# ENGLISH
## User manual: M50 OXYGEN CONCENTRATOR

EN

### TABLE OF CONTENTS



### GLOSSARY

| | | | |
|---|---|---|---|
|  | Consult instructions for use |  | Follow Instruction for Use |
|  | Type BF Applied Part |  | Temperature limit |
|  | Power on |  | Power off |
|  | Caution |  | Fragile, handle with care |
|  | Warning, electricity |  | AC Power |
|  | Stacking Limit By Number |  | Manufacturer |
|  No Open Flames | No open flames |  | Keep dry |
|  No Smoking | No smoking |  | This Way Up |
| IP21 | Drip Proof Equipment |  | Class II symbol (Double insulated) |
| CE 0123 | CE certification mark |  | Suitable for homecare use |
|  | Power switch | | |

### SPECIAL NOTES

- Please read this manual carefully before using this product and save it for future reference.
- For assistance with this manual, contact your home care provider.
- Use the flow and duration settings of this product as prescribed by your physician.
- This equipment is not to be used as a life support device and supplies supplemental oxygen only.
- Children and patients with certain disabilities may be unable to understand or communicate product alarms, and therefore must be supervised when using this device.
- It is advised that patients maintain a backup oxygen supply in case of a machine malfunction or power shortage.
- If you experience an adverse reaction when using this device, contact a physician immediately.
- In the event of an equipment alarm, please contact your home care provider immediately.

## BEFORE USING THIS OXYGEN CONCENTRATOR

⚠ **WARNING:** In high concentrations, oxygen vigorously accelerates combustion. Patients must make all efforts to reduce the risk of fire when undergoing oxygen therapy.

⚠ **WARNING:** This oxygen concentrator and all its components - including cannulas, connections and power cords - must be kept away from all sources of heat, open flame, sparks and static electricity.

EN

⚠ **WARNING:** Do not smoke or allow others to smoke while you are undergoing oxygen therapy. Do not smoke or allow others to smoke in the same room as the oxygen concentrator and accessories.

⚠ **WARNING:** Oils and greases are prone to strong spontaneous combustion when exposed to oxygen under pressure. To avoid the risk of fire and personal injury, do not use oils and greases on or around the oxygen concentrator.

⚠ **WARNING:** This device is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

## 1. INTRODUCTION

Your healthcare professional has determined that supplemental oxygen is of benefit to you and has prescribed an oxygen concentrator set at a specific flow setting to meet your needs. Do not change the flow or duration settings unless your healthcare professional tells you to do so.

**Please read and understand this entire manual before using the device.**

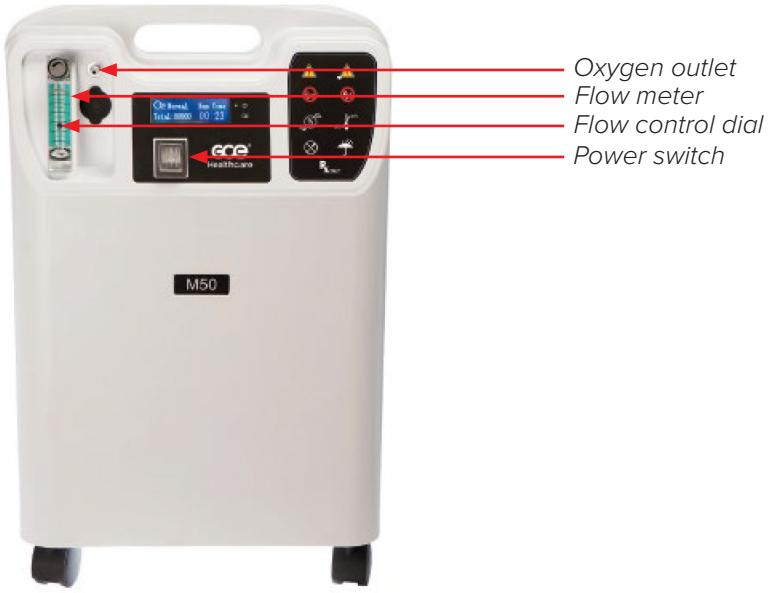
### INTENDED USE

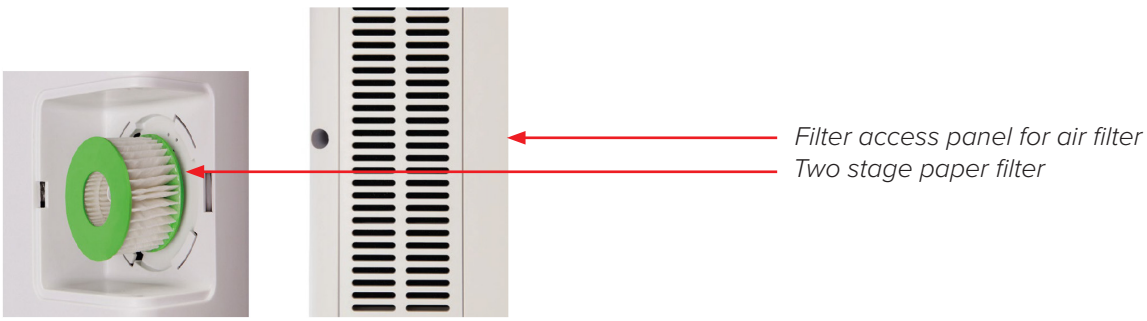
The M50 Oxygen Concentrator is intended to provide supplemental oxygen to patients requiring oxygen therapy. The device is not intended to be life supporting or life sustaining.

### ABOUT YOUR M50 OXYGEN CONCENTRATOR

The M50 Oxygen Concentrator delivers highly concentrated oxygen to patients requiring oxygen therapy. The device concentrates oxygen from the air for medical uses through a process called pressure swing absorption. Your home care provider will show you how to use your M50 device and will be able to answer any questions you may have.

### PARTS OF YOUR M50 OXYGEN CONCENTRATOR



## ACCESSORIES AND REPLACEMENT PARTS

Only use approved replacement parts.

The use of incompatible parts or accessories can result in reduced device performance. Contact your home care provider if you have any questions about the use of accessories or replacement parts.



## WARNINGS AND CAUTIONS

*A warning represents the possibility of harm to the operator or patient.*

⚠ **WARNING:** For your concentrator to operate properly, air must be able to flow freely around the device. The ventilation ports are located at the rear base of the device and at the side air inlet filter. Keep the device at least 30 cm away from walls, furniture and especially curtains that may reduce airflow to the device.

⚠ **WARNING:** Do not use this device adjacent to or stacked on top of other equipment.

⚠ **WARNING:** Keep this oxygen concentrator and its power cord away from heat and light sources.

⚠ **WARNING:** Device operation above or outside of the voltage, flow, temperature, environment. humidity and/or altitude values specified may decrease oxygen concentration levels.

⚠ **WARNING:** Oxygen generated by this concentrator is supplemental and should not be considered life supporting or life sustaining. In certain circumstances oxygen therapy can be hazardous; any user should seek medical advice prior to using this device.

⚠ **WARNING:** Do not use the oxygen concentrator if either the plug or power cord is damaged. Do not use extension cords or electrical adapters.

⚠ **WARNING:** Do not connect the concentrator in parallel or in series with other oxygen concentrators or other oxygen therapy devices.

⚠ **WARNING:** Do not attempt to clean the concentrator while it is plugged into an electrical outlet.

⚠ **WARNING:** Do not place the cannula or oxygen tubing under bedding, cushions or other materials.

### CAUTIONS

*A caution represents the possibility of damage to the equipment.*

- Do not place liquids on or near the device.
- If liquid is spilled on the device, turn the power off and unplug from the electrical outlet before attempting to clean up the spill. Contact your home care provider if the device does not continue to work properly.

### DANGER

*To reduce the risk of burns, electrocution, fire or personal injury:*

- Do not disassemble. Refer all servicing to an approved service professional.
- Avoid using the device while bathing. If your physician has prescribed continuous usage, the concentrator must be located in another room at least 3 meters away from the bath.
- Do not come into contact with the concentrator while wet. Do not place or store the device where liquids can spill into the concentrator.
- Do not insert foreign objects into the oxygen concentrator,
- Do not retrieve the product if it has fallen into water. Unplug immediately and contact your home care provider.

### RADIO FREQUENCY INTERFERENCE

The use of portable communications equipment such as a cell phone near your M50 device may interfere with the proper operation of the oxygen concentrator. All portable RF communications equipment should be kept more than 30cm away from your M50 Oxygen Concentrator.

The M50 Oxygen Concentrator cannot be used in environments with high radio frequency interference. This includes environments where the following activities may occur: electrocautery, electrosurgery, defibrillation, X-ray (gamma ray), infrared radiation, transient electromagnetic fields and magnetic resonance (MRI).

EN

### TRANSPORT, STORAGE AND OPERATING CONDITIONS

| | OPERATING | TRANSPORT AND STORAGE |
|---|---|---|
| TEMPERATURE | 10°C to 37°C (50°F to 98°F) | -30°C to -70°C (-22°F to -94°F) |
| RELATIVE HUMIDITY | 15% to 95%,<br>no condensation | 15% to 95%,<br>no condensation |
| ALTITUDE | 0 to 1828 meters | - |
| ATMOSPHERIC PRESSURE | 80 kPa ~ 101 kPa | 80 kPa ~ 101 kPa |
| ENVIRONMENT | Dry, well-ventilated,<br>dust-free and pollution-free<br>Away from electromagnetic interference | Placed upright and vertical at all times |
| ELECTRICAL | North America: 115V, 50Hz<br>Rest of the world: 230V, 50Hz | - |

## 2. USING YOUR M50 OXYGEN CONCENTRATOR

⚠ **WARNING:** Do not use extension cords or electrical adapters.

1. Choose a location for your concentrator that allows it to draw in air freely. Make sure the device is at least 30 cm away from walls, furniture, curtains, or any other item that may restrict airflow to the device. Do not place the device near any heat source.
2. After reading and understanding the contents of this manual, plug the power cord into a grounded wall outlet.
3. Do either Step A or Step B below.

A. If you are **not** using a humidifier, connect your nasal cannula to the oxygen outlet.

B. If you are using a humidifier, follow the steps below:

   i. Remove the humidifier cap by turning it counter clockwise.
   ii. Fill the humidifier bottle with distilled or cooled, pre-boiled water between the min and max markings.
   iii. Replace the humidifier cap and tighten until secure.
   iv. Mount the filled humidifier on top of the M50 Oxygen Concentrator using the hook and loop fastener.
   v. Tighten the hook and loop fastener to secure the humidifier to the device.
   vi. Connect the cannula to the oxygen outlet and humidifier inlet.

**NOTE: Replace the water in your humidifier bottle on a daily basis.**

4. Press the power switch to the On [I] position.
5. After turning on your M50 Oxygen Concentrator, allow at least 30 minutes for oxygen delivery to reach optimal concentration.
6. If using a humidifier, make sure that the humidifier bottle is secure:
   a. Use your finger to gently block the oxygen outlet on the humidifier bottle for 20 seconds.
   b. Once the float in the flow meter drops to the bottom of the gauge, remove your finger.
   c. If the bottle makes a whistling sound - it means that the humidifier is properly secured to your device.
   d. If you cannot hear this sound, remove the humidifier bottle, unscrew the cap, replace tightly and repeat the above test.
   e. If no whistling sound is heard after taking these steps, contact your home care provider.
7. Adjust the oxygen flow so that the float mark is centered on the line marking the flow rate prescribed by your physician:
   a. Turn the flow control dial clockwise to increase the output flow rate.
   b. Turn the flow control dial anti-clockwise to decrease the output flow rate.
8. Connect your oxygen tube to the oxygen outlet and put on your cannula as directed by your home care provider.
9. When you are not using the oxygen concentrator, press the power switch to the Off [O] position to turn off the power.

## 3. CLEANING, MAINTENANCE AND SERVICING

**Always press the power switch to the Off [O] position and unplug your M50 Oxygen Concentrator before cleaning.**

The **exterior of your M50 Oxygen Concentrator** should be cleaned twice per month using a damp cloth with a mild household cleaner. Always wipe the exterior dry after cleaning.



The **air and two stage paper filters** should be replaced every 12 months or as required by an authorized home oxygen provider.

You must clean the **air filter** in the M50 Oxygen Concentrator at least once a week.

1. Open the access panel to the air filter to the rear of the oxygen concentrator.
2. Remove the air filter from the device.
3. Rinse and allow to dry naturally.
4. Once dry, reinstall the air filter.

Your **cannula and humidifier** must be cleaned and replaced as required by the manufacturer or your home oxygen provider.

### Maintenance and Servicing

While the M50 Oxygen Concentrator is designed to minimize the requirement for maintenance, this device should be inspected by an authorized provider once a year. Only authorized maintenance service personnel can disassemble, repair or perform routine maintenance on this oxygen concentrator.

## 4. LCD, ALARM AND TROUBLESHOOTING GUIDE

**LCD Guide**

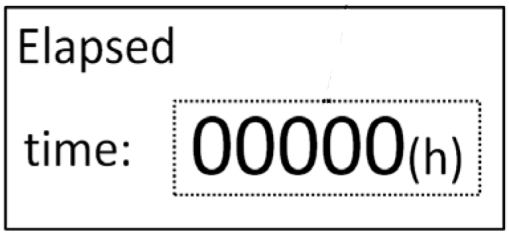
| START-UP DISPLAY | WORKING DISPLAY |
|---|---|
|  |  |
| Displayed for ten seconds after the oxygen concentrator is switched on. Replaced by the working display after ten seconds. | Displayed ten seconds after initial start-up display appears. |
| Indicates cumulative elapsed time of operation over the machine's lifespan. | Please see table 1 for full display guide. |

**Table 1: Working Display Screen Guide**

EN

| DISPLAY VALUE/ CODE | MEANING | STATUS | VERIFICATION OF FUNCTION METHOD | PRIORITY |
|---|---|---|---|---|
| 000000 | Elapsed time (hours). | LCD will display working interface after "0000" displays 10s | Visual inspection | ---- |
| High | High Oxygen Concentration | ---- | Visual inspection | ---- |
| Low | Low Oxygen Concentration Alarm - oxygen concentration below 82% | Red indicator light flashes twice per second - and short, repeating audible alarm (sound pressure level 60 dB) | Adjust the flow meter to maximum (to force oxygen concentration decline), wait for alarm to trip | High |
| H01 | Output flow is too low | Red flashing light with beeping alarm | Check the outlet for any damage or blockage | High |
| H02 | **Temperature Alarm -** operating temperature of machine exceeds 60°C | Red indicator light flashes twice per second - and short, repeating audible alarm (sound pressure level 60 dB) | Block the machine's outlet, wait for alarm to trip | High |
| H08 | Pressure Alarm (Pressure fault, compressor failure and stoppage, molecular sieve failure, low voltage, gas path blocked) | Machine stops operating. Red indicator light flashes twice per second - and short, repeating audible alarm (sound pressure level 60 dB) | Service Technician Only) -Use variable frequency power supply to set the power supply voltage below 85% of the rated voltage | High |
| E01 | Temperature sensor failure | Red indicator light flashes twice per second - and short, repeating audible alarm (sound pressure level 60 dB) | Remove the plug of temperature sensor | High |
| 00:00 | Current working time | ---- | Visual inspection | ---- |
|  | This symbol displays when alarm occurs | ---- | Visual inspection | ---- |
| No display | Power failure alarm | Short, repeating audible alarm (sound pressure level 60 dB) | Unplug the power cord | Low |

**Alarm Testing**

As part of a periodic inspection by your provider, the following tests should be carried out.

| ALARM | HOW TO TEST |
|---|---|
| Low oxygen concentration alarm | Adjust the flow meter to maximum output to force a decline in oxygen concentration. Wait for the alarm to trip. |
| Temperature alarm | Block the oxygen outlet on the device with your finger. Wait for the alarm to trip. |
| Pressure alarm | **TO BE PERFORMED BY AN AUTHORIZED MAINTENANCE PROFESSIONAL ONLY.** Use a variable frequency power supply to set the power supply to below 85% of the device's rated voltage. |
| Temperature sensor failure alarm | **TO BE PERFORMED BY AN AUTHORIZED MAINTENANCE PROFESSIONAL ONLY.** Remove the temperature sensor plug. Wait for the alarm to trip |



**Troubleshooting Guide**

The guide below lists common problems, as well as why they happened and what you can do to resolve them. If you are unable to resolve a problem, or if you experience an issue that is not listed below, please contact your home care provider.

| PROBLEM | WHY IT HAPPENED | WHAT TO DO |
|---|---|---|
| The device is switched on but not working. | Internal part failure. | Contact your home care provider. |
| The device is switched on but not working, or only working intermittently. | The power cord is damaged. | Check whether the power cord is damaged. |
| | The power cord plug is not properly inserted into the electrical outlet. | Make sure the device is properly plugged in to the electrical outlet. |
| | The oxygen concentrator is not receiving power from the electrical outlet. | Check your household outlet fuse or circuit. |
| | | Contact your home care provider. |
| Oxygen is not flowing or the oxygen flow is limited. | The oxygen tubing or cannula is kinked or blocked, stopping the delivery of oxygen. | Unkink the oxygen tubing/cannula or replace if necessary. |
| | The humidifier is not properly connected to the device. | Reinstall the humidifier. |
| The float in the flow meter does not move up or down when adjusting the flow control dial. | The flow control dial is not open. | Turn the flow control dial slowly and carefully. |
| | The flow control dial is faulty. | Contact your home care provider. |
| There is water in the cannula. | There has been a change in temperature;<br><br>OR<br><br>The device is too close to a wall, curtains or furniture. | Dry the inside of the humidifier cover. |
| | | Do not use hot water in the humidifier bottle. |
| | | Do not overfill the humidifier bottle. |
| | | Keep the oxygen concentrator and cannula in the same room at the same temperature. |
| | | If using an extension hose with your oxygen concentrator, speak to your home care provider about fitting a water trap to collect excess moisture. |

## 5. LCD, ALARM AND TROUBLESHOOTING GUIDE

**Technical Specifications**

| | |
|---|---|
| Model | M50 |
| Rated power (W) | 300 (1.5A)<br>310 (3A) (North America) |
| Electrical requirements | 220V (+/- 10%) 50Hz (+/- 10%)<br>115V (+/- 10%) 60Hz (+/- 10%)<br>(North America) |
| Flow rate (L/min) | 0.5 to 5 |
| Concentration (rated flow) | 90% to 96% |
| Outlet pressure | 0.05±10% MPa |
| Dimensions | 390 mm x 230 mm x 600 mm |
| Net weight | 15.2 kg |
| Sound level | 42 dBA |
| Expected service life | 5 years |
| Equipment class and type | IEC Class II Equipment<br>Type BF Applied Part<br>IP21 Drip Proof |
| Features | Standard: Abnormal temperature alarm; low oxygen concentration alarm; power failure alarm; timer; no flow alarm<br>Additional: Positive pressure outlet |

**Disposal**

Dispose of this device in accordance with local regulations.

**Standards compliance**

This device is designed to conform to the following standards:

- IEC 60601-1 Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 2nd edition, Medical Electrical Equipment, Part 1-2: General Requirement for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-1-8: 2012 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems +Amendment 1:2012
- IEC 60601-1-11: 2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- BS EN ISO 80601-2-69: 2014 Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment

## APPENDIX A: EMC INFORMATION

If you have any questions regarding the guidance and declarations listed below, please contact your home care provider.

**Guidance and Manufacturer's Declaration - Electromagnetic Emissions:** This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure that it is used in such an environment.

EN

| EMISSIONS TEST | COMPLIANCE | ELECTROMAGNETIC ENVIRONMENT-GUIDANCE |
|---|---|---|
| RF emissions CISPR 11 | Group 1 | This device uses 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 emissions CISPR 11 | Class B | The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/Flicker emissions IEC 61000-3-3 | Complies | |

**Guidance and Manufacturer's Declaration - Electromagnetic Immunity:** This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure 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 | ±15kV air<br>±8kV contact | ±15kV air<br>±8kV contact | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical Fast Transient/Burst IEC 61000-4-4 | ±2kV for power supply lines<br><br>±1kV for input-output lines | ±2 kV for supply mains<br><br>±1 kV for input/output lines | Mains power quality should be that of a typical home or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV differential mode<br><br>±2 kV common mode | ±1 kV differential mode<br><br>±2 kV common mode | Mains power quality should be that of a typical home or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 seconds | <5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 seconds | Mains power quality should be that of a typical home or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital or home environment. |

EN

| | | | |
|---|---|---|---|
| Note: UT is the a.c. mains voltage prior to application of the test level. | | | |
| Conducted RF<br>IEC 61000-4-6<br><br>Radiated RF<br>IEC 61000-4-3 | 3Vrm<br>150kHz-80MHz<br><br>10V/m<br>80MHz-2.7GHz | 3Vrm<br><br>10V/m | Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended 30 cm separation distance. |

**Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and This Device**

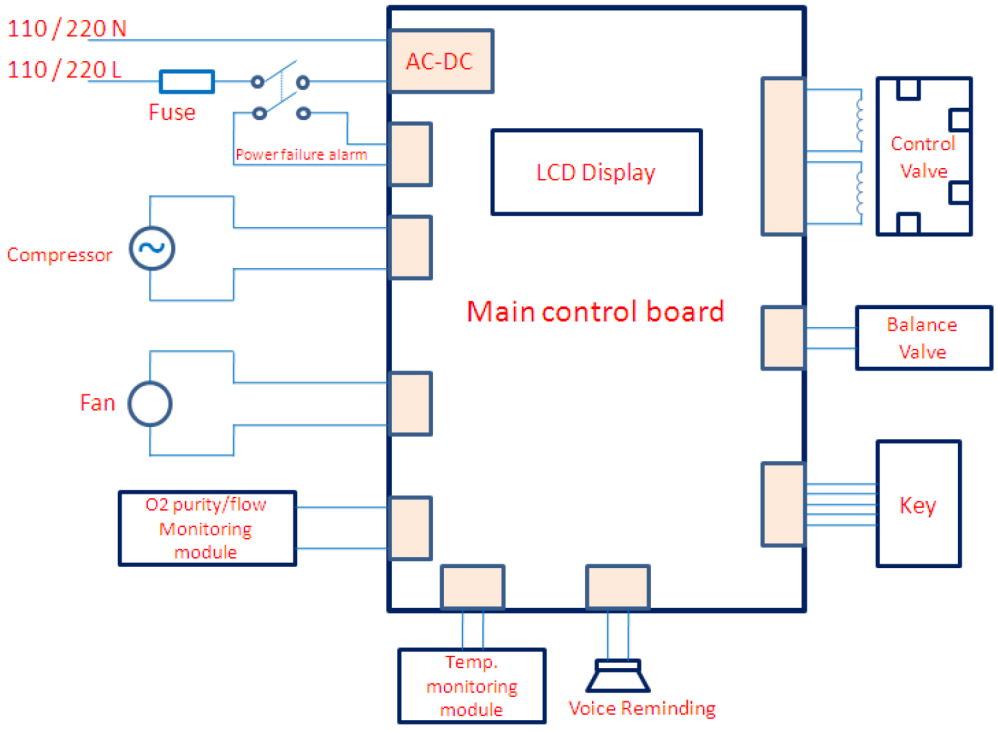
This device is intended for use in electromagnetic environments in which radiated RF disturbances are controlled. The user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device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

| RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (WATTS) | SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (METERS) | | |
|---|---|---|---|
| | 150KHZ~80MHZ<br>$D=1.2\sqrt{P}$ | 80MHZ-800MHZ<br>$D=1.2\sqrt{P}$ | 800MHZ-2.5GHZ<br>$D=2.3\sqrt{P}$ |
| 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 with maximum output power not stated above, the recommended separation distance (d) in meters can be estimated using the formula applicable to the transmitter frequency, where P is the maximum output power rating of the transmitter in watts (W) provided by the transmitter manufacturer.

NOTE 1: At 80 MHz and 800MHz, 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 buildings, objects and people.

## APPENDIX B: CIRCUIT DIAGRAM



## LIMITED WARRANTY

GCE Healthcare warrants that the system shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of 2 years from the date of sale by GCE Healthcare to the dealer.

The humidifier supplied with the system is warranted to be free of defects in materials and workmanship for a period of 90 days from date of sale to the dealer (GCE's direct customer). Filters, cannula, tubing are not covered under warranty.

Accessories are warranted to be free of defects in materials and workmanship for a period of 90 days from the time of purchase. If the product fails to perform in accordance with the product specifications, GCE Healthcare will repair or replace – at its discretion – the defective material or part. GCE Healthcare will pay customary freight charges from GCE Healthcare 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.

GCE Healthcare 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.

This warranty is given in lieu of all other express or implied warranties, including the implied warranties of merchantability and fitness for a particular purpose. In addition, in no event shall GCE Healthcare be liable for lost profits, loss of good will, or incidental or consequential damages, even if GCE Healthcare has been advised of the possibility of the same. Some states or provinces do not allow the exclusion of limitation of implied warranties or the disclaimer of incidental and consequential damages. Accordingly, the laws of your state or province may give you additional protections.

To exercise your rights under this warranty, contact your local authorized GCE Healthcare representative.



SYSMED(CHINA) CO.,LTD
11-2-3, No.17 WenSu Street, HunNan
New District, ShenYang, China
Visit the MQ web site at:
http://www.sysmed.cn/

**Distributed:** GCE, s.r.o.
Zizkova 381,
583 01, Chotebor
Czech Republic
www.gcegroup.com

CE 0123


SYSMED(CHINA) CO.,LTD
11-2-3, No.17 WenSu Street, HunNan
New District, ShenYang, China
Visit the MQ web site at:
http://www.sysmed.cn/

**Distributed by:** GCE s.r.o.
Zizkova 381,
583 01, Chotebor
Czech Republic
www.gcegroup.com

GCE® Healthcare

Doc. Nr.: 233602060137; Rev. 01; DOT 2020-11-10; A4