

PALLONE RIANIMATORE MONOUSO
DISPOSABLE RESUSCITATOR BAG
INSUFFLATEUR DE REANIMATION MONOUSAGE
BALON DE REANIMACION MONOUSO
REANIMADOR DESCARTÁVEL
EINWEG-BEATMUNGSBEUTEL
ΑΝΑΖΩΟΓΟΝΗΤΗΣ ΜΙΑΣ ΧΡΗΣΗΣ
RESUSCITATOR FÖR ENGÅNGSBRUK
RESUSCITATOR DE UNICĂ FOLOSINȚĂ
ELDOBHATÓ ÚJRAÉLESZTŐ
РЕАНИМАТОР ЗА ЕДНОКРАТНА УПОТРЕБА

جهاز إنعاش يمكن التخلص منه

Manuale d'uso - User manual - Manuel de l'utilisateur - Guia de uso - Guia para utilização - - Betriebs und wartungs anweisungen - Εγχειρίδιο χρήσης και συντήρησης - Instruktioner för användning och underhåll - Manual de utilizare și întreținere - Kezelési és karbantartási útmutató - Инструкции за употреба и поддръжка

- تعليمات الاستخدام والصيانة

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.

AVIS: Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.

ATENCIÓN: Los operadores deben leer y entender completamente este manual antes de utilizar el producto.

ATENÇÃO: Os operadores devem ler e entender completamente este manual antes de usar o produto.

ACHTUNG: Die Bediener müssen das vorliegende Handbuch vor der Verwendung des Produkts sorgfältig lesen und vollständig verstehen.

ΠΡΟΣΟΧΗ: Οι χειριστές πρέπει να διαβάσουν προσεκτικά και πλήρως κατανόηστε το παρόν εγχειρίδιο πριν χρησιμοποιήσετε το προϊόν.

OBSERVERA: Operatörerna måste noggrant läsa och fullständigt förstå den här bruksanvisningen innan du använder produkten.

ATENȚIE: Operatorii trebuie să citească cu atenție și să înțeleagă prezenta manual înainte de a utiliza produsul.

FIGYELEM: A kezelőknek figyelmesen és teljesen el kell olvasniuk a termék használatát előtti olvasni a jelen kézikönyvet.

ВНИМАНИЕ: Операторите трябва да прочетат внимателно и изцяло разберете настоящото ръководство, преди да използвате продукта.

تنبيه: يجب على المشغلين القراءة بعناية وبشكل كامل فهم الدليل الحالي قبل استخدام المنتج.

REF RE-22415 (GIMA 34277) - RE-22515 (GIMA 34248) - RE-22615 (GIMA 34249)



Besmed Health Business Corp.
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New Taipei City 24888, Taiwan
Made in Taiwan



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INSTRUCTION FOR USE

PRODUCT NAME:

Besmed Disposable Resuscitator Set Model:

- RE-22415 - Single Use Resuscitator with 60 cm H₂O POP-OFF, 1600 ml, Adult
- RE-22515 - Single Use Resuscitator with 40 cmH₂O POP-OFF, 500 ml, Child
- RE-22615 - Single Use Resuscitator with 40 cmH₂O POP-OFF, 280 ml, Infant

PRODUCT DESCRIPTION

Besmed Disposable resuscitator set are manually operated and meant as an adjunct to artificial respiration and cardiopulmonary resuscitation. The resuscitator set can be used to ventilate apnoeic patients, and augment ventilation in spontaneously breathing patients undergoing oxygen therapy. The resuscitator set come in different sizes and are designed according to different compression capacities for infants, children, and adult patients.

Technical Specification:

Product Name	Disposable Resuscitator Set		
Manufacturer	Besmed Health Business Corp.		
Representative Photo			
Device type	Disposable		
Patient Usage type	Single use		
Patient group	Adult	Child	Infant
Accessories	Manometer, mask, reservoir, oxygen tube, PEEP valve and connector		
Pop-Off	W/ Pop-Off		
Deliverable pressure	60 cmH ₂ O	40 cmH ₂ O	
Bag volume	1600 ml	500 ml	280 ml
Reservoir volume	2500 ml		1000 ml
Suitable patient body weight	>40 kg	11 - 40 kg	5 – 10 kg

Stroke volume range; One hand	770 ml	300 ml	160 ml
Stroke volume range; Two hands	900 ml	350 ml	190 ml
Minimum delivered volume	>600 ml	>150 ml	
Maximum cycle rate	20 breaths/min		40 breaths/min
Oxygen concentration	With reservoir: > 85% - Without reservoir: > 35%		
Dead Space	< 5.5 ml		

Material	Resuscitator body:	PVC
	Mask:	PP + TPR
	Reservoir bag:	PVC
	Oxygen tubing:	PVC
	non-rebreathing valve:	PC
	Oxygen reservoir / gas intake socket:	PC
	Duckbill / gas intake / oxygen intake valve:	PVC
	Pop-off valve:	PC, PVC, stainless steel
	Manometer:	Silicone
	PEEP valve:	PC, Silicone, Stainless Steel (for spring)
	Connector:	Silicone
Package		Non-sterile package
Operation temperature		25±5 °C, Room Temperature
Storage temperature		-40 to 60°C, 30-60% RH
Shelf Life		5 years
Specifications	Patient connection port and face mask connectors	Connection stayed intact
	Dismantling and reassembling	Proper ventilation occurred after dismantling and reassembling the device
	Patient valve function after contamination with vomitus	There is no change in the performance of the device after contamination with vomitus.

Specifications	Drop test	No function variation in the device after dropping	
	Immersion in water	There is no change in the performance of the device after immersion in water.	
	Expiratory resistance	2.07 cmH ₂ O	
	Inspiratory resistance	3.03 cmH ₂ O	
	Dead space and rebreathing	4.78 ml	
	Minimum delivered volume	629.23 ml	
	Pressure limitation	There is no performance deviation.	
		The resuscitator without and with reservoir bag is more than 35 % and 85 %	
	Patient valve malfunction	1.07 cmH ₂ O	
Attestation	Test item	Guideline	Result
	Cytotoxicity	ISO 10993-5	PASS
	Skin irritation test	ISO 10993-10	PASS
	Sensitization	ISO 10993-10	PASS
	Emissions of particulate matter	ISO 18562-2	PASS
	Emissions of VOCs	ISO 18562-3	PASS

INTENDED USER:

Medical personnel received the training of respiratory care.

INTENDED USE:

Besmed Disposable resuscitator set are designed for use as an adjunct to artificial respiration and cardiopulmonary resuscitation. The resuscitator can be used to ventilate the apneic patients and to augment ventilation and oxygen delivery to the spontaneously breathing patient.

DIRECTION FOR USE:

1. Prior to use, read the Instructions, cautions, and warnings.
2. Connect the oxygen supply tubing to a regulated oxygen source.

3. Adjust the gas flow so that the reservoir expands completely during inspiration and nearly collapses as the squeeze bag refills during exhalation.
4. Prior to connection to a patient, check the function of the resuscitator, preferably attached to a test lung, by observing that the intake, reservoir, and patient valves are allowing all phases of the ventilator cycle to occur.
5. As required, connect the resuscitation mask to the patient connector.
6. Follow accepted Advance Cardiac Life Support (ACLS) or Institution-approved for ventilation.
7. Compress the squeeze bag to deliver a breath. Observe the chest rise to confirm inspiration.
8. Release pressure on the squeeze bag to allow exhalation. Observe the chest fall to confirm exhalation.
9. During ventilation, check for:
 - Signs of cyanosis
 - Adequacy of ventilation
 - Airway pressure
 - Proper function of all valves
 - Proper function of reservoir and oxygen tubing
10. Should the non-rebreathing valve become contaminated with vomiting, blood, or secretion during ventilation, disconnect the device from the patient and clear the non-rebreathing valve as follows:
 - Rapidly compress the squeeze bag to deliver several sharp breaths through the non-rebreathing valve to expel the contaminate. If the contaminate does not clear.
 - Rinse the non-rebreathing valve in water and then rapidly compress the squeeze bag to deliver several sharp breaths through the non-rebreathing valve to expel the contaminate. If the contamination still does not clear, discard the resuscitator.



Warning:

1. Do not use the resuscitator set in toxic atmospheres.
2. Do not administer supplemental oxygen in the presence of open flames.
3. This device is intended for use by qualified medical and emergency personnel trained in pulmonary ventilation and advanced cardiac life support techniques.
4. Proficiency in the assembly, disassembly, and use of this device should be demonstrated before use on a patient.
5. Always monitor airway pressure with a manometer when ventilating a patient.
6. Only qualified personnel trained in the use of Positive End Expiratory Pressure (PEEP) should level the function of the resuscitator before using it on a patient.
7. If overriding the pressure relief valve, great caution must be taken not to allow the pressure in the patient's airways to become too high.

Caution:

1. If overriding the pressure relief valve, great caution must be taken not to allow the pressure in the patient's airways to become too high.
2. Do not attempt to disassemble the pressure relief valve assembly. Disassembly will damage the component.
3. Dispose of in accordance with local regulations procedures or hospital protocol

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.

نقطة

LEGEND OF SYMBOLS

	IT - Dispositivo medico conforme alla Direttiva 93/42/CEE GB - Medical Device complies with Directive 93/42/EEC FR - Dispositif médical conforme à la directive 93/42 / CEE ES - Dispositivo médico segun a la Directiva 93/42 / CEE PT - Dispositivo médico em conformidade com a Diretiva 93/42/CEE DE - Medizinprodukt gemäß Richtlinie 93/42/CEE C GR - Ιατρική συσκευή σύμφωνα με την οδηγία 93/42 / CEE HU - Dispozitiv medical realizat în conformitate cu prevederile Directivei 93/42/CEE RO - Dispozitiv medical realizat în conformitate cu prevederile Directivei 93/42/CEE SE - Den medicintekniska produkten överensstämmer med Direktiv 93/42/EEG BG - Медицинско устройство, отговарящо на Директива 93/42/EEC SA - جهاز طبي يتوافق مع التوجيه CEE/93/42		IT - Rappresentante autorizzato nella Comunità europea GB - Authorized representative in the European community FR - Représentant autorisé dans la Communauté européenne ES - Representante autorizado en la Comunidad Europea PT - Representante autorizado na União Europeia DE - Autorisierter Vertreter in der EG GR - Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Ένωση HU - Meghatalmazott képviselő az Európai Közösségben RO - Reprezentant autorizat pe teritoriul Comunității Europene SE - Auktoriserad representant i Europeiska gemenskapen BG - Оторизиран представител в Европейската общност SA - ممثل معتمد في الاتحاد الأوروبي
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	IT - Importato da GB - Imported by FR - Importé par ES - Importado por PT - Importado por GR - Εισαγωγή από DE - Eingeführt von HU - Importáltá RO - Importat de SE - Importerad av BG - Внесено от SA - مستورد عن طريق		IT - Fabbricante GB - Manufacturer FR - Fabricant ES - Fabricante PT - Fabricante DE - Hersteller GR - Παραγωγός HU - Gyártó RO - Producător SE - Tillverkare BG - Производител SA - الشركة المصنعة
	IT - Leggere le istruzioni per l'uso GB - Consult instructions for use FR - Consulter les instructions d'utilisation ES - Consultar las instrucciones de uso PT - Consulte as instruções de uso DE - Gebrauchsanweisung beachten GR - Διαβάστε προσεκτικά τις οδηγίες χρήσης SE - Läs bruksanvisningen RO - Citiți instrucțiunile de utilizare HU - Olvassa el a használati utasításokat BG - Прочетете инструкциите за употреба SA - اقرأ بدقة وحرص تعليمات الاستخدام		IT - Non utilizzare se l'imballaggio è danneggiato GB - Don't use if package is damaged FR - Ne pas utiliser si le colis est endommagé ES - No usar si el paquete está dañado PT - Não use se o pacote estiver danificado DE - Nicht verwenden, wenn das Paket beschädigt ist GR - Μην το χρησιμοποιείτε αν η συσκευασία είναι κατεστραμμένη SE - Använd inte en förpackning som är skadad RO - A nu se utilizeza dacă ambalajul este deteriorat HU - Ne használja, ha a csomagolás sérült BG - Да не се използва, ако опаковката е с напушена цялост SA - لا تستخدم في حالة تلف الحزمة
	IT - Numero di lotto GB - Lot number FR - Numéro de lot ES - Número de lote PT - Número de lote DE - Chargennummer GR - Αριθμός παρτίδας HU - Tételszám RO - Număr de lot SE - Satsnummer BG - Номер SA - رقم الدفعة		IT - Codice prodotto GB - Product code FR - Code produit ES - Código producto PT - Código produto DE - Erzeugniscode GR - Κωδικός προϊόντος SE - Produktkod RO - Cod produs HU - Termékkód BG - Код на продукта SA - كود المنتج
	IT - Data di scadenza GB - Expiration date FR - Date d'échéance ES - Fecha de caducidad PT - Data de validade DE - Ablaufdatum HU - Lejárati dátum RO - Valabil până la data de SE - Utgångsdatum BG - Срок на годност SA - تاريخ انتهاء الصلاحية		IT - Data di fabbricazione GB - Date of manufacture FR - Date de fabrication ES - Fecha de fabricación PT - Data de fabrico DE - Herstellungsdatum GR - Ημερομηνία παραγωγής SE - Tillverkningsdatum RO - Data fabricației HU - Gyártás dátuma BG - Дата на производствоукупав SA - تاريخ التصنيع
	IT - Conservare al riparo dalla luce solare GB - Keep away from sunlight FR - À conserver à l'abri de la lumière du soleil ES - Conservar al amparo de la luz solar PT - Guardar ao abrigo da luz solar GR - Κρατήστε το μακριά από ηλιακή ακτινοβολία SE - Skyddas från solljus RO - A se păstra ferit de razele soarelui HU - Napfénytől védve tárolandó BG - Да се съхранява на място, защитено от слънчева светлина SA - يحفظ بعيداً عن ضوء الشمس		IT - Conservare in luogo fresco ed asciutto GB - Keep in a cool, dry place FR - À conserver dans un endroit frais et sec ES - Conservar en un lugar fresco y seco PT - Armazenar em local fresco e seco GR - Διατηρείται σε δροσερό και στεγνό περιβάλλον SE - Förvara på svalt och torrt ställe RO - A se păstra într-un loc răcoros și uscat HU - Száraz, hűvös helyen tárolandó BG - Да се съхранява на хладно и сухо място SA - يحفظ في مكان بارد وجاف
	IT - Non prodotto con lattice di gomma naturale GB - Not made with natural rubber latex FR - Non fabriqué avec du latex de caoutchouc naturel ES - No contiene látex de caucho natural PT - Sem látex de borracha natural DE - Ohne Naturkautschuk hergestellt GR - Χωρίς λάτεξ HU - Latex-mentes RO - Nu conține latex SE - Latexfri BG - Не съдържа латекс SA - خالية من اللاتكس		IT - Non contiene ftalato DEHP GB - No-DEHP formulation FR - Ne contient pas de DEHP ES - No contiene ftalato DEHP PT - Não contém ftalato DEHP DE - Frei von DEHP GR - Δεν περιέχει φθαλικό DEHP SE - Innehåller inte DEHP-ftalato RO - Conținut sau prezentă de ftalați HU - Ftalát-mentes BG - Не съдържа фталати SA - بدون الفثالات
	IT - Limite di temperatura GB - Temperature limit FR - Limite de température ES - Limite de temperatur PT - Limite de temperatura DE - Temperaturgrenzwert GR - Διατηρείται μεταξύ -10 και 49°C HU - és °C között tárolandó PL - Przechowuj pomiędzy °C RO - A se păstra la temperaturi cuprinse între °C SE - Lagras mellan och °C BG - Да се съхранява между и °C SA - يحفظ بين ودرجة مئوية		IT - Non sterile GB - Non-sterile FR - Pas stérile ES - No estéril PT - Não estéril DE - nicht steril GR - όχι αποστειρωμένο PL - Nie sterylne CZ - Nesterilní SE - Ej steril FI - Ei-steriili SI - Ni sterilo SK - Nesterilné RO - Nesteril NL - Niet steril HR - Nije sterilno HU - Nem steril DK - Ikke-steril BG - Нестерилен LT - Ne sterilus LV - Nav sterilis EE - Mittesteriliine SA - ليس معقم
	IT - Dispositivo medico GB - Medical Device FR - Dispositif médical ES - Producto sanitario PT - Dispositivo médico DE - Medizinprodukt GR - Ιατροτεχνολογικό προϊόν PL - Wyrób medyczny CZ - Zdravotnický prostředek SE - Medicinteknisk produkt FI - Lääkinnällinen laite SI - Medicinski pripomoček SK - Zdravotnícka pomôcka RO - Dispozitiv medical NL - Medisch hulpmiddel HR - Medicinski uređaj HU - Orvostechnikai eszköz DK - Medicinsk udstyr BG - Медицинско изделие LT - Medicininis prietaisai LV - Mediciniskā ierīce EE - Meditsiiniline seade SA - جهاز طبي		IT - Dispositivo monouso, non riutilizzare GB - Disposable device, do not re-use FR - Dispositif pour usage unique, ne pas réutiliser ES - Dispositivo monouso, no reutilizable PT - Dispositivo descartável, não reutilizar DE - Für einmaligen Gebrauch, nicht wiederverwenden GR - Προϊόν μιας χρήσεως. Μην το χρησιμοποιείτε εκ νέου SE - Engångsanordning, får ej återanvändas RO - Dispozitiv de unică folosință, a nu se refolosi HU - Eldobható eszköz, ne használja újra BG - Изделие за еднократна употреба, да не се използва повторно SA - أداة أحادية الاستخدام، لا تستخدم من جديد