5.3.2 Mainboard

Figure 5-4

Connection and function	Leading feet	Function	Connection and function	Leading feet	Function
J1 Knob	1	TS-P	J8 Power supply input	1	External battery12V+
	2	GND		2	External battery 12V-
	3	TS-B		3	Adapter 12V-
	4	TS-A		4	Adapter 12V+
	5	5V			
	6	GND			
J2 PEEP Valve	1	A+(3.3V)	J11 Alarm lamp	1	5V
	2	NC		2	High alarm
	3	A-		3	Low alarm
J3 Solenoid valve	1	A+(12V)	J14 RS232 port	1	GND
	2	A-		2	RX
	3	NC		3	TX
	4	B-			
	5	B+(12V)			
J4	1	Signal+	J15	1	Loudspeaker
	2	GND		2	Loudspeaker

5.2.2 Pneumatic Connecting Diagram

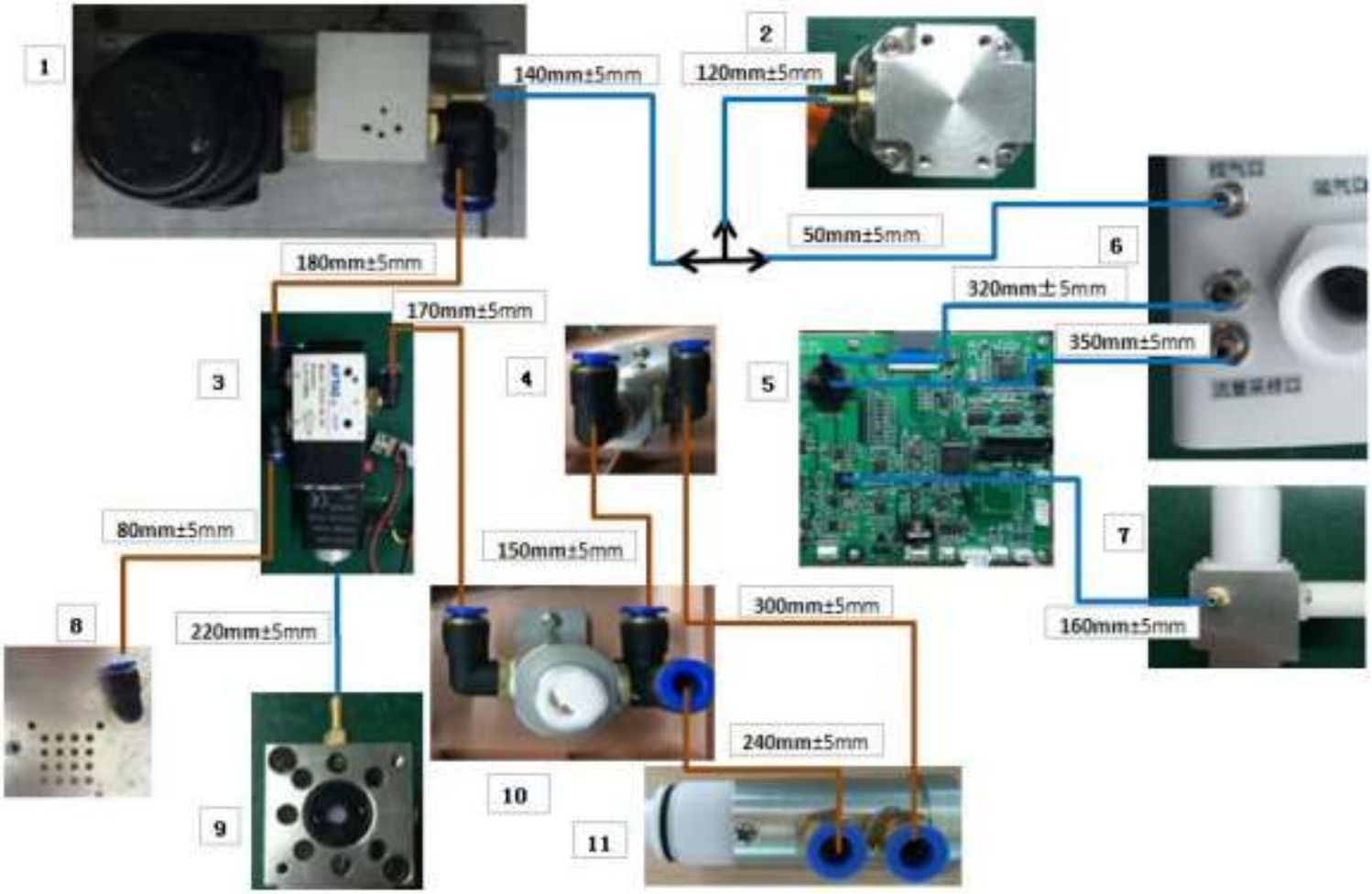

Figure 5-3 Pneumatic Connecting Diagram

	6/4PU tube		Φ2x1.5 silica gel tube
	Tee fitting	--	--
1	Reducing valve components	2	PEEP valve
3	Solenoid valve	4	Oxygen regulating valve
5	Mainboard	6	Back cover components
7	Expiratory components	8	Back board
9	Safety valve	10	Tee fitting
11	Venturi components		

5.3.2 Mainboard

Figure 5-4

Connection and function	Leading feet	Function	Connection and function	Leading feet	Function
J1 Knob	1	TS-P	J8 Power supply input	1	External battery12V+
	2	GND		2	External battery 12V-
	3	TS-B		3	Adapter 12V-
	4	TS-A		4	Adapter 12V+
	5	5V			
	6	GND			
J2 PEEP Valve	1	A+(3.3V)	J11 Alarm lamp	1	5V
	2	NC		2	High alarm
	3	A-		3	Low alarm
J3 Solenoid valve	1	A+(12V)	J14 RS232 port	1	GND
	2	A-		2	RX
	3	NC		3	TX
	4	B-			
	5	B+(12V)			
J4	1	Signal+	J15	1	Loudspeaker
	2	GND		2	Loudspeaker

ventilator to make it difficult to operate and risk device disconnection.

⚠**CAUTION:** If voltage fluctuation exceeds 10%, Aeonmed recommends using an AC stabilizer.

A new fully charged battery can provide ventilator work at least four hours with good working condition. The unit can be used without external power supply in special circumstances. This is not recommended.

External power socket is located in right side panel of ventilator, it is the power input port, and is connected to the AC power socket through the power adapter. If any faults are noted, stop using the ventilator immediately, and contact the manufacturer for maintenance.

5.2 Connect Oxygen Supply and Patient Circuit

Shangrila510S can work with oxygen bottle gas supply in the ambulance or on the wall. When the ventilator is working, make sure the gas supply has been connected without any false, no break, no leak or wrong connecting, and check the pressure monitor is right. If something wrong happens, stop using the ventilator immediately then check connectors. Please connect the oxygen supplies, patient circuit, and accessories fellow these steps:

⚠**CAUTION：**

- Ensure the gas supply is always between 0.25MPa and 0.6MPa.
- Connect gas supply to inlet on the left side of ventilator.
- The high-pressure input ports of the ventilator will be used as Fresh Gas and will be supplied to the patient.

⚠**CAUTION：** The silicone threaded tube shown in the figure below is schematic figure. If there are inconsistency between the figure and the actual product, the actual product shall govern.

Step 1

Connect silicone threaded tube to the right hand side panel suction port of the ventilator.

Step 2

Connect pressure controlling pipe

Step 3

Connect the O_2 inlet pipe

Step 4

Connect flow sampling pipe

Step 5

Connect gas outlet pipe to breath valve

Step 6

Connect pressure controlling pipe

Step 7

Connect flow sampling probe

Step 8

Connect flow sampling pipe

Step 9

Connect elbow

Step 10

Connect the test lung

⚠**WARNING:**

- Connect only oxygen to the oxygen inlet. Do not attempt to connect any other gas.
- To minimize the risk of patient injury, use only patient circuits qualified for use in oxygen-enriched environments with the Shangrila510S ventilator. To avoid an electrical shock hazard, do not use antistatic or electrically conductive tubing. To ensure a leak-tight connection, only use connectors and tubes with ISO-standard cone and socket.
- Aeonmed recommends that you use one of the patient circuits identified by Aeonmed, or their equivalents to ensure that the maximum pressure/flow values specified by EN794-1 are not exceeded (see related content in part 9 specifications). Using a circuit with a higher resistance does not prevent ventilation but can cause compromise the patient's ability to breathe through the circuit.
- Only use the ventilator to patient whose tidal volume over 20ml and avoirdupois over 3.5kg. This machine is not suitable with newborn. Only use this ventilator for patient whose tidal volume over 20ml and body weight is over 3.5kg. This machine is not suitable for use on newborns.
- The distance between breathing valve and patient is as short as possible, or it can increase the concentration of CO_2.

For optimal ventilator performance, let the unit run for at least 3 minutes before using on a patient to allow system to warm up if necessary.

⚠**NOTE**：Alarm functionality is tested and verified as part of ventilator test before using. Details about Alarms will be displayed in part 4.

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

TÜV SÜD Product Service

Certificate

No. Q5 065725 0022 Rev. 03

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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:

TÜV SÜD EN ISO 13485 tuvsud.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, 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). 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:Q5 065725 0022 Rev. 03

Report No.: BJ22085903

Valid from: 2023-01-01
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Christoph Dicks
Head of Certification/Notified Body

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TÜV SÜD Product Service

Certificate

No. Q5 065725 0022 Rev. 03

Applied Standard(s):

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

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TÜV SÜD Product Service

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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:

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Product Category(ies):

Anaesthetic Workstation, Vaporizer, Ventilator, Medical Air Compressor, Infusion Pump, Ceiling Pendant, Multi-Parameter Patient Monitor, Videoscope System, Patient Warming System.

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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

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