NIDEK Medical

USER'S GUIDE

The MAX Family

MAX 30 OXYGEN CONCENTRATOR

[Original language is English]

WARNING

Federal Law (US) restricts this device to sale by, or on the order of, a licensed physician. This oxygen concentrator should be used only under the supervision of a licensed physician.

DANGER: Do not smoke when using oxygen or when near this device.

CONTENTS

GLOSSARY OF SYMBOLS

	ON (Mains Power switched on)
	OFF (Mains Power switched off)
	Type B Device
	Class I Electrical Protection
	DO NOT EXPOSE TO OPEN FIRE
	DO NOT USE OIL OR GREASE
	Technical Information
	Consult the accompanying documents
	Keep in a vertical position
	Fragile – Handle with care
	QMS certified to Annex II of 93/42/EEC by the approved organization 0413

1. GENERAL SAFETY GUIDELINES

Only persons who have read and understood this entire manual should be allowed to operate the Max 30 Oxgyen Concentrator (hereafter known as the *device*).

The WARNINGS below indicate a potentially hazardous situation. If conditions are not avoided a situation could occur that results in serious injury or death.

- Oxygen is not a flammable gas, but it accelerates the combustion of materials. Do not use in explosive atmosphere. To avoid risk of fire and explosion the concentrator should be kept away from Flames, Heat sources, Incandescent sources, Smoking Materials, Matches, Oil, Grease, Solvents, Aerosols, etc. Do not allow oxygen to accumulate on upholstery or other fabric such as bedding or personal clothing. If concentrator is operating while not connected to patient, position cannula so that the gas flow is diluted in the ambient air.
- Improper patient connection to and use of the cannula may result in injury including strangulation. Avoid situations that might cause the cannula or hose to become entangled about the patient's neck.
- Use of other accessories not described in this User's Guide are not recommended. Patient benefit may be diminished.
- No modification to the equipment is allowed. To do so may affect patient benefit.
- Contraindications; those who continue to smoke (because of the increased fire risk and the probability that the poorer prognosis by smoking will offset the treatment benefit).
- Device must have power to operate. In the event of power loss and for continued operation a backup source is recommended.
- DO NOT disassemble due to danger of electrical shock. Refer servicing to qualified service personnel.

The CAUTIONS below indicate a potentially hazardous situation. If conditions are not avoided a situation could occur that results in property damage or minor injury or both.

- Use the power cord provided, and check that the electrical characteristics of the power socket used match those indicated on the manufacturer's plate on the rear panel of the device.
- We recommend against the use of extension cords and adapters, as they are potential sources of sparks and fire.
- The ***device*** has an audible alarm to warn the user of problems. In order that the alarm may be heard, the maximum distance that the user can move away from it must be determined to suit the surrounding noise level.
- The ***device*** must only be used for oxygen therapy and only on a medical prescription. The indicated daily duration and flow must be followed, otherwise it may present a risk to the health of the patient.
- Do not use in a specifically magnetic environment (MRI, X-ray, etc.). May cause device malfunction.
- This unit may be equipped with a polarized plug. That is one blade wider than the other. If it does not fit into the outlet, reverse the plug. If it still does not fit, contact a qualified electrician. Do not defeat this safety feature.
- Note: Medical Device Regulations require users and service providers to report to the manufacturer any incident that could, if repeated, result in injury to any person.

CONFORMITY WITH IEC60601-1:2003

(2ND EDITION)

"The manufacturer, assembler, installer or distributor are not considered to be responsible themselves for the consequences on the safety, reliability and characteristics of a device unless the:

- Assembly, fitting, extensions, adjustments, modifications or repairs have been performed by persons authorized by the party in question.
- Electrical installation of the corresponding premises complies with local electrical codes. (e.g. IEC/NEC)
- Device is used in accordance with the instructions for use.

If the replacement parts used for the periodic servicing by an approved technician do not comply with the manufacturer's specifications, the manufacturer is not responsible in the event of an accident or non-performance.

This device complies with the requirements of the FDA Quality System Regulation and 93/42/EEC European directive but its operation may be affected by other devices being used near by, such as diathermy and high frequency electrosurgical equipment, mobile telephones, CB and other portable devices, microwave ovens, induction plates or even remote control toys or any other electromagnetic interferences which exceed the levels specified by the EN 60601-1-2 standard.

UNPACKING and PACKAGING

The device is packaged to protect it from damage while being transported and stored. After the device is removed from the package, inspect for damage. If damage is detected, please contact your equipment provider. Operating environmental condition guidelines are discussed later in Section 5.7 of this User's Guide.

1.1 Method for Waste Disposal

All waste from the *device* (Patient Circuit, Filters, Etc.) must be disposed of using methods appropriate to the civil authority of the location where disposed.

1.2 Method for Disposing of the Device

This device has been supplied by an environmentally aware manufacturer. A majority of the parts in the device are recyclable.
Follow local governing ordinances and recycling plans regarding disposal of the device or components normally used in operation. Any accessories not original to the device must be disposed of in accordance with the individual product markings for disposal. Furthermore, as part of the marking directive 93/42/EEC, the serial number of the device disposed of must be sent to Nidek Medical if the unit has the CE marking.

2. DESCRIPTION

The device is intended to supply supplemental oxygen to persons requiring oxygen therapy. It is not intended to be life supporting or life sustaining. It produces an oxygen enriched product by concentrating the oxygen contained in room air. It can be used to administer oxygen with nasal cannulas or another type of device.
Note: the performances described pertain to the use of the device with accessories recommended by Nidek Medical Products, Inc. Refer to section 5.1.

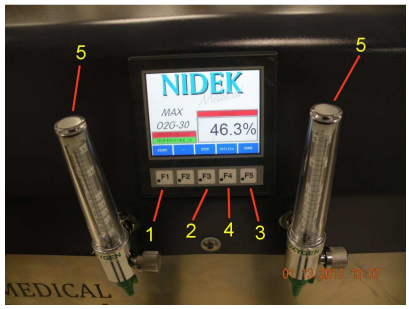


Figure 2.1

2.1 Front panel (Fig. 2.1)
1. **Start Button**
2. **Stop Button**
3. **Home Button**
4. **Utility Button**
5. **Flow Meters**

2.2 Rear panel (Fig. 2.2)
6. **Circuit Breakers**
7. **Mains Switch**
8. **Hour Meters (x 2)**
9. **Cabinet Air Filter (x 3)**
10. **Mains Power Supply**
11. **Manufacturer's Technical Label**
12. **Alarm Battery (9V)**

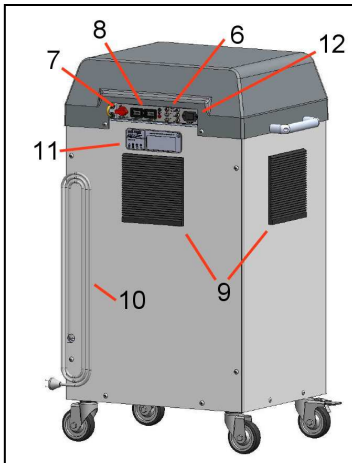
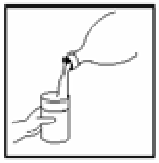


Figure 2.2

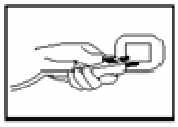
3. STARTING UP / INSTALLATION

3.1 Use in direct oxygen therapy

a. Ensure that the Mains Switch (Fig. 2.2–7) is in the **"O"** (OFF) position.



b. Connect the oxygen tube to one of the Flow Meters (Fig. 2.1-5)
   - If used with a high flow humidifier bottle:
     - Unscrew the flask and fill it with distilled water up to the line. Then screw the lid on the humidifier flask until there are no leaks.
     - Connect the oxygen tube to the humidifier outlet nozzle. The tube between the cannula and the ***device*** **should be limited to 20 meters (60 feet) long** in order to ensure that the oxygen flow rate remains within specification values.
     - Ensure that all of the parts are connected correctly so as to avoid leaks
     - Connect humidifier bottle directly to the flow meter.



c. Plug the Mains Power Supply (Fig. 2.2-10) into a power outlet of the correct voltage and frequency as defined on the manufacturer's technical label (Fig. 2.2-11).

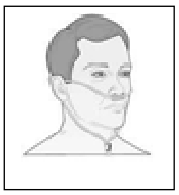
d. Turn the Mains Switch (Fig. 2.2-7) to the **"I"** (ON) position. Press the START button (Fig. 2.1-1) on the front of the display panel. The panel displays will remain red until the oxygen concentration exceeds the set point. Once the set point is reached, the displays will turn green and indicate the concentration on the display panel. (See section 5.5 Indicators for further information)

Note: the required oxygen concentration is normally obtained within five minutes after the unit is started.

e. Adjust the Flow Meter (Fig. 2.1-5) to the prescribed value.

Note: View the Flow Meter from straight on for accurate settings.

f. Check that the oxygen flows out of the administration device (nasal cannulas or other) by placing the orifice(s) on the surface of a glass of water. The flow should disturb the surface of the water.
g. Adjust the nasal cannula to suit your face.
h. At the end of the treatment, press the Stop Button (Fig. 2.1-2) to shut the device down. If the device will not be restarted, then place the Mains Switch (Fig. 2.2-7) in the **"O"** (OFF) position to shut the device down. The oxygen enriched air flow continues for approximately one minute after the device is stopped.



Note: After turning the unit off, the user must wait 5-10 minutes before turning it back on. System pressure must dissipate before the unit will properly restart.

4. CLEANING - MAINTENANCE

4.1 Cleaning

Only the outside of the ***device*** is to be cleaned, with a soft, dry cloth or, if necessary, a damp sponge, then thoroughly dried with wipes and an alcohol based solution. Acetone, solvents or any other inflammable products **must not be used**. Do not use abrasive powders.
The removable cabinet air filters (Fig. 2.2-9) are located on each side and on the back of the machine. Each must be cleaned in warm water and household detergent weekly or after approximately 100 hours of use. More frequent cleaning is recommended in dusty environments. Dry before reinstalling.

4.2. Daily disinfection

Because there is a final product filter inside the device, daily disinfection concerns only the external oxygen therapy accessories: humidifier bottles and nasal cannulas (refer to the respective instructions for use).
The device must be switched off when alcohol based solutions are used.

a. The following minimum guidelines must be observed:

Humidifier: (If prescribed by a physician)

Clean according to the manufacturer's instructions. If no instructions are provided, do the following:

Daily:

- Empty the water from the humidifier.
- Rinse the humidifier flask under running water.
- Fill humidifier up to the mark with distilled water.

Regularly:

- Disinfect the humidifier parts by immersing them in a disinfectant solution (In general, we recommend using a solution of 1 part vinegar diluted with 10 parts water).
- Rinse and dry.
- Check that the humidifier lid seal is in good condition.

Oxygen tubing and nasal cannula: Follow the manufacturer's instructions.

b. For each new patient:

Follow the instructions from the humidifier manufacturer. The ***device*** must be cleaned and disinfected as per the above instructions. The cabinet air filters (Fig. 2.2-9) should be washed or replaced. The entire oxygen administration circuit (oxygen therapy nasal cannulas, etc.) must be changed.

4.3 Maintenance

No special maintenance needs to be carried out by the patient. Your equipment supplier performs periodic maintenance operations to assure continued reliable service from the ***device***.

5. USEFUL INFORMATION

5.1 Accessories and spare parts

The accessories used with the ***device*** must:

- be oxygen compatible,
- be biocompatible,
- Comply with the general requirements of the FDA Quality System Regulation or the 93/42/EEC European Directive as appropriate.

The connectors, tubes, nasal cannulas, or masks must be designed for oxygen therapy usage.
The accessories with a **Nidek Medical** part number reference, or included in the set of accessories supplied with the device, comply with these requirements. Contact your equipment supplier to obtain these accessories.

Note: The use of certain administration accessories which are not specified for use with this concentrator may reduce its performance and void the manufacturer's responsibility (ISO 8359).

AVAILABLE ACCESSORIES IF PRESCRIBED BY A PHYSICIAN

- Humidifier: Part Ref. 9251-8774 (6-15LPM)
- Cannula with 2 m (7 ft) tubing: Part Ref. 9251-8780 (up to 15LPM)
- Extension Tubing 7.7 m (25ft): Part Ref. 9012-8781
- Tubing Adapter: Part Ref. 9012-8783

The items listed above are available from Nidek Medical Products, Inc.

5.2 Materials in direct or indirect contact with the patient

- Concentrator enclosure — Aluminum / Kydex
- Mains power supply — PVC
- Cabinet air filters — Polyester
- Mains Switch — Nylon
- Casters — Polyurethane
- Oxygen outlet — Stainless Steel
- Printed labels — Polycarbonate
- Pipe/Tubing — Aluminum, PVC, polyurethane and/or silicone
- Humidifier — Polypropylene
- Inlet Filters — Polypropylene

5.3 Operating principles

The compressor sends filtered ambient air to an electronic valving system, which allows compressed air to pass to the column in production. The columns contain a molecular sieve, whose function is to adsorb the nitrogen and thus allow oxygen to pass. During this process, the column which is being "regenerated" is connected to the ambient air and flow of oxygen enriched product is passed through it (from the column "in production"). In this way, when one column is in production, the other is in a nitrogen desorption or "regeneration" phase. The oxygen enriched product then passes through a bacterial filter located prior to the booster pump. The oxygen enriched product finally passes thru a booster pump to increase the pressure to 50psi (3.4bar) and out to the oxygen discharge fitting.

5.4 Alarms - Safety devices

5.4.1 Alarms

- **No voltage detection:** In the event of a loss of mains power, a continuous audible alarm is activated. The alarm can be tested by actuating the Mains Switch (Fig 2.2-7) when the mains power supply is not plugged into the wall receptacle.
- **Oxygen concentration:** The oxygen monitor measures the concentration and activates an audible and visual alarm if it falls below the alarm set point percentage. (See section 5.5 Indicators for more information on visual alarm)
- **Maintenance of the device alarms:** No special maintenance is required. The alarm set point is factory set and the setting cannot be adjusted. All OCSI models are set at 87% ± 3%. The equipment supplier checks that the device is still operating correctly when the routine checks are performed on the ***device***.

5.4.2 Safety devices

Compressor motors (x 4):

- Thermal safety is ensured by a thermal switch situated in the stator winding (145 ± 5° C).

Electrical protection of the ***device:***

- A 15A circuit breaker (Fig. 2.2-6) is incorporated into the back cabinet of all models. There are also 5 additional 5A circuit breakers for each of the compressors and the control board.
- Class I device protection (EN60601-1 standard)

Safety valve:

- The ***device*** is fitted on the low pressure compressor outlet and is calibrated to 3.4 bar (50 psig). It is also fitted with a safety valve on the high pressure compressor outlet that is calibrated to 7.0 bar (115 psig).

5.5 Indicators

Fig 5.5.1 - Panel Display (Home Screen)

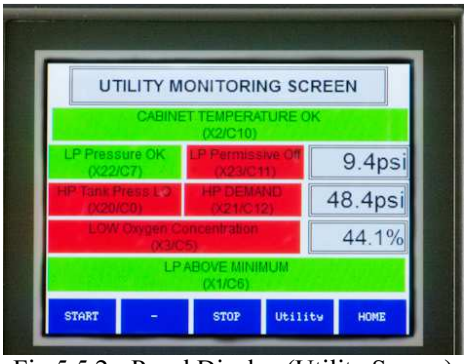


Fig 5.5.2 - Panel Display (Utility Screen)

Oxygen Concentration Status Indicator

The Oxygen Concentration Status Indicator is an electronic module capable of checking the effective oxygen concentration supplied by the concentrator. The oxygen monitor measures the concentration and activates an audible and visual alarm if it falls below the alarm set point percentage. When the ***device*** is started, the display located on the front panel will show the oxygen concentration percentage. It should take approximately 5 minutes for the percentage to reach the set point. Once this happens, the heading bar will turn green and your device is ready to use.

5.5.1 Green Headings

The display panel will show the oxygen concentration and pressure headings in red until the set points are reached. When all headings are green, the device is ready to provide oxygen enriched air to the patient.

5.5.2 Red Headings

The HOME and UTILITY screens will show red headings if there is a system fault. These issues could include high or low pressure, low oxygen concentration or high temperature. Please see section 5.10 of this guide for troubleshooting your device.

5.6 Expected Service Life

The expected service life of this device is 15,000 hours or 3 years.

5.7 Technical characteristics

Physical Properties

- Dimensions: L x W x H: 530 x 610 x 1120 mm (21 x 24 x 44 in.)
- Caster diameter: 100 mm (4.0 in.)
- Tilt angle (transport with humidifier fitted): 70°
- Weight: 91 kg / 200 lbs
- Noise level within ISO 8359 guidelines

Flow values:

- Continuously Adjustable Variable Area Flow-meter, up to two outlets: 1 to 15 lpm each

Accuracy of flow supplied:

- In compliance with the ISO 8359 standard, the flow supplied is equal to the flow set on the flowmeter, accurate to within ± 10% or 200 ml/min, whichever is the larger of the two.

Average oxygen content:

- 2 lpm: > 90% (Values at 21°C and at one atmosphere pressure)
- 30 lpm: from 87% to 95.5% (Values at 21°C and at one atmosphere pressure)
- Minimum recommended flow: 2 lpm (outlets combined)
- Maximum recommended flow: 30 lpm (outlets combined)
  The variation of the maximum recommended flow does not exceed ± 10 % of the indicated value when a back pressure of 6.9 kPa (1 psig) is applied to the output of the device. The maximum outlet pressure is: 50psig (3.4bar)

Electrical power supply:

	MAX 30lpm 230V	MAX 30LPM 230V
Frequency	50Hz	60Hz
Model	3005	3010
Average Power	2100 Watts	2000 Watts
Protection Class	Class I	Class I
Mains Protection	15A	15A

Filters:

- On both sides and back of the device: THREE cabinet air filters (Fig. 2.2-9).
- At the compressor input: THREE inlet air filters (technician only).
- Before the oxygen outlet: a final product filter < 0.3 µm. (technician only)

Air circulation:

- Multiple tubeaxial fans (x10) cool the compressor compartment and the heat exchanger coils.

Environmental limit conditions:

The performance of the device (especially the oxygen concentration) are quoted at 21°C (70°F) and one atmosphere. Performance may change with temperature and altitude.

- The device must be stored, transported and used in the vertical position only.
- Ambient temperature of between 10°C and 40°C (50ºF to 105°F) operation.
- Storage temperature from -20°C to 60°C (0°F to 140°F).
- Relative humidity of between 15 % and 95 % operation and storage, both non-condensing.
- Altitude (21°C): Up to 1500m (5000ft) without degradation;

Consult your equipment provider for further information regarding 1500 m to 4000m (5000 to 13000ft).
Complies with EN60601-1:2003 standard; spilling of a glass of water.

5.8 Standards – Max 30

ISO 80601-2-69:2014 Oxygen concentrators for medical use.
EN60601-1[UL60601-1:2003]
CAN/CSA-C22.2No.601.1-M90 w/A1&A2: Electrical Safety- Medical Devices.
EN60601-1-2:2001 Electromagnetic Compatibility

Max 30 **Serial No.** _____
Date first used: _____
Maintained by: _____
Your equipment provider address: _____
Telephone : _____

5.9 Preventative Maintenence:

a. Wash THREE cabinet air filters (Fig. 2.2-9) weekly.
b. Inspect THREE inlet air filters during each service. Replace filters annually, or more often depending on environment.
c. Check oxygen concentration every 15,000 hours or 3 years to verify the continuing OCSI function.

The manufacturer's instructions for the preventive maintenance of the devices are defined in the service manual, part ref: 2010-9800 NUVO MAX Installation and Service Manual. Check with your service provider for any updates to recommended schedules. The work must be carried out by suitably trained technicians certified by the manufacturer. Use original spare parts only (see section 4.3 Maintenance in this User's Guide). Upon request, the supplier can provide circuit diagrams, spare parts lists, technical details or any other information of use to qualified technical personnel for parts of the device which are designated as being the manufacturer's responsibility or by the manufacturer as repairable.

Medical Device Regulations require users and service providers to report to the manufacturer any incident that could, if repeated, result in injury to any person.

5. 10. Troubleshooting.

Observations	Possible Causes	Solutions
The **I-O** (ON/OFF) button is in the **"I"** (ON) position but the device does not operate.	Mains Power cable (Fig. 2.2-10) is not correctly plugged into the wall outlet.	Check the cable connection.
Capacitor is not charged Internal electrical fault.	Capacitor is not charged Internal electrical fault.	Check the circuit breaker (Fig. 2.2-6) on the back of the unit; Reset if necessary. Contact your equipment supplier.
The alarm test does not work. (See Section 5.4.1 in this User's Guide)	Capacitor is not charged Internal electrical fault.	Plug unit in for 10 minutes and retest. Contact your equipment supplier.
The **I-O** (ON/OFF) button is in the **"I"** (ON) position, the compressor is operating and there is a flow but the green light is not lighted.	Faulty indicator.	Contact your equipment supplier.
The **I-O** (ON/OFF) button is in the **"I"** (ON) position but there is no flow. The audible alarm sounds continuously.	Pneumatic connection broken or other pressure problem.	Stop the device by pressing the **I-O** (ON/OFF) button. Contact your equipment supplier.
The **I-O** (ON/OFF) button is in the **"I"** (ON) position, the compressor is operating and there is a flow but the audible alarm sounds continuously.	Internal electrical fault. Pneumatic circuit fault or low purity.	Stop the device by pressing the **I-O** (ON/OFF) button. Contact your equipment supplier.
The compressor stops in mid-cycle, then starts again after a few minutes.	Compressor thermal safety device has been activated. Dirty Filters. Fan is not working.	Stop the device by pressing the **I-O** (ON/OFF) button and wait for it to cool down. Clean cabinet filter. Restart. If the device does not start, contact your equipment supplier.
The oxygen enriched air flow is interrupted at the nasal cannula outlet.	Tube disconnected or humidifier cap is not tight.	Check that tubing connections are secure and that the humidifier is sealed.
The flow at the nasal cannula outlet is irregular.	Cannula tubing is kinked or restricted.	Straighten the tubing; contact your equipment supplier if damaged.

Maintenance Items

Cabinet Air Filter: Part Ref: 9600-1053; (Fig. 2.2-9) Wash weekly; Replace as needed.
Inlet Air Filter Element: Part Ref: 9800-1027; Inspect at each service visit; Replace annually.

Please record all maintenance activity in the Maintenance Log found in the service manual and online at www.nidekmedical.com under the 'Maintenance Log' tab.

6. EMC, Electromagnetic Statements

Appendix A: EMC Information

Important: Failure to follow these guidelines listed may result in increased emissions and/or decreased immunity of the subject device.

- Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
- The use of Accessories, transducers, and cables other than those specified by the manufacturer, may result in increased Emissions or decreased immunity of the device.
- The device should not be used adjacent to or stacked with other equipment and that adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- Use on Nidek Replacement electrical parts.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions
This device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

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 **A**	NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio -frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic Emissions IEC 61000-3.2	Class **A**	
Voltage Fluctuations /Flicker Emissions	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity
This device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV Air	Complies	Floors should be wood, concrete, or ceramic tile. floors are covered with synthetic material, the relative humidity should be at least 30%.
Conducted RFIEC 61000- 4-6	3 Vrms 150 kHz to 80 Hz	Complies	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level (3 V/m) in each frquency range. Interference may occur in the vicinity of equipment marked with the following symbol: Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the distance calculated from the equation applicable to the frequency of the transmitter. d= 1.2 P (80-800MHz) P=Transmitter power level in watts d= 2.3 P (800MHz-2.5GHz) d=distance in meters
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	Complies	
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 2 kV for power supply lines ± 1 kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of the typical location in a typical commercial or hospital environment
Voltage Dips, short interruptions and voltage variations on power supply input line. IEC 61000-4-8	<5% U_T (>95% dip in U_T) for 0.5 cycles	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continuous operation during power mains interruption, it is recommended that the device
	40% U_T (60% dip in U_T) for 5 cycles	Complies	
	70% U_T (30% dip in U_T) for 25 cycles	Complies	
Note: U_T is the a.c. mains voltage prior to the application of the test levels	<5%% U_T (>95% dip in U_T) for 5 seconds	Complies	

NOTES:

NOTES:

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