

# NIDEK

*Medical*

## USER'S GUIDE

### Mark 5 Nuvo(OCSI)

### M5C5

## OXYGEN CONCENTRATOR

[Original language is English]



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.

**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.**

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### GLOSSARY OF SYMBOLS

- |  |  |
|--|--|
|  : ON (power switched on)       |  : Do not use oil or grease           |
|  : Off (power switched off)     |  : Technical information              |
|  : Type B device                |  : Consult the accompanying documents |
|  : Class II protection          |  : Keep in the vertical position      |
|  : Do not expose to open flames |  : 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 [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 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.)

### 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 and the 93/42/EEC European directive 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, 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.

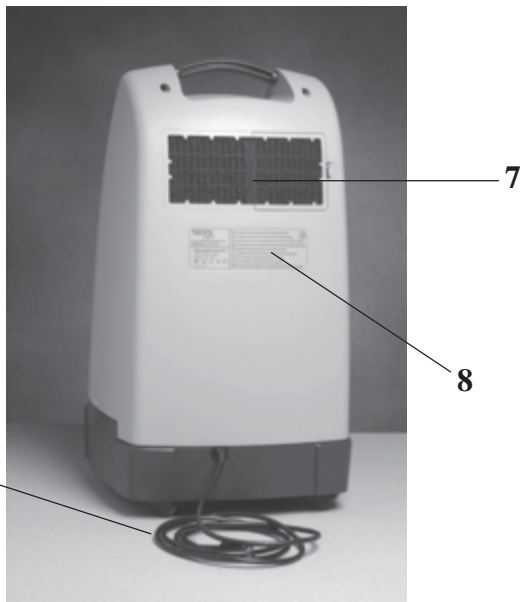
It has a power failure alarm and an operating fault alarm.

**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/O) On/Off Power Switch
- 2 - Humidifier (space reserved)
- 3 - Oxygen enriched air outlet
- 4 - Flow adjustment knob (l/min)
- 5 - Circuit Breaker
- 6 - OCSI (Oxygen Concentration Status Indicator) Indicator Lights



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

- 7 - Cabinet Air Filter
- 8 - Manufacturer's 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:

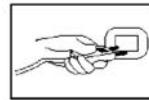


Unscrew the flask and fill it with water up to the line (see humidifier instructions). Then screw the lid on the humidifier flask until there are no leaks.

- 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 **20 meters (60 feet) 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/O**) to the ON position (**I**). The green indicator will light when the oxygen concentration exceeds the set point.

- 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.

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

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

### For the equipment supplier or medical staff:

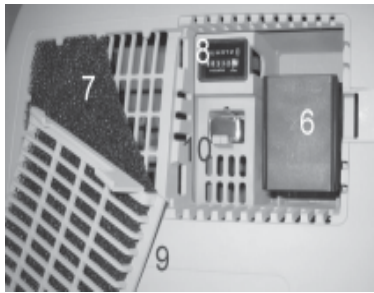
The flow adjustment knob may be locked to limit it to a specific predetermined value.

### 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 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



- 6 Filter / Silencer
- 7 Cabinet Air Filter
- 8 Hour Meter
- 9 Ventilation Grille
- 10 Battery

#### III.2. Daily disinfection

Because there is a bacterial filter inside the device, daily 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)

*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 water containing a small amount of chlorine bleach).
- 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:

The humidifier must be sterilized if possible or changed. The **MARK 5 Nuvo [M5C5]** must be cleaned and disinfected as per the above instructions. The bacterial filter inside the device should be changed. The cabinet air filter may be changed as well. 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. Your 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 or the 93/42/EEC European Directive as appropriate.

The connectors, tubes, nasal cannulas, probes 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 dealer to obtain these accessories.

**Remark:** 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:	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 items listed above are available from  
Nidek Medical Products, Inc.

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

Concentrator casing .....	Polycarbonate
Mains cable .....	PVC
Cabinet Air Filter .....	Polyester
I/O (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 ambient air to a rotary distribution 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 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. Alarms

- No voltage detection:

In the event of a loss of mains power, a continuous 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.

- 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, see p. 7).

#### IV.4.2. Safety devices

- Compressor motor:

Thermal safety is ensured by a thermal switch situated in the stator winding ( $145 \pm 5$  °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.

- Safety valve:

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

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

### IV.5. OCSI (oxygen concentration status indication module) function

#### IV.5.1. Operating principle

The Oxygen Monitor (6) is an electronic module capable of checking the effective oxygen concentration supplied by the *MARK 5 Nuvo [M5C5]* 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 *MARK 5 Nuvo [M5C5]* is started, the indicator lights operate as follows:

#### IV.5.2. 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

#### IV.5.3. 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 and loss of mains power. The low oxygen concentration warning will light when the oxygen concentration set point level is not reached. 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.

#### IV.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. Models operating at 50 Hz are set at 83% and 60 Hz models are set at 85%.

- The equipment supplier checks that the device 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: 23-25 kg. (50 - 55 lbs)

Noise level < 47 dBA (to ISO 8359)

#### Flow values:

Continuously Adjustable Flowmeter: 0 to 5 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 flow set on the flowmeter, accurate to within  $\pm 10\%$  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).

Maximum recommended flow: 5 l/min.

The variation of the maximum recommended flow does not exceed  $\pm 10\%$  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:

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

### Filters:

At the rear of the device: a cabinet air filter.  
At the compressor input: a filter cartridge, behind cabinet air filter.  
Before the oxygen outlet: a bacterial filter < 0.3  $\mu\text{m}$ . (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 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): Upto 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; no particular protection. Spilling of a glass of water.


## **IV. 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.  
EN60601-1-2:2000 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 used.

## **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. Furthermore, as part of the marking (directive 93/42/EEC), the serial number of the device disposed of must be sent to the **Nidek Medical** technical service department if the unit has the  marking.

**MARK 5 Nuvo [M5C5] Serial No.** \_\_\_\_\_

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

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

**Your distributor:** \_\_\_\_\_

**Address :** \_\_\_\_\_

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

### **PREVENTIVE MAINTENANCE:**

- Wash cabinet filter weekly
- Replace air inlet filter annually
- Check oxygen concentration every 2 years to verify the continuing OCSI function.

The manufacturer's instructions for the **preventive maintenance** of the devices are defined in the maintenance manual and any updates to it must be followed.

The work must be carried out by suitably trained technicians.

**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.

## IV. 10. Troubleshooting.

Observations	Possible Causes	Solutions
The <b>I-0</b> (ON/OFF) button is in the " <b>I</b> " (ON) position but the device does not operate. The audible alarm sounds continuously.	Power cable (9) 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 IV 4.1.	Faulty 9 Volt battery. Internal electrical fault.	Replace battery. Contact your equipment supplier.
The compressor operates and the <b>I-0</b> (ON/OFF) button is in the " <b>I</b> " (ON) position but the green indicator is not lighted.	Faulty indicator.	Contact your equipment supplier.
The <b>I-0</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-0</b> (ON/OFF) button and contact your equipment supplier.
The <b>I-0</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.	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. 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 kinked or restricted.	Straighten the tubing; contact your equipment supplier if damaged.



### Maintenance Items

Cabinet Air Filter: Part Ref: 9250-1025; Replace annually, Clean every week.

Inlet Air Filter: Part Ref: 9250-1028; Replace annually, more often in dusty environment.

Battery, 9 Volt: Part Ref: 7206-0027; Replace annually or sooner if needed.



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