Ambulanc (Shenzhen) Tech Co. Ltd.

Emergency transport and Critical Cure Ventilator of T6

Certificate of Analysis

Product name: Emergency transport and Critical Cure Ventilator

Model:T6 Batch No.: T62110019

Test items	requirements				Test results
Appearance	There are no scratch, sags and crests, cracks, smudges, etc. on the appearance with uniform color. All structural connections are reliable, and the gaps between the connecting joints are uniform.				■ Qualified □ Unqualified
label	The label is pasted flat and firm and the silkscreen is clear, with correct contents and direction and without skewing.				■ Qualified □ Unqualified
Functional	Shuttle: The shuttle can control movement, selection, confirmation, parameter adjustment and confirmation after startup. Button: press the host button,the host implements the corresponding button function. Touch screen: Touch function is normal.				■ Qualified □ Unqualified
Control Parameter precision	Respiratory rate 1 ~ 100:±1 Above 100: ±5% of Set value (unit: bpm)	1	0 ~ 2	1	■ Qualified □ Unqualified
		60	59 ~ 61	60.4	
		100	95 ~ 105	100.5	
		150	142.5~157.5	151.1	
	Inspiration time ±0.1 or ±10% of set value, whichever is greater	0.2	0.1~0.3	0.22	■ Qualified □ Unqualified
		1	0.9~1.1	1.03	
		2	1.8~2.2	2.01	
		10	9~11	10.08	

	(unit: s)				
	Inspiration/expiration ratio 2:1 ~ 1:4: ±10% of set value Other: ±15% of set value	4:1	4.6:1 ~ 3.4: 1	3.97:1	■ Qualified □ Unqualified
		1:1	0.9:1 ~ 1:0.9	1.05:1	
		1:10	1:8.5 ~ 1:11.5	1:9.11	
	Tidal volume ± (1.5ml + 15% of set value) (Neonate) ± (10ml + 10% of set value) (Adult/Pediatric) (unit: ml)	2	0.2 ~ 3.8	1.7	■ Qualified □ Unqualified
		10	7 ~ 13	10.1	
		20	15.5 ~ 24.5	18.0	
		100	80 ~ 120	103.3	
		300	260 ~ 340	300.1	
		1000	890 ~ 1110	999	
		2000	1790 ~ 2210	1929	
	FiO_2 ± (3vol.%+1% of set value) (unit: %)	21	18~24	20.8	■ Qualified □ Unqualified
		40	37~43	40.8	
		60	57~63	61.2	
		70	67~73	70.9	
		100	97~100	100.6	
	Inspiratory pressure ± (0.9 cmH2O ±10% of set value) (unit: cmH_2O)	1	0~2	0.9	■ Qualified □ Unqualified
		40	35.1~44.9	40.75	
		60	53.1~66.9	60.76	
		90	80.1 ~ 99.9	91.01	
	CPAP/PEEP ± (0.9 cmH2O ±10% of set value) (unit: cmH_2O)	0	0~0.9	0.9	■ Qualified □ Unqualified
		10	8.1~11.9	10.15	
		20	18.1 ~ 21.9	20.06	
		40	36~44	40.88	
	Oxygen flow rate ±2 or ±15 of set value, whichever is greater	2	0~4	1.99	■ Qualified □ Unqualified
		20	17~23	19.4	
		25	35.5~34.5	24.9	
		65	55.25~74.75	61.7	

	(unit: L/min)				
Monitoring Parameter precision	Respiratory frequenc ±2bpm or ±5% of reading value, whichever is greater (unit: bpm)	1	0~4	1	■ Qualified □ Unqualified
		60.2	58~62	60.2	
		101	95~105	100.5	
		151	142.5~157.5	151.1	
		250	237.5~262.5	250	
	Tidal Volume 0～100: ± (2+15% of reading value) 100～300: ± (3+15% of reading value) Above 300: ±15% of reading value (unit: ml)	1	0～3.61	1.9	■ Qualified □ Unqualified
		9	4.9～11.3	8.1	
		19	12.9～22.1	19.7	
		95	71.7～104.1	104.9	
		982	849.5～1148.5	999	
		2048	1634.5～2211.5	1942	
		2959	2468.4～3339.6	2882	
	Oxygen concentration ± (2.5vol.%+2.5% of reading value) (unit: %)	21	17.8～23.8	20.8	■ Qualified □ Unqualified
		40	37.3～44.3	40.8	
		60	57.2～65.2	61.2	
		70	66.6～75.2	70.9	
		99	98.1～103.1	100.6	
	Airway pressure ± (2 ±4% of reading value) (unit:：cmH20)	0.7	0～3.1	0.8	■ Qualified □ Unqualified
		40.7	37.7～45.0	41.8	
		60.7	56.7～65.6	61.2	
		90.4	86～97.4	90.2	
		103	97.2～109.5	103.3	
	CO_2 concentration 0～40: ±2 41～70: ±5% of reading value	38 (5%)	36~40	38.6	■ Qualified □ Unqualified
		60.8 (8%)	57.4~64.1	62.3	
		149.7 (19.7%)	135~165	152.4	

	71～100: ± 8% of reading value 101～150: ± 10% of reading value (unit： mmHg)				
Alarm Function	Air source pressure alarm，Airway pressure alarm，Tidal volume alarm，Minute ventilation alarm，Respiratory frequency alarm，Oxygen concentration alarm，$EtCO_2$ alarm，PEEP alarm，Apnea alarm，Battery level alarm，when the parameter monitoring value reaches the alarm condition,the host will generate the above alarm.				■ Qualified □ Unqualified
Lable and manual	The lable of the T6 should include a) product name,Mode,b)tests per kit ,c)LotNo.,expiration,storage,d)Manufacturer address				■ Qualified □ Unqualified
Attachment	It should be consistent with the packing list.				■ Qualified □ Unqualified
package	Package is intact,Lables and indicators are correct.				■ Qualified □ Unqualified
Carton box	The carton box should be free of stain and impact mark, with flat surface and clear and correct printed label.				■ Qualified □ Unqualified
conclusion	Qualified				

Checked by/Date: 李赛 2021.10.25

Approved by/Date: 王瑞强 2021.10.25