INSTRUCTIONS FOR USE

Mark 5 Nuvo Lite Family
(Nuvo Lite and Nuvo Lite 3)
OXYGEN CONCENTRATOR

For models: 525, 535, 925 and 935
(and variants thereof)

[Original language is English]

Nuvo Lite (Model 925) shown for reference.

⚠	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.
⚠ 🚭 🔥	This device supplies highly concentrated oxygen enriched product gas that promotes rapid burning. 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.
⚠ 🚭	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.
⚠	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).
℞Only	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.

Contents

1 GLOSSARY OF SYMBOLS

ON (Power switched on)

OFF (Power switched off)

Manufacturer Name and Address

Type B Device

Class II Protection

IPX1 Protection from vertically falling water drops

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

Visual Alarm Indicator

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

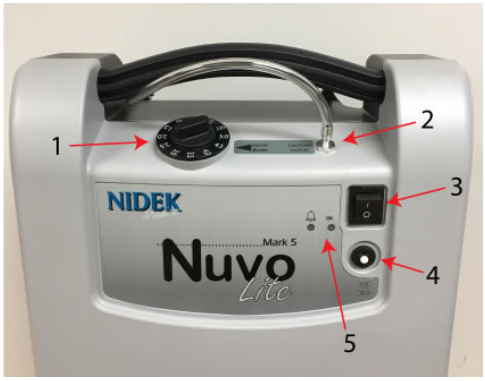
2.1 Intended Use and Operation

The Mark 5 Nuvo Lite Family (Nuvo Lite and Nuvo Lite 3) 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.

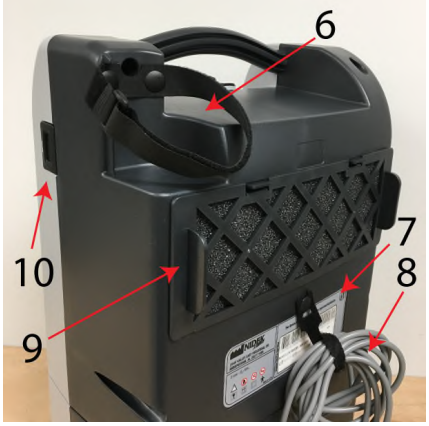
The Mark 5 Nuvo Lite Family begins their operation with air being pulled into the external air intake filter. This filtered air enters the compressor via a suction resonator and fine filter. Pressurized air then exits the compressor and passes through a heat exchanger, which reduces the temperature of 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 exits the device through a fire resistant outlet.

2.2 Device Features



Front panel (Fig. 1)

1 – Flow adjustment knob
2 – Oxygen Product Outlet
3 – Mains Power Switch
4 – Circuit Breaker
5 – Indicator Lights (green and yellow)



Rear panel (Fig. 2)

6 – Humidfier (space reserved)
7 – Technical Label
8 – Mains Cable
9 – Air Filter / Grill (Inlet Filter under – Fig 5)
10 – Hour Meter

⚠	Use the power cord provided. Check that the electrical characteristics of the power outlet used match those indicated on the manufacturer's technical label (Fig 2-7) 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.

No voltage detection: In the event of a loss of mains power, an intermittent audible alarm is activated and the green light is no longer illuminated.

☑	Test alarm by actuating the Power Switch (Fig 1-3) when the mains cable is not plugged into the power outlet.

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 indicator lights (Fig 1-5) located on the front panel operate as described below.

Green indicator: This light indicates that power is applied to the concentrator and that it is ready to provide oxygen enriched air to the patient.

☑	On initial power up, this indicator light will flash green until the device has reached normal operating conditions. This should happen within approximately 2 minutes.

Yellow indicator: This light and a continuous audible alarm will activate when the oxygen concentration level falls below the set point.

Devices manufactured prior to 2018 included a red indicator light.

☑	No special maintenance is required. The alarm set-point is factory set and the setting cannot be adjusted. All OCSI models are set at 85% ± 3%.

Blocked Cannula detection: If supplied, the device has a Blockage Alarm. A continuous audible alarm and both indicator lights will be lit immediately in the event the flow of oxygen to patient becomes blocked.

Malfunction detection: If low pressure occurs due to a mechanical failure, the indicator light will flash yellow and a continuous audible alarm will actuate.

⚠	If any of the above alarm conditions occur, press the Power Switch (Fig 1-3) to the **"O"** (OFF) position. Call your equipment supplier to service the device.

Thermal safety: The compressor motor is protected by a thermal switch situated in the stator winding (145 ± 5° C). One tubeaxial fan cools the compressor compartment.

Electrical protection:

- A 5A circuit breaker is incorporated into the front cabinet of all 230V models
- A 10A circuit breaker is incorporated into the front cabinet of all 115V models
- Class II devices with insulated casings (EN60601-1 standard)

Safety valve: This is fitted on the compressor outlet and is calibrated to 3.4 bar (50 psig).

Fire Break: This device is fitted with a metal fire break at the Oxygen Product Outlet (Fig 1-2). This break will keep fire from entering the device.

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	**525**	**925**	**535**	**935**
Description	5 LPM 115V	5 LPM 230V	3 LPM 115V	3 LPM 230V
Frequency	60 Hz	50 Hz	60Hz	50 Hz
Average Power	330 Watts	300 Watts	210 Watts	180 Watts
Protection Class	Class II			
Mains Protection	10A	5A	5A	5A
Average Oxygen Content	At 2 LPM > 90%		At 2 LPM > 90%	
Average Oxygen Content	At 5 LPM 87% to 95.5%		At 3 LPM 87% to 95.5%	
Liter Flow	0.125 to 5 LPM		0.125 to 3 LPM	
Outlet Pressure	7 Psig		7 Psig	
Dimensions (L x W x H)	36 x 23 x 58.5 cm (14 x 9 x 23 in.)			
Weight	14.5 kg (32 lbs.)*			
Noise Level	< 58 dBA			

*** Weight dependent on model and features**

☑	In compliance with EN ISO 80601-2-69, the flow supplied is equal to the flow set on the flowmeter, accurate to within ± 10% or 200 ml/min, whichever is greater.
☑	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.

Materials in direct or indirect contact with the patient

Concentrator enclosure	ABS/Polycarbonate
Printed labels	Polycarbonate
Power switch (Fig 1-3)	Nylon
Oxygen product outlet (Fig 1-2)	SS, brass or aluminum

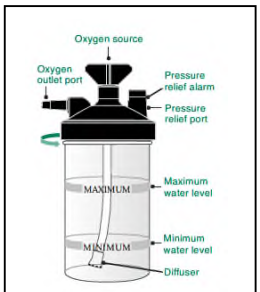
Flow adjustment knob (Fig 1-1)	ABS
Cabinet air filter (Fig 2-9)	Polyester
Mains cable (Fig 2-8)	PVC
Inlet Filter (Fig 5)	Polypropylene
Humidifier	Polypropylene
Casters	Nylon
Pipe/Tubing	Aluminum, PVC, polyurethane and/or silicone

2.5 Accessories and Spare Parts

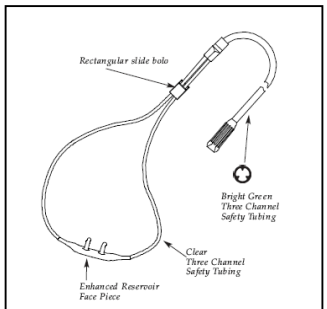
The accessories used with the ***device*** must be oxygen compatible, designed for oxygen therapy use, biocompatible and comply with the general requirements of the FDA Quality System Regulation or the 93/42/EEC European Directive, or any other applicable regulatory requirements.

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**
Humidifier (1 to 5 LPM)	9012-8774
Cannula with 2m (7ft) tubing (1 to 5 LPM)	9012-8780
Extension Tubing 7.7m (25 ft)	9012-8781
Tubing Adapter	9012-8783



Humidifier - Figure 3



Cannula - Figure 4

⚠	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)	8400-1025
Inlet Filter (Under Fig 2-9)	8400-1180
Ventilation Grill (Fig 2-9)	8400-0108
Casters	8300-8068
Mains Cable Wrap	8400-0022

🔧	Please consult the Nuvo Lite Maintenance Manual (PN 2010-8405) for instructions on replacing any above spare parts.

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 2200m (7500ft) 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 2-8) 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 2200 m to 4000m (7500 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 Power Switch (Fig 1-1) is in the "**O**" (OFF) position.

   If used with a humidifier (Fig 3): 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 provided Patient Hose Kit (tubing and elbow) attached to the Oxygen Product Outlet (Fig 1-2). Ensure that all of the parts are connected correctly so as to avoid leaks.

☑	Replace water in humidifier bottle before each treatment.

   If not using a humidifier: Remove the Patient Hose Kit attached to the Oxygen Product Outlet (Fig 1-3) and connect the oxygen tube directly to the outlet.

2) Plug the power cable into a power outlet of the correct voltage and frequency as defined on the manufacturer's technical label (Fig 2-7).

3) Press the Power Switch (Fig 1-3) to the ON **"I"** position.

☑	See the Alarms and Safety Features on page 3 for indicator lights and meanings.

4) Turn the flow adjustment knob (Fig 1-1) to the prescribed value.

☑	The required oxygen concentration is normally obtained within two minutes after the device is started.

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 Power Switch (Fig 1-3) to the **"O"** (OFF) position to stop the device. 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 3-5 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 disinfecting your device: Only the outside of the ***device*** is to be cleaned. After making sure the Power Switch (Fig 1-3) is in the "**O**" (OFF) position, use a soft, dry cloth or, if necessary, a damp sponge, to wipe the cabinet enclosure. Then thoroughly dry with wipes and an alcohol based solution. To prevent the spread of bacteria and viruses, this should be done daily and for each new patient.

☑	Acetone, solvents or any other flammable products must not be used. Do not use abrasive powders.

Cleaning and replacing filters: The removable cabinet air filter (Fig 2-9) must be cleaned in warm water and household detergent. Dry before reinstalling. The inlet / silencer filter (see Fig 5) should be inspected at each patient visit and replaced if required. The final product filter (not pictured) should only be replaced by a technician if required (not common).

Inlet Filter - Figure 5
(under air filter and grill)

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.

The expected service life of this device is 10 years with routine preventive and required maintenance.

Preventive Maintenance: Wash cabinet filter (see "Cleaning and replacing filters") weekly or after approximately 100 hours of use and for each new patient. More frequent cleaning is recommended in dusty environments. Inspect inlet air filter (Fig 5) at each patient visit. 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.

The manufacturer's instructions for the preventive maintenance of the devices are defined in the service manual, (Ref. 2010-8405). 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, 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 CE 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 cable (Fig 2-8) is not correctly plugged into the wall outlet.	Check the cable connection.
The no voltage detection alarm test does not work. (See Alarms and Safety Features)	Capacitor is not charged Internal electrical fault.	Check the circuit breaker (Fig 1-4) on the front of the unit; Reset if necessary. Plug unit in for 10 minutes and retest. Contact your equipment supplier.
The Power Switch (Fig 1-3) 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 Power Switch (Fig 1-3) 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 Power Switch (Fig 1-3) button. Contact your equipment supplier.
The Power Switch (Fig 1-3) 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 Power Switch (Fig 1-3) 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.	Stop the device and wait for it to cool down.
	Dirty Filters.	Clean cabinet filter. Restart. If the device does not start, contact your equipment supplier.
	Cooling fan(s) not operating.	Stop the device by pressing the Power Switch (Fig 1-3) button. 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 B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
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 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 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	Interference might occur in the vicinity of equipment marked with the following symbol: 
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 61000-4-11	<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 be powered from an uninterruptible power supply or a battery.
	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 tests	<5%% U_T (>95% dip in U_T) for 5 seconds	Complies	

Recommended separation distance between portable and mobile RF communications equipment and the device. The device is designed to operate in an environment in which radiated RF disturbances are controlled. The device user can help prevent electromagnetic interference by maintaining a minimum distance between the device and RF communications equipment as shown below.

Rated Maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (M)		
	150KHz to 80 MHz	80MHz to 800MHz	800MHz to 2.5GHz
	d-1.2vP	d-1.2vP	d-2.3vP
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

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.

CE 0413

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