

SootheNeb NBL200 Compressor Nebulizer

311-7014100-007
Version 3.0
2017/05

OPERATION INSTRUCTIONS

Dear SootheNeb NBL200 System Owner:

Thank you for purchasing the SootheNeb NBL200 Compressor Nebulizer. This manual provides important information to help you use the system properly. Before using this product, please read the following contents thoroughly and carefully.

If you have other questions regarding this product, please contact the place of purchase or call the Customer Care Line.

ITEMS SUPPLIED

Before you start to use the SootheNeb NBL200 Compressor Nebulizer, please check if the following items are included in the package:

- | | | |
|--------------------------------|-------------------|-----------------------------|
| 1. 1 compressor | } nebulizer kit } | 8. Connector |
| 2. 1 mouthpiece * | | 9. 1 air hose |
| 3. PVC/Silicon Mask (optional) | | 10. DC Adapter |
| 4. 1 L-PIPE | | • 1 warranty card |
| 5. 1 cap | | • 1 operations instructions |
| 6. 1 spray nozzle | | |
| 7. 1 medicine container | | |

* NOTE

- Nebulizer kit and air hose/connector are required when using the nebulizer. Nebulizer kit and air hose are not sterile and only for single use (disposable). If any of these parts becomes dirty or clogged, please replace it with a new one.
- Mask and DC Adapter may be provided separately.
- Please contact local dealer for purchase, or contact Customer Care Line at 1-888-307-8188 for more information.
- Use only the parts listed above; use of other parts may constitute a hazard.

INTENDED USE

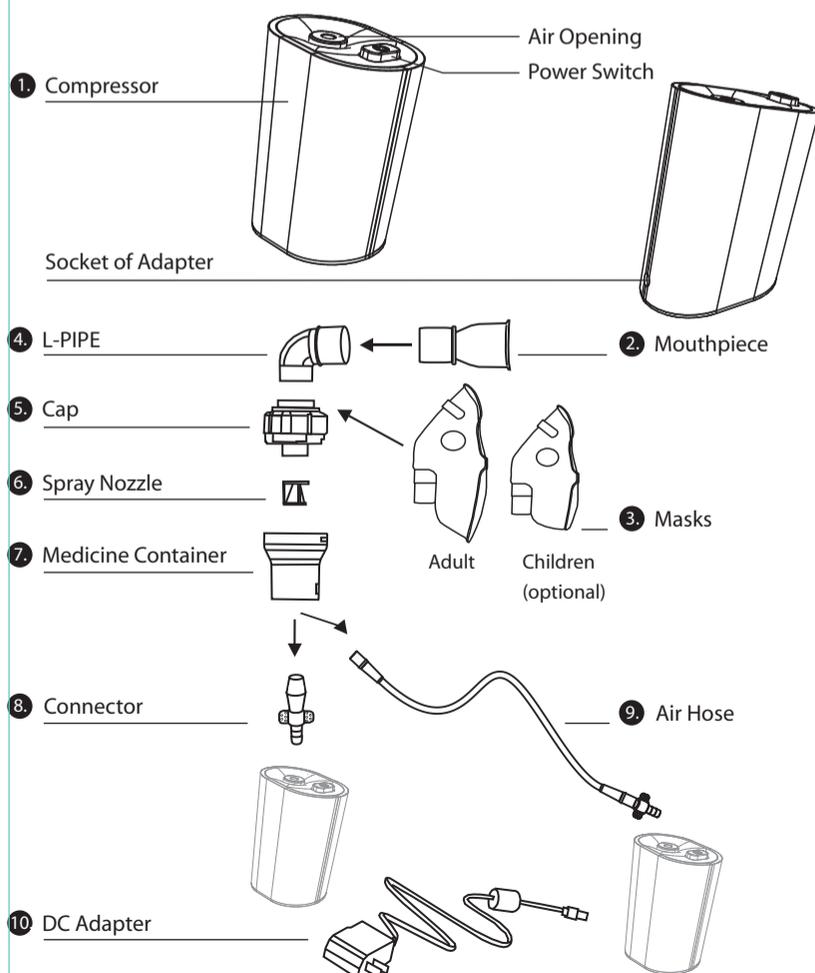
SootheNeb NBL200 is intended to deliver physician-prescribed inhalation medication in an aerosol form to adults or pediatric patients, except for Pentamidine. SootheNeb NBL200 can be used at home.

Cautions: Federal law restricts this device to sale by or on the order of a physician.

FEATURES

- No warming of medicine, thus preventing damage to the structure of the medication
- Low power consumption
- Small nebulization particle size 5 microns
- Convenient design – compact and lightweight, ideal for travelling
- Quiet operation – the noise level is 55 dBA.
- Short treatment time – with high nebulization rate

DESCRIPTIONS OF PARTS



WARNING

For reasons of hygiene, please use the mouthpiece for one specific individual only and do not share it. The mouthpiece must be replaced after each use.

SAFETY PRECAUTIONS

- Use the equipment only for its intended use as described in this manual. Do not use attachments not recommended by the manufacturer.
- Use the equipment with medications only under the instruction of your physician.
- Do not use the equipment if it has any damaged parts, or it has fallen into water.
- To use the equipment for the first time, or after storing it for an extended period, be sure to clean all necessary parts as described in the cleaning instructions.
- Do not use while bathing.
- The unit should not be left unattended while plugged in or turned on.
- Keep the unit out of reach of small unsupervised children. The small parts detached from the device may result children choking from inhaling or swallowing.
- The accessible materials used in the device will not cause the potential allergic reactions to skin.
- Do not try to modify the device.
- Do not place the device in liquid, nor put it where it could fall into liquid. If the device becomes wet, unplug the device before touching it.
- Do not use the device if it is not working properly, or if it has suffered any damage.
- Do not subject the nebulizer to any impacts and do not drop them.
- After a period of no use, and after every use, please clean the compressor unit.
- Do not expose the nebulizer to direct sunlight, high temperatures or humidity.

IMPORTANT INFORMATION ABOUT INHALATION THERAPY

The device is ideally suitable for inhalation at home or when travelling. It guarantees highly effective, fast-acting inhalation treatment for children and adult patients.

Carry out inhalation in a quiet and relaxed state, and inhale slowly and deeply, so that the medication can penetrate to the fine, deep bronchial tubes. Exhale normally.

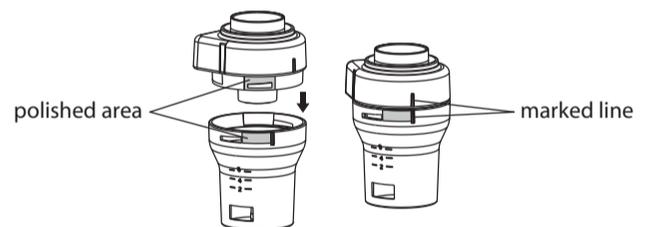
OPERATING INSTRUCTIONS

Important Information Before Use

- Ensure that all parts are clean and dry.
- Before starting treatment, talk to your physician about the duration, dosage and frequency of use of the nebulizer.
- The device is designed for an intermittent use: 30 minutes ON / 30 minutes OFF.
- Do not remove the medication container cover from the unit during nebulization.

Unit Assembly and Usage

1. Correctly position the spray nozzle inside the medicine container.
2. Slowly pour the prescribed medication into the medicine container. The maximum capacity of the container is 6 ml (0.203 oz). Please note that the medication must not exceed this maximum level.
3. Place the cap on top of the medication container and slightly turn it clockwise so that the lines marked on the cap and medicine container are lined up evenly. Then connect the mouthpiece to the L-PIPE, and then connect that to the top of the cap, or you can connect the Mask (optional) to the L-PIPE.



NOTE

The mouthpiece is to be used for oral inhalation only.

4. The nebulizer can be connected to the compressor by using the air hose with connector.
5. Plug the DC adapter into the wall outlet; plug the power cord of the adapter into the socket on the side of the compressor.
6. Press the power switch to turn on the device. Begin treatment according to your physician's instructions.
7. Inhale and exhale naturally. Be sure to stop when the medication is exhausted.

NOTE

When you have completed use, press the power switch to turn the device off before you disconnect the air hose. Unplug the adapter, remove the inhalation accessories used and proceed with cleaning operations as described in the "Cleaning and Maintenance" section.

Inhalation with Mouthpiece and Mask

How to use the mouthpiece

1. Insert the mouthpiece into the L-PIPE.
2. Close your lips around the mouthpiece and start treatment as recommended by your doctor.

How to use the mask

1. Insert the mask into the L-PIPE.
2. Place the mask onto your face and start treatment as recommended by your doctor.

CLEANING AND MAINTENANCE

Please clean your device after each use according to the instructions below.

Before Cleaning

Make sure that the nebulizer is turned off before disassembly.

Cleaning of Nebulizer Accessories

1. After you have disconnected the air hose, remove the mouthpiece / mask, L-PIPE, cap, spray nozzle and medicine container.
2. Discard any remaining medications.
3. Wash mouthpiece / mask, connector, L-PIPE, cap, spray nozzle and medicine container with running water or soak in warm water for 15 minutes.
4. Gently wipe off excess water with a clean dry cloth and allow to air dry on a clean paper towel.

Cleaning of Compressor

1. Use alcohol cotton swabs to wipe the outer casing of the compressor.
2. Let it air dry on a clean paper towel.

NOTE

1. The above-named accessories can be regarded as consumable items, please replace with a new one if it becomes dirty or obstructed. In consideration of the risk of cross-contamination, do not share the accessories with others.
2. Only use the aerosol nebulizer kit distributed by ForaCare for appropriate assembly.

Maintenance for Storage

1. Always handle your nebulizer with care.
2. Disconnect the power plug from the wall outlet when not in use.
3. Keep your nebulizer out of children's reach.
4. If you store your nebulizer, do not bend the air hose.
5. If you store your nebulizer, keep it in the following environmental ranges:
 - a) Temperature: -13°F to 158°F (-25°C to 70°C),
 - b) Relative humidity: 10% to 95%
6. If possible, store your nebulizer in a well-ventilated room.

Disposal

Dispose of the device, components and optional accessories according to your local regulations.

ADDITIONAL INFORMATION

Particle Size Delivery Test according to EN13544:2007

The mass median aerodynamic diameter (MMAD), geometric standard deviation (GSD), respirable fraction (%), 0.5-5 µm, and particle size distribution of the particles generated from SootheNeb NBL200 Compressor Nebulizer are determined by laboratory testing conducted with a cascade impactor method according to the European Standard for nebulizers (EN 13544-1:2007).

Three different drugs were used in the testing to represent three different drug classes: Ipratropium bromide (anti-cholinergic bronchodilator), Ventolin (as known as albuterol, a beta-agonist bronchodilator) and Cromolyn sodium (anti-inflammatory). The dose of each drug that used at the beginning of the cascade impactor testing was:

- Ipratropium: 500 ug / 2 mL
- Ventolin: 5000 ug / 2.5 mL
- Cromolyn: 8000 ug / 2 mL

The test had involved three runs each of three separate device samples tested with three classes of drugs. The durations of each sample collecting by cascade impactor is about 1-3 mins to allow for maximum deposit on each stage without overloading. The result summary of the test is shown in Table 1, CV (%) of repeatability was less than 5%.

Table 1 Results of the repeatability test for SootheNeb NBL200 Compressor Nebulizer.

Features	Mean	C.V. (%) ≤ 5%.
MMAD (µm)	Ipratropium bromide – 2.22 Ventolin – 2.98 Cromolyn sodium – 3.81	I.B. – 4.05 V. – 1.02 C.S. – 0.52
Geometric Std. Dev. (GSD)	Ipratropium bromide – 2.47 Ventolin – 2.63 Cromolyn sodium – 2.42	I.B. – 2.96 V. – 2.47 C.S. – 2.92
Respirable Fraction (%), 0.5-5 µm)	Ipratropium bromide – 83.2 Ventolin – 71.5 Cromolyn sodium – 62.4	I.B. – 1.09 V. – 0.49 C.S. – 1.2

- I.B. = Ipratropium bromide
- V. = Ventolin
- C.S. = Cromolyn sodium
- MMAD (µm) = mass-median aerosol diameter, the diameter above and below which lies 50% of the mass of the particles.
- GSD = Geometric standard deviation
- Respirable fraction (%), 0.5-5 µm) = Respirable mass (µg) / Particle mass collected by the cascade impactor (µg) x 100%

The test result of device sample I with three classes of drugs each in three runs is provided in Table 2 shown more information, including the total dose delivered, respirable mass (0.5-5 µm), course particles fraction (>4.7 microns) (%), fine particles fraction (<4.7 microns) (%), and extra-fine particles fraction (<1 micron) (%).

Table 2 Summary of the test results for device sample I.

Features	Device sample I.
Total output mass (µg)	Ipratropium bromide – 326.5 Ventolin – 1040.4 Cromolyn sodium – 1514.1
Respirable Mass (µg, 0.5-5 µm)	Ipratropium bromide – 106.8 Ventolin – 194.5 Cromolyn sodium – 246.5
Coarse particle Fraction (%) (> 4.7 µm)	Ipratropium bromide – 19.22 Ventolin – 31.19 Cromolyn sodium – 40.84
Fine particle Fraction (%) (< 4.7 µm)	Ipratropium bromide – 80.78 Ventolin – 68.81 Cromolyn sodium – 59.16
Ultra-fine particle Fraction (%) (< 1 µm)	Ipratropium bromide – 17.92 Ventolin – 11.71 Cromolyn sodium – 4.47

The ANOVA statistical analysis of the data from the performance test has been applied in the data analysis. Results show that there is no significant difference (p > 0.05) between the mass size distributions of the medicine particles generated by the proposed device and a legally marketed device (predicate device).

In conclusion, the performance test results support the specifications of SootheNeb NBL200 Compressor Nebulizer, which has mass-median aerosol diameter (MMAD) less than 5 µm and respirable fraction range from 60% to 80% depends on the drug type.

TROUBLESHOOTING

Symptom	Probable Cause	Solution
The device does not work or the device is on but nebulizes weakly.	The plug is improperly inserted into the device.	Re-plug again and make sure that the plug is properly inserted into the device.
	Compressor switch is off.	Turn the switch on.
	Air hose is bent.	Remove any bend or kink in the air hose.
	The spray nozzle does not place in its position.	Place the spray nozzle in its correct position.
The device is on but does not nebulize.	No medicine is left.	Add the appropriate amount of medicine prescribed by your physician to the medicine container.
	The medicine container and cap does not assemble well.	Re-assemble the medicine container and cap.

SPECIFICATIONS

Model no.: SootheNeb NBL200

Dimension & Weight: 98 mm x 88 mm x 50 mm, 155 g

Power Source: DC 6V

Power consumption: 9.6 W

Compressor pressure range: 13 to 17 psi

Operating pressure range: 6 ~ 8 psi

Maximum Flow Rate: 3 LPM

Noise Level: 55 dBA

Maximum operation altitude: 2000 m

Operating conditions: 41°F to 104°F (5°C to 40°C), 15% to 93% relative humidity, 700 hPa to 1060 hPa

Storage conditions: -13°F to 158°F (-25°C to 70°C), 10% to 95% relative humidity

NOTE

Please contact your dealer or Customer Care Line for assistance with any other difficulties.

Cascade Impactor Testing**:

Features	Drug Name	Ipratropium bromide	Ventolin	Cromolyn sodium
MMAD (micron)		2.22	2.98	3.81
GSD (geometric standard deviation)		2.47	2.63	2.42
Respirable fraction (% mass 0.5- 5µm)		83.2	71.5	62.4

**The test method and results are shown in "Additional Information".

The device has been certified to meet the electrical and safety requirements of: IEC 60601-1, IEC 60601-1-2.

Read instructions before use.

Distributed by ForaCare

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Products made in Taiwan

Toll Free: 1-888-307-8188 (8:30 am-5:00 pm PST, Mon.-Fri.).

For assistance outside of these hours, please contact your healthcare professional.

www.foracare.com