Ambulanc (Shenzhen) Tech. Co., Ltd.

Product description for T6

Product: Ventilator

Model: T6

Revision: A1.0

Date: 2020 Dec 20

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1.Product Description

Product Name: Ventilator

Model: T6

Classification: IIb

The following is the original MDD Rule11，

All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class IIa, unless this is done in a manner:

— that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in Class IIb.

2. Intended use

This product is mainly used for emergency ventilation rescue for patients with respiratory

failure, often used in emergency places and transfer processes (such as in ambulances); and used in and outside hospitals for rescue and transfer, ICU, emergency ICU, mechanical ventilation during surgery, and surgical procedures. Mechanical ventilation support for patients during post-anaesthesia recovery and hospital treatment

Scope of application

T6 can be applied in the following cases:

Emergencies

- First-aid resuscitation on the site;
- Ongoing emergency lasting for a long time (e.g. fire); and
- Temporary oxygen uptake via respiratory mask and ventilation via tracheal cannula.

Transfer of patient

- During first-aid treatment on surface, on the sea or in the air;
- During transfer from ward to treatment room in hospital; and
- During transfer from hospital to any other location.

User Qualification

The person operating T6 must be qualified and meet the following conditions:

- Provided with proper medical training in and technical guidance on respiration equipment.
- Provided with training in clinical application with T6 by Shenzhen Amoul Technology Limited.
- Improper operation of the equipment may cause serious injury to persons (the operator and patient).

3. Contraindications:

Bullae of lung, pneumothorax, hemoptysis, active tuberculosis, bronchopleural fistula, pleural effusion, acute myocardial infarction.

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Warning:

T6 is suitable for patients with respiratory failure (infants, children, adults) for ventilation

assistance and respiratory support.

4. Components and accessories

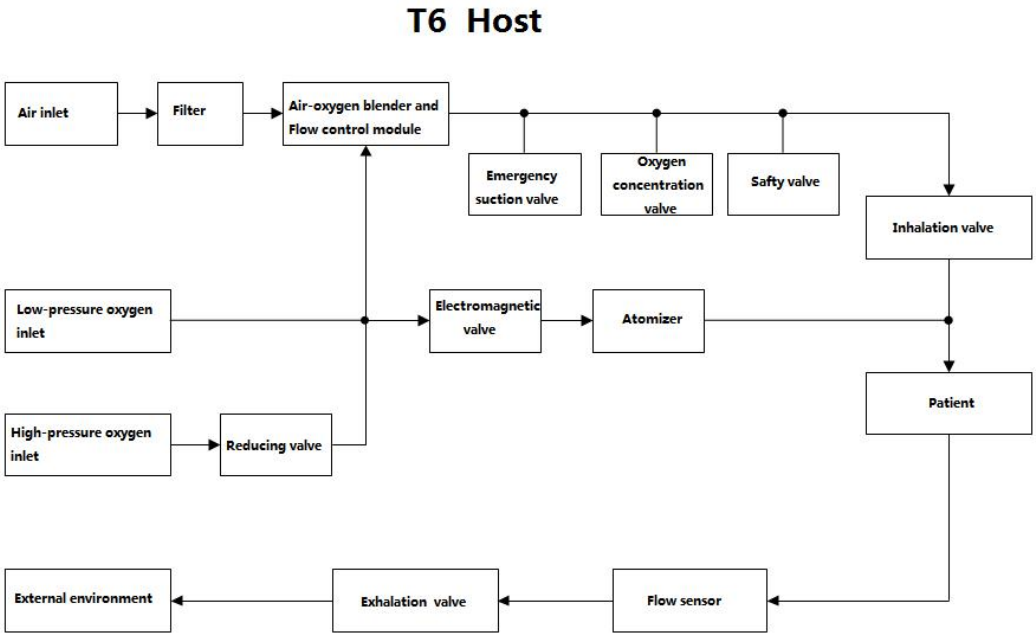
The accessories of T6 includes:

- Reusable double respiratory hose
- Flow Rate Sensor
- Big hanger for rubber mask
- Reusable rubber mask
- Rubber headgear
- High-pressure gas source hose
- Low-pressure gas source hose
- Power adapter
- AC power cable
- Rechargeable Li Battery

5.Product mechanism of action

Use mechanical force to generate or enhance the patient's breathing action and work of breathing. When inhaling, the ventilator mixes the gas with the air-oxygen ratio set by the doctor and presses it into the patient’s trachea, bronchus and lungs; when exhaling, the ventilator can use the elastic retraction of the lungs and thorax to make the lungs and The alveoli shrink automatically and can also be exhausted with the help of a ventilator.

6.Product design principle



7. Type of material

The host: PC+ABS
reusable mask(Adult),reusable ventilation hose:silicone

8. Parameter specification

Control parameters	Range	Accuracy
Respiratory rate	Infant: 0,1～150bpm Adult/Pediatric: 0,1～100bpm	Error: ±1bpm (0-100bpm); ±5% of set value (above 100bpm)
Inspiratory time	0.20-10S	Error: ±0.1s or ±10% of the set value, whichever is greater
Tidal volume	Adult: 100～2000mL Pediatric: 20～300mL Infant: 2～100mL	± (10 mL + 10% of the setting value) (pediatric/adult mode); ± (1.5 mL + 15% of the setting value) (infant mode);;
Oxygen	21%-100%	± (3 vol.%+ 1% of set value)

concentration		While 500ml, 21%-90% response time : 140s; While 150ml, 21%-90% response time : 160s; While 30ml, 21%-90% response time : 220s
Inspiratory pressure	1-90cmH_2O	± (0.9 cmH20 + 10% of the setting value
I:E	4：1～1：10	2:1～1:4：±10% of set value; Others：±15% of set value
Upper pressure limit	10-100 cmH_2O	± (2cmH_2O+ 5% of set value)
Pressure trigger	-20～-0.5 cmH_2O	± (0.4 cmH20 + 10% of the setting value)
Positive end expiratory pressure	0-40cmH_2O	± (0.9cmH20 + 5% of the setting value)
Pressure support	Closed, 1-90cmH_2O	± (0.9cmH20 + 5% of the setting value
Flow trigger	Infant:0.2 ～ 5.0L/min Adult/Pediatric:0.5~ 20.0L/min	± (0.1 L/min + 10% of the setting value) (infant mode); ± (0.4 L/min + 10% of the setting value) (adult/pediatric mode)
Pressure rise time	60ms-2000ms	± (0.05s + 20% of the setting value)
Sensitivity of expiratory trigger	5%-85 %	± 5% (absolute error
Oxygen therapy flow	Adult: 2 ～ 65 L/min Pediatric: 2 ～ 25 L/min infant: 2～ 20 L/min	± 2 L/min or ± 15%, whichever is greater
High-level pressure	1-90cmH_2O	± (2cmH_2O+ 5% of set value)
Low-level	0-40cmH_2O	± (2cmH_2O+ 5% of set value)

pressure		
High-level pressure time	0.2-30s	Error: ±0.1s or ±10% of the set value, whichever is greater
Low-level pressure time	0.2-30s	Error: ±0.1s or ±10% of the set value, whichever is greater
Apnea	5-60s	Error: ±0.1s or ±10% of the set value, whichever is greater
Inspiratory pause	0%-60%	
Monitored parameters		
Respiratory rate	0～250bpm	±2bpm or ±5% of actual reading, whichever is greater
Inspiratory tidal volume	0-3,000ml	± (2mL+ 15% of actual reading) (infant mode); ± (3mL+ 15% of actual reading) (pediatric mode); ±15% of actual reading (adult mode)
Expiratory tidal volume	0-3,000ml	± (2mL+ 15% of actual reading) (infant mode); ± (3mL+ 15% of actual reading) (pediatric mode); ±15% of actual reading (adult mode)
Minute volume	0-100L/min	± (0.4L/min+15% of actual reading)
I:E	150:1-1:150	2:1～1:4：±10% of set value; Others：±15% of set value
Oxygen concentration	21%-100%	± (2.5 vol.%+2.5% of actual reading)
Airway pressure	0-105cmH_2O	± (2cmH_2O+4% of actual reading)
I:E	299:1-1:299	
Positive end expiratory pressure	0-100	± (2cmH_2O+4% of actual reading)
Resistance	5 to 300	
Time constant	50-1000	
Closure	-105-5	±1-25% of the actual reading

pressure(P0.1)		
Rapid-shallow-breathing index	0-10000	±10 of actual reading)
Compliance	0.5-100	