





CHANGER I

CHANGE THE FILTER FOR EACH NEW PATIENT CE0459



VACUUM REGULATORS

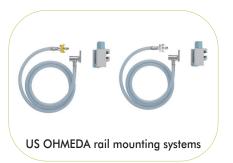


RAIL MOUNTING SYSTEMS

















Other standards available upon request.

DIRECT PROBES





















Other standards available upon request.

RVTM3

The vacuum regulator is used to measure and to adjust the vacuum level within the context of surgical and medical suctions. It enables to drain substances out of the patient's body during surgical procedures. The vacuum regulator should be connected to a vacuum source on the wall either using a direct probe or a rail mounting system. It is the primary device of a suction system. It should be associated with a collection jar and a suction hose.

Main technical features:

Active medical device of class IIa. In compliance with the EN ISO 10079-3: 2009 standard.

- Continuous vacuum regulator.
- Compact, strong and ergonomic device.
- Manual adjustment of the vacuum gauge from -45° to +45° for a better visibility. Vacuum gauge protected by a plastic housing.
- ON/OFF switch-button providing a quick restoration of the pre-adjusted vacuum level.
- Central regulation knob with a free rotation at the end of the course (impossible blocking).

Quick adjustment: 2.5 turns are enough to reach the maximum vacuum level.

- Supplied as a standard with a 100 ml safety jar equipped with a
 mechanical anti-overflow safety valve and a single-use antibacterial
 plastic filter up-front. Made of polycarbonate, autoclavable
 up to 134°C and unbreakable, this safety jar does not require
 any sterilization except in case of accidental liquids' overflow or
 perforated filter. Money and time savings are guaranteed!
- Fixing of the safety jar by an easy-click rotation.
- Rotation of the safety jar to avoid any pinch of the tubing.
- 3 in 1 system (patented)

Device with a metal outlet tubing nipple integrated in the body of the regulator: for a better safety, emergency suctions can even be processed if running out of stock of filters or safety jars.

• Easy & safe maintenance

<u>Easy and safe</u> replacement of the vacuum gauge if needed. The inner system of the regulator is protected but accessible at the back of the device.

 A unit serial number is laser engraved on the body of each vacuum regulator ensuring its identification and traceability.
 8 digits number indicating the manufacturing year and month as well as the unit serial number of the device.

Many versions available:

- Vacuum levels:
 - 0-1000 mbar/hPa 0-760 mmHg 0- 600 mbar/hPa - 0-400 mmHg 0- 250 mbar/hPa - 0-200 mmHg
- Configurations: Single and Twin.
- Colors: Yellow and Grey.

- Inlets: 12x100 F 1/4G M 1/8NPT F 3/8G BSP F.
- Connections to the wall outlet: Direct probe or Rail mounting system.
- Standards: AFNOR (French Standard) BS (British Standard)
 DIN (German Standard) US OHMEDA DIAMOND (American Standard) DISS (American Standard) NORDIC (Scandinavian Standard) UNI (Italian Standard).
 Other standards available on demand.
- Weight (with direct probe): 490 g.
- Dimensions (with safety jar and direct probe):
 Height 230 mm x Width 70 mm x Depth 90 mm.

Use, cleaning and maintenance:

The adjustment of the vacuum regulator must be done in a closed suction circuit.

- Block the outlet of the RVTM3 vacuum regulator
- Open the ON/OFF switch-button (green part visible)
- Gradually turn the central regulation knob counterclockwise till the needle of the gauge indicates the requested suction level.

Clean the exterior of the device with water and soap. Rinse and dry. If using disinfecting products please check their compatibility with plastics (ABS, polypropylene, polyamide). Do not lay under water.

Change the antibacterial plastic filter of the safety jar after each patient: firmly pull out the filter while making a rotating movement and insert a new filter by pushing it until click-lock adjustment.

The 100 ml safety jar with plastic filter up-front, being protected by the filter at the inlet, does not require any sterilization except in case of accidental liquids' overflow or perforated filter. The safety jar is autoclavable up to 134°C .

The RVTM3 should be serviced every 1 to 3 years depending on use.

It is recommended to lubricate the ON/OFF switch-button every year with a silicone "High Vacuum Grease" (ref. 11853).

Single-use filters:

• Ref. 11813: Tube of 10 antibacterial plastic filters.

Same filters for both RVTM2 and RVTM3 vacuum regulators

Filter = Cleanness of the circuits and fight against nosocomial infections.

Change the filter for each new patient!



Patented model



Easy and safe maintenance.

Very good readability of the serial number on the body of the device: clean and precise laser marking.

Compact, strong and ergonomic device.

Vacuum gauge manually adjustable from -45° to +45° for a better visibility.

Protected by a plastic housing.

ON/OFF switch-button providing a quick restoration of the preadjusted vacuum level.

Central regulation knob with a free rotation at the end of the course (impossible blocking).

Quick adjustment: 2.5 turns are enough to reach the maximum vacuum level.

Fixing of the safety jar by an easy-click rotation.

Rotation of the safety jar to avoid any pinch of the tubing.

100 ml safety jar made of polycarbonate, unbreakable, autoclavable up to 134°C and equipped with a mechanical anti-overflow safety valve.

Single-use antibacterial plastic filter up-front

- ► Hygiene: protection of the patient, the device and the vacuum pipeline network;
- Useless sterilisation: time and costs' savings;
- ► Perfect visibility of the clogging level.

3 in 1 system Patented

- ▶ Normal use
- With safety jar + antibacterial filter Optimal protection of the device and the vacuum pipeline network. This use is highly recommended by the manufacturer.
- ► Emergency use
- 2 With outlet tubing nipple + antibacterial filter
- With outlet tubing nipple
 The metal outlet tubing nipple is integrated in the body of the vacuum regulator
 thus reducing the manipulations and avoiding the risk of losing the nipple.
 Emergency use in case the safety jars and the antibacterial filters run out of stock.





RV01

RVTM3 vacuum regulator 0-600 mbar, yellow, with 100 ml safety jar and DIN direct probe.

RV02

RVTM3 vacuum regulator 0-400 mmHg, grey, with 100 ml safety jar and BS direct probe.



RV03

RVTM3 vacuum regulator 0-1000 mbar, yellow, with 100 ml safety jar and AFNOR complete rail mounting system.



RV04

RVTM3 Twin vacuum regulator 600-1000 mbar, yellow, mounted with 100 ml safety jars and AFNOR direct probe.



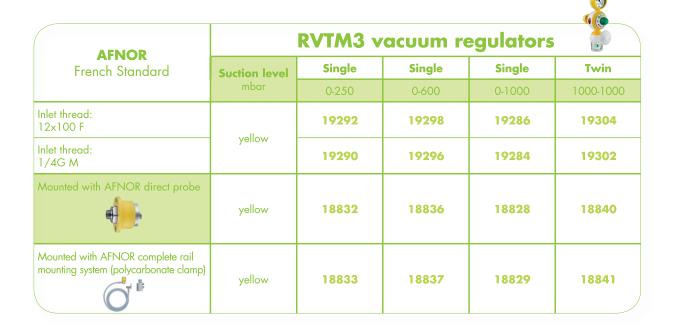
RVTM3 vacuum regulator 0-250 mbar, grey, with integrated outlet tubing nipple and OHMEDA direct probe.





RV06

Complete suction system composed of: One RVTM3 vacuum regulator mounted with AFNOR complete rail mounting system, one 2 L collection jar, one catheter holder 1 tube, silicone suction tubing and one vacuum–stop.



	3				
BS					
British Standard	Suction level	Single	Single	Single	Twin
	mbar	0-250	0-600	0-1000	1000-1000
Inlet thread:	yellow	19290	19296	19284	19302
1/4G M	grey	19236	19242	19230	19248
Mounted with BS direct probe	yellow	18904	18908	18900	18912
	grey	18868	18872	18864	18876
Mounted with BS complete rail mounting system (polycarbonate clamp)	yellow	18905	18909	18901	18913
O ^t	grey	18869	18873	18865	18877

	3						
DIN	RVTM3 vacuum regulators						
German Standard	Suction level	Single	Single	Single	Twin		
	mbar	0-250	0-600	0-1000	1000-1000		
Inlet thread:	yellow	19290	19296	19284	19302		
1/4G M	grey	19236	19242	19230	19248		
Mounted with DIN direct probe	yellow	19030	19034	19026	19038		
	grey	18994	18998	18990	19002		
Mounted with DIN complete rail mounting system (polycarbonate clamp)	yellow	19031	19035	19027	19039		
Q, t	grey	18995	18999	18991	19003		

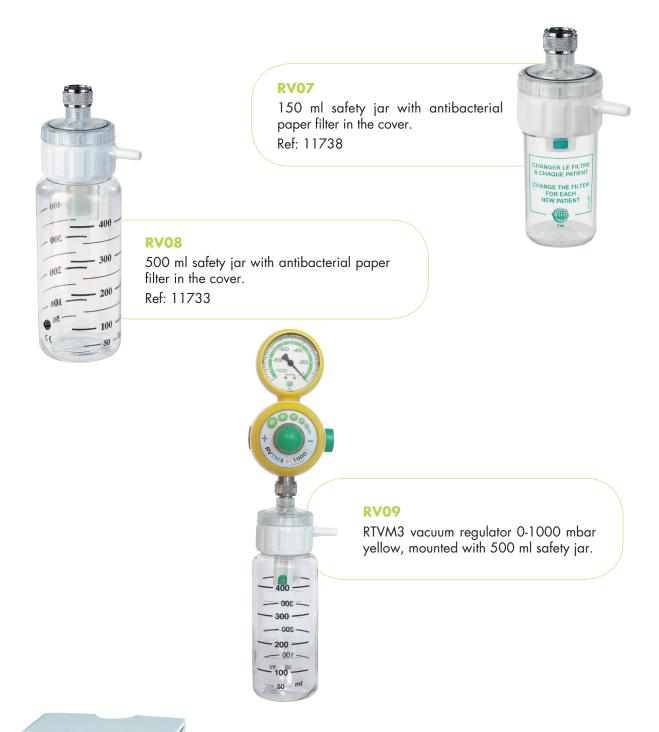
US OHMEDA American Standard RVTM3 vacuum regulators					
ISO colour (yellow)	Suction level mbar	Single	Single	Single	Twin
US colour (white)		0-250	0-600	0-1000	1000-1000
Inlet thread:	yellow	19290	19296	19284	19302
1/4G M	grey	19236	19242	19230	19248
Inlet thread:	yellow	19291	19297	19285	19303
1/8NPT F	grey	19237	19243	19231	19249
Mounted with US OHMEDA direct probe	yellow	19358	19360	19356	19362
	grey	19340	19342	19338	19344
Mounted with US OHMEDA complete rail mounting system (polycarbonate clamp)	yellow	-	-	-	-
O'O'	grey	-	-	-	-

⁻ Available upon request only.

NORDIC	F	RVTM3 v	acuum r	egulator	5
Scandinavian Standard	Suction level	Single	Single	Single	Twin
	mbar	0-250	0-600	0-1000	1000-1000
Inlet thread:	yellow	19290	19296	19284	19302
1/4G M	grey	19236	19242	19230	19248
Inlet thread:	yellow	19291	19297	19285	19303
1/8NPT F	grey	19237	19243	19231	19249
Mounted with NORDIC direct probe	yellow	19198	19202	19194	19206
	grey	19162	19166	19158	191 <i>7</i> 0
Mounted with NORDIC complete rail mounting system (polycarbonate clamp)	yellow	19199	19203	19195	19207
O t	grey	19163	19167	19159	19171

	RVTM3 vacuum regulators					
UNI Italian Standard	Suction level	Single	Single	Single	Twin	
	mbar	0-250	0-600	0-1000	1000-1000	
Inlet thread: 1/4G M	yellow	19290	19296	19284	19302	
Mounted with UNI direct probe	yellow	19396	19400	19392	19404	
Mounted with UNI complete rail mounting system (polycarbonate clamp)	yellow	19397	19401	19393	19405	

SAFETY JARS WITH ANTIBACTERIAL PAPER FILTER (FORMER MODELS)





RV10

Box of 100 single-use antibacterial paper filters.

Ref: 11818

100 ML SAFETY JAR WITH SINGLE-USE ANTIBACTERIAL PLASTIC FILTER UP-FRONT

Easy and quick replacement of the filter.

It is useless to sterilize the safety jar after each filter replacement as the safety jar is protected by the filter at the inlet.

Technical and financial advantages of the antibacterial plastic filter up-front:

Hygiene: very hygienic system limiting the contamination risk of the device and the vacuum pipeline network. The plastic housing avoids any direct contact with the contaminated filter.

<u>Visibility of the contamination level</u>: thanks to its vertical up-front position, the antibacterial plastic filter is visible even from a distance. As a result it is very easy to check its clogging level and to warn the medical staff about the necessity to replace it in the case of a long-stay patient.

<u>Very easy replacement of the filter</u>: firmly pull out the filter while making a rotating movement, throw it away and insert a new filter by pushing it until click-lock adjustment.

<u>Significant time savings</u>: the safety jar is protected by the filter at the inlet. Thus there is no need for systematic sterilization except in case of accidental liquids' overflow or perforated filter. The very long cleaning and autoclave process of the jar is then avoided.

<u>Generated costs' savings</u>: the easy and quick replacement of the filter as well as the occasional sterilization of the safety jar both generate significant time savings thus improving the global operation costs.

<u>Possibility of connecting the safety jar without filter</u> in case of emergency or in case the filters run out of stock.

CHANGER LE FILTRE
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CHANGE THE FILTER
FOR EACH NEW
PATIENT (£ 0459)
TIM

RV11 Ref. 18753

Change the filter for each new patient!

By replacing the filter after each patient you take part in the fight against nosocomial infections.



RV12

Tube of 10 single-use antibacterial plastic filters. Ref. 11813

WHY AN ANTIBACTERIAL FILTER?

Suction may generate airborne contamination which could contaminate the devices, the connecting probes, the wall outlets, the pipeline networks and the vacuum pumps. In addition, when out of use, bacteria may – without any filter – freely circulate into the patient circuit.

Filter = Cleanness of the circuits and fight against nosocomial infections.

	Reference	Description
		VACUUM GAUGE WITH HOUSING
	18736	0-1000 mbar vacuum gauge, yellow*
1	18737 18738	0-600 mbar vacuum gauge, yellow* 0-250 mbar vacuum gauge, yellow*
	19486	0-750 middi vacuum gauge, yellow*
	19487	0-400 mmHg vacuum gauge, yellow*
	20150	0-200 mmHg vacuum gauge, yellow*
(2+3	3+4+5+6)	BODY
	18670	RVTM3 body 0-1000/0-600 mbar – 0-760/400 mmHg with ON/OFF switch-button
	18671	RVTM3 body 0-250 mbar with ON/OFF switch-button
3	19510	Complete ON/OFF switch-button
4	19511	Batch of 3 gaskets for ON/OFF switch-button
5	11415	Gasket for vacuum gauge
6	18731	Outlet gasket
7	18669	Back housing, yellow*
8	18691	Screw for back housing
		COMPLETE COVER
9	19502	0-1000 mbar complete cover, yellow*
	19503	0-600 mbar complete cover, yellow*
	19504	0-250 mbar complete cover, yellow*
	19505	0-760 mmHg complete cover, yellow*
	19506	0-400 mmHg complete cover, yellow*
	20098	0-200 mmHg complete cover, yellow*
10	19507	Complete membrane
11	19508	Complete regulation knob, green
12	11826	Inlet adaptor 12x100 F
	11823	Inlet adaptor 1/4G M
	11825	Inlet adaptor 1/8NPT F
13		100 ml SAFETY JAR
	18753	100 ml safety jar, complete with cover 9
	19557	COMPLETE COVER
(14+1	5+16+1 <i>7</i> +18+19)	l l
14	18690	White cover only
15	11780	Gasket
16	11 <i>7</i> 01	Safety gasket
17	11698	Safaty ball
18	17294	Safety cage
19	11813	Antibacterial plastic filter (tube of 10)
20	17630	100 ml bottle only
20	1, 300	. s s bomo smy
	*Please contact u	us for the various spare parts in grey.
		3.47



Also available



Distributed by

SUCTION

VACUUM REGULATORS



Certificat



Certificate of Registration

Numéro de certificat 37547-0

Certificate number

TECHNOLOGIE MEDICALE

101 rue Vaillant Couturier FRANCE - 93130 - NOISY-LE-SEC

met en œuvre et entretient un Système de Management Environnemental conforme aux exigences de la norme

operates a Environmental Management System which complies with the requirements of

ISO 14001 : 2015

Pour les activités suivantes / for the activities detailed below

Conception, fabrication, distribution de détendeurs, rails médicaux et dispositifs d'oxygénothérapie et d'aspiration

Design, manufacture, distribution of regulators, medical rails and oxygen therapy and suction

Site(s) de production ou d'activité / Operative unit(s)

TECHNOLOGIE MEDICALE

09 avril 2021

08 avril 2024

101 rue Vaillant Couturier

FRA 93130 NOISY LE SEC

Date début validité

Effective date April 9th, 2021

Valable jusqu'au

April 8th, 2024 Expiry date

Pour le Directeur Général the General Director.

Signature numérique de PASCAL PRUDHON ID

Date: 2021.64.09 18:49:59 +02'00"

Responsable du Pôle Certification Environnement. Sécurité et Performance

Head of the Environment, Safety and Performance Certification Department.





ATTESTATION / CERTIFICATE N° 28577 rev. 6

Délivrée à Paris le 02 mars 2020 issued in Paris on March 2nd, 2020

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité/Approval of full Quality Assurance System
ANNEXE II excluant le point 4 Directive 93/42/EEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / Manufacturer

TECHNOLOGIE MEDICALE 101 rue Vaillant Couturier 93130 NOISY-LE-SEC FRANCE

Catégorie du(des) dispositif(s) / Device(s) category

Détendeurs et produits pour l'oxygénothérapie et l'aspiration

Pressure regulators and products for oxygen therapy and suction

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P181091, P600892, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe il excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P181091, P600892, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : March 2nd, 2020 (included) Valable jusqu'au / Expiry date : May 26th, 2024 (included)

On behalf of the President

Béatrice LYS
Technical Director

GMED - 28577 rev. 6 Renouvelle le certificat 28577-5



Identification des dispositifs / Identification of devices

Désignation du dispositif i Accessoires marqués CE Device designation / CE marked accessories	Réf commerciale du dispositif ou code article Device commercial reference or article code	Classe du DM®
Détendeurs et produits pour l'oxygénothérapie et l'aspiration Pressure regulators and products for oxygen therapy and suction	Switch et Flow-Switch / Switch and Flow-switch Rampe et Dédoubleur de prise / Ambulance panel and Y connector Flexible / Hosepipes Robinet direct / Direct valve RTM3 / RTM3 RVTM3 / RVTM3 Soupape de Jeanneret / Water manometer Vanne de vide / Direct vacuum valve Vanne de vide Australie / Direct vacuum valve (Australia) Venturi TM2 / Venturi TM2 Debflo et Debplus / Debflo and Debplus Debson TM2 / Debson TM2 Humidificateur / Humidifier	lla
	DetregTM / DetregTM Minireg / Minireg RegflowTM / RegflowTM RegsonTM2 / RegsonTM2	lib

<u>Identification du site couvert et des activités</u> <u>Identification of location and activities</u>

TECHNOLOGIE MEDICALE – 101 rue Vaillant Couturier – 93130 NOISY-LE-SEC – FRANCE Conception, fabrication et contrôle final Design, manufacture and final control

GMED 0459



On behalf of the President Béatrice LYS Technical Director