

# MASCHERA CON CUSCINO MONOUSO BESMED

## BESMED DISPOSABLE CUSHION MASK

### Manuale d'uso - User manual

**ATTENZIONE:** Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.  
**ATTENTION:** The operators must carefully read and completely understand the present manual before using the product.



CM-65504 (GIMA 57700)  
CM-65514 (GIMA 57701)  
CM-65524 (GIMA 57702)  
CM-65534 (GIMA 57703)  
CM-65544 (GIMA 57704)  
CM-65554 (GIMA 57705)  
CM-65564 (GIMA 57706)



Besmed Health Business Corp.  
No. 5, Lane 116, Wu-Kong 2nd Road,  
Wu-Ku District, New Taipei City 24888, Taiwan  
Made in China

CM-65810 (GIMA 57711)  
CM-65820 (GIMA 57712)  
CM-65830 (GIMA 57713)  
CM-65840 (GIMA 57714)  
CM-65850 (GIMA 57715)



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## INSTRUCTION FOR USE

### Group Name: Besmed Disposable Cushion Mask Models:

CM-65810 - ULTRA-SMT Anesthesia Mask, w/o hook, Size: 1, Infant  
 CM-65820 - ULTRA-SMT Anesthesia Mask, w/o hook, Size: 2, Pediatric  
 CM-65830 - ULTRA-SMT Anesthesia Mask, w/o hook, Size: 3, Small, Adult  
 CM-65840 - ULTRA-SMT Anesthesia Mask, w/o hook, Size: 4, Medium, Adult  
 CM-65850 - ULTRA-SMT Anesthesia Mask, w/o hook, Size: 5, Large, Adult  
 CM-65504 - Air Cushion Mask, Green Hook, Size: 0, Neonatal  
 CM-65514 - Air Cushion Mask, Pink Hook, Size: 1, Infant  
 CM-65524 - Air Cushion Mask, Red Hook, Size: 2, Child  
 CM-65534 - Air Cushion Mask, Yellow Hook, Size: 3, Adult  
 CM-65544 - Air Cushion Mask, White Hook, Size: 4, Adult  
 CM-65554 - Air Cushion Mask, Blue Hook, Size: 5, Adult  
 CM-65564 - Air Cushion Mask, Transparent Hook, Size: 6, Adult  
 CM-65364 - Disposable Air Cushion Mask, w/ hook, Size: 4, Extra Large, Adult

### Intended Use

Besmed Disposable Cushion mask is intended to channel anesthesia gases or mixture of oxygen to the patients for inhalation via patient's mouth and nose. Anesthesia masks are to be used in conjunction with anesthesia and ventilator breathing systems. It provides a seal such that positive pressure from the positive pressure source is directed into the patient's nose and mouth.

### Product Description

Besmed Disposable Cushion mask is designed for connection to breathing circuit for use as an adjunct to artificial respiration and cardiopulmonary resuscitation, automatic resuscitators, ventilators. Its a non-invasive method to either induce or maintain general anesthesia. It also used in resuscitation procedures as an effective mode of ventilation for unconscious patients. According to patient category, there are six different sizes are available from neonates to adult. Anti-slip design for easy holding. Transparent dome provides clear observation of patient's condition and anatomical shape with soft touch provides better seal and patient comfort.

### Technical Specifications of Besmed Disposable Cushion mask

|               |                                                      |                                                                           |
|---------------|------------------------------------------------------|---------------------------------------------------------------------------|
| Group name    | Disposable Cushion Mask                              |                                                                           |
| Manufacturer  | Besmed Health Business Corp.                         |                                                                           |
| Device name   | Ultra-SMT Anesthesia Mask                            | Air Cushion Mask                                                          |
| Reference No. | CM-65810, CM- 65820, CM-65830,<br>CM-65840, CM-65850 | CM-65504, CM-65514, CM- 65524, CM-<br>65534, CM-65544, CM-65554, CM-65564 |



| Patient category | Patient Group     | Anesthesia Mask                  | Air Cushion Mask                           |
|------------------|-------------------|----------------------------------|--------------------------------------------|
|                  | Neonate           | -                                | CM-65504                                   |
|                  | Infant            | CM-65810                         | CM-65514                                   |
|                  | Pediatric / Child | CM-65820                         | CM-65524                                   |
|                  | Adult             | CM-65840,<br>CM- 65850, CM-65860 | CM-65534, CM- 65544,<br>CM-65554, CM-65564 |

| Material                 | TPR, PP, PVC                                  |                                                 |                                  |
|--------------------------|-----------------------------------------------|-------------------------------------------------|----------------------------------|
|                          | Mask dome: Transparent                        |                                                 |                                  |
| Color and specifications | Patient group (size)                          | Mask cuff<br>(Anesthesia Mask)                  | Hook color<br>(Air cushion mask) |
|                          | Taglia 0                                      | Transparent                                     | Green                            |
|                          | Taglia 1                                      | Pink                                            | Pink                             |
|                          | Taglia 2                                      | Yellow                                          | Red                              |
|                          | Taglia 3                                      | Green                                           | Yellow                           |
|                          | Taglia 4                                      | Red                                             | White                            |
|                          | Taglia 5                                      | Blue                                            | Blue                             |
|                          | Taglia 6                                      | -                                               | Transparent                      |
| Component type           | Accessory                                     |                                                 |                                  |
| Device type              | Disposable                                    |                                                 |                                  |
| Patient usage type       | Single patient use                            |                                                 |                                  |
| Patient weight           | Taglia 0                                      | < 2 kg                                          |                                  |
|                          | Taglia 1                                      | 2 ~ 10 kg                                       |                                  |
|                          | Taglia 2                                      | 10 ~ 25 kg                                      |                                  |
|                          | Taglia 3                                      | 25 ~ 60 kg                                      |                                  |
|                          | Taglia 4                                      | 60 ~ 100 kg                                     |                                  |
|                          | Taglia 5                                      | >100 kg                                         |                                  |
| Specifications           | Engagement of 22 mm latching sockets to cones | Did not disconnected at $(50 \pm 5)$ N for 10 s |                                  |
|                          | Leakage from 22 mm latching sockets           | No signs of leakage at $(8 \pm 0.5)$ kPa        |                                  |
|                          | Drop procedure for 22 mm latching sockets     | No signs of damage                              |                                  |

|                       |                            |                                |        |
|-----------------------|----------------------------|--------------------------------|--------|
| Latex/DEHP content    |                            | None                           |        |
| Package               | Non-sterile package        |                                |        |
| Connection diameter   | Diameter                   | Patient group (size)           |        |
|                       | 15 mm                      | Size 0, Size 1                 |        |
|                       | 22 mm                      | Size 2, Size 3, Size 4, Size 5 |        |
| Operation temperature | 25 ± 5°C, Room Temperature |                                |        |
| Storage temperature   | -20°C ~ 60°C               |                                |        |
| Relative humidity     | Da 30 - 60% UR             |                                |        |
| Shelf life            | 5 years                    |                                |        |
| Attestation           | Test Item                  | Guideline                      | Result |
|                       | Conical connectors         | EN ISO 5356-1:2015             | PASS   |
|                       | Cytotoxicity               | EN ISO 10993-5:2009            | PASS   |
|                       | Sensitization              | EN ISO 10993-10:2023           | PASS   |
|                       | Skin Irritation            | EN ISO 10993-23:2021           | PASS   |
|                       | Usability                  | IEC 62366-1                    | PASS   |

### Intended users

Medical personnel received the training of respiratory care.

### Indication

Besmed Disposable Cushion mask is designed to ensure a tight seal around the patient nose and mouth to deliver oxygen gases to the patient. Besmed Disposable Cushion masks are transparent to facilitate visual inspection of breathing condition of the patient. Signs of inadequate ventilation can be identified early such as reduced chest movement, absent or quiet breathing sounds, patient cyanosis, audible gas leaks. Also, late signs of inadequate ventilation include haemodynamic consequences of hypoxaemia or hypercarbia.

### Instruction for use

Check for clean airflow passage prior to use

Connect to breathing circuit or resuscitation with appropriate fitting.

Set the gas to the proper flow and check for gas flow through the device

Position the elastic strap behind the neck.

Make sure all connections are compatible and fit firmly.

Gently pull the ends of the strap until the mask is secure.

### Contraindications

Besmed Disposable Cushion mask is possibly not suitable for the use to the patients with recent facial, oral, skull surgery, or trauma, and patients who have claustrophobia, vomiting, or active GI bleeding. Inability to maintain an adequate seal between the mask and the patient's face, which may result in inadequate oxygenation.

### Risks/Side Effects

Inappropriate size of mask and strap tension may cause discomfort.

Mask related complication includes claustrophobia, ulceration, facial rash, or itching.

Cramped hands and tired muscles and limits the user's ability to perform other tasks especially in obese and patients with a larger head.

### Warning/ Caution

Read this instruction before use.

Do not use if the package is open or damage or contaminated.

Any skin redness, itching or any abnormal situation happens, stop using this mask.

Single use devise only. Do not re-use.

Do not soak, wash, rinse or sterilize the product.

Any serious incident that has occurred in relation to the device should be reported to Besmed or its Authorized Representative/competent authorities and the Regulatory Authorities of the country.

### Disposal

Dispose of in accordance with local regulations.

### Legend of symbols

|                                                                                    |                                                   |                                                                                     |                                                        |
|------------------------------------------------------------------------------------|---------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------|
|    | Medical Device compliant with Directive 93/42/EEC |    | Product code                                           |
|    | Imported by                                       |    | Manufacturer                                           |
|    | Please read instructions carefully                |    | Date of manufacture                                    |
|    | Lot number                                        |    | Disposable device, do not re-use                       |
|   | Expiration date<br>(see box / package)            |   | Keep in a cool, dry place                              |
|  | Keep away from sunlight                           |  | Authorized representative<br>in the European community |

|                                                                                  |                                    |                                                                                   |                                  |
|----------------------------------------------------------------------------------|------------------------------------|-----------------------------------------------------------------------------------|----------------------------------|
|  | Not made with natural rubber latex |  | No-DEHP formulation              |
|  | Temperature limit                  |  | Non-sterile                      |
|  | Medical Device                     |  | Disposable device, do not re-use |

**GIMA WARRANTY TERMS**

The Gima 12-month standard B2B warranty applies.