Earlens Simulator Instructions For Use

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1. **Introduction**
   Carefully read all instructions prior to use.

2. **Earlens Simulator Description**
   The Earlens Simulator consists of the simulator unit and functional Processor. It provides a means of listening to the output of the Hearing Aid. Figures 1, 2, and 3 show the components of the Simulator.

   ![Figure 1. Front view](image1)
   ![Figure 2. Backside view](image2)
   ![Figure 3. Top-down view with lid up](image3)

3. **Intended Use**
   The Earlens Simulator is an optional tool, available for the convenience of the hearing professional, to demonstrate the output of the Earlens Hearing Aid. The Simulator does not affect the operation of the Earlens Hearing Aid to amplify sound in the ear and is not intended to support, supplement, or augment the performance of the Earlens Hearing Aid to amplify sound in the ear.

4. **Warnings**
   Before using the Earlens Simulator, read and make sure you understand each of the following safety warnings.
   - Do not crush, short circuit, modify or disassemble any component of the Simulator.
   - Do not incinerate any component of the Simulator or use near open flame.
   - Handle waste from electronic equipment per local regulations.
5. Precautions

Before using the Earlens Simulator, read and make sure you understand each of the following safety precautions.

- Avoid getting the Simulator wet, as this may damage the device.
- Do not place the Simulator into a microwave, or near a significant source of static electricity.
- Handle the Simulator carefully. Do not drop it and prevent hard knocks. These may damage the device.
- If the Simulator fails to operate or if it appears damaged, stop use and contact Earlens Customer Service.

6. Operating Instructions

Set-up

a. Plug the micro-USB end of the cable into the back of the Simulator.
b. Plug the USB end of the cable into to the wall adaptor.
c. Plug wall adaptor into an AC power source.
d. Plug in headphones with a 3.5mm jack.
e. Turn the power and volume knob to the right to turn-on the Simulator.
f. Adjust the volume by turning the knob left (softer) and right (louder).

Due to the amount of high frequency gain the Earlens Hearing Aid can provide, feedback may occur between the headphones and Processor microphones when using the Simulator. Use of circumaural headphones is recommended for an optimal listening experience.

7. Operating Specifications

<table>
<thead>
<tr>
<th>Simulator Output</th>
<th>Capable of producing sound from 125-10,000Hz</th>
<th>Compatibility</th>
<th>110V and 220V AC power source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage Conditions and Temperature Limit*</td>
<td>-20°C to 55°C Maximum relative humidity of 93% non-condensing.</td>
<td>Use conditions</td>
<td>Avoid high temperatures and sustained exposure to direct sunlight.</td>
</tr>
</tbody>
</table>

* If the system is stored at a temperature outside the operating temperature range, allow the system to stabilize at room temperature for a minimum of 1 hour before use.
8. Graphic Symbols Contained in Device Labeling

The following symbols appear on the Simulator or packaging:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>Reference</th>
<th>Symbol</th>
<th>Description</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Symbol" /></td>
<td>Refer to instruction manual/booklet</td>
<td>IEC 60601-1:2005 ISO 7010-M002</td>
<td><img src="image2" alt="Symbol" /></td>
<td>Temperature limit</td>
<td>ISO 15223-1:2016, 5.3.7</td>
</tr>
<tr>
<td><img src="image3" alt="Symbol" /></td>
<td>Separate collection for electrical and electronic equipment</td>
<td>WEEE Directive 2012/19/EU, Annex IX</td>
<td><img src="image4" alt="Symbol" /></td>
<td>Atmospheric pressure limitation</td>
<td>ISO 15223-1:2016, 5.3.9</td>
</tr>
<tr>
<td><img src="image5" alt="Symbol" /></td>
<td>Keep Dry</td>
<td>ISO 15223-1:2016, 5.3.4</td>
<td><img src="image6" alt="Symbol" /></td>
<td>Caution</td>
<td>ISO 15223-1:2012, 5.4.4</td>
</tr>
<tr>
<td><img src="image7" alt="Symbol" /></td>
<td>Date of manufacture</td>
<td>ISO 15223-1:2016, 5.1.3</td>
<td><img src="image8" alt="Symbol" /></td>
<td>Batch code</td>
<td>ISO 15223-1:2016, 5.1.5</td>
</tr>
<tr>
<td><img src="image9" alt="Symbol" /></td>
<td>Catalog number</td>
<td>ISO 15223-1:2016, 5.1.6</td>
<td><img src="image10" alt="Symbol" /></td>
<td>CE conformity marking</td>
<td>MDD 93/42/EEC, Annex XII</td>
</tr>
<tr>
<td><img src="image11" alt="Symbol" /></td>
<td>Humidity limitation</td>
<td>ISO 15223-1:2016, 5.3.8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Manufacturer (Ref. ISO 15223-1:2016, 5.1.1):

Earlens Corporation, Inc.
4045A Campbell Ave.
Menlo Park, CA 94025

European Authorized Representative (Ref. ISO 15223-1:2016, 5.1.2):

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