

Humidification Chamber (HC400)
(Accessory of Respiratory Humidifier)
Instructions for use

File No:MK/YF91-16

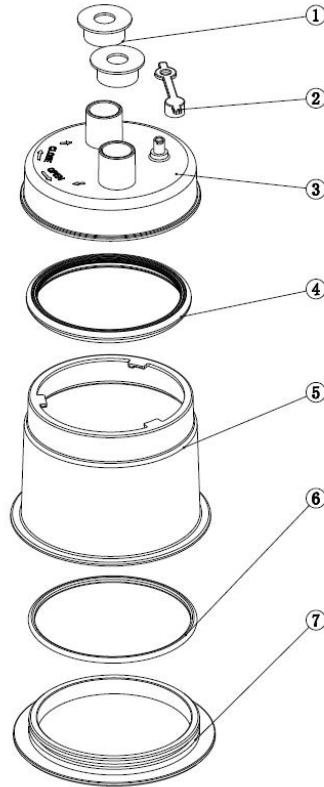
Ver:V1.5

1 Product Introduction

1.1 Product Name: Humidification Chamber

1.2 Product Model: HC400

1.3 Structural composition:



① dust cap ② end cap ③ Top cover ④ Top cover sealing ring ⑤ pedestal ⑥ Heater-plate sealing ring
⑦ Heater-plate

2 WARNINGS

- Connect the humidification chamber and breathing tube according to the instructions of respiratory humidifier.
- The water added to the humidification chamber must not exceed the maximum water level or it may enter the breathing tube. Don't fill the humidification chamber with water whose temperature exceeds 37°C.
- Please dispose the medical devices according to the medical device waste disposal methods.

3 Specifications

- ① Maximum water injection capacity: 400mL
- ② Connection Interface: 22 mm conical connector
- ③ Max Flow Range: 120L/min
- ④ Maximum limited pressure: 6 kPa
- ⑤ Transport/Storage Condition: Refer to the respiratory humidifier manual
- ⑥ Shelf life: 3 years

4 Use Instructions

- Before use, visually inspect all components, ensure that all connections are secure, check the humidification chamber base and heater-plate are undamaged, clean and dry.
- Before use, please ensure that the humidification chamber has been cleaned and disinfected, and that the heating plate of the humidification chamber is clean, flat and dry.
- Fill the humidification chamber with water through the water inlet until the position of max water level.
- Slide the humidification chamber on to the Heater-plate of respiratory humidifier, ensure it is level and securely positioned. Connect the breathing circuit and set the parameters according to the respiratory humidifier operation instruction.
- Observe the water level in the humidification chamber regularly and fill with EP sterile water if necessary.
- If the humidification chamber leaks, replace the top cover sealing ring or the heater-plate sealing ring.
- The accessory is reusable, it can be reused after reprocessing (cleaning and disinfecting).

5 Thermal Reprocessing Procedures



Humidification Chamber cannot be processed with chemical disinfection

Procedure the Humidification Chamber by thermal disinfection as following procedures every time before multiple patient reuse.

This Instructions describes the recommended and validated procedure for Thermal Reprocessing Procedures of the Humidification Chamber in accordance with ISO17664.

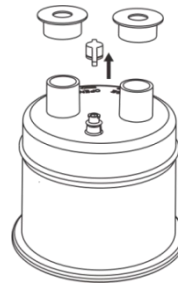
Cleaning and disinfection personnel should be professionally trained.

Validated Number of Cycles: 20 cycles

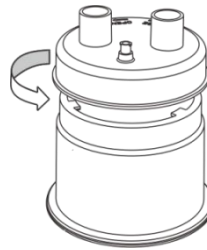
NOTE:If a healthcare facility requires an additional disinfection cycle after reassembly, the number of validated cycles must be halved.

<p>a.Initial treatment at the point of use</p>	<p>-The maximum period of time that may elapse between use and cleaning:If the humidification chamber cannot be delivered to the disinfection supply center within 1 hour, users should remove obvious dirt on it in time after use, and do moisturizing treatment as needed.</p> <p>-A description of the pre-cleaning techniques critical to further processing:Perform a visual inspection of each humidification chamber component. If any visible deterioration of a humidification chamber component is apparent (cracking, crazing, tears etc),the humidification chamber component should be discarded and replaced. Slight discolouration of the silicone components may occur and is acceptable.</p> <p>-The containers for transportation:Sealed container</p> <p>-The requirements for transportation:Sealed transfer vehicle</p>
<p>b.Preparation before cleaning</p>	<p>-Disassembly of the device:Disassemble components of the humidification chamber. Visually inspect to insure that all components are free from defects, tears, or other visible marks of deterioration, according to the following component disassembly steps.</p>

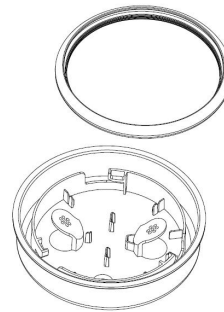
Step1:Remove the dust cap and the end cap from the top cover.



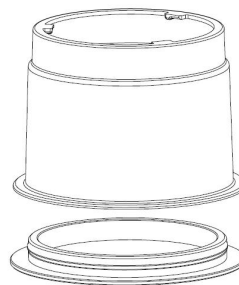
Step2:Remove the top cover from the humidification chamber by turning it counterclockwise.



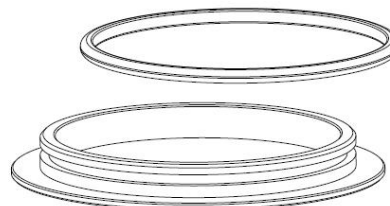
Step3:Remove sealing ring of top cover.

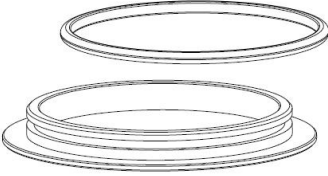
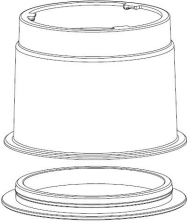


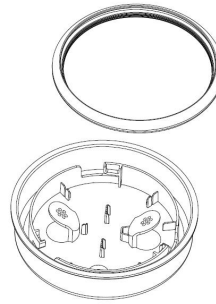
Step4:Remove the chamber base from pedestal.



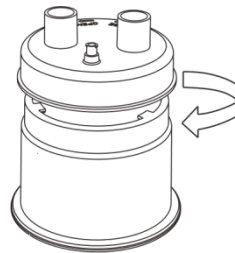
Step5:Remove sealing ring of chamber base.



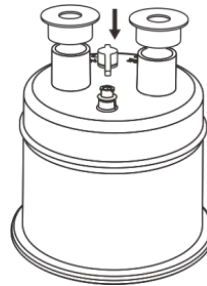
<p>c. Automated Cleaning</p>	<p>-Place the separated components in fully automatic washer-disinfector. -Cleaning: Set the water temperature to 45°C and the period 30 minutes. -Cleaning agent requirements: Purified water -Rinsing: Set the rinsing procedure for about 1 minute . -The quality of water to be use: Purified water.</p>
<p>d. Automated Disinfection</p>	<p>-Disinfection:Set the water temperature to 93°C and the period 5 minutes. Refer to the manual for full automatic washer-disinfector for specific disinfection operations. -The quality of water to be used: purified water</p>
<p>e. Drying</p>	<p>Drying: Set the drying temperature to 70°C and the period 40 minutes. If the component of the Humidification Chamber is not completely dry, it can be placed in the air to dry, but it can not be directly exposed to the sun.</p> <p>⚠ Refer to the manual for fully automatic washer-disinfector for specific drying operations.</p>
<p>f. Inspection and maintenance</p>	<p>Perform a visual inspection of each humidification chamber component. If any visible deterioration of a humidification chamber component is apparent (cracking, crazing, tears etc). The humidification chamber component should be discarded and replaced. Slight discolouration of the silicone components may occur and is acceptable.</p>
<p>g. Reassembly and Packaging</p>	<p>Reassembly: Reassemble the Humidification Chamber according to the following component assembly steps.</p> <p>Step1: Assemble sealing ring to chamber base.</p>  <p>Step2: Assemble the chamber base to pedestal.</p>  <p>Step3: Assemble sealing ring to top cover.</p>



Step4: Assemble the top cover to the humidification chamber by turning it clockwise.



Step5: Assemble the dust cap and the end cap to the top cover.











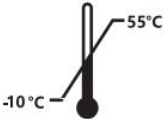











Note: Avoid scratching the upper cover seal ring and the base seal ring with sharp instruments during assembly, otherwise the humidifier may leak.

Packaging: Use medical disposable self-adhesive plastic packaging materials for packaging.

h. Storage	<p>-The maximum storage time:7 days.If the maximum storage time is exceeded, the humidification chamber must be cleaned and disinfected even though it is not in use.</p> <p>-Store in a dry, dust-free environment away from direct sunlight.</p> <p>-Storage temperature: -10°C to 55°C.</p>
I. Transportation	<p>The requirements for transportation to point of use: Sealed transfer vehicle</p>

6 Symbol Definitions

Symbol	Definition	Symbol	Definition
	Caution (ISO 7010-0434A)		Do not use if package is damaged and consult instructions for use (ISO 7000-2606)
	Non-sterile (ISO 7000-2609)		Consult instructions for use or consult electronic instructions for use (ISO 7000-1641)
	Max water level		Exceed max water level
	This way up (ISO 7000-0623)		Keep dry (ISO 7000-0626)
	Keep away from sunlight (ISO 7000-0624)		Fragile, handle with care (ISO 7000-0621)
	Temperature limit (ISO 7000-0632)		Serial number (ISO 7000-2498)
	Manufacturer (ISO 7000-3082)		Date of manufacture (ISO 7000-2497)
	Stacking limit by number (ISO 7000-2403)		Unique device identifier (ISO 15223-1)
	Authorized representative in the European Community/European Union		Distributor (ISO 7000-3724)
	Importer (ISO 7000-3725)		CE Marking

Product name: Humidification Chamber

Model: HC400

Manufacturer: Micomme Medical Technology Development Co., Ltd.

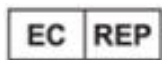
Manufacture address: No.6 Kesheng Road, Hi-Tech Zone,410221 Changsha, Hunan, PEOPLE'S
REPUBLIC OF CHINA

Website: www.micommed.com

Service hotline: +86 4000-2000-33

Shelf life: 3 years

Revised on: July.5th, 2024



Name: Shanghai International Holding Corp. GmbH (Europe)

Add: Eiffestrasse 80, 20537 Hamburg, Germany

Tel: 0049-40-2513175

Fax: 0049-40-2557