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## 1 INTENDED USE

The Watchhaler is an inhalation system (Spacer or Holding Chamber) for the inhalation of approved liquid compressed gas metered dose inhaler systems (MDI) for the therapy of the upper and lower respiratory system. The Watchhaler can be applied to awake, actively cooperating children, starting from the age of 3 up to 10 years old under supervision.

## 2 WARNING NOTES

- Observe the cleaning instructions in Chapter 7 „Hygiene“ prior to the first application.
- In order to avoid a health risk e.g. an infection due to contamination, it is necessary to follow the instructions in the Chapters „Hygiene“, „Drying“ and „Storage and transport“.
- The Watchhaler may only be used by one patient (a change of patient is not permissible, even after hygienic treatment). Use of this product by health service facilities is not permissible; please contact the manufacturer in these cases.
- The Watchhaler is not a toy.

## 3 LIABILITY

The Activaero GmbH is not responsible for damages or malfunctions, which occur due to inappropriate or non-intended activities of the operator.

#### 4 SCOPE OF DELIVERY

Ensure that all following specified parts are available and undamaged, when unpacking the Watchhaler transport box. If you should have received an incomplete or damaged delivery, please contact your specialist dealer.

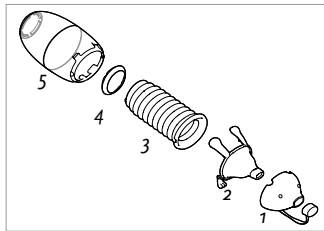


FIG. 1  
 1 Head piece cover with protective cover  
 2 Head piece holder  
 3 Folding balloon  
 4 Slide ring  
 5 Housing  
 6 Instructions for use (without illustration)

#### 5 APPLICATION

Please observe the hygiene instructions prior to each use (Cleaning, disinfection and drying). Examine the Watchhaler before each use for foreign bodies (danger of suffocation!) and damages. Ensure before treatment, that the Watchhaler works as intended. The folding balloon must fold itself up when inhaling and then return to its completely expanded shape. The Watchhaler can be used with most of the approved metered dose inhalers (MDI). It is however important, that the mouthpiece of the metered dose inhaler (MDI) fits onto the Watchhaler mouthpiece. The metered dose inhaler (MDI) can generally be applied to two different positions on the Watchhaler mouthpiece when filling:

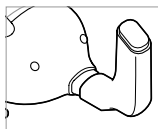


FIG. 2  
 The mouthpiece of the metered dose inhaler (MDI) encloses half of the mouthpiece of the Watchhaler.

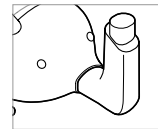


FIG. 3  
 The mouthpiece of the metered dose inhaler (MDI) encloses the complete mouthpiece of the Watchhaler.

The Watchhaler can not be used, if the metered dose inhaler (MDI):

- cannot be clearly positioned on the mouthpiece of the Watchhaler.
- cannot be manually initiated.

#### 5.1 FILLING THE WATCHHALER

##### IMPORTANT NOTES ON FILLING THE WATCHHALER:

- Always ensure before filling, that the Watchhaler is not damaged and that no parts have broken off. The Watchhaler must be replaced immediately, if it is damaged.
- Observe the instructions for use of your metered dose inhaler (MDI) and/or follow the instructions of your physician or pharmacist with regard to dosage and application of your metered dose inhaler (MDI) with the Watchhaler.

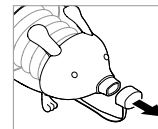


FIG. 4  
 Remove the protective cover from the mouthpiece of the Watchhaler.

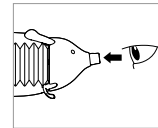


FIG. 5  
 Ensure before each filling, that the folding balloon is empty and fully expanded.

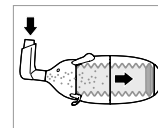


FIG. 6  
 Place the mouthpiece of the metered dose inhaler (MDI) onto the Watchhaler mouthpiece. Release the metered dose inhaler (MDI).

## 5.2 INHALATION

If possible, train the use of the Watchhaler playfully and without medicine together with the child before application. If necessary, demonstrate how to inhale (without medicine), so that the folding of the balloon is visible. Pay attention to the following sequence during inhalation:

1. Breathe out completely
2. Put the mouthpiece (yellow part) into the mouth
3. Suck on the mouthpiece, as if it was a straw
4. Release the mouthpiece and exhale (Folding balloon expands again)

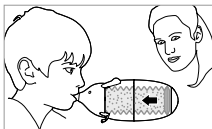


FIG. 7  
Filled Watchhaler

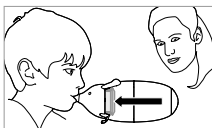


FIG. 8  
Folding balloon is compressed during the inhalation.

### IMPORTANT NOTES ON INHALATION WITH THE WATCHHALER:

- Give the child the already filled Watchhaler.
- The inhalation must take place immediately after filling.
- If necessary, help the child hold the Watchhaler correctly (like a drinking bottle).
- Pay attention to the movement of the slide ring during the inhalation (see Fig. 8).
- Do NOT exhale into the device.
- The inhalation has been completed after a deep breath, the child can then continue to breathe freely.

## 6 DISASSEMBLING AND ASSEMBLING THE WATCHHALER

### 6.1 DISASSEMBLING THE WATCHHALER

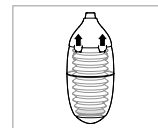


FIG. 9  
Releasing the head piece from the housing: Press the small tabs on the Watchhaler forwards. The housing may not be disassembled further.

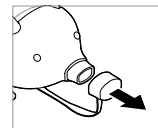


FIG. 10  
Remove the protective cover from the mouthpiece of the Watchhaler.

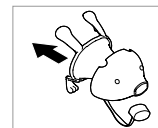


FIG. 11  
Press firmly onto the mouthpiece of the Watchhaler to separate the head piece holder from the head piece cover. The protective cover remains connected to the mouthpiece cover.

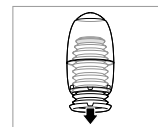


FIG. 12  
Remove the folding balloon, by holding the housing with the opening pointed downwards.

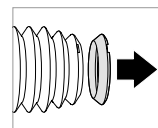


FIG. 13  
Remove the slide ring from the folding balloon.

## 6.2 ASSEMBLING THE WATCHHALER

Assemble the Watchhaler, as described in the following illustrations. Ensure that the individual components are intact. Ensure furthermore, that the openings on the rear side of the Watchhaler are not clogged or damaged.

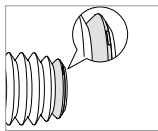


FIG. 14  
*Attach the slide ring to the folding balloon as illustrated. Make sure that the ribs of the folding balloon are not dented.*



FIG. 15  
*Hold the housing with the opening upwards and insert the folding balloon. Check the correct seat of the folding balloon.*

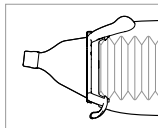


FIG. 16  
*Hook the ears of the head piece holder (yellow part) into the housing until the tabs engage. The Watchhaler may not be used any longer, if the fastening mechanics are defective. Make sure, that the folding balloon is well positioned between the head piece holder and the housing.*

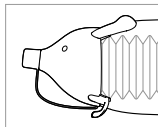


FIG. 17  
*Put the head piece cover (orange part) onto the head piece holder. The connection must engage audibly. Close the mouthpiece of the Watchhaler with the protective cover.*

## 7 HYGIENE

Clean the Watchhaler components, i.e. the folding balloon, head piece holder and head piece cover with protective cover, prior to first use and following each treatment (within 2 hours at the most). Disinfect the cleaned Watchhaler components immediately after cleaning.

The housing and the slide ring must only be cleaned, if they are contaminated. Use a new, washed, damp cloth, e.g. a dishcloth or a kitchen roll (not recycled material!). Always make sure, that the openings on the rear side of the housing are not clogged. Do not remove the orange cap. Verification of the suitability of the Watchhaler for effective cleaning and disinfection was provided by an independent test laboratory using the recommended and mentioned techniques. Access to the test documentation is possible on request.

### 7.1 CLEANING

Folding balloon, head piece holder and head piece cover with protective cover must be cleaned after each use with warm tap water (at least 40 °C) and detergents (commercial household detergents, without disinfectant and if possible without skin-friendly substances). Place the mentioned parts into the rinsing liquid for at least 5 minutes and clean the surfaces with a clean cloth. Subsequently, rinse all parts thoroughly for at least one minute with tap water; all foam residues must be removed.

### 7.2 DISINFECTION

Disinfect the cleaned Watchhaler components with a vaporisator or with steam disinfection equipment (e.g. disinfection equipment DI 6.00 of petra-electric, PZN 2590773). Please do not disinfect the transparent housing. Observe the instructions for use of the disinfection device. Ensure, that steam can flow through the components from bottom to top and that the opening of the folding balloon is pointing downwards. The residence time is approx. 15-20 minutes.

### 7.3 DRYING

In order to avoid germ growth in the Watchhaler and a possible infection, always make sure that the Watchhaler components are sufficiently dried after cleaning and disinfecting. For this purpose, place all Watchhaler components with the opening downwards on a dry, clean and absorbent surface, e.g. a freshly washed dishcloth or kitchen roll (not recycled material!). Allow the parts to dry completely (at least 4 hours). Shake out possibly still present condensate. Drying should not take place in rooms with high air humidity (e.g. in the bathroom).

### 8 STORAGE AND TRANSPORT

Place the protective cover on the mouthpiece for storage and transport. Do not put the Watchhaler into a plastic bag when it is still damp. Do not keep the Watchhaler in the car or in damp environments (e.g. in the bathroom). Do not allow acids and caustic solutions as well as solvents to come into contact with the Watchhaler components. The manufacturer is not liable, if these instructions are ignored.

### 9 SERVICE LIFE

For hygienic reasons the service life of the Watchhaler is one year and/or 1000 applications and must be replaced after this time. Replace the Watchhaler immediately, in case of visible damages.

### 10 DISPOSAL

The cleaned Watchhaler components can be disposed together with the domestic refuse. The packing can be disposed together with used paper.

### 11 TECHNICAL DATA

Maximum inhalation flow .....	15 l/min
Complete inhalation volume .....	300 ml
Weight .....	170 g
Dimensions (L x W x H) .....	218mm x 92mm x 84mm

#### MATERIALS

Folding balloon, valve membrane .....	Silicone
Head piece, protective cover, slide ring and valve cap .....	PP plastic
Housing .....	ABS plastic

#### TEMPERATURE RANGES

Storage and transport .....	-40 to 80 °C
Use .....	15 to 40 °C
Preparation: .....	Housing: up to 80 °C (Other components: up to 120 °C)