Warning
Read and understand these Instructions for Use and all safety precautions it contains. Improper use can cause serious or fatal injury/illness.

Warning
Read and understand the full Patient Information (PI) for information and warnings related to LONHALA. The PI is contained in the LONHALA box.
TABLE OF CONTENTS

A. Safety Precautions .................................................................................................................................. 3
B. Getting Started ........................................................................................................................................ 5
C. Steps for Using Batteries or AC Adapter with MAGNAIR ................................................................. 6
D. Assembling Your MAGNAIR ..................................................................................................................... 8
E. Using LONHALA MAGNAIR ..................................................................................................................... 11
F. Cleaning the Handset ................................................................................................................................ 15
G. Troubleshooting ......................................................................................................................................... 20
H. Specifications ........................................................................................................................................... 23

Intended Use and Authorized Users

MAGNAIR is intended for single-patient use in the delivery of LONHALA to patients who self-administer treatments or have treatments administered by a caregiver or health care provider.

MAGNAIR Handset is not sterile.
A. SAFETY PRECAUTIONS

These Instructions for Use contain information and safety precautions for MAGNAIR® (MAGG-nair) Nebulizer System for use with LONHALA® (lon-HAL-luh) (glycopyrrolate) Inhalation Solution.

**Warning**

MAGNAIR is designed specifically for use only with LONHALA. To reduce the risk of severe or fatal injury/illness, *Never* use other medications in MAGNAIR. Read and follow all warnings and instructions in the Instructions for Use prior to using this device.

Save these *Instructions for Use* for future reference.

**If for any reason you do not understand any part of these Instructions for Use, please contact the Sunovion Customer Service line 1-888-394-7377 before proceeding with your treatment.**

Take special note of all safety precautions marked *Danger* and *Warning*.

**IMPORTANT INFORMATION FOR USE**

- US Federal law restricts this device to sale by or on order of a physician.

Read all Dangers and Warnings before using.

**Dangers**

To reduce the risk of serious or fatal injury from electrocution:

1. **Do Not** place or store MAGNAIR where it can be in water or fall into water (e.g., near a bathtub or sink).
   - Do Not place or drop into water or other liquid.
   - Do Not use while bathing.

2. **Do Not** reach for MAGNAIR if it has fallen into water or other liquid. If using AC adapter, unplug.
   - Retrieve MAGNAIR only after it has been unplugged.

**Warnings**

1. The MAGNAIR Handset is intended for *Single Patient Use Only*. Do not share your MAGNAIR with anyone else.

2. MAGNAIR is designed specifically for use only with LONHALA. To reduce the risk of severe or fatal injury/illness, *Never* use other medications in MAGNAIR.

3. Read and follow all warnings and instructions in the Instructions for Use prior to using this device.

4. To reduce the risk of serious or fatal injury from electrocution, fire, burns, and to reduce the risk of damage and malfunction of the unit:
   a. **Do Not** overload wall outlets or use extension cords.
   b. Keep all electrical cords away from heated surfaces.
   c. **Do Not** spray liquids onto the housing of the Controller. Liquid may cause damage to the electrical parts and could lead to a malfunction. In the event that liquids enter the Controller, contact the Sunovion Customer Service line (1-888-394-7377).
   d. **Do Not** drop or insert any object into any opening on MAGNAIR.
   e. **Do Not** operate where oxygen is being administered in a closed environment, such as an oxygen tent.

5. Always unplug this product from AC power immediately after using and before cleaning.

MAGNAIR questions? Contact the Sunovion Customer Service line (1-888-394-7377).
Warnings

6. Before use, check your Controller and Handset for proper assembly. All parts must be connected and firmly in place. Use of an improperly assembled MAGNAIR could diminish or eliminate the effectiveness of the treatment.

7. **Use Only** adapters and accessories that are authorized for MAGNAIR. Use of unapproved adapters and accessories can lead to improper treatment, injury, or damage to the Controller.

8. **Never** operate the Controller if it is improperly or incompletely assembled or damaged. If you suspect either situation, call the Sunovion Customer Service line (1-888-394-7377).

9. **Never** operate MAGNAIR if:
   a. it has damaged cords or plugs;
   b. it is not working properly;
   c. the inside of the Controller has been exposed to any liquids.

10. To maintain the efficiency of MAGNAIR, remove the Aerosol head from the MAGNAIR Handset body and clean and air-dry all MAGNAIR Handset parts after each treatment. Follow the instructions in **Section F** to clean the MAGNAIR Handset properly.

11. Cleaning the MAGNAIR Handset properly will help prevent the Aerosol head from clogging. If the Aerosol head becomes clogged, the aerosol mist may be reduced, altered, or stopped, which could increase the nebulization time (up to 15 minutes) and/or diminish the effectiveness of the treatment. **Do Not Stop Treatment** until MAGNAIR shuts off.

12. This product contains small parts that may present a choking hazard to small children. The MAGNAIR AC adapter and Connection cord also presents a strangulation hazard.

13. Close supervision is necessary when this product is used near children or the physically or mentally impaired.

14. **Do Not** allow pets near the Connection cord or AC adapter as they may chew on and damage them.

15. **Do Not** use your MAGNAIR while driving or in any situation that takes away your full attention.

16. **Do Not** disassemble the blue Controller at any time. There are no user serviceable parts inside the Controller. Contact the Sunovion Customer Service line (1-888-394-7377) for help.

17. **Do Not** use alcohol for cleaning and disinfection. Some parts will be damaged by alcohol.

18. The LONHALA vial is for single use only and must not be reused, refilled, or used in any other device.

19. **Use Only** AC adapters and accessories that are authorized by PARI. Use of unapproved adapters or accessories can lead to improper treatment, injury, or cause/receive interference leading to damage to the Controller.

20. **Do Not** modify the Controller without authorization from the manufacturer.

21. **Do Not** use the Controller in areas exposed to elevated electromagnetic or electrical radiation such as a MRI scanner or high frequency surgical equipment.

22. **Do Not** place the Controller near other medical devices during operation unless both devices are monitored constantly to insure both are operating properly.

23. **Do Not** use the Controller within 12 inches (30 cm) of portable wireless communication devices such as cell phones or antenna cables or external antennas.

24. **Do Not** use the Controller near airplane or train control systems. Confine use to passenger areas only. Do not use aboard aircraft.

25. **Do Not** use the Controller near anti-theft systems and radio frequency identification (RFID) readers, which are used in a wide variety of settings, including stores, libraries, and hospitals. Do not power on the Controller when passing through security screening or theft protection (RFID) systems at entrances or exits of stores, libraries or hospitals. Note that some entrance and exit security systems are not visible.

Technical electromagnetic compatibility data is available in tabular format upon request from PARI Pharma GmbH or on the Internet at https://www.pari.com/fileadmin/Electromagnetic-compatibility-4.pdf.

MAGNAIR questions? Contact the Sunovion Customer Service line (1-888-394-7377).
B. GETTING STARTED

Check to make sure you have all of the following MAGNAIR parts and become familiar with how to identify each piece. If any parts are missing, call the Sunovion Customer Service line (1-888-394-7377). See Fig. B1.

![MAGNAIR Nebulizer System diagram]

LONHALA vials packaged separately.

MAGNAIR questions? Contact the Sunovion Customer Service line (1-888-394-7377).
C. STEPS FOR USING BATTERIES OR AC ADAPTER WITH MAGNAIR

MAGNAIR is designed to be used with AA batteries or with the AC adapter.

STEPS FOR USING BATTERIES WITH MAGNAIR

Four (4) high quality AA batteries will provide approximately 2 weeks of treatment.

C1. Open the battery door on the Controller by placing your thumb on the black tab of the battery door and firmly pushing the tab to open the door. Note that the battery door is designed to have a tight fit. See Fig. C1.

C2. Load the batteries. Each battery chamber has a small figure that shows the proper position of each battery. Using the battery tips as guides and starting left-to-right, insert the batteries: tip out, tip in, tip out, tip in. See Fig. C2.

MAGNAIR questions? Contact the Sunovion Customer Service line (1-888-394-7377).
C. STEPS FOR USING BATTERIES OR AC ADAPTER WITH MAGNAIR (cont.)

C3. Close the battery door.
   To close the battery door, push it closed until you hear it Click into place. See Fig. C3.

   NOTE: Rechargeable and disposable batteries vary considerably in terms of storage life and output. If used exclusively, batteries have an operating life of ~2 weeks, based on high quality disposable AA batteries that meet the specifications listed in Section H and following the cleaning procedure described in Section F. To reduce the risk of battery leakage, it is recommended to remove the batteries if you plan to store the Controller for more than 30 consecutive days.

   If you choose not to use the AC adapter, it is strongly recommended to have an extra set of batteries with you at all times.

STEPS FOR USING THE AC ADAPTER WITH MAGNAIR

The AC adapter will automatically adjust to the incoming voltage. The AC adapter will power MAGNAIR with and without installed batteries.

C4. Plug the AC adapter into the Controller.
   To connect the AC adapter to the Controller, place the Controller on a flat, stable surface. The inlet is located on the underside of the black battery door. Push the round end of the AC adapter cord into the inlet. Do Not try to insert the AC adapter into the blue colored part of the Controller. See Fig. C4-C5.

C5. Plug the AC adapter into the wall outlet.
   NOTE: the AC adapter will not charge the batteries in the Controller. See Fig. C4-C5.
D. ASSEMBLING YOUR MAGNAIR

Your Handset parts (Medication cap, Aerosol head, Handset body, and Mouthpiece) will be replaced when you receive your next supply of LONHALA. Discard your old Handset parts and use the new Handset parts every time you get a LONHALA MAGNAIR Refill Kit.

Warning
Clean the Handset before the first use and after every use. (See Section F.)
Inspect all Handset parts to ensure they are clean and not damaged. Do Not leave the Aerosol head in the Handset body after use, and Do Not use dirty or damaged parts because this can impair the function of the Handset.

D1. Wash your hands.

D2. Open the top of the Handset body.
Lift the clasp on top of the Handset body slightly and flip it up to open. See Fig. D2.

D3. Insert the Aerosol head into the Handset body as shown, taking care Not to touch the center of the Aerosol head. Hold the Aerosol head like you would hold a small frying pan so that the silver text side is facing up and the brown ring is facing down. Notice that the Aerosol head has a small tab on the side. Align the small tab with the matching notch in the Handset body. See Fig. D3.
D4. Close the Handset body, making sure the Aerosol head is properly inserted and the tab is aligned with the notch and level with the Handset body. You may hear a Click. If you do not close your Handset body completely or align the Aerosol head correctly, your medication may leak and you will not get your full treatment. See Fig. D4.

Do not force the top of the Handset body closed. If the top of the Handset body cannot close (no Click is heard), make sure that the Aerosol head is seated correctly and level.

D5. Attach the Mouthpiece to the Handset body. Make sure the Blue valve is pressed down into the slot on the Mouthpiece and is positioned on the top of the Mouthpiece before attaching the Mouthpiece onto the Handset body. See Fig. D5.
D6a. Connect the Controller to the Handset body using the Connection cord.

- One end of the Connection cord has a blue round connector. Insert the Connection cord into the inlet on the blue side of the Controller. Push the Connection cord in as far as it will go. You may hear a slight Click if inserted correctly. See Fig. D6a.

D6b. Connect the Controller to the Handset body using the Connection cord as shown.

- The other end of the Connection cord is blue and gray. Insert the Connector (with gray mark facing up) into the Handset body as far as it will go, ensuring the gray mark on the Connection cord lines up with the blue mark on the Handset body.

- Check that the ends of the Connection cord are fully inserted into the Controller and the Handset body. If they are not, the Handset may not work properly. See Fig. D6b.
E. USING LONHALA MAGNAIR

E1. With clean hands, open the foil pouch enough to remove the 2 LONHALA vials.
Manually separate by twisting apart the 2 LONHALA vials and return 1 vial back to the opened foil pouch and store in the Carrying bag to be used at the next treatment. Discard the vial if not used within 7 days. See Fig. E1.

Warning
MAGNAIR will only operate with vials containing LONHALA. Do not try to use any other type of medication with your MAGNAIR or use the vials in any other type of device.

E2. Insert 1 LONHALA vial into the Medication cap.
The Medication cap has a top and a bottom. Insert a LONHALA vial with the flat tab first through the bottom of the Medication cap and press it in as far as it will go. You should hear a Click if the LONHALA vial was inserted correctly. See Fig. E2.

You should be able to hear a Click when the LONHALA vial is inserted correctly.
E. USING LONHALA MAGNAIR (cont.)

E3. Prepare to attach the Medication cap.  
**Do Not** touch the part of the Handset body that pierces the LONHALA vial.  
See Fig E3a.

Make sure the Aerosol head is installed before attaching the Medication cap because your medicine could leak and you will not get your full treatment.

Place the Medication cap with the LONHALA vial on top of the Handset body.  
See Fig. E3b.

Turn the Medication cap in a clockwise direction. As you turn the Medication cap, the LONHALA vial will open and you should hear a Click. The notch (at the base of the opening) in the Medication cap should line up with the blue line on the Handset body.  
See Fig. E3c.

**Warning**  
**Do Not** Loosen or remove the Medication cap or unclasp the Handset until treatment is completed because your medicine could leak and you will not get your full treatment.
E4. Insert the Mouthpiece into your mouth.

- Sit in an upright position and relax. This makes inhaling easier.
- Hold the Handset body with your hand then place the Mouthpiece into your mouth and seal your lips around it.
- **Do Not** tilt the Handset. Make sure the Handset is level.
- **Do Not** cover the blue valve with your lips.
- **Do Not** Loosen or remove the Medication cap until your treatment is complete because your medication could leak and you will not get your full treatment. See *Fig. E4*.

![Fig. E4](image)

E5. Turn on the Controller.

- Press the On/Off button to start your treatment.
- A green LED light beside the On/Off button will light up and a single **Beep** will be heard to indicate proper functioning. See *Fig. E5*.

![Fig. E5](image)
E6. Breathe in (inhale) and breathe out (exhale) normally through the Mouthpiece. The Mouthpiece should remain in your mouth throughout the treatment period. Do Not breathe through your nose. While you are exhaling, you may see the blue flap lift and some mist escape. See Fig. E6.

- Continue inhaling and exhaling through the Mouthpiece until the Controller Beeps and shuts off.
- To pause your treatment, press the On/Off button. To continue your treatment, press the On/Off button again. See Fig. E5.

E7. At the end of treatment, the Controller will automatically shut off. When all of the medication has been delivered, you will hear 2 Beeps, the green LED light will turn off, and the Controller will automatically shut off. Your treatment should take 2 to 3 minutes. See Fig. E7.

Warning
If you do not clean the Handset parts after every use, your treatment time might take more than 3 minutes. If the treatment is taking longer than 3 minutes, continue with your treatment until the Controller shuts off to make sure that you get your full treatment.
F. CLEANING THE HANDSET

Warning
To ensure proper operation and to reduce the risk of severe or fatal injury/illness. Important: Rinse and clean the MAGNAIR Handset parts after every use. Use clear liquid dishwashing soap. Do Not use white dishwashing soap (e.g., Ivory or Dove) or antibacterial liquid dish soaps, as these may contain additives harmful to the Aerosol head. Do Not leave the Aerosol head in your Handset. Do Not wash the Controller, Connection cord, or AC adapter.

Caution
• Do Not put MAGNAIR parts into a microwave oven.
• Do Not clean the MAGNAIR parts in a dishwasher.
• Do Not clean the Aerosol head and Handset parts with brushes or abrasives.

CLEANING THE HANDSET

F1. Disconnect the Handset from the Connection cord. See Fig. F1.

F2. Turn the Medication cap in a counterclockwise direction as shown, to remove from the Handset body. See Fig. F2.
F3. Remove the LONHALA vial.
Place the top of the Medication cap into the palm of your hand and push up as shown to remove the LONHALA vial. Throw away the LONHALA vial into wastebasket. See Fig. F3.

F4. Remove the Mouthpiece from the Handset body by giving it a gentle twist and pull to separate from the Handset body. See Fig. F4.

F5. Loosen the blue valve. Carefully loosen the blue valve from the slot in the Mouthpiece. Make sure the valve is still attached on one side to the Mouthpiece. See Fig. F5.
F. CLEANING THE HANDSET (cont.)

F6. Remove the Aerosol head from the Handset body by lifting the clasp on the side of the Handset. Then remove the Aerosol head by lifting the handle.

Do Not touch the center of the Aerosol head. See Fig. F6.

Set aside the Aerosol head to be cleaned separately in Step F10.

F7. Rinse each of the disassembled Handset parts well under warm (above 105°F) running tap water. (approx. 10 seconds). See Fig. F7.

F8. Wash all Handset parts in warm (above 105°F), soapy water made by adding a few drops (~¼ teaspoon) of clear liquid dishwashing soap into a bowl (~1 quart) of clean warm tap water. Swish the Handset parts around in the soapy water to clean. See Fig. F8.

• Do Not wash the Connection cord, Controller, and AC adapter.

• Do Not use white dish soap or antibacterial hand soaps because they may clog the Aerosol head.

• Do Not use a brush or abrasive to clean any of the Handset parts because it may damage them.
F9. Rinse the Handset parts well under running warm tap water (approximately 10 seconds). See Fig. F9.

F10. Clean the Aerosol head following the instructions in Steps 7 through 10.

10A. Rinse both sides of the Aerosol head well with warm running water for about 10 seconds on each side.

10B. Wash the Aerosol head by holding the handle and swishing it back and forth in the warm soapy water for about 10 seconds.

10C. Rinse both sides of the Aerosol head well with warm running water for about 10 seconds on each side.

Rinsing the Aerosol head well helps prevent clogging and ensures proper operation.

- Do Not add dishwashing liquid directly onto the Aerosol head, add to water only.
- Do Not use a brush or abrasive to clean the Aerosol head because it may damage it.
F11. **Inspect all Handset parts** to make sure they are completely clean. If any Handset parts are still dirty, soak the parts in warm soapy water for 5 more minutes. Rinse well with warm running water until clean.

**Warning**  
Contamination and moisture may affect the Aerosol head and encourage the growth of bacteria. Therefore, it is important to remove the Aerosol head from the Handset body and clean the Handset parts after every use. If Handset parts are still dirty after cleaning, then soak and rinse as described in step F11.

F12. **Air-dry all Handset parts.**  
Remove excess water by shaking all parts. Place all Handset parts on a dry, clean, lint-free towel and allow them to air-dry. Do Not dry using a paper towel. Do Not touch the center of the Aerosol head. See Fig. F12.

F13. **Store disassembled Handset parts.**  
After the Handset parts are completely dry, place them in the provided Carrying bag or a dry, dust-free environment for storage. Do Not put the Handset parts back together until ready to use again for your next treatment of LONHALA.

**Warning**  
A damp environment encourages the growth of bacteria. Make sure all Handset parts are dried properly.

**CARING FOR THE CONTROLLER, CONNECTION CORD AND AC ADAPTER**

- Make sure the Controller is off. Remove the Connection cord and AC adapter cord from the Controller.
- Remove the AC adapter from the wall socket.
- Clean the Controller housing, the Connection cord, and AC adapter with a damp cloth.

**Warning**  
- Never let the Controller come in contact with water and never use cleaning agents.
- If liquid does get into the Controller, contact the Sunovion Customer Service line (1-888-394-7377).

MAGNAIR questions? Contact the Sunovion Customer Service line (1-888-394-7377).
## G. TROUBLESHOOTING

### CONTROLLER FEEDBACK INDICATORS

<table>
<thead>
<tr>
<th>Controller AUDIBLE SIGNAL</th>
<th>Controller VISUAL SIGNAL</th>
<th>Conditions</th>
<th>Action Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 1 Brief Beep at start of dose.</td>
<td>Solid green LED for duration of dose.</td>
<td>Normal: generating aerosol mist, no errors detected.</td>
<td>No action required. MAGNAIR is on and working properly.</td>
</tr>
<tr>
<td>2 1 Brief Beep at start of dose.</td>
<td>Flashing orange-green LED.</td>
<td>Low battery power.</td>
<td>Replace batteries or use AC adapter.</td>
</tr>
<tr>
<td>3 1 Brief Beep at start of dose followed by a 2-tone Beep.</td>
<td>Green LED followed by flashing orange-green and then shuts off.</td>
<td>No connection detected. Two Beeps occurred immediately after starting. No drug detected. Two-tone Beep occurred 10-30 seconds after starting.</td>
<td>Check connection between the Controller and the Handset. Check to confirm a LONHALA vial has been inserted and the Handset clasp is closed properly. Tilt the Handset from side to side then tap the Handset to dislodge LONHALA and restart the Controller.</td>
</tr>
<tr>
<td>4 1 Brief Beep.</td>
<td>LED starts green, then turns orange and shuts off.</td>
<td>Treatment interrupted. The Controller On/Off button has been intentionally or unintentionally pressed.</td>
<td>Press the Controller On/Off button to resume treatment.</td>
</tr>
<tr>
<td>5 2 Brief Beeps.</td>
<td>LED flashes green for 2 seconds, and then shuts off.</td>
<td>Normal: end of dose.</td>
<td>No action required. LONHALA vial contents are empty.</td>
</tr>
</tbody>
</table>
### POTENTIAL FAULTS AND POSSIBLE CAUSES / RESOLUTIONS

<table>
<thead>
<tr>
<th>Fault</th>
<th>Possible Causes / Resolutions</th>
</tr>
</thead>
</table>
| 1     | **MAGNAIR cannot be turned on — no green LED and no Beep.**  
**No power**  
The batteries are discharged. Replace them or use the AC adapter.  
The batteries are not inserted correctly. Remove batteries and reinsert following diagram on the battery compartment.  
The AC adapter is not connected correctly. Check the wall connection and the Controller connection. |
| 2     | The LED flashes orange-green, there is a 2-tone Beep and the Controller turns off.  
**No connection between Handset and Controller**  
Check the connection between the Controller and the Handset. |
| 3     | No aerosol mist appears when MAGNAIR is first turned on, or MAGNAIR turns off after a few seconds.  
**Low power**  
Check for bad batteries.  
**Missing or improper insertion/assembly of LONHALA vial**  
Confirm that a new LONHALA vial has been inserted.  
Tap MAGNAIR slightly to move the liquid to the bottom of the LONHALA vial. If aerosol mist is still not generated after MAGNAIR has been restarted, the LONHALA vial may not have been pierced or is empty. Replace the vial if empty.  
If partial dose has been received, contact your health care provider for instructions. |
| 4     | The indicator light (LED) flashes orange-green during operation.  
**Low battery power**  
Replace the batteries or use the AC power. |
| 5     | Mist appears but the Controller turns off prematurely.  
**Low battery power**  
Replace the batteries or use the AC power.  
**The Handset was not being held upright**  
Hold the Handset upright and press the On/Off button.  
**Insufficient medication**  
If partial dose has been received and/or medication spills, call your health care provider.  
If Handset clasp is broken and/or does not close properly, call Sunovion Customer Service (1-888-394-7377). |
### POTENTIAL FAULTS AND POSSIBLE CAUSES / RESOLUTIONS

<table>
<thead>
<tr>
<th>Fault</th>
<th>Possible Causes / Resolutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 MAGNAIR will not switch off automatically.</td>
<td>Turn MAGNAIR off by pressing the On/Off button.</td>
</tr>
<tr>
<td>7 Aerosol mist continuously escapes in large volumes from the opening slots in the Medication cap.</td>
<td>Improper Handset assembly. Check that the Handset has been assembled correctly and the Blue valve flap is pushed down.</td>
</tr>
<tr>
<td>8 The Medication cap will not close.</td>
<td>LONHALA vial is not seated properly. Press the LONHALA vial base toward the cap until you hear it snap into place.</td>
</tr>
</tbody>
</table>
| 9 The LONHALA vial has been inserted incorrectly.                   | If the LONHALA vial has been inserted incorrectly, the following steps must be carried out:  
1. Open the Medication cap.  
2. If the LONHALA vial has been opened, throw away the LONHALA vial, rinse and dry the Handset parts, then insert a new vial.  
3. If the LONHALA vial has not been opened, place the Medication cap back on the Handset and turn the Medication cap containing your LONHALA vial in a clockwise direction until it clicks, then restart your treatment by pressing the On/Off button. |
| 10 Increasing or long inhalation time.¹ Treatment time may vary up to 15 minutes if the Aerosol head has become clogged. | The Aerosol head may be clogged. Clean the Aerosol head by soaking it in soapy water for 5 minutes and rinse both sides well (Section F). |
| 11 Top of Handset body has become detached from bottom of Handset body. | Line up the hinge part on the top of the Handset body with the hinge portion of the bottom of the Handset body. Press firmly until the parts snap together. You should hear a Click. |

---

¹ If the fault cannot be eliminated after following these steps, call the Sunovion Customer Service line (1-888-394-7377) immediately.
H. SPECIFICATIONS

ELECTRICAL
AC adapter
Input .......................................................... 100 V-240 V, 50 Hz/60 Hz
Output ......................................................... 7.5 V
Batteries
Disposable .................................................. 4 x 1.5 V (high quality alkaline or photography-grade)
Rechargeable .............................................. 4 x 1.2 V (Ni-Cd)

OPERATIONAL
Temperature .................................................. 41° to 104°F (5° to 40°C)
Relative humidity (non-condensing) .................... 15% to 93%
Air pressure .................................................. 10 to 15 PSI (700 to 1060 hPa)
Aerosol output ............................................. 0.85-1.15 mL
Aerosol output rate ....................................... 0.4 mL/min

MECHANICAL
MAGNAIR Handset weight, without medication ........ approx. 2.6 oz (73 g)
MAGNAIR Controller weight (with batteries) ............ approx. 7.6 oz (220 g)
Nebulizer dimensions (W x H x D) ........... 2.4 in. x 4.7 in. x 7.19 in. (6 x 12 x 18 cm)
Controller dimensions ................. H 1.6 in. (4 cm), Ø 4.6 in. (11.6 cm)

TRANSPORT / STORAGE
Temperature .............. -13° to 158° F (-25 to +70°C)
Relative humidity (non-condensing) ............. 0 to 93%
Air pressure .................. 7 to 15 PSI (500 to 1060 hPa)

HANDSET MATERIALS
Polypropylene, polyoxymethylene, polyamide, silicone, stainless steel, thermoplastic elastomers.
Does not contain any natural rubber (latex).

DISPOSAL
The MAGNAIR parts and batteries must be thrown away in accordance with local (state, county, or municipal) regulations.

PERFORMANCE CHARACTERISTICS

<table>
<thead>
<tr>
<th>LONHALA (glycopyrrolate) Inhalation Solution, 25 mcg/mL</th>
<th>Mean1</th>
<th>95% Confidence Range2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivered dose by breath simulation (mcg)</td>
<td>14.20</td>
<td>11.11–17.29</td>
</tr>
<tr>
<td>Delivered dose by breath simulation (% Label Claim)</td>
<td>56.80</td>
<td>44.45–69.16</td>
</tr>
<tr>
<td>MMAD3 (μm) by NGI4</td>
<td>3.71</td>
<td>2.92–4.49</td>
</tr>
<tr>
<td>Coarse Particles (Dia. &gt;5 μm) by NGI (mcg)</td>
<td>5.83</td>
<td>2.32–9.33</td>
</tr>
<tr>
<td>Coarse Particles (Dia. &gt;5 μm) by NGI in % of Delivered Dose</td>
<td>27.72</td>
<td>11.20–44.24</td>
</tr>
<tr>
<td>Fine Particles (Dia. ≤5 μm) by NGI (mcg)</td>
<td>15.20</td>
<td>11.46–18.93</td>
</tr>
<tr>
<td>Fine Particles (Dia. ≤5 μm) by NGI in % of Delivered Dose</td>
<td>72.28</td>
<td>55.77–88.79</td>
</tr>
<tr>
<td>Extra-Fine Particles (Dia. &lt;1 μm) by NGI (mcg)</td>
<td>0.11</td>
<td>0.03–0.20</td>
</tr>
<tr>
<td>Extra-Fine Particles (Dia. &lt;1 μm) by NGI in % of Delivered Dose</td>
<td>0.55</td>
<td>0.15–0.94</td>
</tr>
<tr>
<td>GSD5 by NGI</td>
<td>1.66</td>
<td>1.49–1.83</td>
</tr>
</tbody>
</table>

1 n=15 devices from 3 device lots; 5 devices tested per drug product batch x 3 batches drug product
2 95% Confidence Range: Two-sided tolerance interval, Proportion of total population=0.95, Confidence (1- Alpha)=0.95
3 MMAD: Mass Median Aerodynamic Diameter
4 NGI: Next Generation Impactor
5 GSD: Geometric Standard Deviation

MAGNAIR questions? Contact the Sunovion Customer Service line (1-888-394-7377).
This is a computer generated laser proof. It is not to be used as a comparison of final printed color. It is the ultimate responsibility of the Supplier/Contractor to provide Sunovion printed packaging components with barcodes that can be read by the end user. It is the Supplier’s option to use the codes as supplied or to replace with a new code that is modified to better meet press requirements.