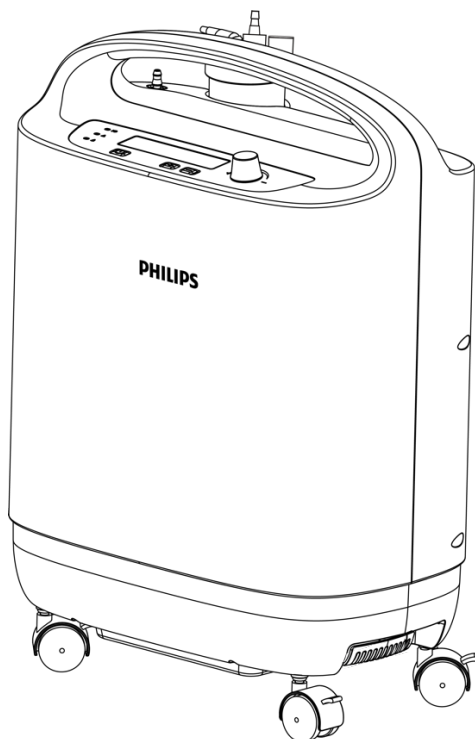


PHILIPS**Oxygen
Concentrator****Oxygenate 5**

KSW-5

User Manual

Read this manual carefully before use!
Not all features are available in all markets.



About this Manual

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Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd. (hereinafter called Konsung) cannot be held liable.

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All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your oxygen concentrator. Please refer to the actual product and its display.

Responsibility of the Manufacturer

Konsung only considers itself responsible for any effect on safety, reliability and performance of the oxygen concentrator if: assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by Konsung, and the electrical installation of the relevant room complies with national standards, and the instrument is used in accordance with the instructions for use.

Upon request, Konsung may provide necessary circuit diagrams, and other information to help a qualified technician to maintain and repair some parts, which Konsung may define as user serviceable. Contents of this manual are subject to changes without prior notice.

Conventions

- Warning:** Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.
- Caution:** Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.
- Note:** Provides application tips or other useful information to ensure that you get the most from your product.

How to Contact Philips Respironics

If you need your device serviced, contact Philips Respironics directly to help facilitate this activity. Call the Philips Respironics Customer Service department at 1-724-387-4000 or 1-800-345-6443 (US or Canada). You can also use the following address:

Respironics Inc

1001 Murry Ridge Lane, Murrysville, PA 15668 USA

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1 Product Introduction

The Oxygen Concentrator is composed of an air compressor, air pretreatment, control valve, molecular sieve adsorption tower, control and alarm system, and production gas treatment system.

By providing oxygen to patients, the treatment the oxygen concentrator delivers can help recovery in cardiovascular and cerebrovascular, respiratory, chronic obstructive pneumonia and other diseases, and hypoxia. The oxygen concentrator is suitable for different levels of physiological hypoxia groups such as the elderly, pregnant women, and it can also be used to eliminate fatigue and restore the body function after heavy physical or mental exertion. The concentrator's service life is five years.

1.1 Intended use and population

Intended Use: For medical institutions to deliver oxygen for patients with hypoxia and in home care settings for patients in need of supplemental oxygen.

Intended patient population: Adult, Pediatrics & Infants (Above 3 years old).

Medical condition: Medical institutions; institutions or healthcare facilities with health care capabilities.

Intended user: Medical professional or trained patient.

Contraindications: There are no known contraindications..

Oxygen concentrator mainly uses air as raw material and uses molecular sieve pressure swing adsorption process to produce oxygen with oxygen concentration $93\% \pm 3\%$ (V/V). For medical institutions and other production of oxygen for hypoxia patients to use oxygen.

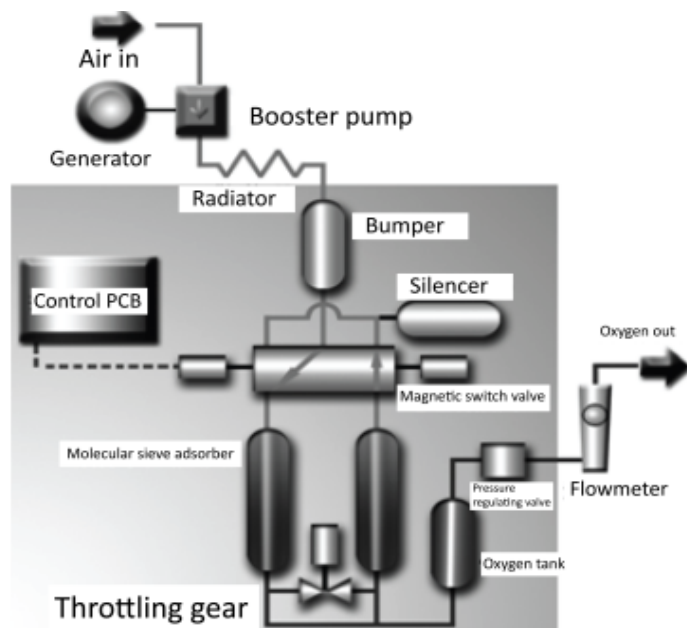
WARNING

The oxygen concentrator is not for life supporting use or unconscious patients.

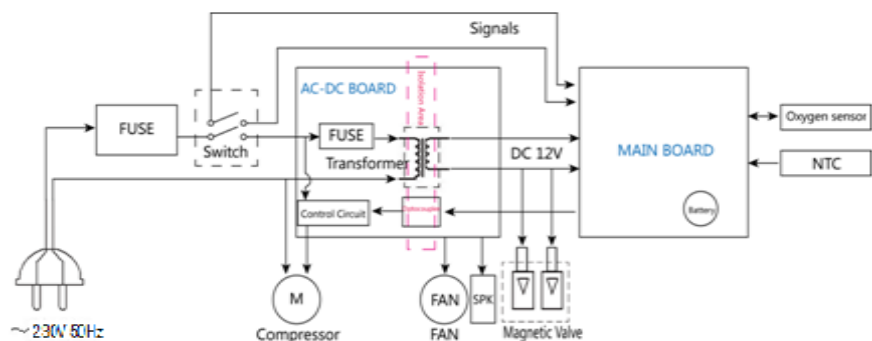
1.2 Operating Principle & Flowcharts

Operating principle: Oxygen concentrator uses the pressure swing adsorption (PSA) technology and through the molecular sieve to process air to produce high-grade medical standard oxygen.

The following figure shows the operating principle of the oxygen concentrator.
























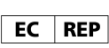
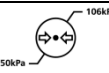
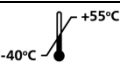







The following figure shows the electrical control process of the oxygen concentrator:



1.3 Equipment symbols

Some symbols may not appear on your equipment.

Symbol	Description	Symbol	Description
	General warning sign		No open flame: Fire, open ignition source and smoking prohibited
	Warning; Electricity		No smoking
	No sitting		No stepping on surface
	Refer to instruction manual/booklet		MR unsafe
	Not to be serviced by users		Type BF applied part
	Class II equipment		Serial number
	Part number		Model number
	Batch code		Input
	Catalogue number		Medical device
	Unique Device Identifier		Country of manufacturer
	Manufacturer		Importer
	CE mark		Authorized representative in the European community
	Atmospheric pressure limitation		Temperature limit
	Increase or decrease (Knob)		Humidity limitation

Symbol	Description	Symbol	Description
IP21	The oxygen concentrator can provide protection against ingress of solid foreign objects of 12.5 mm diameter and greater; the oxygen concentrator can provide protection against vertically falling water drops.		WEEE symbol-This symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling. By separating this product from other household-type waste, the volume of waste sent to incinerators or land-fills will be reduced and natural resources will thus be conserved.
	ON (power)		Fuse
○	OFF (power)		Alternating current

2 Safety Guidance



Special Warning

- People in urgent need of oxygen and seriously ill patients must keep as a stand-by, other oxygen-supply devices for emergency use (such as oxygen cylinders, oxygen bags).
- The concentrator is suitable for oxygen supplementation, and it is not intended to be life supporting or life sustaining.
- This device must be used under the guidance of a physician.
- Personal and family use should be in accordance with the guidance of a physician when the concentration is higher than 93%.



Safety Information

- The oxygen concentrator uses the power of AC 220-240 V 50Hz. Please use safe and qualified sockets and wiring boards with safety electrician certification.
- If any object or liquid enters the unit, disconnect the power plugs immediately, and have the unit tested by the service provider before re-use.
- For prolonged periods of non-use, unplug the concentrator from the power outlet. Use caution not to pull out the power cord from the concentrator when removing the plug.

2.1 Safety Tips for Oxygen Concentrator

WARNING

- There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do not use the oxygen concentrator or accessories near sparks or open flames.
- To ensure receiving the therapeutic amount of oxygen delivery according to your medical condition, the KSW-5 (Oxygenate 5) oxygen concentrator must:
 - 1) be used with settings that have been individually determined or prescribed for you at your activity levels with your accessories.
 - 2) be used with the specific combination of parts and accessories that are in line with the specification of the concentrator manufacturer.
- Use only water-based lotions or salves that are oxygen-compatible before and during oxygen therapy. Never use petroleum or oil-based lotions or

salves to avoid the risk of fire and burns.

- Do not lubricate fittings, connections, nasal cannula, or other accessories of the oxygen concentrator to avoid the risk of fire and burns.
- Use only spare parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.
- Use of the oxygen concentrator at an altitude above 2000 m or outside a temperature of 5°C to 40°C or a relative humidity above 75% (non-condensing) is expected to adversely affect the flowrate and the percentage of oxygen and consequently the quality of the therapy.
- 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 oxygen concentrator is turned on, but not in use; the oxygen will make the materials flammable. Turn the oxygen concentrator off when not in use to prevent oxygen enrichment.
- Please ensure that the air inlet sources are kept free from any obstruction to reduce any reduction in the airflow.
- If you feel discomfort or are experiencing a medical emergency while undergoing oxygen therapy, seek medical assistance immediately to avoid harm.
- Geriatric, pediatrics or any other patient unable to communicate discomfort can require additional monitoring and or a distributed alarm system to convey the information about the discomfort and or the medical urgency to the responsible care giver to avoid harm.
- Smoking during oxygen therapy is dangerous and is likely to result in facial burns or death. This device produces enriched oxygen gas, which accelerates combustion. Do not allow smoking or open flames within the same room as the concentrator or any oxygen-carrying accessories. If you smoke, you must always turn the oxygen concentrator off, remove the cannula and leave the room where either the cannula or the oxygen concentrator is located. If unable to leave the room, you must wait 10 minutes after you have turned the oxygen concentrator off.
- 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.
- Do not use the equipment near flammable materials such as grease, oil, detergent etc. Under a certain pressure, oil, grease or grease substances when combined with oxygen can self-ignite and lead to intense combustion. These substances must be kept away from the oxygen concentrator, piping, connectors, and all other oxygen devices. Do not use

any lubricant other than the manufacturer's recommendation.

- Do not place debris and water oil containers on top of the oxygen concentrator.
 - Do not place any debris at the bottom of the oxygen concentrator, and it is not recommended to place the concentrator on a soft surface (such as bed or sofa) that can cause tilting or sinking. Do not allow either the air intake or the air outlet vents to become blocked. This can cause the concentrator to overheat and affect performance.
 - Do not touch the cabinet or air outlet with your hands during the operation of the oxygen concentrator to avoid injury caused by overheating.
 - The device has passed the electromagnetic compatibility test conducted by testing center for TUV product. The device will not produce harmful RF interference if used in residential area. But in order to maintain normal use, please do not use the concentrator near high frequency emitting equipment, such as speaker, MRI or CT etc.
 - Do not place oxygen concentrator in parallel or in series with other concentrators or oxygen treatment equipment.
 - Oxygen therapy is dangerous in some specific environments. The manufacturer recommends that the user consult the physician before using the oxygen concentrator.
 - Avoid the production of any spark near the oxygen concentrator, including sparks due to various friction static electricity.
 - Call the emergency hotline and seek the help of a health care professional immediately if any discomfort is felt or an accident happened while using the concentrator.
 - The plug is used as a disconnecting device between the oxygen concentrator and supply mains, please do not place the plug in a position where it is difficult to disconnect.
-

2.2 Electrical Safety Requirement

CAUTION

- Electrical shock hazard, do not disassemble the concentrator. Only a qualified service technician should remove the covers or service the unit.
- The concentrator should be kept away from an explosive atmosphere.
- Oxygen is a combustion-supporting gas. No smoking near the working oxygen concentrator.
- The oxygen concentrator should be kept away from matches, burning cigarettes and other objects of high temperature or fire textiles and other normally non-combustible materials that are easily ignited and explosive in oxygen-enriched air. Ignoring of this warning may result in serious fire, property damage, and personal injury or death.
- Oxygen concentrator cannot be placed and used in the following environments: near heat or fire, wet, no shelter, smoke and pollution, too high or too low temperature.
- Do not use the equipment in a confined space or airflow obstruction environment. Oxygen concentrator should be placed indoors with ventilation, and avoiding direct sunlight. 0.5 m or more should be left between concentrator and the walls, windows, furniture and other similar objects.
- If the power cord or plug of the oxygen concentrator is damaged, or concentrator does not work properly, or the concentrator was dropped or damaged, please contact qualified maintenance personnel to check and repair.
- Keep the power cord away from hot or heated surfaces.
- Do not move the oxygen concentrator while it is plugged to the mains.
- Do not tread, sit on or lie on the oxygen concentrator.
- Do not drop or insert anything at the concentrator intake or outtake port. If any object or liquid enters the unit, disconnect the power plugs immediately, and have them tested by the professional person before re-use.
- Ensure there are no humidification devices in the same room or within 2 meters around while using the concentrator. This may affect the performance and oxygen purity.
- Turn off the equipment before relocating the power source to a different power outlet. Please pay attention to electricity safety. Do not use the oxygen concentrator if either the plug or power cord is damaged. Do not

attempt to clean the concentrator or replace the filters while it is plugged into an electrical outlet.

- Install the regulator device when the voltage is higher than the normal range or in fluctuation.
- To extend the life span of the concentrator, reboot 5 minutes after each shutdown to prevent the compressor from starting under pressure.
- Do not open the cabinet and intake window of concentrator under any conditions.
- Oxygen concentrator is to be strictly kept away from children to avoid accidents.
- Do not leave the concentrator unattended after it is connected to the power supply. Unplug the device if it is not in use.
- Turn off the concentrator after use. For long periods of non-use, unplug the power cord from the power outlet. Use caution not to pull out the power cord from the concentrator when removing the plug.

2.3 Safety Tips for Oxygen Therapy

NOTES

- No smoking while using the oxygen concentrator.
- Follow the physician's guidance for it is used for medical treatment.
- Oxygen poisoning and oxygen allergy patients are contraindicated.
- The oxygen flowrate should be set according to the recommendation of the physician and not be too high or too low. Contact the supplier or physician immediately and adjust the flowrate according to physician's instructions if you or service person suspects that the oxygen concentration is insufficient; patients with severe lung disease should consult a physician for flow level.
- Keep the concentrator stable while in use and avoid sloping or inverting.
- Be aware that the electrical cord and/or tubing could present a tripping or strangulation hazard.
- Do not pump the equipment, such as using an oxygen bag, when the bottle has water.
- To prevent overflow, keep the water level between MINIMUM and MAXIMUM, and change the water often.
- Use the original humidifier bottle provided with the concentrator or one

that is certified by the manufacturer.

- Clean and replace the filter in case of blockages to the outlet and flow of oxygen delivery. Unclean filter affects the life of oxygen concentrator.
- Use the concentrator with caution. Excessive oxygen inhalation can cause some damage, e.g., oxygen poisoning including CO₂ retention, newborn blindness due to excessive oxygen intake, irritating dry cough, nausea, vomiting and headache, nasal duct injury, or nasal bleeding.

3 Installation and Operation

3.1 Open-case Inspection

First check the carton or other packaging for obvious damage. If any damage is detected, contact the distributor. Take out all bulk packaging from the carton. Carefully take out all components from the carton.

Check whether there is any damage to concentrator surface such as notches, dents, scratches and so on. Check whether the accessories are available according to packing list.

NOTE: Unless the oxygen concentrator is used immediately, the concentrator must remain in the carton. before use.

3.2 Storage and Transportation

The oxygen concentrator should be stored in an environment without corrosive air and with good ventilation.

Be careful during transport, do not let it reverse or thwart, or tilt angle greater than 5°.

When the storage temperature is below 5°C or higher than 40°C, the oxygen concentrator cannot work properly. The oxygen concentrator is allowed to stand for 4 hours in a normal working temperature environment of warm or cool from the minimum or maximum storage temperature.

When the oxygen concentrator is moved from one place to another, condensation may occur because of temperature or humidity difference. In this case, never start the oxygen concentrator before the condensation disappears.

Do not place the oxygen concentrator and its accessories in a place where the humidity is too high, too hot, too cold, dusty or dirty.

3.3 Installation

1. Remove all packages, take out the oxygen concentrator and all accessories.
2. Place the oxygen concentrator indoors in a convenient, safe, and well-ventilated area. Do not block the inlet and outlet of the oxygen concentrator.
3. Press the caster lock to lock the casters of the oxygen concentrator. Lock the casters to prevent danger from the oxygen concentrator slipping.
4. Take out the humidifier bottle, remove the top cover, and pour clean water (or distilled water) into bottle, ensuring that the water level is

between the "MAXIMUM" and "MINIMUM", and then replace the top cover.

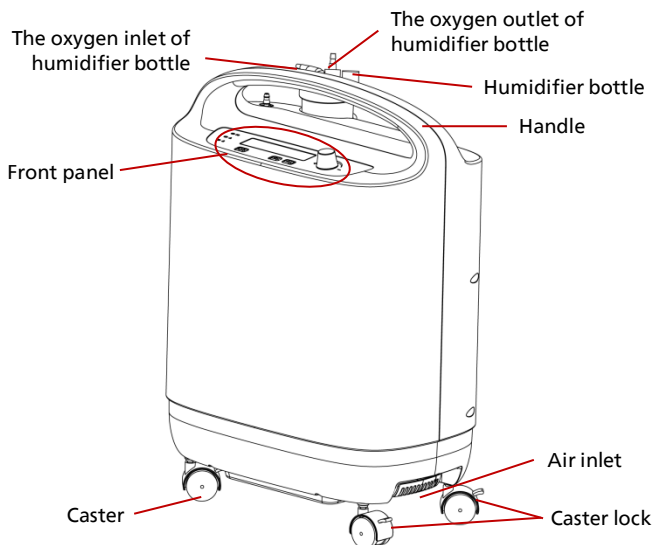
5. Place the humidifier bottle into the humidifier bottle holder and secure it with the band.
6. Connect the humidifier bottle to the oxygen outlet of the concentrator with the connecting air tube, and the oxygen outlet of the humidifier bottle is connected with the oxygen nasal cannula.
7. Plug the power cord into an AC power outlet.

NOTES

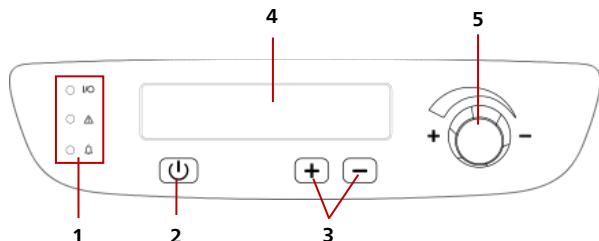
- Do not place any objects on the top of the oxygen concentrator.
- The oxygen concentrator should be located so as to avoid pollutants or fumes. The recommended minimum distance from the patient is 1 m.
- Position the oxygen concentrator at least 0.5 m from walls, draperies, or any other objects that might prevent the proper flow of air in and out of the oxygen concentrator.
- Keep the oxygen concentrator in a clean environment so as to prevent the intake of any pollutants.

3.4 Parts and Function Introduction

Main unit



Front panel



1. Indicator LED

- ○ I/O: Power indicator
 - ◆ This indicator lights green when the oxygen concentrator is connected to the main power supply and the power switch at the back of the device is pressed to the On (I) position.
- ○ ▲: Air pressure/concentration/temperature/ O2 sensor /Low voltage indicator/flowrate adjustment failure indicator
 - ◆ The indicator lights yellow if the system air pressure is higher than 260kPa or lower than 20kPa. And the screen shows the corresponding error code. And the oxygen concentrator alerts with a buzzer sound.
 - ◆ When the oxygen concentration is lower than 82%, the indicator lights yellow. And the oxygen concentrator alerts with a buzzer sound.
 - ◆ When the temperature of the system exceeds the maximum allowable temperature limit ($65^{\circ}\text{C} \pm 5^{\circ}\text{C}$), the oxygen generator stops working. The indicator lights yellow and the screen shows the corresponding error code. And the oxygen concentrator alerts with a buzzer sound.
 - ◆ After tuning on, if the oxygen concentrator does not receive any information from the O2 sensor the indicator lights yellow and the screen shows the corresponding error code. And the oxygen concentrator alerts with a buzzer sound.
 - ◆ When the power supply voltage is lower than 85% of the standard voltage, the indicator lights yellow and the screen shows the corresponding error code. And the oxygen concentrator alerts with a buzzer sound.
 - ◆ The flow meter or the gas path is blocked and the flowrate adjustment fails. The indicator lights yellow and the screen shows

the corresponding error code. And the oxygen concentrator alerts with a buzzer sound.

- ○ 🔔: power failure alarm indicator
 - ◆ If accidental power off happened while operating the concentrator, the indicator lights red and flashes with buzzer alarm tone. This can prompt the user to disconnect the power and check the power supply system.

2. Start/Stop oxygen button

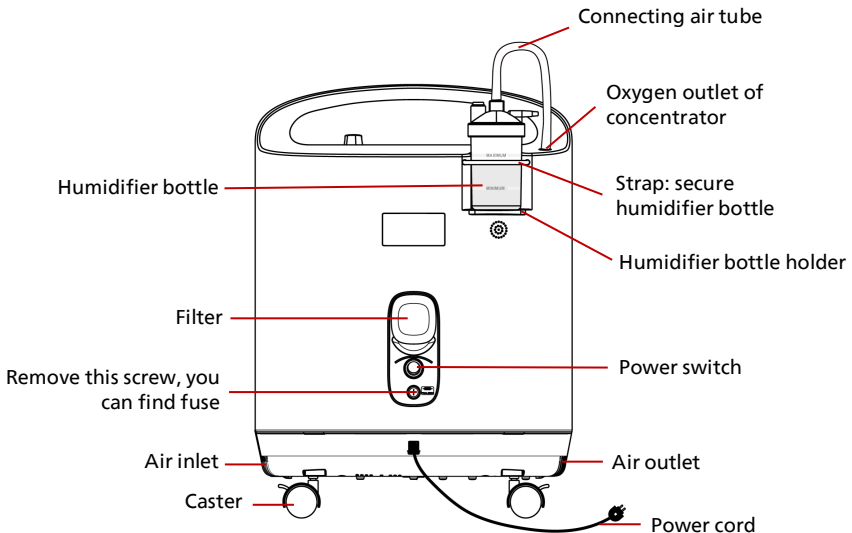
3. Timer timing: increase, decrease button

- ◆ Adjust the timing, increase the value or decrease the value.

4. Display screen

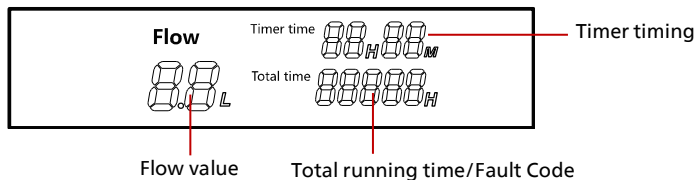
- 5. **Flowrate knob:** Adjusts the flowrate; rotates to the left to increase the flowrate; and rotates to the right to decrease the flowrate.

Back view



Note: The temperature near the air outlet will be higher while the concentrator is operating; do not get close to the air outlet to avoid being burned.

Display screen




No lubricants are to be used other than those recommended by the manufacturer.

The following table shows the main structure and material of concentrator.

Main Structure	Material	Description
Air compressor	ZL102 cast alum, filling PTFE	Provides the air pressure necessary for adsorption and used to separate oxygen from air
Filter system	Foam filter, ABS resin, nonwovens	Used to provide gas cooling, water removal, filtration, etc.
Control valve	/	Control the compressed air treated by the air pretreatment system into the molecular sieve adsorption tower for periodic pressurization and exhaust
Molecular sieve adsorption tower	6063 aluminum alloy, molecular sieve	The molecular sieve is filled in a closed container. Oxygen in the air is separated by the characteristic of selective adsorption of gas by a molecular sieve.
Control and alarm system	PCB, silicon components	Automatic control and fault alarm according to preset working procedures
Producing gas treatment system	ABS resin, Polypropylene	Collecting, filtering, regulating and humidifying the oxygen generated by the oxygen concentrator.


3.5 Power ON/OFF

Power On: Press the **Power switch** to position On (I). The oxygen concentrator is in working state. Then press button  to start oxygen supply.

The oxygen concentrator will automatically be on self-check during which time the buzz and the LCD without lights indicate a normal situation.

Oxygen concentration can reach a stable status after the concentrator has operated for about 12 minutes.

Combination of the power-on-self-test routines and operator action ensures a functional test of the alarm signals.

Power off: After use, press button  to stop the oxygen supply and then press the **Power switch** to Off (O) position. Unplug the power cord from the wall outlet.

WARNING

Do not turn on/off the oxygen concentrator frequently. Allow 5 or more minutes between shutting down the device and restarting. This allows for the gas to be discharged and preserves the life of the concentrator.

3.6 Oxygen Therapy Operation

During normal use, the operator or user should face the oxygen concentrator, and the operator should operate the oxygen concentrator in front of its front panel.

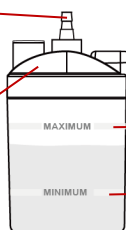
Do not place the oxygen concentrator in a location where it is difficult to disconnect the power supply.

1. Check that the concentrator has been connected with power supply and make sure it in power off status.
2. Remove the top cover of humidifier bottle and fill pure water (or distilled water), making sure the water level is between the "MAXIMUM" and "MINIMUM" mark of the bottle and then replace the cover to the bottle.

This port is connected to the oxygen outlet of concentrator with connecting air tube

This port is connected with nasal cannula

Top cover




MAXIMUM water level

Minimum water level

3. Install the humidifier bottle on the humidifier bottle holder of concentrator and attach with the strap.

4. Connect the humidifier bottle to the oxygen outlet with the connecting air tube and connect the outlet of the humidifier bottle with the oxygen nasal cannula (as shown below).




5. Press the **Power switch** to the On (I) position. The oxygen concentrator is in working state when the power indicator turns green.
6. Press button  to start oxygen supply.

Note: After starting the oxygen supply, adjust the flow to the desired rate. Gas should be flowing freely to the nasal cannula. You should be able to hear or feel the flow of gas to the prongs of the nasal cannula. Wave your hand in front of the prongs. If you do not feel the gas flowing, check the cannula connections for leaks.

Or place the end of the nasal cannula under the surface of a half-full cup of water and look for bubbles. If there are no bubbles, check the cannula for damage and check cannula connections for leaks.

7. Wear the nasal cannula as shown in the figure below. Place prongs of the nasal cannula in nose.



8. Adjust the nasal cannula to appropriate position for easy inhale of the pure oxygen and maximum comfort. The oxygen concentration will reach to 90% within 3 minutes.
9. Turn off the oxygen concentrator after use. Press button  to stop oxygen supply. Remove the nasal cannula. Press the **Power switch** to the Off (O) position. Unplug the power cord from the wall outlet.

Every few seconds the concentrator purges waste gas with a sound which is a normal operational sound.


WARNING

- To ensure that you receive the correct therapeutic amount of oxygen delivery according to your medical condition, the oxygen concentrator must be used:
 - ♦ Only after one or more settings have been individually determined or prescribed for you at your specific activity levels.
 - ♦ With the specific combination of parts and accessories that are in line with the specification of the oxygen concentrator manufacturer and that were used while your settings were determined.
 - The proper placement and positioning of the prongs of the nasal cannula is critical to the effectiveness of the therapy. Ensure the nasal cannula is placed in the nose correctly.
 - Choose a safety-qualified socket and socket board with safety electrical certification.
 - To prevent damage to the concentrator, electric shock or other accidents, servicing must be completed by a qualified technician.
 - Oxygen uptake time and oxygen flowrate adjustment should follow the physician's advice.
 - If the flowrate is lower than 0.5L/min, check that the tubing or accessory is free of clogs, kinks or there is no damage to the humidifier.
 - Drain the water from the humidifier for long periods of non-use. Store the humidifier bottle safely after it is cleaned and dried.
 - The concentrator should be appropriately placed. Keep it from falling, avoid collision, strong vibration, pets, pests, children or other mechanical damage.
-

3.7 Other Operations

3.7.1 Timing Operation

Use the timer function to set a timer length.

1. Press the **Power Switch** to the On (I) position, then press button  to start the oxygen supply.
2. Press the **Timing (+, -)** button on front panel to set timer.
3. Using the **Increase (+)** button to adjust the timing hours (maximum is 10

hours).

4. Then press button  to confirm the setting.

When the hour is set, the system comes into count down time and the oxygen concentrator screen will show the remaining time. When remaining time becomes 0, the oxygen concentrator will go to standby state.

3.7.2 Adjust Flowrate

Rotate the **Flowrate Knob** to adjust the flowrate.

Rotate the **Flowrate Knob** counterclockwise to increase the flowrate and clockwise to decrease the flowrate.

The greater the flow value, the greater the air flow, oxygen purity will be reduced.

The recommended maximum flowrate is 5L/min; the recommended maximum concentration is 93%±3%.

3.7.3 View Total Running Time

The total running time is the sum of the working hours of the oxygen concentrator starting from the first use.

4 Troubleshooting

4.1 Oxygen Concentrator Alarm and Indicator System

Alarm system design aims at monitoring the operation of the oxygen concentrator in case of such situations as power off, abnormal pressure or indicator of running condition of the equipment.

All of the oxygen concentrator alarms are low priority alarms. The alarm system has been set up in the factory, and the user cannot change the alarm system settings.

It includes an acoustic alarm system and a visual alarm system.

The list of alarm messages is as follows:

Alarm	Alarm reason	Audible	Visual	Priority	Measure
Power off	The network power is disconnected during operation	Triple + double + triple + double beep	The indicator quickly flashes red, frequency: 1.4 ~ 2.8Hz	High	Turn off the power immediately. If an alarm still exists after confirming that the power supply and connection are normal, please turn off the oxygen concentrator and contact local dealer or manufacturer.
Low concentration	Oxygen concentration is lower than 82%	Single beep	The indicator lights yellow	Low	Contact your local distributor or manufacturer. Spare oxygen should be prepared for those who are in urgent need of oxygen.
Abnormal air pressure	The internal pressure of the oxygen concentrator is higher than 260kPa or lower than 20kPa	Single beep	The indicator lights yellow and the screen displays code "E05" if the air pressure is high.	Low	Turn off the power immediately. Check and make sure that the outlet and inlet of air are clean and free of blocks. Restart the equipment and inform the distributor or manufacturer of the shut down and if the alarm is still on.
			The indicator	Low	


			lights yellow and the screen displays code "E02" if the air pressure is low.		
High temperature	The oxygen concentrator system temperature is higher than the maximum allowable temperature limit.	Single beep	The indicator lights yellow and the screen displays code "E35".	Low	Turn off the power immediately. Check and make sure that the outlet and inlet of air are clean and free of blocks. Restart the equipment and inform the distributor or manufacturer of the shut down and if the alarm is still on.
Oxygen sensor communication failure	The oxygen concentrator did not receive signal from the oxygen sensor.	Single beep	The indicator lights yellow and the screen displays code "E31".	Low	Contact your local distributor or manufacturer. Spare oxygen should be available for those who are in urgent need of oxygen.
Low Voltage	The supply voltage of the concentrator is 85% lower than the standard voltage.	Single beep	The indicator lights yellow and the screen displays code "E03".	Low	Turn off the concentrator immediately. Restart it after confirming that the voltage of the network power supply is normal.

The alarm presetting cannot be adjusted.

- Alarm priority: Power failure alarm is high priority, while others are low priority.
- The alarm system (excluding power failure) needs to be verified by professionals. Contact our service personnel if verification is required.
- If the concentrator is used in a separate area with the same or similar devices, do not confuse it with the preset values of other devices.

- The operator shall operate the oxygen concentrator in front of its operating panel.

Information signal

- When the operator presses any button on the front panel, the oxygen concentrator will respond with button prompt tone.
- Stop alarm: After the power off alarm is triggered, press the **Power Switch** to the Off (O) position to stop the alarm. If the other alarms are triggered, press the  button to stop the alarm.

4.2 Fault List

Symptoms	Possible Causes	Solutions
After turning on the power switch, the light, alarm system and oxygen concentrator does not work.	<ol style="list-style-type: none"> 1. The power cord plug is loose. 2. No power. 3. Fuse is broken. 	<ol style="list-style-type: none"> 1. Plug in tightly. 2. Check the power supply. 3. Replace the fuse.
After turning on the power switch, the light works, but the oxygen concentrator does not work.	<ol style="list-style-type: none"> 1. Air compressor protection. 2. Inlet or outlet jammed. 3. Ambient temperature is lower than 5°C 	<ol style="list-style-type: none"> 1. If oxygen concentrator shuts down after restarting of 45 minutes, please contact the vendor. 2. Clean the filter. Clear the inlet and outlet of any jams or blocks. 3. Raise the ambient temperature.
Cannot obtain the requested oxygen concentration.	<ol style="list-style-type: none"> 1. Oxygen nasal cannula is blocked, damaged or is kinked. 2. Humidifier bottle is blocked or damaged. 	<ol style="list-style-type: none"> 1. If the flowrate is normal, remove the nasal cannula, and clean, correct any bends or kinks or replace it. 2. If the flowrate is normal, remove the humidifier bottle, clean or replace it.

4.3 Fault Code

The description of fault code displayed on the concentrator is as follows (fault code is shown in the total running time area).

Code	Fault Description
E02	The pressure suddenly drops below the limit pressure (20kPa) during operation
E03	The supply voltage of the concentrator is lower than 85% of the standard voltage
E04	After running for 2 minutes, the deviation between actual flow and set flow exceeds 2L
E05	The pressure exceeds the limit pressure (260kPa) during operation
E31	Cannot receive data from oxygen sensor
E35	The temperature detected by the compressor control resistance exceeds the allowed range

If the fault is not in the above cases and there is still no oxygen output, please contact the distributor or the manufacturer.

Non-professional maintenance personnel or personnel without manufacturer authorization are strictly prohibited to open the concentrator cabinet for maintenance.

5 Maintenance and Cleaning

Only the dealer or a trained person authorized by the manufacturer can perform pre-maintenance or performance commissioning of the oxygen concentrator.

Manufacturers recommend that the oxygen concentrator's running time is not less than 30 minutes each time. Do not turn on or off the oxygen concentrator frequently. Only turn on the concentrator after 5 minutes at the very least, has passed from turning it off.

The replacement period is not fixed since the molecular sieve is greatly affected by the environment (temperature, humidity). The replacement period is mainly based on concentration change. If the concentration falls below 82% mentioned in ISO 80601-2-69, it can be understood that the oxygen concentration is impacted and the molecular sieve should be replaced.

The oxygen delivery settings of the oxygen concentrator should be periodically reassessed for the effectiveness of the therapy.

The accessories and oxygen concentrator setup to deliver oxygen to the patient should include a heat or smoke detector to reduce the extent of the propagation of fire if ignition occurs.

The oxygen concentrator and its accessories cannot be maintained or serviced while still in use on a patient. Disconnect the patient from the concentrator and reconnect the patient to another source of oxygen during the period of service or while changing accessories.

WARNING

- Disconnect the power cord from the electrical outlet before you perform maintenance to avoid electric shock.
 - Persons without training or authorization of manufacturer cannot open the cabinet.
 - Do not operate the concentrator without the filters installed, or while the filters are wet. These actions could permanently damage the concentrator.
-
-

5.1 Care and Cleaning of Cabinet

Clean the outside of the cabinet monthly.

Disconnect the power cord from the electrical outlet before you clean the cabinet.

Wipe the cabinet surface with a clean, soft cloth or towel, and then wipe the surface with dry cloth or towel. Do not pour the liquid into the cabinet gap. Concentrator cabinet cannot be washed with water.

A mild household neutral detergent can be used to clean the cabinet.

5.2 Care and Cleaning of The Humidifier Bottle

Empty the humidifier bottle each time after using the concentrator.

Rinse the humidifier bottle with clean water and dry it. If there is any remaining residue, you can use a mild neutral detergent or solution of white vinegar and hot water with proportion of 1:10 to wash it.

Check that the humidifier bottle cover is in good condition.

5.3 Clean or Replace Filter

The cleaning and replacement of the filter sponge is important to protect and extend the service life of the compressor and molecular sieve. It is critical to inspect the filter on a routine basis.

Remove the filter sponge and clean it with clean water. If it is dirty, use mild soap or detergent to clean it. Rinse thoroughly and air dry, then install the sponge back to the filter.

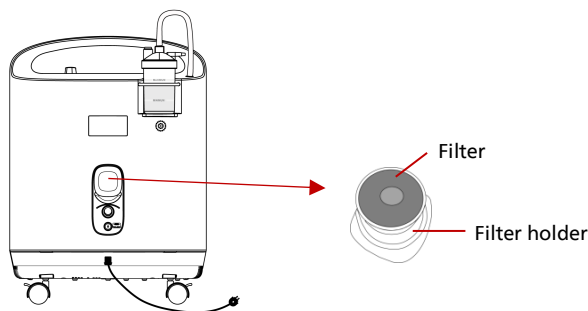
The intended service life of the filter is two years.

It is recommended to clean the filter sponge every 500 hours.

Replace the filter sponge depending on the actual use and environmental impact of the concentrator.

Clean or replace the filter

Remove the filter holder and replace the filter.

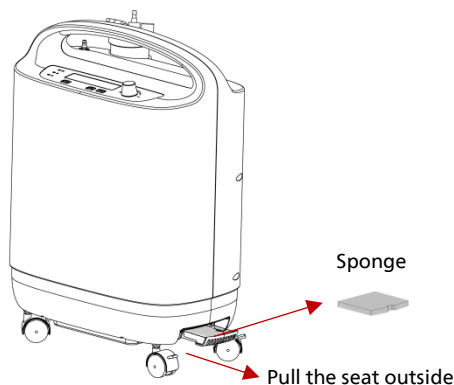


Clean or replace the sponge at the air inlet

Pull out the sponge seat at the air inlet of the oxygen concentrator. Take out the sponge for cleaning or replacement.

The cleaned sponge should be completely dried before being placed in the seat.

Replace the sponge according to the actual usage time and environmental effect and at least once in 2 years.



Reusing the device

Ksw-5 (Oxygenate 5) is suitable for multi-patient use. Please ensure that both the primary filter and secondary filter (sponge as shown above) are changed between patients and use a new nasal cannula for every patient.

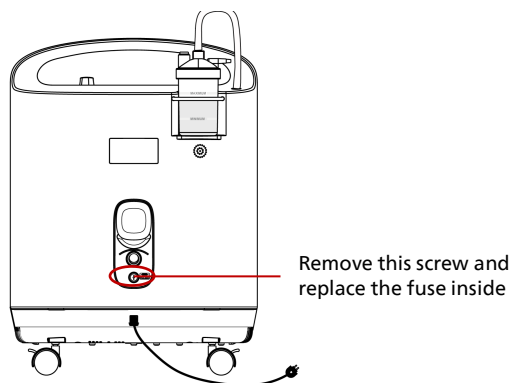
5.4 Overload Protection

WARNING

Please disconnect the power supply before replacing the fuse.

When you suspect or determine the overload protection (turn on oxygen concentrator when the power connection is normal, a power failure alarm occurs), you can use the tool to remove the screw and replace the fuse before restarting the concentrator.

Fuse model: F5AL250V



5.5 Environmental Protection

The materials used in the concentrator do not create an environmental hazard. The packing materials of the concentrator are recyclable, and they must be collected and disposed according to the proper regulation in the country or region where the package of the system or its accessories is opened.

Any material of the concentrator system or accessories, that may cause environmental hazards, must be collected and disposed of in compliance with the local laws and requirements. Disposal of the waste water, disposable nasal cannula, filter and oxygen concentrator should follow local laws and regulations in case of environmental pollution.

The emissions during normal use (such as waste water, waste consumable materials, acoustic energy, air/heat, gasses, vapour, particulates, EMC, hazardous substances and other waste) will cause ozone; make sure to use the oxygen concentrator correctly.

5.6 Check System Gas Leakage and Gas Flowrate

Connect the nasal cannula to the gas outlet connector of the oxygen concentrator or, if used, to the bubble humidifier outlet connector per the manufacturer's instructions.

With the oxygen concentrator turned on adjust the flowmeter to the desired flowrate. Gas should be flowing freely to the nasal cannula. You should be able to hear or feel the flow of gas to the prongs of the nasal cannula.

Wave your hand in front of the prongs. If you do not feel the gas flowing, check the cannula connections for leaks.

Or place the end of the nasal cannula under the surface of a half full cup of water and look for the bubbles.

6 Accessories

WARNING

- The oxygen concentrator, its parts and accessories should be specified for use at specific flows.
- Disposable accessories are designed for single-patient use only. Reuse of them may cause a risk of contamination, cross infection and affects the measurement accuracy.
- Use only manufacturer approved accessories or as listed in this chapter. Incompatible parts or accessories can result in degraded performance, or the performance of concentrator cannot meet the specifications claimed in this specification sheet.
- 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.
- Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.
- The accessory material that contacts the user or other personnel has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1.
- 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.

List of accessories

No.	Name	Specification	Unit	Qty.	Remarks
1	Humidifier bottle	IV-200	pcs	1	/
2	Nasal cannula	1.6 meter	pcs	1	Sample
3	Filter	/	pcs	4	/
4	Sponge	/	pcs	1	/

7 Product Specification

7.1 Main Unit

Main unit	
Electrical Safety classification	Class II, BF type applied part; non AP/APG equipment
Ingress of water or particulate matter into equipment	IP21
Operating mode	Continuous
Product service life	5 years
Oxygen outlet pressure	30 kPa - 80 kPa
Power supply	230V ~, 50 Hz
Uncertainty of measurement	±3%
Fuse	F5AL250V
Accessory	
Maximum pressure of humidifier bottle	80 kPa
Flow range of humidifier bottle	1 L/min ~ 5 L/min
Maximum pressure of nasal cannula	80 kPa
Flow range of nasal cannula	> 5 L/min

7.2 Environmental Specifications

Operating environment	Temperature: 5°C - 40°C
	Relative humidity: 15% - 75% (non-condensing)
	Barometric pressure: 86kPa - 106kPa
Storage and transportation environment	Temperature: -40°C- +55°C
	Relative humidity: 15% - 93% (non-condensing)
	Barometric pressure: 50kPa - 106kPa

7.3 Main Technical Specification

Below table shows concentrator models and main technical parameters.

Model	Flow (L/min)	O2 density (V/V)	Noise (Sounds Pressure dBA)	Size (mm) (LxWxH)±20mm	Power consumption (VA)	Weight (kg) ±3kg	Timing period
KSW-5	5	93%±3%	< 40 typical	410X265X530	< 360 typical	18	Yes

Note: Based on oxygen concentrations measured under STPD (standard temperature and pressure, 101.3 kPa at an operating temperature of 20°C, dry).

Noise sounds pressure typical level is measured according to MDS-Hi 2018 (when measured at 1M from the front of the device). Noise sounds pressure level is ≤ 54 dB, measured according to noise test method given by ISO 80601-2-69:2014. Power consumption is ≤450 VA, measured according to power consumption test method given by ISO 80601 -2-69:2014.

Accuracy of oxygen concentration

The oxygen concentration corresponding to the flowrate within the rated range is shown in below:

Oxygen Concentrator's flowrate	Acceptance Criteria	Actual oxygen concentration
1 L/min	93%±3%	95%
2 L/min		95%
3 L/min		95%
4 L/min		95%
5 L/min		93%

8 EMC

Below cables information are provided for EMC reference.

Cable	Max. length	Shielded/unshielded	Qty.	Cable classification
AC Power Line	1.5m	shielded	1	AC Power

Important information regarding Electro Magnetic Compatibility (EMC)

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

Oxygen Concentrator with no Essential Performance/Following Essential Performance is intended to be used in a professional healthcare facility environment.

When the AC input voltage is interrupted, the Oxygen Concentrator will shut down and if the power is restored, it should be recovered by operator manually This degradation could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance.

WARNING

- Use of the oxygen concentrator adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the oxygen concentrator and the other equipment should be observed to verify that they are operating normally.
- Use of accessories and cables other than those specified or provided by the manufacturer of this oxygen concentrator could result in increased electromagnetic emissions or decreased electromagnetic immunity of this oxygen concentrator and result in improper operation.
- 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 ME equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

8.1 Table 1- Electromagnetic Emissions

Declaration - electromagnetic emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable

8.2 Table 2- Electromagnetic Immunity

Declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient /burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

8.3 Table 3- Electromagnetic Immunity

Declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m

8.4 Table 4- IMMUNITY to Proximity Fields From RF Wireless Communications Equipment

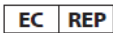
Declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC_61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.					



Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.
NO.8, Shengchang West Road, Danyang Development Zone,
Jiangsu Province, 212300, P.R. China



Respironics Deutschland GmbH & Co. KG
Gewerbestrasse 17, 82211 Herrsching, Germany



Shanghai International Holding Corp. GmbH (Europe)
EC REP Eiffestrasse 80, 20537 Hamburg, Germany



Philips Electronics UK Ltd.
Ascent 1, Aerospace Boulevard
Farnborough, GU14 6XW



SUNGO Certification Company Limited
3rd floor, 70 Gracechurch Street, London. EC3V 0HR