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ResMed HumidAire 2i™

Disinfection and Sterilisation Guide

English



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ResMed HumidAire 2i – Disinfection and Sterilisation Guide

This Disinfection and Sterilisation Guide is intended for multi-patient use of the HumidAire 2i in a sleep lab, clinic or hospital. If you use the water chamber as a single user in the home, refer to the User Guide for cleaning instructions.

The following are the recommended and validated procedures for cleaning, disinfection and sterilisation of the water chamber. We advise that each healthcare facility consult its own procedures before carrying out the following instructions.

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 sterilisation agents, always follow the manufacturer's instructions.

Note: The HumidAire 2i is available in both a clear polycarbonate (PC) version as well as a smokey grey polysulphone (UDEL). See the table below to determine which cleaning and disinfection/sterilisation method is appropriate for your HumidAire 2i.



Clear polycarbonate (PC) version



Smokey grey polysulphone (UDEL) version

Type	Option 1 Manual Cleaning and High-Level Thermal Disinfection (see Table 1)	Option 2 Automatic Cleaning and High-Level Thermal Disinfection (see Table 2)	Option 3 Manual Cleaning and High-Level Chemical Disinfection (see Table 3)	Option 4 Manual Cleaning and Steam Sterilisation (see Table 4)
Clear polycarbonate (PC)	Yes	Yes	Yes	No
Smokey grey polysulphone (UDEL)	No	No	No	Yes

Symbols Which Appear On The Device

 Sterilisable up to 132°C (UDEL tub only)

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ResMed Validated Procedures

Table 1: Option 1 (Manual Cleaning and High-Level Thermal Disinfection)

Option 1 (Manual Cleaning and High-Level Thermal Disinfection)	
Disassembly	Disassemble the humidifier water chamber according to the “Disassembling and Reassembling” instructions on page 7.
Pre-cleaning	Rinse all water chamber components 10 times and brush thoroughly with a soft bristle brush in a warm (45°C) solution of neodisher MediZym (2%). Note: <i>Pre-cleaning must occur immediately after use.</i>
Cleaning	<ol style="list-style-type: none"> Clean all components of the water chamber with a soft bristle brush for one minute while soaking them in the detergent¹ solution. Pay particular attention to all crevices and cavities. Thoroughly rinse each component according to the manufacturer’s instructions.
Drying	Allow the water chamber to air dry out of direct sunlight.
Disinfection (high-level thermal disinfection)	<ol style="list-style-type: none"> Using a certified hot water disinfection system, fully immerse each component in water using one of the temperature-time combinations listed below. Take care that no bubbles are trapped against the components or inside the tubing. Based on prEN ISO 15883-1, the water chamber can be thermally disinfected at the following temperature-time combinations²: 70°C for 100 minutes 75°C for 30 minutes 80°C for 10 minutes 90°C for 1 minute. On completion, remove the water chamber from the hot water disinfection system. Thoroughly rinse each component in drinking quality water (five litres per assembly).
Drying	Air dry out of direct sunlight.
Inspection	Perform a visual inspection of the water chamber. If any visible deterioration is apparent (cracking, crazing, tears etc), the water chamber should be discarded and replaced. Slight discolouration of the silicone components may occur and is acceptable.
Reassembly	Reassemble the humidifier water chamber according to the “Disassembling and Reassembling” instructions on page 7.
Packaging & Storage	Store in a dry, dust-free environment away from direct sunlight. Storage temperature: -20°C to 60°C.

¹ **Cleaning:** ResMed has tested the detergent neodisher MediZym™ (diluted at 2%) for 20 cycles using warm water (approximately 45°C) according to the manufacturer’s instructions.

² **Disinfection:** ResMed water chambers have been tested for disinfection for 20 cycles by fully immersing each component in hot water (approximately 90°C) for 1 minute.

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Table 2: Option 2 (Automatic Cleaning and High-Level Thermal Disinfection)

Option 2 (Automatic Cleaning and High-Level Thermal Disinfection)	
Disassembly	Disassemble the humidifier water chamber according to the “Disassembling and Reassembling” instructions on page 7.
Pre-cleaning	Rinse all water chamber components 10 times and brush thoroughly with a soft bristle brush in a warm (45°C) solution of neodisher MediZym (2%). <i>Note: Pre-cleaning must occur immediately after use.</i>
Cleaning	<ol style="list-style-type: none"> Support the components in the standard racking of the automatic washer-disinfector so that each will drain water. Add the detergent¹ solution and activate the automatic washer-disinfector for a standard cycle of cleaning, followed by thorough rinsing.
Disinfection (high-level thermal disinfection)	<ol style="list-style-type: none"> Activate the automatic washer-disinfector for a standard cycle of thermal disinfection². Ensure that the machine has thoroughly rinsed each component.
Drying	Air dry out of direct sunlight.
Inspection	Perform a visual inspection of the water chamber. If any visible deterioration is apparent (cracking, crazing, tears etc), the water chamber should be discarded and replaced. Slight discolouration of the silicone components may occur and is acceptable.
Reassembly	Reassemble the humidifier water chamber according to the “Disassembling and Reassembling” instructions on page 7.
Packaging & Storage	Store in a dry, dust-free environment away from direct sunlight. Storage temperature: -20°C to 60°C.

¹ **Cleaning:** ResMed has tested the detergent neodisher MediZym™ (diluted at 0.5%) for 20 cycles using warm water (approximately 45°C) according to the manufacturer’s instructions.

² **Disinfection:** Due to specific regional requirements, ResMed water chambers have been tested for disinfection for 20 cycles using hot water (approximately 93°C) for 10 minutes.

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Table 3: Option 3 (Manual Cleaning and High-Level Chemical Disinfection)

Option 3 (Manual Cleaning and High-Level Chemical Disinfection)	
Disassembly	Disassemble the humidifier water chamber according to the “Disassembling and Reassembling” instructions on page 7.
Pre-cleaning	Rinse all water chamber components 10 times and brush thoroughly with a soft bristle brush in a warm (45°C) solution of Alconox (1%). Note: <i>Pre-cleaning must occur immediately after use.</i>
Cleaning	<ol style="list-style-type: none"> Clean all components of the water chamber with a soft bristle brush for one minute while soaking them in the detergent¹ solution. Pay particular attention to all crevices and cavities. Thoroughly rinse each component according to the manufacturer’s instructions.
Drying	Allow the water chamber to air dry out of direct sunlight.
Disinfection (high-level chemical disinfection)	<ol style="list-style-type: none"> Soak the disassembled water chamber components in a commercially available solution of ortho-phthalaldehyde 0.55% (eg, CIDEX™ OPA)². Take care that no air bubbles are trapped against the components. Thoroughly rinse³ each component according to the manufacturer’s instructions.
Drying	Air dry out of direct sunlight.
Inspection	Perform a visual inspection of the water chamber. If any visible deterioration is apparent (cracking, crazing, tears etc), the water chamber should be discarded and replaced. Slight discolouration of the silicone components may occur and is acceptable.
Reassembly	Reassemble the humidifier water chamber according to the “Disassembling and Reassembling” instructions on page 7.
Packaging & Storage	Store in a dry, dust-free environment away from direct sunlight. Storage temperature: -20°C to 60°C.

1 Cleaning: ResMed has tested the detergent Alconox (diluted at 1%) for 20 cycles using hot water (approximately 60°C) or warm water (approximately 50°C) according to the manufacturer’s instructions.

2 Disinfection: ResMed water chambers have been validated for 20 cycles using solutions of ortho-phthalaldehyde (0.55% CIDEX OPA for 12 minutes) according to the manufacturer’s instructions.

3 Rinsing: Thoroughly rinse each component in drinking quality water (five litres per assembly) by immersing it completely for a minimum of one minute in duration. Repeat the rinse procedure two additional times using fresh water for a total of three rinses.

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Table 4: Option 4 (Automatic Cleaning and Steam Sterilisation)

Option 4 (Automatic Cleaning and Steam Sterilisation)	
Disassembly	Disassemble the humidifier water chamber according to the “Disassembling and Reassembling” instructions on page 7.
Pre-cleaning	Rinse all water chamber components 10 times and brush thoroughly with a soft bristle brush in a warm (45°C) solution of neodisher MediZym (2%). Note: <i>Pre-cleaning must occur immediately after use.</i>
Cleaning¹	<ol style="list-style-type: none"> Support the components in the standard racking of the automatic washer-disinfector so that each will drain water. Add the detergent solution and activate the automatic washer-disinfector for a standard cycle of cleaning, followed by thorough rinsing.
Sterilisation²	Using a certified sterilisation system, use one of the following temperature profiles: 132°C with a three-minute hold time 121°C with a 30-minute hold time.
Drying	Drying is achieved as part of the sterilisation process.
Inspection	Perform a visual inspection of the water chamber. If any visible deterioration is apparent (cracking, crazing, tears etc), the water chamber should be discarded and replaced. Slight discolouration of the silicone components may occur and is acceptable.
Reassembly	Reassemble the humidifier water chamber according to the “Disassembling and Reassembling” instructions on page 7.
Packaging & Storage	Store in a dry, dust-free environment away from direct sunlight. Storage temperature: -20°C to 60°C.

¹ **Cleaning:** ResMed has tested the detergent neodisher MediZym™ (diluted at 0.5%) for 20 cycles using warm water (approximately 45°C) in the washer-disinfector (manufacturer: Miele; type: G7736MCU; program: Vario TD210) according to the manufacturer’s instructions.

² **Sterilisation:** ResMed water chambers have been tested for 20 cycles using the temperature-time combinations: 132°C with a three-minute hold time or 121°C with a 30-minute hold time.

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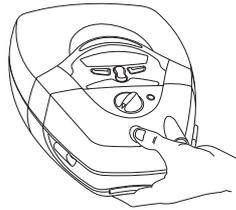
Disassembling and Reassembling the HumidAire 2i



WARNING

Beware of electrocution. Do not immerse the device or power cord in water. Always unplug the device before cleaning and be sure that it is dry before plugging back in.

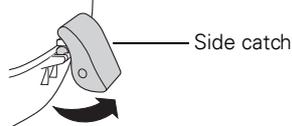
- 1 Turn the main power switch at the back of the device to OFF, and unplug the power cord from the power outlet.
- 2 Allow 10 minutes for the tub plate and any excess water to cool.
- 3 Remove the water chamber. To do this, lift the latch at the bottom of the water chamber and pull the water chamber away from the docking station.



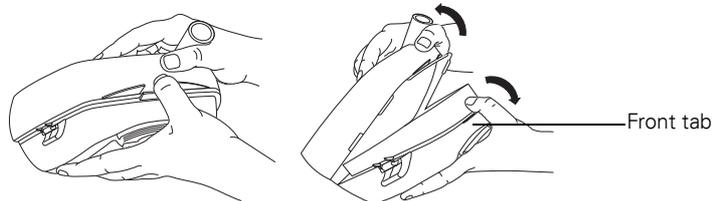
- 4 Discard any excess water by turning the water chamber upside down, allowing the water to drain out of the air outlet.

5 Disassembling the Water Chamber

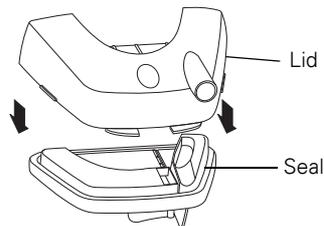
1. To open the side catches pull out from the lower edge.



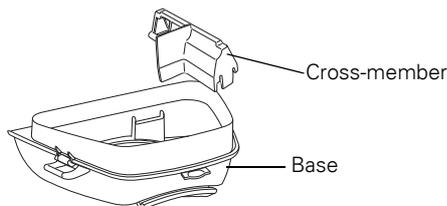
2. Separate the water chamber by pulling the two halves apart. Use your thumb to pull down on the front tab.



3. Inside the chamber lid is the seal. Remove the seal by peeling it away from the inside of the lid.

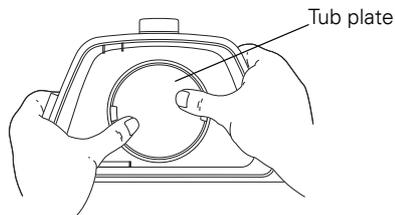


4. Remove the cross-member from the water chamber base.

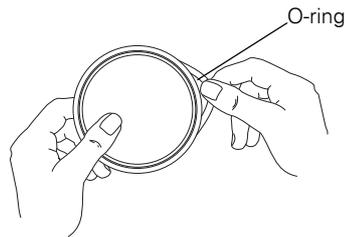


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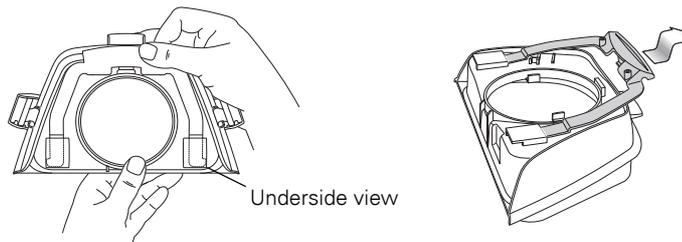
- 6** 1. Push down on the tub plate from inside the chamber to remove it from the chamber.



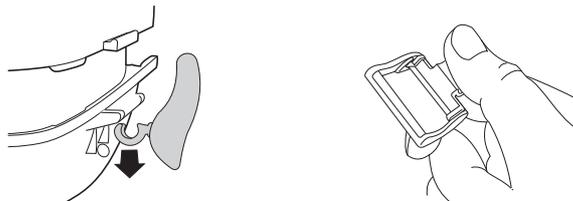
2. Remove the O-ring from the tub plate.



3. Turn the water chamber base upside down. Firmly pull the latch up and away from the chamber until separated from the base.



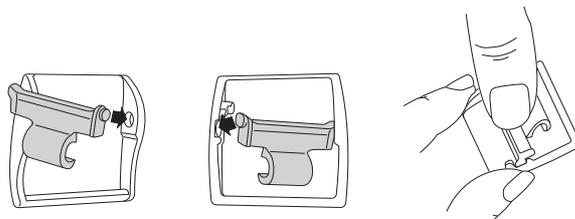
4. Disengage the catches from the sides of the water chamber base. Then, separate the inner and outer moulding of the catch, pull back the inner moulding and squeeze. The inner moulding will pop out.



7 Reassembling the Water Chamber

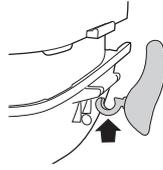
When all the water chamber parts are clean and dry, reassemble the water chamber:

1. Reassemble the catches by inserting one side of the inner moulding to the outer moulding and pushing downwards.

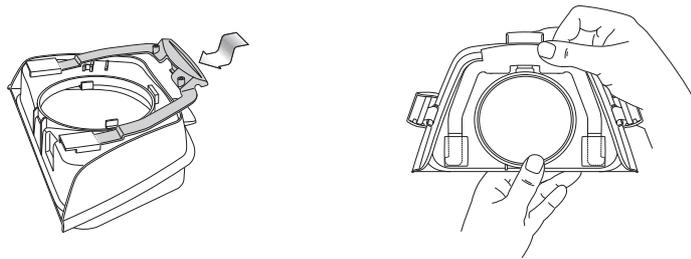


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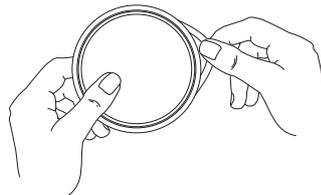
2. Take the assembled catches and fit them to the water chamber base.



3. Turn the water chamber base upside down. Insert the latch's feet into the locking tabs. Push firmly and click into place.



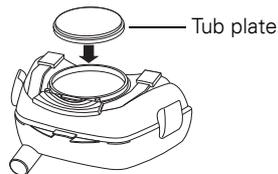
4. Refit the O-ring in the channel of the tub plate.



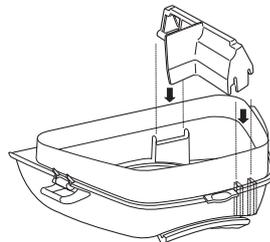
CAUTION

Ensure that you replace the O-ring if it is nicked or punctured.

5. Push the tub plate into the water chamber with the open side facing down. Then firmly press the tub plate down into the water chamber.

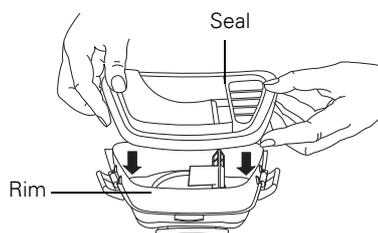


6. Place the cross-member on its supports inside the water chamber base.

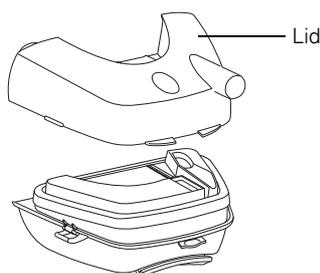


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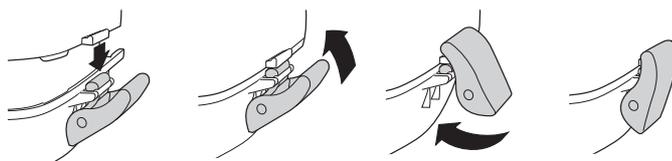
7. Fit the seal onto the rim of the water chamber base. Press along the edge to ensure that the seal is fitted properly.



8. Fit the lid onto the water chamber base. Press the lid and base firmly together to close.



9. Lock the catches on the side of the water chamber.



Troubleshooting

If the water chamber leaks after being reassembled, examine the unit for the following:

Possible cause	Solution
Water chamber may be damaged or cracked	Replace affected section of water chamber.
Water chamber seal may be twisted	Make sure the seal is seated properly inside the water chamber.
Side catches are not engaged properly	Make sure two side catches are engaged properly.
Tub plate is incorrectly fitted	Ensure tub plate is fitted correctly.
O-ring is punctured or nicked	Replace O-ring.

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Patents pending. Protected by design registrations: AU 147335, CH 128.711, CH 128.712, DE 40202008, DE 40201723, ES 153516, ES 153518, FR 021407, GB 3001820, GB 3001821, JP 1164266, JP 1164267, SE 75598, SE 75715, US D476077, US D477868. Other designs pending.

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