

yuwell

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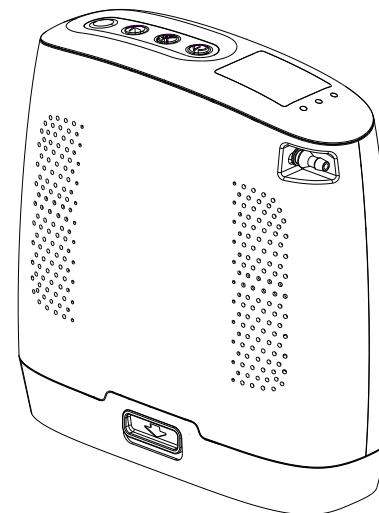
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Portable Oxygen Concentrator Model : Spirit-3

User's Manual

DO NOT OPERATE THIS UNIT WITHOUT FIRST
READING AND UNDERSTANDING THIS MANUAL

SAFETY NOTES

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INTENDED USE

INTENDED PURPOSE: This oxygen concentrator is intended for oxygen supplement.

CONTRA-INDICATIONS: Oxygen poisoning and oxygen allergy user/patient DO NOT using this oxygen concentrator. This device is to be used as an oxygen supplement and is NOT considered life-supporting or life-sustaining. Users who require continuous oxygenation must plan for alternate reserve sources of power and oxygen in the event of a failure or loss of power and oxygen.

PATIENT TARGET GROUP OR GROUPS: Adults only.

INTENDED USERS: Intended to be used by patients and care givers who are trained by an experienced person who has been authorized by the manufacturer and has appropriate training, knowledge, and experience.

 **WARNING:** In case of any serious incident that has occurred in relation to the device, please report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

 **WARNING:** U.S. Federal law restricts this device to sale by or on the order of a physician.

Symbol	Description
 WARNING	Describes a hazard or unsafe practice that if not avoided can result in severe bodily injury, death or property damage.
 CAUTION	Describes a hazard or unsafe practice that if not avoided can result in minor bodily injury or property damage.
	The symbol means mandatory (something that must be observed). The specific mandatory content shall be indicated by words or pictures in or near by the symbol. The figure on the left shows "general mandatory"
	The symbol means forbidden (something that is not allowed). The specific prohibited contents shall be indicated by words or pictures in or near the symbols. The figure on the left shows "general prohibition"

SAFETY NOTES

I . IMPORTANT MESSAGE

- ⓘ To reduce the risk of electrical shock, DO NOT remove the cabinet. Only the qualified person could provide the services.
- ⓘ Before operating the device, read and understand this manual.
 - The user should ensure the compatibility of the device and all of the parts and accessories used to connect to the patient before use.
 - The user should ensure that the oxygen delivery settings were determined and recorded for the patient individually together with the configuration of the equipment to be used, including accessories.
 - The user should periodically reassess the settings of the therapy for effectiveness.
 - If the performance of the oxygen concentrator is changed, contact qualified service personnel for technical support.

II . BEFORE INSTALLATION

- ⓘ Non-professional people DO NOT open the oxygen concentrator's cabinet. Removing the oxygen concentrator or replacing the internal components may cause injury to personnel or damage to the device.

III . LOCATING

- Place the concentrator on a solid, flat surface that the operator can hear and see the alarms.
- ⓘ It is not allowed to place the oxygen concentrator in the air flow blocking environment.
 - Be certain to place the device so all sides are at least 10 cm (4 inches) away from walls, draperies, furniture, or other obstruction. MUST place the oxygen concentrator in a well-ventilated area.
 - Always place the device in the expected position that the operator can hear the audio alarming.

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- ⓘ Oxygen concentrator MUST locate so as to avoid pollutants or fumes.
- ⓘ Oxygen concentrator must avoid heat source, fire source, wetness, exorbitant or over-low extra environment condition.
- ⓘ Sundries and vessel do not be placed on top of the concentrator.
- ⓘ It is forbidden to place any sundries at the bottom of the oxygen concentrator, and it is forbidden to place the device on soft surfaces (such as beds, sofas....etc.) that may cause inclinations or sinks. Prevent the air inlet and exhaust ports from blocking, which may cause shutdown or decrease of oxygen concentration.
- ⓘ Do not place the oxygen concentrator where it is difficult to unplug the power plug.
- ⓘ Do not use oxygen concentrator in MR (Magnetic Resonance) environment.

IV . FIRE WARNING OR EXPLOSION

- ⚠ WARNING: There is a risk of fire associated with oxygen equipment and therapy. Do not use near sparks or open flame.
- ⚠ WARNING: Smoking during oxygen therapy is dangerous and is likely to result in serious injury or death of the patient and others from fire.
- ⚠ WARNING: Use only water based lotions or salves that are oxygen compatible during setup or use during oxygen therapy. Never use petroleum or oil-based lotions or salves to avoid the risk of fire and burns.
- ⚠ WARNING: Do not lubricate replaceable fittings, connections, tubing, or other accessories of the device to avoid the risk of fire and burns.
- ⚠ WARNING: Use only spare parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.
- ⚠ WARNING: Oxygen makes it easier for a fire to start and spread. Do not leave the nasal cannula on bed coverings or chair cushions, if the device is turned on, but not in use; the oxygen will make the materials flammable. Turn the device off when not in use.

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⚠ **WARNING:** Smoking during oxygen therapy is dangerous and is likely to result in facial burns or death. Do not allow smoking or open flames within the same room of the device or any oxygen carrying accessories. If you smoke, you must always turn the device off, remove the cannula and leave the room where either the cannula or the device is located. If unable to leave the room, you must wait 10 minutes after the flow of oxygen has been stopped.

- Oxygen concentrator should be kept away from flammable and explosive places.
- Oxygen is a combustion supporting gas. Do not smoke when using, and keep away from matches, burned cigarettes and other combustible sources. Textiles and other normally non combustible materials are easily ignited and cause severe combustion in oxygen rich air. The neglect of this warning may lead to serious fire, property damage and personal injury or death.
- The use of oxygen therapy requires special care to reduce the risk of fire. Some materials will burn in the air, while others will not burn in the air, but will easily ignite and burn rapidly in oxygen rich environment. From the safety point of view, it is necessary to keep inflammables away from oxygen concentrator.
- Oil, grease or grease like substances contact with oxygen under a certain pressure will produce spontaneous combustion and violent combustion. These substances must be kept away from the oxygen concentrator, tubing, connectors, and all other oxygen devices. Do not use any lubricants other than those recommended by the manufacturer.
- The metal outlet fitting of the Spirit-3 used to deliver oxygen to the patient could reduce the propagation of fire for the safety of the patient.

V. MAINTENANCE

- Only authorized or factory trained personnel should perform preventive maintenance or performance adjustments on the oxygen concentrator.
- The manufacturer recommends that the oxygen concentrator should be operated for no less than 30 minutes at a time. Do not turn on and off the

SAFETY NOTES

oxygen concentrator frequently, and turn it on again after 3–5 minutes of shutdown, so as not to affect the service life of the compressor.

- The manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of oxygen concentrator that are designated by the manufacturer as repairable by service personnel.

⚠ **WARNING:** Against servicing and maintenance while the oxygen concentrator is in use.

- All functions and maintenance operations in this manual can be safely used by patients.
- It is recommended to maintain and test once a year: contact your local distributor or manufacturer to periodically test the essential performance and basic safety of the oxygen concentrator.

VI. RADIO FREQUENCY INTERFERENCE

- This device is suitable for hospital, family and other buildings directly connected with civil low voltage network power supply.
- The radio frequency energy used by this machine only acts on the internal operation of the machine. Therefore, its radio frequency emission is very low and it is not to affect other electrical equipment nearby.
- As the number of radio frequency transmitting devices or other electrical noise sources increases sharply in medical places, serious interference caused by too close distance or too strong power of the transmitter may cause the machine to stop working.
- In case of such a situation, the use site should be checked to find out the interference source, and the following measures should be taken to eliminate the interference: (1) close the nearby equipment and then turn it on; (2) change the direction or position of the interference equipment; (3) increase the distance between the interference equipment and the device.

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VII. TO REDUCE THE RISK OF BURNS, ELECTROCUTION, FIRE OR INJURY TO PERSONS

- Avoid using while bathing. If continuous usage is required by the physician's prescription, the oxygen concentrator must be located in another room at least 2.5m from the bath.
- ⊗ Do not place or store the oxygen concentrator in places where water or other liquids are easy to drip.
- If the oxygen concentrator falls into the water, do not touch it. Cut off the power supply and remove the battery immediately and contact a qualified dealer or manufacturer.
- ⊗ After the oxygen concentrator is connected to the power supply, do not leave the device unattended.
- The operation method of oxygen concentrator is detailed in this manual. If the user feels that there is insufficient oxygen, please contact the supplier or physician immediately and adjust the flow according to the physician's prescription.
- When using, if the device is close to children or people with inconvenient behavior, please supervise it.
- ⊗ Do not use parts, accessories or adapters that are not approved by the manufacturer. The use of accessories not specified by the oxygen concentrator will reduce the performance of the machine.
- ⊗ Do not connect this device in parallel or in series with other oxygen concentrator or oxygen treatment equipment.
- There are certain dangers in oxygen treatment in certain environments. Consult your doctor before using this product.
- Avoid any sparks in the vicinity of medical oxygen equipment, including sparks due to friction and static electricity.
- If the power cord or plug of the oxygen concentrator is damaged, if the device could not work properly, if the device is dropped or damaged, please contact qualified maintenance personnel for inspection and repair.

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- ⊗ Keep the power cord away from heated or heated surfaces.
- ⊗ Do not move oxygen concentrator when inserting power supply.
- ⊗ Do not drop or insert any substance into the opening of the device.
- The shelf life of the device is 5000 hours after manufacturing (includes all components, excepts single use consumable materials). And the Service Life is equal to the shelf life.
- In case of any accident during the use of the device, call the emergency hotline immediately and seek the help of professional medical staff.
- It can take up to 30 minutes to stabilize to deliver the set flowrate and concentration of oxygen to user after turn on the oxygen concentrator.
- Oxygen flowrate should be set according to the physician prescription.
- Patients with severe pulmonary disease should consult a professional doctor about the amount of oxygen inhalation.
- ⊗ The power cord and oxygen tubing may cause tripping or suffocation. When placing the power cord and oxygen tubing, it is necessary to avoid being trampled by personnel or squeezed or pressed by things.
- ⊗ No Modification of the oxygen concentrator is allowed. Modifications could result in hazards to the user.
- For the effectiveness of treatment, the oxygen output setting of the oxygen concentrator needs to be regularly evaluated by physician.
- This device is not intended for use with a tracheotomized patient.
- This device does not contain latex accessories.
- This device and accessories do not contain phthalates.
- ⊗ To reduce the risk of infecting another user or operator of reuse the oxygen concentrator, the cabinet should be cleaned by 75% alcohol before reuse. And all external tubing, cannula or other accessory should be replaced.
- ⊗ When not in use, do not leave the oxygen concentrator in the vehicle to

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avoid danger caused by too high or too low temperature.

⚠ **WARNING:** The settings of other models or brands of oxygen therapy equipment do not correspond with the settings of this Yuwell Spirit-3.

- Spirit-3, its parts and accessories are specified for use at specific flows.

Incompatible parts or accessories might result in degraded performance.

- The distributor or the responsible person should instruct the operator to assess the needs of the patient for backup supplies of supplementary oxygen in case of oxygen concentrator or power failure:

a) at installation based on

-- the condition of the patient,

-- the environment in which the patient lives, and

-- the ability to resupply the patient with backup supplies of supplementary oxygen; and

b) periodically as these attributes change.

- The user can electrically isolate the circuits of oxygen concentrator from the supply mains by unplugging the power plug.
- Lay operator or lay responsible organization should contact the manufacturer or the manufacturer's representative:
 - for assistance, if needed, in setting up, using or maintaining the me equipment; or
 - to report unexpected operation or events.
- Over temperature alarm of the oxygen concentrator can be a means to reduce the extent of the propagation of fire if ignition occurs.
- All parts of this oxygen concentrator are suitable for use within the patient environment.
- Lint, dust, pet hair, pests may cause blockage of the air intake and exhaust of the oxygen concentrator, please check and clean it regularly.

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- Heat from a fireplace or radiant heater may accelerate the aging of the oxygen concentrator's internal components.
- Moisture from a nebuliser or steam kettle may accelerate the aging of molecular sieves in oxygen concentrator.
- Take care to prevent children from adjusting the settings of the oxygen concentrator.

⚠ **WARNING:** To ensure receiving the therapeutic amount of oxygen delivery according to your medical condition, Yuwell Spirit-3 Portable Oxygen Concentrator must

-- be used only after one or more settings have been individually determined or prescribed for you at your specific activity levels.

-- be used with the specific combination of parts and accessories that are in line with the specification of the device manufacturer and that were used while your settings were determined.

⚠ **WARNING:** The settings of Yuwell Spirit-3 Portable Oxygen Concentrator might not correspond with continuous flow oxygen.

⚠ **WARNING:** Wind or strong draughts can adversely affect accurate delivery of oxygen therapy.

-- using this device beside an open window or in front of a fan can affect the accuracy of delivery of oxygen.

-- using this device in the back seat of an open convertible car can affect the accuracy of delivery of oxygen.

⚠ **WARNING:** If you feel discomfort or are experiencing a medical emergency, seek medical assistance immediately to avoid harm.

⚠ **WARNING:** Geriatric, paediatric or any other patient unable to communicate discomfort can require additional monitoring to avoid harm.

⚠ **WARNING:** Use of this device at an altitude above 3000 m or outside temperature of 5 °C ~ 35 °C or relative humidity above 90% is expected to adversely affect the flowrate and the percentage of oxygen and consequently

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the quality of the therapy.

- ⚠ **WARNING:** Open flames during oxygen therapy are dangerous and is likely to result in fire or death. Do not allow open flames within 2 m of the oxygen concentrator or any oxygen carrying accessories.
- ⚠ **WARNING:** Do not use this device while sleeping unless prescribed by your clinician and use a pulse-oximeter to monitor the SpO₂ of patient's.
- ⚠ **WARNING:** Do not use this device over 14h with 95% concentration oxygen and consult with doctor before oxygen therapy.
- ⚠ **CAUTION:** In the event of a fire, please remove the nasal cannula immediately and the oxygen concentrator will stop outputting oxygen at this time.

FEATURES

I . SUMMARY

- This manual will tell you about your concentrator and will serve as a reference as you use your concentrator.

▸ USE SPECIFICATION

INTENDED MEDICAL INDICATION: This oxygen concentrator is intended for use as an oxygen supplement device in home, institution and various mobile environment. It provides high concentration of oxygen to persons requiring oxygen therapy.

INTENDED PATIENT POPULATION: Adults only.

INTENDED PART OF THE BODY OR TYPE OF TISSUE APPLIED TO OR INTERACTED WITH: During oxygen inhalation, the nasal cannula is in direct contact with the user's facial skin and nasal cavity.

INTENDED USER PROFILE: Intended to be used by patients and care givers who are trained by an experienced person who has been authorized by the manufacturer and has appropriate training, knowledge, and experience.

USE ENVIRONMENT: In home, institution and various mobile environment.

OPERATING PRINCIPLE: The oxygen concentrator, whose material is air, uses molecular sieve as adsorbent to produce oxygen by Pressure Swing Adsorption. When an inhalation is detected, an electronically controlled delivery valve opened for a defined amount of time depending on the measured breath rate and flow setting to ensure the patient is receiving the oxygen pulse.

This device adopts the pulse oxygen supply method, and the device automatically outputs oxygen when it detects that the user is inhaling.

FEATURES

II . CHARACTERS

- The product structure is mainly composed of oxygen concentrator, rechargeable lithium-ion battery, power supply , DC power cord , and nasal oxygen tube .
- All plastic shell, safe and reliable.
- With time-consuming function: display the total working time through the display screen.
- Failure alarm function (including pressure failure alarm, compressor failure alarm, over heat alarm) and low oxygen concentration alarm.

III . SPECIFICATIONS

1. Flowrate : Setting 1 – Setting 4.
2. Oxygen Concentration at Nominal Output (Measured after warm up 30minutes) : 90% +6%/-3%
3. Maximum Limited Pressure: 150kPa
4. The rated range of the concentration of oxygen as a function of flowrate:
 - Tested at STPD (101.3kPa, 20°C, dry) conditions and rated operating condition specified in the manual.

Flowrate	Oxygen Concentration
Setting 1	87%~96%
Setting 2	87%~96%
Setting 3	87%~96%
Setting 4	87%~96%

- Oxygen concentration may be affected by over the rated ranges of ambient temperature, humidity and atmospheric pressure.
- The measurement uncertainty of Oxygen Concentration is $\pm 3\%$.

FEATURES

Breath Rate, Breath/Minute (BPM)	Setting 1	Setting 2	Setting 3	Setting 4
	Pulse Volume (mL)			
15	14.0	28.0	42.0	50.0
20	10.5	21.0	31.5	37.5
25	8.4	16.8	25.2	30.0
30	7.0	14.0	21.0	25.0
35	6.0	12.0	18.0	21.4
40	5.3	10.5	15.8	18.8
Total Volume per Minute (mL/min)	210	420	630	750

5. The rated range of delivered oxygen setting: Setting 1 to Setting 4.
 - The deviation is $\pm 15\%$ at STPD (101.3kPa, 20°C, dry).
 - The measurement uncertainty of the delivered oxygen is $\pm 4.5\%$.
 - The maximum deviation of the delivered oxygen at 20 BPM over the rated environment range is $\pm 15\%$.
6. Rated Breath Rate: 15BPM~40BPM
7. Inspiratory Trigger Sensitivity: minimum 0.5cm H₂O
 - The measurement uncertainty of the Inspiratory Trigger Sensitivity is $\pm 0.05\text{cm H}_2\text{O}$.
8. Sound Pressure Level (when measured at 1 m from device): 55dB(A) at Setting 4, 20 BPM;
Sound Power Level: 63dB(A) at Setting 4, 20 BPM.
9. Audio Alarm: 53dB(A) to 85dB(A) which tested @ Setting 4

FEATURES

10. Input Power: 110VA while charging

11. Power Source:

AC Power Supply: Input AC 100V–240V, 50Hz/60Hz

Output DC 12V,10A

Battery: DC 14.4V

DC Power Supply: DC 12V–16V

12. Battery Charge Time: Maximum recharge time is 5 hours from fully discharged to fully charged, depending on the power source and usage.

13. Net Weight :1.8kg (without battery); 2.4kg (with battery)

14. Dimensions : 22 × 8 × 22 (cm)

15. Altitude: Up to 3000 meters above sea level without degradation of concentration levels. Beyond 3000 meters below 87% efficiency

⚠ CAUTION: Use of this device at an altitude above 3000 m or outside a temperature of 5°C ~ 35°C or a relative humidity above 15% ~ 90% is expected to adversely affect the flowrate and the concentration of oxygen and consequently the quality of the therapy.

16. Safety System

- System Over Hot: Alarming and Shut Down
- Pressure Failure: Alarming and Shut Down;
- Compressor Failure: Alarming and Shut Down;
- Battery Over Hot: Alarming and Shut Down
- Low Oxygen Concentration: Alarming;
- No Breath Detected: Alarming;
- No Flow: Alarming;
- Low Battery: Alarming.

17. Minimum Operating Time: 30minutes

FEATURES

18. Electric classification: class II equipment, type BF applied part, IP22, applied part: nasal cannula.

19. Classification : over voltage category: II ; pollution degree: 2 ; altitude: ≤3000 m

20. Work system: work continuously.

21. Oxygen Output Temperature: ≤46°C

Applied Part Temperature (Nasal Cannula): ≤ 41°C

22. Normal Operating Condition (with Oxygen Concentration Status Indicator):

- Temperature range: 5°C ~ 35°C
- Relative humidity: 15% ~ 90%
- Atmosphere pressure: 70kPa ~ 106kPa

⚠ CAUTION: When operating condition over the rated ranges of ambient temperature, humidity and atmosphere pressure, the performance of the oxygen may be dropped.

23. Storage and Transportation Condition:

- Temperature range: -20°C ~ +60°C
- Relative humidity: ≤93% Non-condensing
- Atmosphere pressure: 70kPa ~ 106kPa

⚠ CAUTION: The device should be stored with no strong sunlight, no corrosive gas and well ventilated indoor area. The device must be transported and used in the vertical position only.

⚠ CAUTION: It takes 4 hours for the oxygen concentrator to cool from the minimum/maximum storage temperature between uses until the oxygen concentrator is ready for its intended use when the ambient temperature is 20°C.

HANDLING

I . UNPACKING

⚠ CAUTION: Unless use the oxygen concentrator, retain containers and packing materials for storage until use of the concentrator is required.

1. Check for any obvious damage to the carton or other packaging. If damage is evident, please notify the carrier or local dealer.
2. Remove all loose packaging from the carton.
3. Carefully remove all the components from the carton.

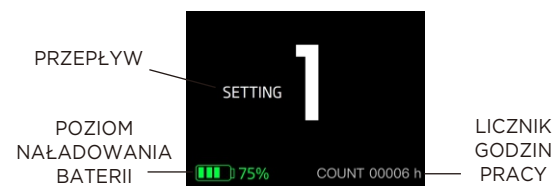
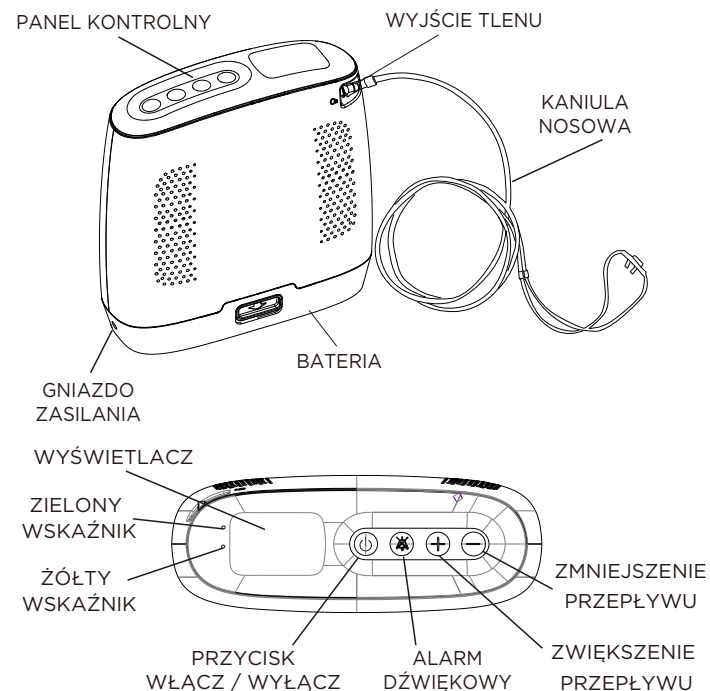
II . INSPECTION

1. Examine exterior of the oxygen concentrator for nicks, dents, scratches or other damages.
2. Inspect all components.

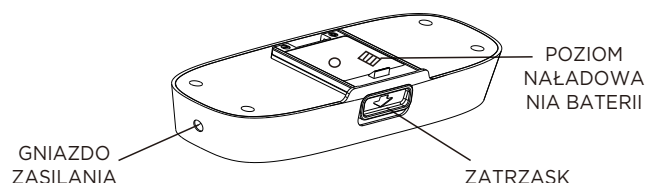
III . STORAGE

1. Store the repackaged oxygen concentrator in a dry area.
2. Do not place other objects on top of the oxygen concentrator.

OPERATING & INSTALLATION



OPERATING & INSTALLATION



II . PREPARE WORK

1. Place the oxygen concentrator in a well ventilated place and away from heat sources.
2. Install the battery.

⚠ **WARNING:** Connect the AC power output plug into the battery power input connector. Connect the AC power plug to the power source.

⚠ **WARNING:** DO NOT use extension power strip.

NOTE: Inspect the power cord/plug and the exterior of the oxygen concentrator for nicks, dents, scratches or other damages before usage. If it is necessary, call qualified service personnel for examination and repair.

III . BATTERY OPERATION

Make sure the battery is installed in the correct position and charged. The oxygen concentrator will turn on and start working. The estimated percentage of remaining battery level (%) is shown on the display.

Symbol	Status
	Battery is empty
	0 < Battery ≤ 25%
	25% < Battery ≤ 50%
	50% < Battery ≤ 75%
	75% < Battery ≤ 100%

OPERATING & INSTALLATION

During operating, if the battery level is lower than 10%, the device will send out a yellow indicator and audio alarm. When the battery is low, perform one of the following:

- a. Use the AC power supply or DC Power cable as power source.
- b. Turn off the oxygen concentrator and replace a fully charged battery.
- c. If the battery is empty, charge the battery or remove the battery.

⚠ **CAUTION:** Under normal operation and maintenance conditions, the battery can reach more than 70% of the initial capacity after 500 charge-discharge cycles.

⚠ **CAUTION:** It is the responsibility of the patient to periodically check the battery and replace as necessary. Yuwell assumes no liability for persons choosing not to adhere to manufacturers recommendations.

⚠ **WARNING:** Please remove the battery if the oxygen concentrator is not likely to be used for some time.

⚠ **WARNING:** Only use the specified Yuwell Spirit-3 Battery for this oxygen concentrator.

▸ Battery Charging

To ensure that your battery is properly charged, check that the correct AC power supply or DC power cable is in use and that the plug is properly plugged into the power outlet. Observe the display indicating the state of charge.

NOTE: The battery should be fully charged before use for the first time.

▸ Battery Installation

NOTE: The Spirit-3 is shipped from the factory with the battery removed.

⚠ **CAUTION:** Before operating, make sure that the oxygen concentrator is turned off and the cable on the power input connector has been removed.

Hold the Spirit-3 in one hand, and use the other hand to insert the battery into the bottom of the device by sliding battery into place until the latch returns to the upper position and a "click" sound occurs. As shown in Figure 5.

OPERATING & INSTALLATION

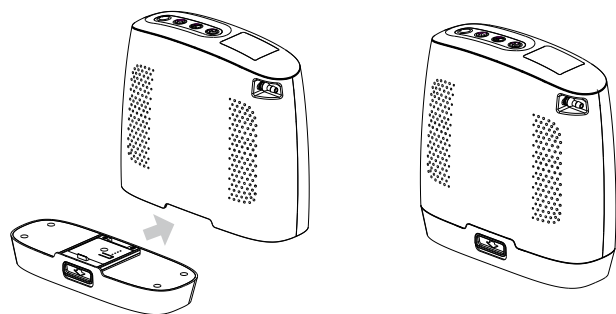


Figure 5

▸ Battery Removing

Place the Spirit-3 on a flat position. Hold the device in one hand, use another hand to push the latch down and pull out the battery from the device. As shown in Figure 6.

NOTE: When the battery is not installed, you can check the battery gauge on the battery to determine the amount of charge available.

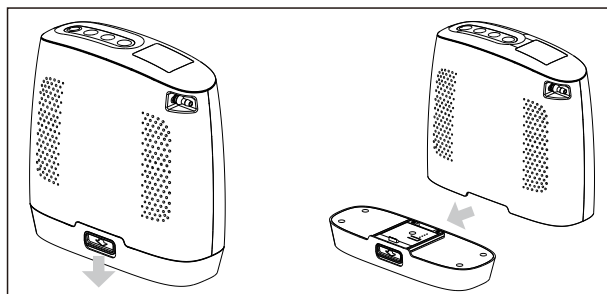


Figure 6

OPERATING & INSTALLATION

IV. AC POWER SUPPLY

- The AC Power Supply is design for the usage of the Spirit-3 only.
- When operating, connect the power output plug into the Spirit-3 then connect the AC power plug to the power source. As shown in Figure 7.

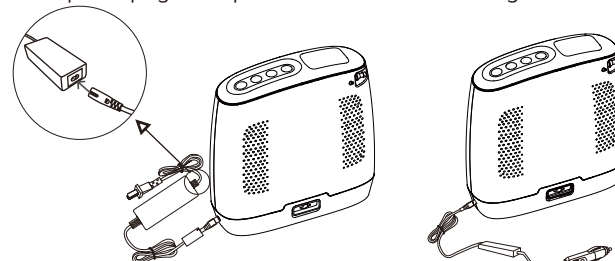


Figure 7

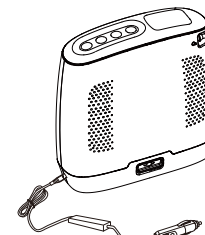


Figure 8

V. DC POWER CABLE

- The DC Power Cable is design for the usage of the Spirit-3 only.
- When operating, connect cable into the Spirit-3 then connect the DC power plug (Cigarette Lighter Adapter) to the power source. As shown in Figure 8.

⚠ CAUTION: When operating in the vehicle, always start the engine is first, then connect DC cable into cigarette lighter adapter.

⚠ CAUTION: Operating the Spirit-3 by DC cable without the engine running may drain or damage the vehicle's battery.

VI. OXYGEN INHALING OPERATION

- Press the On/Off Button to turn on the Spirit-3. The panel shows "yuwell" and the green/yellow indicators and alarm come on about 1 second then the yellow/red indicators and alarm will come off. After several seconds later, the displayer will show the battery level and unit status. The unit is operating normally.
- Press the Increase/Decrease Flow Setting Button to adjust the oxygen

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delivery as prescribed by the physician or clinician.

- ⊖ Oxygen therapy operation time and flow setting MUST according to the physician's prescription.
- ⊖ The oxygen delivery setting has to be determined for each patient individually with the configuration of the device is used, including accessories.
 - Connect the nasal cannula to the oxygen outlet fitting and the other end match the patient. The nasal cannula head should be placed in the nostril to start oxygen inhalation.
 - After turn on the device more than 1 minute and the nasal cannula is not connected to the user, the device will provide an oxygen pulse every 4 seconds. Place the end of the nasal cannula under the surface of half-full cup of water and look for bubbles to make sure the oxygen delivery.

NOTE: The operator is within 1m of the oxygen concentrator.

NOTE: It might take up to 30 minutes to stabilize to deliver the setting flowrate and concentration of oxygen to user after turn on the oxygen concentrator.

⚠ **CAUTION:** During operating, if oxygen could not be delivered, please check whether the tubing is blocked, kinked, damaged or the nasal cannula is not equipped in right place.

⚠ **CAUTION:** The proper placement and positioning of the nasal canal in the nose is critical to the consistent operation of this device.

NOTE: Some respiratory efforts of the patient such as breathing by the mouth might not trigger the oxygen concentrator.

VII. ALARM SIGNAL

The Spirit-3 oxygen concentrator has the following failure alarm function

- 1) Start-up period
- 2) Low oxygen concentration
- 3) No breath detected
- 4) No flow

OPERATING & INSTALLATION

- 5) Low battery
- 6) Empty battery
- 7) Pressure failure
- 8) Compressor failure
- 9) System over temperature
- 10) Battery over temperature

NOTE: All the alarms of the device are low priority.

NOTE: All the alarm conditions are technical alarm conditions.

When the oxygen concentrator starts, the LCD displayer, green and yellow indicators will be turned on and the alarm will sound once to ensure the alarm system is working properly, then the yellow indicators will come off.

After 5 minutes of the oxygen concentrator starts, the oxygen sensor will work normally and control the indicator lights depending on oxygen concentration level.

- Explanation of the indicators

Symbol	Status	Indicator lights
OK	System is in good condition: oxygen concentration $\geq 82\%$	Green
⚠	1) Oxygen concentration < minimum rated concentration (start-up period) 2) Oxygen concentration < 82% 3) No breath detected 4) No flow 5) Low battery 6) Empty battery 7) Pressure failure 8) Compressor failure 9) System over temperature 10) Battery over temperature	Yellow

OPERATING & INSTALLATION

► Description of the alarm conditions

NOTE: Oxygen concentrator will reach to stable state after warm-up (approximately 30 minutes).

1. Oxygen concentration is greater than 82%. Green light illuminates, system is in good condition. The green light will become to flashing while detected the breathing of the user.
2. Oxygen concentration is less than 82%. Yellow light illuminates, alarm sounds and the device keeps working. The green light will flash each time a breath is detected. Please contact the supplier immediately, the user can continue to use and ensure that there is backup oxygen source nearby. The alarm status does not affect each other.
 - The maximum and mean delay of low oxygen concentration alarm system delay is 60 s.
3. In case of pressure failure alarm, the yellow light illuminates, alarm sounds, panel shows word "Pressure failure", and the device shutdown. Please turn off the device, use backup oxygen source and contact equipment provider.
 - The maximum and mean delay of low pressure alarm system delay is less than 10 s.
 - The maximum and mean delay of high pressure alarm system delay is less than 5 s.
4. In case of compressor failure alarm, the yellow light illuminates, alarm sounds, panel shows word "Compressor Failure", and the device shutdown. Please turn off the device, use backup oxygen source and contact equipment provider.
 - The maximum and mean delay of compressor failure alarm system delay is less than 10 s.
5. In case of over temperature alarm, the yellow light illuminates, alarm sounds, panel shows word "Hot System", and the device shutdown. Please turn off the device, use backup oxygen source and contact equipment provider.

OPERATING & INSTALLATION

- The maximum and mean delay of over temperature alarm system delay is less than 10 s.
6. In case of no breath detected alarm, the yellow light illuminates, alarm sounds, panel shows word "No Breath Detected", and the device keeps working. Please contact the supplier immediately, the user can continue to use and ensure that there is backup oxygen source nearby.
 - The maximum and mean delay of no breath detected alarm system delay is 15 s.
 7. Battery detection
 - 5% < battery power ≤ 10%. Yellow light illuminates, alarm sounds and the device keeps working. The green light will flash each time a breath is detected. The panel shows word "Low Battery". Please connect to the power source to charge immediately.
 - The battery power ≤ 5%. Yellow light illuminates, alarm sounds and the device keeps working. The green light will flash each time a breath is detected. The panel shows word "Empty Battery". Please connect to the power source to charge immediately.
 - In case of battery over heat alarm, the yellow light illuminates, alarm sounds, panel shows word "Hot Battery", and the device shutdown. Please turn off the device, use backup oxygen source and contact equipment provider.
 - The maximum and mean delay of battery over temperature alarm system delay is less than 10 s.
 8. In case of no flow alarm, the yellow light illuminates, alarm sounds, panel shows word "No Flow", and the device keeps working. Please contact the supplier immediately, the user can continue to use and ensure that there is backup oxygen source nearby.
 - The maximum and mean delay of no flow detected alarm system delay is 30 s.
 9. Oxygen concentration is less than the minimum rated concentration during the start-up period. Yellow light illuminates. The device is in

OPERATING & INSTALLATION

warm-up status. Wait for 3 minutes, if the alarm still persists, contact supplier immediately.

▸ Audio alarm paused function

When the oxygen concentrator alarms, press the "Audio alarm paused" button, the alarm sounds will be turned off, and the panel shows "⚠". Press the "Audio alarm paused" button again or 2 minutes later, the alarm will sound again, and the panel no longer shows "⚠".

The alarm sound pause function lasts for 2 minutes, and the oxygen concentrator will resume the alarm state after 2 minutes.

Alarm limits

Alarm	Alarm limits
High pressure	Pressure is greater than 180 kPa
Low pressure	Pressure is less than 5 kPa
Compressor High current	Current is greater than 6.0 A(DC)
Compressor Low current	Current is less than 0.2 A(DC)
System over temperature	Temperature of the gas around sensor is greater than 73 °C
Battery over temperature	Temperature of the battery is greater than 56 °C
Low oxygen concentration	Oxygen concentration is less than 82 %
No breath detected	Inhalation pressure is less than 0.3 cmH ₂ O
No flow	Oxygen flowrate is less than 0.3 L/min
Low battery	5 % < Battery level ≤ 10 %
Empty battery	Battery level ≤ 5 %

▸ Operator's position

The operator is within 1 m of the oxygen concentrator.

OPERATING & INSTALLATION

VIII.SYMBOLS

Symbol	Description	Symbol	Description
~	Alternating Current	⚠	Caution
□	Class II Equipment	⚠	Type BF Applied part
⏏	Stacking Limitation	↑↑	Keep Up
☂	Keep Dry	🍷	Fragile
🌡	Temperature limit	🌡	Humidity Limitation
🌡	Atmospheric Pressure Limitation	👤	Refer to instruction manual
🚭	No Smoking	🚭	No open flame: Fire, open ignition source and smoking prohibited
🚫	Do Not Disassemble	🚫	Use No Oil or Grease
EC REP	European Representative	🏭	Manufacturer
🔌	Power On/Off	🔌	External Power is Connected
+	Increase Flow Setting	—	Decrease Flow Setting
⊖ ⊕	Polarity marking of DC power Positive inside,negative outside	🔋	Battery Level
⚠	Audio Alarm Paused	⚠	Alarm

OPERATING & INSTALLATION

Symbol	Description	Symbol	Description
	Do Not Dispose of In Unsorted Municipal Waste		Medical Device
	Serial Number		Date of Manufacture
	MR Unsafe: An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.		
IP22	Enclosures Protection Classification The first characteristic number "2": Protected against access to hazardous parts with a finger. The second characteristic number "2": Against dripping(15° tilted).		

IX. TURN OFF

After oxygen therapy operating, remove the nasal cannula or tubing from oxygen outlet fitting. Press the “” Button to turn off the Spirit-3.

X. ACCESSORIES

- ▶ The maximum oxygen flow for the accessories is not greater than 10L/min. And the maximum pressure for the accessories is not greater than 150kPa.
- ▶ This oxygen concentrator, its parts and accessories are specified for use at specific flows.
- ▶ Incompatible parts or accessories may result in degraded performance.

The responsible organization is accountable for ensuring the compatibility of the oxygen concentrator and all of the parts or accessories used to connect to the patient before use.

⚠ CAUTION: Use only water-based lotions or salves that are oxygen-compatible prior to and during oxygen therapy. Never use petroleum-based or oil-based lotions or salves to avoid the risk of fire and burns.

OPERATING & INSTALLATION

- ▶ Nasal cannula

⚠ CAUTION: The proper placement and positioning of the prongs of the nasal cannula in the nose is critical to the amount of oxygen delivered to the respiratory system of the patient.

⚠ CAUTION: Please only use the accessories that Yuwell provided or recommended to ensure the compatibility of the device and the accessories.

⚠ CAUTION: Recommended nasal cannula: Adult PVC, 2m long manufactured by INTERSURGICAL MEDICAL APPARATUS (CHANGZHOU) CO., LTD.

Model: 116100

⚠ CAUTION: The nasal cannula is single-used and should be used immediately after opening the package and destroyed afterwards. The nasal cannula is absolutely prohibited to be used if the package is damaged before usage. Re-using the cannula may increase the re-infection risk.

⚠ CAUTION: Failure to use the recommended nasal cannula, such as the paediatric cannula used by adult patient, may affect the effectiveness of oxygen therapy.

⚠ CAUTION: Only for use with a nasal cannula less than 10 m in length.

- ▶ Carry bag:

The Carry Bag provides a protective case with an adjustable shoulder strap to help you to carry the Spirit-3 anywhere. The Spirit-3 can be operated by battery during transport with the Carry Bag.

1. Insert the oxygen concentrator upward into the bag through the zipper opening at the bottom of the bag, install the battery, and close the zipper.
2. The oxygen outlet is located at the top of the bag and exposed for

OPERATING & INSTALLATION

connecting accessories. The displayer can be seen at the top of the bag.

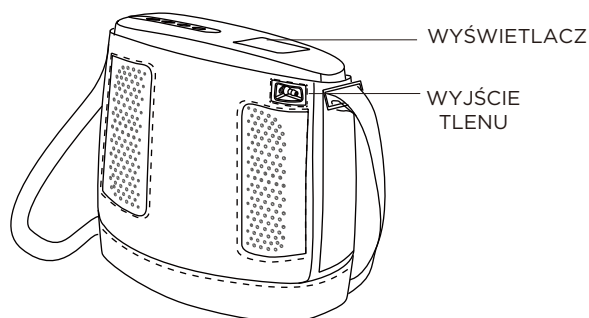


Figure 9: Carry bag

MAINTENANCE

⚠ CAUTION: Before maintaining the oxygen concentrator, Remove the power and take out the battery first to avoid electrical shock.

⚠ CAUTION: During both normal condition and single fault condition, the housing, battery, nasal cannula and carry bag can become contaminated with body fluids or expired gases. To reduce the infection risk, please perform the maintenance routinely.

Regular Inspection

Check at least once a month to check whether the appearance of oxygen concentrator, battery and power supply is damaged, whether the power cord is in good condition, and whether there is abnormal noise in the operation of the oxygen concentrator. If necessary, please contact the supplier for professional inspection.

Replacement Cycle of Sieve Beds

When the low oxygen concentration alarm occurs and the filter felt is cleaned or replaced, contact the supplier for maintenance or replacement.

NOTE: In places with high dust or soot levels, maintenance may need to be performed more often.

NOTE: After cleaning and disinfecting the oxygen concentrator, parts or accessories, please wrap them in plastic bags and store them in a dry environment until next use.

I . CLEAN CASE

⚠ CAUTION: Do not dismantle the exterior case and battery case of the oxygen concentrator.

⚠ WARNING: Liquid will damage the internal components of the oxygen concentrator and its equipment. To avoid damage or injury from electrical shock:

- Turn Off the concentrator remove the battery, and unplug the power cord before cleaning.

MAINTENANCE

- DO NOT allow any cleaning agent to drip inside the air inlet and outlet openings.
- DO NOT spray or apply any cleaning agent directly to the cabinet.
- DO NOT hose down the product.
- DO NOT submerge the device or accessories in liquid.

▸ Clean the exterior case and battery case once a month as follows:

- 1) Use a cloth or sponge with a mild detergent or warm soapy water to clean the exterior case.
- 2) Allow the oxygen concentrator to air dry, or use a dry towel, before operating the oxygen concentrator.

⚠ CAUTION: Before delivery to a new patient, after cleaning and before drying, it should also be disinfected as follows:

Wipe the exterior case and battery case with a cloth or sponge dipped in 70%~80% medical alcohol.

II . MAINTENANCE OF BATTERY

When not in use for a period of time, remove the battery from the oxygen concentrator and store it separately.

Battery needs to be used and stored carefully to ensure stable performance and long service life. Only use the battery provided by Yuwell for the oxygen concentrator.

▸ Keep Dry

Store the battery in a cool and dry place.Keep the liquid away from the battery at any times. If the battery is damp, stop using immediately and dispose of the electricity properly.

▸ Temperature Effect of Battery Performance

The battery can supply power for up to 5 hours under most environmental conditions. In order not to affect the operation time of the battery, avoid long-

MAINTENANCE

term operation at the temperature lower than 5 °C or higher than 35°C.

▸ Battery Level

Display the remaining battery level continuously. This value is only an estimate, and the actual remaining level may be different from this value.

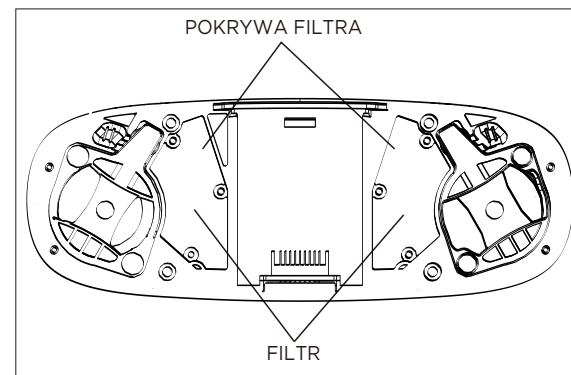
III . CLEAN OR REPLACE FILTER

Please clean or replace the filters in time, it's very important to protect compressor and to extend the oxygen concentrator life.

▸ Disassembly filter (Figure 10)

1. Remove the battery.
2. Screw out the screw fixing the filter cover which located at the bottom of the oxygen concentrator and remove the filter cover .
3. Remove the filter felt

The actual cleaning time of filter felt should be determined according to the actual use time and environmental impact.



NOTE: If the filter felt is black or dirty, it should be cleaned or replaced immediately no matter how long it is used.

■ MAINTENANCE

▸ Clean the filter

- 1) Clean the filter with a mild detergent or warm soapy water and then rinse thoroughly with clean water.
- 2) DRY the filter thoroughly before reinstallation.
- 3) The filter must be cleaned or replaced 100 hours or as necessary.

⚠ CAUTION: Do not operate oxygen concentrator without filter installed or when filter is wet. These actions can permanently damage the oxygen concentrator.

IV. CLEAN CARRY BAG

Clean the carry bag once a month as follows:

- 1) Use a cloth or sponge with a mild detergent or warm soapy water to clean the carry bag.
- 2) Allow the carry bag to air dry, or use a dry towel.

⚠ CAUTION: Before delivery to a new patient, after cleaning and before drying, it should also be disinfected as follows:

Wipe the carry bag with a cloth or sponge dipped in 70% ~ 80% medical alcohol.

V. VERIFY ALARM SYSTEM

- Verify the alarm system at least once a month: Turn on the oxygen concentrator and without connection the nasal cannula, about 15 seconds later, the yellow light illuminates, alarm sounds, panel shows "No breath detected". Press the "Audio alarm paused" button, the audio alarm will be turned off, and the yellow light still illuminate. Press the "Audio alarm Paused" button again, the audio alarm will sound again.
- Methods to check the function of the alarm system for each of the alarm conditions are specified in the Technical Manual (Document No.:YY-OXG3300C-03).

■ MAINTENANCE

VI. INSTRUCTIONS FOR PROCESSING AND REPROCESSING

- In order to prevent injury caused by infection or damage to the oxygen concentrator, only qualified personnel can clean and disinfect the oxygen concentrator and its accessories for multiple patients.
- Follow the instructions below to eliminate possible pathogen infection between patients caused by component or accessory contamination. If necessary, preventive maintenance should also be carried out at this time.
 - 1) Replace the nasal cannula.
 - 2) Check whether the appearance of the oxygen concentrator is damaged or needs to be repaired.
 - 3) Perform all procedures in the Maintenance section.
 - 4) Ensure that the oxygen concentrator functions normally and all alarms are in normal working condition.
 - 5) Before delivering to a new patient, ensure that the delivery includes the oxygen concentrator and this manual.

TROUBLESHOOTING

Use the table below to take actions when the oxygen concentrator indicates an abnormal condition.

Symptom	Probable cause	Solution
Displayer is no working after installing battery and turning on.	Battery installed not in place.	Re-install the battery
	Battery is empty.	1) Change another battery. 2) Use AC power Supply or DC Power Cable to supply power.
	If the phenomenon persists, please contact the supplier.	
After turning on the device, device is working, but no oxygen output. or less.	Nasal cannula is broken.	Replace the nasal cannula.
	If the phenomenon persists, please contact the supplier.	
Device is working, but yellow indicator illuminates.	Oxygen concentrator < 82%	1) Clean or replace the filter felt. 2) If the phenomenon persists, please use the alternate oxygen source and contact the supplier.
	No flow	1) Check whether the tubing is blocked. 2) Please use the alternate oxygen source and contact the supplier.
	No breath detected	Connect the nasal cannula to the oxygen outlet, wear it to the face, make sure there is no kink and breathe through the nose.
	Low battery level	1) Change another battery. 2) Use AC power Supply or DC Power Cable to supply power.

TROUBLESHOOTING

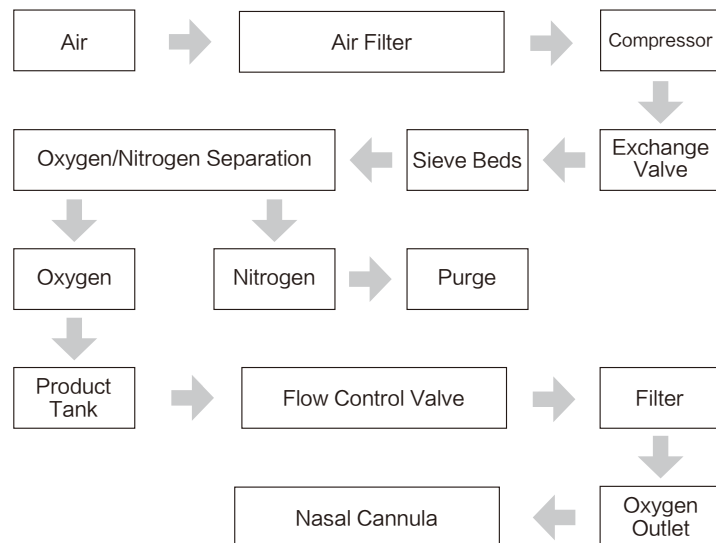
Symptom	Probable cause	Solution
Device is not working, and yellow indicator illuminates.	Low pressure failure	Please use the backup oxygen source and contact the supplier.
	High pressure failure	Please use the backup oxygen source and contact the supplier.
	Compressor failure	Please use the backup oxygen source and contact the supplier.
	Battery over heat	Remove the battery. Please use the backup oxygen source and contact the supplier.
	System over heat	Please use the backup oxygen source and contact the supplier.

⚠ CAUTION: If you have any other problems, TURN OFF the concentrator first, use your backup oxygen source, and contact the supplier immediately.

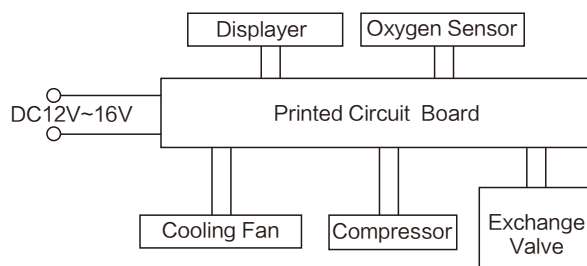
⚠ CAUTION: Steps of disassembling the oxygen concentrator (only for service personnel) are specified in the Technical Manual (Document No.:YY-OXG3300C-03).

OTHER ATTENTION ITEMS

I . GAS PASS OPERATION SKETCH MAP



II . ELECTRICAL RATIONALE



OTHER ATTENTION ITEMS

III . PACKING LIST

1. Oxygen Concentrator	1 unit
2. Manual	1 piece
3. Filter	2 pieces
4. Carry Bag	1 piece
5. Rechargeable Lithium-ion Battery	1 piece
6. AC Power Supply	1 piece
7. DC Power Cable	1 piece

Information for accessories

Name	Manufacturer	Type	Technical data
Carry Bag	JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO., LTD	/	/

IV . DEVICE DISPOSAL

The lay responsible organization must contact its local authorities to determine the proper method of disposal of the oxygen concentrator and accessories.

Particular attention shall be given to the disposal of the molecular sieves.

V . LANGUAGE

We will provide instruction manuals suitable for the local language.

EMC INFORMATION

- ⚠ **WARNING:** Far away from HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging in hospitals, where the intensity of EM DISTURBANCES is high.
- ⚠ **WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- ⚠ **WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment 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 oxygen concentrator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- ESSENTIAL PERFORMANCE:** For Spirit-3 Portable Oxygen Concentrator, the delivered oxygen dose, in both normal condition and single fault condition, within the accuracy as indicated in the instructions for use, or generation of an alarm condition: absence of the inspiratory trigger alarm condition, gas supply failure alarm condition.
- ⚠ **CAUTION:** If the oxygen concentrator is not working normally or an alarm condition occurs, the user should attempt to move the oxygen concentrator to a different area to determine if the issue is due to electromagnetic interference with other equipment in the vicinity.

EMC INFORMATION

Table 1: Guidance and declaration of manufacturer – electromagnetic immunity.

Phenomenon	Basic EMC standard or test method	Immunity test levels
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Electrical fast transients / bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V/m 0.15 MHz – 80 MHz 6V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
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

EMC INFORMATION

Table 2: Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHZ)	Band (MHZ)	Service	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13,17	Pulse modulation 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500				
5785				

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

EMC INFORMATION

Table 3: Guidance and declaration of manufacturer – electromagnetic emission

Phenomenon	Compliance
Conducted and radiated RF EMISSIONS CISPR 11	Group 1, Class B
Harmonic distortion IEC 61000-3-2	Class A
Voltage fluctuations and flicker IEC 61000-3-3	Complies