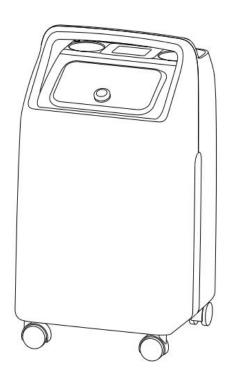
Model: INT-10L-D/INT-10L-S

Oxygen Concentrator User Manual



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INTRODUCTION

The INT-10L-D/INT-10L-S stationary oxygen concentrator are an externally powered, Class II, Type BF device. The essential function of the device are to provide oxygen at a volume that remains within tolerance-the tolerance was defined based on technical judgment from within the manufacturer's expertise in this specific medical application. In addition, the device's ability to detect certain error conditions such as low oxygen concentration and create an alarm is also considered a part of its essential function.

This user manual contains important information and safety precautions for the INT-10L-D/INT-10L-S Oxygen Concentrator. Before using your oxygen concentrator, please read and understand this entire user manual. Save this user manual for future reference.

INTENDED USE OF THE DEVICE

The INT-10L-D/INT-10L-S Oxygen Concentrator are used on a prescriptive basis patients who are diagnosed as requiring supplemental oxygen. The oxygen concentrator will provide supplement, high oxygen concentration oxygen to these patients. It is not life-supporting or life-sustaining. It may be used continuously in a home or institutional/hospital setting.

SYMBOL DESCRIPTIONS

Symbol	Description	Symbol	Description	Symbol	Description
<u>^</u>	Caution		No smoking	Ī	Fragile,Handle with care
*	Keep Dry	**	This Side up	LOT	Batch code
	Class II equipment	水	Type BF applied part	SN	Serial Number
\sim	Date of Manufacture	***	Manufacturer	O'C MIN	Temperature limit

95%RH MAX % 0%RH MIN	Humidity	1060hPa MAX 700hPa MIN	Atmospheric pressure limitation		Refer to instruction manual/ booklet
CE	CE marking	EC REP	European Authorized Representative	IP21	Protected against solid foreign objects of 12.5mm diameter and

WARNING

- 1. The device to sale by or on the order of a physician.
- 2.It is responsibility of the patient and/or provider to make back-up arrangements for an alternative oxygen supply.
- 3. Availability of an alternate source of oxygen is required in case of power outage or mechanical failure.
- 4. The device should be located as to avoid pollutants or flames.
- 5.Portable and mobile RF communications equipment can affect medical devices.It is not recommended to operate the device near or adjacent to other equipment other than the INT-10L-D/INT-10L-S oxygen concentrator.If adjacent use is necessary,the INT-10L-D/INT-10L-S oxygen concentrator should be observed to verify normal operation in the configuration in which it will be used.
- 6. When storing or transporting the device, always keep it upright.
- 7. 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.
- 8.To ensure receiving the therapeutic amount of oxygen delivery according to your medical condition Model INT-10L-D/INT-10L-S 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 concentrator manufacturer and that were used while your settings were determined.
- 9.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.
- 10.Do not lubricate fittings, connections, tubing, or other accessories of the oxygen concentrator to avoid the risk of fire and burns.
- 11.Use only spare parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.

Use of this device at an altitude above 4000m or outside a temperature of 0 $^{\circ}$ C to 70 $^{\circ}$ C or a relative humidity above 95% RH expected to adversely affect the flow rate and the percentage of oxygen and consequently the quality of the therapy.

- 12.Oxygen makes it easier for a fire to start and spread. Do not leave the nasal cannula or mask 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.
- 13.If you feel discomfort or are experiencing a medical emergency while undergoing oxygen therapy, seek medical assistance immediately to avoid harm.
- 14.Smoking during oxygen therapy is dangerous and is likely to result in facial burns or death. Do not allow smoking within the same room where the oxygen concentrator or any oxygen carrying accessories are located.
- 15. 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.
- 16.Foshan Keyhub Electronic Industries Co., Ltd. assumes no liability for persons choosing not to adhere to manufacturer recommendations.
- 17.Patient shall consult with doctor before oxygen therapy.Prolonged exposure to high concentration oxygen will cause oxygen toxicity.

Contraindication

- 1. The device is not intended to be life-supporting nor life-sustaining.
- 2.In certain circumstances, oxygen therapy can be hazardous. Please seek medical advice before using this device.
- 3. The device is designed to provide a flow of high purity oxygen up to 10LPM continuous. The device should only be used by patients prescribed oxygen therapy within this range.
- 4.As the device will alarm through audio and visual indicators, patients who are unable to communicate discomfort, hear, see and or understand the alarms may require additional monitoring.

ADVERSE EVENTS/HAZARDS

Failure to adhere to the statements below may impair performance of the device and may void all warranties.

- 1.**DO NOT** use oil, grease or petroleum-based products on or near the device.
- 2.**DO NOT** use power suppliers or air filters other than those that came with the system.
- 3.**DO NOT** allow smoking or open flames within 2m of the device as the device produces enriched oxygen gas which accelerates combustion.
- 4.**DO NOT** obstruct the air flow to the inlet and exhaust vents on the oxygen concentrator. the device should be located in the ventilated area.
- **5.DO NOT** submerge the device liquid. The device should not be exposed to water or precipitation as it may damage the electronic components of the device and will void all warranties.
- 6.**DO NOT** operate or expose the device to temperatures and humidity levels outside the specified operational environment conditions outlined in the specifications section. Excessive temperatures and humidity levels may damage the device.
- 7.**DO NOT** plug the device into the same electrical outlet as major appliances. Doing so may cause an electrical overload.
- 8.Use of certain humidifiers not specified for use with oxygen concentrator may impair performance

PRODUCT DESCRIPTION



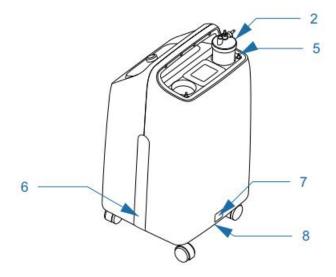


Figure 1 Figure 2

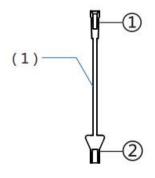


Figure 3

- Oxygen Connecting Tubing(① connecting to the oxygen outlet,②connecting to the inlet of humidifier bottle)
- 2. Humidifier bottle
- 3. Control panel
- 4. On&Off button/Flow control knob
- 5. Oxygen outlet
- 6. Air inlet
- 7. Power socket
- 8. Switch

Accessories:

INT-10L-D have the following items:

- . 1 User manual.
- . 1 Oxygen Concentrator set.
- . 2 Humidifier Bottle
- . 2 Oxygen connecting tubing
- . 2 Nasal Cannula
- . 1 Power Cord
- . 1 Nebulizer Kit(Optional)

INT-10L-S have the following items:

- . 1 User manual.
- . 1 Oxygen Concentrator set.
- . 1 Humidifier Bottle
- . 1 Nasal Cannula
- . 1 Oxygen connecting tubing
- . 1 Power Cord
- . 1 Nebulizer Kit(Optional)

Control Panel for INT-10L-S



Figure 4

Control Panel for INT-10L-D

1. When the dual flow open, the window of "A Flow" and the total "O2 concentration" take turns to display.see below Figure 5/6 shows.



Figure 5



Figure 6

		Ic	con
Buttons	Functions Description	INT-10L-S	INT-10L-D
On/Off&Flow Control Button	1.Press the button to turn on or turn off the unit; 2. Rotate the knob to adjust the oxygen flow, clockwise rotation for increase the flow, counterclockwise rotation for reduce the flow and the stepped size is 0.1L/min.	ON OFF	● ○ ON OFF
	3.For INT-10L-D,this button control the B flow.		
Nebulization Button	Press the button to turn on or turn off the the nebulization function.(For the machine with nebulization function only)	(NEBU.)	NEBU.
Timer Button	Press the button to select suitable time for your oxygen therapy.	TIMER	TIMER
Mute Button	1.The machine has the function of voice prompt and the user can be guided by voice, press the button to turn on or turn off the sound of the voice 2.The alarm of SOS can't be eliminated.	MUTE	MUTE
SOS Button	The machine has the function of emergency calling.press the button to turn on the SOS and the machine will have the urgent call for help.keep pressing the button for canceling the SOS.(Only for INT-10L-S)	SOS	/
A Flow Button	Press it for controlling the A flow(For the INT-10L-D only)	/	AFLOW

Icon	Desciption
CUM	Cumulative running time of the machine.
Timer 88:88 Hr. Min.	The "timer"lights up on the display when press the "TIMER" button.
Norm.	The machine is operating normally and the "Norm."lights up on the display with
North.	green color.
Abarra	The machine is operating abnormally and the "Abnor."lights up on the display
Abnor	with Red color.
Nebu.	The "Nebu."lights up on the display with Blue color when press "NEBU"
	button.(For the machine with nebulization function only)
HEDA	The "HEPA" lights up on the display with yellow color every 600 hours, it
HEPA	indicates that the filter needs to be replaced.
Low O ₂	The "Low O2." lights up on the display with yellow color when the oxygen
	concentration is below 82%.

OPERATION

WARNING: Read the safety section and operating instructions in this manual before use.

PREPARATION

The oxygen delivery setting has to be determined for each patient individually with the configuration of the equipment to be used, including accessories.

1. Before operating your unit always checks to be sure the air filter (located on the top of your unit, Figure 7) is existed .Proper replace of this filter is discussed in the Caring for Your Concentrator section on page 18.

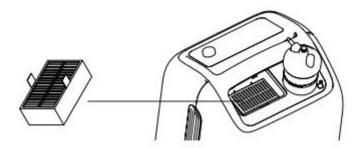


Figure 7

2. Attach the appropriate oxygen accessories to the oxygen outlet.

Oxygen Tubing Connection

NOTE:Pay attention to connect the oxygen tubing well,If it is not connecting well, it may affect your oxygen therapy.

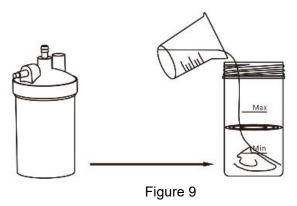
a. Attach the oxygen tubing directly to the connector.(Figure 8)



Figure 8

Oxygen Tubing Connection with Humidification:

- a. If your physician has prescribed an oxygen humidifier as part of therapy.
- b. Follow these steps:
- c. Fill the humidifier bottle with distilled water. Do not exceed max. (Figure 9)



d. Attach the oxygen tubing directly to the humidifier bottle outlet fitting.(Figure 10)

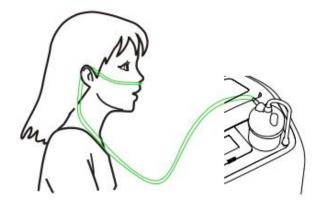


Figure 10

If you are prescribed to use the nasal cannula, connecting tubing, or other accessories as part of your therapy, they should connect to the humidifier outlet.

3.Remove the power cord completely from the line cord strap, Make sure the power switch is in the "O" position, and insert the plug into the wall outlet; the unit is double insulated to guard against electric shock.

MARNING

Improper use of the power cord and plugs can cause a burn, fire or other electric shock hazards .Do not use the unit if the power cord is damaged

If the machine is stored below -5°C, please make sure to place the machine in the environment of 5° C ~ 40° C for 30 minutes before using it.

OPERATING YOUR OXYGEN CONCENTRATOR



WARNING: Oxygen makes fires more likely to start or spread. Do not leave the nasal cannula or mask on bed coverings or chair cushions, if the oxygen concentrator is turned on but without using; the oxygen may make the materials flammable. Turn the oxygen concentrator off when not in use so as to prevent the oxygen enrichment.

WARNING: Do not remove the covers of this device. Servicing must be referred to an authorized and trained INT provider.

Oxygen causes rapid burning. Do not smoke while your oxygen concentrator is operating, or when you are near a person utilizing oxygen therapy. Keep the oxygen concentrator at Least 2 m from hot, sparking objects or naked sources of flame.

- 1. Press the power switch to On"I" position,now the power is on,the screen lights up,and the screen displays concentrator total elapsed run time information of "00000"hrs.
- 2. Turn on the unit by pressing the ON/OFF button ,the oxygen concentrator starts running,and the timer display window displays the single running time and oxygen concentration window displays the current oxygen concentration.
- 3. Adjust the Oxygen Flow
- a. For INT-10L-S:It adopts advanced automatic intelligent electronic flow valve controlling system, rotate the knob to adjust the oxygen flow from 0.5-10L/min and the stepped size is 0.1L/min

b:For INT-10L-D:Dual flow is available; A Flow adopts advanced three gears automatic intelligent electronic flow valve controlling system, when open the machine, the flow setting is 0L/min, and just press "A Flow" button on the operation panel to select the suitable flow of 2L/Min; 3L/min and 5L/min;

B Flow adopts advanced automatic intelligent electronic flow valve controlling system,rotate the knob to adjust the oxygen flow from 0.5-10L/min and the stepped size is 0.1L/min;when two flow open at the same time,A flow have the first priority to set the flow,and then can set the B flow.see below chart described:

A Flow	0L/MIN	2L/MIN	3L/MIN	5L/MIN
B Flow(Adjustable)	0.5-10L/MIN	0.5-8L/MIN	0.5-7L/MIN	0.5-5L/MIN

CAUTION—It is very important to follow your oxygen prescription. Do not increase or decrease the flow of oxygen-consult your physician.

4. When you are not using the oxygen concentrator, turn off the unit by pressing the ON/OFF button, and then press the power switch to the Off "O" position.

Note: the equipment should place in the area which the user can touch the power switch easily.

5.Description for other functions:

- a. Time setting function: Press the "Timer" button to select suitable time for your oxygen therapy. the setting are 30mins/45mins/1hr/2hrs/ 3hrs/ 4hrs/ 5hrs/ 6hrs/7hrs/8hrs, and the display showing the time accordingly. The machine turn off automatically while time expired and the time can be setting by cycle.
- **b. SOS function**: The machine has the function of emergency calling.press the "SOS" button to turn on the SOS and the machine will have the urgent call for help.keep pressing the button for canceling the SOS. (Only for INT-10L-S)
- **c.Mute Button:** Press the "Mute" button to turn on or turn off the sound of the voice and the alarm of SOS can't be eliminated.

d.Nebulization Instruction: (FOR NEBULIZATION TYPE ONLY)

Infuse liquid medicine into nebulization cup before starting nebulization. (Figure 11)

1. Connect the accessory tube with the output oxygen connector. Liquid medicine in the nebulization cup starts to be nebulized, although it is not very obvious enough.

Caution: nebulization cup must be connected to output oxygen connector, and it is prohibited to be connected with humidifier bottle.

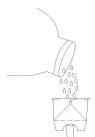


Figure 11

- 2. Press "Nebu" to start nebu.function. Now the "Nebu" is on with nebulization indicating light on and the visual nebulization effect is obvious.
- 3. Once the potion in the nebulization cup runs out, press the "Nebu" button as well for a few seconds now nebulization is off. Remove the nebulization cup and make the unit running in normal condition.

CAUTION: The nebulization Mode must be used with a nebulization cup.

The output pressure will be higher when the nebulization Mode starts, so please do not inhale oxygen directly without nebulization cup.

Circuit breaker (Reset button)

Your oxygen concentrator is equipped with a circuit breaker (reset button), to protect the electrical circuits from overload, at the bottom of the back of the machine. In the event of an overload, the circuit breaker button will pop out. To reset the circuit breaker, please push down the button.

DESCRIPTION OF THE ALARM

1. The description of the indication light:

A.When the "Norm "green light is on,indicate that the oxygen concentrator is working well and oxygen concentration ≥82% (V/V) .

B.When the "Low O2 "yellow light is on,indicate that the oxygen concentration is abnormal ,oxygen concentration<82% (V/V).

C.When the "Abnor"red light is on, indicate that the oxygen concentrator is working abnormal.

2. The description of the alarms and warning:

Alarm and Warning	Condition	Priority	Visual Signal	Error code	Audible Signal	sound range	Туре
No flow	The flow less than 0.5L/min (or the real flow is 70% less than the setting flow)	High Priority	RED (flashing)	E01	Di-Di-DiDi-Di Di-Di-DiDi-Di Beep every 5 seconds	≥60dB	Technical alarm

Low oxygen	oxygen concentration<60%	High Priority	RED (flashing)	E02	Di-Di-DiDi-Di Di-Di-DiDi-Di Beep every 5 seconds	≥60dB	Technical alarm
high temperature	The machine temperature≥60°C	High Priority	RED (flashing)	E03	Di-Di-DiDi-Di Di-Di-DiDi-Di Beep every 5 seconds	≥60dB	Technical alarm

3.Description of alarm error code

Error Code	Description
E01	!!! no flow alarm
E02	!!! Low Oxygen
E03	!!! high temperature alarm

4. The instruction for how to stop the audible alarm.

When the machine have an abnormal alarm , the user could press" $\overset{}{\swarrow}$ " button to stop the audible alarm for 2 minutes .

NOTE-The user should operate the control panel in front of the oxygen concentrator.

NOTE—The Alarm parameters are set by the manufacturer and cannot be adjusted without permission

NOTE—To verify whether the alarm system is working well, the user could block the oxygen outlet for 20S after the machine start up, and check whether the alarm occurs.

NOTE—If an audible sound is detected and the "Abnor" lights up on the display, the unit is not operating properly. Refer to the Minor Troubleshooting chart on page 19, and contact your INT provider if necessary.

WARNING: Geriatric, pediatric or any other patient unable to communicate discomfort should 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.

Transport the oxygen concentrator

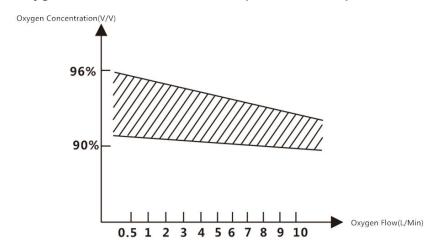
The INT Oxygen Concentrator is equipped with a casters for transportation. To transport the concentrator, please do these first:

- 1. Remove and store any accessories, such as tubing, cannulas, masks, and humidifier bottle, if equipped.
- 2. Fold and wrap the power cord and attach it to the concentrator cabinet using the strap.

SPECIFICATION

Specification	INT-10L-S/INT-10L-D
Device Electrical Classification	Class II,Type BF
G.W.	25.5Kgs
Dimensions	368x346x695(L*W*H)mm
Mode of Operation	Continuous
Flow setting control	0.5 to 10LPM
Oxygen concentration	93%±3% (0.5-10LPM)
Oxygen concentration sensor alarm	82% or less
Maximum outlet pressure	8.5psi
Average sound level	45dB(A)
Power supply	230VAC~50Hz
Power Consumption	580W

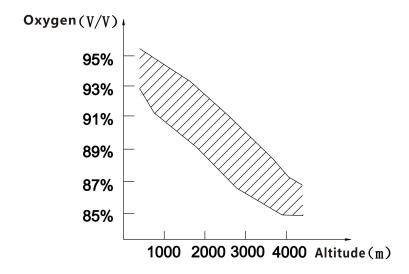
Oxygen Concentration under the operational Temperature/Humidify range and flow rate



Device operation above or outside of the voltage,LPM,temprature,humidify and/or altitude values specified my decrease oxygen concentration levels.

Oxygen concentration over altitude and flow rate

Oxygen concentration over altitude range 0-4000m



Environmental conditions for Use, Storage and Transport

Operational Temperature range: 10 $^{\circ}$ C to 35 $^{\circ}$ C

Operational Humidify Range: 15% to 80% RH

Storage Temperature Range:0 ℃ to 60 ℃

Storage Humidify Range: 0% to 95% RH

At atmospheric pressure range:700 to 1060 hPa

*The variation of the flow does not exceed the greater 10% of the set value or.2.LPM when a back pressure of 7kPa(1 psi) is applied to the device output.

MAINTENANCE

All maintenance except **cleaning the cabinet**, and **cleaning the humidifier bottle**, described in the following section, is to be performed only by authorized service personnel.

DANGER: The concentrator was specifically designed to minimize routine preventive maintenance. Preventive maintenance or adjustments to the concentrator are to be performed only by authorized service personnel; the performance of such maintenance or adjustment by any other personnel could void the warranty and create a hazardous condition, which could result in death or serious personal injury.

WARNING: Ensure that the concentrator is unplugged from the AC power source and the power switch is at the "**OFF**" position before performing maintenance on the concentrator.

Cleaning the cabinet

Clean the cabinet monthly, or more often if it gets dirty or your environment is very dirty.

- 1. Ensure that the power cord is unplugged and the power switch is at the "OFF" position.
- 2. Clean the cabinet with a mild household cleanser and a clean, non-abrasive cloth or sponge.

WARNING: DO NOT immerse the concentrator in water or other liquid.

DO NOT pour liquids on the concentrator while cleaning.

DO NOT allow any liquid to enter the concentrator.

CAUTION: Many cleansers must be diluted before use. Follow the manufacturer's directions carefully to avoid damaging the cabinet.

Cleaning the humidifier bottle

Change the water in the humidifier bottle every day.

Wash the humidifier bottle weekly with warm soapy water, and rinse thoroughly with hot water before refilling.

Replacement Parts

Below replacement parts and accessories are available through your distributor.

Cannula, Mask and Tubing

Clean and replace the cannula, mask and tubing as distributor's instruction.

Intake Filter

It is recommended that the Air Filter be replaced every 600 hours.the "HEPA" lights up on the display with 1 time voice prompt to remind to replace the Air Filter on time.if the INT oxygen concentrator is used in a dusty environment, filter replacement may be required more frequently. Contact your equipment provider for additional replacement filters.

Long press "TIMER" for 5 seconds to eliminate the alarm;

^{*}Degradation may occur for settings less than 1LPM.

Installing a new air filter:

- 1.Remove the Air Filter Access Door.
- 2.Remove the old Air Filter.
- 3. Pull the Air Filter out of its housing.
- 4. Replace the Air Filter.
- 5. Put the new Air Filter into its housing.
- 6. Firmly push down on the Air Filter until it is securely in place.

Expected service life of parts and accessories

Humidifier Bottle	1 years or 100 times
Nasal Cannula	single use only

Preventive Maintenance Checklist

Model No: Serial No:

ON EACH INSPECTION				
Record Elapsed Hours on Hour Meter				
Clean t Filter(s) (Refer to Cleaning the Filter.)				
Check Prescribed L/min. Flow-rate				
DURING PREVENTIVE MAINTENANCE SCHEDULE, OR BET	NEEN P	ATIENT	S	
12000 hours of continuous use				
12000 hours of continuous use				
Check Oxygen Concentration				
Clean/Replace Filter(s) (Refer to Cleaning the Filter.)				
Check Power Loss Alarm				
To be conducted by supplier or qualified service technician. Refe	r to serv	ice man	ual.	•

TROUBLESHOOTING

The following troubleshooting chart can help you analyze and correct oxygen concentrator malfunctions. If below suggested procedures do not work, please switch to an alternate reserve oxygen source and contact your distributor.

WARNING: DO NOT REMOVE THE CABINET UNLESS YOU ARE A QUALIFIED TECHNICIAN CHART OF TROUBLESHOOTING

Symptom	Possible Cause	Remedy
A. Unit does not operate.		Check power connection at the
Power light is off when	1. Power cord not properly inserted into	wall outlet.

the power switch is "on ."	wall outlet.	
	2. No power at wall outlet.	Check your home circuit breaker and reset if necessary. Use a different wall outlet if the situation occurs again.
	3.The fuse blew out.	Contact your INT provider to change the fuse .
B. Unit operates; the Power light is on when the Power switch is "On". Red "Abnor" light is on. Audible alarm may be sounding.	1. Air filter is blocked.	Check the air filter. If the filter is dirty, following the replace instructions on page 18.
	2. Exhaust is blocked.	Check the exhaust area; make sure there is nothing restricting the unit exhaust.
	3.Blocked or defective cannula, catheter, face mask or oxygen tubing.	Inspect tubes and cannula to ensure that they are not kinked or blocked.
	4. Blocked or defective humidifier bottle.	Detach the humidifier from the oxygen outlet .If proper flow is obtained, clean or replace humidifier.
	5. Compressor is not working	Check whether the compressor is working or abnormal sound,if yes,contact your INT provider immediately.
C.Abnormal sound when turn on the unit if the machine place for a long time.	1.After long-time placement,compressor friction increases.	Turn on the unit as usual and run the machine for 20 minutes.check whether the abnormal is existed,if yes,contact your INT provider.

- 1) This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
- 2) * Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
- 3) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

* Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

EMC Information

Guidance and manufacture's declaration - electromagnetic emission

The K5BW *is* intended for use in the electromagnetic environment specified below. The customer of the user of the K5BW should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The K5BW use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The K5BW is suitable for use in all establishments, including domestic establishments and those directly
Harmonic emissions IEC 61000-3-2	Not Applicable	connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacture's declaration - electromagnetic immunity

The K5BW is intended for use in the electromagnetic environment specified below. The customer or the user of K5BW should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U _T (>95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 sec	<5% U _T (>95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the K5BW requires continued operation during power mains interruptions, it is recommended that the K5BW be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m mains voltage prior to appl	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacture's declaration – electromagnetic immunity

The K5BW is intended for use in the electromagnetic environment specified below. The customer or the user of the K5BW should assure that it is used in such an environment.

Immunity	IEC 60601 test	Compliance	Electromagnetic environment - guidance
test	level	level	Liectionagnetic environment - guidance

			Portable and mobile RF communications equipment should be used no closer to any part of the K5BW, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	3 Vrms	$d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d=1,2\sqrt{P}$ 80 MHz to 800 MHz $d=2,3\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the K5BW is used exceeds the applicable RF compliance level above, the K5BW should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the K5BW.
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between

portable and mobile RF communications equipment and the K5BW.

The K5BW is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the K5BW can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the K5BW as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter			
Rated maximum output	(m)			
power of transmitter	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
(W)				
	$d = 1,2\sqrt{P}$	$d = 1,2\sqrt{P}$	$d = 2,3\sqrt{P}$	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



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