User Manual

Oxygen Concentrator

SO1 5A / SO1 5B

CE 0123

Table of Contents

IMPORTANT SAFEGUARDS 1
1. Symbols 8
2. Product Information 8
2.1 Intended Use 10
2.2 Contraindication 11
2.3 Technology Principle 11
2.4. Intended Clinical Benefits 11
2.5. Specifications 12
3. Model 13
4. Package Contents 14
5. System Features 15
5.1 SO1 5A 15
5.2 SO1 5B 17
6. First Time Setup 20
6.1 Checking 20
6.2 Untie the Compressor Bandage 20
6.3 Installing the Humidifier 20
6.4 Connecting to Cannula Valve 21
6.5 Connecting to Nasal Cannula 22
6.6 Starting 22
7. Operating 23
7.1 Flow Rate Control 24
7.2 Remote Control (For SO1 5B) 24
7.3 Timing (For SO1 5B) 25
7.4 Turning the Device Off 26
8. Alarm 26
8.1 Grading for Alarm and Description 26
8.2 Visual Alarm 26
8.3 Auditory Alarm 27
8.4 Alarm Silence 27
8.5 Alarm Information and Description 27
8.6 Alarm Verification 30
9. Cleaning and Disinfection 31
9.1 Cleaning and Disinfection the Enclosures 31
9.2 Cleaning and Disinfection the Humidifier and the Connecting Tube 32
9.3 Replace and Clean the Filter Cotton 33
9.4 Replace the Air Intake Filter 33
9.5 Cleaning and Disinfection between Patients 34
9.6 Preventive Maintenance 34
10. Disposal 34
11. Troubleshooting 35
12. EMC Requirements 38
13. Limited Warranty 43

IMPORTANT SAFEGUARDS

⚠ Make sure you read and understand all the information contained in this manual before you operate your device.

⚠ We recommend an alternate source (oxygen bottle, oxygen bag, etc.) to be used for supplemental oxygen in the event of a power outage or the device breakdown.

⚠ This device is used for oxygen supplement, not for life support.

WARNING: Important safety information for hazards that might cause serious injury.
CAUTION: Information for preventing damage to the device.
NOTE: Information to which you should pay special attention.

Warning

• No smoking when operates. Keep the device room without any ignition source (matchsticks or a flaming cigarette). The no smoking sign must be obvious.
• This device supplies high concentration oxygen that can make the uninflammable material rapid burning. If this warning is ignored may result in serious fire, property loss, injury, even death.
• Oil, grease, or petroleum-based products contact the oxygen under certain pressure may spontaneously and violently burn. So please keep them away from the device, pipeline, connector and the other oxygen devices. Use the recommended lubricant only.
• Prior to installation and start-up of the device, please read these instructions carefully.
• The product must be operated as instructed in the user manual.
• All rights reserved. Republication, duplication or modification in whole or in part is prohibited without prior written permission from BMC.
• The information in this document is subject to change without notice.
• If you are unable to understand the warnings, cautions or setting up, using or maintaining the oxygen concentrator, or if you want to report unexpected operation or events, contact a healthcare professional, dealer or technical personnel from manufacturer or the manufacturer's representative before attempting to use this equipment for assistance.
• The device is designed only for indoor use.
• Never block the air openings of the concentrator or place it on a soft surface, such as a bed or couch, where the air opening may be blocked.
• Keep concentrator at least 30 cm away from walls, draperies and furniture.
• Do not use in a closet.
• Do not place or store oxygen concentrator where it can drop into water or other liquid.
• This product is to be used as an oxygen supplement and is not intended to be life-supporting or life-sustaining.
• Only use this product if the patient is capable of spontaneous breath.
• Do not use this product in any way other than described in the product parameters and intended use sections of this manual.

• There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do not use the oxygen concentrator or accessories near sparks, open flames or other ignition sources. This includes sparks from static electricity created by any type of friction.

• To ensure receiving the therapeutic amount of oxygen delivery according to your medical condition Oxygen Concentrator from BMC (Model: SO1 5A, SO1 5B) must:

- be used with settings that have been individually determined or prescribed for you at your activity levels with your accessories.
- be used with the specific combination of parts and accessories that are in line with the specification of the concentrator or accessory manufacturer.

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

• Do not lubricate fittings, connections, tubing, 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. Accessories designed by other manufacturers have not been tested by BMC and are not recommended for use.

• Use of this device at an altitude above 1828 m or outside a temperature of 10°C - 40°C or a relative humidity above 80% 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 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 more flammable. Turn the oxygen concentrator off when not in use to prevent oxygen enrichment.

• If you feel discomfort or are experiencing a medical emergency while undergoing oxygen therapy, seek medical assistance immediately to avoid harm.

• Geriatric, paediatric 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. Do not allow smoking or open flames within the same room as the oxygen 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 mask 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 are likely to result in fire or death. Do not allow open flames within 2 m of the oxygen concentrator or any oxygen-carrying accessories.

• 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.
• To reduce the risk of injury or death from illness, the oxygen delivery setting has to be determined for each patient individually with the configuration of the equipment to be used, including accessories. Consult the physicians before using.
• To reduce the risk of injury or death from illness, the oxygen delivery settings of the oxygen concentrator should periodically reassessed for the effectiveness of the therapy. Consult the physicians for assisstance.
• Do not change the flowrate setting on the flowmeter unless a change has been prescribed by your physician or therapist.
• In a particular situation the oxygen therapy is harmful. Consult the physicians before using.
• To prevent injury or death from product misuse, closely supervise when this concentrator is used by or near children or physically-challenged individuals and monitor patients using this device who are unable to hear or see alarms or communicate discomfort.
• Do not modify the product without authorization of the manufacturer.
• Do not dismantle the product nor remove any components. There are no user serviceable parts.
• Do not connect any equipment to the device unless recommended by BMC or your health care provider.
• There are many different types of humidifiers, connecting tubes, nasal cannulas and masks that can be used with this device. You should contact your physician, therapist local or home care provider for recommendations on which of these devices will be best for you. They should also give you advice on the proper usage, maintenance, and cleaning.
• If you have allergic reactions to nasal cannula or mask, please contact your physician, therapist local or home care provider for assistance.
• Check all external components and carton for damage. In case of damage, or if the product is not working correctly or any change in the performance occurs, contact BMC for repair.
• Replacement and repair must be performed only by qualified service personnel authorized by manufacturer.
• 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 equipment that are designated by the manufacturer as repairable by service personnel.
• The product is subject to special precautions regarding EMC and must be installed and put into service according to the EMC information provided in the accompanying documents.
• Keep oxygen concentrator at least 3.0 m away from wireless communication equipment such as wireless home network devices, mobile phones, cordless phones and base stations, walkie-talkies, etc.

• Do not bring the device or accessories into a magnetic resonance (MR) environment as it may cause unacceptable risk to the patient or damage to the device or MR medical devices. The device and accessories have not been evaluated for safety in an MR environment.
• Do not use the device or accessories in an environment with electromagnetic equipment such as CT scanners, diathermy, RFID and electromagnetic security systems (metal detectors) as it may cause unacceptable risk to the patient or damage to the device. Some electromagnetic sources may not be apparent, if you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, disconnect the power cord and discontinue use. Contact your home care provider.
• Use of this equipment with other equipment should be avoided because it could result in improper operation.
• The equipment may be disturbed by other equipments even if the other equipments meet the requirements of the corresponding national standard.
• To determine if the emissions from the concentrator are causing the interference, turn the concentrator Off. If the interference with the other device(s) stops, then the concentrator is causing the interference. In such rare cases, interference may be reduced or corrected by one of the following measures:
- Reposition, relocate, or increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected.

• Textiles, oil or petroleum substances, grease, greasy substances and other combustibles are easily ignited and burn with great intensity in oxygen enriched air and when in contact with oxygen under pressure. Do not use these substances on the concentrator or its components to avoid fire, death, injury or damage.
• Keep all matches, lighted cigarettes, electronic cigarettes or other sources of ignition out of the room in which this concentrator is located and away from where oxygen is being delivered.
• Keep the oxygen tubing, cord, and concentrator out from under such items as blankets, bed coverings, chair cushions, clothing, and away from heated or hot surfaces including space heaters, stoves, and similar electrical appliances.
• Never leave oxygen concentrator unattended when plugged in. Make sure oxygen concentrator is off when not in use.
• Don’t position the equipment so that it is difficult to operate the disconnection device.
• Avoid using while bathing. If continuous usage is required by the physician's prescription, the concentrator must be located in another room at least 2.5 m from the bath.
• Do not come in contact with the oxygen concentrator while wet.
• Do not reach for oxygen concentrator that has fallen into water. Unplug immediately.
• Do not use frayed or damaged AC adapter cords.
• To avoid choking and / or strangulation from tubing entanglement, keep children and pets away from nasal cannula and tubing and close supervision is necessary when the nasal cannula is used by or near children and / or disabled persons.

• Do not pile up the long tubing at the head of the bed, as it may wrap around the head or neck of the patient during sleep.
• To reduce the risk of injury or death from illness, replace the nasal cannula on a regular basis. Check with your equipment provider or physician to determine how often the cannula should be replaced.
• Do not share cannulas between patients.
• To prevent injury from infection or damage to concentrator, only qualified personnel should perform cleaning and disinfection of the oxygen concentrator and accessories between patients.
• To prevent accidents caused by incorrect operation, always disconnect the power plug from the outlet before maintenance.
• To avoid fire, death, injury or damage, do not use any lubricants on concentrator unless recommended by BMC.
• The oxygen concentrator can fail to produce oxygen due to power failure or device malfunction. Always have a backup source of oxygen readily available.
• Follow your local and / or national guidelines for waste disposal.
• When moving the device, please move along the air inlet window in order to maintain the balance of the device.
• Children are forbidden to play with the remote control to avoid eating the battery in the remote control by mistake.
• Nasal cannula is a disposable accessory, and have cross-infection if re-use.
• This device cannot be used in oxygen rich environment.
• There is no need to carry out internal gas connection and line connection inspection during the service life of the product; after the service life of the product is exceeded, it needs to be inspected every 1 year by qualified service personnel authorized by manufacturer.
• Don't near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
• 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.
• 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.
• 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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠Caution

• To avoid damage, please keep the device vertical in transit. No upside down!

• Select the qualified electrical outlet and the patch panel with the electrical safety certification.

• Don't disassemble the enclosures without authorization!

• If the supply voltage is instable or beyond the prescribed scope, please add a voltage stabilizer.

• The manufacturer recommends that the uptime is more than 30 minutes and do not frequently open / close the device. It can be started up again after shutting down 3 to 5 minutes. Otherwise the service life may be reduced.

• Locate and position the device in a well ventilated space so that the air intake and the air exhausts are not obstructed.

• Any sundries are not allowed putting under the device bottom. Do not place the device on the soft surface (like bed, sofa) that may lead to tilted or declined. The air inlet and outlet should be kept away from the plush, hair or other analogues to avoid blocking which may lead to closing down or oxygen concentration decreased.

• Do not move or relocate the device by pulling the power supply cord.

• Put the device on indoor and ventilated place to avoid direct sunshine. Each side of the device should keep a more than 30 cm distance with the wall, furniture and other analogues. Keep away from the carpet piles, heater, electric fire and hot air ventilating device. Do not put the device in a narrow place.

• Fill water to the humidifier according to the manufacturer's instruction. Please do not add too much water in it!

• Only the authorized agency and trained personnel can maintain and adjust the device performance.

• The device will be easily disturbed by radio frequency if portable communication equipment is nearby.

• Do not touch the device when humid. Do not use or store the device in the place which may easy to fall into water or other liquid.

• Do not instill or insert anything in the device.

• Do not leave the device alone after connecting with the power.

• Ensure the power is disconnected after using.

• Use the appointed components, attachments only. Otherwise the device's performance will be reduced.

• Do not make the device in parallel or in series with another oxygenator.

• Ensure the power is disconnected before moving the device.

• Avoid spark near the device. Including the electrostatic spark generated by friction.

• Keep the openings free from lint, hair and similar foreign items.

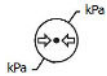
• To avoid damage from clogging, do not operate the device without the filter installed.

• 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.
• The device should be located so as to avoid pollutants or fumes.
• For any serious incidents that occur in relation to this device, these should be reported to BMC and the competent authority in your country.
• The device uses non-detachable power supply cord. If it is damaged and needs to be replaced, please contact the manufacturer for replacement.

1. Symbols

	Refer to instruction manual / booklet
	General warning sign
	Caution
	TYPE BF APPLIED PART
	CLASS II equipment
	No smoking
	No open flame: Fire, open ignition source and smoking prohibited
	Do not assemble
	No sitting
	Alternating current
IP21	Enclosure protection classification "2" means protection against solid foreign objects of 12.5 mm ø and greater "1" means protection against vertically falling water drops
	OFF (power)
	ON (power)
	Do not re-use
	Serial number
	Manufacturer
	Date of Manufacture
	Keep dry

	Batch code
	Catalogue number
	Non-ionizing electromagnetic radiation
	MR Unsafe
	Marking of Electrical and Electronic Equipment
	CE marking
	Logo of BMC Medical Co., Ltd.
	Medical device
	Unique device identifier
	Model Number
	Made in China
	Authorized Representative in the European
	Use by date
	Not made with natural rubber
	Does not contain or presence of [PHTHALATES]
	Importer
	Temperature limit
	Humidity limitation



Atmospheric pressure limitation



Fragile, handle with care



This way up



Stacking limit by number

2. Product Information

2.1 Intended Use

The oxygen concentrator is intended to provide supplemental oxygen to persons requiring oxygen therapy. It is not intended to be life supporting or life sustaining. It is for use in the home or hospital/institutional environment.

WARNINGS!

• The oxygen concentrator is not intended to be life supporting or life sustaining.

• Only use this product if the patient is capable of spontaneous breath.

• The instructions in this manual are not intended to supersede established medical protocols.

• Don't use in parallel or series with other oxygen concentrators or oxygen therapy devices.

• Do not bring the device or accessories into a Magnetic Resonance (MR) environment as it may cause unacceptable risk to the patient or damage to the device or MR medical devices. The device and accessories have not been evaluated for safety in an MR environment.

• Do not use the device or accessories in an environment with electromagnetic equipment such as CT scanners, Diathermy, RFID and electromagnetic security systems (metal detectors) as it may cause unacceptable risk to the patient or damage to the device. Some electromagnetic sources may not be apparent, if you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, disconnect the power cord and discontinue use. Contact your home care provider.

• When the device is in use, it cannot be maintained.

CAUTIONS!

• The patient is an intended operator and can use all functions.

• Read and understand the entire user manual before operating this system. If you have any questions concerning the use of this system, contact your home care provider or health care professional.

2.2 Contraindication

It is forbidden for patients with oxygen poisoning and oxygen allergy.

2.3 Technology Principle

In the device, the air passes through a molecular sieve at normal temperature to provide the high concentration oxygen which conforms to the medical oxygen standards. The method is called Pressure Swing Adsorption (PSA).

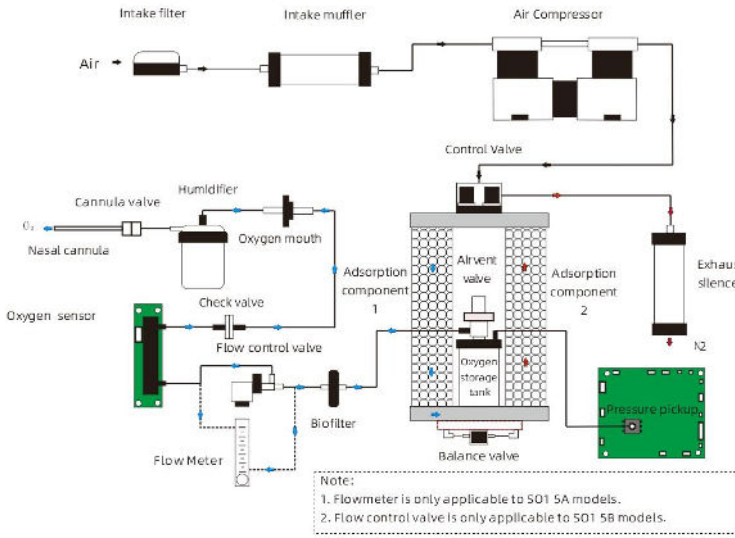


Fig. 2-1

2.4. Intended Clinical Benefits

Reduce mortality and improve quality of care by improving and stabilizing blood oxygen saturation levels of patients.

2.5. Specifications

Dimensions (L x W x H)	388×279×607 mm		
Weight	18 kg		
Conditions		**Operation**	**Transport and Storage**
	Temperature	10°C ~ 40°C	-30°C ~ 70°C
	Humidity	15% ~ 80% Non-condensing	15% ~ 95%, Non-condensing
	Atmospheric Pressure	86 kPa ~ 106 kPa	50 kPa ~ 106 kPa
		Up to 1828 meters (6000 ft) above sea level without degradation of concentration levels. From 1828 meters (6000 ft) to 4000 meters (13129 ft) below 90% efficiency.	If the storage or transportation temperature is under 5°C or over 50°C, the device needs putting into the normal working temperature for more than 4 hours before using.
Rated flow	0.5 - 5.0 L/min, (±0.5 L/min, uncertainty 0.3 L/min) @STPD (standard temperature and pressure, dry) conditions 0.5 - 5.0 L/min, (±0.5 L/min, uncertainty 0.3 L/min) @over the rated ranges		
Output oxygen concentration	0.5 - 5.0 L/min: 93%±3%, uncertainty 2% @STPD (standard temperature and pressure, dry) conditions 0.5 - 5.0 L/min: 93%±3%, uncertainty 2% @over the rated ranges		
Output Pressure	50±10 kPa		
Sound press level	≤ 50 dB(A) @3 L/min, uncertainty 2 dB(A) ≤ 50 dB(A) @5 L/min, uncertainty 2 dB(A)		
Sound power level	≤ 58 dB(A) @3 L/min, uncertainty 2 dB(A) ≤ 58 dB(A) @5 L/min, uncertainty 2 dB(A) Note: Audible sound energy parameters are based on ISO 4871 declared dual indicators.		
Mode of Operation	Continuous		
Rating voltage	~ 230 V, 50 Hz		
Rating power	380 VA		

Type of Protection Against Electric Shock	 (CLASS II equipment)
Degree of Protection Against Electric Shock	 (TYPE BF APPLIED PART)
Degree of Protection Against Ingress of Water	IP21
The time required from switching on the oxygen concentrator until it can be relied upon to deliver the set flow rate and concentration of oxygen	30 min
Battery in the remote control (Optional)	CR2025
RATED maximum pressure for Nasal cannula	100 kPa
RATED range of oxygen flows for Nasal cannula	0-15 L/min

3. Model

Model	Display Area	Work mode	Remote control
SO1 5A	100 mm*50 mm	Continuous flow	×
SO1 5B	155 mm*87 mm	Continuous flow, Timed flow	✓

4. Package Contents

After unpacking the system, make sure you have everything shown here (Different models of the product may contain different components):

No.	Articles	Qty.	Notes
1	Oxygen concentrator	1	
2	Humidifier	1	
3	Connecting tube	2	
4	Cannula valve	1	
5	Nasal cannula	1	
6	Remote control	1	Only for SO1 5B
7	Filter cotton	1	
8	Accompanying Documents	1	

If the use, maintenance and cleaning are in strict accordance with the User Manual, the product's service life (including Humidifier, Connecting tube, Remote control, Filter cotton) is five years or 10000 hours, which is subject to the first due date.

The shelf life of Nasal cannula can be found on theirs outer packaging.

The applied part is defined as Nasal cannula. Other parts that may contact patients mainly include Humidifier, Connecting tube, Cannula valve, and Remote control (options).

NOTES!

• All parts and accessories are not made with natural rubber latex.

• If any of the above parts are missing, contact your home care provider.

• Contact your home care provider for additional information on the available accessories of this device. When using accessories, always follow the instructions enclosed with the accessories.

WARNINGS!

• This device should only be used with the accessories manufactured or recommended by BMC or with those recommended by your prescribing physician. The use of inappropriate accessories may affect the performance of the device and impair the effectiveness of therapy.

• Do not pile up the long tubing at the head of the bed, as it may wrap around the head or neck of the patient during sleep.

• Do not connect any equipment to the device unless recommended by BMC or your health care provider.

5. System Features

5.1 SO1 5A

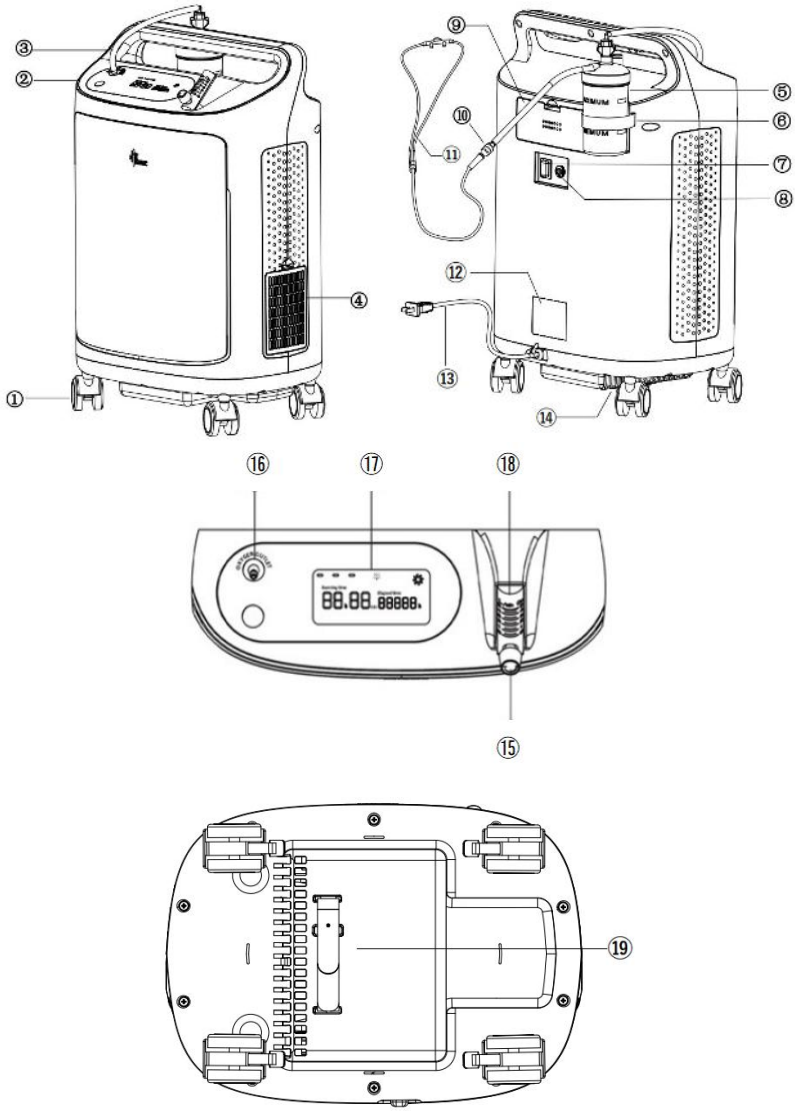


Fig. 5-1

Part	Function
1	Caster, easy for users to move the device
2	Control Panel
3	Connecting tube, connect the oxygen outlet and the Humidifier inlet
4	Air inlet window
5	Humidifier
6	Humidifier band
7	Power Switch
8	Overload protector
9	Filter Door
10	Cannula valve
11	Nasal cannula
12	Specifications Label
13	Power supply cord
14	Air outlet
15	Oxygen Flow Meter knob
16	Oxygen outlet
17	Display information panel
18	Oxygen Flow Meter
19	Bandage, bundle compressors during transportation

CAUTION!

• The pictures in this manual are only for reference, if they are different from the material object, the latter shall prevail.

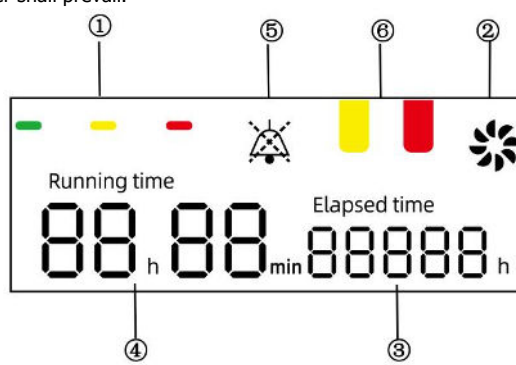
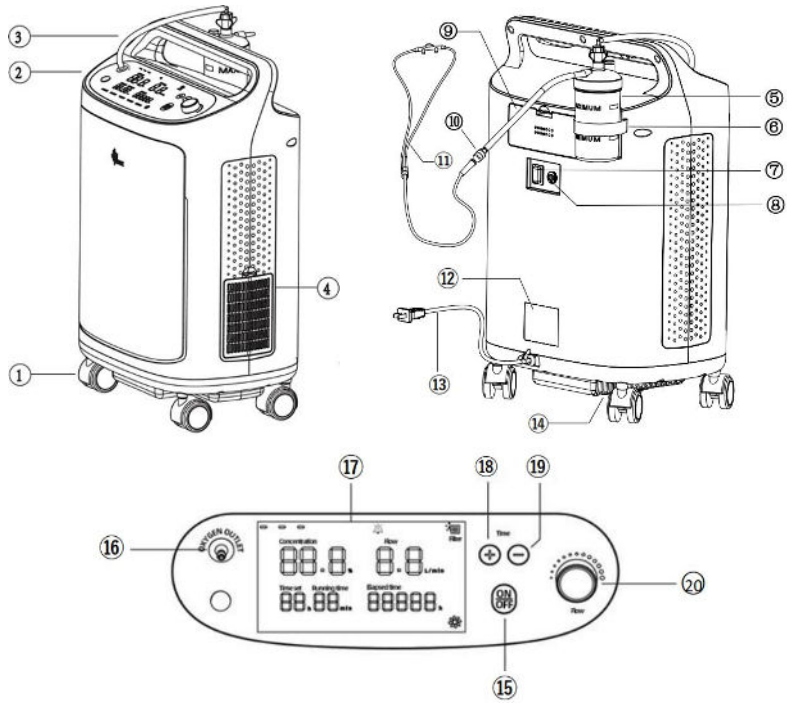


Fig. 5-2

Part	Function
1	Operating status indicator light (Green, Yellow, Red) Green: Power on indicator light Yellow: Medium priority alarm indicator light Red: High priority alarm indicator light
2	Running icon: Indicates that the device is working
3	Elapsed time
4	Running time / Alarm Code
5	Alarming Silence Indicator
6	Operating status indicator light (Yellow, Red) Yellow: Medium priority alarm indicator light Red: High priority alarm indicator light

5.2 SO1 5B



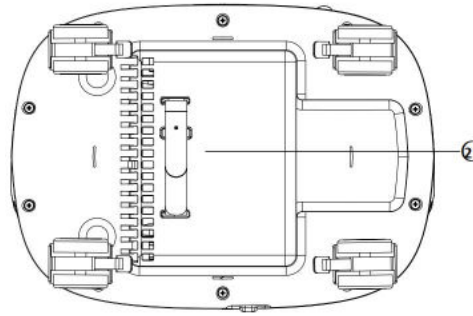


Fig. 5-3

Part	Function
1	Caster, easy for users to move the device
2	Control Panel
3	Connecting tube, connect the oxygen outlet and the Humidifier inlet
4	Air inlet window
5	Humidifier
6	Humidifier band
7	Power Switch
8	Overload protector
9	Filter Door
10	Cannula valve
11	Nasal cannula
12	Specifications Label
13	Power supply cord
14	Air outlet
15	ON / OFF button
16	Oxygen outlet
17	Display information panel
18	Increase timing button
19	Decrease timing button
20	Flow rate control knob
21	Bandage, bundle compressors during transportation

CAUTION!

• The pictures in this manual are only for reference, if they are different from the material object, the latter shall prevail.

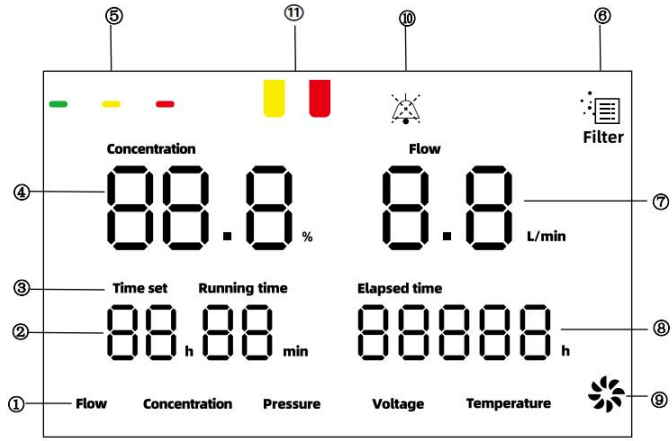


Fig. 5-4

Part	Function
1	Alarm Indicator
2	Running time / Timing
3	Time set / Timing Indicator
4	Oxygen Concentration
5	Operating status indicator light (Green, Yellow, Red) Green: Power on indicator light Yellow: Medium priority alarm indicator light Red: High priority alarm indicator light
6	Change Air Intake Filter Indicator
7	Oxygen flow rate
8	Elapsed time
9	Running icon: Indicates that the device is working
10	Alarming Silence Indicator
11	Operating status indicator light (Yellow, Red) Yellow: Medium priority alarm indicator light Red: High priority alarm indicator light

6. First Time Setup

6.1 Checking

Check whether the carton and other packing materials are complete. If there is any damage, please notify the Transport Company or local reseller timely.

WARNING!

• If the device has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, disconnect the power cord and discontinue use. Contact your home care provider immediately.

CAUTIONS!

• The device, its parts and accessories are specified for use at 0 - 5 L/min flows.

• The operator 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.

• Only authorized accessories can be used with the device.

• If use unauthorized accessories may cause unacceptable risk.

6.2 Untie the Compressor Bandage

When first used, you should untie the compressor bandage. After the bandage is loosened, the tail end of the bandage shall be bonded to the nylon-buckle of the bandage to avoid abnormal sound during operation. If you need to transport, you need to bundle it before transport.

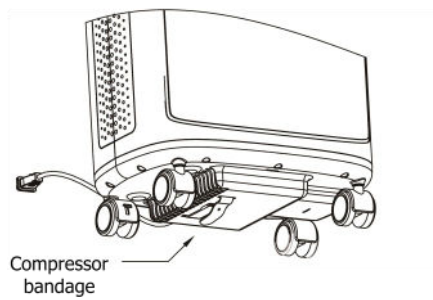


Fig. 6-1

6.3 Installing the Humidifier

1) Rotate the Humidifier cap and it will be disassembled. Add purified water into the Humidifier and ensure the water level between the marks “MAXIMUN” and “MINIMUN”, rotate the Humidifier cap to tight, as shown in Fig. 6-2.

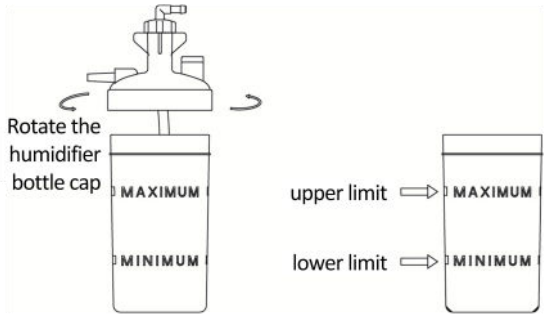


Fig. 6-2

2) Plug one end of the Connecting tube into the oxygen outlet of the oxygen concentrator. Plug the other end of the Connecting tube into the inlet of the Humidifier.

3) Attach the Humidifier in the specified position on the rear panel of the oxygen concentrator, and bind the binding tape to the Humidifier.

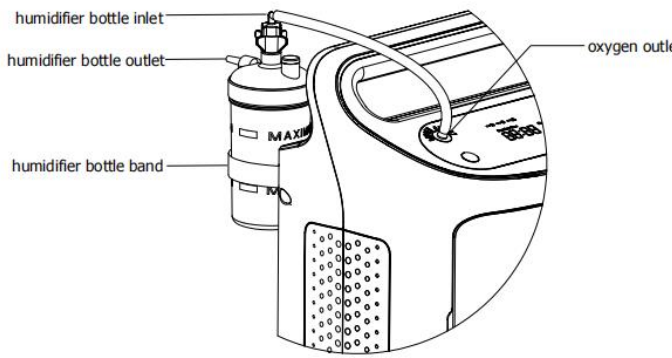


Fig. 6-3

6.4 Connecting to Cannula Valve

Plug one end of the Connecting tube into the outlet of the Humidifier. Plug the other end of the Connecting tube into the Cannula valve.

When the Nasal cannula is ignited, the Cannula valve can interrupt the flow of oxygen to the patient.

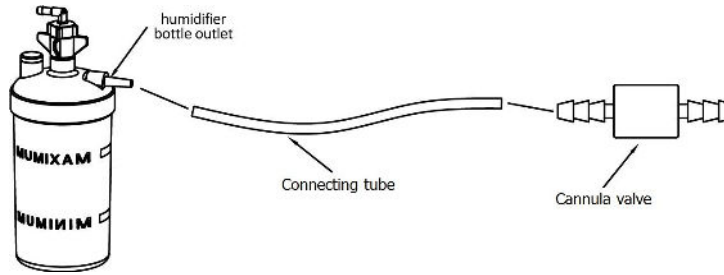


Fig. 6-4

6.5 Connecting to Nasal Cannula

Plug one end of the Nasal cannula into the Cannula valve, and another end (nasal cannula) into the patient.

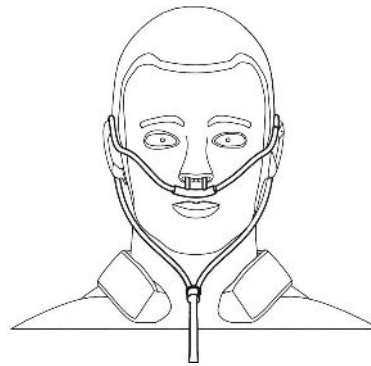


Fig. 6-5

CAUTIONS!

• 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.

• With the oxygen concentrator turned on adjust the flow meter to the desired flow 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.

• Avoid pediatric cannula use in adult patients.

6.6 Starting

1) Plug in Power supply cord to an electrical outlet.

2) Press Power switch to ON position, then the backlight of LED segment displays and all the indicator lights (green, yellow and red) will come on.

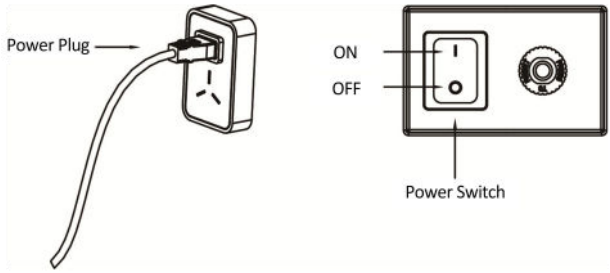


Fig. 6-6

3) For SO1 5A, the oxygen concentrator is starting to work. Then the LED Segment Displays shows the Running time and Elapsed time.
4) For SO1 5B, press the **ON / OFF** button on control panel, and the oxygen concentrator will start to work. Then the LED Segment Displays shows the oxygen Concentration, oxygen flowrate, Running time and Elapsed time.

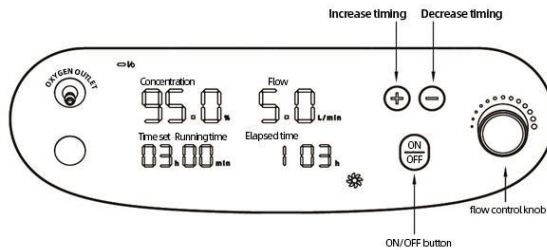


Fig. 6-7

WARNINGS!

• Select the qualified electrical outlet and the patch panel with the electrical safety certification.

• If the supply voltage is instable or beyond the prescribed scope, please add a voltage stabilizer.

7. Operating

Before using check whether the outside surface is intact, the components conform to the component list or not.

The elapsed time is the whole running time after manufacture. The burn-in inspection time has been reset before delivering. Before using, check whether the elapsed time is 0 hour to ensure the device is bran-new.

7.1 Flow Rate Control

1) For SO1 5A, turn the Flow Meter knob to the setting prescribed by your physician or therapist. Turn anticlockwise to increase the flowrate. Turn clockwise to reduce the flowrate. To properly read the flowmeter, locate the prescribed flowrate line on the flowmeter (the black float center indicates the value). (Seen in the picture)

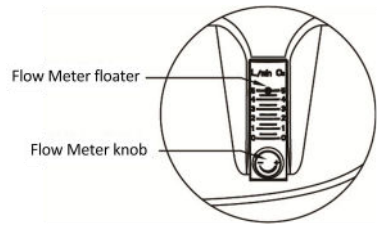


Fig. 7-1

2) For SO1 5B, turn the flowrate control knob to the setting prescribed by your physician or therapist. Turn clockwise to increase the flowrate. Turn anticlockwise to reduce the flowrate (0.5 L/min ~ 5.0 L/min, 0.5 L/min one step). The flowrate value can be read on the LED Segment displays. (Seen in the picture)

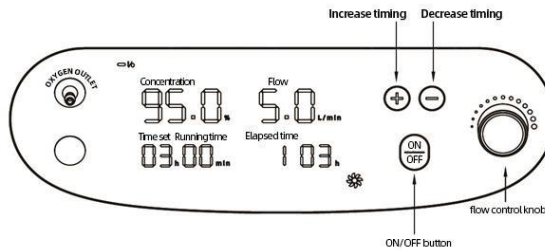


Fig. 7-2

WARNINGS!

• The oxygen supply time and flow rate follow the physician's order.

• If the Humidifier has a continuous releasing voice, indicate that the Nasal cannula is blocked and the safety valve is open. Please clean the tube.

• If the displayed flow rate is less than 0.5 L/min please check whether the Nasal cannula and component is blocked, knotted or the Humidifier is damaged.

7.2 Remote Control (For SO1 5B)

1) **ON / OFF** button is used to start / stop the operation.

2) Flow button is used to adjust the oxygen flowrate.

3) Time set button is used to set operation time.

4) Backlight button is used to turn off / on display backlight.

5) Control distance: ≤ 4 meters.

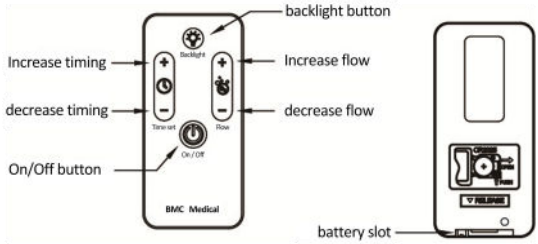


Fig. 7-3

CAUTIONS!

• Remote control function is only for SO1 5B.

• If the remote control is not used for a long time, the battery shall be removed to avoid battery leakage.

• Pay attention to the polarity marking. Don't reverse battery polarity.

7.3 Timing (For SO1 5B)

SO1 5B has a timing function. You can adjust the timing button to set within the range 0 ~ 4 hours.

When the Running time Indicator light up, it means the oxygen concentrator is in the continuous flow mode.

1) Time increase: 10 minutes will be added by pressing this Increase Timing Button one time; 30 minutes will be added by long pressing this Increase Timing Button.

2) Time reduce: 10 minutes will be reduced by pressing this Decrease Timing Button one time; 30 minutes will be reduced by long pressing this Decrease Timing Button.

3) Timing mode: when the timing is not zero, the Timing Indicator will light up, it means the oxygen concentrator is in the Timing mode.

4) When reaching the setting time, the oxygen concentrator will be in the 30 seconds heat dissipation state, and then switch to the standby state.

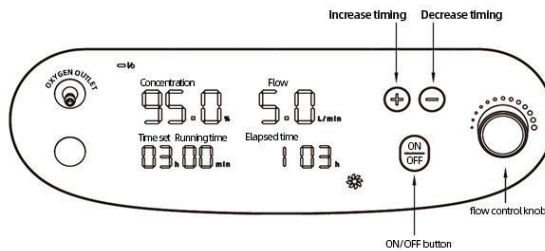


Fig. 7-4

7.4 Turning the Device Off

1) Take off the Nasal cannula.
2) For SO1 5A, press the power switch to OFF position.
3) For SO1 5B, press the **ON / OFF** button and the oxygen concentrator will stop working. Press the power switch to OFF position to power off the oxygen concentrator.
4) Disconnect the power supply cord from the electrical outlet.

CAUTION!

• Do not position the oxygen concentrator where it is difficult to disconnect the oxygen concentrator.

8. Alarm

This chapter describes device alarms and the responses operators make to different alarms. After running 5 minutes, disconnect the device from the power supply by unplugging the power cord, an audible alarm sounds like "beep beep beep, beep-beep, beep beep beep, beep-beep" and the red indicator light flickers, which means the alarming system of the device works normally.

CAUTIONS!

• When the high priority alarm occurs, the oxygen concentrator stops oxygen production and the alarm system no longer operates. When the oxygen concentrator is restarted or the oxygen production is restarted, the alarm system runs again.
• The operator needs to operate the oxygen concentrator in front of the control panel of the oxygen concentrator.

8.1 Grading for Alarm and Description

The priority for alarming and description of the oxygen concentrator is presented as follows:

Priority	Description
High	Requires operator to make instant response
Medium	Requires operator to make instant on-time response

8.2 Visual Alarm

The priority for the visual alarming is expressed by the alarming information or the alarming code on the screen and the color of the LED light, which is described as follows:

Priority	Visual	Description
High	Red	Red light flickers
Medium	Yellow	Yellow light flickers

8.3 Auditory Alarm

In the case of alarming, the alarming sounds at different priority will occur and are described as follows:

Priority	Auditory	Description	Sound pressure level range (dBA)	Measure-ment radius (m)
High	●●● ●● ●●● ●●	beep beep beep beep beep beep beep beep beep beep	55 ~ 60	1.5
Medium	● ● ●	beep beep beep	50 ~ 55	1.5

8.4 Alarm Silence

When the oxygen concentrator sounds a high priority alarm (except Power Loss Alarm), quickly switch the Power switch off and on in 1 second and it will become silent for about 60 seconds and then the alarm sound again immediately after the end of the silence; if quickly switch the Power switch off and on in 1 second again during the silence period, the alarm sound will resume.

8.5 Alarm Information and Description

Alarm	Alarm Conditions	Alarm Priority	Alarm Delay	Description
Power Loss	Technical	High	≤ 3 s	When the power loss happened, the red indicating light flickers along with the alarm sound.
Power on Self Test Failed	Technical	High	≤ 3 s	Within 1 minute after starting to work, the pressure sensor is abnormal for 30 s, the red indicating light is flashing along with the alarm sound then the device stopped working. For SO1 5A, Alarm Code is "E-06"; For SO1 5B, Pressure Indicator flickers.
	Technical	High	≤ 3 s	Within 1 minute after starting to work, the temperature sensor is abnormal for 30 s, the red indicating light is flashing along with the alarm sound then the device stopped working. For SO1 5A, Alarm Code is "E-07"; For SO1 5B, Temperature Indicator flickers.

	Technical	High	≤ 3 s	Within 1 minute after starting to work, the oxygen concentration sensor is abnormal for 30 s, the red indicating light is flashing along with the alarm sound then the device stopped working. For SO1 5A, Alarm Code is "E-08"; For SO1 5B, Concentration Indicator flickers.
Flow Abnormal	Technical	Medium	≤ 3 s	After starting to work for a quarter hour, when the flow is greater than 6.5 L/min for 5min, the yellow indicating light is flashing along with the alarm sound and the device works normally. For SO1 5A, Alarm Code is "E-11". Only For SO1 5A.
	Technical	Medium	≤ 3 s	After starting to work for 3 minutes, when the oxygen output flow differs greatly from the set flow for about 1 min, the yellow indicating light is flashing along with the alarm sound and the device works normally. For SO1 5B, Flow Indicator flickers. Only For SO1 5B.
Concentration Abnormal	Technical	Medium	≤ 3 s	After starting to work for a quarter hour, when the concentration is less than 82% and greater than 70% for 5 min, the yellow indicating light is flashing along with the alarm sound and the device works normally. For SO1 5A, Alarm Code is "E-12"; For SO1 5B, Concentration Indicator flickers.

	Technical	High	≤ 3 s	After starting to work for a quarter hour, when the concentration is less than 70% for 5 min or oxygen concentration sensor is abnormal for 5 min, the red indicating light is flashing along with the alarm sound then the device stopped working. For SO1 5A, Alarm Code is "E-02"; For SO1 5B, Concentration Indicator flickers.
Pressure Abnormal	Technical	Medium	≤ 3 s	After starting to work for 3 minutes, when the system pressure is lower than the set value for 3 min, the yellow indicating light is flashing along with the alarm sound and the device works normally. For SO1 5A, Alarm Code is "E-13"; For SO1 5B, Pressure Indicator flickers.
	Technical	High	≤ 3 s	After starting to work for 3 minutes, when the system pressure is higher than the set value for 3 min, the red indicating light is flashing along with the alarm sound and the device stops working. For SO1 5A, Alarm Code is "E-03"; For SO1 5B, Pressure Indicator flickers.
Temperature Abnormal	Technical	High	≤ 3 s	After starting to work for 1 minute, when the internal temperature is greater than set value for 3 min, the red indicating light is flashing along with the alarm sound and the device stops working. For SO1 5A, Alarm Code is "E-05"; For SO1 5B, Temperature Indicator flickers.

Voltage Abnormal	Technical	Medium	≤ 3 s	After starting to work, when the power supply falls below the value necessary to maintain normal operation for 3 min, the yellow indicating light is flashing along with the alarm sound and the device works normally. For SO1 5A, Alarm Code is "E-14"; For SO1 5B, Voltage Indicator flickers.

8.6 Alarm Verification

This section describes how to verify the functions of the alarm system by service personnel.

Power Loss	
SO1 5A SO1 5B	After starting and running for 5 minutes, unplug the power cable and the device sends a high priority alarm.
Power on Self Test Failed Flow Abnormal Concentration Abnormal Pressure Abnormal Temperature Abnormal	
SO1 5A SO1 5B	The device automatically checks the signals of oxygen concentration sensors, pressure sensors, and temperature sensors within one minute after starting up and running.
Voltage Abnormal	
SO1 5A SO1 5B	Set the output voltage of the AC voltage regulator to 193 V, insert the power supply cord of the device into the AC voltage regulator, run the device, and the device sends a medium priority alarm.

9. Cleaning and Disinfection

WARNINGS!

• Regular cleaning of the device and its accessories is very important for the prevention of respiratory infections.

• To avoid electric shock, always unplug the device before cleaning and disinfecting.

• Use mild soap that is nontoxic to humans.

• Follow the manufacturer's instructions on cleaning the tubes and on determining the frequency of cleaning.

• Do not open or modify the device. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorized service agent.

CAUTIONS!

• Overheating of the materials could lead to early fatigue of these materials.

• Do not use solutions containing chlorinated lime, chlorine, or aromatic to clean the device and its accessories. Liquid soap containing moisturizing agents or antimicrobials should not be used either. These solutions may harden cleaned materials or reduce their lifespan.

• Do not clean or dry the device and its accessories when the temperature is higher than 80°C (176°F). High temperatures could reduce product life.

• Do not immerse the device in any fluids.

• Excess moisture may impair the proper operation of the device.

9.1 Cleaning and Disinfection the Enclosures

Preparation before cleaning and disinfection: purified water, clean soft moist cotton or sponge, cotton swab, brush, several pieces of gauze, 5% sodium hypochlorite, a number of disposable gloves.

Cleaning:

1. It is recommended to clean the device’s enclosure before each use, and clean it at least once a month.
2. First, unplugged the power supply cord, wipe the enclosure with a clean soft slightly wet cotton cloth or sponge for more than 3 times, each time for no less than 2 minutes, and replace the cotton cloth or sponge after each wipe. Wrap a cotton swab with a clean, damp cloth and wipe to clean any holes or gaps in the enclosure. Note: Do not leak the liquid into the slot of the chassis.
3. The flow meter knob installed on the enclosure of the oxygen concentrator (the float flow meter knob used for SO1 5A) needs to be cleaned and brushed more than 3 times with a brush, each time for no less than 2 minutes, due to the non-slip grooves on the knob.
4. Wait for the device’s enclosures to dry before use.

Disinfection:

1. Clean the enclosure as indicated above.
2. Use a household chlorine bleach containing 5% sodium hypochlorite. Combine 10 parts

purified water to 1 part bleach.
3. Using a damp cloth with the bleach solution, wipe the enclosure, and allow it to remain damp for 5 minutes.
4. Then wipe the enclosure with a clean, damp cloth for at least 3 minutes, and wrap a cotton swab with a clean, damp cloth to clean the holes or gaps in the enclosure.
5. Finally, wipe the enclosure with a soft cloth for no less than 3 minutes until dry.

CAUTION!

• Disinfection must not be performed more than 10 times.

9.2 Cleaning and Disinfection the Humidifier and the Connecting Tube

Preparation before cleaning and disinfection: Alconox (diluted at 1%), soft bristled brush, soft cloth, purified water, OPA (0.55%), soft bristled brush, several pieces of gauze, a number of disposable gloves.

Cleaning:

1. The water in the Humidifier should be replaced every day.
2. The Humidifier and the Connecting tube should be cleaned every week.

Clean the Humidifier and Connecting tube with a soft bristled brush for one minute after soaking the Humidifier and Connecting tube in detergent solution (see table below) for 5 minutes. Pay particular attention to all crevices and cavities. Then rinse with running purified water for 5 minutes. Wipe them dry with a soft cloth or air dry out of direct sunlight.

Detergent	Water temperature
Alconox (diluted at 1%)	Warm water (approx 113 to 140°F or 45 to 60°C)

Disinfection:

1. Clean the Humidifier or the Connecting tube as indicated above.
2. Immerse the Humidifier parts or the Connecting tube in OPA (0.55%) for 12 minutes at 20°C (68°F), ensure that the solution contact all surfaces.
3. After immersing, remove the Humidifier components or the Connecting tube from the disinfectant and rinse thoroughly under running purified water for 5 minutes.

CAUTIONS!

• Disinfectants generally damage the surface of materials and shorten the service life of objects. Attention should be paid to reading the instructions for the use of disinfectants, choosing applicable ones as far as possible, and following the recommendations of disinfectant manufacturers.
• After disinfection, check whether there are any signs of damage on the parts. If any damage is found, replace it in time.
• No more than 10 times of disinfection.

9.3 Replace and Clean the Filter Cotton

Clean the filter cotton every 15 days or 30 days according to the operating environment and frequency. And ensure at least once a month.

1) Take down the air inlet window, and replace the old inlet filter cotton with a new one.

2) Clean the old inlet filter cotton with water, and fully dry it for re-use.

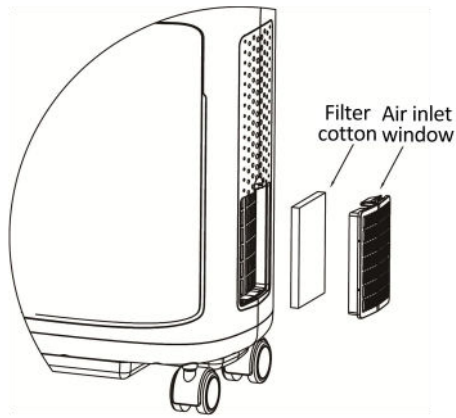


Fig. 9-1

CAUTION!

• The damp-dry filter cotton mustn't be used.

9.4 Replace the Air Intake Filter

The Air Intake Filter needs be replaced per 1000 hours.

1) Open the Filter Door.

2) Remove the old Air intake filter and replace with a new one.

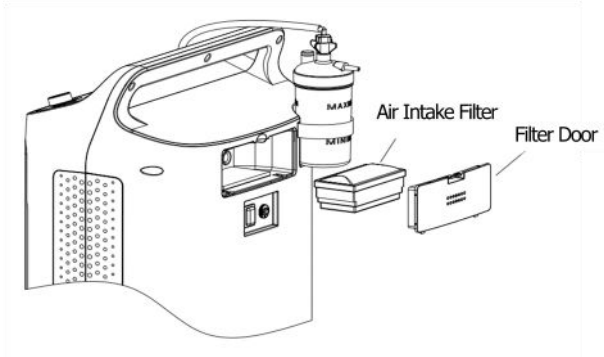


Fig. 9-2

CAUTION!

• The Air Intake Filter may be replaced more frequently based on actual sanitary conditions.

9.5 Cleaning and Disinfection between Patients

Follow these instructions to eliminate possible pathogen exchange between patients due to contamination of components or accessories.

1) Dispose of and replace all patient side accessories not suitable for multiple patient use, including but not limited to: Nasal Cannula and Cannula valve.
2) Perform maintenance procedures described in this manual.
3) Check oxygen concentrator for possible external damage or signs that it may require service or repair.
4) Ensure oxygen concentrator functions properly and all alarms are in working order.
5) Before repackaging and distribution to new patient, ensure packaging contents contain the concentrator and user manual.

9.6 Preventive Maintenance

Activity	Frequency
Check oxygen concentration	Every 6 months of continuous use
Check power loss alarm	Every 6 months of continuous use

10. Disposal

This product complies with the requirements of Directives 2011/65/EU and (EU) 2015/863 (RoHS) on the restriction of hazardous substances.

According to the European Directive 2012/19/EU (WEEE) on electrical and electronic equipment, products cannot be discarded indiscriminately and must be disposed of in accordance with the laws and regulations of the country in which disposal occurs.

The crossed-out wheeled bin symbol  indicates that the product bearing this symbol may not be disposed of together with general household waste, but instead requires separate disposal. This requirement for separate disposal is based on the European Directive 2012/19/EU for electrical and electronic equipment. You can hand in the product at a municipal collection point, for example. This reduces the impact on natural resources and prevents contamination of the environment through the release of hazardous substances.

For further information regarding product disposal, please contact your specialist distributor.

CAUTION!

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

11. Troubleshooting

The table below lists common problems you may have with the device and possible solutions to those problems. If none of the corrective actions solve the problem, contact your home care provider.

Problem	Possible Cause	Solution(s)
After opening the power switch, the red indicating light is flashing along with the alarm sound.	1) The plug and outlet poor contact.	1) Insert the plug into outlet tight.
	2) The outlet has no power output.	2) Change an outlet.
	3) The output power is in low level.	3) Do not use the extension cord. Change an outlet.
	4) Because of the overload protector	4) Press the overload protector to reset.
	5) If it is not improved, please connect with the supplier.	
After starting up, the device soon stops working, and the red indicating light is flashing along with the alarm sound. Alarm Code is "E-06", or Pressure Indicator is on.	The pressure sensor in the device is abnormal.	Please shut down the device immediately and connect with the supplier.
After starting up, the device soon stops working, and the red indicating light is flashing along with the alarm sound. Alarm Code is "E-07", or Temperature Indicator is on.	The temperature sensor in the device is abnormal.	Please shut down the device immediately and connect with the supplier.
After starting up, the device soon stops working, and the red indicating light is flashing along with the alarm sound. Alarm Code is "E-08", or Concentration Indicator is on.	The oxygen concentration sensor in the device is abnormal.	Please shut down the device immediately and connect with the supplier.
After starting up, the running sound and the flow rate show are all normal, but have no or little oxygen output.	1) Oxygen leakage: the Humidifier is not sealed.	1) Tighten the Humidifier and its cap.
	2) The Humidifier's safety valve is open.	2) Shake the Humidifier lightly to close the safety valve.
	3) Oxygen leakage: the	3) Tighten the air outlet and its tube.

	Humidifier's outlet tube has a poor connection.	
	4) The Nasal cannula is damaged.	4) Change the Nasal cannula.
	5) If it is not improved, please connect with the supplier.	
The device works normally; the yellow indicating light is flashing along with the alarm sound. Alarm Code is "E-11", or Flow Indicator is on.	1) The oxygen flow rate is too large.	1) Adjust the Flow Meter to a normal value.
	2) The oxygen flow rate is large different from the set flow rate.	2) Adjust the Flow Meter to a normal value.
	3) If it is not improved, please connect with the supplier. But the device can continue to be used.	
The device works normally; the yellow indicating light is flashing along with the alarm sound. Alarm Code is "E-12", or Concentration Indicator is on.	1) The oxygen concentration is lower than 82%.	1) Clean or change the inlet filter cotton, or change the Air Intake Filter.
	2) The oxygen flow rate is larger than the normal value.	2) Adjust the Flow Meter to a normal value.
	3) If it is not improved, please connect with the supplier. But the device can continue to be used.	
The device works normally; the yellow indicating light is flashing along with the alarm sound. Alarm Code is "E-13", or Pressure Indicator is on.	1) The inlet filter cotton is dirty.	1) Clean or change the inlet filter cotton.
	2) The Air Intake Filter is dirty.	2) Change the Air Intake Filter.
	3) The flow rate is too large.	3) Adjust the Flow Meter to a normal value.
	4) The air inlet is blocked.	4) Clean the foreign matter surrounding the air inlet.
	5) If it is not improved, please connect with the supplier. But the device can continue to be used.	
The device works normally; the yellow indicating light is flashing along with the alarm sound. Alarm Code is "E-14", or Voltage Indicator is on.	1) The power supply is low than the normal value.	1) Please add a voltage stabilizer.
	2) If it is not improved, please connect with the supplier. But the device can continue to be used.	
The device does not work; the red indicating light is flashing along with the alarm sound.	1) The working temperature is too high.	1) Check whether the working condition conforms to the requirements or not.
	2) The air outlet at the bottom is blocked.	2) Clean the air outlet.

Alarm Code is "E-05", or Temperature Indicator is on.	3) If it is not improved, please shut down the device and connect with the supplier.	
The device does not work; the red indicating light is flashing along with the alarm sound. Alarm Code is "E-03", or Pressure Indicator is on.	The system pressure is too high.	Please shut down the device immediately and connect with the supplier.
The device does not work; the red indicating light is flashing along with the alarm sound. Alarm Code is "E-02", or Concentration Indicator is on.	The oxygen concentration is too low.	Please shut down the device immediately and connect with the supplier.

12. EMC Requirements

The essential performance of the device is as follows:

Delivery of oxygen, in both normal condition and single fault condition, within the performance levels as indicated in the instructions for use or generation of an alarm condition.

1) Power supply failure technical alarm condition
2) Low oxygen concentration technical alarm condition
3) Malfunction technical alarm condition
4) Start-up period technical alarm condition

Guidance and manufacturer's declaration - electromagnetic emissions	
The device is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment.	
Emissions Test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies

WARNINGS!

• This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.

• The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

• The device may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

• During operation of the device, due to electrostatic interference, the following phenomena may occur: (1) Temporary loss of function or degradation of performance, such as abnormal screen display, etc. The device will recover to normal after being restarted; (2) Automatic restart of the device. These phenomena will not affect the normal use of the device, and will not cause permanent performance degradation or function loss of the device.

Guidance and manufacturer's declaration - electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output	±2 kV for power supply lines Not Applicable
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines 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° 0% U_T; 250/300 cycles	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° 0% U_T; 250/300 cycles
Power frequency (50 Hz / 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz
Note: U_T is the AC mains voltage prior to application of the test level.		

Guidance and manufacturer's declaration - electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**
Conducted RF IEC 61000-4-6	3 V 0.15 MHz ~ 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz ~ 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz
Note 1: At 80 MHz and 800 MHz, the higher frequency range applied. 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. [b] Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 10 V/m.		

Recommended separation distances between portable and mobile RF communications equipment and the device

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

Rated maximum output of transmitter (W)	150 kHz ~ 80 MHz $d = 1.17\sqrt{p}$	80 MHz ~ 800 MHz $d = 0.35\sqrt{p}$	800 MHz ~ 2.5 GHz $d = 0.70\sqrt{p}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.70
10	3.70	1.11	2.22
100	11.7	3.50	7.00

Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (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.

Guidance and manufacturer's declaration - electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.

	Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Modulation [b] (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
Radiated RF IEC 61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380–390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
	450	430–470	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	2	0.3	28
	710	704–787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
	745						
	780						
	810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
	870						
	930						
	1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
	1845						
	1970						
	2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
	5240	5100–5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	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.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) 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.

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:

$$E = \frac{6}{d}\sqrt{P}$$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Radiated fields in close proximity IEC 61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	**Test Frequency**	**Modulation**	**IMMUNITY Test Level (A/m)**
	30 kHz	CW	8
	134.2 kHz	Pulse modulation [a)] 2.1 kHz	65 [b)]
	13.56 MHz	Pulse modulation [a)] 50 kHz	7.5 [b)]
a) The carrier shall be modulated using a 50% duty cycle square wave signal. b) r.m.s., before modulation is applied.			

13. Limited Warranty

BMC Medical Co., Ltd. warrants that the device shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of three (3) years or 10000 hours which comes first prevails for main unit and three (3) months for all accessories from the date of sale by BMC Medical Co., Ltd. to the dealer. If the product fails to perform in accordance with the product specifications, BMC Medical Co., Ltd. will repair or replace, at its option, the defective material or part. BMC Medical Co., Ltd. will pay customary freight charges from BMC Medical Co., Ltd. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

BMC MEDICAL CO., LTD. DISCLAIMS ALL LIABILITY FOR ECONOMIC LOSS, LOSS OF PROFITS, OVERHEAD OR CONSEQUENTIAL DAMAGES WHICH MAY BE CLAIMED TO ARISE FROM ANY SALE OR USE OF THIS PRODUCT. SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.

To exercise the rights under this warranty, contact the local authorized dealers or:

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