



**User's Guide
Mark 5 Nuvo
M5C5**

**Oxygen Concentrator
Manufactured by:
Nidek Medical Products, Inc.
BIRMINGHAM, ALABAMA, USA**



Federal Law (US) restricts this device to sale by, or on the order of, a licensed physician. Read and understand this entire manual before using this device.

TABLE OF CONTENTS

IMPORTANT SAFETY GUIDELINES	1	ACCESSORIES AND SPARE PARTS	2
DESCRIPTION / PURPOSE OF USE	1	ALARMS AND SAFETY DEVICES	3
START UP / INSTALLATION	2	SPECIFICATIONS	3
CLEANING / MAINTENANCE	2	TROUBLESHOOTING AND SYMBOLS	3

IMPORTANT SAFETY GUIDELINES

- If you are experiencing any signs of discomfort consult your Equipment Provider or your physician immediately.
- The unit should only be used for oxygen therapy and by medical prescription. The prescribed daily duration and flow rate must be followed, otherwise it may present a risk to the health of the patient.
- Do not leave unit on or unattended if not in use by the patient.
- Do not use extension cords or adapters.
- Do not smoke, or allow others to smoke near the unit while in use.
- Do not use in a magnetic environment such as MRI, X-ray, etc.
- Do not remove the covers of the unit.
- Do not place unit where the intake filter ventilation could be obstructed or blocked.
- Oxygen is not a flammable gas, but accelerates the combustion of materials. To avoid all risks of fire, the unit must be kept away from all flames, incandescent sources and sources of heat, as well as any combustible products such as oil, grease, solvents, aerosols, etc.
- 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.

GLOSSARY OF SYMBOLS

- | | | | | | |
|--|------------------------------|--|----------------------------|--|-------------------------------|
| | ATTENTION | | DO NOT GREASE | | CLASS II DEVICE |
| | DO NOT EXPOSE TO OPEN FLAMES | | TYPE B DEVICE | | TECHNICAL INFORMATION |
| | DO NOT SMOKE | | FRAGILE – HANDLE WITH CARE | | KEEP IN THE VERTICAL POSITION |

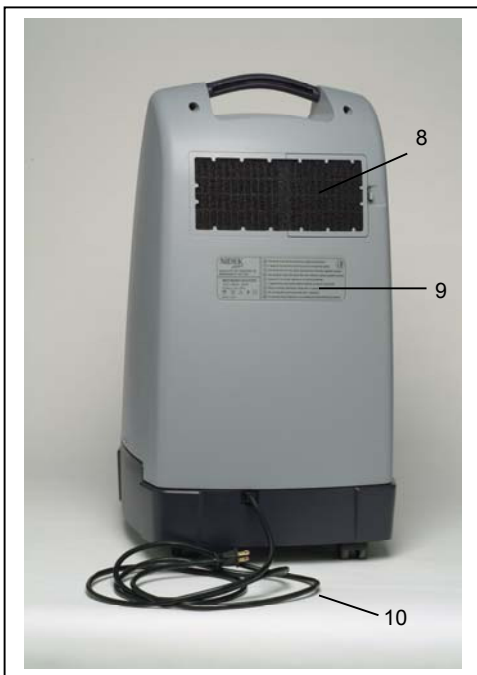
DESCRIPTION / PURPOSE OF USE

The Mark5 Nuvo M5C5 is intended solely for medical use in oxygen therapy programs under the supervision of a physician. This device is available by prescription only and is not intended to support or sustain life. It produces oxygen enriched product by concentrating the oxygen contained in room air. The prescribed daily duration and flow rate must be followed, otherwise it may present a risk to the patient's health.



Front Panel Illustration

1. Power Switch
2. Oxygen Outlet
3. Humidifier (space reserved)
4. Flow Adjustment Knob (l/min)
On Flowmeter
5. Circuit Breaker
6. Indicator Lights
7. Symbols



Rear Panel Illustration

8. External Cabinet Filter
9. Technical Label
10. Power Cord

START UP / INSTALLATION

1. Ensure that the Power Switch (1) is in the (0) Off position.
2. Position unit where the External Cabinet Filter (8) is not obstructed.
3. Plug the Power Cord (10) into a power outlet of the correct voltage and frequency as defined on the Technical Label (9) located on the rear panel of the machine.
4. Connect oxygen tubing to the oxygen outlet (2) connector. If a humidifier has been prescribed, add water to the recommended level and attach the humidifier to the oxygen outlet (3) then attach the oxygen tubing to the humidifier outlet.
5. Press Power Switch to the (I) On position. The Red Indicator Light (6) will illuminate and the audible alarm will sound until the system pressure rises to the accepted level.
Note: The required oxygen concentration is normally obtained within five minutes after the machine is turned on.
6. Turn the Flow Adjustment Knob (4) to the prescribed flow rate. The ball inside the flowmeter (4) should be centered on the line indicating the flow rate. View the flowmeter in a horizontal plane for accurate settings.
6. Place your nasal cannula or mask as instructed by your Equipment Provider.
7. At the end of treatment, press the Power Switch (1) to the (0) Off position.
Note: The oxygen enriched air flow continues for approximately one minute after the machine is turned off.

CLEANING / MAINTENANCE

Note: Unplug the unit before performing maintenance or cleaning.

Only the outside of the unit is to be cleaned with a soft dry cloth or, if necessary, a damp sponge with a mild soap. Do not use acetone, solvents, abrasive powders or any inflammable products to clean the cabinet.

The removable External Cabinet Filter (8) must be cleaned weekly. More frequent cleaning may be required in dusty environments. Clean filter by washing in soapy water, rinsing thoroughly and allowing filter to air dry before replacing.

Follow Manufacturer's Instructions for the cleaning requirements of the Humidifier (if prescribed) and oxygen tubing, etc.

Note: No additional maintenance is required or should be performed by the patient. The Manufacturer's Instructions for Preventative Maintenance and Repair of the Device is defined in the Technical Manual provided to your Equipment Provider.

ACCESSORIES AND SPARE PARTS

The accessories and spare parts used with or for this unit must comply with the general requirements of the FDA Quality System Regulation.

Note: The following accessories are recommended for use with this unit.

- 9012-8774 Humidifier
- 9012-8777 Cannula Line Water Trap
- 9012-8778 Cannula with 15' Tubing
- 9012-8780 Cannula with 7' Tubing
- 9012-8781 25' Tubing Extension
- 9012-8782 Supply Line Adapter

ALARMS / SAFETY DEVICES

- **Power Failure Alarm** – In the event of a loss of power, a continuous audible alarm is activated.
- **Process Failure Alarm** – In the event of a process failure, the Red Light Indicator (6) and audible alarm is activated.
- **Electrical Protection Device** – in the event of a surge or drop in the power supply the Circuit Breaker (5) will trip. Restart the unit by depressing the reset button on the Circuit Breaker (5)
- **Green Light Indicator (6)** indicates that the unit has power and is ready to provide oxygen enriched air to the patient.
- **Red Light Indicator (6)** indicates that a system fault has occurred or there is no power to the unit.

SPECIFICATIONS

Flow Values: 0 to 5 Liters per Minute

Characteristics:

Length – 15.5” or 394 mm

Width – 15.6” or 396 mm

Height – 27.8” or 706 mm

Weight – 49-51 lbs. or 22-23 kg.

(Varies with models)

Electrical:

120 VAC, 60 Hz, 4.0 amps, 400 watts

230 VAC, 50-60Hz, 2.0 amps 400 watts

Two-Prong polarized plug

Double Insulated Cabinet

Average Oxygen Content:

• at 2 Liters per Minute – 94%

• at 4 Liters per Minute – 93%

• at 5 Liters per Minute – 90%

Storage Instructions: This device should only be stored, transported and operated in the vertical position.

Disposal of Device and Accessories: The unit and accessories (tubing, humidifier, etc.) should be disposed of using the methods appropriate to the local waste authority where used.

TROUBLESHOOTING

OBSERVATIONS	POSSIBLE CAUSES	SOLUTIONS
The (I/O) Power Switch is in the (I) On Position but the device does not operate. The audible alarm sounds continuously	Power Cord (10) is not plugged into outlet Power failure	Check that the unit is properly plugged into the electrical outlet Check the Circuit Breaker (5) and reset if necessary
Red Light Indicator (6) remains lit	Product pressure or purity is not at an acceptable level	Contact your Equipment Provider
The audible alarm does not sound when unit is first turned on	Faulty 9 volt battery Internal electrical fault	Contact your Equipment Provider
The unit is operating but the Green Light Indicator (6) is not lit	Faulty indicator	Contact your Equipment Provider
The unit is operating but there is no flow (flowmeter ball not moving)	Internal system failure	Stop device immediately and contact your Equipment Provider
The unit is operating but the audible alarm sounds continuously	Internal fault	Stop device immediately and contact your Equipment Provider
The unit suddenly stops and then starts again in a few moments.	Dirty Filters Compressor Thermal Shut-Off	Clean External Cabinet Filter (8) Contact your Equipment Provider
The oxygen flow is interrupted or the flow at the cannula feels irregular	Tubing is disconnected or not tight Tubing is restricted	Check tubing connections Straighten tubing Contact your Equipment Provider

NIDEK MEDICAL PRODUCTS, INC.
3949 VALLEY EAST INDUSTRIAL DRIVE
BIRMINGHAM, ALABAMA 35217 USA