

NIDEK Medical

USER'S GUIDE

Mark 5 Nuvo with Modular Bed NUVO, NUVO 8 & NUVO 10 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.

CE413: 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 with Modular Bed (MB)*.

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 MB* 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 MB* 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 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 MB* 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 MB* 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 an 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 MB* 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.

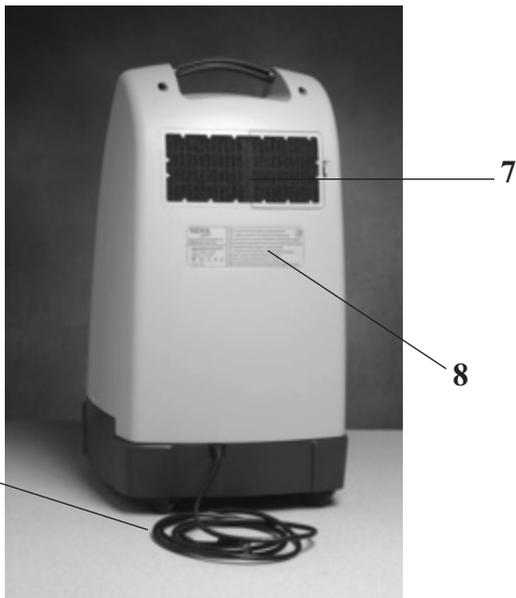
It has a power failure alarm and an operating fault alarm.

Note: the performances described pertain to the use of the *Mark 5 Nuvo MB* 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 product outlet
- 4 - Flow adjustment knob (l/min)
- 5 - Circuit Breaker
- 6 - OCSI (Oxygen Concentration Status Indicator) Indicator Lights (if equipped)



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.

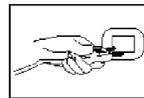
b. If used with a humidifier:



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 MB** 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 / 0**) to the ON position (**I**). The green indicator will light when the oxygen concentration exceeds the set point (OCSI) or normal operating pressures. **Note:** After turning the unit off, the user must wait 3-5 minutes before turning it back on. System pressure must dissipate before the unit will properly restart.

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/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.

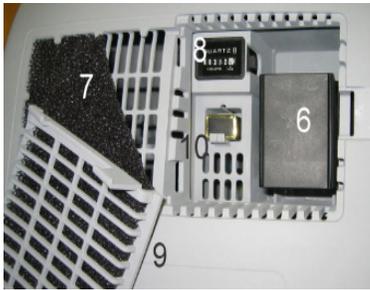
For the equipment supplier or medical staff:

III. CLEANING - MAINTENANCE

III.1. Cleaning

Only the outside of the *Mark 5 Nuvo MB* 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. Dry before reinstalling.



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

III.2. Daily disinfection

Because there is a final product 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)

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 MB* 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 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 MB*.

IV. USEFUL INFORMATION

IV.1. Accessories and spare parts

The accessories used with the *Mark 5 Nuvo MB* 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.

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:	P/N	9012-8774
Humidifier High Flow:	P/N	9251-8774
Cannula with 2 m (7 ft) tubing:	P/N	9012-8780
Cannula High Flow:	P/N	9251-8780
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.....	ABS/Polycarbonate
Mains cable.....	PVC
Cabinet air filter.....	Polyester
I/O (On/Off) switch.....	Nylon
Casters.....	Nylon
Flow adjustment knob.....	ABS
Oxygen product 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 an electronic valving system, 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 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 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)

- **No Oxygen Flow Alarm (Optional):**

If supplied the Nuvo MB Oxygen Concentrator has a No Flow Alarm. This device provides an continuous audible alarm in the event the Oxygen Flow to patient becomes blocked.

IV.4.2. Safety devices

- **Compressor motor:**

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

- **Electrical protection of the *Mark 5 Nuvo MB*:**

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

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

- **Safety valve:**

This is fitted on the compressor outlet and is calibrated to 3.4 bar (50 psig).

IV.5. ALARMS INDICATORS

IV.5.1. OCSI (oxygen concentration status indicator) if equipped

The oxygen monitor (6) is an electronic module capable of checking the effective oxygen concentration supplied by the *Mark 5 Nuvo MB* 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 MB* is started, the indicator lights operates 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 (OCSI equipped). On initial power up it will flash green until the unit has reached normal operating conditions.

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 or abnormal pressures. For OCSI units 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 (± 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. All OCSI models are set at 84%.

- The equipment supplier checks that the device is still operating correctly when the routine checks are performed on the *Mark 5 Nuvo MB*.

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.) (Nuvo 10 H: 760mm (29.8))

Caster diameter: 50 mm (2.0 in.).

Tilt angle (transport with humidifier fitted): 70°.

Weight: 24 kg /54 lbs

Noise level within ISO 8359 guidelines

Flow values:

Continuously Adjustable Flowmeter: 1 to 5, 2 to 8, or 2 to 10 (depending on model)

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 ± 10% or 200 ml/min, whichever is the larger of the two.

Average oxygen content:

5 l/min, 8 l/min, 10 l/min: 90%. +5.5% / -3.0%
(Values at 21°C and at one atmosphere pressure).

Minimum recommended flow: 1 l/min on 5L unit, 2 l/min on 8 & 10L units.

Maximum recommended flow: 5 l/min, 8 l/min or 10 l/min model specific.

The variation of the maximum recommended flow does not exceed ± 10 % of the indicated value when a back pressure of 6.9 kPa (1 psig) is applied to the output of the device. The maximum outlet pressure is: 7psig for 5 l/min, 15 psig for 8 l/min, and 20 psig for 10 l/min.

Electrical power supply:

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

8 l/min Model:	<u>115 V Units</u>	<u>230 V Units</u>
Frequency:	60Hz	50/60Hz
Average Power:	490 watts	490 watts
Protection Class:	Class II	Class II
Mains Protection:	10A	5A

10 l/min Model:	<u>115 V Units</u>	<u>230 V Units</u>
Frequency:	60Hz	50/60Hz
Average Power:	700 watts	490/585 watts
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: an inlet air filter, behind cabinet air filter.
Before the oxygen outlet: a final product filter < 0.3 µm. (technician only)

Air circulation:

One tubeaxial fan cools the compressor compartment and a second fan cools the heat exchanger coil on 8 & 10 lpm models.

Environmental limit conditions:

The performance 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): Up to 1500m (5000ft) without degradation; Consult your equipment provider for further information regarding 1500 m to 4000m (5000 to 13000ft).
- Complies with EN60601-1 standard; 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 MB** (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 recycleable. 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.

Nuvo Serial No. _____

Date first used: _____

Maintained by: _____

Your distributor: _____

Address : _____

Telephone : _____

IV. 10. Troubleshooting.

Observations	Possible Causes	Solutions
The I-0 (ON/OFF) button is in the “ I ” (ON) position but the device does not operate.	Power cable (9) is not correctly plugged into the wall outlet.	Check the cable connection.
The audible alarm sounds intermittently.	Power failure.	Check the circuit breaker (5) on the front of the unit; Reset if necessary.
Red light remains lighted.	Oxygen concentration is too low. or pressures are out of specified range.	Contact your equipment supplier.
The alarm test does not work. See IV 4.1.	Capacitor is charged Internal electrical fault.	Plug unit in for 10 minutes and retest Contact your equipment supplier.
The compressor operates and the I-0 (ON/OFF) button is in the “ I ” (ON) position but the green indicator is not lighted.	Faulty indicator.	Contact your equipment supplier.
The I-0 (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-0 (ON/OFF) button and contact your equipment supplier.
The I-0 (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 or low purity.	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. 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; Wash weekly; Replace as needed.

Inlet Air Filter: Part Ref: 9250-1180; Inspect at each patient visit; Replace annually.

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

V. EMC, Electromagnetic Statements

Appendix A: EMC Information			
<p>Important: Failure to follow these guidelines listed may result in increased emissions and/or decreased immunity of the subject device.</p> <ul style="list-style-type: none"> Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. Portable and mobile RF communications equipment can affect Medical Electrical Equipment. The use of Accessories, transducers, and cables other than those specified by the manufacturer, may result in increased Emissions or decreased immunity of the device. The device should not be used adjacent to or stacked with other equipment and that adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used. Use on Nidek Replacement electrical parts. 			
<p>Guidance and Manufacturer's Declaration – Electromagnetic Emissions This device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</p>			
Emissions Test	Compliance	Electromagnetic Environment – Guidance	
RF Emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF Emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
Harmonic Emissions IEC 61000-3.2	Class A		
Voltage Fluctuations /Flicker Emissions	Complies		
<p>Guidance and Manufacturer's Declaration - Electromagnetic Immunity This device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment</p>			
Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV Air	Complies	Floors should be wood, concrete, or ceramic tile. floors are covered with synthetic material, the relative humidity should be at least 30%.
Conducted RFIEC 61000- 4-6	3 Vrms 150 kHz to 80 Hz	Complies	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level (3 V/m) in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the distance calculated from the equation applicable to the frequency of the transmitter. $d= 1.2 P (80-800\text{MHz})$ P=Transmitter power level in watts $d= 2.3 P (800\text{MHz}-2.5\text{GHz})$ d=distance in meters
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	Complies	
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 2 kV for power supply lines ± 1 kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of the typical location in a typical commercial or hospital environment
Voltage Dips, short interruptions and voltage variations on power supply input line. IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continuous operation during power mains interruption, it is recommended that the device
	40% U_T (60% dip in U_T) for 5 cycles	Complies	
	70% U_T (30% dip in U_T) for 25 cycles	Complies	
	<5% U_T (>95% dip in U_T) for 5 seconds	Complies	
<p>Note: U_T is the a.c. mains voltage prior to the application of the test levels</p>			



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