

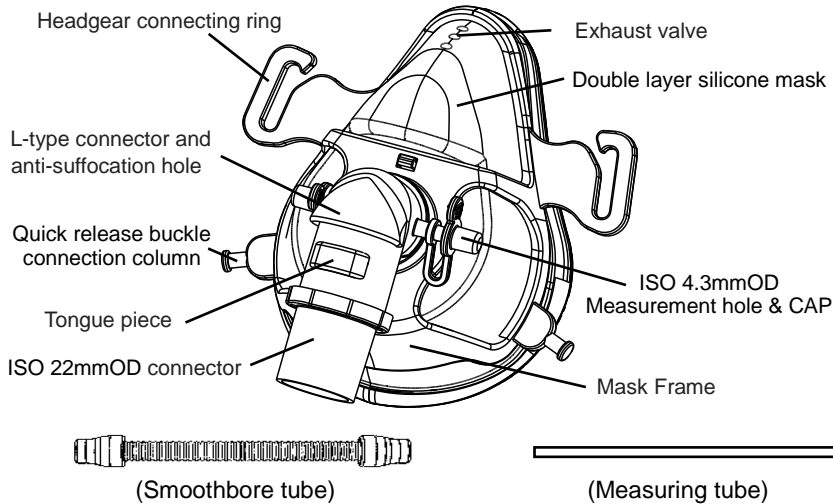


CPAP Face Mask with Smoothbore Tube (Double Layer)

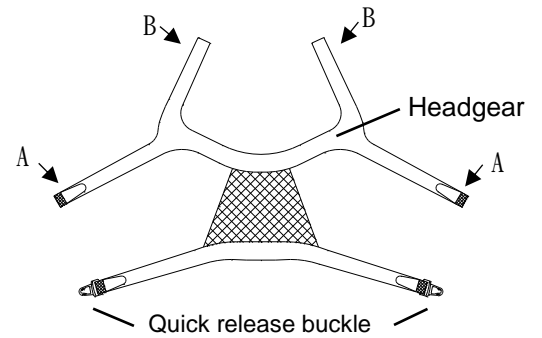
Intended use :

This product is designed for use under recommendations from your health care professional or sleep therapist. This product is used on adult patients (weight above 30kg) whom CPAP or bi-level therapy has been prescribed. The product is re-usable for single patient in medical institutions, home care and sleep treatment center.

Product Parts



Headgear Assembly Diagram



➤ Instructions for use :

- Inspect the packaging and product appearance before using. Please do not use if there are any worn or damaged parts.
- Take out the mask set and L-type connector from the box and snap the L-type connector into the mask.
- See headgear assembly diagram, hook headgear point A to the mask frame connecting rings on both sides, and then bond the two B points.
- Hold the mask over nose and mouth, and then position the headgear.
- Fast release buckle to the mask frame Quick release buckle connection column.
- Adjust the head straps and the hook and loop of the mask comfortably.
- L-type connector side ISO 4.3mmOD hole for measurement monitoring use.
- Connect the measuring tube /smoothbore tube to use for needed users.
- After wearing, connect the ventilation tube connector to the ISO 22mm OD for use.
- Quick release buckle on both sides can be easily removed, also be connected easily.

✧ Cleaning :

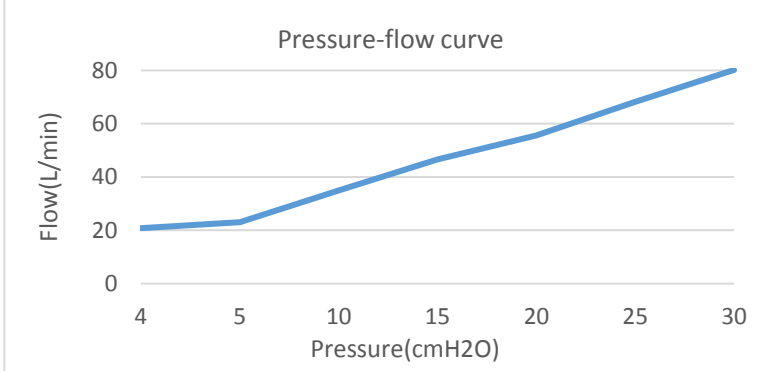
- ✧ This product is reusable for single patient.
- ✧ Follow the procedures for cleaning/sterilization in medical institutions.
- ✧ Wash the headgear with warm water and neutral detergent or soap. After rinse, air-dry the strap and keep away from direct sunlight or the dryer.
- ✧ Mask and L-type connector can be disconnected for cleaning.
- ✧ Wash with warm water and neutral detergent or soap.
- ✧ After rinse, dry in a cool place. Do not put it in the dryer.
- ✧ The uncovered can be autoclaved 25 times with the 15minute*121°C high temperature steam (pressure) sterilization method.

Warning :

- △ Multiple patients reuse will result in cross-infection of disease.
- △ Prohibit the use of if the patient has the following symptoms: vomiting, facial trauma burns, impaired myocardial function, Gastroesophageal Reflux Disease, abnormal cough reflex, unconsciousness.
- △ To be worn by professional medical staff guidance.
- △ Do not cover or block anti-asphyxiation holes and breathing valve.
- △ Do not connect worn breathing apparatus has not been started before operation.
- △ If you feel unwell, STOP using it immediately and seek medical advice immediately.
- △ Do not use alcohol · bleach or solvents containing chlorine and other components to clean the mask set.
- △ Do not put the mask set and headgear in the place of the sun exposure or high temperature preservation.
- △ Do not dismantling the silicone mask and, this action will mask a small loss of functionality, and reduce product life.
- △ Occur in a leak, slight tightening of the headgear, no improvement in the condition of leakage and then gently tighten the headgear, do not force too much cause discomfort.
- △ Dispose of it according to the local medical waste disposal regulations.

● **Specifications and materials :**

- Double Layer Mask size : S / M / L.
- L-type connector : 22mmOD meet ISO 5356-1.
- Headgear : General.
- Measuring tube : 6mmOD, 3.8mmID, 200cm.
- Smoothbore tube : 180cm, 22mmID meet ISO 5356-1.

Mask size	LARGE	MEDIUM	SMALL				
Dead space	172 mL	164 mL	152 mL				
Therapy pressure	4 to 20 cm H ₂ O						
Sound power	Average : 31.2 db(A)						
Sound pressure	Average : 22.5 db(A)						
Connector	22mmOD meet ISO 5356-1						
Measuring hole	4.3mmOD meet EN 20594-1						
Resistance	50 L/min : 0.22 cmH ₂ O, 100 L/min : 0.46 cmH ₂ O						
Exhaust Flow Rate at Given Therapy Pressure	Pressure (cmH ₂ O)	5	10	15	20	25	30
	Flow (L/min)	23	35	47	56	68	80
<div style="text-align: center;">  <p>Pressure-flow curve</p> </div>							



IFU-1641 REV 01



Obelis s.a. Boulevard Général Wahis 53 1030
Brussels, BELGIUM Tel : +(32) 2.732.59.54
Fax : +(32)2.732.60.03 E-Mail : mail@obelis.net



Manufacturer : DA CHUNG MEDICAL CO., LTD.
Address : No. 600, Sec. 1, Dong Shan Rd., Dong Shan
Township, Yilan County, Taiwan. TEL: +886 3 959 4777
Website : <http://www.dc-med.com.tw>