

SILICONE FULLFACE CPAP MASK



USER MANUAL & KULLANMA KILAVUZU



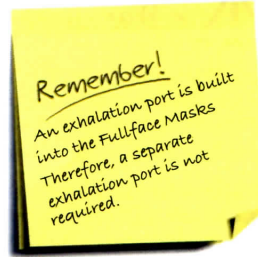
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➤ Intended Use:

Fullface Masks is designed for the use of adult patients for whom the CPAP, Bi-PAP therapy is prescribed by a healthcare professional or respiratory therapist. The Fullface Masks are used with the CPAP, Bi-PAP, Auto-PAP therapy devices, Ventilators, Anesthesia devices for single patient use in home or multi-patient use in medical centers.



➤ Before First Use:

- ✓ Read and understand the instructions.
- ✓ Remove all packaging before using the Fullface Masks.
- ✓ Hand wash mask.
- ✓ Inspect all parts of your Fullface Masks for damage; replace that are visibly deteriorated due to cracking, crazing, tears, etc.
- ✓ Clean patient's face.
- ✓ Always keep the vent holes clear and open.



✓ Do not wear this Fullface Masks unless the CPAP system is turned on and operating properly.

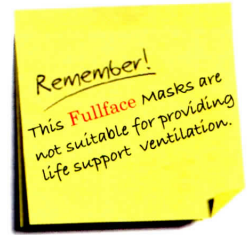


➤ Warnings & Precautions:



- ✓ Discontinue use and contact your healthcare professional, if skin redness, irritation or discomfort occurs while using nasal or full-face mask.
- ✓ Discontinue using Fullface Masks if you have any adverse reaction, and consult your physician or sleep therapist.

✓ **This mask should not be used in the presence of impaired cardiac sphincter function, excessive reflux, impaired cough reflex, and hiatal hernia and if the patient is uncooperative, obtunded, unresponsive, or unable to remove the mask by themselves.**



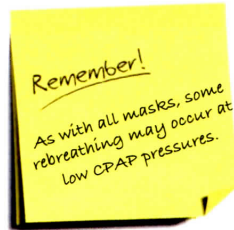
- ✓ The Fullface Masks should fit comfortably. Verify that the mask is the correct size.



- ✓ Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.



- ✓ At low PAP pressures the flow through the exhalation port may not be poured out completely and rebreathing may occur.



- ✓ If oxygen is used with device, the oxygen flow must be turned off when the device is not operating. Otherwise, Oxygen accumulated in the device enclosure will create a risk of fire.



- ✓ Do not use the masks, If you are using a pill that potentially causes vomiting.

➤ Cleaning Instructions:



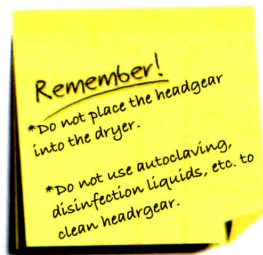
Cleaning the Mask:

- ✓ Clean the Fullface masks before first use and daily.
- ✓ The headgear does not need to be removed for daily cleaning of the Fullface masks.
- ✓ Hand wash in warm water with a mild dishwashing detergent.
- ✓ All components should be rinsed well with drinking quality water and allowed to air dry out of direct sunlight.



Cleaning the headgear:

- ✓ The headgear should be wash weekly or as needed. The headgear does not need to be removed for daily cleaning of the mask.



For Multi-patient use in the Hospital:

- For disinfection of the masks, can be use autoclaving (134°C and 3 min.)
- Disposal: Dispose of in accordance with local regulations for medical waste.



➤ Spare Parts and Numbers:

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Sp.ADStSi



Silicone Head support

Sp.ADStPC



*Polycarbonate Head support

Sp.KonwClp-N



Connector with clips

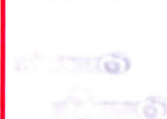
* The inlet of mask diameter is conical and 22mm according to TS EN ISO 17510-2 standard.

Sp.DrsKon-N



Elbow connector

SP.O2T-N



*Oxygen plug for Fullface mask (a pair)

Item: Sp.SiGv-FA



*Silicone body (S, M, L, XL)

Sp.HdGr



UBL/ Urethane foam/ Nylon and Lycra head gear

Item: Sp.PCGv-FA



*Polycarbonate body

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* This part can be differ by the type of mask.



➤ Step by step usage directions



Step 1. Before fitting your mask, remove the tubing connector from the mask by pressing the side clips. Connect the tubing connector to air tubing.



Step 2. Before fitting your mask, attach the hook and loop fastener on the forehead.



Step 4. Attach the headgear clips on the cheek.



Step 3. Hold the mask against your face and pull the headgear over your head.



Step 5. Fasten the headgear clips on the cheek and forehead.



Step 6. Adjust the mask to minimize air leakage as comfortable as possible.



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➤ Technical Details:

Therapy Pressure : 4 cmH₂O to 20 cm H₂O

Limited Warranty:

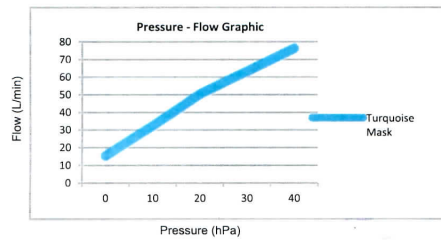
KNGMED warrants that your Fullface mask systems (including mask frame, silicone cushion, headgear and tubing) shall be from defects in material and workmanship from the date of purchase for the period of 90 days.

This warranty is only available to the initial consumer. It is not transferable.

This limited warranty does not cover:

- any damage caused as a result of improper use, abuse, modification or alternation of the product,
- repairs carried out by any service organisation that has not been expressly authorized by KNGMED to perform such repairs,
- any damage or contamination due to cigarette, pipe, cigar or other smoke. Warranty replaces all other expressed or implied warranties, including any implied warranty of merchantability or fitness for a particular purpose.

KNGMED shall not be responsible for any incidental or consequential damages claimed to have resulted from the sale, installation or use of any KNGMED product.



Remember!

Ensure that the mask is thoroughly clean and dry before storing it for any length of time. Store the mask in a dry place out of direct sunlight.



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IFU.TE 7.8.2/Rev.07.23.12.2020

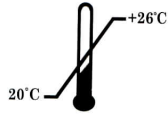
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Fullface CPAP Masks

Information & Symbols



Keep away
from sunlight.



Storage
temperature
+23 °C (±3 °C)



Warning &
Cautions



Consult instructions
for use



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LOT, REF numbers, production and expiration dates is on the box.



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