PULMO-MIST

AEROSOL COMPRESSOR INSTRUCTIONS FOR USE

Models 4323, 4334, and 4335

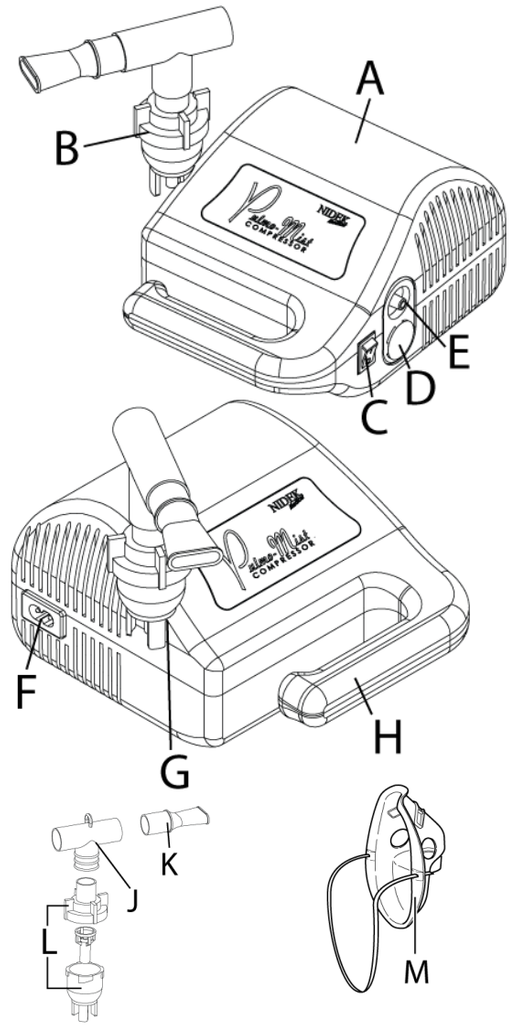
THIS IS A MEDICAL DEVICE. OPERATE THE DEVICE ONLY AS INSTRUCTED BY YOUR PHYSICIAN OR RESPIRATORY THERAPIST.

CONTENTS

IMPORTANT SYMBOLS

⚠	WARNING – A hazard or unsafe practice that can result in serious injury or death if conditions are not avoided.
⚠	Caution - A hazard or unsafe practice that can result in minor injury and / or property damage if conditions are not avoided.
☑	Note – Information important enough to emphasize or repeat
	Type B Device
	Class II Protection
	ON (Power switched on)
	OFF (Power switched off)

PULMO-MIST FEATURES



A – Pulmo-Mist Compressor
B – Nebulizer Kit (see J-L)
C – Mains Switch
D – Filter Cap (filter inside)
E – Air Outlet
F – Mains Connection
G – Nebulizer Holder
H – Handle
J – T-Piece
K – Mouthpiece
L – Nebulizer Cup
M – Aerosol Mask

☑ The parts included are required for the device to function correctly and are in compliance with EN 13544-1+A1.

☑ The accessories used with the device must comply with the general requirements of the FDA Quality System Regulation, the 93/42/EEC European Directive, or other applicable regulatory requirements.

The accessories below, available from **Nidek Medical Products, Inc.** and our distributors, comply with these requirements. Contact your equipment supplier to obtain these accessories.

Accessories and Consumables	Part Ref
Disposable Nebulizer Kit (B) – included in box (5ml capacity nebulizer cup, T-piece, mouthpiece and 2 m (7 ft) tubing)	9012-8787
Aerosol Mask (M)	9012-8791
Replacement Filters and Cap (5 filters and 1 cap)	7631-1071A

GETTING TO KNOW YOUR PULMO-MIST

WHAT IT DOES

The Pulmo-Mist Compressor is intended to provide a source of compressed air for medical purposes by order of a physician. When the compressor is used in conjunction with a pneumatic nebulizer, it converts certain medications into an aerosol form for inhalation by the patient for certain respiratory disorders.

⚠ This unit is not a life-support device. Geriatric, pediatric, or any other patient unable to communicate discomfort while using this device should receive additional monitoring.

⚠ This unit is not suitable for use in anesthetic breathing systems or lung ventilator breathing systems.

WHO SHOULD USE IT

Legally certified medical experts (such as a physician, nurse and therapist), healthcare personnel or a patient and / or caregiver under the guidance of qualified medical experts.

⚠ This product should not be used on patients that are unconscious or are not spontaneously breathing.

⚠ Close supervision is necessary when this product is used by, on or near children and physically impaired individuals.

WHERE IT SHOULD BE USED

A medical facility (such as a hospital, clinic and doctor's office) or in household room. The device should be placed on a table or firm surface within 1.5 meters (5 ft) from an electrical outlet and away from any soft surfaces that could block the air vents. The device should not be used outdoors or in the presence of aerosol (spray) products or flammable anesthesia mixtures with air, oxygen or nitrous oxide.

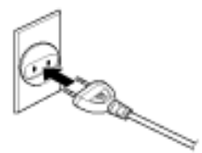
⚠ **To reduce the risk of electrocution:**
DO NOT use while bathing or around water.
DO NOT place, drop into or submerge the device in water or any other liquid.
UNPLUG IMMEDIATELY if the device falls into water.

⚠ **To reduce the risk of fire, burns or injury:**
DO NOT leave the device unattended if plugged in.
DO NOT place the power cord near heated or hot surfaces.
DO NOT use the device with a damaged cord or plug.

⚠ We discourage the use of **EXTENSION CORDS**; however, if it is necessary that you do use one, be sure that it is in good condition. Check that the wire diameter is at least 1.0 mm (18 gauge) for 8 meter (25 ft) long cords or 1.3 mm (16 gauge) for 15 meter (50 ft) long cords.

BEFORE USING YOUR PULMO-MIST

1. Make sure the Mains Switch (C) is in the O (OFF) position.
2. Plug the Power Cord into the Mains Connection (F).
3. Plug the Power Cord into a power outlet (see bottom label for electrical outlet requirements).
4. Remove the top from the nebulizer cup (L) by rotating counter-clockwise and pulling upwards.
5. While holding the tank of the nebulizer cup (L) upright, add the correct amount of prescribed medication to the cup.



☑ The capacity of the cup is 2 to 5 ml. DO NOT overfill.

6. Align the top of the nebulizer cup (L) with the bottom, and while still upright, rotate the top clockwise to engage the locking slides.
7. Attach the T-Piece (J) to the mouthpiece (K) or the mask (M).
8. Connect one end of the tubing to the bottom of the nebulizer cup (L) and the other to the Air Outlet (E) while being mindful to keep the nebulizer cup (L) upright and not spill the medication.
9. Use the Nebulizer Holder (G) as a temporary holder until ready for treatment.

☑ Make sure all connections are secure before beginning your treatment.

OPERATING YOUR PULMO-MIST

1. Hold the Nebulizer Kit (B) upright – or at no more than a 45° angle – to avoid medication flowing into the mouth.
2. Press the Mains Switch (C) to the I (ON) position. The compressor and nebulization should start. Observe aerosol mist coming from the Mouthpiece (K).

⚠ DO NOT block the air vents on the Pulmo-Mist Compressor (A). This could result in the compressor overheating or malfunctioning.

DO NOT touch the Pulmo-Mist Compressor (A) during treatment, as it may become hot.

DO NOT leave the device on for long periods of time. This could result in the compressor overheating or malfunctioning.

3. Inhale medication according to your doctor or healthcare professional's instructions.
4. After the treatment is complete, press the Mains Switch (C) to the O (OFF) position.
5. Unplug the device from the wall.
6. Discard any remaining medication and the Nebulizer Kit (B) including tubing. The Nebulizer Kit and tubing are single use items per the manufacturer and should not be reused.

CLEANING YOUR PULMO-MIST

If the compressor is dirty, wipe the case with a soft cloth dampened with a mixture of warm water and mild detergent.

DO NOT wipe down with a soaked cloth.
DO NOT submerge in water.
The device is NOT waterproof.

Your physician or service provider may specify certain cleaning procedures for your nebulizer. If so, follow their recommendations, if not, do at least the following:
After each use you should clean by washing all nebulizing parts (T-Piece (J), Mouthpiece (K), Nebulizer Cup (L) – and Aerosol Mask (M), if purchased, in a mixture of warm water and mild detergent. Rinse thoroughly with clean tap water. Once per day, you should disinfect by using either a commercial disinfectant and follow the manufacturer's instructions, or use a mixture of 1 part vinegar to 3 parts water. Submerge all nebulizing parts in the vinegar mixture for no less than 30 minutes. After removing all parts, rinse thoroughly with hot tap water and discard any remaining mixture. Allow to air dry in a clean environment. Once all parts are dry, reassemble the Nebulizer Kit (B) and store in a dry, sealed bag until ready for use.

MAINTENANCE AND STORAGE

Nebulizer Kit (B), tubing and Aerosol Mask (M) are single use per the manufacturer and should be discarded after each use.

The air filter should be cleaned at least once a month, or sooner if it shows dirt. It should be replaced if it looks worn or it is torn.
To clean or replace the filter, remove the Filter Cap (D) and take out the filter underneath. To clean, wash with warm soapy water and allow to completely dry before reinstalling. Replacement Filter Caps (D) and filters can be purchased through Nidek Medical Products, Inc. or your distributor. Part reference numbers can be found in the "Pulmo-Mist Features" section of this IFU.

DO NOT run device without the filter installed.

DO NOT remove the outer case of this unit.
There is a risk of Electrical Shock and will void the manufacturer's warranty.

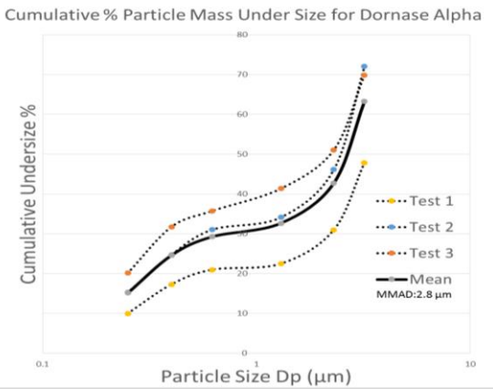
PULMO-MIST SPECIFICATIONS

Electrical Requirement	
Model 4323	120 VAC 60 Hz
Model 4334	230 VAC 50 Hz
Model 4335	230 VAC 60 Hz
Compressor Model	BC115V BC230V
Compressor Service Life	5 years
Running Current	1.4 A @ 115V / 60 Hz
	0.6 A @ 230V / 50-60 Hz
Power Consumption	50-60 watts
Sound Level	55 dBA
Operating Temperature	10°C to 40°C (50°F to 104°F)
Storage Temperature	-20°C to 60°C (-4°F to 140°F)
Aerosol Output Rate Mid-Point	7 LPM @ 10 psig (70 kPa)
Minimum / Maximum	6 / 8 LPM @ 10 psig (70 kPa)
Maximum Compressor Pressure	35 psig (241 kPa)
Thermal Protection	135° ± 5°C (275° ± 41°F)
Enclosure Protection	IPX0
Dimensions	15 cm x 10 cm x 18 cm (6 in x 4 in x 7.5 in)
Weight	1.4 kg (3.1 lbs)
Standards / Directives	EC directive 93/42/EEC
	EN 13544-1 + A1
	EN 13485
	60601-1
	60601-1-2
Nebulizer Specifications	
Cup Fill Capacity	2ml to 5ml
Nebulization Rate	0.1 ml / min or greater

Materials in direct or indirect contact with the patient

Pulmo-Mist Enclosure (A)	ABS
Compressor	Nylon, PTFE, Silicone, Steel, Copper
Power Cord	PVC
Printed labels	Polycarbonate
Mains Switch (C)	Nylon
Filter Cap (D)	Nylon
Filter (located under filter cap)	Polyester Foam
Tubing (internal)	Silicone
Nebulizer Kit (B)	PVC, Polypropylene, Polystyrene, K-resin
Mask (M)	PVC, Polypropylene

Particle Size Distribution Curve



Performance information may not apply to drugs supplied in suspension or high viscosity form, consult your drug supplier.

This device fulfils the provisions of the EC directive 93/42/EEC (Medical Device Directive) and FDA 21CFR 820 – Quality System Regulation.

TROUBLESHOOTING YOUR PULMO-MIST

Observation	**Possible Cause**	**Solution**
Nothing happens when the Mains Switch (C) is pressed to the I (ON) position.	Is the power cord plugged into the Mains Connection (F)?	Check the power cord is firmly inserted into the Mains Connection (F).
	Is the power plug plugged into an outlet?	Check the power plug is plugged into a working outlet with the correct voltage.
No nebulization or low nebulization rate, when the power is on.	Is there too much / little medication in the tank?	Check that the correct amount of medication is in the tank
	Is the nebulizer kit assembled correctly?	Assemble the nebulizer kit correctly.
	Is the tubing kinked or blocked?	Check that the tubing is not kinked or blocked.
	Is the air filter dirty?	Replace air filter with a new one.
The device is very hot.	Are the vents blocked?	Check that there is nothing blocking the vents.
The unit shuts down repetitively.	Do your outlets supply enough voltage?	Check the bottom label for necessary electrical requirements.
The motor seems sluggish or weak.		

DISPOSAL OF YOUR PULMO-MIST

Method for Waste Disposal
All waste from the device (Patient Circuit, Filters, Etc.) must be disposed of using methods appropriate to the civil authority of the location where disposed.
Disposing of the Device
This device has been supplied by an environmentally aware manufacturer. A majority of the parts in the device are recyclable.
Follow local governing ordinances and recycling plans regarding disposal of the device or components normally used in operation. Any accessories not original to the device must be disposed of in accordance with the individual product markings for disposal.

LIMITED WARRANTY STATEMENT

This product has limited warranty and is appreciable to the original dealer-purchase of this equipment. The warranty is void if the unit or any other component part thereof has been damaged by accident, abuse, misuse, neglect, alteration, improper usage or any other causes not arising out of defects in material or workmanship. Nidek Medical Products, Inc. makes no other warranties of any kind whatsoever express or implied with respect to the Pulmo-Mist or its component parts and all implied warranties including but not limited to warranties or merchantability and fitness for a particular purpose are hereby expressly disclaimed and excluded by Nidek Medical Products, Inc.

Nidek Medical Products, Inc.
3949 Valley East Industrial Drive
Birmingham, AL 35217 USA
P: (205) 856-7200 F: (205) 856-0533
www.nidekmedical.com

EC REP
mdi Europa GmbH
Langenhagener Str. 71
30855 Hannover-Langenhagen Germany
P: +49-511-39-08 95 30 F: +49-511-39-08 95 39
www.mdi-europa.com