INOGEN at HOME™

USER MANUAL

inogen®

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1. Glossary of Symbols

Symbol Key

WARNING — A warning indicates that the personal safety of the patient may be involved. Disregarding a warning could result in significant injury

CAUTION — A caution indicates that a precaution or service procedure must be followed. Disregarding a caution could lead to a minor injury or damage to equipment

On/Off (Power)

Flow setting indicator

Blue Indicator Light

General alarm indicator light

Follow instructions for use

Type BF Applied Part

Class II Equipment

No Open Flames

No Smoking

No Oil or Grease

Do Not Disassemble

U.S. Federal Regulation Restricts this device to sale by order of physician. May also be applicable in other countries

Do not dispose of in unsorted municipal waste

AC Power

Keep Dry

IP21 — Enclosure Ingress Protection against solid objects of 12.5mm minimum diameter and vertically falling drops of water

Manufacturer

Complies with applicable EU directives including medical devices directive

As Packaged (Per Box)

Authorized representative in the European Community

Fragile

Humidity

Temperature

This Side Up

2. Warnings, Cautions and Contraindications

Contraindications

- This equipment is to be used as an oxygen supplement and is NOT INTENDED to be life supporting or life sustaining.

Warnings

- The device produces concentrated oxygen gas which accelerates combustion. DO NOT USE THE DEVICE WHEN SMOKING OR NEAR OPEN FLAME, MATCHES, PETROLEUM, OIL, GREASE, SOLVENTS, RADIANT HEATERS, AEROSOLS etc. Use only water based lotions or salves that are concentrated oxygen compatible during oxygen therapy.
- Concentrated oxygen makes it easier for a fire to start and spread. Do not leave the nasal cannula on upholstery or other fabric such as bedding or personal clothing if the oxygen concentrator is turned on but not in use. Concentrated oxygen will make the materials flammable. Turn off the oxygen concentrator when not in use.
- Do not use the oxygen concentrator in the presence of pollutants, smoke or fumes, flammable anesthetics, cleaning agents or other chemical vapors. This may internally contaminate the oxygen concentrator and degrade its performance.
- Do not use the oxygen concentrator if either the plug or the power cord is damaged to prevent accidental electrical shock.
- Do not submerge the oxygen concentrator in liquids, expose to liquids, or otherwise allow liquids to enter into the case, this may lead to electrical shock and/or damage. If the oxygen concentrator is exposed to liquids turn it off and unplug from electrical outlet before attempting to clean and dry the liquid spill.
- When using a compatible humidifier do not refill humidifier while attached to the oxygen concentrator. Remove the humidifier from the oxygen concentrator prior to refilling to prevent accidental spills on the concentrator and prevent electrical shock hazard.
- Do not use cleaning agents other than those specified in this manual. Always unplug the oxygen concentrator before performing any cleaning. Do not use alcohol, isopropyl alcohol, ethylene chloride, or petroleum based cleaners. This may impair the proper function and/or increase the risk of fire and burns.
- Do not disassemble the oxygen concentrator or attempt any maintenance other than tasks described in this user manual; disassembly creates a hazard of electrical shock and will void the warranty. Servicing of the concentrator is to be performed by qualified and trained personnel only.
- Do not use any columns other than those specified in this user manual. The use of non-specified columns may create a safety hazard and/or impair equipment performance and will void the warranty.

- To avoid danger of choking and strangulation hazard, keep tubing away from children and pets.
- If you begin to feel ill or are experiencing discomfort while using the oxygen concentrator, consult your health care provider immediately.

Cautions

- USA Federal law restricts this device to sale or rental by or on the order of a physician, or any other practitioner licensed by the State in which he/she practices to use or order the use of this device; may also be applicable in other countries. Under certain circumstances, the use of non-prescribed oxygen therapy can be hazardous.
- Availability of an alternate source of oxygen is recommended in case of power outage or mechanical failure. Consult your equipment provider for type of back-up system recommended.
- Additional monitoring or attention may be required for patients using this device who are unable to hear or see alarms or communicate discomfort. If the patient shows any signs of discomfort, a physician should be consulted immediately.
- Accessories not specified for use with the oxygen concentrator may impair performance. Always use accessories according to manufacturer's instructions.
- Nasal cannula should be rated 5 liters per minute to ensure proper patient usage and oxygen delivery.
- Replace the nasal cannula on a regular basis. Check with your equipment provider or health care professional to determine how often the cannula should be replaced.
- It is recommended the oxygen concentrator accessory tubing and cannula include a means to reduce the propagation of fire.
- Do not operate the concentrator without the intake filter and particle filter in place. Particles drawn into the oxygen concentrator may damage the equipment.
- Refer to the environmental range specifications for proper storage and use conditions. Temperatures in excess of the indicated range may cause device malfunction.
- Do not obstruct air intake or exhaust when operating the oxygen concentrator. Blockage of air circulation or proximity to a heat source may lead to internal heat buildup and shutdown or damage. Always maintain a minimum of six inches of clearance.
- Do not place anything in the power supply port other than the supplied wall cord. Avoid the use of electrical extension cords with the concentrator. If an extension cord must be used, use an extension cord that has an Underwriters Laboratory (UL) Mark and a minimum wire thickness of 18 gauge. Do not connect any other device to the same extension cord.
- Do not sit or stand on the concentrator, doing so can be hazardous.

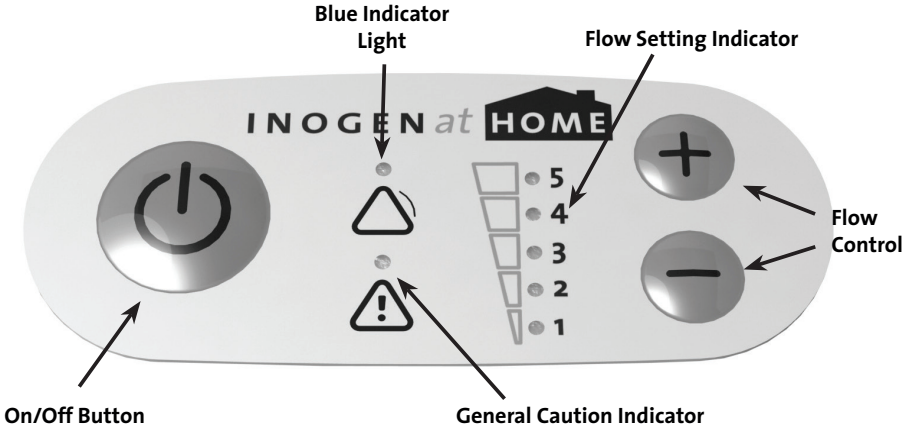
In order to ensure a safe installation and operation of the Inogen At Home Oxygen Concentrator Model GS-100, read and understand this entire manual before using the device.

The Inogen At Home Oxygen Concentrator has a 5 year expected life except 1 year expected life for user serviceable sieve bed columns.

3. Indications for Use

The Inogen At Home Oxygen Concentrator is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Inogen At Home Oxygen Concentrator may be used in a home or institution.

4. User Interfaces, Controls and Serviceable Items



User Interfaces

General Caution Indicator Light (Low, Medium Priority Alarm)
A yellow light indicates either a change in operating status or a condition that may need response. A flashing light is higher priority than non-flashing.

Blue Indicator Light (Change Column Soon)
Column maintenance is required within 30 days.
Contact your equipment provider to arrange service.

User Interfaces

Audible Indicators

An audible alarm (beep) indicates either a change in operating status or a condition that may need response (alarm). More frequent beeps indicate higher priority conditions.

Flow Setting Indicator

A green indicator light indicates the selected flow setting.

User Controls

ON / OFF Button

Press once to turn “ON”; Press and hold for one second to turn “OFF”.

Flow Setting Control Buttons

Use the – or + flow setting control buttons to select the setting as shown on the display. There are five settings, from 1 to 5.

Serviceable Items

Particle Filter

The filter must be in place at the intake end of the concentrator during operation.

Air Inlet Filter

The filter must be in place at the top of the concentrator during operation.

Cannula Nozzle Fitting

The nasal cannula connects to this nozzle for output of oxygen.

Nasal Cannula

Nasal cannulas should be replaced on a regular basis, consult with your physician or equipment provider, or cannula manufacturer’s instructions.

5. Operating Instructions

1. Place the concentrator in a well-ventilated location; air intake and exhaust must have clear access. Ensure that the concentrator is at least 6 inches (15 cm.) away from walls, furniture and curtains that could impede adequate airflow to the device.
2. Ensure particle filter is in place.
3. Ensure intake filter is in place.
4. Follow instructions A or B below:
   A. If you are not using a humidifier bottle, connect your nasal cannula tubing to the nozzle fitting. Nozzle fitting is located on the top of the concentrator. See illustrations 4A1 and 4A2.
   B. If you are using a humidifier bottle, follow the manufacturer's instructions. Place the humidifier bottle in the designated holder. See illustrations 4B1 and 4B2.
5. Attach the power cord to the back of the concentrator and plug the other end into an electrical outlet. Do not position the concentrator so that it is difficult to disconnect the power cord. Turn on the concentrator by pressing the ON/OFF button ⏻. See illustration 5. A single short beep will sound and all indicator lights will illuminate for a few seconds.
6. Use the + or − buttons to adjust the device to the prescribed setting. There are five flow settings, from 1 liter per minute to 5 liters per minute. The current setting can be viewed on the display. The green LED will illuminate once the set flow rate of oxygen is achieved. You may begin breathing from the device; the required oxygen concentration is normally reached within five minutes after device is powered on.
7. Ensure that the tubing is not kinked or pinched in any way and that oxygen is flowing through the nasal cannula. If oxygen is not flowing, the green LED will not be illuminated. Refer to the troubleshooting guide section of this manual.
8. Adjust the nasal cannula so that it is properly aligned on your face or as directed by your healthcare provider.
9. Turn off the concentrator by pressing the ON/OFF button ⏻. Turn off the concentrator when not in use.

4A1

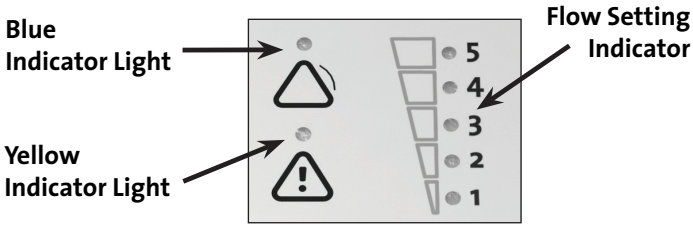
4A2

4B1

4B2

5

6. Audible and Visual Indicators



The concentrator has an audible alarm and three visual indicators **(green, yellow and blue)**.

Notifications

The concentrator monitors various parameters during operation and utilizes an intelligent alarm system to indicate a malfunction of the concentrator.

Mathematical algorithms and time delays are used to reduce the probability of false alarms while still ensuring proper notification of an alarm condition If multiple alarm conditions are detected, the highest priority alarm will be displayed.

To insure that audible notifications may be heard, the operators position must be determined to suit the surrounding noise level.

Note that failure to respond to the cause of an alarm condition for low, medium and high priority alarms potentially will result in discomfort or reversible minor injury only and develop within a period of time sufficient to switch to a backup source of oxygen.

The following notification messages are accompanied by an audible and/or visual indicator.

Indicator	Condition/Action/Explanation
Flow rate on LED Display	Current flow rate of oxygen being displayed at a setting from 1-5 liters per minute.
Flow rate indicator	Flow status indicator is **green.**
Blue Indicator Light	Column maintenance is required within 30 days. Contact your equipment provider to arrange service.

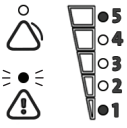
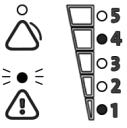
Low Priority Alarms

The following low priority alarm messages are accompanied by a **double beep** and a **solid yellow light**.

Indicator	Condition	Action/ Explanation
4	Low Oxygen	Concentrator is producing oxygen at a slightly decreased level. Contact your equipment provider to arrange service.
3	Service Needed	The concentrator is operating to specification but requires service at the earliest convenience. Contact your equipment provider to arrange service.
2	Sensor Fail	One of the concentrator's sensors has malfunctioned. If the condition persists, contact your equipment provider to arrange service.
Flow setting flashing	Low Flow	The concentrator is producing oxygen at a slightly decreased rate. If condition persists, contact your equipment provider to arrange service.

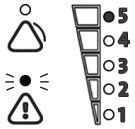
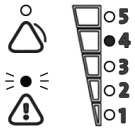
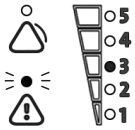
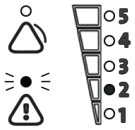
Medium Priority Alarms

The following medium priority alarm messages are accompanied by a triple beep, repeated every 25 seconds, and a **flashing yellow light.**

Indicator	Condition	Action/ Explanation
5 	Oxygen Error	The concentrator is producing oxygen at a low concentration. Switch to a backup oxygen source and contact your equipment provider to arrange service.
4 	Flow Error	Proper oxygen delivery has not been detected. Check for kinked tubing. If condition persists, switch to a backup oxygen source and contact your equipment provider to arrange service.

High Priority Alarms

The following high priority alarm messages are accompanied by a five beep pattern, repeated every 10 seconds and a **flashing yellow light** warning indicating immediate response by the operator is required.

Indicator	Condition	Action/ Explanation
5 	Fire Hazard	Smoke has been detected inside the device and device is shutting down. Allow the concentrator to air out in a smoke-free environment and restart. If condition persists, switch to a backup source of oxygen and contact your equipment provider.
4 	System Hot	Concentrator temperature is too high for operation. Ensure air intake and outlet vents have clear access and particle filters are clean. Allow the concentrator to cool for 10 minutes and restart. If condition persists, switch to a backup source of oxygen and contact your equipment provider.
3 	System Cold	Concentrator temperature is too cold for operation. Allow the concentrator to warm up in a room temperature environment for 10 minutes and restart. If condition persists, switch to a backup source of oxygen and contact your equipment provider.
2 	System Error	Switch to a backup source of oxygen and contact your equipment provider.
Sound indicator only	Power Error	Concentrator lost power during operation. Try unplugging the power cord and plugging it back in. If alarm does not reset, press and hold the power button down for 2 seconds. If condition persists, switch to a backup source of oxygen and contact your equipment provider.

NOTE When power is lost during operation, the buzzer will alarm continuously.

7. Troubleshooting

Contact your home care provider if you need assistance with the device.

Problem	Possible Cause	Recommended Solution
Any problem accompanied by information on concentrator display, visual and/or audible indicators	Refer to Chapter 4	Refer to Chapter 4
Concentrator does not power on when On/Off button is pressed	Power cord is not connected properly	Check power cord for proper connection
	Malfunction	Contact your equipment provider
No oxygen	Concentrator is not powered on	Press On/Off button to power concentrator
	Cannula is not connected properly or is kinked or obstructed	Check cannula and its connection
	The oxygen tubing or cannula is faulty	Inspect and replace the items if necessary

8. Cleaning, Care and Maintenance

Cleaning and Care

Periodically you may clean the outside case using a cloth dampened with a mild liquid detergent (such as Dawn™) and water.

Follow manufacturer's instructions on cleaning and care of concentrator accessories; clean or replace these accessories according to your healthcare provider or respective manufacturer's instructions for use.

Filter Cleaning and Replacement

The particle filter must be cleaned weekly to ensure the ease of air flow. Remove filter from the side of the device. Clean the particle filter with a mild liquid detergent (such as Dawn™) and water; rinse in water and dry before reuse. Ensure the filter is completely dry before reinstalling into the concentrator.

Air Inlet Filter

Replace when filter is dirty according to visual indicator.

The air inlet filter may be replaced by the equipment provider or by the user.

Output Filter

The output filter is intended to protect the user from inhalation of small particles in the product gas flow. The device includes an output filter conveniently located behind the removable cannula nozzle fitting. Inogen requires that this filter be replaced between patients.

The output filter may be replaced by the equipment provider or by the user.

Routine Maintenance

No special maintenance, other than weekly particle filter cleaning, needs to be carried out by the user.

Replacement Parts and Recommended Accessories

Contact your home care provider if you have any questions about equipment. Use only the following replacement parts and accessories with this device:

- Inogen At Home Particle Filter (RP-400)
- Inogen At Home Output Filter Replacement Kit (RP-107)
- Inogen At Home Air Inlet Filter (RP-401)
- Inogen At Home Column Pair (RP-402)
- Humidifier Connector Tube (Salter Labs #S0-676)
- Humidifier Bottle (Salter Labs #7600)
- Nasal Cannula (Salter Labs #16SOFT)
- AC Power Cord (RP-109)

Service

The concentrator is specifically designed to minimize routine preventative maintenance.

For assistance, if needed, in setting up, using, maintaining, or reporting unexpected operation or events, contact your equipment provider, or the manufacturer.

Column Change Procedure

There are two columns (metal tubes) on the concentrator located behind the particle filter. These two columns will be removed and replaced when service is required. Ensure adequate time to complete all steps without disruption is allotted when performing this maintenance.

1. Turn off the concentrator by pressing the power button to shut down the device.

2. Unplug the concentrator from the electrical outlet.

3. Lay down the concentrator on its side.

4. Press the two latch buttons on the sides of the device to remove the cover from the bottom of the concentrator in order to access the two columns.

5. Press the latch button with thumb or finger and pull the column out of the concentrator using the pull ring attached to the bottom of the column cap.

6. Remove the column completely from the concentrator.

7. Repeat steps 5-6 to remove the other column.

Installation of the new columns (metal tubes):

8. Remove the upper and lower dust caps from each column. There should be a total of two dust caps removed from each column. Make sure there is no dust or debris where the dust caps were located.

9. Insert the new column into the concentrator. Do not leave the column exposed after the dust caps are removed; it should be inserted into the concentrator as soon as the dust caps have been removed, to minimize environmental exposure.

10. The spring loaded latch button should fully return to the closed position when the column is completely inserted.

11. Repeat steps 9-10 to install the other column.

12. Replace the lower cover and return the concentrator to its upright position.

13. Connect the power supply cord from the concentrator and plug into an electrical outlet. **Do Not Power On** the concentrator.

14. Press and hold the plus button for ten seconds. Flow indicators 1, 3 & 5 will be illuminated and column will be reset. Release the plus button.

15. Press the power button to turn on the concentrator and use normally.

NOTE Column change instructions are only to be used when maintenance is required. Columns should only be removed during this maintenance procedure.

Storage

When not in use, store indoors away from excessive moisture and temperatures. Storage conditions outside of range specified may result in damage and device malfunction.

Disposal of Equipment and Accessories

Follow your local governing ordinances for disposal and recycling of the concentrator and accessories.

9. Specifications, Inogen At Home, Model GS-100

Dimensions:	16.5”H x 13”W x 7”D
Weight:	18 lbs
Warm-Up Time:	Less than 5 minutes
Oxygen Concentration:	90 +6%/-3% at all settings
AC Power:	100-240VAC, 275 W Max, 50-60Hz
Environmental Ranges for Use:	Temperature: 41 to 104˚F (5 to 40˚C) Humidity: 15 to 95%, non-condensing Altitude: 0 to 10,000 ft (0 to 3048 m)
Environmental Ranges for Shipping & Storage:	Temperature: -13 to 158˚F (-25 to 70˚C) Humidity: 0 to 93% non-condensing Altitude: n/a
Maximum Outlet Pressure:	19.6-40.6 psia (135-280 KPa Absolute)@ 20˚C
Flow Control Settings:	5 Settings: 1 to 5 liters per minute

Standards Compliance

This device is designed to conform to the following standards:

- EN ISO 8359:2012, Oxygen Concentrators for Medical Use – Safety Requirements (ISO 8359:1996, Second edition, Amendment 1)
- ASTM F 1464:2005, Oxygen Concentrators for Domiciliary Use
- IEC 60601-1:Edition 3.1: 2012, Medical Electrical Equipment -- Part 1: General requirements for basic safety and essential performance

Classification:

- IEC Class II Equipment
- Type BF Applied Part
- IP21 Enclosure Ingress Protection against solid objects of 12.5mm minimum diameter and vertically falling drops of water
- Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
- Continuous Operation

Guidance and Manufacturer's Declaration - Electromagnetic Immunity:

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3V/m 80 MHz to 2.5 GHz	3 Vrms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1.2\sqrt{P}$ 150 kHz to 80 MHz $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	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 EC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME EQUIPMENT or ME SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [ME EQUIPMENT or ME SYSTEM] be powered from an uninterrupted power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital or home environment.

NOTE	At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTE	U_T is the a.c. main voltage prior to application of the test level.

[a]: Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the concentrator is used exceeds the applicable RF compliance level above, the concentrator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[b]: Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This Device:

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

Rated Maximum Power Output of Transmitter (W)	**Separation Distance According to Frequency of Transmitter (M)**		
	150 kHz to 80 MHz d=1.2√P	**80 MHz to 800 MHz** d=1.2√P	**800 MHz to 2.5 GHz** d=2.3√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 rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE	At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE	The guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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

Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The concentrator uses RF energy only for its internal function. Therefore its RF emissions are very low and not likely to cause any interference in nearby equipment.
RF emissions CISPR 11	Class B	The concentrator 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 IEC 61000-3-3	Complies	

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