



I-neb™ AAD® System

User Guide

Single Patient Use

Contents

Before you start	4-8
Preparing your treatment	9
Taking your the treatment	10-11
Pausing your treatment	12
Maintenance and cleaning	13-15
Periodic maintenance	16
Troubleshooting	17-18
Screen display menu	19-21
Audible signals	22
Lost disc?	23
Technical information	24
Chamber identification	25
Spare parts	25
Contacting Customer Services	26
Disclaimer	27

Intended Use

- The intended purpose of the I-neb AAD System is that it is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medication approved for use with the I-neb AAD System, for inhalation by the patient in the home care, nursing home, sub-acute institution, or hospital environment.
- The I-neb has been developed for adults and children age 2 upwards who can co-ordinate breathing into a mouthpiece. The I-neb should always be used in conjunction with patient data supplied by the specific drug licence.
- I-neb should only be used on conscious and spontaneously breathing patients.
- If you require any further information about your treatments contact your nurse/clinician/healthcare provider.
- If you have any problems with your I-neb, contact the patient helpline at

1.877.4VENTAVIS
(1.877.483.6828)

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

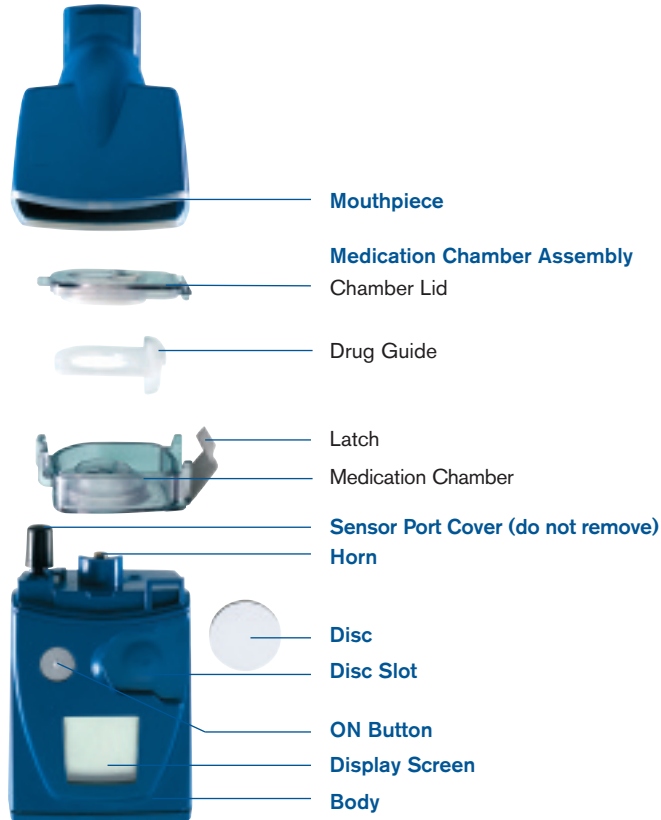
**This user guide will help you use your I-neb. Pay special attention
to the notes which will help prevent damage to your I-neb and
help you get the best results.**

The I-neb AAD System Overview:

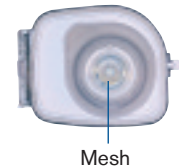
The picture opposite shows all the parts of the I-neb. Although it looks like there are a lot of parts, the I-neb is very easy to use.

Product Features

- Micropore mesh and high frequency horn to make aerosol quietly
- AAD (adaptive aerosol delivery) technology to ensure accurate dosing
- Small in size (about 6 inches high)
- Lightweight (about 7.5 ounces)
- Fully portable
- Battery – powered with universal voltage adapter
- Long life battery (up to 40 treatments/charge)



Chamber Lid

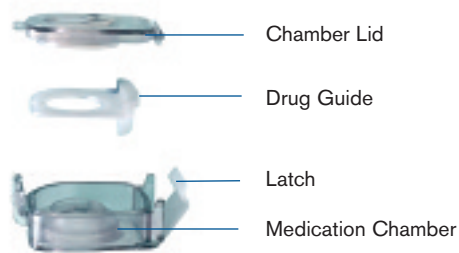


Battery charger and charging lead



Washing basket

Before you start



Your I-neb box will contain:

- I-neb
- 2 Medication chamber assemblies (2 chamber lids, 2 drug guides and 2 medication chambers each). See chamber identification table on page 25 for further information. Your healthcare provider will tell you which chamber to use.
- 2 discs (2.5 and 5.0 micrograms)
- Battery charger
- Mouthpiece
- Washing basket
- Protective bag
- Quick start guide
- User guide

⚠ WARNINGS! & CAUTIONS:

The I-neb is a sensitive medical device and should be handled with care. To make sure that your I-neb works properly and lasts a long time, follow the important instructions below.

⚠ WARNING! As with all aerosol drug delivery devices, there is a remote possibility that in a case in which the amount of drug being inserted into the device is greater than the dose that is to be delivered by the device, a device malfunction may result in an overdose of drug being delivered to the user. In the event that you experience any of the overdose symptoms listed in the drug information for the drug you are taking with this device, you should contact your physician immediately.

Cleaning:

- Before you use the I-neb for the first time or after long storage, wash, rinse and dry the mouthpiece and medication chamber assembly (see Weekly Wash instructions page 15, step 33).
- Never wash the I-neb or parts in a dishwasher.
- Do not place the I-neb in a microwave or regular oven. Do not try to dry it in an oven.
- Do not use bleach or any other cleaning agents to clean the I-neb.
- Do not use mineral water to clean or rinse the I-neb.
- Never remove the rubber seals from the medication chamber lid.

Use:

- Never use I-neb to inhale water.
- Never poke the mesh or on button with sharp objects. Handle the chamber lid with care.
- Do not use I-neb around medical gases or run oxygen through the device. If you are using oxygen at home, you may continue to wear the oxygen while taking a treatment.
- Do not leave the device alone with a small child. Small parts can be dangerous to children.
- When not in use, keep the I-neb out of reach of small children or infants.
- Handle the I-neb with care. Do not shake or drop the I-neb.
- Before starting a treatment, remove or turn off mobile or cordless

phones within 4 feet of the device. They may interfere with operation of the I-neb.

- Other electrical equipment may be affected by the I-neb. When using the I-neb, move away from other equipment or turn the equipment off.
- Do not expose the I-neb to high temperatures, high humidity or direct sunlight.
- Do not carry the I-neb with medicine in the medication chamber. It may spill.
- Do not attempt to take apart or change the I-neb.

Battery Care:

- Do not wash the battery charger with water.
- Do not handle the battery charger

with wet hands. Only use the charger in a dry place indoors.

- Only use the I-neb with the battery charger and battery that are provided.
- Do not connect this battery to other equipment.
- Do not short circuit the battery.
- Do not dispose of the battery in fire. It may explode.
- Do not attempt to take apart the battery.
- Do not drop medication on the battery charger. Immediately wipe up spills with gauze or a clean cloth.
- Unplug the battery charger from the electrical outlet after charging.

Before you start continued

1



Before you take your first treatment, there are four things you will need to do:

1. charge the battery,
2. insert the prescribed dosing disc,
3. wash the medication chamber assembly,
4. and get used to assembling the I-neb.

Charging the battery:

Before you take your first treatment, charge the battery for 3-6 hours or until you see the fully charged symbol (as above).

2



To charge the battery, clip the I-neb onto the battery charger and connect the plug to an electrical outlet. When the I-neb is fully charged unplug it from the outlet. Unclip the battery charger by pressing the grey buttons on the side of the charger unit.

CAUTION: Do not leave the battery charger plugged into the electrical outlet after charging.

3



Insert the prescribed dosing disc:

When you start your therapy, your healthcare provider will tell you which dose and disc to use. Please refer to the disc identification table on page 25. Always use the dosing disc prescribed by your healthcare provider. If you lose your disc, use the matching one from your backup device. Make sure it is the correct color and dose number. Call the patient helpline for a replacement or if you have any questions about which disc to use:

1.877.4VENTAVIS
(1.877.483.6828)

4



The disc is supplied on a card. Your healthcare provider will tell you which disc to use.

Remove the disc from the card. Keep the card for future reference.

Slide the disc fully into the slot at the front of the I-neb.

It doesn't matter which way the disc is inserted.

CAUTION: Leave the disc in place on the I-neb in between treatments.

CAUTION: If you do not insert a disc, I-neb will not work.

5



6



Washing the medication chamber assembly:

Before you use the I-neb for the first time or after long storage, you will need to wash, rinse and dry the mouthpiece and medication chamber assembly (see Weekly Wash instructions page 15, step 33).

Assembling the I-neb:

Before you take your first treatment, practice taking the medication chamber assembly apart and putting it back together again (see page 7, step 7).

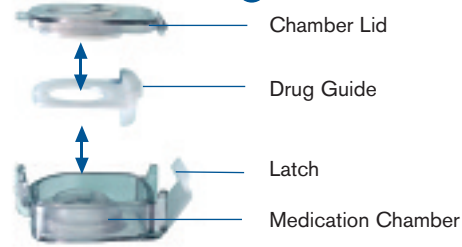
To take it apart, twist the medication chamber assembly in a counter clockwise direction (to the left). Unclip the grey latch. Carefully take off the chamber lid.

⚠ WARNING! DO NOT LIFT THE SEAL ON THE CHAMBER LID

⚠ WARNING! DO NOT DAMAGE THE MESH IN THE CENTER OF THE LID.



7



Take out the drug guide. The medication chamber is now completely apart.

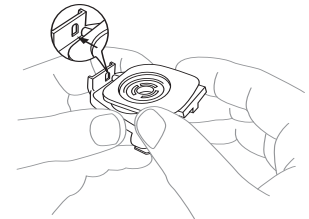
To put it back together again, follow these steps in reverse order.

Take time to practice putting the parts of the medication chamber onto the body of the I-neb. The center of the medication chamber fits over the horn. Once in place, twist the chamber in a clockwise direction (to the right).

To replace the chamber lid, place the pin on the lid in the slot on the medication chamber. The slot is located on the opposite side of the chamber latch.

Clip the latch back up over the lid, clipping it into place. Make sure that the latch has snapped tightly shut.

CAUTION: If the lid is not secure, aerosol may not be produced.



Before you start continued



The latch on the medication chamber will be directly across from the sensor port cover (see the picture above).



To place the mouthpiece on the I-neb, line up the vent hole with the back of the I-neb body. Move it forward to click it into place.

Make sure it is firmly in place. There should be no gaps.

To remove the mouthpiece after treatments, press the top of the mouthpiece and roll it forward.



Located inside the mouthpiece is a flap valve. The position of the valve is important to normal operation of the I-neb.

Look at the flap valve before use. Make sure it is not twisted. If it is twisted, place the valve under running water to correct the position.

CAUTION: If the flap valve is twisted, the I-neb may not be able to detect your breathing and medication may not be delivered.

Preparing for your treatment



Select the correct medication chamber for your dose of medication. Your healthcare provider will tell you which dose to take.

Look at the chamber identification table on page 25. It will help you to choose the right chamber. Attach the medication chamber by pushing it on the I-neb and twisting it in a clockwise direction (to the right).

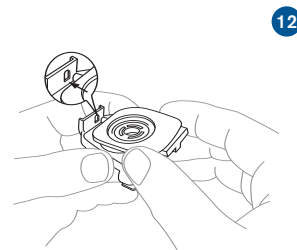
Make sure the color of the disc matches the color of the chamber latch.



Place the I-neb on a flat surface. Use a pipette to transfer all the medication from the ampule into the center of the medication chamber. Slowly pipette the medication around the horn. Some of the medication will overflow into the other part of the medication chamber. This is normal. It is important to completely fill the center portion of the chamber.

Note: It's important that there are no bubbles in your medication. If medication sits on top of the drug guide, press down lightly on the tab of the drug guide.

Note: See patient info provided with your medication for instructions on opening the ampule.



Replace the chamber lid and mouthpiece.



Make sure the I-neb remains upright. You are now ready to start your treatment.

CAUTION: Never carry the I-neb with medication in the chamber. It may spill.

Taking your treatment

14



⚠ WARNING!
BEFORE STARTING YOUR TREATMENT, MAKE SURE THERE ARE NO MOBILE OR CORDLESS PHONES WITHIN 4 FEET OF THE I-NEB. EVEN WHEN TURNED OFF, THEY MAY INTERFERE WITH THE OPERATION OF THE I-NEB.

15



Turn the I-neb on by pressing the ON button.

CAUTION: Make sure the mouthpiece is in place before turning the I-neb on.

CAUTION: Do not use sharp objects such as pens to turn the I-neb on, they may damage the ON button.

16



Wait until the start up screen appears. The start up screen will show a number (25 or 50). This is the dose you are about to take. If in doubt look at the table on p 25.

17



Pick up the I-neb.

Hold the I-neb horizontally with the display screen facing down.

Note: Tilting the I-neb too far either up or down will cause it to stop delivering medication

18



Seal your lips around the mouthpiece. Breathe in and out through your mouth. Do not breathe through your nose. Hold your nose for a few breaths to make sure you are breathing through your mouth. Release your nose and breathe normally.

Tip: Holding your nose for a few breaths will help you get used to the feeling of breathing in through your mouth. This can help make treatment times shorter.

19



It will take a few breaths for the I-NeB to start delivering medication. When the medication starts to be delivered, you will feel a vibration with each breath. This lets you know the medication is being delivered.

During the treatment, the number showing your dose will disappear. The battery symbol and face will remain.

20



Continue until you hear the buzzer. The buzzer lets you know that your medication has been delivered and the treatment is complete.

A smiley face will appear on the screen. The I-NeB will automatically shut off at the end of the treatment.

Pausing your treatment

21



You may pause your treatment at any time by removing the mouthpiece from your mouth. If you don't breathe on your I-Nebs for two minutes, it will go into 'pause mode'. To continue your treatment, pick up the I-Nebs and start breathing through the mouthpiece. If you don't start the treatment again within 10 minutes, the I-Nebs will automatically shut off.

22



If the I-Nebs shuts off you cannot restart your treatment. You must take it apart, empty the medication chamber, and clean it as shown in step 24.

CAUTION: If you pause for more than 10 minutes, you will not be able to continue your treatment session.

23



To continue your treatment, pick up the I-Nebs and start breathing through the mouthpiece. It will take a few breaths for the I-Nebs to start delivering medication.

Maintenance and cleaning

24



To clean the I-neb:

Place the I-neb on a flat surface.

25



Carefully take the mouthpiece off the I-neb. Press on top of mouthpiece. Roll it forward and pull it off.

26



Take the chamber lid off by unclipping the latch and removing.

⚠ WARNING! HANDLE THE CHAMBER LID WITH CARE. THE MESH IN THE CENTER OF THE LID IS EASILY DAMAGED.

27



Carefully take out the drug guide.

CAUTION: Do not remove the medication chamber

Maintenance and cleaning continued

28



The I-neb is very accurate. It delivers the right amount of medication when you breathe in. There will be some medication left in the chamber after your treatment. This is normal. Carefully pour out the medication left in the chamber.

⚠ WARNING!
DO NOT TRY TO RE-USE ANY LEFT-OVER MEDICATION.

29



Remove the medication chamber by twisting counter clockwise (to the left). Use gauze or an antiseptic wipe to wipe away any moisture around the horn and sensor port cover.

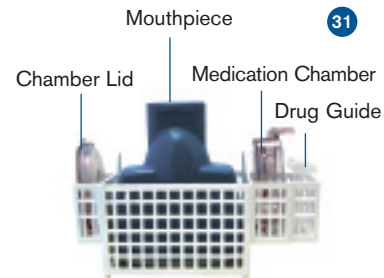
Check the battery level. If you see 1 to 2 bars, your battery is running low. Recharge the battery (see page 6).

30



For cleanliness, the mouthpiece and all the parts in the medication chamber should be cleaned regularly. To keep the I-neb working properly, you must wash the medication chamber after each treatment. It is also important to boil the mouthpiece and medication chamber parts for 6-10 minutes once a week (see page 15, step 33)

31



Place the mouthpiece, medication chamber, chamber lid and drug guide into the right places in the washing basket.

CAUTION: The basket must be used to protect all parts during washing.

CAUTION: Don't use bleach or similar products to clean I-neb. Don't use brushes or sharp objects to clean the parts .

CAUTION: Don't place any of the parts in a dishwasher.

32



To keep your I-neb working, it must be regularly cleaned as follows:

Routine Wash

After each use: Place the mouthpiece, medication chamber, chamber lid, and drug guide in the washing basket. Place the basket in warm soapy water (use liquid detergent). Move the basket back and forth in the water.

Rinse the washing basket containing the parts in soft or filtered water. If you have hard water, rinse with water that has been boiled and allowed to cool. Shake off excess water and leave parts to air dry.

⚠️ WARNING!

DON'T PLACE THE CHAMBER LID DIRECTLY UNDER RUNNING WATER.



33



34



Weekly Wash

Once per week: Place the mouthpiece, medication chamber, chamber lid, and drug guide in the washing basket. Put the basket into a pan of water with a couple of drops of liquid detergent. Bring the water to a boil.

Boil for 6-10 minutes. Rinse with soft or filtered water. If you have hard water, rinse with water that has been boiled and allowed to cool. Shake off excess water and leave parts to air dry.

If stored for long periods, complete the Weekly Wash before using the I-neb (see step 33).

Periodic maintenance

35



Whenever the body of the I-neb has liquid spilled on it, wipe with a clean damp cloth.

CAUTION: Don't put the body of I-neb in water or under running water.

CAUTION: Don't remove the rubber seals from the chamber lid.

36



There is a small valve in the mouthpiece. This valve is important to make the I-neb works correctly. Make sure this is not twisted in any way. If the valve is twisted, run the valve under running water to correct the position.

37



Every 6 months

After 6 months throw away the mouthpiece and medication chamber assembly (consisting of: chamber lid with mesh, drug guide and medication chamber). Replace with new parts.

38



Charging the battery

When the battery symbol shows 1 to 2 bars, clip the I-neb onto the battery charger. Plug the charger into an electrical outlet. Charge the battery for 3-6 hours or until you see the fully charged symbol.

When the I-neb is fully charged, unclip the I-neb from the battery charger. Unplug the charger from the electrical outlet.

Troubleshooting

What if....

- *my treatment time suddenly increases?*
- *the I-neb doesn't deliver my medication when I breathe in?*
- *I feel as if I have to keep up with the medication delivery?*
- *I feel like the medication is not being delivered (no vibration is felt when I breathe in)?*



Things to check

Make sure you are breathing through your mouth and not your nose.



Make sure you are holding the I-neb correctly.

What if?

41



If your treatment is taking longer than normal, check to see if there is medication left in the chamber. To check the medication, follow these steps:

- Stand the I-neb on a flat surface.
- Remove the mouthpiece and chamber lid.
- Look inside the chamber to see if there is medication left.

42



If your treatment is taking longer than normal or there is a problem with the aerosol being produced, the I-neb may need to be cleaned. Follow the instructions for Weekly Wash on page 15, step 33.

43



Check to make sure the valve in the mouthpiece is not twisted. If the valve is twisted, run the valve under running water to correct the position (See point 36).

If you continue to have problems with the I-neb, contact the patient helpline number:

1.877.4VENTAVIS
(1.877.483.6828)

Screen display menu

44



During your treatment different codes and symbols will appear on your screen. These help you understand how the I-neb is working.

Code 11 screen

Start up error.

Solution: Stand the I-neb upright on a flat surface. Reset the I-neb by pushing the ON button and holding it in. Wait for the start up screen to appear. Pick up I-neb and start your treatment. *(Code 11 will remain on the screen for 10 minutes or until the ON button is pressed for 5 seconds as described above).*

45



Code 22 screen

There is no disc in the I-neb, I-neb failed to read the disc, or electrical equipment is located nearby and is interfering with the I-neb.

Solution: Stand I-neb upright on a flat surface. Check that the disc is correctly in place. Remove and reinsert or replace the disc. Turn off and move any electrical equipment nearby. Reset I-neb by pushing the ON button and holding it in. Wait for the start up screen to appear. Pick up the I-neb and start your treatment. *(Code 22 will remain on the screen for 10 minutes or until the ON button is pressed for 5 seconds as described above).*

46



Code 33 screen

Your I-neb needs maintenance. Begin using your backup device and call the helpline as soon as possible to arrange the return of your I-neb for maintenance. Pick up the I-neb and start treatment. *(Code 33 will remain on the screen for 10 minutes or until the ON button is pressed for 5 seconds)*

Contact the patient helpline to arrange return of your I-neb.
Helpline phone number:

1.877.4VENTAVIS
(1.877.483.6828)

47



Code 44 screen

Memory failure.

Solution: Reset by pressing the ON button and waiting for the start up screen to appear. Pick up I-neb and start your treatment. *(Code 44 will remain on the screen for 10 minutes or until the ON button is pressed for 5 seconds).*

Screen display menu continued

48

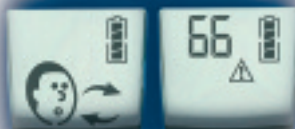


Code 55 screen

There is no medication in the medication chamber at the beginning of treatment.

Solution: Stand the I-neb upright on a flat surface. Add medication to the medication chamber. Reset by pressing the ON button and waiting for start up screen to appear. Pick up the I-neb and start your treatment. (Code 55 will remain on the screen for 10 minutes or until the ON button is pressed for 5 seconds).

49



Code 66 screen

This means that I-neb is being held at the wrong angle.

Solution: Hold the I-neb horizontally with the screen facing down. Continue to breathe normally through the I-neb (See below).



50



Blank screen

Dead battery.

Solution: The I-neb can be used when connected to the battery charger. To continue with your treatment, attach the I-neb to the battery charger and plug into an electrical outlet (see step 2 on page 6). Switch I-neb on, wait for the start screen to appear. Pick up the I-neb and start your treatment.

Once your treatment is complete, recharge the battery (see page 16, step 38)

51



Start up Screen.

Your drug dose (25 or 50) should appear.

52



Treatment in progress.

The mouthpiece vibrates when the medication is delivered.

53



Treatment successfully completed.

54



Pause Mode

Solution: To continue, you must start breathing within 10 minutes. Pick up the I-neb and start breathing normally. It will take a few breaths for the I-neb to start delivering medication.

Any other screen display

Contact the helpline to arrange return for repairs.

Patient Helpline Phone Number: **1.877.4VENTAVIS (1.877.483.6828)**

I-neb will make two audible signals:

55



Four short beeps when you breathe in through the mouthpiece.

This sound is made when the I-neb is being held at the wrong angle.

At the same time, the screen will flash code 66.

Solution: Hold the I-neb horizontally with the screen facing down.

56



One long continuous tone

This sound is made when you have successfully completed your treatment.

At the same time, the screen will show a smiley face.

Solution: Your treatment is complete. Clean the I-neb following the wash instructions (see page 15 step 32).



Lost disc?



If you lose your disc, use the duplicate one (the one with the same dosing number and color) that came with your second I-neb.

Contact the patient helpline immediately to obtain a replacement disc:

1.877.4VENTAVIS
(1.877.483.6828)

Technical information

The I-neb is a 'clean, non-sterile' product and is for single patient use only. The I-neb can only be used with the battery and charger supplied. Do not attempt to take the I-neb body apart or tamper with the software or hardware in this product.

Tested to IEC60601-1 and IEC60601-1-2.

Class II Type B 

 0120

This device complies with part 15 of the FCC Rules.

Power Battery Voltage

6W 3.8V

Battery Charger and Charging Lead

100-240VAC 50-60Hz

Weight

8 ounces (including battery)

Dimensions

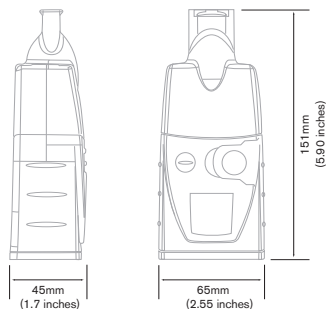
1.7 x 2.55 x 5.90 inches

Storage temperature range:

-4 F to 140 F

Operating temperature range:

50 F to 104 F



Compliant with the WEEE/RoHS recycling directives.

If you are subject to the WEEE/RoHS directives, refer to www.respironics.com for the passport for recycling this product.

CAUTION: Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

⚠ WARNING! THE I-NEB MUST NOT BE USED IN THE PRESENCE OF ANAESTHETIC GASES OR IN OXYGEN ENRICHED ATMOSPHERES.

Chamber Identification

Before you use I-neb, your healthcare provider will advise you which dose to take. The table below identifies the two different medication chambers for use with I-neb. The latches on the medication chambers are color coded to match the discs.

⚠ WARNING! MAKE SURE TO ALWAYS USE A DISC AND MEDICATION CHAMBER WITH MATCHING COLORS.

Dose	Chamber Latch Colour	Disc	Start Up Screen Display
2.5 mcg Ventavis	Red 		
5.0 mcg Ventavis	Purple 		

Spare Parts

Please consult the following table if you need to order spare parts. Consult the table prior to calling to order spares. Helpline/Order line: **1.877.483.6828**

Item	Description
85-171	Medication Chamber Assembly (Red latch, dove grey lid) 2.5 mcg Ventavis
85-181	Medication Chamber Assembly (Purple latch, dove grey lid) 5.0 mcg Ventavis
85-131	Battery
85-126	Washing Basket
85-104	Charging Lead
85-147	I-neb Pouch
85-148	Carry Bag
RP 6461	Power Cord for Charger 115V
PL590	Spare Disc 2.5 mcg Ventavis (red)
PL591	Spare Disc 5.0 mcg Ventavis (purple)

Information you will need when calling Customer Services

Serial Number:

Name:

Address:

Zip code:

Telephone No:

Date of Birth*:

Date I-neb was supplied:

Doctor's Name:

Doctor's Address:

Doctor's zip code:

Doctor's Telephone No:

*Respironics will use your date of birth to assign a private unique number to you. This unique number ensures your personal details are always kept up-to-date and that you will receive the latest equipment and information.

Medication taken using the I-neb System:

Name of drug:

Name of drug:

Name of drug:

Disclaimer

In the interests of continuing technical development, we reserve the right to change designs, equipment and accessories without notice.

The information in this document is believed to be correct at the time of closing for press. Respiroics Ltd assumes no responsibility for any data, statements, descriptions, information or illustrations in this document.

Any mention of non Respiroics Ltd products or services is for informational purposes only, and constitutes neither an endorsement nor a recommendation of such products. Respiroics Ltd assumes no responsibility for the selection, performance or use of such products and all understandings, agreements or warranties (if any) in respect of such products shall be directly between the manufacturer or supplier of such products and their purchasers or prospective users.

I-neb helpline:

1.877.4VENTAVIS
(1.877.483.6828)



Manufactured by
Respironics Ltd Heath Place, Bognor Regis,
West Sussex PO22 9SL UK
www.respironics.com

© Respironics Limited ALL RIGHTS RESERVED

Respironics is a trademark, and I-neb are registered trademarks of Respironics Ltd or companies within the group respectively, registered in the UK and other countries.

US 6,367,470; 09/781610; 10/203337; 10/185536; GB 0227105.4;
PL871 Issue 2 bdc 8048 10/05