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## GENERAL SAFETY GUIDELINES

**Only persons who have read and understood this entire manual should be allowed to operate the *Mark 5 Plus*.**

**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 Plus*** 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. In the event 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).

**USE AND MAINTENANCE OF THE DEVICE**

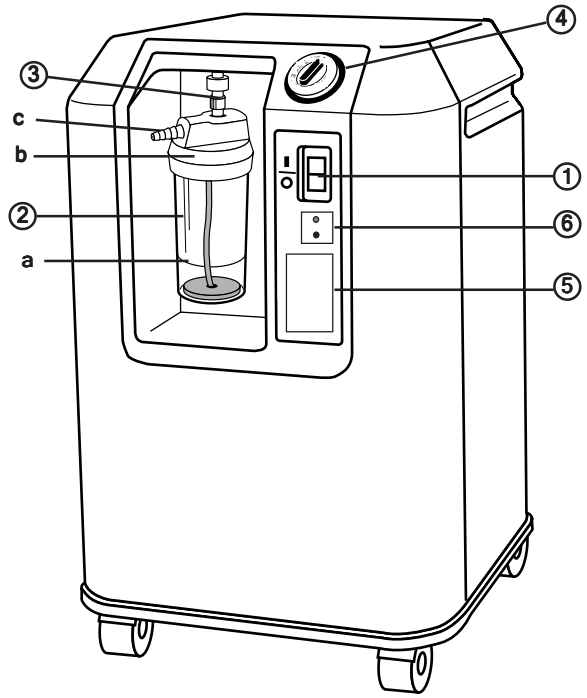
• Use the power cord provided, and check that the electrical characteristics of the power socket used match those indicated on the manufacturer's plate on the rear panel of the machine.
• We recommend avoiding the use of extension cords or adapters, as they are potential sources of sparks and fire.
• The ***MARK 5 Plus*** 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 (MRI, etc.).
•The ***Mark 5 Plus*** 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 IEC601-1 (§ 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 IEC /NEC requirements.
- 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.
•Do not open the device while in operation: risk of electrical shock.
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.1

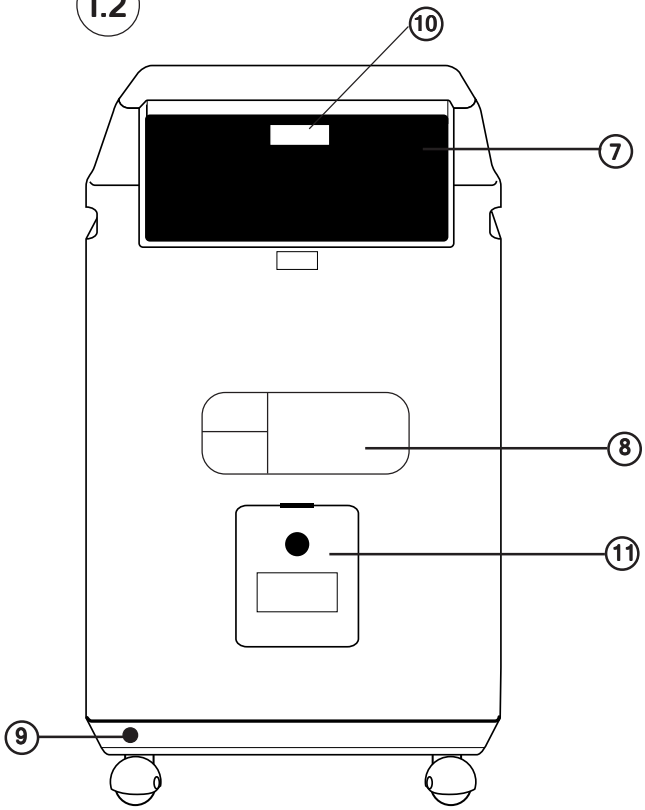



**AVAILABLE ACCESSORIES**
**IF PRESCRIBED BY A PHYSICIAN**

| | |
|---|---|
| Humidifier: | P / N 9012-8774 |
| Cannula: | P / N 9012-8780 |
| Extension Tubing 25ft. (7.6m): | P / N 9012-8781 |
| Tubing Adapter | P / N 9012-8783 |

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

I.2



## I. DESCRIPTION

The ***Mark 5 Plus*** is an oxygen concentrator designed to satisfy oxygen therapy prescriptions at home or in the clinic. It provides a continuous flow of oxygen enriched Product by separating the oxygen and nitrogen contained in ambient air. It can be used either to administer oxygen with nasal cannulas or another probe or mask type of device.

The ***Mark 5 Plus*** 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 range of flow rates with an internal 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 Plus* with the accessories recommended by Nidek Medical Products, Inc.**

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

① Start/stop (on/off) Rocker Switch
② Humidifier (space reserved)
  a) Flask
  b) Lid
  c) Outlet connector
③ Oxygen enriched air outlet
④ Flow adjustment knob (l/min.)
⑤ Safety instructions
⑥ Oxygen monitor (when installed).

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

⑦ Dust filter
⑧ Manufacturer's label
⑨ Electrical power cord
⑩ Hour meter (located under the dust filter)
⑪ Internal filter access panel (service provider)

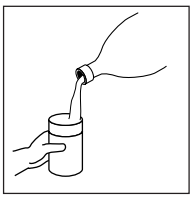
## II. STARTING UP / INSTALLATION

### II. 1. Use in direct oxygen therapy

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

b - 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.

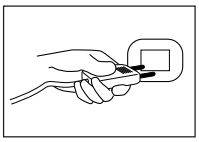
c - If used with a humidifier:
Unscrew the flask and fill it with water up to the line (see the humidifier instructions). Then screw the humidifier flask onto its lid until there are no leaks from it.



d - 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 Plus*** **should be limited to 60 feet (20 meters) long**, in order to ensure that the oxygen flow rate remains within specification values.

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

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



g - Press the switch to the start position I/ON (LED lit). Units without OCSI will sound an alarm for a few seconds. Units with OCSI will suppress the green LED until oxygen concentration exceeds the set point.

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 cannulas or mask to suit your face.

Remark: the required oxygen concentration is normally obtained within five minutes after the unit is switched on.

At the end of the treatment, press the Rocker Switch (1) to place it in the O/(OFF) position to stop the device. The oxygen enriched air flow continues for approximately 1 minute after the device is stopped.

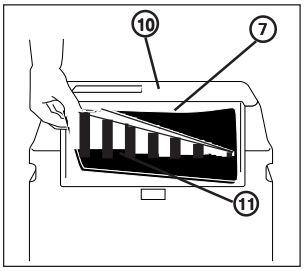
**For the equipment supplier or medical staff:**
The flow adjustment knob may be locked to limit it to a given range of values. (See procedure in the maintenance manual).

## III. CLEANING - MAINTENANCE

### III. 1. Cleaning

Only the outside of the ***Mark 5 Plus*** 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 dust filter (7) must be cleaned in soapy water weekly or after approximately 100 hours of use. More frequent cleaning is recommended in dusty enviroments.




Fit a dry filter.

**10** Hour meter
**11** Ventilation grill
**7** Removable dust filter

### III. 2. Everyday disinfection

Due to the presence of the bacterial filter inside the device, everyday disinfection only concerns the external oxygen therapy accessories: humidifier, probes, nasal cannulas (refer to the respective instructions for use).

**The use of alcohol based solutions means that the device must be switched off.**

**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 Plus*** must be cleaned and disinfected as per the above instructions. The bacterial filter inside the device should be changed. The dust 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 Plus***.

## IV. USEFUL INFORMATION

### IV. 1. Accessories and spare parts

The accessories used with the ***Mark 5 Plus*** must:
- be oxygen compatible,
- be biocompatible,
- comply with the general requirements of the FDA or the 93/42/EEC European Directive as appropriate.
The connectors, tubes, nasal cannulas, probes or masks must be designed for oxygen therapy.

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.

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

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

| | |
|---|---|
| Concentrator casing | ABS |
| Mains cable | PVC |
| Dust filter | Polyester |
| ON/OFF switch | Nylon |
| Casters | Elastomer |
| Flow adjustment knob | ABS/Polycarbonate |
| Gas outlet | Steel |
| Printed labels | Polypropylene |
| Pipe/ Tubing | Aluminium, PVC or silicone |
| Humidifier | Polypropylene |
| Support | Chromed brass/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 flow control valve 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 power, a continuous audible alarm is activated (and the green light is extinguished if equipped with oxygen monitor).

• Process fault:

In the case of a process fault, a visible and audible (after 15 minutes) 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 ± 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 Plus*** :

A 5A circuit breaker is incorporated into the START/STOP switch of all 230V models. A 10 A circuit breaker is optionally available with 115V models.

• Safety valve:

This is fitted on the compressor outlet and is calibrated to 42 psig (2.8 bar.).

• Class II devices with insulated casings (IEC 60601 standard).

**IV. 5. Oxygen Monitor function (Optional)**

**IV. 5. 1. Operating principle** (oxygen concentration indication module)

The Oxygen Monitor (6) is an electronic module capable of checking the effective oxygen concentration supplied by the ***Mark 5 Plus*** concentrator.

The Oxygen Monitor detects any drop in the concentration below a pre-set level and activates an audible and visual alarm. A green light indicates that the concentration is above the pre-set oxygen concentration level.

A red light indicates a concentration below the preset level. When the light is red for more than 15 minutes (±2 minutes), a continuous audible alarm is activated. Call the equipment supplier to service the machine.
Note: when the ***Mark 5 Plus*** is started, the Oxygen Monitor operates as follows:
1) in addition to the normal ***Mark 5 Plus*** test, LED indicator lights are suppressed until oxygen concentration reaches normal levels.
2) the light remains lit for a few minutes (5-10 minutes at maximum) until the concentration of the gas supplied reaches and exceeds the preset level.
3) The red light is off and the green light is lit after this period, showing that the concentrator is operating satisfactorily.

**IV. 5. 2. Maintenance of the Oxygen Monitor:**

- No special maintenance is required,
- The equipment supplier checks that the oxygen monitor is still operating correctly when the routine checks are performed on the ***Mark 5 Plus***.

The alarm set-point is factory set and there is no means to adjust the settings. Models operating at 50 Hz are set at 83%; 60 Hz models are set at 85%.

**IV. 6. Technical characteristics**

Dimensions: L x W x H: 15 x 15 x 66 in. (381 x 381 x 660mm)
Castor diameter: 1.5 in. (38 mm).
Tilt angle (transport with humidifier fitted): 70°.
Weight: 55-60lbs. (25-28kg.) (varies with model)
Noise level < 46 dBA to 52 dBA(to ISO 8359)

**Flow values:**

0.125 / 0.25/ 0.5 / 1/ 1.5/ 2/ 2.5/ 3/ 3.5/ 4/ 4.5/ 5 l/min. (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 flow selector, 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. 91%.
• 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 1 psig(7kPa) is applied to the output of the device. The maximum outlet pressure is 9 psig(62 kPa).

**Electrical power supply:**

| | **115 V Units** | **230 V Units** |
|---|---|---|
| Frequency: | 60Hz | 50/60Hz |
| Average Power : | 420 - 440 VA | 400-420 VA |
| ProtectionClass: | ClassIIb | Class IIb |
| Mains Protection: | 10A(optional) | 5A |

**Filters:**
At the rear of the device: a dust filter.
At the compressor input: a filter cartridge (technician only).
Before the oxygen outlet: a bacterial filter < 0.3 µm. (technician only)

**Air circulation:**
A blower cools the compressor compartment.

**Environmental limit conditions:**
The performances of the device (especially the oxygen concentration) are quoted at 70°F (21°C) and one atmosphere. They may change with temperature and altitude. For further information, please consult the maintenance manual.
- The device must only be stored, transported and used in the vertical position.
- Ambient temperature of between 10 °C and 40 °C (operation).
- Storage temperature range from 0 °C to 50 °C.
- Relative humidity of between 30 % and 75 % (operation and storage).
- IPXX: No particular protection against penetration by liquids or solids (complies with the EN 60601-1 standard: spilling of a glass of water).

### IV. 7. Standards

ISO 8359: Oxygen concentrators for medical use.
EN 60601: Electrical Safety-Medical Devices.

### IV. 8. Symbols - Abbreviations

**I** : ON

**O** : Off (power switched off).

: Type B device

: Class II device

: Do not smoke.

CE **0413** : Complies with the 93/42/EEC directive certified by the approved organization n° 0413.

: Do not expose to open flames.

: Do not grease.

: Technical information.

: Consult the accompanying documents.

: Keep in the vertical position.

: Fragile - handle with care.

: Oxygen concentration warning light.

### IV. 9. Method for disposing of waste

All waste from the ***Mark 5 Plus*** (patient circuit, filter, etc.) must be disposed of using the appropriate methods.

### IV. 10. Method for disposing of the device

In order to preserve the environment, the concentrator must only be disposed of using the appropriate methods.
Furthermore, as part of the CE marking (directive 93/42 / EEC), the serial number of the device disposed of must be sent to the **Nidek Medica**l technical service department if the unit has the CE mark.

***Mark 5 Plus*** **Serial No.** _____

**Date first used:** _____

_____

**Maintained by:** _____

_____

**Your distributor:** _____

**Address :** _____

_____

_____

**Telephone :** _____

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

The work must be carried out by suitably trained technicians.

**Only use original spare parts.**

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 by the manufacturer as repairable.

**IV. 12. Fault Conditions and Corrections.**

| Observations | Probable causes | Solutions |
|---|---|---|
| The I-O (ON/OFF)button is in the ON position. The green indicator does not light up and the device does not operate.<br>The continuous alarm sounds. | Power cable not plugged in correctly.<br>Power failure. | Check the cable connection.<br>Check the fuses or circuit breaker on the power panel. |
| Red light of Oxygen monitor remains lighted. | Oxygen concentration is too low. | Contact your equipment supplier. |
| The alarm test does not work. | Internal electrical fault. | Contact your equipment supplier. |
| The compressor operates and the I-O (ON/OFF) button is in the ON position but the green indicator does not light up. | Faulty indicator. | Contact your equipment supplier. |
| The I-O (ON/OFF) button is lit 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 lit, the compressor is operating, there is a flow but the audible alarm sounds continuously. | Internal electrical fault.<br>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.<br>Fan not working.<br>Dirty Filters. | Stop the device and wait for it to cool down.Check that the patient circuit is not obstructed. Clean cabinet filter.Start up again. Reset the circuit breaker (4) if necessary by pressing the I-O (ON/OFF) switch. 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.<br>Cannula Tubing kinked. | Check that tubing connections are secure and that the tubing is not kinked. |
| The flow at the nasal cannula outlet is irregular. | Pneumatic circuit problem. | Contact your equipment supplier. |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