

PRODIGY®

Mini-Mist™

portable nebulizer



Owner's Manual

Dear Prodigy® Owner:

Thank you for choosing the Prodigy Mini-Mist™ vibrating mesh nebulizer. Please read this manual carefully as it contains important information about your Prodigy® system. A warranty registration card is included with your system. Please return the completed card to us immediately.

Designed to help administer medications and moisture into air passages, the Prodigy Mini-Mist™ nebulizer helps control respiratory symptoms and loosen secretions in the lungs. This owner's manual will help you learn how to use the Prodigy Mini-Mist™ nebulizer effectively. Customer Care is available 24 hours/7 days a week by calling **1.800.243.2636**. All questions concerning the correct type, dosage and regimen of medication should be directed to your healthcare professional.

Equipped with the latest technology, the Prodigy Mini-Mist™ allows operation in all directions—upside down or tilted—for up to ten (10) seconds. Great for use anytime, anywhere.

The Prodigy Mini-Mist™ nebulizer offers:

- Ultimate portability for wherever you go
- Revolutionary vibrating mesh technology that provides precise, powerful and effective treatment every time
- Low power consumption
- Low medication residue
- Virtually silent operation

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Important Safety Instructions

Read this before using your Prodigy Mini-Mist™ nebulizer. The following basic safety precautions should always be taken.

- Clean and disinfect the nebulizer and all of its parts before using the device for the first time after purchase or if the device has not been used for a long period of time.
- Clean the nebulizer parts—medication chamber and mouthpiece—carefully after each use. Otherwise, it may not function properly.
- **DO NOT** allow cotton swabs or foreign objects to come in contact with the mesh of the medication chamber. Otherwise, it may not function properly.
- This is a single-patient device. **DO NOT** allow multiple patients to use the same device.
- Follow the instructions of your healthcare professional for the correct type, dosage and regimen of medication.
- **DO NOT** place any other liquid in the medication chamber (other than water) that is not prescribed by your healthcare professional.
- Operate the unit only as intended by your healthcare professional. **DO NOT** use the device for any other purpose.
- Provide close supervision when this device is used by, on or near children or compromised individuals.
- **DO NOT** use different types of batteries at the same time.
- **DO NOT** store or carry a nebulizer that contains liquid medication or water.
- **DO NOT** immerse the main unit of the nebulizer in water.

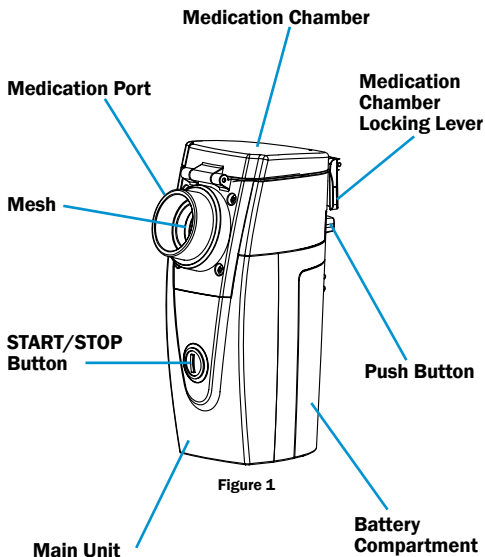
- Do not use tap or mineral water in the nebulizer for nebulizing purposes.
- Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.
- Make sure no parts are damaged, the device is assembled properly and the device operates normally prior to use.
- Do not place or attempt to dry the device or any of its parts in a microwave oven.
- Do not leave the cleaning solution in the nebulizer parts. Rinse the nebulizer parts with distilled water after disinfecting.
- Changes or modifications not approved by Prodigy Diabetes Care will void the user warranty.
- **DO NOT** disassemble or attempt to repair the unit or its components.

CAUTION: Keep the device out of the reach of infants and children. The device may contain small pieces that can be swallowed. Children should use only with adult supervision.

WARNING: The nebulization characteristics of the unit differ by the properties of medication. The nebulization rate may decrease, especially when used with different medications. In addition, the nebulization rate may also decrease when the temperature of medication is comparatively low.

Components and Functions

Main Unit



Components

Electrodes

Power conductor from the main unit to the vibrator on the medication bottle.

START/STOP Button

Turns the power for the main unit on and off.

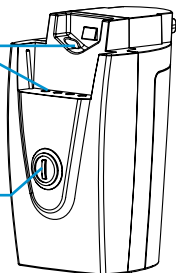


Figure 2

Push Button

Use this button to remove the medication chamber from the main unit.

Battery Compartment

Holds two (2) AA alkaline batteries.

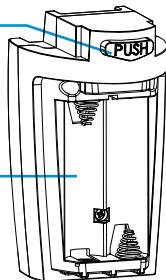


Figure 3

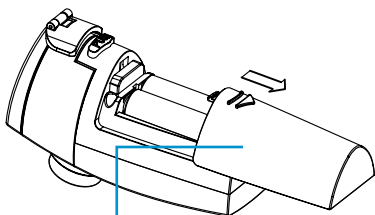


Figure 4

Battery Cover

Securely fastens to keep batteries in place.

Medication Chamber

Holds maximum capacity of 8 mL for treatment.

Mesh

Vibrates to ensure precise treatment.

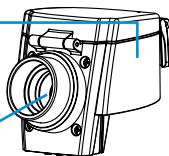


Figure 5

Medication Chamber

Locking Lever

Opens the medication chamber for filling or cleaning. Snaps into place to prevent medication from leaking.

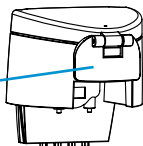


Figure 6

Mouthpiece

Patient interface. Attaches onto circular medication port. Used by patient to inhale medication.



Figure 7

Unit Assembly

General Information

You must clean and disinfect all removable parts before using the device. For cleaning and disinfecting instructions, refer to "Cleaning the Nebulizer." Read all information contained in this book prior to use.

The device must be assembled before it is used.

- Components may fit tightly as they are made to prevent the medication from leaking.
- Hold the device securely with both hands.
- Install all parts securely. You may hear a click sound as you install some of the parts

Step 1: Attach the medication chamber to the main unit

Align the medication chamber and the main unit. The electrodes on the medication chamber should line up with the electrodes on the main unit. You will hear a click to ensure it is securely fastened. The medication chamber sits on top of the main unit and snaps into place.

ATTENTION:

- Please ensure that the medication chamber is attached correctly and is secure; otherwise, it may result in a bad connection and the nebulizer may not function properly.
- Please keep the electrodes of the main unit and medication chamber clean; otherwise, the nebulizer may not function properly.

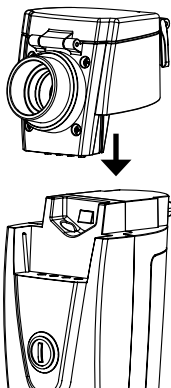


Figure 8

Step 2: Attach the mouthpiece

Attach the mouthpiece by placing it onto the medication port of the medication chamber. The mouthpiece can be attached with the holes facing in any direction.

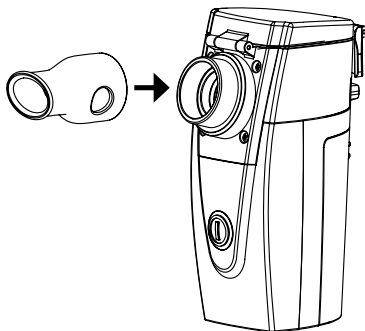


Figure 9

Battery Installation

This device operates using two (2) AA alkaline batteries or two (2) AA rechargeable batteries.

WARNING: DO NOT install worn and new batteries together. DO NOT use different types of batteries together. Remove the batteries if the device will not be used for three (3) months or longer.

Step 1: Remove the battery cover

- Slide the battery cover off in the direction of the arrow as shown in the illustration. *See Figure 10.*
- Remove the battery cover. The battery cover may appear to be tight fitting as it is designed to prevent fluids from getting into the device.

Step 2: Insert the batteries

Correctly align the polarities (+ and -) with the battery indication marks on the device.

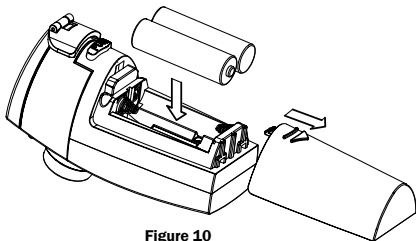


Figure 10

Step 3: Replace the battery cover

Replace the battery cover by sliding it back onto the device until it snaps into place. *See Figure 11.*

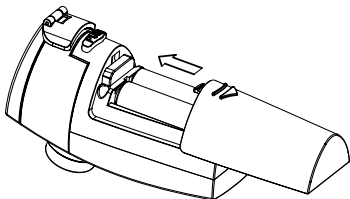


Figure 11

Battery Life and Battery Replacement**Alkaline Batteries**

- The battery low indicator (orange light) flashes to signal the batteries are low. At this point, the device will not nebulize. Immediately replace both batteries. Follow the previous steps as described in “Battery Installation.”

Rechargeable Batteries

- The battery low indicator (orange light) flashes to signal the rechargeable batteries have little or no residual power remaining. If the device will not nebulize, immediately recharge the batteries.
- Recharge the batteries using a commercially available battery charger suitable for the batteries used in the device.

Filling the Medication Chamber

Remove the mouthpiece from the main unit of the Prodigy Mini-Mist™ nebulizer.

Step 1: Remove the medication chamber from the main unit

Press the PUSH button on the rear side of the main unit and pull the medication chamber up and off of the main unit. See Figure 12.

ATTENTION:

- To avoid damaging the nebulizer, please ensure the PUSH button is pressed down before pulling upward on the medication chamber.
- To avoid rupturing the mesh, please do not poke the mesh with your finger or any foreign object.

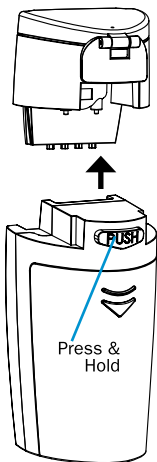


Figure 12

Step 2: Insert the medication

Open the medication chamber by pulling up on the medication chamber locking lever. Add the medication slowly. Do not allow medication to overflow over the medication port.

ATTENTION: The recommended fill volume is a maximum of 8 mL and a minimum of 0.5 mL.

Close the cover and lock lever to prevent medication from leaking. See Figure 13.

Step 3: Re-attach the medication chamber to the main unit

Attach the medication chamber by aligning the electrodes and then place it on top of the main unit and push down until it snaps into place. See Figure 14.

CAUTION:

- Please ensure the medication chamber is attached securely and correctly; otherwise, it may result in a bad connection and cause the nebulizer to malfunction.
- Please keep the electrodes of the main unit and the medication chamber clean; otherwise the nebulizer may not function properly.

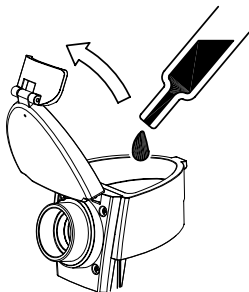


Figure 13

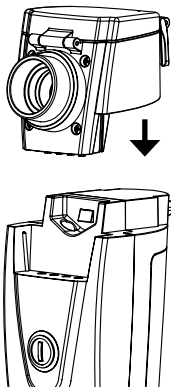


Figure 14

Step 4: Attach the mouthpiece

Attach the mouthpiece by placing it onto the medication port of the medication chamber. The mouthpiece can be attached with the holes facing in any direction. See *Figure 15*.

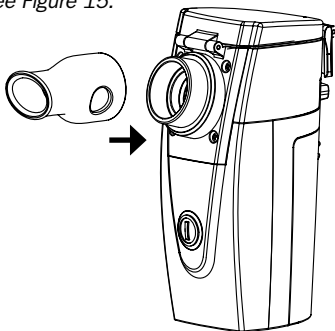


Figure 15

Operating the Nebulizer

Press the START/STOP button (power indicator) on the nebulizer to turn on the power. Then, hold the nebulizer in your hand and start inhalation with relaxed posture.

Step 1: Turn on the power

Press the START/STOP button and the green power indicator will light up signifying the nebulizer is powered on. *See Figure 16.* Once nebulization (medication coming through mouthpiece as a foggy mist) has started, the power indicator turns orange. When medication runs out, the power indicator turns red and the nebulizer turns off automatically.

ATTENTION:

- If there isn't any medication inside the medication chamber and the power is turned on, the nebulizer's green power indicator will turn red, blink for two (2) seconds and turn off automatically.
- It is normal for the nebulizer to take a few seconds to start spraying after turning power on. However, it will spray continuously once it starts.

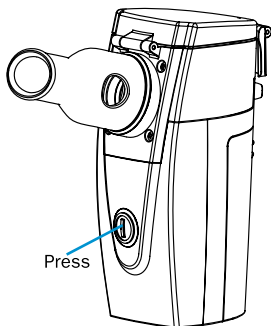


Figure 16

Step 2: Inhalation

Hold the nebulizer in your hand stably and start inhalation with relaxed posture by placing lips on or very close to the mouthpiece. *See Figure 17.* Do not cover the holes of the mouthpiece when you inhale; otherwise, the nebulization rate will decrease. *See figure 18.*



Figure 17

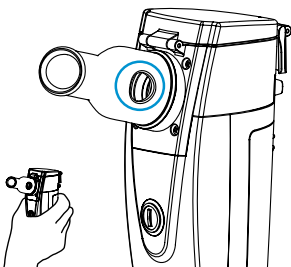


Figure 18

ATTENTION:

- If the device does not detect any medication in the medication chamber, the power indicator turns red and it will shut off automatically.
- During treatment, you may adjust the nebulizer to any angle in order to be more relaxed. However, make sure the medication stays in contact with the mesh; otherwise, the nebulizer will shut off automatically after a few seconds.
- When the medication is close to depletion, it is recommended that you tilt the nebulizer slightly towards you. This allows the remaining medication to contact the mesh to nebulize.
- Provide close supervision when the nebulizer is used by children or compromised individuals.

Step 3: Turn off the power

The nebulization shuts off automatically once the medication is depleted.

However, if you wish to stop the treatment, press the START/STOP button to turn the power off. The power indicator light will go off. See Figure 19.

The unit will emit a high frequency sound and turn off the power automatically when the medication is depleted.

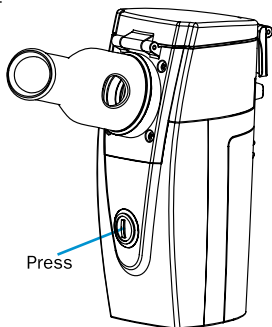


Figure 19

Cleaning the Nebulizer

Following the cleaning instructions after each use will prevent any remaining medication in the bottle from drying and adhering to the mesh cap and the device not nebulizing effectively.

Before storing or carrying, make sure to clean the nebulizer instantly with distilled water after each use.

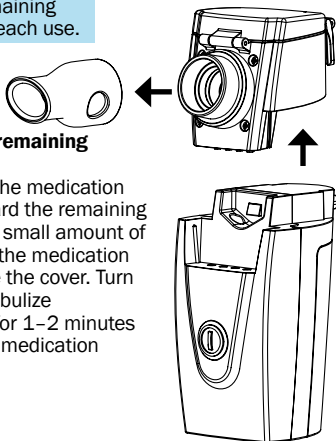
Step 1: Dismantle the nebulizer

Remove the mouthpiece and then remove the medication chamber from the nebulizer.

See Figure 20.

ATTENTION:

Clean out the remaining medication after each use.



Step 2: Clean the remaining medication

Open the cover of the medication chamber and discard the remaining medication. Pour a small amount of distilled water into the medication chamber and close the cover. Turn on the device to nebulize the distilled water for 1–2 minutes to remove residual medication from the mesh.

Figure 20

Step 3: Cleaning the components

The medication chamber and mouthpiece should be cleaned (see Step 1) after each use. Rinse with distilled water. Gently wipe off excess water with a soft clean cloth or allow the parts to air dry in a clean environment.

Step 4: Cleaning the main unit

Dab a piece of gauze with water and lightly wipe off any stains from the main unit. Wipe dry with a piece of new gauze. See Figure 21.

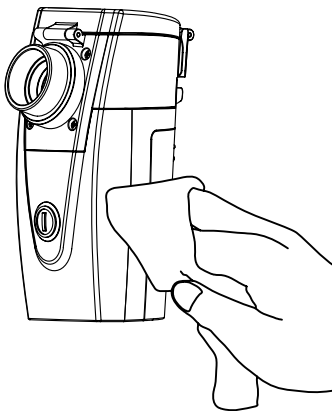


Figure 21

Clean the electrodes on the main unit and medication chamber with a cotton swab. This ensures a normal electrical conduction and a normal nebulization.
See Figure 22.

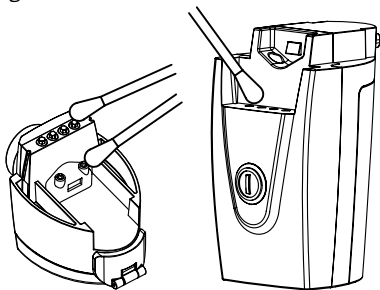


Figure 22

ATTENTION:

- Please do not dry with cotton or cloths of other materials; otherwise, dust or cloth fibers may be left on the mesh, causing the nebulizer to malfunction.
- Please do not allow cotton swabs or foreign objects to come into contact with the mesh of the medication chamber.
- Do not clean the nebulizer with volatile liquids such as benzene or thinner.

Assemble the device and store in the storage case or in a clean environment.

Daily Disinfecting

CAUTION:

- Do not rinse or immerse the main unit in any liquid.
- Do not wash or rinse any of the parts under strong running water.
- Do not touch the mesh with your hand or any other object.
- Do not use household bleach or any other abrasive chemicals for disinfecting.

Daily disinfection is required for the medication chamber and mouthpiece.

Step 1: Make a disinfecting solution

Make a vinegar solution (1 part white vinegar and 3 parts distilled water) OR mild detergent soap (dishwashing soap in distilled water).

Step 2: Open medication chamber

Open the medication chamber and pour in a small amount of disinfecting solution.

Step 3: Turn the device on

Nebulize for 1–2 minutes by pressing the START/STOP button on the main unit.

While nebulizing, soak the mouthpiece in the disinfecting solution for 10–15 minutes.

Step 4: Remove medication chamber

Once finished, remove the medication chamber from the main unit. Discard any remaining disinfecting solution from the medication chamber.

Step 5: Rinse

Rinse the medication chamber and mouthpiece in distilled water.

ATTENTION:

- Do not leave the cleaning solution in the nebulizer parts. Rinse the nebulizer parts with distilled water after disinfecting.
- Do not soak the medication chamber in the disinfecting solution.

Step 6: Dry

Gently wipe off excess water with a soft clean cloth or allow the parts to air dry in a clean environment.

Step 7: Assemble and store

Assemble the Prodigy Mini-Mist™ and store in the carrying case or in a clean environment.

Caring for the Device

To keep your device in the best condition and protect the unit from damage, please follow these instructions:

- Do not subject the device or the components to any strong shocks such as dropping the device on the floor.
- Do not store the device in extreme conditions including hot or cold temperatures, high humidity or under direct sunlight.
- Remove the batteries if the device will not be used for three (3) months or longer.
- Replace the batteries with two (2) new batteries. Do not use different types of batteries together.
- Do not rinse or immerse the main unit in any liquid.
- Do not clean the main unit using abrasive cleaners or any type of chemical.
- Do not allow any moisture to contact the electrodes; this may shorten the life of the nebulizer.
- Do not carry the medication chamber filled with medication or distilled water.
- Use only authorized Prodigy® parts and accessories.
- Do not carry the nebulizer when medication or distilled water is in the medication chamber. The medication may leak out and damage, stain or rust the nebulizer.

System Troubleshooting

❖ The power indicator does not illuminate

- The batteries are installed incorrectly; refer to the “Battery Installation” section for proper placement of batteries. See page 12.
- The batteries are dead; replace both batteries immediately. See page 13.
- Recharge batteries with a commercially available charger. See page 13.

❖ The power indicator is illuminated but the unit does not nebulize

- Slightly slant the main unit towards you; the START/STOP button will be pointing down.
- Fill the medication chamber with the proper amount of prescribed medication, with a maximum of 8 mL. See page 14.
- Check for any liquid that may have collected around the electrodes of the main unit and absorb with a soft cloth. See page 22.
- Check for dry residual medication. Disinfect and clean appropriate components and accessories. See page 20.
- The batteries are dead; replace both batteries immediately. See page 13.
- Recharge batteries with a commercially available charger. See page 13.
- Low nebulization rate may indicate it's time to replace the nebulizer—due to mesh rupturing or severe clogging.

❖ Medication overflows from the medication chamber

- The medication chamber is ruptured and the nebulizer needs replacing.

❖ The unit is on, however, it nebulizes weakly or is taking too long for treatment

- Make sure the medication chamber is properly installed. See page 10.
- Follow directions for cleaning after each use. See page 20.
- Follow directions for disinfecting. See page 19.
- Replace batteries per installation instructions. See page 13.
- Nebulization rate may vary based on the medication used.

❖ The nebulizer shuts off during usage

- Adjust the nebulizer's angle so the medication is in contact with the mesh.
- The medication has run out and the medication chamber needs to be refilled. See page 14.
- The medication chamber is loose and not completely attached. Re-attach the medication chamber correctly and restart the power. See page 10.
- Batteries need to be replaced. See page 13.

❖ The nebulizer does not shut off automatically

- Electrodes on the medication chamber are clogged with medication or water and need to be cleaned. See page 22.
- Electrodes on the nebulizer and medication chamber are stained. Remove the stains and restart the power. See page 22.

If your nebulizer still does not function properly, please contact Customer Care at **1.800.243.2636** for 24-hour assistance.

Specifications

Dimensions: 55.6 mm (L) x 42 mm (W) x 109.2 mm (H)

Weight: 98 g (excluding batteries)

Power Supply: Two (2) AA 1.5V Alkaline batteries

Power Consumption: 2.0 W

Vibrating Frequency: 120 kHz

Nebulization Rate: 0.2 mL/min (minimum)

Particle Size: MMAD approximately 5 microns

Recommended Fill Volume: 0.5 mL minimum
8 mL maximum

Lifetime of Reusable Parts: Approximately 12 months for medication chamber, mask adapter and mouthpiece.

Operating Conditions: 50°F – 104°F (10°C – 40°C)
30 – 85% R.H.

Storage Conditions: 39.2°F – 104°F (-20°C – 70°C)
≤ 85% R.H.

Accessories: Mouthpiece, alkaline batteries and owner's manual.

Optional Accessories: Inhalation mask, carrying case, rechargeable batteries and charger.

**Specifications may change without prior notice.*

Performance Characteristics

The quality of the device has been verified and is in line with the provisions of the EC council directive 93/42/EEC (EN IEC60601-1 General requirements for safety, EN IEC60601-1-2: 2001 Electromagnetic compatibility requirements and tests) date dated 14 June 1993 concerning medical devices and the EN performance standards as follow:

EN 13544-1 2007: Respiratory therapy equipment-part1 ; nebulizing systems and their components.

Symbols Information

Symbol	Referent
	Do not re-use. Single use only.
	Consult operating instructions.
	Keep away from sunlight.
	Keep dry.
	Temperature limitation.
	Use by.
	Date of manufacture.
LOT	Batch code.
REF	Catalog number.
SN	Serial number.
CONTROL	Control.

PRODIGY®

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