full face mask

Digitally signed by Iarovoi Petru
Date: 2021.01.28 16:13:16 EET
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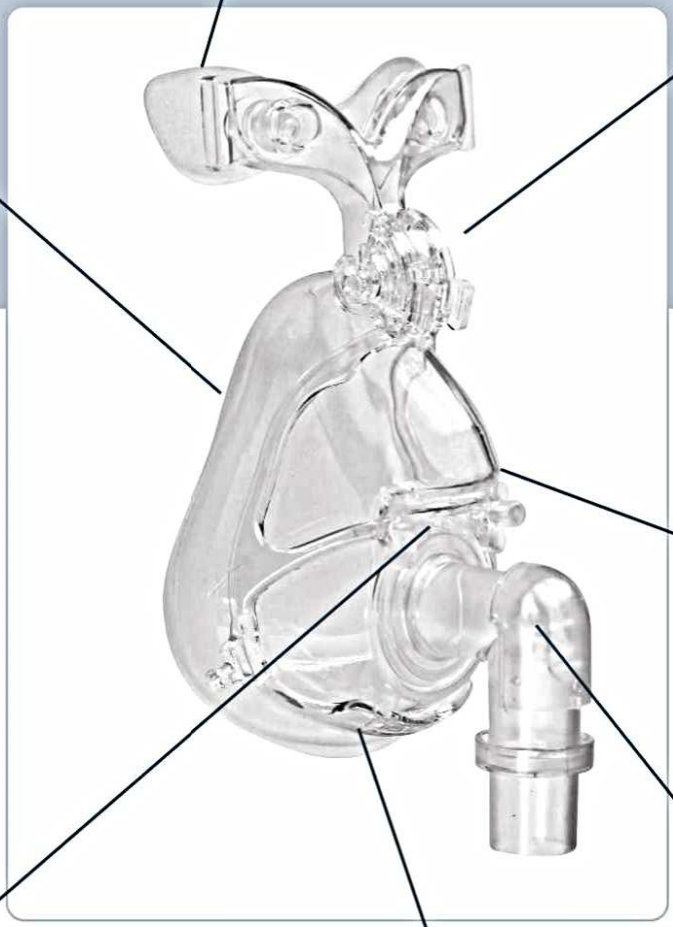
full face mask

Silicone
Head Support

Double Frame
Silicone Body

Adjustable polycarbonate
head support



Breatheable Foam
Headgear

Reinforced
Polycarbonate Frame

Oxygen and
Pressure Port

Exhalation Port

Nonvented Elbow
Connector for noninvasive
ventilator usage

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full face mask

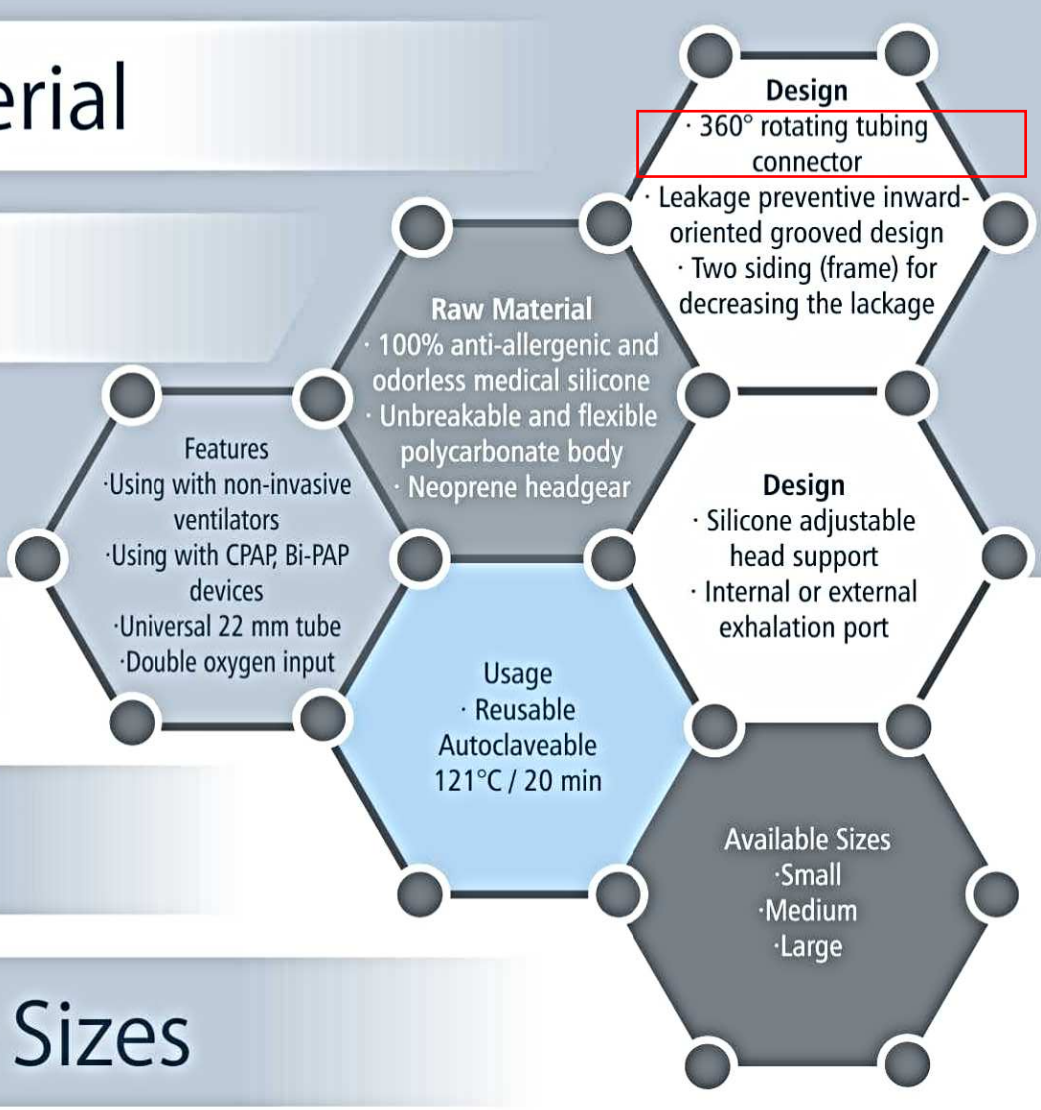
Raw Material

Features

Design

Usage

Available Sizes



Available Sizes (Small, Medium, Large)

1. SemiVent (item no:)	#7600040-S
	#7600040-M
	#7600040-L
2. NonVented (item no):	#7600041-S
	#7600041-M
	#7600041-L
3. Vented (item no):	#7600042-S
	#7600042-M
	#7600042-L

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full face mask

Cleaning the Mask at Home:

- Clean the Silicone masks and head gears before first use and daily with a mild dishwashing detergent.
- The headgear does not need to be removed for daily cleaning of the 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.
- Replace any parts of your mask that have visibly deteriorated as cracking, crazing, tears, etc.

For Multi-patient use in the Hospital:

- Use mask autoclaving (121°C and 20 min.) or disinfection liquids instructions to reprocess the mask between patients.

- Discontinue using mask if you have any adverse reaction, and consult your physician or sleep therapist.
- Clean the Full mask before first use and daily.
- Inspect all parts for damage or wear and replace any parts that have visibly deteriorated as cracking, crazing, tears, etc.

- 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.

- The Full face mask and headgear should fit comfortably and the Full mask should not dig into your skin. Verify that the Full mask and headgear are the correct size.
- Do not use the masks, If you are using a pill that potentially causes vomiting

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Full silicone fullface mask is designed for use the patients for whom prescripted the CPAP, Bi-PAP, Auto-PAP or VPAP therapy by a health care professional or respiratory therapist. Full silicone full face mask is used with the CPAP, Bi-PAP, Auto-PAP or VPAP therapy devices for single patient use in the home or multi-patient use in the hospital or a health center.

Warnings

Shelf life: 5 (five) years.

Storage temperature: - 20 °C +60°C

full face mask

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

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full face

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KNGMED	TECHNICAL DATA SHEET Ora-Nasal CPAP MASK	Doc No.	BL 7.2.2.2
		Pub. Date	04.06.2020
		Rev.	01
		Rev. Date	30.03.2023

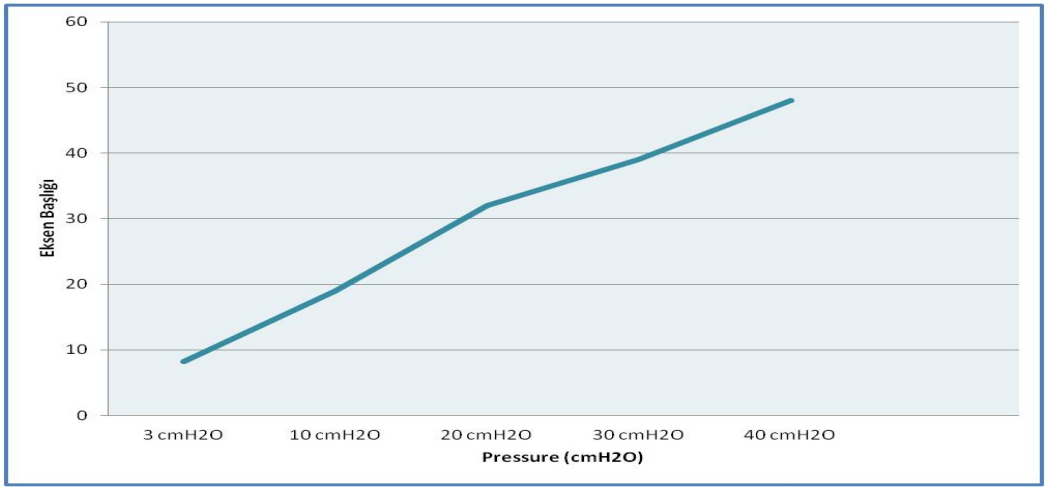
NAME OF THE MANUFACTURER	KNGMED MEDİKAL ELEKTRONİK SAĞLIK HİZMETLERİ VE KİMYASAL MADDELER İTHALAT İHRACAT ve TİCARET LİMİTED ŞİRKETİ
ADDRESS	29 EKİM MAH. 10007 SOK. NO:26/B MENEMEN/İZMİR-TURKEY
PRODUCT CODE	7600040-S, 7600040-M, 7600040-L 7600041-S, 7600041-M, 7600041-L 7600042-S, 7600042-M, 7600042-L
PRODUCT BRAND NAME	KNGMED ORA-NASAL
PRODUT GENERIC NAME	ORA-NASAL CPAP BIPAP VPAP MASK
PRODUCT COMMERCIAL NAME	ORA-NASALCPAP MASK
INTENDED USE	Masks are intended for use by people whom the CPAP, Bi-PAP therapy is prescribed by a healthcare professional or respiratory therapist. Masks are for single-patient use at home or in a hospital/healthcare setting. In order to ensure the correct use of masks at home, in the hospital/health institution environment, cooperation should be made with the doctor and healthcare personel.
PRODUCT DESCRIPTION	The Ora-Nasal Mask (222 Series) channels airflow from ventilator/Positive Air Pressure(PAP) devices non-invasively to the patients who suffer from obstructive sleep apnea (OSA) or respiratory insufficiency and respiratory failure.
STERILE / NON STERILE	NON STERILE
FEATURES OF THE PRODUCT:	TRANSPARENT BODY SOFT SILICONE, NON-ALLERGIC FACE PILLOWS HEAD SUPPORT 4 POINT HEAD GEAR CONNECTION 22MM STANDARD CONNECTOR DIAMETER OXYGEN AND PRESSURE PORT, DIAMETER Ø 4MM SUPPORT STRAP MADE OF ELASTİC MATERİAL, WİDTH 20 MM
PRODUCT PARTS	SILICONE BREATHING FACE MASK, TRANSPARENT MASK BODY CONNECTOR 90 DEGREES ELBOW HEAD STRAP
PRODUCT PICTURE	
PRODUCT COMPONENTS	MASK BODY FRAME FACE PILLOW (S-M-L SIZES) ELBOW CONNECTOR MASK CONNECTOR HEAD GEAR HEAD GEAR ATTACHES
RAW MATERIALS USED IN PRODUCTS	LIQUID SILICONE MASK PILLOW, POLYCARBONATE BODY FRAME, POLYCARBONATE MASK CONNECTOR POLYCARBONATE 90 DEG. ELBOW VELCRO/FOAM HEADGEAR

	POLYCARBONATE HEADGEAR ATTACHES
PRODUCT SIZES	SMALL MEDIUM LARGE
SHELF LIFE AND STORAGE INSTRUCTIONS	ACCORDING TO THE APPLIED STABILITY TESTS THE DEFINED SHELF LIFE IS 5 YEARS. DO NOT LEAVE UNDER DIRECT SUN LIGHT. OPENED OR HARMED PACKAGES SHALL NOT BE USED.
DURATION OF PRODUCT USAGE	THE PRODUCT REUSABLE
STERILIZATION METHOD	AUTOCLAVE STERILIZATION AT 121°C FOR 15 MINUTES.
CLEANING	HAND WASH THE MASK BEFORE FIRST USE AND DAILY. THE HEADGEAR SHOULD BE HAND WASHED WEEKLY, OR AS NEEDED. THE HEADGEAR DOES NOT NEED TO BE REMOVED FOR DAILY CLEANING OF THE MASK. RİNSE ALL PARTS WİTH CLEAR WATER. ALLOW ALL PARTS TO AIR-DRY. PERFORM A VISUAL INSPECTION.**SINGLE PATIENT USE**
DEAD SPACE MEASUREMENT	DEAD SPACE (mL) Small: 225 mL; Medium: 236 mL; Large: 245 mL
NOISE LEVEL	27dB
Classification	IIA
Applicable Standards	EN ISO 14971 EN ISO 17510-2 TS EN 10993-1 EN ISO 13485 Med. Dev. 93/42/EEC
CERTIFICATION	PRODUCT IS CE CERTIFED ACCORDING TO 93/42/EEC DIRECTIVE OF EU COMISSION. NOTIFIED BODY : DNV GL PRESAFE AS (NORWAY) CE MARKING ID : 2460 CERTIFICATE NO : 267558-2018-CE-ARE-NA-PS NOTIFIED BODY CONFIRMATION LETTER REF : C693441

Technical Data Sheet of Ora-Nasal Masks

Thearpy Pressure-Exhaust Flow Rate:

Mask	REF	Exhaust Rate Pressure				
		$3cmH_2O$	$10cmH_2O$	$20cmH_2O$	$30cmH_2O$	$40cmH_2O$
KNGMED Ora-Nasal Mask	#7600040 #7600041 #7600042	8,2	19	32	39	48

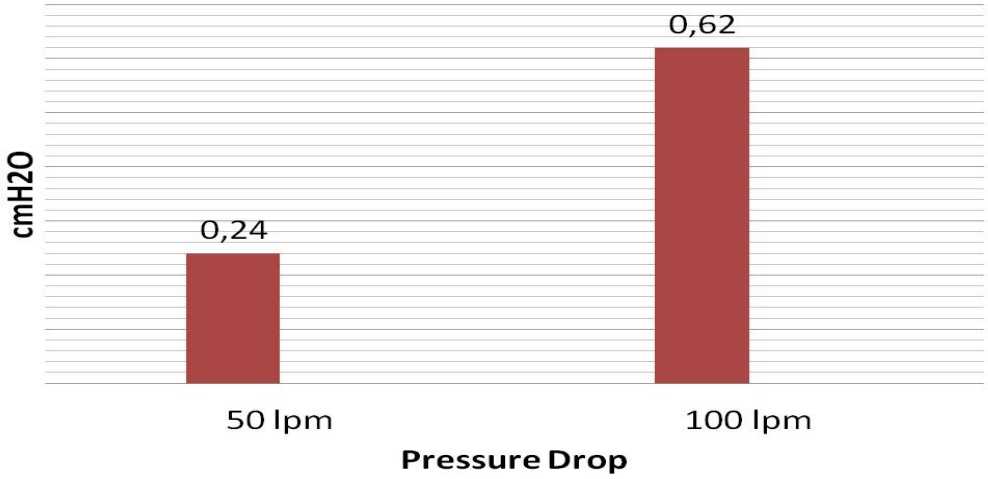


Pressure(cmH2O)

Pressure Drop:

Pressure Drop			
Mask	**REF**	**Flow Rate**	
		50L/Min	100L/Min
KNGMED Ora-Nasal Mask	#7600040 #7600041 #7600042	0.24	0.62

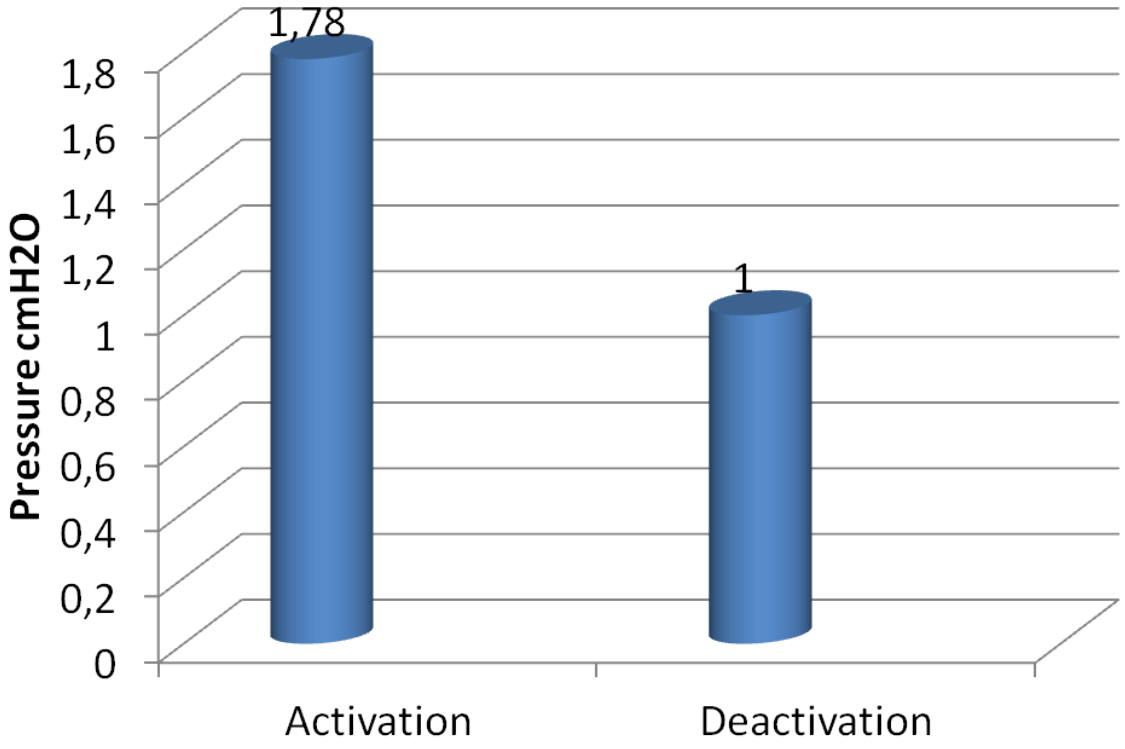
Pressure Drop Graphic



Anti Asphyxia Valve Activation/Deactivation Pressure:

AAV Pressure Activation/ Deactivation			
Mask	**REF**	Activation	Deactivation
		Pressure*	
KNGMED Ora-Nasal Mask	#7600040 #7600042	1.73	0.88

AAV Pressure Activation/ Deactivation Graphic



* Tested all pressures are below the minimum pressure rate of CPAP Therapy devices. (<3cmH2O).

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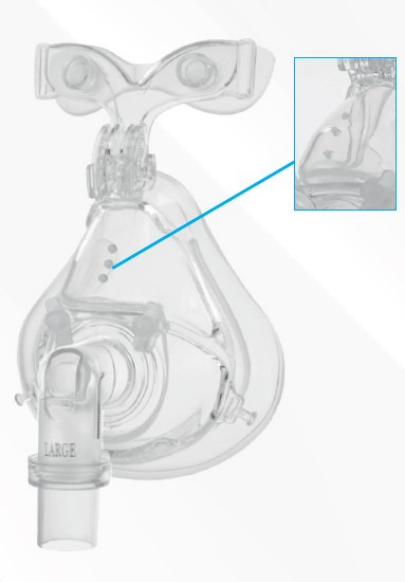
Specification of Fullface Masks

Kngmed FullFace Masks

7600041



7600042

7600040

Product Number	
Mask	**REF**
KNGMED Fullface Mask Standard Elbow	**#7600041**
KNGMED Fullface Mask EE Elbow	**#7600040**
KNGMED Fullface Mask EE Elbow with Exhalation	**#7600042**

Available Sizes	**Small, Medium, Large**
Intended Use	**FullFace Mask is intended to provide an interface for application of CPAP or bi-level or ventilation therapy to patients. This mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The standard elbow (SE) does not have any exhalation port. If the SE elbow is used, it is necessary a separated exhalation port.**

Dead Space	**Small: 125 ml, Medium: 151 ml, Large:169 ml,**
Material List	**Face plate: Polycarbonate** **Cushion: Medical Grade silicone** **Port Cap: Silicone** **Elbows: Polycarbonate** **Elbow Split: Polycarbonate** **Headgear Clips: Polycarbonate** **Headgear: UBL/Foam/Spandex**
Production	**LSR Injection**
Manufacturer	**Kngmed Medical / Made in Turkey**
Instruction for Use	**Labeling present on each mask**
Standards	**EN ISO 14971** **EN ISO 17510-2** **TS EN 10993-1** **EN ISO 13485** **Med. Dev. 93/42/EEC**

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