H5i™ disinfection guide

This disinfection guide is intended for multipatient use of the H5i in a sleep lab, clinic, hospital or at a health care provider. If you are using the H5i as a single user in the home, refer to the Welcome Guide for cleaning instructions.

This guide describes ResMed’s recommended and validated procedures for cleaning and disinfection of the humidifier. However, the steps for disinfection vary regionally. As a result, each healthcare facility should consult its own procedures before carrying out those within this guide.

⚠️ GENERAL WARNINGS AND CAUTIONS

- ResMed cannot give any assurance that deviations from the procedures listed in this guide, and their effect on the performance of the product, will be acceptable.
- When using detergents, disinfectants or sterilization agents, always follow the manufacturer’s instructions.
- Beware of electrocution. Do not immerse the device, power supply or power cord in water. Always unplug the device before cleaning and be sure that it is dry before plugging back in.

Parts suitable for disinfection or sterilization

<table>
<thead>
<tr>
<th>Part</th>
<th>High level thermal disinfection</th>
<th>High level chemical disinfection</th>
<th>Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>H5i cleanable water tub (including tub lid, plate and base)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Air outlet</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
Disassembling the H5i

The following instructions provide guidance on how to correctly disassemble the H5i:

1. Slide the latch.
2. Lift open the flip lid.
3. Remove the water tub.
4. Discard any excess water from the water tub.
5. Unclip all four side latches.
6. Pull apart the tub lid, plate and base.
7. Remove the maximum water level mark from the plate by pinching and pushing out the locks.
8. Locate the air outlet on the back of your H5i.
9. Remove the outlet clip by pulling apart the clip ends and sliding it off.
10. Remove the air outlet by pushing it through to the inside of the H5i.
Decontaminating

Before the disinfection process, each component must be cleaned and rinsed so no visible contamination is present.

1. Clean all components with a soft bristle brush for one minute while soaking them in the detergent solution. Pay particular attention to all crevices and cavities.
2. Thoroughly rinse each component according to the manufacturer’s instructions.

ResMed has tested the following detergents according to the manufacturer’s instructions:

<table>
<thead>
<tr>
<th>Detergent</th>
<th>Water temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alconox™ Tergazyme</td>
<td>Hot water (approx 60°C)</td>
</tr>
<tr>
<td>(diluted at 1%)</td>
<td>Warm water (approx 50°C)</td>
</tr>
<tr>
<td>Aniosyme™ DDI</td>
<td>Room temperature water (approx 20°C)</td>
</tr>
<tr>
<td>(diluted at 0.5%)</td>
<td></td>
</tr>
<tr>
<td>Neodisher MediZym™</td>
<td>Warm water (approx 45°C)</td>
</tr>
<tr>
<td>(diluted at 2.0%)</td>
<td></td>
</tr>
</tbody>
</table>

Disinfecting

In the procedures below, only one disinfection or sterilization procedure needs to be performed:

- High level thermal disinfection
- High level chemical disinfection
- Sterilization.

High level thermal disinfection

1. Soak the disassembled components in a hot water bath at 90°C for 1 minute. Take care that no air bubbles are trapped against the components.
2. Air dry out of direct sunlight.

High level thermal disinfection equivalent water bath parameters:

<table>
<thead>
<tr>
<th>Process Temperature</th>
<th>Process Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. 70 °C</td>
<td>100 minutes</td>
</tr>
<tr>
<td>2. 75 °C</td>
<td>30 minutes</td>
</tr>
<tr>
<td>3. 80 °C</td>
<td>10 minutes</td>
</tr>
<tr>
<td>4. 90 °C</td>
<td>1 minute</td>
</tr>
</tbody>
</table>

ResMed water tubs have been tested for disinfection for 100 cycles using hot water approximately 93°C for 10 minutes.
High level chemical disinfection

1. Soak the disassembled components in a commercially available solution of a chemical sterilant. Take care that no air bubbles are trapped against the components.

2. Thoroughly rinse each component in drinking quality water (five litres per assembly) by immersing it completely for a minimum of one minute in duration.

3. Repeat the rinse procedure two additional times using new drinking quality water for each rinse, for a total of three rinses.

4. Air dry out of direct sunlight.

ResMed cleanable water tubs have been validated for 100 cycles according to the manufacturer’s instructions using solutions of:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Process Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>CIDEX™ OPA Ortho-phthalaldehyde 0.55%</td>
<td>12 minutes</td>
</tr>
<tr>
<td>Anioxyde™ 1000</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Sekusept aktiv™ 2.0%</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

Sterilization
The H5i cleanable water tub and air outlet have been validated for 100 cycles for sterilization by STERRAD™ 100 S, STERRAD 100 NX and STERRAD NX.

Inspecting
Perform a visual inspection of all components. If any visible deterioration is apparent (cracking, crazing, tears etc), the water tub should be discarded and replaced. Slight discoloration of the silicone components may occur and is acceptable.
Reassembling the H5i

When all the parts are clean and dry, reassemble the H5i as follows:

1. Reinsert the air outlet ensuring that the straight side is facing up.
2. Place the outlet clip back onto the air outlet. Ensure that the outlet clip goes past the ridge on the air outlet.
3. Reinsert the maximum water level mark into the plate ensuring that it clicks into place.
4. Place the plate back onto the base ensuring that the maximum water level mark faces up.
5. Place the tub lid back onto the plate/base ensuring that the centre holes are aligned.
6. Clip all four side latches.
7. Fill the water tub and return the water tub to the H5i.
8. Close the flip lid ensuring that it clicks into place.

Packaging and storage

Store in a dry, dust-free environment away from direct sunlight.

Storage temperature: -20°C to 60°C.