

MDI Holding Chamber User Manual

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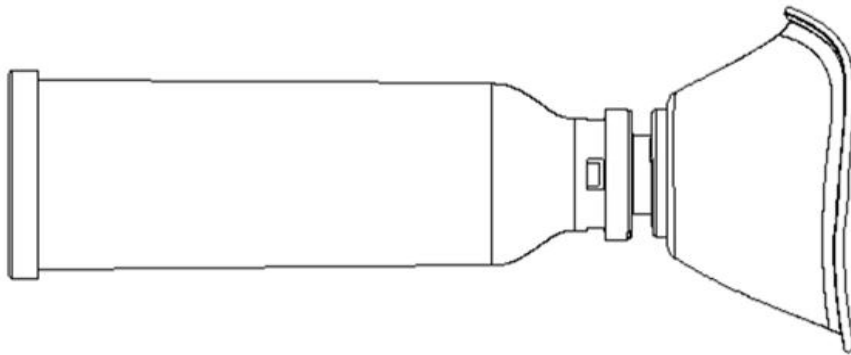


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Preface

Dear users:

Thank you for purchasing our company's MDI holding chamber product. Please read this manual carefully before formal use. This manual has made appropriate explanations on the product's structure, working principle, usage, storage environment, etc. After reading, please keep it properly for future use.

Safety information

Before using the MDI holding chamber, please read the User Manual carefully.

1. Overview

This manual is applicable to the following MDI holding chamber product models: HM-HC01, HM-HC02, HM-HC03, HM-HC04 and HM-HC05.

The MDI holding chamber is used to inhale drugs delivered by a pressurized metered-dose inhaler. The product contains a one-way valve to control the direction of the patient's inhalation and exhalation through the product. It has a universal port and is designed to be compatible with most pressurized metered-dose inhaler drugs. This product is non-sterile, reusable, and is limited to single patient use.

2. Working Principle

The basic principle of the MDI holding chamber is to provide a certain amount of drug storage space. When the drug passes through the MDI holding chamber, the drug particles and the air in the tank are fully mixed and stay for a short time, so that the patient can inhale it, so that the spraying and inhalation actions are carried out separately, solving the coordination problem of inhalation. This product is designed to minimize the delivery of larger particles of atomized drugs, which can significantly reduce drug deposition in the mouth, throat and upper respiratory tract. At the same time, the drug can be inhaled repeatedly to increase the amount of drug inhaled into the lungs, thereby reducing irritation to the mouth, throat and upper respiratory tract.

3. Intended use/intended purpose

The MDI Holding Chamber is intended to be used by adult and child (≥ 5 years) who are under the care or treatment of a physician or licensed healthcare professional. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers, which are useful in the treatment of asthma, COPD, and other respiratory ailments. The intended environments for use include the home, hospitals and clinics. It is a non-sterile, single patient, multiple use device.

4. Contraindications, warnings and precautions

4.1 Contraindications

None.

4.2 Warnings

- a) The MDI holding chamber should be used by one person only. Do not use the device by multiple patients to avoid cross infection.
- b) The MDI holding chamber and its accessories are designed for single-patient reuse, do not reuse them among different people to avoid cross-contamination.
- c) It is recommended to clean the product before first use, and it is recommended to clean the product once a day.
- d) Do not use other accessories unless recommended by manufacturer, all accessories meet the requirements of ISO10993.

- e) The children should use the device under the supervision by adult.
- f) When unpacking, please check whether the product is intact. If it is damaged, do not use it.
- g) You should rinse your mouth and wash your face immediately after inhaling the medicine to avoid irritation and other adverse reactions caused by residual medicine.
- h) During use, if you experience any discomfort such as irritation, allergy, etc., stop using it immediately and consult your doctor.
- i) Do not use any accessory or parts from other manufacturer, it may cause gas leakages or compatibility issues.
- j) Any serious incident that has occurred in relation to the MDI holding chamber should be reported to Insight and the authority having jurisdiction in your locale.

4.3 Precautions

- a) Check the connection of the device before use.
- b) Do not use the device if package was damaged.
- c) Use and store the device under the environment conditions specified by the manufacturer.
- d) Follow local laws and recycling plans regarding disposal or recycling of components and packaging.
- e) The MDI holding chamber should be replaced regularly according to its service life. If any parts are damaged, they should be replaced

immediately.

f) The MDI holding chamber should be kept clean to avoid contamination that may affect the treatment effect.

g) To ensure the effectiveness of the MDI holding chamber, it should be stored in a cool, dry, dark place.

5. Structural composition

The MDI holding chamber is consists of a chamber, an intake valve flap, a mist outlet, a base and a mask. The masks have three types: adult mask (transparent), child mask (transparent) and child mask (TPE-edge), and users can choose the mask based on their needs.

5.1 Structure

The structural diagrams are listed as figure 5-1 and figure 5-2:

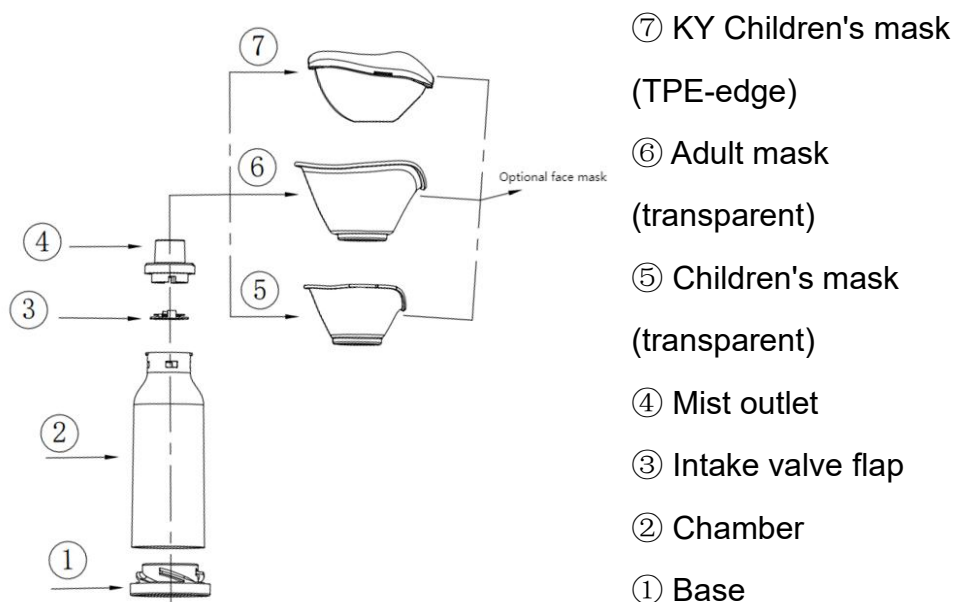


Figure 5-1: Diagram for HM-HC01, HM-HC02, HM-HC04, HM-HC05

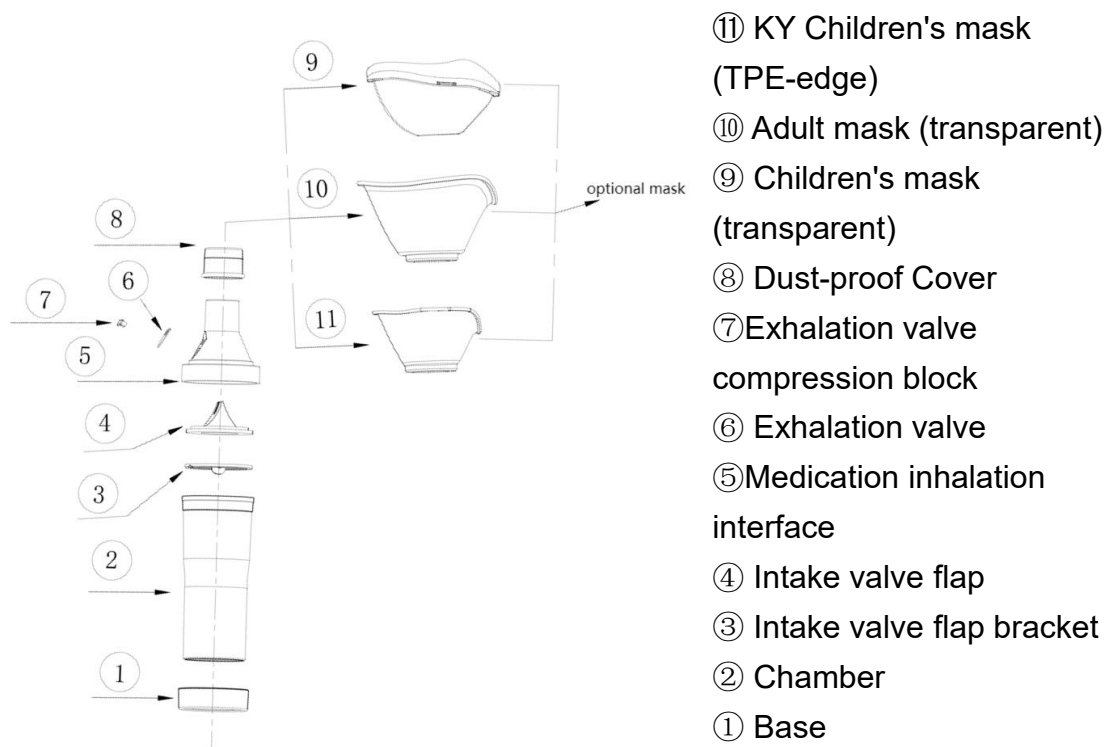


Figure 5-2: Diagram for HM-HC03

5.2 Photos of models

Photo		
Model	HM-HC01	HM-HC04

Photo		
Model	HM-HC02	HM-HC05
Photo		
Model	HM-HC03	

5.3 Standard Configuration

5.3.1 Standard configuration of HM-HC01, HM-HC02, HM-HC04, HM-HC05

Components	Quantity	Components	Quantity
Chamber	1	Base	1
Intake valve flap	1	Mask (optional)	1
Mist outlet	1	User Manual	1

5.3.2 Standard configuration of HM-HC03

Components	Quantity	Components	Quantity
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Chamber	1	Medication inhalation interface	1
Intake valve flap	1	Intake valve flap Bracket	1
Exhalation valve	1	Exhalation valve compression block	1
Base	1	Mask (optional)	1
Dust-proof Cover	1	User Manual	1

6. Performance parameters

6.1 Physical properties

Model Project	HM-HC01	HM-HC02	HM-HC04	HM-HC05	HM-HC03
Structural composition	-Chamber, -Mist outlet, -Intake valve flap, -Base (round shape)	-Chamber, -Mist outlet, -Intake valve flap, -Base (round shape)	-Chamber, -Mist outlet, -Intake valve flap, -Base (square shape)	-Chamber, -Mist outlet, -Intake valve flap, -Base (square shape)	-Chamber, -Medication inhalation interface, -Intake valve flap, -Intake valve flap bracket, -Base (square shape) -Exhalation valve, -Dust-proof Cover, -Exhalation valve compression block
Size	φ56*184.3mm	φ56*156.3mm	φ56*184.3mm	φ56*156.3mm	φ51.6*156.6mm
Weight	58.9g	52.2g	60.7g	54g	43.4g
Volume	225mL	175mL	225mL	175mL	135mL
Attachment	Adult mask; Children's mask; KY children's mask	Adult mask; Children's mask; KY children's mask	Adult mask; Children's mask; KY children's mask	Adult mask; Children's mask; KY children's mask	Adult mask; Children's mask; KY children's mask
<p>Note:</p> <p>1) The mask is an optional accessory. You can choose one or more masks;</p> <p>2) The difference between HM-HC04 and HM-HC01, HM-HC05 and HM-HC02 is that the base shape is different, and the other structural components are the same.</p>					

7. How to use

Note: Before use, please check whether the MDI holding chamber is intact and completely dry. Please choose the appropriate model and mask according to the age of the patient.

a-1) Install the mask on the mist outlet (HM-HC01, HM-HC02, HM-HC04, HM-HC05).

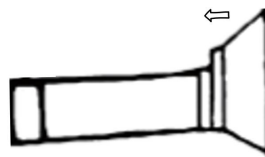


Figure a-1

a-2) Remove the dust-proof cover firstly for HM-HC03, then Install the mask on the mist outlet.

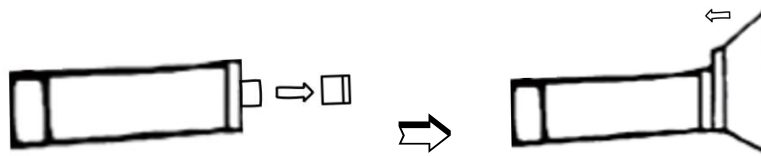


Figure a-2

b) Remove the sealing cap of the MDI and shake the MDI vigorously up and down 5-6 times.



Figure b

c) Insert the MDI into the base of the MDI holding chamber.

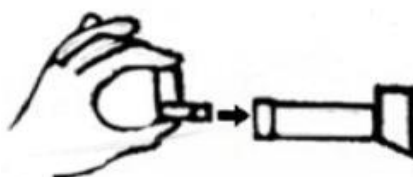


Figure c

d) Place the mask fully over your mouth and nose, press down once on the MDI, and start inhaling.

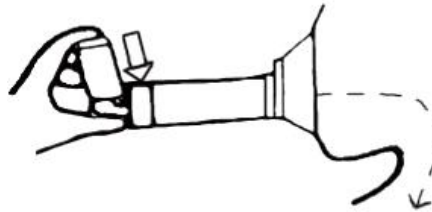


Figure d

e-1) When inhaling drugs for adults, first take a deep breath, hold the breath for 5-10s, slowly exhale, and then take a deep breath. After inhaling all drugs, remove the mask.

e-2) When the child inhales the drug, slowly breathe deeply for 8-10 times, and remove the mask after about 20-30s, and only press the drug once each time.

f) If you need to spray the drug multiple times, wait at least 30 seconds and repeat the d) to e) steps.

h) After use, pull out the MDI, cover the seal, remove the mask, rinse your mouth and wash your face immediately.

i) Clean the MDI holding chamber after each use, dry it and store it in a cool and dry place for future use.

8. Cleaning, disinfection and sterilization methods

8.1 Cleaning

a) Disassemble the chamber, intake valve flap, mist outlet, base and

mask.

Note: Other parts of the model HM-HC03 cannot be removed except the base, dust-proof cover, and mask.



Figure a)

b) Rinse them with running water for about 5 minutes, until there are no visible stains on the inside and outside surfaces.



Figure b)

c) After rinsing, place each part upright on the clean cloth for air dry.



Figure c)

d) Assemble all parts, place them in a cool and dry place for storage, avoiding direct sunlight.

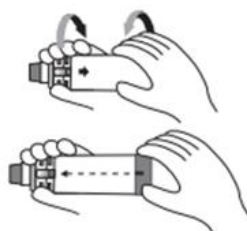


Figure d)

Note: Do not use any tools such as brushes to scrub.

Note: Clean it after each use.

8.2 Disinfect

Note: Cleaning is required before disinfecting.

a) Disassemble the chamber, intake valve flap, mist outlet, base and mask.

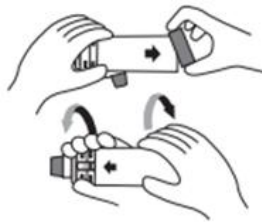


Figure a)

b) Soak the parts in 70%-75% alcohol for 5 minutes.



Figure b)

c) Place each part upright on the clean cloth for air dry.

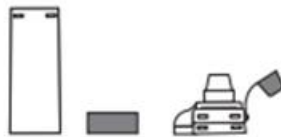


Figure c)

d) Assemble all parts, place them in a cool and dry place for storage, avoiding direct sunlight.

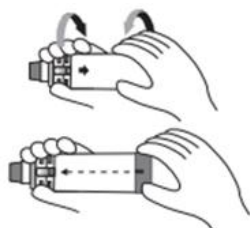


Figure d)

Note: Do not steam at high temperature!

Note: Disinfect at least once a week.

8.3 Sterilization

This product is non-sterile and does not require sterilization.

9. Environmental requirements

Item	Description
Working conditions	Temperature: 5°C~40°C Humidity: 10%RH~95%RH Atmospheric pressure: 70kPa~106kPa
Storage & transportation conditions	Temperature: -40°C~55°C Humidity: 10%RH~95%RH Atmospheric pressure: 50kPa~106kPa

10. Service life

The service life is 3 years, when the device is removed from the package for use, the use life is 12 months or until the end of the service life, whichever is short.




11. Common Problems and Solutions







No.	Frequently asked questions	Countermeasures
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1	If the MDI holding chamber is not cleaned in time, too much drug will be deposited on the tube wall, affecting the treatment effect.	Clean once a day at the prescribed time
2	When the aerosol nozzle is inserted into the MDI holding chamber, the aerosol bottle is not inverted, resulting in inadequate aerosol release.	Aerosol is inserted in an inverted position
3	Breathing too fast or inspiratory flow rate is insufficient, the valve does not open /opens insufficiently	Take slow, deep breaths while inhaling the drug
4	Not inhaling the medicine immediately after spraying, holding your breath or inhaling intermittently, or exhaling excessively into the spacer	Inhale the medicine immediately after spraying, take slow and deep breaths continuously, and exhale normally.
5	When pressing the aerosol, the force is too small and the aerosol is not fully released.	When spraying, press the aerosol firmly to the bottom.
6	After pressing the medicine, the bottle is pulled out of the MDI holding chamber and the medicine comes out from the base	After pressing the medicine, take out the medicine bottle after inhaling it.
7	The inhalation time is too short, and the MDI holding chamber is removed before 20 seconds.	The inhalation time should be kept between 20-30s
8	Failure to remove the aerosol cap	Open the bottle cap before

	before inhaling the medicine	inserting the aerosol.
9	The drug was not shaken vigorously along the long axis of the aerosol before spraying	Shake the aerosol vigorously up and down 5-6 times before spraying
10	The child should lie flat when taking the medicine	The child should stand while taking the medicine.
11	Failure to clean the face or mouth of residual drugs after taking drugs	Rinse your mouth and face immediately after taking the medicine, and spit out the mouthwash
12	Using a damaged MDI holding chamber	If the MDI holding chamber is damaged, replace it immediately
13	The mask does not fit the face or does not cover the entire mouth and nose when inhaling the medicine	When inhaling the medicine, the mask fits the face and covers the entire mouth and nose
14	When installing the MDI holding chamber, the components are not connected tightly, resulting in air leakage.	During installation, make sure all components are installed in place

12. Symbols

Symbol	Explanation
	Manufacturer
	Authorised representative in the European Community
	Lot Number

	Serial Number
	Date of Manufacturing
	Caution
	Batteries or electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste
	Non-sterile
	Medical device

13. Contact information



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