

Document type	Technical document	Project number	T6 transport ventilator(hereby reference 624)
Document number	R -624-01	Print requirements	<input type="checkbox"/> colorful <input checked="" type="checkbox"/> black and white

624 Quality Record

Prepared by		Verified by		Approved by	
Date	2022-09-29	Date	2022-09-29	Date	2022-09-29

Reference

Document number	Description

Revision Record

Version	ECR/PCN TCN	Change	Prepared by	Date of approval
A1.0	/	First issue	Li Sai	2021.09.10
A 2.0	ECR20210937	Add abnormal power outage alarm	Li Sai	2021.10.26
A 3.0	ECR20211247	Optimize the test content	Li Sai	2021.12.22
A 4.0	ECR20220102	Optimize the test content	Li Sai	2022.01.20
2.0	PCN20220401	Add the interface test items and new test equipment, the simulated lung	Huang Hankang	2022.04.07

Distribution department	<input checked="" type="checkbox"/> Production Department <input type="checkbox"/> Purchase Department <input type="checkbox"/> Quality Department <input type="checkbox"/> Marketing Department <input type="checkbox"/> Research and development system
Archive method	<input checked="" type="checkbox"/> Electronic Document <input checked="" type="checkbox"/> Paper Document <input type="checkbox"/> Other:

Product information and precautions

Product name: Ventilator

Process code: 624

Product model: T6

Host serial number:

Product serial number:

Production Task Order No.:

Date of manufacture:

Test form notes:

1. When passing the tests, check "OK"; if failure, check "NG"; no test is involved, check "NA".
2. No "NG" test in the test form, check "PASS"; have "NG" test in the test form, check "FAIL", execute the company troubleshooting process.

Test equipment record sheet

No.	Name	Type	Number	Validity
1	Air flow analyzer			
2	Electrical safety analyzer			
3	Pressure-resistant tester			
4	CO ₂ gas module			
5	Smoker			
6	Noise meter			
7	Stopwatch			
8	Air source (with reduction valve and pressure gauge)	/	/	/
9	Reduction valve	/	/	/
10	Flow meter (100 mL/min)	/	/	/
11	Simulated lung			
12	Multimeter			
13	624 Current leakage test tooling			

Product Assembly Test Traceability Sheet

Assembly traceability record sheet

No.	Component	Assembly process	Version	Assembly by	Examined by	Remarks
1	624-Air Source Control Module	D-2.624.00018				
2	624-Air outlet line assembly	D-2.624.00016				
3	624-Air path assembly	D-2.624.00015				
4	624-Front shell assembly	D-2.624.00011				
5	624-Rear shell assembly	D-2.624.00012				
6	624-Mainframe	D-624-01				
7	624-Electrical connection	D-624-03				
8	624-Packaging	D-624-02				

Test traceability record sheet

No.	Component	Debugging process	Version	Debug by	Examined by	Remarks
1	Main board	F-2.624.00009				
2	Power board	F-2.624.00010				
3	624-Air Source Control Module	F-2.624.00018				
4	624-Air outlet line assembly	F-2.624.00016				
5	Whole machine aging	L-000-01				
6	Whole machine test	Q-624-1				
7	Electrical safety test	Q-624-02				

Components and material traceability records sheet

No.	Name	The trace number	No.	Name	The trace number
1	Power supply module (1.119.00039T)		5	Oxygen Battery CGQ03MOX3T1	




				(1.114.00010)	
2	Main board (2.624.00009)		6	Three-way electromagnetic valve (1.205.00204)	
3	Power board (2.624.00010)		7	Three-way electromagnetic valve (1.205.00349)	
4	Respiratory module (1.205.00223)		8	624-Battery pack assembly (2.624.00024)	
Software version trace					
No.	Software name	Version	No.	Software name	Version
1	Main board software		2	Power board software	
Filed by / Date			Reviewed by / Date		

Appearance, power supply and function inspection record sheet

(in-process inspection PQC)

Test item		Inspection content	Receiving standard	Inspection result
Appearance inspection	1	Left view	Appearance, label, silk screen 1. No scratch, unevenness, cracking, dirt with uniform color; 2. The silicone plugs of CO2 and SPO2 are flush with the outer surface with no unevenness, and the silk screen is clearly visible; the position of CO2 and SPO2 joints is not at the wrong position and fitting the surface tightly; the gaps between the handle and the outer surface are uniform without loosening.	<input type="checkbox"/> OK <input type="checkbox"/> NG
	2	Front view	Appearance, label, silk screen 1. No scratch, unevenness, cracking, dirt with uniform color; 2. Inspiratory valve, expiratory valve, atomization, flow sensor, button, company logo, silk screen of power supply indicator is clear, the content and direction is correct, no skew; 3. The gap around the screen is uniform, the power indicator light is concave compared with the outer surface, and the indicator light is bright 1 meter away; the shuttle and concave face gap is uniform, no tilt and good rotation; there is no obvious gap between the mat and the front shell, there is no glue on the edge with close fit; the color of alarm indicator light is uniform, no obvious protrusion, and the alarm indicator signal can be clearly observed from 4 meters away. 4. Block, atomization, flow sensor connector is not skew, the Y-type pipe can be closely combined with the plug, and the color of the flow sensor is correct.	<input type="checkbox"/> OK <input type="checkbox"/> NG
	3	Right view	Appearance, label, silk screen 1. No scratch, unevenness, cracking, dirt with uniform color; 2. The silk screen of air outlet is clearly visible, without skew, with correct content and direction; 3. The gap between the handle and the outer surface is uniform and not loose; the horn holes are evenly distributed, sized and without blockage.	<input type="checkbox"/> OK <input type="checkbox"/> NG
	4	Rear view	Appearance, label, silk screen 1. No scratch, unevenness, cracking, dirt with uniform color; 2. The silk screen of the external power supply, gas source pressure and battery keys are clearly visible, without skew,	<input type="checkbox"/> OK <input type="checkbox"/> NG

			<p>with correct content and direction;</p> <p>3. The rear cover fits with the outer surface, the gap is small and uniform; the length and thickness of the two hooks are the same, can be 90° rotation, the hook vertically downward without bending. The battery can be easily loaded in, and can hear the "click" sound, the gap is small and uniform, the battery button is slightly moved, the battery can easily pop up; the footpad and the rear shell have no obvious gap, there is no glue on the edge with close fit.</p>	
	5	Top view	<p>Appearance, label, silk screen</p> <p>1. No scratch, unevenness, cracking, dirt with uniform color;</p> <p>2. The handle is firm without loose, the gap is small and uniform; the alarm indicator color is uniform, the edge is not obvious protrusion, and fit with the shell.</p>	<input type="checkbox"/> OK <input type="checkbox"/> NG
Power test	1	Light color test	<p>Check that the light color is correct.</p> <p>Indicator light: power lamp and battery light are green, alarm light is yellow or red.</p>	<input type="checkbox"/> OK <input type="checkbox"/> NG
	2	Battery power supply test	<p>Check the switch under battery power supply.</p> <p>Switch on and off 5 times and test the following contents.</p> <p>1、 Power on self-check: company LOGO and self-check progress bar appear, battery light on;</p> <p>2、 Operating status: the upper left corner of the screen displays power and power supply, not connected;</p> <p>3、 Shutdown: all indicator lights are out of power;</p> <p>Power on, self-inspection, working state, shutdown did not appear screen malfunction, crash, automatic restart and other bad.</p>	<input type="checkbox"/> OK <input type="checkbox"/> NG
	3	External power supply test	<p>Check the switch under external power supply.</p> <p>Switch on and off 5 times and test the following contents.</p> <p>1、 Power on self-check: company LOGO and self-check progress bar, power light on;</p> <p>2、 Operating status: the power lamp is on, the upper left corner of the screen shows no power, the power supply is connected;</p> <p>3、 Shutdown: all indicator lights are out of power;</p> <p>Power on, self-inspection, working state, shutdown did not appear screen, crash, automatic restart and other bad.</p>	<input type="checkbox"/> OK <input type="checkbox"/> NG

	4	Battery charging test	Check the insufficient battery charging.	<p>a) Install the adapter and the uncharged battery, turn on the host engine, and enter the working mode.</p> <p>b) Battery power icon shows charging, power light on, and battery light flashing.</p> <p>c) When the battery power icon displays 100%, the battery is fully charged and the battery light turns on normally.</p> <p>After shutdown: plug in the adapter, the power light and battery light are all on; unplug the adapter, and the power light and battery light are all out.</p>	□OK □NG
Key test	1	Power on / off button test	The Power on / off button function is normal	<p>1. Under the shutdown state, press the "on / off" button, the machine can turn on normally;</p> <p>2. In the standby interface, press the "on / off" button, the machine can shut down normally;</p> <p>3. When the machine is working normally, press and hold on the "on / off" key for 5-10s, and the machine is shut down.</p>	□OK □NG
	2	Alarm reset button	Test the function of the alarm reset key	Simulate one or more alarm information, press the alarm reset button, the alarm information disappears, and the alarm information recovers after 30 seconds.	□OK □NG
	3	atomization button test	Test if function of atomization is normal	Press the atomization button when the machine is working normally, the atomization icon pop up at the interface and the countdown begins.	□OK □NG
	4	Menu key test	Test if the menu key is normal	Press the menu button "  ", the main interface will pop up the main menu, press the menu button again, the main interface is closed.	□OK □NG
	5	Lock screen button test	Test if the function of lock screen button is normal	<p>Press the lock screen button "", the display cannot perform touch control, and the shuttle is used normally.</p> <p>Press the lock screen button again, the screen touch back to normal, the shuttle is used normally.</p>	□OK □NG
	6	Muting button test	Test if the function of muting button is normal	Simulated alarm, press the mute key "  ", the alarm sound disappears, the alarm muting icon appears, press the mute button again, the mute button light is out, the alarm sound.	□OK □NG

	7	Flying shuttle test	Test if the flying shuttle use function is normal	The shuttle can control movement, selection, validation and parameter adjustment and validation after starting on.	<input type="checkbox"/> OK <input type="checkbox"/> NG
interface testing	1	USB	Test the USB interface function	Insert the U disk, view the main interface, USB icon in the upper right corner.	<input type="checkbox"/> OK <input type="checkbox"/> NG
	2	VGA (Sampling inspection)	Sampling inspection of VGA interface function	Use the VGA cable to connect the host and the display screen, observe the screen display, no color difference, screen flashing, display malfunction phenomenon. (10 being selected and 1 being inspected)	<input type="checkbox"/> OK <input type="checkbox"/> NG
Power consumption test	1	quiescent power dissipation	Test the shutdown state power consumption	No power cord, installation, fully charged battery tooling (624 leakage current test tooling), so that the host is in the shutdown state; Measure the power consumption in the shutdown state using the multimeter (select "mA" current gear). Standard requirements: the measured value is <1mA.	<input type="checkbox"/> OK <input type="checkbox"/> NG
conclusion:			<input type="checkbox"/> PASS <input type="checkbox"/> FAIL		
Test / Date:					

Control / monitoring parameters test record sheet (Process Inspection PQC)

No.	test item	Inspection content	Acceptance standard	Host monitoring value	The VT monitoring value	Inspection result
1	Inspiratory tidal volume (mL)	100	80~120			<input type="checkbox"/> OK <input type="checkbox"/> NG
		500	440~560			
2	Expiratory tidal volume (mL)	100	80~120			<input type="checkbox"/> OK <input type="checkbox"/> NG
		500	440~560			
3	inspiratory duration (s)	2	1.8~2.2	/		<input type="checkbox"/> OK <input type="checkbox"/> NG
4	Respiratory rate (bpm)	5	4~6			<input type="checkbox"/> OK <input type="checkbox"/> NG
		20	19~21			
5	oxygen concentration (%)	21	20~24			<input type="checkbox"/> OK <input type="checkbox"/> NG
		40	37~43			
		100	97~103			
6	CPAP/PEEP (cmH2O)	5	3.85~6.15			<input type="checkbox"/> OK <input type="checkbox"/> NG
		10	8.6~11.4			
		30	27.6~32.4			
7	Inspiratory pressure (cmH2O)	5	3.6~6.4			<input type="checkbox"/> OK <input type="checkbox"/> NG
		20	17~22.1.9			
		40	35.1~44.9			
conclusion:		<input type="checkbox"/> PASS <input type="checkbox"/> FAIL				
Test / Date:						
Review / Date:						

Whole machine aging record (process inspection PQC)

Aging Start Time:		Aging End Time:		Total aging time (8h):	
The inspection stage	surveillance project	Accept the standard	actual measurement	detection result	
Before aging	Boot self-inspection	Boot normally	/	<input type="checkbox"/> OK <input type="checkbox"/> NG	
	ambient temperature	40°C ~ 50°C		<input type="checkbox"/> OK <input type="checkbox"/> NG	
After aging	Boot self-inspection	Boot normally	/	<input type="checkbox"/> OK <input type="checkbox"/> NG	
	ambient temperature	40°C ~ 50°C		<input type="checkbox"/> OK <input type="checkbox"/> NG	
fault phenomenon					
conclusion:	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL				
remarks:	1、 If there is any fault before aging, it is necessary to remove the fault before aging; 2、 If there is a fault after aging, describe it in the fault phenomenon. If there is no fault, fill in				
Test / Date:					
Review / Date:					




Electrical Safety Test Record (Final Inspection FQC) ○AC121V ○AC264V ○50HZ ○60HZ						
project	examination requirements		Acceptance criteria	measured value	Test conclusion	
Ground Resistance	Normal state		$\leq 0.1\Omega$		<input type="checkbox"/> OK <input type="checkbox"/> NG	
	Single fault state		$\leq 0.2\Omega$		<input type="checkbox"/> OK <input type="checkbox"/> NG	
Leakage Current	Outer shell leakage current		Normal state	$\leq 100\mu A$		<input type="checkbox"/> OK <input type="checkbox"/> NG
			Single fault state	$\leq 500\mu A$		<input type="checkbox"/> OK <input type="checkbox"/> NG
	Current leakage of patient	B, BF type application part	Normal state	$\leq 10\mu A$		<input type="checkbox"/> OK <input type="checkbox"/> NG
			Single fault state	$\leq 50\mu A$ (D.C)		<input type="checkbox"/> OK <input type="checkbox"/> NG
					$\leq 500\mu A$ (A.C)	
		Add 110% grid voltage to the F-type application section	single fault	$\leq 5000\mu A$		<input type="checkbox"/> OK <input type="checkbox"/> NG
	leakage current to the ground		Normal state	$\leq 500\mu A$		<input type="checkbox"/> OK <input type="checkbox"/> NG
			Single fault state	$\leq 1000\mu A$		<input type="checkbox"/> OK <input type="checkbox"/> NG
Electric strength	Between A-a1, setting: high pressure 1.5kv (Between charged parts and palpable metal parts with protected ground)		It took 60 seconds without breakdown and flashover		<input type="checkbox"/> OK <input type="checkbox"/> NG	
	Between A-a2, setting: high pressure 4kv (Between charged parts and unprotected ground outer shell components)		It took 60 seconds without breakdown and flashover		<input type="checkbox"/> OK <input type="checkbox"/> NG	
	Between B-a, setting: high pressure 4kv (Between the applied part and the charged part)		It took 60 seconds without breakdown and flashover		<input type="checkbox"/> OK <input type="checkbox"/> NG	
	Between B-d, setting: high pressure 1.5kv (Between the application section and the outer shell)		It took 60 seconds without breakdown and flashover		<input type="checkbox"/> OK <input type="checkbox"/> NG	
Whether the boot is normal after the test					<input type="checkbox"/> OK <input type="checkbox"/> NG	
conclusion:		<input type="checkbox"/> PASS <input type="checkbox"/> FAIL				
Test / Date:						

Appearance, power supply and function inspection record sheet

(final inspection PQC)

Test item		Inspection content	Receiving standard	Inspection result
Appearance inspection	1	Left view	Appearance, label, silk screen 1. No scratch, unevenness, cracking, dirt with uniform color; 2. The silicone plugs of CO2 and SPO2 are flush with the outer surface with no unevenness, and the silk screen is clearly visible; the position of CO2 and SPO2 joints is not at the wrong position and fitting the surface tightly; the gaps between the handle and the outer surface are uniform without loosening.	<input type="checkbox"/> OK <input type="checkbox"/> NG
	2	Front view	Appearance, label, silk screen 1. No scratch, unevenness, cracking, dirt with uniform color; 2. Inspiratory valve, expiratory valve, atomization, flow sensor, button, company logo, silk screen of power supply indicator is clear, the content and direction is correct, no skew; 3. The gap around the screen is uniform, the power indicator light is concave compared with the outer surface, and the indicator light is bright 1 meter away; the shuttle and concave face gap is uniform, no tilt and good rotation; there is no obvious gap between the mat and the front shell, there is no glue on the edge with close fit; the color of alarm indicator light is uniform, no obvious protrusion, and the alarm indicator signal can be clearly observed from 4 meters away. 4. Block, atomization, flow sensor connector is not skew, the Y-type pipe can be closely combined with the plug, and the color of the flow sensor is correct.	<input type="checkbox"/> OK <input type="checkbox"/> NG
	3	Right view	Appearance, label, silk screen 1. No scratch, unevenness, cracking, dirt with uniform color; 2. The silk screen of air outlet is clearly visible, without skew, with correct content and direction; 3. The gap between the handle and the outer surface is uniform and not loose; the horn holes are evenly distributed, sized and without blockage.	<input type="checkbox"/> OK <input type="checkbox"/> NG
	4	Rear view	Appearance, label, silk screen 1. No scratch, unevenness, cracking, dirt with uniform color; 2. The silk screen of the external power supply, gas source pressure and battery keys are clearly visible, without skew,	<input type="checkbox"/> OK <input type="checkbox"/> NG

			<p>with correct content and direction;</p> <p>3. The rear cover fits with the outer surface, the gap is small and uniform; the length and thickness of the two hooks are the same, can be 90° rotation, the hook vertically downward without bending. The battery can be easily loaded in, and can hear the "click" sound, the gap is small and uniform, the battery button is slightly moved, the battery can easily pop up; the footpad and the rear shell have no obvious gap, there is no glue on the edge with close fit.</p>	
	5	Top view	<p>Appearance, label, silk screen</p> <p>1. No scratch, unevenness, cracking, dirt with uniform color;</p> <p>2. The handle is firm without loose, the gap is small and uniform; the alarm indicator color is uniform, the edge is not obvious protrusion, and fit with the shell.</p>	<input type="checkbox"/> OK <input type="checkbox"/> NG
Power test	1	Light color test	<p>Check that the light color is correct.</p> <p>Indicator light: power lamp and battery light are green, alarm light is yellow or red.</p>	<input type="checkbox"/> OK <input type="checkbox"/> NG
	2	Battery power supply test	<p>Check the switch under battery power supply.</p> <p>Switch on and off 5 times and test the following contents.</p> <p>1、 Power on self-check: company LOGO and self-check progress bar appear, battery light on;</p> <p>2、 Operating status: the upper left corner of the screen displays power and power supply, not connected;</p> <p>3、 Shutdown: all indicator lights are out of power;</p> <p>Power on, self-inspection, working state, shutdown did not appear screen malfunction, crash, automatic restart and other bad.</p>	<input type="checkbox"/> OK <input type="checkbox"/> NG
	3	External power supply test	<p>Check the switch under external power supply.</p> <p>Switch on and off 5 times and test the following contents.</p> <p>1、 Power on self-check: company LOGO and self-check progress bar, power light on;</p> <p>2、 Operating status: the power lamp is on, the upper left corner of the screen shows no power, the power supply is connected;</p> <p>3、 Shutdown: all indicator lights are out of power;</p> <p>Power on, self-inspection, working state, shutdown did not appear screen, crash, automatic restart and other bad.</p>	<input type="checkbox"/> OK <input type="checkbox"/> NG

	4	Battery charging test	Check the insufficient battery charging.	<p>a. Install the adapter and the uncharged battery, turn on the host engine, and enter the working mode.</p> <p>b. Battery power icon shows charging, power light on, and battery light flashing.</p> <p>c. When the battery power icon displays 100%, the battery is fully charged and the battery light turns on normally.</p> <p>After shutdown: plug in the adapter, the power light and battery light are all on; unplug the adapter, and the power light and battery light are all out.</p>	□OK □NG
Key test	1	Power on / off button test	The Power on / off button function is normal	<p>1. Under the shutdown state, press the "on / off" button, the machine can turn on normally;</p> <p>2. In the standby interface, press the "on / off" button, the machine can shut down normally;</p> <p>3. When the machine is working normally, press and hold on the "on / off" key for 5-10s, and the machine is shut down.</p>	□OK □NG
	2	Alarm reset button	Test the function of the alarm reset key	Simulate one or more alarm information, press the alarm reset button, the alarm information disappears, and the alarm information recovers after 30 seconds.	□OK □NG
	3	atomization button test	Test if function of atomization is normal	Press the atomization button when the machine is working normally, the atomization icon pop up at the interface and the countdown begins.	□OK □NG
	4	Menu key test	Test if the menu key is normal	Press the menu button "  ", the main interface will pop up the main menu, press the menu button again, the main interface is closed.	□OK □NG
	5	Lock screen button test	Test if the function of lock screen button is normal	<p>Press the lock screen button "", the display cannot perform touch control, and the shuttle is used normally.</p> <p>Press the lock screen button again, the screen touch back to normal, the shuttle is used normally.</p>	□OK □NG
	6	Muting button test	Test if the function of muting button is normal	Simulated alarm, press the mute key "  ", the alarm sound disappears, the alarm muting icon appears, press the mute button again, the mute button light is out, the alarm sound.	□OK □NG

	7	Flying shuttle test	Test if the flying shuttle use function is normal	The shuttle can control movement, selection, validation and parameter adjustment and validation after starting on.	<input type="checkbox"/> OK <input type="checkbox"/> NG
Alarm sound	1	Alarm sound test	Test if the function of the speaker is normal	1. simulate any alarm, alarm sound appears; 2. Adjust the alarm volume, the speaker alarm sound is normal	<input type="checkbox"/> OK <input type="checkbox"/> NG
conclusion:			<input type="checkbox"/> PASS <input type="checkbox"/> FAIL		
Test / Date:					

Control / monitoring parameters test record sheet (final Inspection PQC)						
No.	test item	Inspection content	Acceptance standard	Host monitoring value	The VT monitoring value	Inspection result
1	Inspiratory tidal volume (mL)	100	80~120			<input type="checkbox"/> OK <input type="checkbox"/> NG
		500	440~560			
2	Expiratory tidal volume (mL)	100	80~120			<input type="checkbox"/> OK <input type="checkbox"/> NG
		500	440~560			
3	inspiratory duration (s)	2	1.8~2.2	/		<input type="checkbox"/> OK <input type="checkbox"/> NG
4	Respiratory rate (bpm)	5	4~6			<input type="checkbox"/> OK <input type="checkbox"/> NG
		20	19~21			
5	oxygen concentration (%)	21	20~24			<input type="checkbox"/> OK <input type="checkbox"/> NG
		40	37~43			
		100	97~103			
6	CPAP/PEEP (cmH2O)	5	3.85~6.15			<input type="checkbox"/> OK <input type="checkbox"/> NG
		10	8.6~11.4			
		30	27.6~32.4			
7	Inspiratory pressure (cmH2O)	5	3.6~6.4			<input type="checkbox"/> OK <input type="checkbox"/> NG
		20	17~22.1.9			
		40	35.1~44.9			

conclusion:	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL
Test / Date:	
Review / Date:	

Trigger and Support Pressure Test Record (Final inspection FQC)

No.	test item	Inspection content	Acceptance standard	Host monitoring	VT monitor	Inspection result
1	Trigger pressure (cm H ₂ O)	-2	-2.6~-1.4		/	<input type="checkbox"/> OK <input type="checkbox"/> NG
2	Trigger flow rate (L/min)	3	2.3~3.7		/	<input type="checkbox"/> OK <input type="checkbox"/> NG
3	Pressure Support (cm H ₂ O)	5	3.85~6.15			<input type="checkbox"/> OK <input type="checkbox"/> NG
		10	8.6~11.4			
		30	27.6~32.4			
conclusion:		<input type="checkbox"/> P ASS <input type="checkbox"/> FAIL				
Test / Date:						

End-expiratory CO₂ Test Record (Final inspection FQC)

test item	Standard gas concentration	Acceptance standard	Module monitoring value	Inspection result
End-expiratory Carbon dioxide (mmHg)	15.2mmHg(2%)	13.2~17.2		<input type="checkbox"/> OK <input type="checkbox"/> NG
	38mmHg(5%)	36~40		
	60.78mmHg (8%)	57.7~63.8		
conclusion:		<input type="checkbox"/> P ASS <input type="checkbox"/> FAIL		
Test / Date:				

Atomization flow rate test record (Final Inspection FQC)

test item	Acceptance standard	The V T monitoring value	Inspection result
Atomization flow rate (L/min)	7±1		<input type="checkbox"/> OK <input type="checkbox"/> NG
conclusion:	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL		
Test / Date:			

Abnormal power-off alarm test record (final inspection FQC)

test item	Acceptance standard	stopwatch (unit:s)	Inspection result
Disconnect the battery and and the external power supply	The buzzer alarm time is more than 120s		<input type="checkbox"/> OK <input type="checkbox"/> NG
Unplug the battery without external power supply			
conclusion:	<input type="checkbox"/> P ASS <input type="checkbox"/> FAIL		
Test / Date:			

Respiratory System Leakage Inspection Record Form (Final Inspection FQC)

test item	VT airway pressure display (Unit: KP a)	Acceptance standard (Unit: mL/min)	VT measuring flow rate (Unit: ml/min)	detection result
Respiratory system leakage inspection	4.9~5.1	≤200		<input type="checkbox"/> OK <input type="checkbox"/> NG
conclusion:	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL			
Test / Date:				

Ventilator Noise Inspection Record (Final Inspection (FQC))

test item	Inspection content	Acceptance criteria (unit: d B)	Measured value(unit: d B)	inspection result
System noise inspection	Noise value under normal work	≤45		<input type="checkbox"/> OK <input type="checkbox"/> NG
conclusion:	<input type="checkbox"/> P ASS <input type="checkbox"/> FAIL			
Test / Date:				
Review / Date:				

Safety Pressure Test Record of ventilator gas system (Final Inspection (FQC))

test item	test content	Acceptance criteria (unit: cm H2O)	Measuring value	test result
Safety pressure test of gas circuit system (whole machine)	System safety pressure value when the machine is connected to the respiratory pipe	≤110		<input type="checkbox"/> OK <input type="checkbox"/> NG
conclusion:	<input type="checkbox"/> P ASS <input type="checkbox"/> FAIL			
Test / Date:				
Review / Date:				

Shipment Inspection (OQC) Record Form			
No.	inspecting item	acceptance standard	conclusion
1	labeling	a) The label is complete; b) The host machine and the carton label serial number are consistent; The label content is clear and complete, and meets the requirements of the drawings.	<input type="checkbox"/> OK <input type="checkbox"/> NG
2	Accessories	Should be consistent with the packing list	<input type="checkbox"/> OK <input type="checkbox"/> NG
3	package	Mainframe, pearl cotton and attachment boxes shall meet the requirements of relevant operation instructions	<input type="checkbox"/> OK <input type="checkbox"/> NG
4	carton	No stains, smooth surface, no impact marks and other phenomena, and the printing marks are clear and correct	<input type="checkbox"/> OK <input type="checkbox"/> NG
fault phenomenon			
conclusion:		<input type="checkbox"/> PASS <input type="checkbox"/> FAIL	
remarks:		Without "NG", the test conclusion should check "PASS"; if it has "NG", the test conclusion should check "FAIL" and perform the company troubleshooting process.	
Test / Date:			
Review / Date:			

Adverse event record					
No.	fault phenomenon	analysis of causes	treatment measure	result	remarks
1					notekeeper: Reviewed by:
2					notekeeper: Reviewed by:
3					notekeeper: Reviewed by:
4					notekeeper: Reviewed by:
5					notekeeper: Reviewed by:

Product release sheet			
product name	Ventilator	product model	T6
Product serial number		expiration date	8 years
No.	Audit content and standards		audit result
1	The product is manufactured and inspected in accordance with GMP, ISO13485, ISO9001, and approved product registration standards or product technical requirements		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N / A
2	The key process of the product is verified		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N / A
3	The product has completed all the prescribed process flow, and has been confirmed by the relevant responsible person		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N / A
4	The batch production record of the product is complete, and confirmed by the relevant person in charge		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N / A
5	All the specified quality control records of purchase, process, finished product inspection and verification of these products are complete, and the results meet the specified requirements. The inspection / test / verification / validation personnel and their audit and authorized approval personnel have issued the records according to the regulations		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N / A
6	The whole process of product realization, especially in the process of procurement, production, unqualified, rework, rework, repair, downgrade of use, emergency release and other special circumstances have been dealt with according to the regulations		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N / A
7	The product specification, label and its version shall meet the specified requirements		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N / A
The non-confirmities description			
Review conclusion	<input type="checkbox"/> approve the release <input type="checkbox"/> do not approve release Quality Authority Person Signature / Date:		

remarks	
---------	--

After-sales maintenance log			
time	event	conclusion	Maintenance personnel

remarks	<p>Post-maintenance conclusions include: A — continue to use; B — change equipment; C — returned to the manufacturer</p> <p>Event descriptions can be written in multiple lines.</p> <p>This page shall be filled in truthfully by the after-sales engineer after returning to the company, and returned to the document control personnel in time.</p>
----------------	---