DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH





User Manual

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- Equipment must be used as instructed in the operating instructions.

The paid theoretical framework diagram will be supplied according to customer requirements by DIXION, plus calibrating method and other information to help the customer, under the assistance of qualified technicians, repair the equipment parts where can be done by customer himself based on the stipulation by DIXION.

Warranty:

Manufacturing techniques and materials:

Warranty valid for 18 months after ship date when cargo is picked-up at factory, the components and assemblies of this product is guaranteed to be free from defects manufacturing techniques and materials, provided that the equipment is properly operated under conditions of normal use and that the equipment is regularly maintained per requirements specified by our company. The warranty period for spare parts is three months from shipping date. Consumable parts are not included in this warranty. Our company's obligation under the above warranty is limited to repairing the equipment free of charge.

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DIXION's obligation under the above warranties does not include the freight and other fees. DIXION is not responsible for any direct, indirect or final product broken and delay which result from improper use, alteration by using the assemblies ungratified and maintenance by anyone other than DIXION.

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- Machines without maintenance or machines are broken.
- Malfunction or damage caused by force majeure such as fire and earthquake.
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- Any product of any other manufacturer.

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DIXION is not responsible for the security; reliability and operating condition of this product in case that:

- The assemblies are disassembled, extended and readjusted.
- This product is not operated correctly in accordance with the manual instruction. The power supply used or operating environment does not follow the requirements in this manual.

Return

Follow the steps in case that the product needs to be returned to DIXION:

1. Obtain the rights of return

Contact with the customer service of DIXION by informing them the number and type of the product. The number is marked on the surface of the product. Return is unacceptable if the number cannot be identified. Enclose a statement of the number, type and the reason of return as well.

2. Transportation charges

Transportation and insurance charges must be prepaid by the user for transporting the product to DIXION for repairing. (Customers charges is added with regard to the products sold to non-Chinese mainland users)

User Responsibility

This product will perform in conformity with the description contained in the operating manual and accompanying labels and /or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This product must be checked periodically. Do not use product if defective. Replace all broken, missing, worn, distorted or contaminated parts. If repair or replacement becomes necessary, a telephone call or written request for service advice should be made to the nearest DIXION customer service center. This product or any of its parts must be repaired in accordance with the written instructions provided by DIXION and by DIXION trained personnel. The product must not be altered without the prior written approval of DIXION. The user of this product shall assume the full responsibility for any malfunction resulting from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than DIXION personnel.

▲ Caution:

• This equipment is not for family use.

A WARNING:

• Malfunctioning equipment may become invalid and cause bodily injury if a set of effective and approving repairing proposals cannot be submitted by the institution which is responsible for using this equipment.

Comments

We're interested what your think about the accuracy and usefulness of this manual. To ensure that you and future users have the highest quality manuals, please contact us.

Definitions

This manual uses three special indicators to convey information of a specific nature. they include:

WARNING:Indicates a condition that can endanger the patient or the ventilator operator.

A CAUTION: Indicates a condition that can damage the equipment.

A NOTE : Indicates points of particular emphasis that make operation of the ventilator more efficient or convenient.

Instead of illustrations, other symbols may also be utilized. Not all of them may necessarily appear in the equipment and manual. The symbols include:

A CAUTION: This manual complies with EN1041.

\odot	ON only for part of the equipment	★	Type B equipment
Ò	OFF only for part of the equipment	\wedge	Warning or Caution, ISO 7000-0434
	Direct Current	A	NOTE: refer to the manual, IEC601-1
\sim	Alternating Current	4	Dangerous Voltage
	Protectively earth - +		Battery
Ą	Equipotential	\bowtie	Alarm Silence
M	Date of manufacture	SN	Serial Number
	Manufacture	町))	Buzzer
EC REP	CE Representative	C E ₀₄₈₃	The system, with this label under the stipulations in the operating manual, complies with the requirements related from 93/42/EEC. 0483 is the certificate number to certify authorizations

Electromagnetic compatibility

Important information regarding Electro Magnetic Compatibility (EMC):

Aeros 4300 VENTILATOR needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; Aeros 4300 conforms to this IEC 60601-1-2:2014 standard for both immunity and emissions. Nevertheless, special precautions need to be observed.

Aeros 4300 VENTILATOR with Following ESSENTIAL PERFORMANCE is intended used in Professional healthcare facility environment.

PERFORMANCE: A/C mode, the parameter by default, control is correct.

WARNING: Use of Aeros 4300 VENTILATOR adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

Cable	Max. cable Shielded/un	length, shielded	Number	Cable classification
AC cable	5.0m	Unshielded	1 Set	AC Power

Below cables information are provided for EMC reference.

➢ WARNING: The Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the Aeros 4300 VENTILATOR could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

➢ WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Aeros 4300 VENTILATOR, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

EMI Compliance Table

	Table	
Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class A	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2 Class A	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Professional healthcare facility environment

Table 1 - Emission

EMS Compliance Table

Table 2 - Enclosure Port

Phenomenon	Basic EMC	Immunity test levels
	standard	Professional healthcare facility environment
Electrostatic	IEC 61000-4-2	±8 kV contact
Discharge		$\pm 2kV$, $\pm 4kV$, $\pm 8kV$, $\pm 15kV$ air
Radiated RF EM field	IEC 61000-4-3	3V/m
		80MHz-2.7GHz
		80% AM at 1kHz
Proximity fields	IEC 61000-4-3	Refer to table 3
from RF wireless		
communicatio		
ns equipment		
Rated power	IEC 61000-4-8	30A/m
frequency		50Hz or 60Hz
magnetic fields		

Table 3 – Proximity fields from RF wireless communications equipment

	1	
Test frequency	Band	Immunity test
(MHz)	(MHz)	levels
(()	Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

Phenomenon	Basic EMC	Immunity test levels
	standard	Professional healthcare facility environment
Electrical fast	IEC 61000-4-4	±2 kV
transients/burst		100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV
Conducted	IEC 61000-4-6	3V, 0.15MHz-80MHz
disturbances		6V in ISM bands between 0.15MHz and
induced by RF		80MHz 80%AM at 1kHz
fields		
Voltage dips	IEC 61000-4-11	0% U _T ; 0.5 cycle
		At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% U _T ; 1
		cycle and
		70% U _T ; 25/30 cycles
		Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% U _{T;} 250/300 cycles

Table 4 – Input a.c. power Port

Table 5 – Signal input/output parts Port

Phenomenon	Basic EMC	Immunity test levels
	standard	Professional healthcare facility
		environment
Electrostati	IEC 61000-4-2	±8 kV contact
С		±2kV, ±4kV, ±8kV, ±15kV air
Discharge		
Electrical fast	IEC 61000-4-4	±1 kV
transients / bursts		100 kHz repetition frequency
Conducted	IEC 61000-4-6	3V, 0.15MHz-80MHz
disturbances		6V in ISM bands between 0.15MHz and
induced		80MHz 80%AM at 1kHz
by RF fields		

Warnings, cautions, and notes

Please take the time to familiarize yourself with the following caveats as they cover safety considerations, special handling requirements, and regulations that govern the use of the Aeros 4300 Ventilator.

• To ensure proper servicing and avoid the possibility of physical injury, only qualified personnel should attempt to service or make authorized modifications to theventilator.

• Using Aeros 4300 ventilator in a contaminative air environment is forbided.

• To avoid a fire hazard, keep matches, lighted cigarettes, and all other sources of ignition (e.g. flammable and/or heaters) away from the Aeros 4300 and oxygen hoses.

• Do not use oxygen hoses that are worn, frayed, or contaminated by combustible materials such as grease or oils. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen.

• In case of fire or a burning smell, immediately disconnect the ventilator from the oxygen supply, facility power, and backup power source.

• DIXION recognizes that cleaning, sanitation, and disinfection practices vary widely among health care institutions. It is not possible for DIXION to specify or require specific practices that will meet all needs, or to be responsible for the effectiveness of cleaning, disinfection, and other practices carried out in the patient care setting.

• Patients on ventilator should be appropriately monitored by competent medical personnel and suitable monitoring devices.

• Aeros 4300 ventilator not intended to be a comprehensive monitoring device and does not activate alarms for all types of dangerous conditions for patients on life-support equipment.

• For a thorough understanding of ventilator operations, be sure to thoroughly read this manual before attempting to use the product.

• Do not use sharp objects to make selections on the LCD display orpanel.

• Check the ventilator periodically as outlined in this Manual; do not use if defective. Immediately replace parts that are broken, missing, obviously worn, distorted, or contaminated.

• An alternative ventilation way should always be available when using the Aeros 4300 Ventilator. Such as: manual breath equipment.

• Aeros 4300 ventilator can not record automatically, so record useful message by yourself when using the ventilator.

• Before using the ventilator, carry out pre-use inspection according to Chapter 2 of this manual, and use it only after the function is confirmed to be normal. The user is responsible for the consequences of using the function without performing the function confirmation.

• Every 6 months after use, the ventilator needs a comprehensive preventive maintenance.

Customer assistance

For further assistance contact your local DIXION representative.

Foreword

This manual is divided into two parts: the operator's guide (Chapter 1-5) and the technical reference. (Chapter 6-7).

While this manual covers the ventilator configurations currently supported by DIXION, it may not be all-inclusive and may not be applicable to your ventilator. Call DIXION Technical Services at 800-810-8333 or 8610-8368-1616 for questions about the applicability of the information.

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1 Introduction

Aeros 4300 ventilator conforms to the principle of simple and easy operation requested for emergency equipment. It can be used by many medical units and clinical offices at all levels to perform emergency treatment for accident affairs, such as first-aid center, ambulance, anesthesia unit, chest surgery, cranial surgery, respiratory unit, various large mines, factories, swimming places.

1.1 Aeros 4300 General

- Pneumatically driven electrically controlled ventilation system.
- Internal intelligent malfunction judging warning system.
- The combination of pressing buttons and turning knobs makes controlling easier.
- 5 ventilation modes includes: A/C、 SIGH、 SIMV、 SPONT and Manual.
- Can work by internal battery more than 3 hours with good working condition.
- Simple to operate, small in weight and volume, reliable in performance.

A WARNING:

• Aeros 4300 can not work with a MRI environment.

1.2 Introduction of ventilator panel

1.2.1 Front panel



Figure 1-1 Front panel

Front panel includes: Logo of DIXION firm, model of the Ventilator, window area, and ventilation mode indicated area, power switch, and parameters setting area. Figure 1-1 shows the appearance of the ventilator front panel.



1. Display Window Area

Figure 1-2 Display Window Area

Figure 1-2 shows that the Display Window Area includes 4 parts:

1. Alarms indicator lights: 10 lights are divided into 2 arrays. The upper indicates high-urgency alarms ,and below array indicates medium-urgency alarms;

Alarms display area: Continents include: Apnea, Battery low, Ex. power lost, No Vt, O₂
 Deficiency, Paw low, Paw high and System breakdown (All the alarms happen with light and buzz);
 Battery icon: Shows the capacity of the battery.

4. Monitor area: Pressure-time waveform and Vt, MV, f_{total} ,P_{peak}Display.

▲ NOTE :

• There is a "Setting" key in the Figure 1-2.The screen will do a Display-Setting conversion when the "Setting" key is pressed. Press the key again the Setting-Display conversion will be executed. Without any operation, after 30 seconds the Setting-Display conversion will close automatically.

• The detail about "Setting area" will be described in the part3.3.

2. Condition indicator area



Figure 1-3 Condition indicator area

Condition indicator area includes:

1. Ventilation mode setting: When you press the keys, indicator lights at the top left will be bright. 5 ventilation modes, A/C, Sigh, SIMV, SPONT and Manual;

2. Indicator lights: Show the power (external power supply or internal battery) or trigger of patient conditions at present.

3. Silence: <2 minutes

3. Parameter setting area

Alam coooo (set ag	Aeros 4 f 17 bpm 3 Psens -7 cnH20 5. Ptow 5 cnH20 5. Phigh 33 cnH20 5.	300 05 -Vr(aL) -Vr) (\$ \$	O EML Former Sa O Low batter	SPONT APPIYO Charging Ty O Tragger	
4	bpm) Pseks(cmHc0)	Piow(cmile0)	Prign(cmbb0)	L:E	FIO2 80%	0 1000 Pesk Flow (mL/s)

Figure 1-4 Parameter setting area

Parameter setting area (Figure 1-4) includes 7 adjustment knobs, they control: breathing rates, pressure sensitivity, airway pressure lower limit, airway pressure upper limit, oxygen concentration and peak flow (adjust tidal volume through this setting).

A CAUTION:

• Do not overexert, when you adjust the knobs.

1.2.2 Right hand side panel

There are 3 connectors in the right hand side panel. As Figure 1-5 shows:

1. Gas outlet pipe connector: Gas enters the patient circuit pipe through this Connector.

2. Pressure sampling connector: Connect with the pressure sampling pipe, the other side of the pressure sampling pipe connect with breathing valve. For this samples gas pressure nearest patient. Electronic control system collects patient pressure through it.

3. Gas supply connector: Quick connector connects O_2 Inlet pipe (in which gas has been decompressed).



Figure 1-5 Right hand side panel

1.2.3 Left Hand Side Panel

In the left hand side panel (Figure 1-6) of the ventilator, there is a window which can open. That is the internal battery replace window. Open this window to replace internal battery. The details will be displayed in part 5.4.



Figure 1-6 Left hand side panel

1.2.4 Rear panel



Figure 1-7 Rear panel

As Figure 1-7 shows, rear panel includes 4 parts:

1. Fresh Gas Intake: The intake of fresh gas, the quantity of gas entered there is related to oxygen

concentration. A Do not block it.

2. Power Supply Socket: Power inlet of the ventilator, for power adapter or +12V Vehicle's Power Supply. A fuse is behind it. When the electric power has a big change, the fuse will be destroyed. Replace a new fuse here. Part 5.2.1 will show how to replace it.

- 3. Gas Output: The vent for the expiration process, also for the save valve to vent.
- 4. Buzzer: Buzz when the alarm has been triggered.

1.3 Characteristic

1.3.1 High dependability

Integrate circuit is widely used in the Ventilator internal; all parts of the ventilator were tested by aging examination, high dependability of the electronic circuit. According to the design request, the *Mean Time Between Failures* (MTBF) of Aeros 4300 Ventilator is over 2000hours.

1.3.2 Various monitor parameters

Monitor: Tidal Volume, Minute Volume, Breathing Rate, Airway Pressure Peak, Airway Pressure Waves, Battery Capability, AC, DC, Charge, Trigger.

• The software of Aeros 4300 ventilator has been tested that the possibility of hazards arising from errors in the software program is minimized.

1.3.3 Perfect alarm ability

Monitoring Parameters: O₂ Deficiency, Airway Pressure Upper Limit, Airway Pressure Lower Limit, Apnea, No Tidal Volume, DC Failure, Low Battery Capability, System Breakdown. There are 2 arrays of lights in the front panel, one is red color, and the other is yellow. Different colors show different alarm levels. When the red lights turn on, it means the high-urgency alarm has been triggered. The high-urgency alarm includes: Apnea, No Tidal Volume, Airway Pressure Upper Limit, Airway Pressure Lower Limit; Yellow lights turn on means the medium-urgency alarm has been triggered, medium-urgency alarm includes: O₂ Deficiency, external power failure. When the system Breakdown alarm has been triggered, red lights turn on and buzzer buzzes continuously, noting displays in the LCD.

1.3.4 Contraindication

The machine is not suitable for the below circumstances:

- 1. Pneumothorax and mediastinal emphysema is not good drainage.
- 2. A large number of pleural effusion.
- 3. Giant lung bulla.
- 4. Low blood volume shock is not corrected.
- 5. Acute myocardial infarction with heart failure.

However, when necessary, high frequency ventilation can be used in pneumothorax, bronchial fistula, acute myocardial infarction and heart failure.

2 Getting Start

This section tells you how to set up the ventilator, includes:

- Things to do before beginning patient setup
- Connecting the power supply
- Connecting the oxygen supply
- Connecting the patient circuit and accessories

A WARNING:

- All components must be securely mounted and connected by a qualified service technician according to the appropriate DIXION connection instructions.
- To avoid the possibility of damage to ventilator components or interrupted ventilator operation, always use the ventilator on a level surface in its proper orientation.
- To minimize the increased risk of fire due to an oxygen-enriched environment, do not use the ventilator in a hyperbaric chamber.
- To avoid raising the oxygen concentration of room air, use the ventilator in an adequately ventilated room.
- Do not remove the internal battery during ventilator is working or the DC power supply has been built.
- To avoid an electrical shock hazard while servicing the ventilator, be sure to remove all power to the ventilator by disconnecting the power source and turning off all ventilator power switches.
- Before operation, the internal battery must have been connected in the ventilator, or the protection of external power off will become inefficacy. When using the ventilator, make sure a changed battery has been connected. Details about the management for internal battery will be showed in section 5.4.

- Do not block the cooler vent in the rear panel.
- To avoid the possibility of damage to ventilator components, do not use the horizontal surfaces of the ventilator to place stack objects.

▲ NOTE:

- For first-time connection, refer to the separate connection instructions supplied with your ventilator.
- DIXION recommends that before using the ventilator for the first time, wipe the ventilator exterior surface clean and disinfect its components according to the instructions in part 5 of this manual. Follow your institution's protocol for cleaning and disinfecting the ventilator and its components.

2.1 Requirements of operating the ventilator

- 1. This manual must be read and understood before using this ventilator.
- 2. Requirements for the people who operates the ventilator:
- 1) High responsibility for patients.
- 2) Some knowledge about ventilation.
- 3) Good heath condition, smart respond

2.2 Connecting the power supply

A WARNING:

- Put the power cord and screwed tubing in a certain place, to avoid apnea the patient.
- Only connect external power adapter with ISO-standard socket. And pay attention to polarity if necessary.
- For two-phase alternating current circuit user, do not attempt to switch earth line and zero line.
- Low battery alarm may be occur, if you power on the ventilator with it do not have external power supply for a long time. If this happens, connect the ventilator with the external power supply (use the exclusive power adapter) to charge for 10 hours at least. If the alarm is still existed, the internal battery must be replaced. (Please connect qualified technician).
- Replace internal battery at a temperature during 0~45°C.

A CAUTION:

• If power supply net have a fluctuate over 10%, DIXION suggests using an AC manostat.

A full charged new battery can supply the ventilator work for at least 3 hours. It's convenient for you to use Aeros 4300 on some special occasion without external power supply.



Figure 2-1 External power supply

External Power Supply Socket is in the rear panel, As Figure 2-1 shows, a fuse is behind it. Please use Power adapter which is accord CE attestation to supply power for the ventilator. If something abnormal happens, stop using the ventilator immediately, and connect the manufacturer for some repairing.

2.3 Connecting oxygen supplies, patient circuit and accessories

Aeros 4300 can work with oxygen bottle, gas supply in the ambulance or on the wall. When the ventilator is working, make sure the gas supplies 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 connecting. Please connect the oxygen supplies, patient circuit and accessories fellow these steps:

▲ NOTE:

• Make sure the gas supply is always between 0.28MPa and 0.6MPa, and velocity of flow is between 50L/Min and 90L/Min.



Figure 2-2 Connect gas outlet pipe to the right hand side panel



Figure 2-3 Connect pressure sampling pipe



Figure 2-4 Connect the O_2 inlet pipe



Figure 2-5 Connect gas outlet pipe to breath valve



Figure 2-6 Connect pressure sampling pipe



Figure 2-7 Connect simulation lung to breath valve



Figure 2-8 Connect mask to breath valve

A 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 oxygenenriched environments with the Aeros 4300 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.
- DIXION recommends that you use one of the patient circuits identified by DIXION, or their equivalents to ensure that the maximum pressure/flow values specified by EN794-1 are not exceeded (see related content in part 7 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 100ml and avoirdupois over 10kg. This machine is not suitable with infant.
- The distance between breathing valve and patient is as short as possible, or it can hoist the concentration of CO₂.

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.

A NOTE:

• Alarm functionality is tested and verified as part of ventilator test before using. Details about Alarms will be displayed in part 3.3 and part 4.

2.4 Power on



Figure 2-9 power on

Presses the power button, all indicator lights on the front panel are ON (See Figure 2-9) together with a short buzz. If something abnormal happened, stop using the ventilator immediately, and connect the manufacturer for some repairing. Details about it will be displayed in the section 5.1 and 5.3 "System breakdown alarm".

▲ Caution :

• If the ventilator can power on with LCD displays normally but without any buzz, the alarm is failure. You should pay attention to this case. Connect the manufacturer for some repairing if necessary.

2.5 Things to do before beginning patient setup

Not only disinfect the ventilator before using, but also carry out the preoperative checkout procedures before putting the system back in use.

▲ Warning :

• Failure to make sure of correct setup and operation before use can result in patient injury.

Please follow these steps to do before you begin Ventilator Settings (described in part 3):

1. Gas supply and external power supply

Check the gas supply and external power can supply enough resource for the ventilator. Check the patient circuit for leak, disconnect or connecting mistakes. And make sure all cables, plugs, sockets and screw pipe are accord to safe requirement. Cut down the external power supply, check the external power lost alarm occurs.

2. Check Apnea Alarm

Set the ventilator to SPONT mode, meanwhile start to time until the alarm is triggered. This period should be about 12 to 18 seconds.

3. Check the work state of the ventilator

This is a standard work state of the ventilator settings:

Ventilation mode:	A/C;
Rates of breath:	16bpm;
I:E:	1:2;
Airway pressure upper limit (×0.1kPa):	40;
Airway pressure lower limit (×0.1kPa):	5;
Patient trigger pressure (×0.1kPa):	-3;
Tidal volume:	500mL;
Oxygen concentration:	48%;

4. Check tidal volume

Cut off the gas supply, turn to the A/C ventilation mode, it should be 0 of the tidal volume monitor. Recover the gas supply and adjust peak flow to maximum, check the tidal volume monitor is at a range of 1000ml to 1200ml.

5. High airway pressure alarm testing:

Adjust the tidal volume to set the airway pressure peak is about 2.5kPa, Then set the Airway Pressure Upper Limit to a numerical value lower than 2.5kPa slightly. The Airway Pressure Upper Limit alarm has been triggered meanwhile the ventilator turn to expiration, the airway pressure decreases.

6. Low airway pressure alarm testing:

Set the airway pressure upper limit to 0.1kPa, then disconnect patient pipe, the airway pressure lower limit alarm takes place after 4-15 sec.

7. Test trigger pressure sensitivity testing:

Set the trigger pressure at -0.1kPa, wear the mask and do a inspiration, the inspiration step of the ventilator begins after airway pressure lower than the setting, meanwhile the "trigger" indicator light on the front panel flashes.

8. SIMV

Set ventilation mode to SIMV, change the breathing rates, see the display of " f_{total} " in 1 minute, it should accordant as setting you just made.

9. Sigh

Let the ventilator work at a standard work state, record the tidal volume. Then change ventilation mode to A/C+Sigh, adjust the airway upper limit pressure to maximum, see the display of the tidal volume data, it should 1.5 time as normal the second time respiration takes place. This happens every 100 times, during this ventilation mode.

10. SPONT

Set the ventilation mode to SPONT, adjust the trigger pressure with -0.2kPa, wear mask. The ventilator begins a ventilation when the airway pressure lower than -0.2kPa. when the patient spontaneous inspiration finishes or the ventilation time get to the certain time determined by breathing rates and I : E, or the airway pressure up to $60 \text{cmH}_2\text{O}$, the ventilator will turn to expiration and waiting for next patient spontaneous inspiration.

3 Ventilator settings

This section tells you:

- Aeros 4300 Ventilator's panel operation
- How to set Aeros 4300's 5 ventilation mode
- How to set alarm limits.

A WARNING:

- Do not connect to the patient before finish the patient setting.
- Security is the first factor we designed this ventilator, but never ignore to monitor ventilator's display and patient's state.

▲ CAUTION:

• Do not overexert when you adjust the knobs. If any knobs fail to work, stop using the ventilator immediately. Contact service representative if necessary.

A NOTE:

 If you find some monitor data is not accurate, check patient firstly, then check the ventilator's work state.

3.1 Panel Operation

3.1.1 Parameters Settings

Table 3-1 Parameters Setting

f(bpm) 4	Breathing rates setting: press "setting" key, then turn corresponding knob to adjust breathing rates. The monitor data is displayed on LCD. Clockwise the setting increase. Anti-clockwise to decrease. Adjustable range: 4 to 99bpm.
Psens(cmH2O)	Trigger pressure setting: similar as breathing rates setting, adjustable range: -20 to 0 cmH ₂ O.
	Airway Pressure Upper Limit setting: similar as breathing rates setting, adjustable range: 0 to 20 cmH ₂ O.
Phigh(cmH2O)	Airway Pressure Upper Limit setting: similar as breathing rates setting, adjustable range: 20 to 80 cmH ₂ O.
	I : E setting: turn corresponding knob to adjust I :E. clockwise the setting increase. Anti-clockwise to decrease. From 2:1 to 1:4, 6 ratios are optional.
FiO2 80% 48%	Oxygen concentration: similar as breathing rates setting, adjustable range: 48% to 100%.
O 1000 Peak Flow Peak Prove (mU/s)	Tidal volume setting: similar as breathing rates setting. Adjust Tidal volume through adjust peak flow. Adjustable range: 0 to 1000mL/s.

3.1.2 Parameters Monitor



Table 3-2 Parameters Monitor

3.1.3 States settings and indicators



Figure 3-1 States settings and indicators area

1. States settings and indicators area: Sates indicator includes 5 ventilation mode indicator, external power indicator, internal battery charging indicator and patient trigger indicator.

5 ventilator mode includes: **[A/C]**, **[Sigh]**, **[SIMV]**, **[SPONT]**, **Manual]**. Settings for the 5 ventilation modes are based on Table 3-3.

Table 3-3 Setting for Ventilation Modes

Кеу	How to use
	A/C (Assistant/Control): When you press the key, indicator light at the top left will be bright. With this ventilation, inspiration trigger is depend on patient's demand, other parameters is determined by the setting your give the ventilator.
	Sigh: When you press the key, indicator light at the top left will be bright. With this ventilation, every 100 times during the A/C period, an at least 1.5 times Vt will supported.
	SIMV (Synchronized Intermittent Mandatory Ventilation): When you press the key, indicator light at the top left will be bright. With this ventilation, spontaneous breathing rates and tidal volume is control by patient himself, a control ventilation happens every a certain period which you set.
SPORT	SPONT(spontaneous): When you press the key, indicator light at the top left will be bright. With this ventilation, all breathing parameters are due to patient himself.
Mary	Manual: When you press the key, the ventilator will do a force ventilation to the patient, unloosen will finish the ventilation. This key can simulate breathing of patient.

3.2 Ventilation mode introduction

3.2.1 A/C

In A/C mode, the ventilator delivers only mandatory breaths. when the ventilator detects patient inspiratory effort, it delivers a patient-initiated mandatory(PIM)breathe(also called an assisted breath). If the ventilator does not detect inspiratory effort, it delivers a ventilator-initiated mandatory (VIM) breath (also called a control breath) at an interval based on the set respiratory rate. Breaths can be pressure- or flow-triggered in A/C mode.

Figure 3-2 shows A/C breath delivery when no patient inspiratory effort is detected and all inspirations are VIMs. And Tb is the breath period in seconds.



Figure 3-2 A/C mode, no patient effort detected

Figure 3-3 shows A/C breathe delivery when patient inspiratory effort is detected. The ventilator delivers PIM breathes at a rate more than the set respiratory rate. And Tb is the breath period in seconds.



Figure 3-3 A/C mode, patient effort detected

Figure 3-4 shows A/C breath delivery when there is a combination of VIM and PIM breaths. And Tb is the breath period in seconds.



Figure 3-4 A/C mode VIM and PIM breaths

▲ Caution :

• Setting of trigger pressure' false or ability for breath of patient intensify may lead to A/C mode delivers too much.

3.2.2 A/C+SIGH

A/C+SIGH, base on A/C mode. The difference is a high tidal volume (1.5 times as set) delivers every 100 breath.

3.2.3 SIMV

SIMV (Synchronized Intermittent Mandatory Ventilation) is a mixed ventilator mode that allows both mandatory and spontaneous breaths. The mandatory breaths can be volume or pressure-based, and the spontaneous breaths can be pressure-assisted (for example, when pressure support is in effect.) You can select pressure- or flow-triggering in SIMV.

The SIMV algorithm is designed to guarantee one mandatory breath each SIMV breath cycle. This mandatory breath is either a patient-initiated mandatory (PIM) breath (also called an assisted breath) or a ventilator-initiated mandatory (VIM) breath (in case the patient's inspriratory effort is not sensed within the breath cycle).

As Figure 3-5 shown, each SIMV breath cycle (Tb) has two parts: the first part of the cycle is the mandatory interval (Tm) and is reserved for a PIM. If a PIM is delivered, the Tm interval ends and the ventilator switches to the second part of the cycle, the spontaneous interval (Ts), which is reserved for spontaneous breathing throughout the remainder of the breath cycle. At the end of an SIMV breath cycle, the cycle repeats. If a PIM is not delivered, the ventilator delivers a VIM at the mandatory interval, then switch to the spontaneous interval.



Figure 3-5 SIMV breath cycle (mandatory and spontaneous intervals)

A WARNING:

• This mode may cause insufficient ventilation or apnea if patient 'state becomes depravation.

3.2.4 SPONT

In SPONT (spontaneous) mode, inspiration is usually initiated by patient effort. Breaths are initiated via pressure or flow triggering, whichever is currently active. An operator can also initiate a manual inspiration during SPONT. An operator can also initiate a manual inspiration during SPONT. VIM breaths are not possible in SPONT mode.

3.3 Alarm Settings

We offer you a setting display window (Figure 3-6), for Airway Pressure Upper Limit, Airway Pressure Lower Limit, Breathing Rates and Trigger Pressure setting more convenient.

1. Setting Key: the setting display window occurs when you press this key. Press it again to return to waveform display window.

2. Breathing Rates: Turn the Breathing Rates Setting knob to set breathing rates.

3. Trigger Pressure: Adjust the Psens knob to set the value required.

4. Airway Pressure Lower Limit: Adjust the Plow knob to set the value required.

5. Airway Pressure Upper Limit: Adjust the Phigh knob to set the value required.

The range for settings upper is base on Table 3-1.

A WARNING:

• When the alarm settings reach the limit, the alarm system may failure.



Figure 3-6 Setting Display Window

4 Alarm Handling

This section describes ventilator alarms and what to do if they occur. Figure 4-1 shows the alarm indicators. Aeros 4300 Ventilator has high- urgency alarm and medium-urgency alarm.

High-prior alarms require immediate attention to ensure patient safety. During a high –urgency alarm, the red indicator lights bright, together with the buzzer buzz.

Medium-prior alarms require prompt attention. During a medium-urgency alarm, the yellow indicator lights bright, together with the buzzer buzz.

Solution for these alarms will be described in part 4.3.

A WARNING:

• Pay attention to the alarms, check patient condition first.

• If you find something wrong with alarm system, do not use the ventilator or it may endanger patient

4.1 Alarm performance

1. Airway Pressure Upper Limit: 20~80cmH₂O. accuracy: ±10%.

2. Airway Pressure Lower Limit: 0~20 cmH₂O, accuracy: ±100Pa (below 0.5kPa); ±20% (other).

3. No tidal volume: when the value of tidal volume monitored is zero for 10s. accuracy: ±20%.

4. Low gas supply: occur when the gas supply pressure<0.3MPa. accuracy: ±10%. above 120s.

5. Apnea alarm time: 15s, accuracy: ±20%.

6. External power lost: alarm time is above 120s, accuracy: ±20%.

7. Low battery: occur when the rest of battery power is about 30 minutes.

8. System failure: occur when one of these takes place. Control chip of the ventilator failure; tidal volume >200mL, but airway pressure is 0 (e.g. patient pipe leaks); tidal volume is 0mL, but airway pressure >1kPa (e.g. patient pipe blocks).

9. Alarm Silence: ≤120 seconds.

Alarms occur with light and buzz. Operator can silence buzz if necessary.

4.2 Alarm display



Figure 4-1 Alarm Display

1. Alarm indicator lights: 2 rows, and 5 indicator lights in each. When a High-urgency alarm has been triggered, the upper row bright in red color. In case of Medium-urgency alarms, the under row bright in yellow color.

2. Alarm indicator area: This area can display alarm information: apnea, battery low, ex. power lost, No Vt, O₂ deficiency, paw low, paw high.

Solutions for Alarm message are described on Table 4-1:

4.3 Causation for Alarm

When you see this message	It means	Do this
$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	The ventilator has entered apnea.	Check patient and settings.

Table 4-1 Alarm Messages

When you see this message	It means	Do this
$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$	The internal battery have low capacity	Replace internal battery or allow it to recharge during normal ventilator operation.
$ \begin{array}{c c c c c c c c c c c c c c c c c c c $	The power switch is ON, external power supply is not available, and the ventilator is being powered by the internal battery.	Prepare for power loss. Obtain alternate ventilation. Check integrity of external power source. Contact service if necessary.
$ \begin{array}{c c c c c c c c c c c c c c c c c c c $	No tidal volume monitored.	Check the setting of Peak Flow adjustment. check the state of O ₂ inlet pipe and patient circuit.
$ \begin{array}{ c c c c c } \hline P q & O_2 Deficiency !! & 0 \\ \hline 30 \\ 15 \\ 0 \\ -10 \\ \hline 2 & 4 & 6 & 0 \\ \hline \end{array} $	Oxygen supply pressure is less than the minimum required pressure for correct ventilator operation. Accuracy of O ₂ % delivery may be compromised.	Check patient and oxygen source. Obtain alternative ventilation if necessary.

Table 4-2 Alarm Messages

When you see this message	It means	Do this…
$ \begin{bmatrix} Pq \\ Pq \\ 30 \\ 15 \\ 0 \\ -10 \\ 2 \\ 4 \\ 6 \\ 5 \\ 0 \\ 2 \\ 4 \\ 6 \\ 5 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0$	The patient circuit pressure transducer has measured a pressure lower than the Airway Pressure Lower Limit you set.	Check if your setting is suitable for the patient, and also check patient condition. Obtain alternate ventilation. Remove ventilator form use and contact service if necessary
$ \begin{array}{c c c c c c c c c c c c c c c c c c c $	The patient circuit pressure transducer has measured a pressure upper than the Airway Pressure upper Limit you set.	Check if your setting is suitable of the patient, and also check patient. Obtain alternate ventilation. Remove ventilator form use and contact service if necessary
The red alarm lights bright and the buzzer buzz continuance, and nothing display in the LCD.	System Failure	Check patient. Obtain alternate ventilation. Remove ventilator form use and contact service

Table 4-3 Alarm Messages

5 Maintenance and Service

To ensure proper ventilator operation, perform the following maintenance procedures at the recommended intervals. All procedures should be adapted to your institution policies and protocol. The use life of this ventilator is 6 years.

This section is about some technical reference, it describes:

- Cleaning and disinfecting
- Preventive maintenance
- Troubleshooting
- Storage

For instructions for qualified service technicians on performing more detailed troubleshooting, or other service procedures, see part 6 and part 7 for more information, including theory of operation and parts list. Ventilator electronic components are not field-repairable.

A WARNING:

- Unqualified personnel must mot attempt to service the ventilator. Improper repair or unauthorized modification can compromise safety and result in patient injury.
- Make sure you have cut down the external power supply when you repair theventilator.
- The power adapter is an important part of the ventilator it cannot use near fire, and use in a too humidity environment (such as in raining environment), and do not use the pipe of power adapter as a rope! The power adapter is not field-repairable.

▲ NOTE:

• When handling any pat of the Aeros 4300 ventilator System, always follow your hospital infection control guidelines for handling infectious material.

5.1 Clean and disinfection

Table 5-1 tells you how to clean, disinfect ventilator components.

A WARNING:

- To avoid patient exposure to disinfecting agents, be sure to disinfect parts according to the techniques described in Table 5-1. Exposure to disinfecting agents may reduce the useful life of some parts.
- Handle filter with care, to minimize the risk of bacterial contamination.
- Always follow your institution/s infection control guidelines.
- Follow the instructions in Part 2.5 to check the ventilator can work in a good condition before connect to a patient.

▲ NOTE:

• This manual can only give general guidelines for cleaning and disinfecting. It is the user's responsibility to ensure the validity and effectiveness of the methods used.

Part	Procedure	Comments
Ventilator exterior (including LCD	Wipe clean with a damp cloth and mild soap solution or with one of these chemicals or their equivalents. Use water to rinse off chemical residue as necessary.	Do not allow liquid or sprays to penetrate the ventilator or cable connections. Do not use pressurized air to clean or dry the ventilator.
Screen)	 WARNING: Do not use organic impregnate to clean the ventilator surface. If use ultraviolet radiation to disinfect, do not let the time over 1 hour. 	

Table 5-1 Cleaning and disinfecting

Part	Procedure	Comments
	Disassemble and clean, then autoclave, pasteurize, or chemically disinfect. Single-patient use: Discard.	If submerged in liquid, use pressurized air to blow moisture from inside the tubing before use. Inspect for nicks and cuts, and replace if damaged.
Patient circuit tubing	 CAUTION: Steam disinfection is a viable disinfecting method of Aeros 4 patient circuits supplied by DIXION, but it may shorten the tubin life span. Discoloration (yellowing) and decreased tubing flexibility expected side effects of steam disinfecting this tubing. These effects are cumulative and irreversible. 	
Air inlet filter sponge	Clean and disinfect every 2 to 3 weeks.	Replace a new sponge at least half a year.

Table 5-2 Cleaning and disinfecting

A WARNING:

- Air inlet filter sponge can filter atomy, microorganism etc. over 100µm.
- Disinfecting after special infection or infectious patient use: use 2% soda water to clean the surface of the ventilator. After that clean it withwater.
- After using ventilator on a tuberculosis patient, a special disinfecting is needed. Immerse components in certain disinfection solution over 2 hours. And then put it in a formalin fume box 12 hours for more disinfection.

5.1.1 Cleaning: general guidelines

Do not clean or reuse single-patient use or disposable products. When cleaning parts, do not use hard brushes or other instruments that could damage surfaces.

- 1. Wash parts in warm water and mild soap solution.
- 2. Rinse parts thoroughly in clean, warm water (tap water is fine).
- 3. DIXION recommends that you inspect all parts at every cleaning. Replace any damaged parts.
- 4. Whenever you replace parts on the ventilator, make sure it can work in a good condition before connect it to patient.

▲ CAUTION:

• Follow the soap manufacturer's instructions. Exposure to soap solution that is more highly concentrated than necessary can shorten the useful life of the products. Soap residue can cause blemishes or fine cracks, especially on parts exposed to elevated temperatures during disinfection.

5.1.2 Disinfection

Do not disinfect, or reuse single-patient use or disposable products. When disinfecting tubing, coil it in a large loop, avoiding kinks or crossing tubing. The tubing lumen should be free of any visible droplets prior to wrapping.

5.2 Preventive maintenance

▲ NOTE :

• Avoid the ventilator from shock or collide.

Table 5-3 summarizes preventive maintenance intervals and procedures. The internal battery can charge over 350 times, please charge it at temperature between $0^{\circ}C \sim 45^{\circ}C$. If the internal battery must be replaced, please follow steps described on part 5.4

Frequency	Part	Maintenance
Several times a day or as required by your institution's policy	Patient circuit	Clean and keep dryness.
Every 2 to 3 weeks	Air inlet filter sponge.	Clean.
Every 3 months (or more often, if required)	Internal battery	Do a discharge and recharge process.
Every 2000 hours	Entire ventilator and it's sensors.	Use appropriate preventive maintenance kit. And preventive maintenance must be performed by a qualified service technician .

Table 5-3 Preventive maintenance in	ntervals
-------------------------------------	----------

5.3 Useful life estimation

CAUTION: The useful life of the following parts should be considered in normal environment and operating requirements.

Pressure sampling tube	1500 times
Corrugated tubing used repetitious	Not less than 1 year
Pipelines	8 years
Main unit	6 years
Face mask	Single use
Breathing valve	Single use
Oxygen flexible linker (optional)	3 years

WARNING: Face mask and breathing valve are single use only and are avoided using it repeatedly, because that will result in crossing infection.

5.3.1 Replacing fuses

The location of fuse is in the rear panel of the ventilator, see Figure 5-1.

Replacing steps:

- 1 Plug the screwdriver to groove on the end of fuse box.
- 2 Turn counterclockwise 3~5 circles then pull out fuse tubes lightly.
- 3 Take off fuse tubes.
- 4 Enclose the new ones.
- 5 Push fuse tubes to original place gently.
- 6 Turn clockwise 3~5 circles with screwdriver to tighten.

Connect mains supply.

A WARNING:

• Disconnect from power supply before replacing fuses, otherwise that can injure operator even death.

• Replace fuses with only those of the specified type and current rating, otherwise that can damage the equipment.

A CAUTION:

• The fuse is fragile, so replacement should be carefully. Do not use excessiveforce.



Figure 5-1 Replace fuse

5.3.2 Maintenance during convey the machine

The machine must be put in proper place for the clinic personnel's convenience during operation. During the up and down-stairs movement one must take care of the ventilation loop and power cables. It's better to take the ventilation loop off preventing damage.

A NOTE :

- Make a certain security movement while convey the ventilator. Figure 5-2 shows the correct way to ensure safety.
- Keep liquids far from the electrical components
- Repairing and moving is forbidden while the ventilator is working. Also check nothing is covered with the machine while it works.

Figure 5-2 The correct way to convey Aeros 4300 ventilator

5.4 Troubleshooting

5.4.1 Ventilator technical troubleshooting and analyzing

Symptom	Possible Cause	Recommended Action
ventilator does not work	ilator does not work Fower supply cable is unplugged Power switch is off Fuse is burned	
Ventilator stops operating suddenly, indicator light turns off, and sounds alarm	Power supply is interrupted	Use manual ventilation, and check the power supply.

Table 5-4 Ventilator technical troubleshooting and analyzing

The	external	power	Power supply cable is not	
supply	indicator	light	connect so fastness	Fasten the cable
flickers	sometimes			

5.4.2 Ventilator Clinic troubleshooting and analyzing

1. Airway Pressure Upper Limit

Table 5-5 Airway Pressure Upper Limit alarm sounds continuously

Symptom	Possible Cause	Recommended Action
	Patient circuit is occluded	Check and adjust patient circuit
Maximum pressure alarm	Patient's respiratory tract is occluded	Check the patient
sounds continuously	Maximum pressure setting is too low	Readjust the alarm setting
	Ventilator parameters changed	Recalculate the ventilator parameter

2. Airway Pressure Lower Limit

Table 5-6 Airwa	Pressure	I ow I imit alarm	sounds	continuously
Table 5 6 All Way	11033010		300103	continuousiy

Symptom	Possible Cause	Recommended Action	
Patient breathing circuit	Screw tubes are broken or the connector loosens	Replace or reconnect	
nas leak	valves loosen Tighten them		
gas leak	Simulation lung / ventilator switch failure	Please contact eligible service representative.	
The alarm limit setting too high		Readjust the alarm setting	
Changing of patient's compliance		Check patient's situation	
Self -determinate			
breathing lack when in a SIMV or SPONT ventilation	Minutes volume and total breathing rates too low	Change ventilation mode and parameter to the patient	

3. The patient trigger indicator light flicker

Table 5-7	The patient trigger indicato	r light flicker
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Symptom		Possible Cause	Recommended Action		
Patient	trigger	Setting of trigger is too low	Readjust	the	patient trigger
self-determine breathing			setting.		

5.5 Connecting/Replacing internal battery

When the internal battery has been charged over 10 hours, power on the ventilator without external power supply, the battery icon still shows the internal battery is in low capability together with low battery alarm, you may need to replace a new internal battery.

▲ WARNING:

• Make sure the external power supply has been cut off before youconnect or replace the battery.

Aeros 4300 adapt with replaceable nickel-hydrogen battery (DC power supply), specification: (HY Ni-MH AA1800mAh 12V); size: less than 52X15X145mm.

Follow these steps to replace the internal battery:



Open the battery replacing window in the left hand side panel.



Disconnect the electric connector between internal battery and ventilator.



Pull a tie in the hole gently to take out the battery.



Replace a new battery in the replacing window, and the battery should press the tie, connect the electric connector and close the battery replacing window.

Please refer to the above steps to connect internal battery.

5.6 Oxygen flexible linker (optional)

The steps of charge to oxygen cylinder with it are as follows:

After turning off high-press switch and low-press switch, twist the oxygen stopper plug counterclockwise with wrench.



Step 1:

User Manual

Step 2:

Plug the whorled port of oxygen flexible linker into oxygen charge hole, and fasten it.

Step 3:

Twist the other port of oxygen flexible linker to the vent of oxygen supply clockwise.

Step 4:

Fasten it with wrench.

Step 5: Unbolt the oxygen supply switch with wrench.

Step 6:

Unbolt the oxygen cylinder switch counterclockwise. You can hear fizz and the cylinder is a little hot, that means it's charging. When the sound disappears and the pointer of manometer stops rising, it means the charging is cover.









- **WARNING:** Charging oxygen to the cylinder timely when the pointer of manometer falls to the red line.
- **WARNING:** No smoking and flammable articles when charging and replacement of oxygen cylinder or taking oxygen therapy.
- CAUTION: When charging the pressure better reaches approximate 14MPa, or else it will affect the using time.
- **CAUTION:** Disassembly of the set is reversed process as the above when charge over. Be sure of the two oxygen cylinder closed before disassembly.
- A CAUTION: The above is demonstrative oxygen flexible linker. There may be a little discrepancy between the demonstrative and the real, but the connection way is the same. Please take material object as the standard.
- CAUTION: Do not use over-pressure supply to charge, or else the oxygen cylinder may outburst.

5.7 Transport and storage

5.7.1 Transport

Only well cased products can transport through lorry, railway, ship or plane. Avoid fierce shock and vibration while transport the ventilator. Always transport it with a dewiness environment. The product should be transported with temperature of $-40^{\circ}C$, relative humidity of 10%~100%.

5.7.2 Storage

The product should be stored in the room with temperature of $-20^{\circ}C \rightarrow +55^{\circ}C$, relative humidity of not more than 93%, good ventilation and without corrosion gas.

A CAUTION:

• When the storage conditions are beyond the requirements of operational environment, and the storage state is transferred into operation state, the product only can be used after being stored in environment for over 24 hours.

6 Theory of operation

This section is about some technical reference, mainly about product principle and design character of Aeros 4300 ventilator.

The simplified block diagram for Aeros 4300 ventilator is as shown in Figure 6-1. In the right part of the figure, the blocks connected by pipes form the gas circuit portion of the main unit and in the left part, the blocks connected by arrows are the electronic control portion of the main unit.

After entry, oxygen passes the relief pressure valve which limits the pressure to 0.3MPa. Then, it passes the solenoid valve, from which part of the oxygen goes to the throttle valve which controls the rate of oxygen stream supplied to the patient while the other part moves to the air-oxygen regulating valve which controls the concentration of oxygen supplied to the patient. The gas moving at high speed through the throttle valve provides negative pressure at the inlet of the air-oxygen mixer, entraining a certain proportion of air or oxygen and the mixed gas enters the airway. For safety purpose, safety valve is designed in the airway and used to limit the max. airway pressure of a patient. The pressure is normally set at 6kPa. When the airway pressure exceeds the safety pressure of the gas circuit system, the safety valve will release. he air flow passes the inhalation flow sensor and is converted to monitoring signal of the system, which indicates the aspiratory tidal volume and minute ventilation, and then, it goes to the patient via the gas tubing. The air exhaled by patient is discharged out of the unit through the tube and expiratory valve.

This is the brief description of the process of the mixed air moving into the lungs of a patient. In this process, throttle valve controls the gas entering the airway, which is subject to regulation of operators. During the inhalation, the solenoid valve opens and the expiratory valve closes. During the exhalation, it is the other way round, that is, the solenoid valve closes and the expiratory valve opens. The complete process is controlled by the electronic control system. As shown in the simplified diagram, the main board provides the various operating times of the unit, including inhalation time, the switching signal during autonomous respiration and control signal of solenoid valve. Moreover, it provides basic time clock, signal processing of convection volume sensor, processing of management keyboard and display and various alarm signals. The portion of pressure monitoring and sampling mainly monitors the patient's airway pressure and has it shown on the display screen, generates the pressure alarm signal and patient-triggered signal, and monitors the power of the complete unit.

It alarms in case of power supply anomaly. The section of panel display mainly addresses the parameter setting and data display. The power board functions mainly for supplying power needed for the normal operation of the various parts in the complete system.

• Aeros 4300 ventilator's flow sensor and pressure sensor are integrated internal.



Figure 6-1 Product principle and anticipated application

7 Specification

7.1 Ventilation capability

Tidal volume: 0~1500mL, accuracy: ±40mL (below 200mL); ±20% (other).

A/C breathing rates: 4~99bpm, SIMV breathing rates: 4~40bpm, accuracy: under 20bpm ±2bpm; other ±10%.

I:E Ratio: 2:1 to 1:4, accuracy: ±15%

Oxygen concentration: 48%~100%,accuracy: ±15%

Trigger sensitivity: -2kPa ~0kPa, accuracy: ±50Pa (above -0.5kPa); ±10% (other)

• All dates are base on a NTPD (20°C,1013hPa, dry) environment.

7.2 Patient system

Combined with breathe valve and 1.1m screw tubing. Compliance: 4mL/100Pa, and expiration resistance: $\leq 0.6kPa/L/s$, (For adult use a velocity of flow at 60L/min for children at 30L/min) the cavum is 12mL.

7.3 Size and Weight

Size: Height × Depth × Width (mm): 175×170×300 Weight: 3.5Kg approximately

7.4 Safety Value

Not more than 6kPa.

7.5 Ventilation Mode

A/C, Sigh, SIMV, SPONT, Manual.

7.6 Monitor capability

1. Tidal Volume: 0~2000mL. (0~200mL: accuracy ±40mL; other Tidal Volume: accuracy ±20%)

2.Peak Pressure: Maximum patient airway pressure during a patient breath. (0~8kPa.pressure≤2kPa,accuracy ±300Pa,other ±15%)

3. Total Breathing Rate: 0bpm~100bpm. (Rate ≤20bpm, accuracy ±2bpm, other ±10%)

4. Patient trigger indication.

5. External power supply indication

7.7 Main capability of the Aeros 4300

1. The compliance of the ventilator system: $\leq 4mL/100Pa_{\circ}$

2. Ventilator noise: ≤65dB(A).

3. Electric safe: Meet requirements for Class II, Type B, equipment specified in IEC60601-1 *Medical Electrical equipment: Part one: General requirement for safety.*

4. Power: ≤2 A.

5. The internal consume of the ventilator: about 1.0L/min.

7.8 Special icon, nameplate and graph on the ventilator

Sign	Position	Description
DIXION	Front panel	Logo of manufacturer.
し 》	Rear panel	Position of buzzer.

Table 7-1 Special icon and graph on the ventilator



Figure 7-1 Nameplate and sigh under the ventilator

1. Assemble for ventilation, operation indication for ventilation, usually causation for alarm.

Note: Don't use the ventilator without supervising.



Figure 7-2 Internal battery replace window sign

- 1. Nameplate of ventilator, include lots of information.
- 2. Internal battery replace window sign: open to replace the internal battery.
- ▲ Note: Charge and discharge every 3 months.

7.9 External power supply

1. 220 V, 50~60 HZ, +12V Vehicle Power Supply.

Internal battery: Nickel- hydrogen battery DC12V, 1.5Ah (264 minutes for minimum time charging). 2. Supply power for the ventilator over 6 hours at a normal work condition. For prolonging the lifespan of the internal battery, DIXION suggests you do a discharging and charging at least every 3 months.

Discharge: Cut off the external power supply and power on the ventilator until the low battery alarm takes places.

Charging: Connect external power supply (through the AC adaptor).

7.10 Operating environment

Temperature: -10~50°C; Relative Humidity: 30%~75%; Atmospheric pressure barometric: 70~106kPa

A Warning

• Using ventilator at a environment beyond the operating environment requirement may cause the tidal volume and airway pressure inaccurate, so much as the ventilator can not work.

7.11	The	accuracy	of	tidal	volume	about	pressure's	changing
(VT=7	'00mL	.)						

Pressure	Tidal volume	accuracy
P1=100kPa	700mL	0%
P2=100.5kPa	696.517mL	0.5%
P3=101.5kPa	689.655mL	1.5%
P4=103kPa	679.612mL	3%
P5=106kPa	660.377mL	6%

7.12 Accessories

Name	Description	Code	manufacture corporation	CE symbol
Main unit	Full name: Aeros 4300 ventilator	510(E)	DIXION	_
O2 Inlet pipe	White ,2m	510(E).3	DIXION	_
Fillet	silica gel	WJ137	DIXION	_
Mask	Big model	REF35-40-205	VBM, Germany	CE
Breathe valve	One patient use	71007	Galemed, Tai Wan, China	CE
Bag	1L	50420300	Dongguan, China	CE
AC adapter	12V 3A	MW4012	ELPAC, Shenzhen	CE
Whorl output pipe	1.1m, silica gel	69-16-110/1100 M22/22	VBM, Germany	CE
Battery	HY Ni-MH: AA1800mAh 12V; 52X15X145mm (in the Main unit)	KAN AA(49)	Kaien, zhejiang, China	CE
Oxygen flexible linker (optional)	Blue,1.8m	130003329	DIXION	_

A CAUTION: The factual collocation refers to packing list



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