PROFESSIONAL MEDICAL PRODUCTS

ASPIRATORE MANUALE GIMA CON FILTRO
GIMA MANUAL SUCTION PUMP WITH FILTER
ASPIRATEUR À MAIN GIMA AVEC FILTRE
BOMBA ASPIRADORA MANUAL GIMA CON FILTRO
BOMBA DE SUCÇÃO MANUAL GIMA COM FILTRO
GIMA MANUELLE SAUGPUMPE MIT FILTER
ΧΕΙΡΟΚΙΝΗΤΗ ΑΝΤΛΙΑ ΑΝΑΡΡΟΦΗΣΗΣ GIMA ΜΕ ΦΙΛΤΡΟ
RĘCZNA POMPA SSĄCA GIMA Z FILTREM
POMPA MANUALA DE ASPIRARE GIMA CU FILTRU
GIMA KÉZI SZÍVÓSZIVATTYÚ SZŰRŐVEL
GIMA RUČNA USISNA PUMPA S FILTROM

IT - È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.

EN - All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.

FR - Il est nécessaire de signaler tout accident grave survenu et lié au dispositif médical que nous avons livré au fabricant et à l'autorité compétente de l'état membre où on a le siège social.

ES - Es necesario informar al fabricante y a la autoridad competente del Estado miembro en el que se encuentra la sede sobre cualquier incidente grave que haya ocurrido en relación con el producto sanitario que le hemos suministrado.

PT - É necessário notificar ao fabricante e às autoridades competentes do Estado-membro onde ele está sediado qualquer acidente grave verificado em relação ao dispositivo médico fornecido por nós.

DE - Jeder schwere Unfall im Zusammenhang mit dem von uns gelieferten medizinischen Gerät muss unbedingt dem Hersteller und der zuständigen Behörde des Mitgliedsstaats, in dem das Gerät verwendet wird, gemeldet werden.

GR - Σε περίπτωση που διαπιστώσετε οποιοδήποτε σοβαρό περιστατικό σε σχέση με την ιατρική συσκευή που σας παρέχουμε θα πρέπει να το αναφέρετε στον κατασκευαστή και στην αρμόδια αρχή του κράτους μέλους στο οποίο βρίσκεστε.

HR - Potrebno je prijaviti svaku ozbiljnu nezgodu koja se dogodila u vezi s isporučenim medicinskim proizvođaču i nadležnom tijelu države članice u kojoj se nalazi.

HU - A gyártónak, illetve a székhely szerinti tagállam illetékes hatóságának jelezni kell bármilyen olyan súlyos balesetet, amely az általunk szállított orvostechnikai eszközzel kapcsolatban történt.

PL - Należy poinformować producenta i kompetentne władze danego Kraju członkowskiego o każdym poważnym wypadku związanym z wyrobem medycznym naszej produkcji.

RO - Orice accident grav produs, privitor la dispozitivul medical fabricat de firma noastră, trebuie semnalat producătorului și autorității competente în statul membru pe teritoriul căruia își are sediul utilizatorul.

REF **131422 (GIMA 28125)**

Hangzhou Jinlin Medical Appliances Co., Ltd.
M14-3-4, Hangzhou Economic & Technological Development Zone
Hangzhou Zhejiang 310018 China
Made in China

Shanghai International Holding Corp. GmbH (Europe)
Eifestrasse 80, 20537 Hamburg, Germany

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

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KYOLING® manually powered suction equipments are light portable units that can be powered by one hand leaving the other hand free to do other important duties. The vacuum level for adult or child can be adjusted easily when using adjustable pump. This unit was designed for simple operation and maintenance.

INTENDED USE

It is a manually powered suction equipment intended for oro-pharyngeal suction, the commonest use of manually powered suction is in situations outside of health care structures often described as field use or transport use.

MODEL & SPECIFICATION

There are 4 models for choice. Two types of vacuum mode are available as single vacuum level or adjustable vacuum level for adult or child. HEPA* type microbial filter can be selected as a contamination protection means which can prevent bacterial or viral contamination of the pump. Structure compositions for all models of manually powered suction equipment are listed as follow.

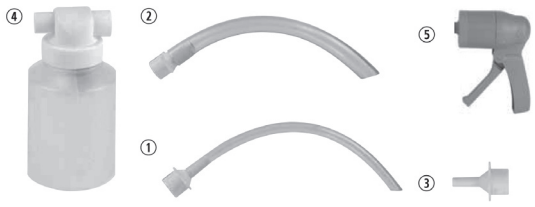
Table 1 Structure composition of manually powered suction equipments

	Structure composition						
Illustration	①	②	③	④		⑤	
Assembly	Suction tubing		Adapter	Collection container		Pump	
	For Child (External diameter of catheter connection: 5.5mm)	For Adult (External diameter of catheter connection: 13mm)	External diameter of catheter connection: 5.5mm	Without microbial filter	Without microbial filter	Normal	Adjustable For Adult For Child
1311 series normal without microbial filter	●	●	○	●	⊠	●	⊠
1312 series adjustable without microbial filter	●	●	○	●	⊠		●
1313 series normal with microbial filter	●	●	○	⊠	●	●	⊠
1314 series adjustable with microbial filter	●	●	○	⊠	●		●

*The typical characteristics of HEPA ● Application ○ Selectable

EN13274-7 NaCl Penetation(0.6pm): 1.1% at 9.5m/min media velocity; Air Flow Resistance: 27.9Pa at 8.2m/min media velocity.

ASSEMBLY FIGURE



Following parts (…...) can be replaced by the user

Table 2 The parts to customers in the form of packaging units

Ill.	Item description	Product code
①	Disposable suction tubing for child	13112003
②	Disposable suction tubing for adult	13112002
③	Disposable adapter for catheter with funnel connector	13112040
④	Disposable collection container with/without microbial filter	13111001/ 13141001
⑤	The pump is normal or adjustable	13113001/ 13123001

INDICATIONS

Manually powered suction equipment can be used by a trained person without the need for a power supply, and used in medical technology, especially in emergency medicine, for suction accumulated blood, mucus, saliva, etc. as well as viscous food components.

CONTRAINDICATION

According to the current clinical experience, there is no contraindications.

PRECAUTIONS

Table 3 Fault-finding and Correction Procedures

Phenomenon	Fault analysis	Correction procedures
It is not possible to squeeze the handle for further suctioning (extremely high resistance will be felt when trying to do so).	A.I The cavity of the suction tubing is blocked	If correct, replace the suction tubing
	A.2 The cavity connecting the pump and the collecting container is blocked	If correct, clean up the blockage in the cavity or replace the pump
	A.3 The overfill protection mechanism is engaged	If it happens before suctioning, pay attention to the 9 article of Directions for Use and adjust the location of the collection container
		If it happens in the suctioning process, pay attention to 10 article of Directions for Use and replace the collection container
	A.4 Piston ring inside pump deformed (flanging)	If not possible for A.1-A.3, replace the pump
	A.5 Lubricant consumption and reduction in pump	If not possible for A.1-A.3, replace the pump
It is difficult to suctioning, and emerge lesser suction	B.I The cavity of the suction tubing is blocked	If correct, replace the suction tubing
	B.2 The cavity connecting the pump and the collecting container is blocked	If correct, clean up the blockage in the cavity or replace the pump
	B.3 Liquid or solid has been drawn into the vacuum pump	If not possible for B.1-B.2, Place in a dry environment for a period of time or replace the pump
Suction process is normal, but emerge lesser suction	C.I The Selected suction tubing is not for adult	If correct, replace the suction tubing for adult
	C.2 The knob is not adjusted to the position of adult's suction	If correct, adjust the knob to the position of adult's suction
	C.3 The cavity connecting the pump and the collecting container is not sealed	If not possible for C.1-C.2, Reassemble or refer to D.1-D.5 measures
	C.4 Piston ring inside pump deformed (unsealed)	If not possible for C.1-C.2, replace the pump
Suction process is normal, but no negative pressure	D.I Defect of collecting container itself (Inhalation valve and / or Gasket for container are not assembled in place)	If correct, reassemble the Inhalation valve and/or Gasket for container, or replace the collection container
	D.2 Defect of collecting container itself (Inhalation valve and / or Gasket for container are damaged)	If correct, replace the collection container
	D.3 The pump and the collection container are not connected properly (unsealed)	If correct, reassembly
	D.4The ringofthe pump is not assembled in place	If correct, reassembly
	D.5 The ring of the pump is damaged	If correct, replace the ring or pump
	D.5 Failure of internal structure of pump(drive mechanism broken)	If not possible for D.1-D.5, replace the pump
There is an attraction that flows to the end-piece in suctioning process	E.I The square valve of the collection container is damaged	Replace the collection container
Springback of the trigger is slow in suctioning process	F.I Liquid or solid has been drawn into the vacuum pump, affect suctioning process	If correct, place in a dry environment for a period of time or replace the pump
	F.2 Failure of internal structure of pump (spring failure, piston ring flanging, lubricant shortage or consumption, exhaust valve block)	If not possible for F.I, replace the pump
Suction process is normal, but unstable negative pressure	G.I If it is an adjustable pump, the knob is not adjusted in place	If correct, adjust the knob to the correct position
	G.2 The pump and collection container are not connected properly	If correct, reassembly
	G.3 If it is an adjustable pump, regulator failure (internal fixed structure slipping)	If not possible for G.1-G.2, replace the pump
	G.4 Failure of internal structure of pump (lubricant shortage or uneven)	If not possible for G.1-G.2, replace the pump

The pump and collection container cannot be assembled effectively	H.I Mismatching of joint assembly, wrong assembly direction of the collecting container and the pump	If correct, make sure the assembly direction is correct
	H.2 Assembly is too tight, the ring of the pump is deformed (enlarged)	If correct, replace the ring or pump
	H.3 Assembly shaking, the clamp structure of the collection container which installed on the pump breaks	If correct, replace the collection container
	H.4 Assembly shaking, the ring of the pump is deformed (smaller) or missing	If correct, replace the ring or pump

WARNINGS

1. Read instructions before use. This equipment should be used by persons with training in suction techniques.
2. If liquid has been inadvertently drawn into the vacuum pump, removal should be done according to the advise in section **- Maintenance**.
3. The use of suction device requires that appropriate infections disease precautions be taken during use, cleaning of the device and disposal of the tubing and the container.
4. Performanee values given are achievable under test conditions. It may vary during actual use.
5. Please do not reuse the spare parts (see section - **Model & Specification**……) again, otherwise biological pollution may be caused.
6. The product contains steel substances, so using in a magnetic resonance imaging environment must be avoided, otherwise it may cause MRI failure.
7. When the overfill protection mechanism is engaged, squeezing the handle for further suctioning may cause the internal structure of the pump to be broken, otherwise it may cause product function failure.
8. When the product is used for child's suction, it is recommended to select an adjustable pump to adjust the knob to the position of child's suction(See Fig. 2), and select the suction tubing for child, otherwise the oral tissue of the child may be damaged during the suction.
9. If liquid or solid has been drawn into the vacuum pump (caused by attracting bubbles in the suction container or other reasons) it may cause product function failure.
10. Please follow the recommendations about operating environmental temperature and storage environmental temperature, otherwise it may cause product function failure.
11. If the pump is stored for a long time (more than 5 years) or repeatedly used (more than 30 times), the correct functioning of the pump should be checked before use. The pump could risk fractures due to the aging of the internal driving structure, which may cause product function failure.
12. The equipment is intended for pharyngeal suction only, and it can not be used as other types of device such as the following: a)end pieces such as suction catheters, Yankauer sucker and suction tips; b)dental suction equipment; c) mucus extractors, including neonatal mucus extractors.

INSTRUCTIONS FOR USE

DIRECTIONS FOR USE

1. Select appropriate size suction tubing (according to the size of the patient). If using other catheter instead of suction tubing, firmly attach it to the adapter.
2. Fit the adapter to the suction container.
3. Fix the suction container to the pump.

Caution: It is particularly important to ensure that the container is properly fitted to the housing of the pump to make the system airtight and allow a vacuum to be created.

4. Select the appropriate vacuum for adult or child. (See below figures), (only for 1312 and 1314 series).

Fig. 1

For adult

Fig. 2

For child

Caution: The adjustment stroke knob enables the production of various suction volumes. The pump in the default state is for adult (See Fig. 1). If the pump is used for child, turn the knob 90 degrees anticlockwise (See Fig. 2).

5. It is operated by pulling the trigger repeatedly towards the handle of the pump.
6. A low pressure condition is produced by the pumping movements and the liquid is sucked out of the patient's mouth and throat through the suction tube into the suction container.
7. The trigger automatically returns each time to the starting position.

Caution: The squeezing action of the trigger will become harder when the container is filled or the catheter is clogged.

1. Blood, secretions and mucus as well as viscous food components can be extracted directly via the suction
2. The suction container has a capacity of 300 ml. It is equipped with an overflow protection mechanism (which protects the pump from contamination) and a valve (prevents reverse flow to the patient). These mechanisms prevent liquids and particles from getting into the vacuum pump or returning to the patient.

Caution: If the pump is turned upside down, overflow protection is activated immediately making suction impossible.

The pump handle and the lower surface of the suction container should always face downwards and not towards you. tubing or by directly connecting a suction catheter by means of the supplied adapter for funnel connectors.

3. During operation, the overflow protection mechanism (float valve) inhibits suction before the container threatens to overflow. Overflow protection is deactivated by removing the suction container from the pump, emptying it where necessary and then fitting it back on the pump. When overflow protection is activated, resistance prevents the pump handle from being used.

Caution: When the overfill protection mechanism is engaged, it is not possible to squeeze the handle for further suctioning (extremely high resistance will be felt when trying to do so).

Overflow Protection
Protects the pomp from contamination

Valve
Prevents reverse flow to the patient

Adapter for suction catheter

4. **Note:** Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CLEANING/DISINFECTING

1. **Note:** The suction tubing, suction container and adapter (see section - **Model & Specification** (…….) are for single use only. Do not clean / disinfect and do not reuse. Reuse may cause cross infection and reduce product reliability and functionality.
2. The suction container must be removed from the pump after use.
3. Discard the container, the adapter and the suction tubing appropriately.

Caution: If required, place label on the container for transportation to the laboratory.

4. The pump (including handle) can be cleaned and disinfected by wiping the entire surface with warm soapy water, mild detergent or a bleach solution.

Caution: Caution: Never immerse the device in water or other liquids as this will damage the pump.

5. Check the pump for damage or wear.
6. Test the function of the pump (see section - **Functional Check**).
7. The pump can now be stored away again assembled..

FUNCTIONAL CHECK

Caution: Perform a functional check before each use and after each cleaning and disinfection.

1. Check the condition of the handle and the pump function.
2. Fix the container to the pump.
3. Obstruct the suction tube connection with your thumb or the palm of your hand while squeezing the handle of the pump. This way you can check that a vacuum is created.

MAINTENANCE

The special maintenance of the Pump:

1. After use and before storage, it needs to be cleaned and disinfected, see section - **Cleaning/Disinfecting**.
2. If liquid has been inadvertently drawn into the pump, turn round the pump till the exhaust port is in the downwards position (See Fig. 3), and squeeze the handle for suctioning until there is no liquid spraying out from the exhaust port. Test the function of the pump (see section - **Functional Check**) before use.
3. If solid has been drawn into the pump inadvertently, keep blowing towards the suction port with compressed air until there is no solid ejected out of the pump. Test the function of the pump (see section - **Functional Check**) before use.

Caution: Do not point the suction port and exhaust port of the pump towards anyone when blowing air.

The exhaust port at downwards position

Fig. 3

SINGLE USE OR REUSE

This spare parts of the devices like Suction tubing, Adapter and Collection container are intended for use in a Single procedure only. The pump can be reused after cleaning for the validity period. It is advised not be reuse the pump more than 30 times.

REGULATIONS TO OTHER DEVICES CONNECTING WITH PRODUCT

The pump can be connected with other devices such as catheter with funnel connector by the adapter.

Caution: Test the function of the connection (see section - Functional Check) before use.

STORAGE AND TRANSPORTATION

It should be stored in a dry and ventilated place. When transporting, it should be handled with care in a moisture proof way. Keep the storage temperature between-40°C to 60°C.

TECHNICAL SPECIFICATION

Table 4 Technical specification about KYOLING® manually powered suction equipments

Model	1311 series normal without microbial filter	1312 series adjustable without microbial filter		1313 series normal with microbial filter	1314 series justable with microbial filter	
Adjustable	/			/		
Vacuum level	-450 mmHg within 10 s	-450 mmHg within 10 s	-225 mmHg within 10 s	-450 mmHg within 10 s	-450 mmHg within 10 s	-225 mmHg within 10 s
Free air flowrate	>0,33 l/s (20 l/min)	>0,33 l/s (20 l/min)	>0,165 l/s (10 l/min)	>0,33 l/s (20l/min)	>0,33 l/s (20l/min)	>0,155 l/s (10 l/min)
Pharyngeal suction	evacuate 200 ml of simulated vomitus in not more than 10 s.	evacuate 200 ml of simulated vomitus in not more than 10 s.	evacuate 100 ml of simulated vomitus in not more than 10 s.	evacuate 200 ml of simulated vomitus in not more than 10 s.	evacuate 200 ml of simulated vomitus in not more than 10 s.	evacuate 100 ml of simulated vomitus in not more than 10 s.
Disposable container volume	300 ml					
Catheter connection (outside diameter)	13mm (for adult) and 6.5mm (for child)					
Suction connection (outside diameter)	17 mm					
Overflow protection	float valve					
Operating environmental temperature	-18 e to +50 e					
Storage environmental temperature	-40 e to +60 e					
Dimensions	180 mm x 220 mm x 80 mm					
Weight	275 g					

PERIOD OF VALIDITY

It is suggested that the product should not be stored for more than 5 years and no more than 30 times of repeated use.

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.

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	Caution: read instructions (warnings) carefully				Manufacturer		Consult instructions for use
	Date of manufacture	REF	Product code	EC REP	Authorized representative in the European community	CE	Medical Device compliant with Regulation (EU) 2017/745
	Keep away from sunlight		Keep in a cool, dry place		Non-sterile		Temperature limit
MD	Medical Device	LOT	Lot number		Expiration date		Not safe for MRI
	Imported by	UDI	Unique Device Identifier				