Shangrila 510S

Portable Ventilator

Digitally signed by Grabazei Alexandru
Date: 2022.06.17 13:45:56 EEST
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Location: Moldova

TECHNICAL
DATA

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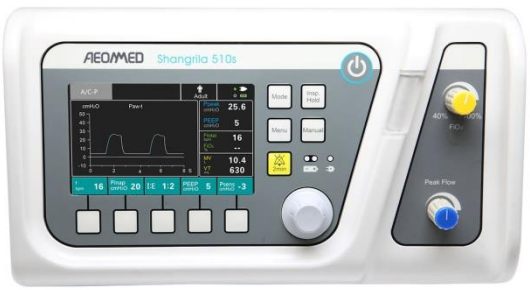
Shangrila 510S is a universally used model. Not only for emergency ventilation, but also it is suitable for ideal transport ventilation. The circumstances include on-site emergency treatment, pre-hospital transport, inter-hospital transport, and even intra-hospital transport.



Patient Type

Adult, Child, Infant (>3.5 kg)

Ventilation Modes

A/C-V with Sigh	A/C-P
SIMV-V	SIMV-P
SPONT/PSV	CPAP
MANUAL	

Enhancements

Apnea back-up ventilation	Manual breath
Alarm silence	

Parameter Setting

Tidal volume (Vt)	0-2000 mL
Pinsp	5-50 cmH_2O
Psupp	0-50 cmH_2O
CPAP (NIV)	0-30 cmH_2O
PEEP	0-30 cmH_2O
Pressure trigger	-20-0 cmH_2O
Flow trigger	2-30 L/min
Frequency (f)	1-120 bpm (A/C) 1-40 bpm (SIMV)
I:E ratio	4:1-1:10
Pause time (Tpause)	0-5 s
O_2 concentration	40-100 %
Inspiration flow	Max. 90 L/min

Monitoring Data

MV	VT	Frequency (f)
FiO_2	Ppeak	PEEP

Waveform Display

P-T	F-T

Alarm Setting

High MV	OFF, 1-25 L
Low MV	OFF, 0-24 L
High FiO_2	OFF, 50-100 %
Low FiO_2	OFF, 35-99 %
High Paw	6-80 cmH_2O
Low Paw	0-40 cmH_2O
AC power failure	Gas supply down
O_2 deficiency	MV high
Low battery	No VT
Apnea	CP high

Language

Chinese	English
Spanish	Italian
Turkish	Other languages

Environmental Requirements

Temperature	
Operating condition	-18-50 °C
Storage condition	-20-60 °C
Relative humidity	
Operating condition	15-95 %
Storage condition	10-95 %
Barometric pressure	
Operating condition	70-110 KPa
Storage condition	50-110 KPa

Electrical

AC voltage	100-240 V, 50/60 Hz
DC voltage	12 V
One battery run time	Minimum 4.5 hours
Two batteries run time	Minimum 10 hours

Gas Supply

Supply pressure (O2)	250-600 kPa
Flow	Max. 180 L/min

Physical Specifications

Total Weight	8 kg
Dimension (H*W*D):	168* 156 *300 mm
LCD screen	5" TFT
Communication Ports	RS232

AEONMED
Reliable Quality Thoughtful Service

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Edition: V201901

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 065725 0022 Rev. 02

Holder of Certificate: **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

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production, Distribution, Installation and Servicing of Anaesthetic Workstation, Vaporizer, Ventilator, Medical Air Compressor, Infusion Pump, Ceiling Pendent, Operating Table, Surgical Light, Multi-Parameter Patient Monitor, Syringe Pump, Patient Warming System, Videoscope System.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ1985904

Valid from: 2020-03-23
Valid until: 2022-12-31

Date, 2020-03-23

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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D-ZM-11321-01-00

Product Service

Certificate

No. Q5 065725 0022 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

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. 04

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

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 065725 0019 Rev. 04

Report No.: BJ19859071

Valid from: 2021-05-21
Valid until: 2024-05-26

Date, 2021-05-21

Christoph Dicks
Head of Certification/Notified Body

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

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