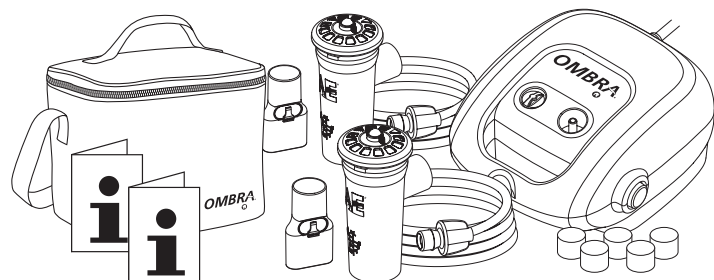




OMBRA[®]



CONTENTS

- **OmBra[®]** Table Top Compressor with Instructions for Use
- Five Replacement Air Filters
- Two **AeroEclipse[®] XL BAN[®]** Nebulizers with Mouthpiece, **EZ Twist[®]** Tubing and Instructions for Use
- Carrying Case

REF 105560

REF 105544



TRUDELL MEDICAL INTERNATIONAL



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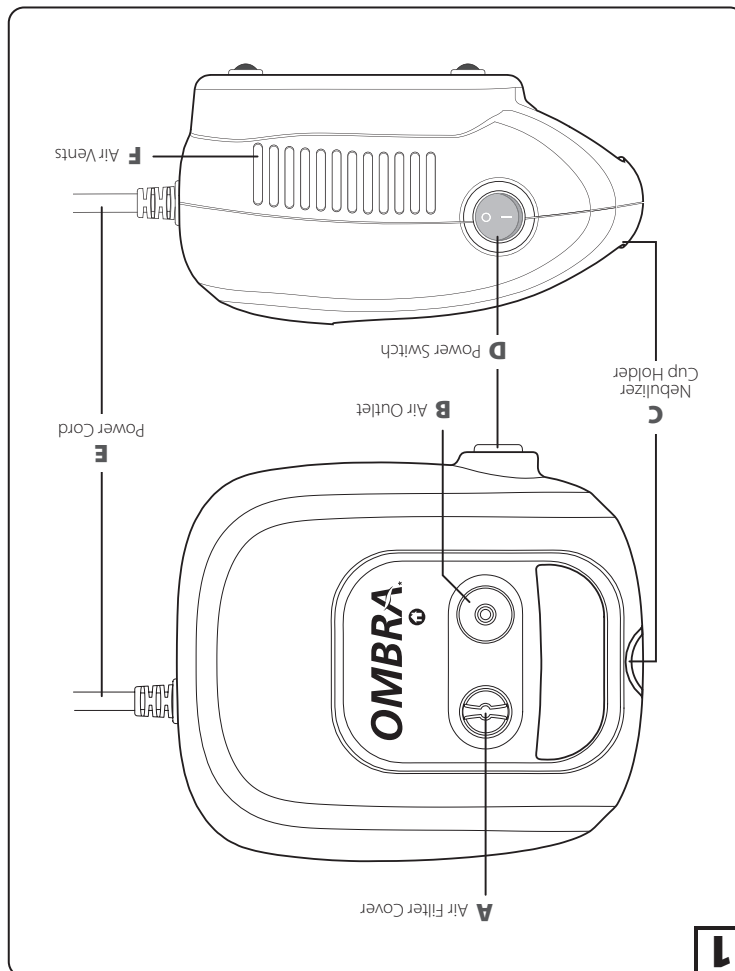
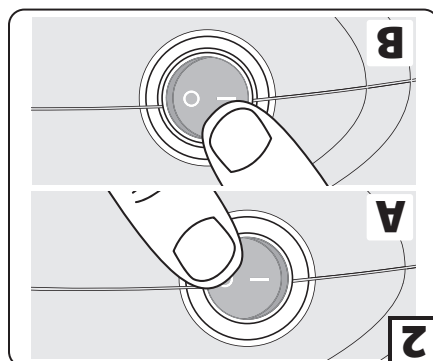
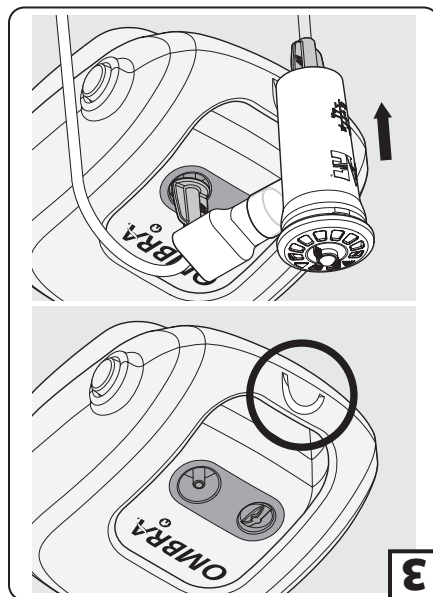
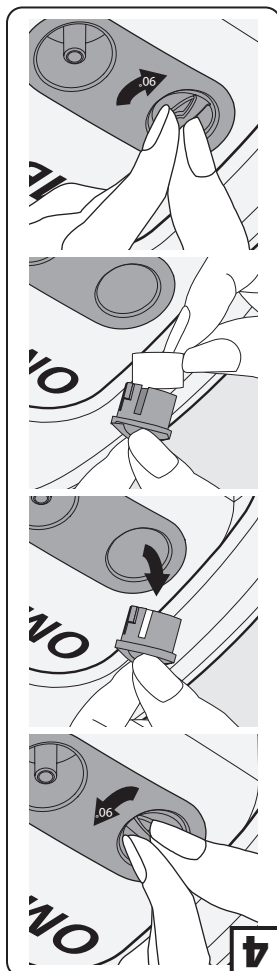
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INTENDED USE

The compressor is intended to be used to deliver compressed air to a jet or pneumatic nebulizer. It is to be used by patients aged 18 months and older. The environments of use include hospitals, clinics and the home.

The clinical benefit is to enable delivery of aerosol medication with compatible nebulizers by providing compressed air to power a jet or pneumatic nebulizer in order to convert liquid medication into an aerosol, so it can be inhaled into the lungs.

The compressor has been designed to be used with the **AeroEclipse® XL BAN®** Nebulizer. For use with other nebulizers, please refer to the specifications section.

If you have concerns regarding the use of the compressor, please speak with your health care provider.

⚠ Warnings

- Do not leave the compressor unattended with children. Contains small parts that can cause choking.
- For your safety, do not change or alter the equipment. It can be unsafe to use accessories, detachable parts and materials not described here.
- Only use the power supply cable that is provided.
- Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Avoid using the compressor next to or stacked with other equipment. This could cause the equipment to work incorrectly. If such use is required, watch the compressor and the other equipment to make certain that they work correctly.
- Do not use portable RF communications equipment (e.g. peripherals such as antenna cables and external antennas) closer than 30 cm (12") to any part of the compressor. This includes cables. Otherwise, the performance of the equipment could degrade.

⚠ Cautions

- Children are not to set up and operate the compressor.
- Be mindful of children near by when using the compressor. Care is required to ensure the compressor is not pulled off the table by tugging on the power cord (E) or nebulizer tube. The tubing and power cord present a strangulation hazard.

📌 Note

- Electromagnetic disturbances may result in a reduction in the compressor output or complete failure of the compressor to provide essential performance.

BEFORE EACH USE

Ensure these instructions have been read and are kept available at all times. Read the instructions for the nebulizer. Carefully check the compressor. Replace it immediately if it is damaged or has missing parts.

INSTRUCTIONS FOR USE

1 Place the compressor on a clean, flat surface or table top.

⚠ Caution: Do not cover the air vents (F) or operate the compressor while it is in the carrying case. Overheating will occur that can damage the compressor. Stop using the compressor if there is visible damage.

⚠ Warning: Do not position the compressor so that it is hard to use the plug on the power supply cord.

2 Check that the power switch (D) is in the 'OFF' position (2A). Plug the compressor into an electrical outlet.

3 Set up the nebulizer according to its instructions.

📌 Note: The nebulizer cup holder (C) can be used to hold it before treatment is to begin (3).

4 Switch on the compressor (2B). Start the treatment according to the nebulizer instructions.

5 Switch off the compressor when finished with the treatment (2A).

6 Disconnect the nebulizer tubing from the air outlet (B) on the compressor.

7 Unplug and store the compressor. Clean the nebulizer according to its instructions.

⚠ Warning: The plug of the power supply cord must be used to fully detach AC power to the compressor.

CLEANING

Compressor

Prior to cleaning the compressor, ensure that it is unplugged from the electrical outlet. Use a damp cloth to wipe the exterior of the housing. Never use harsh cleaners or chemical sprays directly on the compressor or the power switch (D). Do not immerse the compressor or power cord (E) in water or cleaners.

Nebulizer

Clean according to its instructions.

DISINFECTION

The compressor can be disinfected each day.

1 Follow the cleaning instructions. Use any of the following methods to disinfect the outside of the compressor.

A

Wipe the case, switch and handle with a tissue dipped in one of the following:

- 70 % isopropyl alcohol
- 1:50 bleach to water solution (1 tablespoon (15 mL) bleach in 3¼ cups (800 mL) water)
- 3M[®] SoluPrep[†] Solution

B

Wipe the case, switch and handle with PDI[†] Super Sani-Cloth[†] Germicidal Disposable Wipe. Follow the disinfectant instructions for use.

2 Allow to air dry for 5 to 10 minutes.

STORAGE

The compressor can be stored in the carry case or similar protected environment. The carry case has sufficient room to store a nebulizer as well. Always store the compressor out of reach of children and pets.

MAINTENANCE

The compressor is equipped with an air filter that will slowly change colour with use. The original filter is bright white, but it will slowly turn grey with use. The air filter should be changed every year, or sooner if visual inspection indicates. The compressor should never be used without the proper air filter installed. Spare air filters are provided with the compressor and extras can be ordered.

To change the filter (4):

1 Grasp the air filter cover (A) and turn counterclockwise approximately 90 degrees.

2 Pull the air filter cover (A) out.

3 Remove filter from the air filter cover (A) and insert a new filter in its place.

4 Place the air filter cover (A) back into the compressor and turn clockwise approximately 90 degrees to tighten.

⚠ Warnings

- The air filter cover (A) and filter are small parts that are a choking risk for children.
- Do not perform servicing and maintenance while the compressor is in use.
- Power supply cord is not serviceable.

📌 Notes

- Dispose the old filter in the garbage. Do not wash or reuse.
- There is no other needed maintenance. There are no parts inside the compressor that require periodic lubrication or adjustment. Do not open the compressor housing for any reason.
- Basic safety description: Basic safety assured since there is very low risk of physical hazards, such as electrocution, burns, or mechanical hazards.
- Basic safety monitoring method: No basic safety monitoring required for the medical equipment.

DISPOSAL

Do not dispose of in unsorted municipal trash. Please consult local laws and regulations for proper disposal.

SPECIFICATIONS

Model Number	105560
Weight	1.59 kg (3.5 lb)
Dimensions	17.8 cm x 15.5 cm x 10 cm (7" x 6.1" x 3.9")
Sound Level	60 dB(A)
Electrical Requirements	230 Volt AC
Power Cord Length	1.52 m (5')
Power	180 VA Maximum
Frequency	50 Hz
Duty Cycle	30 Minutes On/30 Minutes Off
Equipment Classification	Class II
Applied Part	Nebulizer mouthpiece, Type BF
Ingress Protection Code	IP21
Minimum Pressure	103 kPa (15 psi)
Operating Temperature Range	+5°C to +40°C (+41°F to +104°F)
Operating Humidity Range	10 to 90% (non-condensing)
Operating Atmospheric Range	75 kPa (11 psi) to 101.3 kPa (15 psi)
Storage/Transport Temperature Range	-25°C to +70°C (-13°F to +158°F)
Time to Reach Operating Temperature from Minimum Storage Temperature	10 minutes
Time to Reach Operating Temperature from Maximum Storage Temperature	0 minutes
Storage/Transport Humidity Range	10 to 90% (non-condensing)
Nominal Operating Pressure with the AeroEclipse® XL BAN® Nebulizer	140 kPa (20 psi)
Nominal Operating Flow with the AeroEclipse® XL BAN® Nebulizer	4 L/min
Operating Life	1,095 hours

Technical data on electromagnetic compatibility can be obtained from Trudell Medical International.

PROTECTION AGAINST INGRESS

The IP Code, or Ingress Protection Code, indicates how well the compressor housing protects the compressor internal wires and pump from accidental contact and water. The compressor is designed to resist child fingers from touching inside (the '2' of IP21), and to resist accidental dripping water (the '1' of IP21).

REORDER NUMBERS

AeroEclipse® XL BAN® Nebulizer (Includes: AeroEclipse® XL BAN® Nebulizer with mouthpiece, EZ Twist® Tubing, instructions for use)	10551301010
Air Filters, (5 pack)	10554493050

Qty **UDI** **MD** **AU SPONSOR**

13 **14** **15** **16**

Operating Conditions **Storage/Transport Conditions**

17 **18**

Meaning of Symbols

1 Temperature limit	9 Caution
2 Humidity limitation	10 Do not open. Warranty void if seal is broken.
3 Atmospheric pressure limitation	11 Single patient - multiple use
4 Class II equipment	12 Part number
5 Indoor use only	13 Quantity
6 Disposal of electrical & electronic equipment (WEEE Directive)	14 Unique device identifier
7 Consult instructions for use	15 Medical device
8 Type BF Applied Part	16 Australian Sponsor
	17 Operating Conditions
	18 Storage/Transport Conditions

372-GLC-BN Scan or contact Trudell Medical International to obtain a glossary of the symbols used on packaging and instructions for use.