



Nidek Medical

PRODUCTS

INSTRUCTIONS FOR USE

Max 30 OXYGEN CONCENTRATOR

For models: 3005 and 3010
(and variants thereof)

[Original language is English]



	This unit is not a life-support device. Geriatric, pediatric, or any other patient unable to communicate discomfort while using this device should receive additional monitoring.
 	<p>This device supplies highly concentrated oxygen enriched product gas that promotes rapid burning.</p> <p>DO NOT allow smoking or open flames within the same room of this device or the administration accessory (cannula). Failure to observe this warning can result in severe fire, property damage, and / or cause physical injury or death.</p>
 	<p>Oxygen accelerates the combustion of flammable substances. DO NOT use oil, grease, petroleum based or other flammable products on the device, the administration accessory (cannula) or the patient's face / neck.</p>
	Only persons who have read and understood this entire manual should be allowed to operate the device.
	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).
	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.

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CE0413

1 GLOSSARY OF SYMBOLS

-  ON (Power switched on)
-  OFF (Power switched off)
-  Manufacturer Name and Address
-  Type B Device
-  Class I Electrical Protection
- IPX1** Protection from vertically falling water drops
-  Do Not Smoke
-  Do Not Expose to Open Flames
-  Do Not Expose to Oil or Grease
-  Tools Required / Technician Only
-  Refer to Technical Information / Service Manual
-  Refer to Instructions for Use / User's Guide
-  Keep in Vertical Position
-  FRAGILE – Handle with Care
-  WARNING – A hazard or unsafe practice that can result in serious injury or death if conditions are not avoided.
-  Caution - A hazard or unsafe practice that can result in minor injury and / or property damage if conditions are not avoided.
-  Note – Information important enough to emphasize or repeat

2 YOUR DEVICE

2.1 Intended Use and Operation

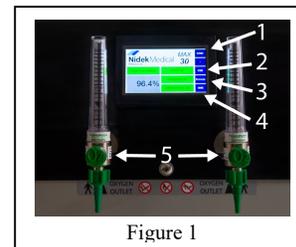
The Max 30 Oxygen Concentrators are used as a means of providing continuous oxygen enriched product gas for patients, adolescent to geriatric, suffering from health conditions that cause low levels of oxygen in the blood (hypoxaemia).

	To ensure your safety, use only after one or more settings have been individually determined or prescribed for you at your specific activity levels – AND – only use the accessories that were used when your settings were determined.
	While undergoing oxygen therapy, if you feel discomfort or experience a medical emergency, seek medical assistance immediately.

The Max 30 concentrators begin their operation with air being pulled into the external air intake filter. This filtered air enters the compressor via a suction resonator and fine filter. Pressurized air then exits the compressor and passes through a heat exchanger, which reduces the temperature of the compressed air. Next, an electronic valve system directs the air into one of two tubes that contain molecular sieve (sieve beds). The molecular sieve adsorbs (physically attracts) the nitrogen from the air as it is pushed through the sieve beds. This allows the oxygen enriched product gas to pass through before being delivered to the pressure regulator. As one tube is generating the product gas, the other is being purged of the adsorbed nitrogen, this process is called pressure swing adsorption (PSA). After passing through the regulator, the rate of product gas being delivered to the patient is set by the flow meter adjusting valve. Finally, it passes through a fine particle filter and then over a sensor that detects the oxygen concentration of the product gas before it finally passes thru a booster pump to increase the pressure to 50psi (3.4bar) and exits the device through a fire resistant outlet. The product gas is delivered to the patient and absorbed by tissues within the nose, lungs and the pathway between the two.

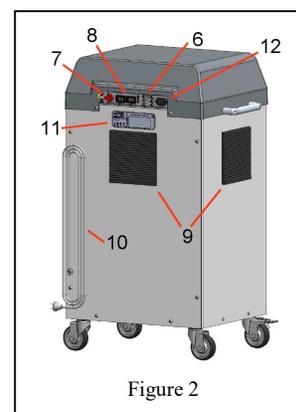
2.2 Device Features

Front panel (Fig. 1)



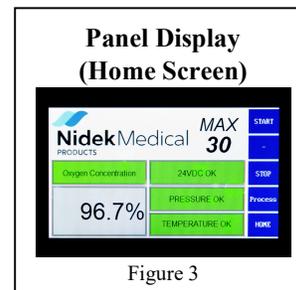
- 1 – Start Button
- 2 – Stop Button
- 3 – Home Button
- 4 – Process Button
- 5 – Flow Meters

Rear panel (Fig. 2)

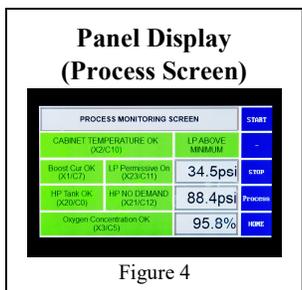


- 6 – Circuit Breakers
- 7 – Mains Switch
- 8 – Hour Meters (x 2)
- 9 – Cabinet Air Fittler (x 3)
- 10 – Mains Power Supply
- 11 – Manufacturer's Technical Label
- 12 – Alarm Battery (9V)

Panel Display (Home Screen)



Panel Display (Process Screen)



	Use the power cord provided. Check that the electrical characteristics of the power outlet used match those indicated on the manufacturer's plate on the rear panel of the device.
	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.

2.3 Alarms and Safety Features

	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.
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No voltage detection: In the event of a loss of mains power, a continuous audible alarm is activated. The display will remain off.

	Test alarm by actuating the Mains Switch (Fig 2-7) when the mains power supply is not plugged into the wall receptacle. Periodically check to alarm to make sure the 9V alarm battery is working properly.
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Oxygen Concentration Status Indicator: The oxygen concentration monitor 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.

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.

Yellow headings: The Home and Process screens (Figs 3 and 4) will show yellow headings if something is operating outside of normal conditions.

	If any of the above alarm conditions occur, press the Power Switch (Fig 2-7) to the "O" (OFF) position. Call your equipment supplier to service the device.
	On initial power up, O2 header bar will remain yellow until the device has reached normal operating conditions and then will turn green (within approximately 5 minutes.)
	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 HOME (Fig 3) screen shows the following: outlet pressure LOW / OK, concentration LOW / OK, and temperature OK / HIGH.

The PROCESS (Fig 4) screen shows the following: cabinet temperature OK / HIGH, low pressure permissive, low pressure acceptable, low pressure above minimum, high pressure demand, high pressure OK, low oxygen concentration and high temperature.

Thermal safety: The compressor motors (4) are protected by a thermal switch situated in the stator winding ($145 \pm 5^\circ \text{C}$).

Electrical protection:

- A 15A circuit breaker is incorporated into the back cabinet of all models
- Five (5) 5A circuit breakers are incorporated into the device for each compressor and the control board.
- Class I device protection (EN60601-1 standard)

Safety valve: 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).

Fire Break: This device is fitted with a metal fire break at the Oxygen Product Outlet (Fig 1-3). This break will keep fire from entering the device. See "Accessories and Spare Parts" (§ 2.5) for fire safe accessories.

2.4 Device Performance and Specifications

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

Model	3005	3010
Description	30 LPM 230V	30 LPM 230V
Frequency	50 Hz	60Hz
Average Power	2100 Watts	2000 Watts
Protection Class	Class I	
Mains Protection	15A	
Average Oxygen Content	At 2 LPM: > 90%	
Average Oxygen Content	At 30 LPM: 87% to 95.5%	
Liter Flow	Minimum: 2 LPM (outlets combined) Maximum: 30 LPM (outlets combined)	
Outlet Pressure	Maximum: 50 psig (3.4 bar)	
Dimensions (L x W x H)	530 x 610 x 1120 mm (21 x 24 x 44 in.)	
Weight	113 kg (250 lbs)	
Noise Level	Within 80601-2-69:2016 guidelines	

	In compliance with EN ISO 80601-2-69, the flow supplied is equal to the flow set on the flowmeter, accurate to within $\pm 10\%$ or 200 ml/min, whichever is greater.
	The variation of the maximum recommended flow does not exceed $\pm 10\%$ of the indicated value when a back pressure of 6.9 kPa (1 psig) is applied to the output of the device.

Materials in direct or indirect contact with the patient

Concentrator enclosure	Aluminum / Kydex
Printed labels	Polycarbonate
Mains switch (Fig 2-7)	Nylon
Oxygen Outlets / Cabinet Screws	SS / Brass
Cabinet air filter (Fig 2-9)	Polyester
Mains cable (Fig 2-9)	PVC

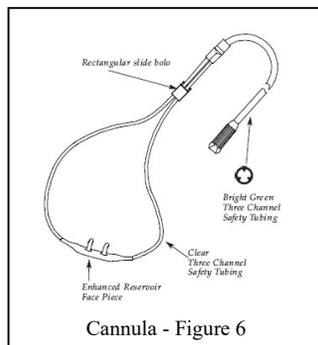
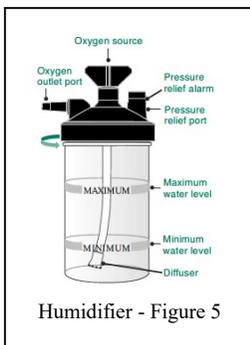
Inlet Filters	Polypropylene
Humidifier	Polypropylene
Casters	Polyurethane
Pipe/Tubing	Aluminum, PVC, polyurethane and/or silicone, copper

2.5 Accessories and Spare Parts

The accessories used with the *device* must be oxygen compatible, designed for oxygen therapy use, biocompatible and comply with the general requirements of the FDA Quality System Regulation or the 93/42/EEC European Directive, or any other applicable regulatory requirements.

The accessories below, available from **Nidek Medical Products, Inc.** and our distributors, comply with these requirements. Contact your equipment supplier to obtain these accessories.

Accessories	Part Ref
High Flow Humidifier (6 to 15 LPM)	9251-8774
High Flow Cannula with 2m (7ft) tubing (2 to 10 LPM)	9251-8780
Extension Tubing 7.7m (25 ft)	9012-8781
Tubing Adapter	9012-8783
Flow Meter	9800-1047A
Fire Safe Valve	9800-8779
Fire Safe Nozzle	9800-8777



	Petroleum and oil based lubricants, lotions and cosmetics are flammable and the use of them while operating the device is hazardous.
	Improper patient connection to and use of the cannula may result in injury, including strangulation. To reduce the risk of this occurring, avoid situations that might cause the cannula or hose to become entangled about the patient's neck and do not attach more than 15.5m (50 ft) in length of tubing.
	Ears, nose and neck may become irritated after prolonged exposure to the cannula. For relief, only a water based lubricant is recommended.
	Nasal passages may become irritated after prolonged exposure to the product gas. If this occurs, consult your physician about using a humidifier during treatment.
	The use of certain administration accessories and/or spare parts which are not recommended by the manufacturer may reduce its performance and void the manufacturer's responsibility.

Spare Parts	Part Ref
Cabinet air filter (Fig 2-9)	9600-1053
Inlet Air Filters	9800-1027
Flow Meter (0 to 15 LPM)	9800-1047
9V Battery	7206-0027

	Please consult the Max 30 Installation and Maintenance Manual (PN 2010-9800) for instructions on replacing any of the above spare parts.
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3 UNPACKING AND INSPECTION

The Oxygen Concentrator is packaged to protect the device 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.

If you do not plan to use your device immediately, please consult the Environmental Storage Conditions below.

Environmental Storage Conditions:

The device should be stored in a dry area, with an ambient temperature between -20°C to 60°C (0°F to 140°F) at 15-95% relative humidity. It must be stored, transported and used in the vertical position only.

Oxygen concentration can be affected after prolonged periods of storage – check device before use.

4 INSTALLATION AND OPERATION

4.1 Installation

Environmental Operating Conditions:

The device should be operated in a dry area, with an ambient temperature between 10°C to 40°C (50°F to 105°F) at 15-95% relative humidity. The device can be operated at an altitude of up to 1500m (5000ft) at a temperature of 21°C (70°F) without causing product degradation.

	DO NOT use in explosive atmosphere. To avoid risk of fire and explosion the concentrator should be kept away from heat sources, incandescent sources, solvents, Aerosols, etc.
	Unit should be placed and operated in a well-ventilated space that is free of pollutants or fumes and protected from the elements with adequate lighting.
	Unit should be placed and operated in a space where the position and storage of the mains cable (Fig 2-10) and oxygen tubing do not present a tripping hazard. The mains cable should be easily accessible for disconnection.
	For patient safety and benefit, no modification to the equipment is allowed. It is also not recommended to interconnect the device with any equipment or accessories not specified in this guide.
	Device must have power to operate. In the event of power loss and for continued operation a backup source is recommended.
	Do not use in a specifically magnetic environment (MRI, X-ray, etc.). May cause device malfunction.

	We recommend against the use of extension cords and adapters, as they are potential sources of sparks and fire.
	Consult your equipment provider for further information regarding altitudes of 1500 m to 4000m (5000 to 13000ft).
	Complies with EN 60529:2001 + A2:2014 rating of IPX1 ; enclosure protects internal electrical components against vertically falling water drops. Complies with EN 60601-1:2006 [11.6.3]; enclosure protects internal electrical components against spilling of a glass of water (i.e. contents of humidifier).

4.2 Start-Up

- 1) Ensure that the Mains Switch (Fig 2-7) is in the “**○**” (OFF) position.

If used with a humidifier (Fig 5): Unscrew the flask and fill it with distilled water up to the line (see manufacturer’s instructions). Then screw the lid on the humidifier flask until there are no leaks. Connect the oxygen tube to the humidifier outlet nozzle. Screw the humidifier directly to the Flow Meter (Fig 1-5). Ensure that all of the parts are connected correctly so as to avoid leaks.

	Replace water in humidifier bottle before each treatment.
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If not using a humidifier: Connect the oxygen tube to one of the Flow Meters (Fig 1-5).

- 2) Plug the Mains Power Supply (Fig 2-10) into a power outlet of the correct voltage and frequency as defined on the manufacturer’s technical label (Fig 2-11).
- 3) Press the Mains Switch (Fig 2-7) to the ON “**I**” position. Press the START button (Fig. 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.

	The required oxygen concentration is normally obtained within five minutes after the device is started.
	See the Alarms and Safety Features on page 3 for panel display colors and meanings.

- 4) Adjust the Flow Meter (Fig 1-5) to the prescribed value.

	View the flowmeter from straight on for accurate settings.
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- 5) 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.
- 6) Adjust the nasal cannula to suit your face.

4.3 Shut Down

At the end of the treatment, press the Stop Button (Fig. 1-2) to shut the device down. If the device will not be restarted, then place the Mains Switch (Fig. 2-7) in the “**○**” (OFF) position to shut the device down. The oxygen enriched air flow continues for approximately one minute after the device is stopped.

	Make sure during operation and after shut down that the cannula is facing away from soft surfaces and clothing. Excess oxygen can accumulate and cause ignition if exposed to a spark or open flame.
	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.

5 CLEANING AND MAINTENANCE

5.1 Cleaning

Cleaning and your device: Visually check the outside of the device periodically. To clean the enclosure, make sure the Mains Switch (Fig 2-7) is in the “**○**” (OFF) position, then use a soft, dry cloth or a damp sponge, to wipe the cabinet enclosure until clean and to prevent dust and dirt from building up on the device. Allow to dry thoroughly before operation.

	Acetone, solvents or any other flammable products must not be used. Do not use abrasive powders.
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Cleaning and replacing filters: The removable cabinet air filters (Fig 2-9) can be found on the back and each side of the device. They must be cleaned in warm water and household detergent. Dry before reinstalling. The Air Inlet Filters and the final product filter (not pictured) should only be replaced by a technician if required.

Cleaning and replacing accessories: Clean the humidifier according to manufacturer’s instructions. If no instructions are provided, do the following: empty the water from the humidifier, rinse the flask and lid under running water. Regularly disinfect the humidifier by immersing the flask and lid in a disinfectant solution (we recommend using a solution of 1 part vinegar to 10 parts water). Rinse under running water and dry. Tubing and cannula should be used according to the manufacturer’s instructions and replaced for each new patient to prevent the spreading of bacteria and viruses.

5.2 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*.

	DO NOT disassemble due to danger of electrical shock. Refer servicing to qualified service personnel.
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The expected service life of this device is 10 years with routine preventive maintenance.

Preventive Maintenance: Wash the cabinet filters (3) weekly or after approximately 100 hours of use and for each new patient. More frequent cleaning is recommended in dusty environments. Inspect inlet air filters (3) during each service. Replace filter annually, or more often depending on environment. Check oxygen concentration every 15,000 hours or 3 years to verify the continuing OCSI function. Periodically check the 9V battery to ensure the proper operation of the power loss alarm.

The manufacturer’s instructions for the preventive maintenance of the devices are defined in the service manual, (Ref. 2010-9800). 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 “Accessories and Spare Parts”). 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.

6 DISPOSAL

6.1 Method for Waste Disposal

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

6.2 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  marking.

7 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.
The alarm test does not work. (See Section 5.4.1 in this User’s Guide)	9V Battery is dead Internal electrical fault.	Replace 9V battery 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.

8 EMC INFORMATION

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 RF IEC 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 frequency 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. $d = 1.2 \sqrt{P}$ (80-800MHz) $P = \text{Transmitter power level in watts}$ $d = 2.3 \sqrt{P}$ (800MHz-2.5GHz) $d = \text{distance in meters}$
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	
	<5% U_T (>95% dip in U_T) for 5 seconds	Complies	
Note: U_T is the a.c. mains voltage prior to the application of the test levels			

9 CONFORMITY WITH EN 60601-1



CONFORMITY WITH EN 60601-1 (§ 6.8.2 b):

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 nearby, 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.

CE0413



Nidek Medical Products, Inc.
3949 Valley East Industrial Drive
Birmingham, Alabama 35217 U.S.A.
Tel: 205-856-7200 Fax: 205-856-0533

EU Representative
mdi Europa GmbH
Langenhagener Str. 71
30855 Hannover-Langenhagen
Germany
Tel: +49-511-39-08 95 30
Fax: +49-511-39-08 95 39
info@mdi-europa.com
www.mdi-europa.com

UK Responsible Person
Qserve Group UK, Ltd
49 Greek Street
W1D 4EG London
United Kingdom
Tel: +310207882630
globalreg@qservegroup.com
www.qservegroup.com