NIDEK Medical

USER'S GUIDE

Mark 5 Nuvo

M5C5

OXYGEN CONCENTRATOR

[Original language is English]

WARNING

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

: ON (power switched on)

: 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.

GENERAL SAFETY GUIDELINES

Only persons who have read and understood this entire manual should be allowed to operate the *MARK 5 Nuvo [M5C5]*.

USE OF OXYGEN

Oxygen is not a flammable gas, but it accelerates the combustion of materials. To avoid all risks of fire, the ***MARK 5 Nuvo [M5C5]*** should be kept away from all flames, incandescent sources and sources of heat (cigarettes), as well as any combustible products such as oil, grease, solvents, aerosols, etc.

Do not use in an explosive atmosphere.

Avoid letting oxygen accumulate on an upholstered seat or other fabrics. If the concentrator is operating while not supplying oxygen to a patient, position it so that the gas flow is diluted in the ambient air.

Place the device in a ventilated area free from smoke and atmospheric pollution (rear filter unobstructed).

The ***MARK 5 Nuvo [M5C5]*** must only be used for oxygen therapy and only on 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 such as (MRI, X-ray, etc.)

USE AND MAINTENANCE OF THE DEVICE

Do not open the device while in operation: risk of electrical shock.

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 machine.

We recommend against the use of extension cords or adapters, as they are potential sources of sparks and fire.

The ***MARK 5 Nuvo [M5C5]*** 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.

CONFORMITY WITH IEC60601-1 (§ 6.8.2 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, modifications or repairs have been performed by persons authorized by the party in question,

• The electrical installation of the corresponding premises complies with local electrical codes. (e.g. IEC / NEC).

• The 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 but its operation may be affected by other devices being used near by, such as diathermy and high frequency electro-surgical equipment, defibrillators, short wave therapy equipment, mobile telephones, CB and other portable devices, microwave ovens, television, induction plates or even remote control toys or any other electromagnetic interferences which exceed the levels specified by the EN 60601-1-2 standard.

I. DESCRIPTION

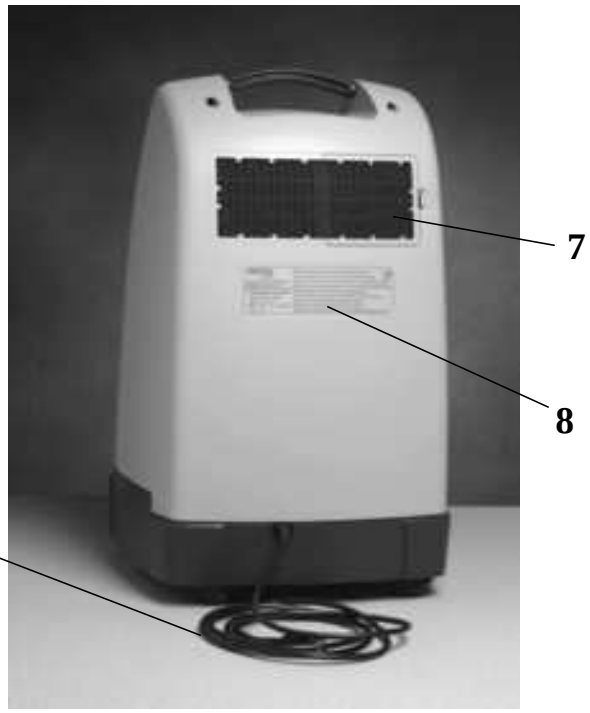
The ***MARK 5 Nuvo [M5C5]*** is intended to supply supplemental oxygen to persons requiring low flow oxygen therapy. It is not intended to be life supporting or life sustaining. It produces oxygen enriched product by concentrating the oxygen contained in room air. It can be used either to administer oxygen with nasal cannulas or another probe or mask type of device.

The ***MARK 5 Nuvo [M5C5]*** 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 [M5C5]* with the accessories recommended by Nidek Medical Products, Inc.

I. 1. Front panel (Fig. I. 1)

1 - **I/0** (ON/OFF) Switch
2 - Humidifier (space reserved)
3 - Oxygen product outlet
4 - Flow adjustment knob (l/min.)
5 - Circuit Breaker
6 - Indicator Lights



I. 2. Rear panel (Fig. I. 2)

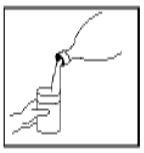
7 - Cabinet Dust Filter
8 - Technical Label
9 - Power Cord

II. STARTING UP / INSTALLATION

II. 1. Use in direct oxygen therapy

a - Ensure that the switch (1) is in the **0**/(OFF) position.

b - If used with a humidifier:

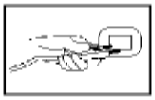


Unscrew the flask and fill it with water up to the line (see the humidifier instructions). Then screw the humidifier flask onto its lid until there are no leaks.

c - 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 ***MARK 5 Nuvo [M5C5]*** **should be limited to 60 feet (20 meters) long**, in order to ensure that the oxygen flow rate remains within specification values.

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

e - Plug the power cable into a power outlet of the correct voltage and frequency as defined on the manufacturer's technical label(8).



f - Press the power switch **(I/0)** to the ON position **(I)**. The red indicator will light and the audible alarm will sound for a few seconds until system pressure rises to the accepted level.

g - 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 in the horizontal plane for accurate settings.

h - 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.

i - Adjust the nasal cannula to suit your face.

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

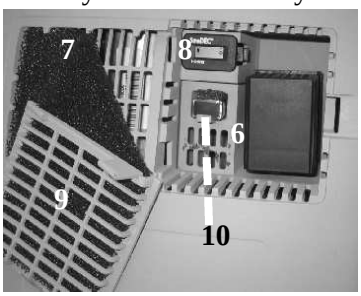
At the end of the treatment, press the **(I/0)** switch to place it in the **(0)** [OFF] position to stop the device. The oxygen enriched air flow continues for approximately 1 minute after the device is stopped.

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

III. CLEANING - MAINTENANCE

III.1. Cleaning

Only the outside of the ***MARK 5 Nuvo [M5C5]*** 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 dust filter (7) must be cleaned weekly in warm water and household detergent or after approximately 100 hours of use. More frequent cleaning is recommended in dusty enviroments. Dry before reinstalling.



6 Filter / Silencer
7 Cabinet Dust filter
8 Hour Meter
9 Ventilation Grille
10 Battery

III.2. Everyday disinfection

Due to the presence of the final product filter inside the device, everyday disinfection concerns only the external oxygen therapy accessories: humidifier, probes, 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 ***MARK 5 Nuvo [M5C5]*** must be cleaned and disinfected as per the above instructions. The cabinet dust filter should be washed or replaced. The entire oxygen administration circuit (oxygen therapy nasal cannulas, etc.) must be changed.

III.3. Maintenance

No special maintenance needs to be carried out by the patient. The equipment supplier performs periodic maintenance operations to assure continued reliable service from the ***MARK 5 Nuvo [M5C5]***.

IV. USEFUL INFORMATION

IV.1. Accessories and spare parts

The accessories used with the ***MARK 5 Nuvo [M5C5]*** must:
• be oxygen compatible,
• be biocompatible,
• comply with the general requirements of the FDA Quality System Regulation.

The connectors, tubes and nasal cannulas must be designed and approved 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 dealer 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.

AVAILABLE ACCESSORIES
IF PRESCRIBED BY A PHYSICIAN

Humidifier:	P/N	9012-8774
Cannula with 2 m (7 ft) tubing:	P/N	9012-8780
Extension Tubing 7.7 m (25ft):	P/N	9012-8781
Tubing Adapter:	P/N	9012-8783

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

IV.2. Materials in direct or indirect contact with the patient

Concentrator casing	Polycarbonate
Mains cable	PVC
Dust filter	Polyester
ON/OFF switch	Nylon
Casters	Nylon
Flow adjustment knob	ABS
Gas outlet	Brass
Printed labels	Polycarbonate
Pipe / Tubing	Aluminium, PVC,polyurethane or silicone
Humidifier	Polypropylene
Filter	Polypropylene

IV.3. Operating Principle

The compressor sends filtered room air to a rotary distribution valve, which allows compressed air to pass to the column in production. The columns contain a molecular sieve that function 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.

IV.4. Alarms - Safety devices

IV.4.1 Alarm

• **No voltage detection:**

In the event of a loss of mains power, a continuous audible alarm is activated. Test alarm by activating **I/0 [On/Off]** switch with power cable unplugged from wall receptable.

• **Process fault**:

In the case of a process fault, a visible and audible alarm is activated (continuous red light and audible alarm, see p. 7).

IV.4. 2. Safety devices

• **Compressor motor**:

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

• **Ambient air valve:**

In the case of a negative pressure in the molecular sieve columns, this valve allows ambient air to enter.

• Electrical protection of the ***MARK 5 Nuvo [M5C5]***

A 5A circuit breaker is incorporated into the front cabinet of all 230V models. A 10 A circuit breaker is included with 115V 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).

IV. 5. Indicator Light Function

IV. 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 receptacle and that the ON/OFF (**I/0**) switch be actuated.

IV. 5.2 Red Indicator

The red indicator light is utilized to warn the patient of a system fault. The two events that can cause the red indicator to be lighted are abnormal system pressure and loss of mains power. The abnormal system pressure warning will light when product pressure falls below approximately 4 psig or above approximately 18 psig. The loss of power indicator will light when mains power is interrupted or the power cord is not plugged into the wall receptacle.

IV. 5.3. Maintenance of the system alarms:

• No special maintenance is required.

• The equipment supplier checks that the unit is still operating correctly when the routine checks are performed on the ***MARK 5 Nuvo [M5C5]***.

IV. 6. Technical characteristics

Dimensions: L x W x H: 394 x 396 x 706 mm (15.5 x 15.6 x 27.8 in.)
Caster diameter: 38 mm (1.5 in.).
Tilt angle (transport with humidifier fitted): 70°.
Weight: 25-28 kg. (50 - 55 lbs -varies with model)
Noise level: < 48 dBA

Flow values:

Continuously Adjustable Flowmeter: 0 to 5 liters/minute. (Some models may have other values)

Accuracy of flow supplied:

The flow supplied is equal to the flow set on the flowmeter, accurate to within ± 10 % or 200 ml/min, whichever is the larger of the two.

Average oxygen content:

• at 2 l/min: 93%.
• at 4 l/min: 93%.
• at 5 l/min: 90%.
(Values at 21°C and at one atmosphere pressure).

Max. recommended flow: 5 l/min.
The variation of the maximum recommended 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:

	115 V Units	230 V Units
Frequency:	60Hz	50/60Hz
Average Power:	410 W	420 W
Protection Class:	ClassII	Class II
Mains Protection:	10A	5A

Filters:
At the rear of the device: a cabinet dust filter.
At the compressor input: an inlet air filter, behind 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.
• The device must be stored, transported and used in the vertical position only.
• Ambient temperature of between 5°C and 40 °C (40°F and 100 °F) (operation).
• Storage temperature range -20 °C to 60°C. (0°F to140°F).
• Relative humidity of between 15 % and 95 % operation and less than 95% storage, both non-condensing.
• Altitude(21°C): Up to 1500 m (5000 ft) without degradation;
Consult your equipment provider for further information regarding 1500 m to 4000 m (5000 to 13000 ft).
• IPX1: Complies with EN60601-1 standard; spilling of a glass of water.

IV. 7. Standards

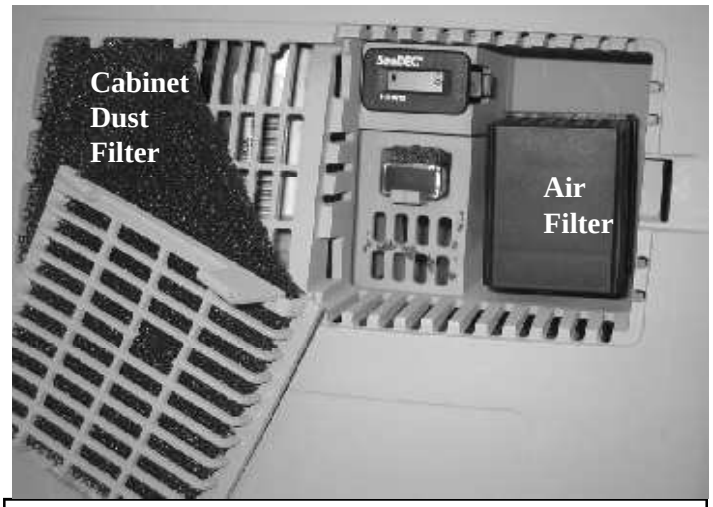
EN 60601-1[UL60601-1:2003],CAN/CSA-C22.2 No.601.1-M90 w/A1&A2: Electrical Safety- Medical Devices.
EN60601-1-2:2000 Electromagnetic Compatibility

IV. 8. Method for disposing of waste

All waste from the ***MARK 5 Nuvo [M5C5]*** (patient circuit, filter, etc.) must be disposed of using the methods appropriate to the civil authority of the location where disposed.

IV. 9. Method for disposing of the device

In order to preserve the environment, the concentrator must only be disposed of using the appropriate methods. All materials of construction are recyclable.



MARK 5 Nuvo [M5C5] **Serial No. _____**

Date first used: _____
_____

Maintained by: _____
_____

Your distributor: _____

Address : _____
_____

Telephone : _____

PREVENTIVE MAINTENANCE:

a. Wash cabinet dust filter weekly.
b. Inspect inlet air filter at each patient visit.
Replace filter annually, or more often depending on environment.
c. Check oxygen concentration every 5,000 hours or one year.

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 the recommended schedules.

The work must be carried out by suitably trained technicians certified by the manufacturer.

Use original spare parts only (see Pg. 7).

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

IV. 10. Troubleshooting.

Observations	Possible Causes	Solutions
The I-O (ON/OFF) button is in the ON position but the device does not operate. The continuous alarm sounds.	Power cable is not correctly plugged in. Power failure.	Check the cable connection. Check the circuit breaker on the front of the unit under the flowmeter.
Red light remains lighted.	Product pressure is too low or too high.	Contact your equipment supplier.
The alarm test does not work. See IV. 4.1	Faulty 9 V Battery Internal electrical fault.	Replace battery Contact your equipment supplier.
The compressor operates and the I-O (ON/OFF) button is in the ON position but the green light is not lit.	Faulty indicator.	Contact your equipment supplier.
The I-O (ON/OFF) button is ON and the compressor is operating 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 ON, the compressor is operating, 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.	Compressor thermal safety device has been activated. Fan is not working. Dirty Filters.	Stop the device and wait for it to cool down. Clean cabinet filter. Restart. Reset the circuit breaker. Contact your equipment supplier. 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 not tight.	Check that tubing connections are secure and that the tubing is not kinked.
The flow at the nasal cannula outlet is irregular.	Cannula tubing is kinked.	Straighten the tubing ; contact your equipment supplier if damaged.

Maintenance Items

Cabinet Dust Filter - Part Ref: 9250-1025; Wash weekly; Replace as needed.
Inlet Air Filter - Part Ref: 9250-1180; Inspect at each patient visit; Replace annually.
Battery, 9Volt - Part Ref: 7206-0027; Replace annually or sooner if needed.

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

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