

PALLONE RIANIMATORE MONOUSO
DISPOSABLE RESUSCITATOR BAG
INSUFFLATEUR DE REANIMATION MONOUSAGE
BALON DE REANIMACION MONOUSO
REANIMADOR DESCARTÁVEL
EINWEG-BEATMUNGSBEUTEL
ΑΝΑΖΩΓΟΝΗΤΗΣ ΜΙΑΣ ΧΡΗΣΗΣ
RESUSCITATOR FÖR ENGÅNGSBRUK
RESUSCITATOR DE UNICĂ FOLOSINȚĂ
ELDOVHATÓ ÚJRAÉLESZTŐ
ΡΕΑΝΙΜΑΤΟΡ ЗА ЕДНОКΡΑΤΗΝΑ УΠΟΤΡΕΒΑ

جهاز إنعاش يمكن التخلص منه

Manuale d'uso - User manual - Manuel de l'utilisateur - Guía de uso - Guia para utilização - - Betriebs und wartungs anweisungen - Εγχειρίδιο χρήσης και συντηρησης - 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 tienen que 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 κατανοήστε 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 prezentul manual înainte de a utiliza produsul.

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

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

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

REF

GIMA 34277 RE-22415

GIMA 34248 RE-22515

GIMA 34249 RE-22615



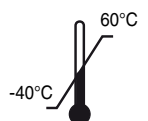
Besmed Health Business Corp.
No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District,
New Taipei City 24888, Taiwan
Made in Taiwan



Casus Europe B.V.
Lange Viestraat 2b, 3511 BK Utrecht
The Netherlands



Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com



ENGLISH**Instruction for Use****Trade Name:**

Disposable Resuscitator set





1 Product Description

- Manual Resuscitator sets (Disposable) are manually operated and meant as an adjunct to artificial respiration and cardiopulmonary resuscitation. Manual Resuscitator sets (Disposable) is meant for artificial inspiration and expiration by simple manual compression. It is composed of 4 components: A. Non-rebreathing (duckbill) valve, B. Resuscitator bag, C. Reservoir valve, and D. Oxygen reservoir, the last two components being optional and to be removed if additional oxygen is not supplied.
- When compressing down the resuscitator, a positive pressure is created, which forces air into a patient's respiratory tract, causing inspiration. During this time, the intake valve is closed,

2. Intended Purpose

Manual Resuscitator sets (Disposable) 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.

2.1 Indications

Device Models	Reference number	Product Description	
	RE-22415	Single Use Resuscitator 1600 ml W/O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Adult	
	RE-22515	Single Use Resuscitator 500 ml W/ 40 cmH2O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Child	
	RE-22615	Single Use Resuscitator 280 ml W/ 40 cmH2O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Infant Single Use Resuscitator with Handstrap 280 ml W/ 40	
Product Group Name	Manual Resuscitator Sets		
Manufacturer	Health Business Corp.		
Device Name	Disposable Resuscitator Set		
Representative Photo			
Device type	Disposable		
Patient Usage type	Usò per un singolo paziente		
Accessories	Manometer, Mask, Oxygen reservoir, oxygen tube, Disposable PEEP valve, Intake vale, and connector		
Connector	15F/22mm		
Oxygen reservoir volume	2.5L		0.6L
Patient group	Adult	Child	InfantBambino (1-3 anni)
Resuscitator bag volume	1600 mL	500ml	280ml
POP-OFF	W/ POP-OFF		
Deliverable pressure	60 cmH ₂ O	40 cmH ₂ O	
Reservoir volume	2500ml		1000ml
Suitable patient body weight	>40 kg	11 - 40 kg	<10 kg
Stroke volume range; One hand	770ml	300ml	160ml
Stroke volume range; Two hands	900ml	350ml	190ml
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	
	Resuscitator body:	Natural rubber	
	Mask:	PVC, and PP + TPR	
	Reservoir bag:	PVC	
	Oxygen tubing:	PVC	
	Disposable Pressure Manometer L Type:	PC, TPR	
	Non-rebreathing valve:	PC	
Oxygen reservoir:	PE		

	Duckbill / gas intake valve:	PVC	
	Pop-off valve:	PC, PVC, stainless steel	
	PEEP valve:	PC, Silicone, (Stainless Steel for spring)	
Package	Non-sterile package		
Latex/ DEHP content	No		
Operation temperature	25±5 °C, Room Temperature		
Storage temperature	da -40°C to 60°C		
Relative humidity	Da 30 - 70% UR		
Shelf Life	5 years		
Specification	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	here is no change in the performance of the device after contamination with vomitus	
	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 cmH2O	
	Inspiratory resistance	3,03 cmH2O	
	Dead space and rebreathing	4,78ml	
	Minimum delivered volume	629,23ml	
	Pressure limitation	There is no performance deviation.	
	Supplementary and delivered oxygen concentration	The resuscitator without and with reservoir bag is more than 35 % and 85 %	
	Patient valve malfunction	1,07 cmH2O	
Attestation	Test item	Guideline	Result
	Functional test	EN ISO 10651-4:2023	PASS
	Conical connector	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
	Emissions of particulate matter	EN ISO 18562-2	PASS
	Emissions of VOCs	EN ISO 18562-3	PASS
Usability	IEC 62366-1	PASS	

2.2 Indications

Manual Resuscitator sets (Disposable) is a device intended to use as an adjunct to artificial respiration and cardiopulmonary resuscitation for emergent patient ventilation.

2.3 Intended User:

Medical personnel received the training of respiratory care.

2.4 Contraindications

This product does not apply to patients who do not suffer from illness or rescue need of emergent respiratory support.

2.5 Risk/Side Effects

An inappropriate inspiratory gas pressure can cause hazardous situation too. A high pressure may put too much stress to skin which can harm alveoli.

The amount of air/oxygen delivered should be very well controlled. The air entering the patient also has access to the stomach via the esophagus, which can inflate if the resuscitator is squeezed too hard (causing air flow that is too rapid for the lungs to absorb alone) or too much (causing excess air to divert to the stomach). This can lead to vomiting and subsequent aspiration of stomach contents into the lungs.

Holding the mask properly on the patient's face is very important while providing ventilation via resuscitators as pressure needed to force-inflate the lungs would be released to the environment. This is difficult when a single user attempts to maintain a face mask seal with one hand while squeezing the bag with other.

3. Instruction for Use:

1. Prior to use, read the Instructions, cautions, and warnings.
2. Check all the connection parts of the product, and tighten all the connections. Avoid leakage or loss when the product is used.
3. Choose the right size of the mask as per patient's face.
4. Connect the oxygen supply tubing to a regulated oxygen source.
5. Adjust the gas flow so that the reservoir expands completely during inspiration and nearly collapses as the squeeze bag refills during exhalation.
6. 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.
7. As required, connect the resuscitation mask to the patient connector.
8. Follow accepted Advance Cardiac Life Support (ACLS) or Institution-approved for ventilation.
9. Compress the squeeze bag to deliver a breath. Observe the chest rise to confirm inspiration.

10. Release pressure on the squeeze bag to allow exhalation. Observe the chest fall to confirm exhalation.
11. During ventilation, check for:
 - Signs of cyanosis
 - Adequacy of ventilation
 - Airway pressure
 - Proper function of all valves
 - Proper function of reservoir and oxygen tubing
12. 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 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 contaminate. If the contamination still does not clear, discard the resuscitator.
13. When the product working, make sure the patient is closely monitored.

4. Warning/ Caution:

1. Read this instruction manual before use.
2. Do not use the resuscitator set in toxic atmospheres.
3. Do not use if the package is open or damage or contaminated.
4. This product is strictly restricted to single patient use, do not attempt to sterilize.
5. Do not administer supplemental oxygen in the presence of open flames.
6. This device is intended for use by qualified medical and emergency personnel trained in pulmonary ventilation and advanced cardiac life support techniques.
7. Ensure that the mask fits securely and set to prevent air leaks.
8. Proficiency in the assembly, disassembly, and use of this device should be demonstrated before use on a patient.
9. Always monitor airway pressure with a manometer when ventilating a patient.
10. 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.
11. 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.
12. Do not attempt to disassemble the pressure relief valve assembly. Disassembly will damage the component.
13. Any serious incident that has occurred in relation to the device should be reported to or its Authorized Representative/competent authorities and the Regulatory Authorities of the country.









5. Disposal:






Dispose of in accordance with local regulations procedures or hospital protocol.

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies

Legend of symbols

	<p>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 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/ЕЕС AR - 93/42/CEE جهاز طبي يتوافق مع التوجيه</p>		<p>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 AR - ممثل معتمد في الاتحاد الأوروبي</p>
	<p>IT - Importato da GB - Imported by FR - Importé par ES - Importado por PT - Importado por GR - Εισαγωγή από DE - Eingeführt von HU - Importálta RO - Importat de SE - Importerad av BG - Внесено от AR - مستورد عن طريق</p>		<p>IT - Fabbricante GB - Manufacturer FR - Fabricant ES - Fabricante PT - Fabricante DE - Hersteller GR - Παραγωγός HU - Gyártó RO - Producător SE - Tillverkare BG - Производител AR - الشركة المصنعة</p>
	<p>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 AR - اقرأ بدقة وحرص تعليمات الاستخدام</p>		<p>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 utiliza dacă ambalajul este deteriorat HU - Ne használja, ha a csomagolás sérült BG - Да не се използва ,ако опаковката е с нарушена цялост AR - لا تستخدم في حالة تلف الحزمة</p>
	<p>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 AR - رقم الدفعة</p>		<p>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 AR - كود المنتج</p>
	<p>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 AR - تاريخ انتهاء الصلاحية</p>		<p>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 производството AR - تاريخ التصنيع</p>
	<p>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 AR - يحفظ بعيداً عن ضوء الشمس</p>		<p>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 AR - يحفظ في مكان بارد وجاف</p>
	<p>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 -</p>		<p>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-ftalat RO - Conținut sau prezență de ftalați HU - Ftalátmentes BG - Не съдържа фталати</p>

	Χωρίς λάτεξ HU - Latex-mentes RO - Nu conține latex SE - Latexfri BG - Не съдържа латекс AR خالية من اللاتكس		AR بدون الفتالات
	IT - Limite di temperatura GB - Temperature limit FR - Limite de température ES - Límite de temperatur PT - Limite de temperatura DE - Temperaturgrenzwert GR - Διατηρείται μεταξύ -10 και 49°C HU - és °C között tartandó RO - A se păstra la temperaturi cuprinse între și °C SE - Lagras mellan och °C BG - Да се съхранява между и °C AR يحفظ بين و درجة مئوية		IT - Non sterile GB - Non-sterile FR - Pas stérile ES - No estéril PT - Não estéril DE - nicht steril GR - όχι αποστειρωμένο SE - Ej steril RO - Nesteril HU - Nem steril BG - Нестерилен AR ليس معقم
	IT - Dispositivo medico GB - Medical Device FR - Dispositif médical ES - Producto sanitario PT - Dispositivo médico DE - Medizinprodukt GR - Ιατροτεχνολογικό προϊόν SE - Medicinteknisk produkt RO - Dispozitiv medical HU - Orvostechnikai eszköz DK - Medicinsk udstyr BG - Медицинско изделие AR 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 χρησιμοποιείται 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” AR أداة أحادية الاستخدام، لا تستخدم من جديد
	IT - Attenzione - Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso GB - Caution - read instructions (warnings) carefully FR - Attention - lisez attentivement les instructions (avertissements) ES - Precaución - lea las instrucciones (advertencias) cuidadosamente PT - Cuidado - leia as instruções (avisos) cuidadosamente DE - Achtung - Anweisungen (Warnungen) sorgfältig lesen GR - Προσοχή - διαβάστε προσεκτικά τις οδηγίες (ειδοτήσεις) SE - Varsamhet - läs anvisningarna (varningar) noga RO - Atenție - Citiți și respectați cu atenție instrucțiunile (avertismentele) de utilizare HU - Figyelem - Figyelmesen olvassa el és kövesse a használati utasításokat (figyelmeztetéseket) BG - Внимание: Прочетете внимателно и спазвайте стриктно инструкциите (предупрежденията) AR - الحذر - قراءة التعليمات (التحذيرات) بعناية		