Replace as needed.
Inlet Air Filter:	Ref: 8400-1180;	Inspect at each patient visit; Replace every 2 years.
Humidifier Tube:	Ref: 8400-8409;	Wash in warm water; Replace as needed.

Please record all maintenance activity on the Maintenance Log found in the Service Manual or online at www.nidekmedical.com under the 'Maintenance Log' tab.

NOTES

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

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