7	Technical Specification		
Ventilation Modes			
	VCV(A/C) PCV(A/C) PRVC SIMV(VCV)+PSV		
	SIMV(PCV)+PSV SIMV(PRVC)+PSV SPONT/CPAP+PSV		
	BIVENT+PSV NIV/CPAP NIV-T NIV-S/T		
Parameters			
Tidal Volume:	20~2000 ml		
Respiration Rate:	1~80 bpm		
• Tinsp:	0.2~9 s		
Tslope:	0~2 s		
Tpause:	0~4 s		
I:E Ratio:	1:10~4:1		
• FiO <sub>2</sub> :	21%~100%		
Trigger Sensitivity:	Pressure (-20~0 cmH <sub>2</sub> O, above PEEP)		
,	Flow (0.5~20 LPM)		
• PEEP:	0~35 cmH₂O		
Psupport:	0~70 cmH₂O		
• Pinsp:	5~70 cmH <sub>2</sub> O		
Special Procedures			
·	Apnea Ventilation Smart Suction Manual Breath		
	Insp/ Exp Hold ETCO <sub>2</sub> Measurement		
	Nebulization Waveform Freeze		
Monitoring			
Pressure Value:	Ppeak, Pplat, Pmean, Pmin, PEEP		
Volume / Flow Value:	Vti, Vte, MV, MVspont		
Time Value:	ftotal,fspont, I:E		
Real Time Curves:	Pressure-Time, Flow-Time, Volume-Time waveforms		
	Pressure-Volume, Volume-Flow, Flow-Pressure loops		
Gas Monitoring:	FiO <sub>2</sub> , ETCO <sub>2</sub>		
Calculated Values:	Compliance(C)		
	Resistance(R)		
	MVleak		
	RSBI		
	WOB		
	PEEPi		
Alarm			
	Paw high / low MVe high / low Circuit disconnection		
	FiO <sub>2</sub> high / low Inspiration / Expiratory tidal volume low		
	High Respiration Rate Apnea AC Failure Nebulizer On		
	Low Battery Air /O <sub>2</sub> supply down High / Low PEEP		
	Leakage out of range Occlusion		
Technical Data	<del></del>		
• Screen:	12" TFT color touch screen (detachable)		
• Supply Gas:	O <sub>2</sub> , 0.28~0.6 MPa		
Power Supply:	AC100~240 V, 50 Hz/60 Hz		
Communication Interface:	RS-232 Port, Nurse call Port, Ethernet Port		
Dimension (WxDxH):	322 mm x 375 mm x 366 mm (Main Unit)		
Difficition (WADALI).	547 mm x 675 mm x 950 mm (Cart)		
• Weight:	12.5 kg (Main Unit)		
vvoigiit.	25 kg (Cart)		
	20 Ng (Odit)		

Remark: Above configurations include standard and optional. Please check price with your Aeonmed sales representative.

Reliable Quality Thoughtful Service

The information contained in this leaflet is correct at the date to publication. The policy of Beijing Aeonmed Co., Ltd. is one of the continued improvement to its products. Because of this policy, Aeonmed reserves the right to make any change, which may affect the information in this leaflet without giving prior notices.

AVT70-1902



#### Superior Mobile ICU ventilator

- Comprehensive ICU ventilator including BIVENT and PRVC
- · Compact, big capacity battery, no air compressor, intra-hospital mobility
- Flexible device configuration: equipped on a trolley, bed or ceiling pendant

#### Cost Effective Solution

- Unique metal-based, autoclavable, heated exhalation valve
- Built-in flow sensor, non-consumable design
- Upgradeable ventilation system software, with an available USB port















#### An Optimal Combination of Invasive and Noninvasive Ventilator

- · As noninvasive ventilation is used increasingly in a wide range of clinical situations, we offer a dual solution
- VG70 combines the advantages of a flexible noninvasive ventilator with a full-featured invasive ventilator for the ICU

## Optimal patient-ventilator synchrony, increase patient comfort

- The Unique Leak Compensation System Keep precise control on the tidal volume of each breath delivered to the patient by adjusting compensation dosage automatically
- Advanced Trigger Technique Enhance sensitivity, avoid spurious triggering

Auto-detect and Adjust Leak Compensation Automatically Adapt to Patient's Breathing Pattern

Multi-parameter Monitoring

## Safe Ventilation Through Whole Treatment Phase

#### **Initial Treatment Phase**

- Noninvasive ventilation mode associated with decreased intubation rates, shortened patient stays, improved patient comfort, and a reduced risk of cross infection
- Preset patient's height and IBW. Reduce clinician's workload

## Stable Condition Phase

- PRVC and BIVENT employ lung-protective strategies, delivering intelligent ventilation
- Comprehensive lung mechanics monitoring include compliance, airway resistance, PEEPi and time constant
- Three waveforms & three loops with user-friendly display provide a continuous monitoring of the patient's condition

### Weaning Phase

- Various ventilation modes enhance the weaning process
- The unique trigger and leakage compensation system safeguards each and every patient breath resulting in smooth and comfortable breathing, avoiding extra workload on the patient and promoting recovery
- RSBI and WOB provide accurate reference for weaning

#### Rehab Phase

- Data export port provides connection to hospital monitors and Patient Data Management Systems
- · Provides pressure support for the patient when spontaneous breathing is present











VG70

Ventilator



VG70 is a critical care ventilator suitable for intra-hospital transport and sub-acute care of infants, children and adults. VG70 combines the advantages of a flexible noninvasive ventilator with a full-featured invasive ventilator. It has comprehensive functionality and a user-friendly design. VG70's internal turbine provides needed air pressure with a low sound level and, along with its internal batteries, prepare it fully for mobile use.



## Patient Type

Adult, Child (>3 Kg)

Ventilation Modes	
VCV	SIMV(VCV)+PSV
PCV	SIMV(PCV)+PSV
PRVC	SIMV(PRVC)+PSV
SPONT/CPAP+PSV	BIVENT/APRV+PSV
NIV-T	NIV/CPAP
NIV-S/T	

Parameter Setting	
Tidal volume (Vt)	50-2000 mL (Adult)
	20-300 mL (Child)
Compliance compensation	ON/OFF
Pinsp	5-70 cmH <sub>2</sub> O
Psupp	0-70 cmH <sub>2</sub> O
CPAP in NIV	2-20 cmH <sub>2</sub> O
PEEP	0-35 cmH <sub>2</sub> O
PEEP in NIV	2-20 cmH <sub>2</sub> O
Phigh	5-60 cmH <sub>2</sub> O
Plow	0-35 cmH <sub>2</sub> O
Psens	-20-0 cmH <sub>2</sub> O
Vsens	0.5-20 L/min
Tube compensation (%)	0-100
ATC tube type	ET/TT
Esens	5-80 %
Inspiratory time (Ti)	0.2-9 s (Adult)
	0.2-5 s (Child)
Backup ventilation Tinsp	0.2-9 s (Adult)
	0.2-5 s (Child)
Pause time (Tpause)	0-4 s (Adult)
	0-2.5 s (Child)
Rising time (Tslope)	0-2 s
Thigh	0.2-30 s
Tlow	0.2-30 s
Frequency (f)	1-80 bpm
NIV ventilation rate	4-20 bpm (Adult)
	4-40 bpm (Child)
SIMV ventilation rate	1-40 bpm
I:E ratio	1:10-4:1
Nebulizer time	30 min or 45 min
O <sub>2</sub> concentration	21-100 %

Enhancements		
Apnea back-up ventilation	1	
Automatic tube compensa	ation (ATC)	
HFT	Suction	
Standby	Screen lock	
Print screen	Alarm silence	
Nebulization	Expiratory hold	
Lung mechanics	Lung recruitment	
Manual breath	Waveform freeze	
Inspiratory hold	EtCO <sub>2</sub> measurement	
Non-invasive ventilation	Leakage compensation	

Monitorin	g Data		
Ppeak	Vti	Rexp	Tispont
Pplat	Vte	Cdyn	FiO <sub>2</sub>
PEEP	MVe	RSBI	FiCO <sub>2</sub>
Pmean	MVespont	Vdaw	EtCO <sub>2</sub>
Pmin	ftotal	I:E	Leak <sub>NIV</sub>
fspont	WOB		

Lung Mechani	CS		
Rinsp	PEEPi	Cstatic	
Elastance	Tc		

Parameter Monitoring Range		
VTi/VTe	0-4000 mL	
MVi/MVe	0-60 L/min	
FiO <sub>2</sub>	18-100 %	
Paw	-20-80 cmH <sub>2</sub> O	

Alarm Setting	
High Paw	5-80 cmH <sub>2</sub> O
High MVe	1-60 L/min, OFF
Low MVe	OFF, 0.1-40 L/min
Apnea time	10-60 s, OFF
Frequency (f)	10-80 bpm, OFF
Low PEEP	OFF, 1-35 cmH <sub>2</sub> O
High EtCO <sub>2</sub>	0.1-13.3 %
Low EtCO <sub>2</sub>	0.1-13.2 %, OFF

Waveform Display				
Flow-T	Paw-T	Volume-T	EtCO <sub>2</sub> -T	
V-F Loop	P-V Loop	F-P Loop		

Other Settings	
Alarm volume	20, 40, 60, 80, 100 %
Trend	72 H
Log	3000 messages
Screen brightness	Day, Night
Language	

Language		
Chinese	English	Other languages
Environmenta	al Requiremen	nts
Temperature		
Operating cond	dition 5	°C-40°C

5 °C-40°C
-20°C-60°C
5-95%
<b>≤95</b> %
70-106 kPa
70-106 kPa

Electrical	
AC voltage	100-240 V, 50/60 Hz
DC voltage	12-24 V,
One battery run time	Minimum 2 hours
Two batteries run time	Minimum 4 hours

Gas Supply	
Supply pressure (O <sub>2</sub> )	280-600 kPa (41-87 psi)
Connection standard	DISS, NIST
Low-flow oxygen inlet	≤600 kPa (pressure)
	$\leqslant$ 15 L/min (flow)

<b>Physical Specifications</b>		
Dimension (main unit)	322*375*366 mm	
Main unit weight	12.5 kg	
Cart weight	25 kg	
Screen size	12" color touch screen	
Communication ports	Nurse call port	
	Ethernet port	
	RS-232 port	
	CO <sub>2</sub> port	
	USB port	
	VGA port	



Edition: V201901

## Data of Package

Type: Aeonmed VG70 ICU Ventilator

2 Carton Box Per Unit

Main Unit Dimension: 650\*530\*940, Gross Weight 29KG Trolley Dimension: 800\*700\*1150, Gross Weight: 37KG



## VG70 Ventilator Configuration List (European Std 112000079)

## Standard

Part Number		Number	Name	Description	Qty
	112000079		VG70 Ventilator	Include VG70 Ventilator Main Unit and Accessory	1
		121000675	VG70 Ventilator Main Unit	Elctronically driven and controlled, built-in flow and pressure sensor, built-in oxygen blender, Include Screen	1
		122009883	Accessory	European Standard	1
		130013843	VG70 Ventilator User Manual	User manual	1
		210002134	Power cable	European standard,5M	1
		130000231	Diaphragm		2
		130009651	Water Trap		1
		130004094	Cover		1
		130001347	One-way diaphragm		1
		130015084	Tool to disassemble exhalation valve		1
		130010423	Fan filter		1
		130004358	Filter Core		1
		130003930	Filter		1
		230000728	Nebulizer		1
		210003734	Internal battery RRC2024	Lithium Battery	1
		210001975	Oxygen sensor		1
		210003856	Fuse T3.15AH250V		2
		230000934	Adult breathing circuit kit	Include: five Silicone threaded circuit Φ22、one Y-piece、 two Water traps、one L-tie-in	2
		230000951	800-21001Adult Test lung		1
		230001094	Face Mask (L)	RAP-422 Adult ,English, with head band, NIV silicone mask	1
		230001187	Elbow(inner diameter 22mm)	Must choose when face mask is chosen	1
		230000952	800-51900-11Bacterial filter	Reusable	2
		122006184	Oxygen inlet filter		1
		122000048	Oxygen pipe line	European Standard	1
	24	40001190	VH3000 humidifier	220V,European standard	1
	122007662 Cart assembly		Cart assembly (220V)	Include cart, power supply unit and etc. European standard.	1
	24	40000030	Arm		1
Total price					





## **EC Certificate**

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 065725 0019 Rev. 01

Manufacturer: Beijing Aeonmed Co., Ltd.

Room 405

Basement 1 to 4th Floor of 901 Unit Building 9, No.26 Outer Ring West Road

Fengtai District 100070 Beijing

PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH

(Europe)

Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies): Anaesthetic Workstation, Vaporizer,

Ventilator, Medical Air Compressor, Infusion Pump, Ceiling Pendant, Multi-Parameter Patient Monitor,

**Videoscope System, Patient Warming** 

System.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: BJ19859044

 Valid from:
 2019-07-16

 Valid until:
 2022-05-03

**Date**, 2019-07-16

Stefan Preiß

1. Punil

Head of Certification/Notified Body

Page 1 of 2

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®



## **EC Certificate**

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 065725 0019 Rev. 01

Facility(ies): Beijing Aeonmed Co., Ltd.

Room 405, Basement 1 to 4th Floor of 901 Unit, Building 9, No.26

Outer Ring West Road, Fengtai District, 100070 Beijing,

PEOPLE'S REPUBLIC OF CHINA

Beijing Aeonmed Co., Ltd.

No. 10 Chaobai Street, Yingbin Road West, Yanjiao Development

Zone, 065201 Langfang City, Hebei Province, PEOPLE'S

REPUBLIC OF CHINA



Certificate Number CN19/41152

The management system of

## Beijing Aeonmed Co., Ltd.

Room 405, Basement 1 to 4th Floor of 901 Unit, Building 9, No.26 Outer Ring West Road, Fengtai District, Beijing, 100070, P.R. China

Dun & Bradstreet D-U-N-S identification number: 52-758-6284

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

## MDSAP (ISO 13485:2016)

RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 /RDC ANVISA n. 67/2009

<u>United States:</u>
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D / 21 CFR 821

For the following activities and devices

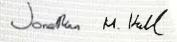
## See second page for the scope.

The certificate is valid from Effective Date: 2019-12-12 until Expiry Date: 2022-12-11 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2022-09-20 Issue 1. Certified since 2019-12-12

Authorised by J Hall Business Manager

MDSAP



SGS United Kingdom Ltd 202B Worle Parkway, Weston-super-Mare, BS22 6WA,UK t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS United Kingdom Ltd is an MDSAP authorized auditing organization

MDSAP M2

Page 1 of 2



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Certificate Number CN19/41152, continued

The management system of

# Beijing Aeonmed Co., Ltd. MDSAP (ISO 13485:2016)

Issue 1

Detailed scope

Design and Development, Production, Distribution, and Servicing of Anesthesia Workstation, Ventilators, Medical Air Compressors, Vaporizers, for the area of anesthesiology, intensive care, respiratory therapy. Contract manufacturing of Operating tables and contract manufacturing and installation of Surgical Lights, for use in the area of Operating Room, ICU

Facility Activities:

Design and Development of Anesthesia Workstation, Ventilators, Medical Air Compressors, Vaporizers, for the area of anesthesiology, intensive care, respiratory therapy.



Additional facilities

No.10 Chaobai Street, Yingbin Road West, Yanjiao Development Zone, Langfang City, Hebei Province, 065201, P.R. China

Dun & Bradstreet D-U-N-S identification number : 55-448-8089

Detailed scope

Production, Distribution, and Servicing of Anesthesia Workstation, Ventilators, Medical Air Compressors, Vaporizers, for the area of anesthesiology, intensive care, respiratory therapy.

Contract manufacturing of Operating tables and contract manufacturing and installation of Surgical Lights, for use in the area of Operating Room, ICU





# EC DECLARATION OF CONFORMITY

ACCORDING TO ANNEXII WITHOUT CHAPTER 4 OF COUNCIL DIRECTIVE 93/42/EEC AND EN ISO 13485; 2016

MANUFACTURER: BEIJING AEONMED CO., LTD.

ADDRESS: Room 405, Basement 1 to 4th Floor of 901 Unit, Building 9, No.26

Outer Ring West Road, Fengtai District, Beijing 100070, China.

FACILITY: BEIJING AEONMED CO., LTD.

ADDRESS: No.2 factory, Block B, 10 Chaobai Street, Yingbin Road West, Yanjiao

Development Zone, 065201, Langfang, Hebei, China

EC REPRESENTATIVE: SHANGHAI INTERNATIONAL HOLDING CORP. GmbH (EUROPE)

ADDRESS: EIFFESTRA & 80 20537 HAMBURG GERMANY

DECLARE ON OUR OWN RESPONSIBILITY THAT

MEDICAL DEVICE NAME TYPE/ MODEL Serial Number

1 Ventilator VG70 VG70 (E) xxxxxxx
VG60 VG60 (E) xxxxxxx
VG50 VG50 (E) xxxxxxx

GMDN NAME AND CODE: Ventilator, Intensive Care 17429

CLASSIFICATION: II b, RULE 11

CONFORMITY ASSESSMENT ROUTE: ANNEX II WITHOUT CHAPTER 4

WE HEREWITH DECLARE THAT ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

THE MANUFACTUREER IS EXCLUSIVELY RESPONHSIBLE FOR THE DECLARATION OF CONFORMITY.

All APPLICABLE HARMONIZED STANDARD (PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES)

EN 60601-1: 2006/AC: 2013	EN1041:2013	ISO 13485:2016
EN 60601-1-2: 2015	EN ISO 14971:2012	ISO80601-2-12:2011
EN 60601-1-8: 2007/AC: 2013	EN 62366-1:2015	EN 62304:2015
EN 60601-1-6: 2015	ISO80601-2-55:2018	

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GmbH ADDRESS: RIDLERSTRA ß E65 80339 MÜNCHEN

**IDENTIFICATION NUMBER:** 0123

EC CERTIFICATE: G1 065725 0019 Rev.01 START OF CE-MARKING: 2013-11-30

QUALITY DIRECTOR: Wei Wang PLACE: BEIJING

Wang Wer 2019.7.26

SIGNATURE:

DATE:

RD-NBP-CE-010 Page 1 of 2 Ver1.04



# EC DECLARATION OF CONFORMITY

ACCORDING TO ANNEXII WITHOUT CHAPTER 4 OF COUNCIL DIRECTIVE 93/42/EEC AND EN ISO 13485; 2016

## TYPE: VG70/VG60/VG50

Rev.	Description	Draft	Audit	Approve
1.00	the first edition	Li Wei	Zhao Yanhui	Tang Guohong
		2013-12-10	2013.12.10	2013.12.10
1.01	change the No. of EC CERTIFICATE	Zhao yanhui	Chen Jing	Wang Wei
		2015-5-4	2015-5-4	2015-5-4
	Modify the EC CERTIFICATE	Wang Liping	Zhao yanhui	Wang wei
1.02		2017-12-07	2017-12-07	2017-12-07
	Standard update Add facility information	Wang jijuan	Zhao yanhui	Wang wei
1.03		2018-11-1	2018-11-1	2018-11-1
	Change Address and certification number	Wang Jijuan	Zhao yanhui	Wang wei
1.04		2019-07-26	2019-07-26	2019-07-26

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