

INOGEN ONE^{G4}

USER MANUAL



 inogen®

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Intended Use, Contraindications and General Precautions

Intended Use

The Inogen One® G4 Oxygen Concentrator provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in the home, institution, vehicle, train, airplane, boats and other transport modalities.

Indications for use and clinical benefit

The Inogen One® G4 Oxygen Concentrator is used on a prescriptive basis by patients requiring supplemental oxygen to increase blood oxygen saturation.

Contraindications

This device is to be used as an oxygen supplement and is NOT INTENDED to be life sustaining or life supporting. ONLY use this product if the patient is capable of spontaneous breath and is able to inhale and exhale without the use of a machine.

- DO NOT use in conjunction with flammable anesthetic or flammable materials.
- DO NOT use this device in tracheotomized patients.
- DO NOT use this device in persons whose breathing during normal resting is unable to trigger the device.

Patient Population

Adults only. Prescription Required.

General Precautions



WARNING The device produces enriched oxygen gas, which accelerates combustion. Do NOT ALLOW SMOKING OR OPEN FLAMES within 10 feet of this device while in use.



WARNING Do not submerge the Inogen One® G4 or any of the accessories in liquid. Do not expose to water or precipitation. Do not operate in exposed rain. This could lead to electrical shock and/or damage.

CAUTION Do not use oil, grease, or petroleum-based products on or near the Inogen One® G4.

CAUTION Never leave the Inogen One® G4 in an environment which can reach high temperatures, such as an unoccupied car in high temperature environments. This could damage the device.

CAUTION USA Federal law restricts this device to sale by or on the order of a physician. May also be applicable in other countries.

CAUTION Nasal cannula should be rated for 3 liters per minute (e.g. Salter Labs 16SOFT) to ensure proper patient usage and oxygen delivery.



WARNING 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.

CAUTION It is the responsibility of the patient to make back-up arrangements for alternative oxygen supply when traveling; Inogen assumes no liability for persons choosing not to adhere to manufacturer recommendations.

CAUTION Under certain circumstances, the use of non-prescribed oxygen therapy can be hazardous. This device should be used only when prescribed by a physician.

CAUTION Additional monitoring or attention may be required for patients using this device who are unable to hear or see alerts or communicate discomfort. If the patient shows any signs of discomfort, a physician should be consulted immediately.

CAUTION The Inogen One® G4 is not designed or specified to be used in conjunction with a humidifier, nebulizer or connected with any other equipment. Use of this device with a humidifier, nebulizer or connected with any other equipment may impair performance and/or damage the equipment. Do not modify the Inogen One® G4 Concentrator. Any modifications performed on the equipment may impair performance or damage equipment and will void your warranty.



WARNING “To ensure you are receiving the therapeutic amount of oxygen according to your medical condition, the device must (1) be used only after one or more settings have been individually determined or prescribed for you at your specific activity levels, (2) be used with the specific combination of parts and accessories that are in line with the specification of the concentrator manufacturer and that were used while your settings were determined.”



WARNING The Inogen One® G4 is MR Unsafe. Do not expose to MRI equipment or other devices that generate strong magnetic fields (for example, x-ray, CT scan, or other types of radiation).



WARNING Use of this device has not been studied in pediatric populations. Consult your physician before using the product for pediatric patients.



WARNING Use of this product outside of the intended use and specifications has not been tested and may lead to product damage, loss of product function, or personal injury.



WARNING Do not use this product in any way other than described in the specifications and intended use sections of this manual.



WARNING Patients who exhibit breathing effort below the specified inspiratory sensitivity value may not be able to consistently trigger the device to receive oxygen therapy.



WARNING The settings of other models or brands of oxygen therapy equipment may not correspond with the settings of this device.



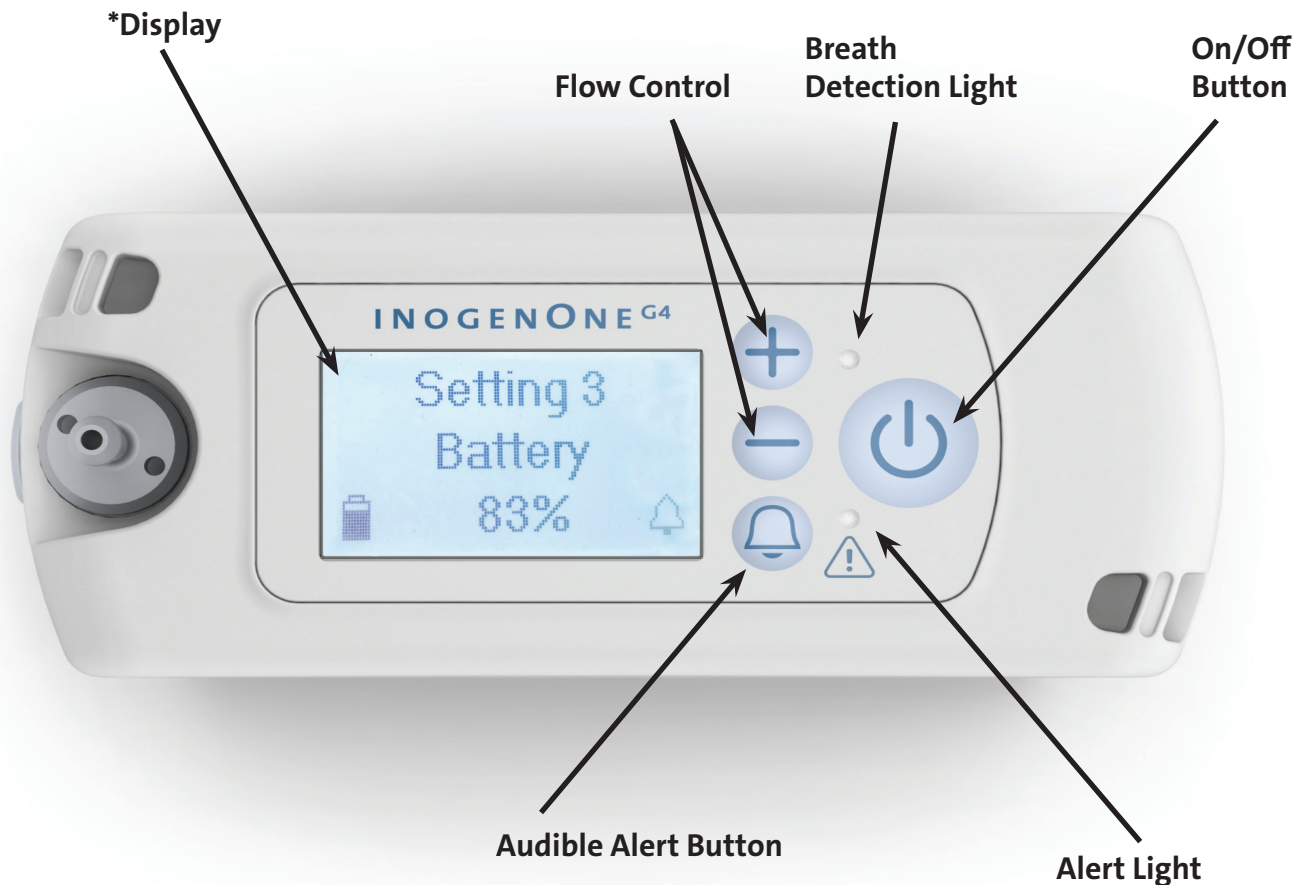
WARNING Oxygen is flammable. Do not leave the nasal cannula on bed coverings or chair cushions. Turn the oxygen concentrator off when not in use.

The expected life for the Inogen One® G4 Oxygen System is 5 years, with the exception of the sieve beds (metal columns) which have an expected life of 1 year and the batteries, which have an expected life of 500 full charge/discharge cycles.

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Description of the Inogen One® G4 Oxygen Concentrator

Important Parts of the Inogen One® G4 Oxygen Concentrator



* Actual display appearance may vary.

* Remove the static cling FCC label from the user interface panel (applicable for all Bluetooth models).

User Controls

ON / OFF Button

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



Audible Alert Button

Pressing this button will toggle the Inogen One® G4's breath detection audible alert on and off.



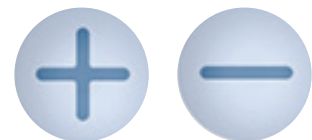
Breath Detection Alert Mode. The Inogen One® G4 will alert with audible and visual signals for “no breath detected” when this mode is enabled and no breath has been detected for 60 seconds.

At 60 seconds, the device will enter into auto pulse mode and once another breath is detected, the device will exit auto pulse mode and deliver normally on inspiration. The display's mode indication area will show a bell icon, flashing yellow light and display message when the alert is enabled.

If power is lost, the breath detection audible alert remains set in the user preferred mode.

Flow Setting Control Buttons

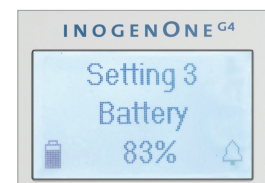
Use the – or + flow setting control buttons to select the setting as shown on the display. There are three settings, from 1 to 3.



User Interfaces

Display

This screen displays information regarding flow setting, power status, battery life and errors. If you would like to change the language on the Inogen LCD Screen contact your Equipment Provider for instructions. Actual display appearance may vary.



User Interfaces (continued)

Indicator Lights

A green light indicates breath detection.


A yellow light indicates either a change in operating status or a condition that may need response (alert). A flashing light is higher priority than non-flashing.



Audible Signals

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

Backlight

A backlight will illuminate the screen for 15 seconds when the  on/off button is briefly pressed.

Input / Output Connections

Particle Filter

The filter must be in place at the intake end of the concentrator during operation to keep input air clean.



Cannula Nozzle Fitting

The nasal cannula connects to this nozzle for Inogen One® G4 output of oxygenated air.



DC Power In

Connection for external power from the AC power supply or DC power cable.



USB Port

For service use only.



Power Supply Options

Single and Double Rechargeable Lithium Ion Batteries

The battery will power the Inogen One® G4 without connection to an external power source. When fully charged, a single battery will provide up to 2.7 hours of operation; a double battery will provide up to 5 hours of operation. The battery recharges when properly installed in the Inogen One® G4 and the concentrator is connected to AC or DC power. Recharging time is up to 3 hours for a single battery and 5 hours for a double battery. See information in the “Battery Care and Maintenance” section.



Power Supply

Overview

The Inogen One® G4 AC power supply (BA-401) is used to power the Inogen One® G4 concentrator from an AC power source.

Description

The Inogen One® G4 AC power supply is specifically designed for use with the Inogen One® G4 Oxygen Concentrator (IO-400). The AC power supply provides the precise current and voltage required to safely power the Inogen One® G4 and is designed to operate from specified AC power sources. When used with AC power sources, the power supply automatically adapts to input voltages from 100V to 240V (50-60HZ) permitting use with most power sources throughout the world.

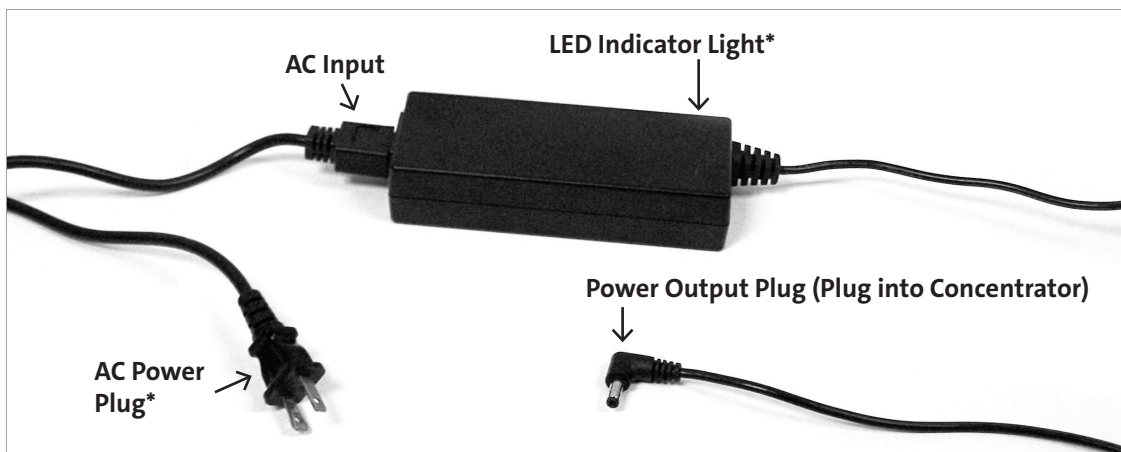
The AC power supply will charge the Inogen One® G4 Batteries when used with AC input power. Due to aircraft power limitations, the AC Power Supply cannot be used to charge the Inogen One® G4 Battery when used on an aircraft.

The AC power supply is used with the following components:

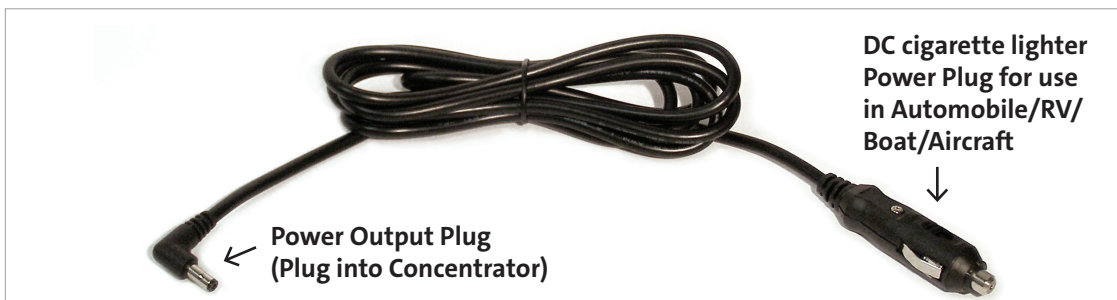
- Power supply with attached power output cable to connect to the Inogen One® G4
- AC power input cable

The DC power cable (BA-306) is specifically designed for use with the Inogen One® G4 Oxygen Concentrator (IO-400). The DC power input cable connects directly to the automobile cigarette lighter or auxiliary DC power supply. Refer to Chapter 3 for additional operating instructions for use with DC power source.

Inogen One AC Power Supply Model# BA-401



Inogen One G4 DC Power Cable Model# BA-306



* Actual product appearance may vary.



WARNING Do not use power supplies or power cables other than those specified in this user manual. The use of non-specified power supplies or power cables may create a safety hazard and/or impair equipment performance. Do not wrap cords around power supply for storage. Do not drive, drag or place objects over cord. Doing so may lead to damaged cords and a failure to provide power to the concentrator. To avoid danger of choking or strangulation hazard, keep cords away from children and pets.

Inogen One® G4 Accessories



WARNING Do not use power supplies/adapters or accessories other than those specified in this user manual. The use of non-specified accessories may create a safety hazard and/or impair equipment performance.

Nasal Cannula

A nasal cannula must be used with the Inogen One® G4 to provide oxygen from the concentrator. A single lumen cannula up to 25 feet in length is recommended to ensure proper breath detection and oxygen delivery.



WARNING To avoid danger of choking and strangulation hazard, keep tubing away from children and pets.

NOTE Increasing the cannula length may reduce the perceived noise during oxygen bolus delivery.

NOTE When using a cannula 25ft. in length with the Inogen One® G4, an increase in flow setting may be required, consult your physician.

Inogen One G4 Carry Strap (CA-401)

The carry strap is designed to attach directly to the concentrator. There is a metal slide for ease of length adjustments, a shoulder pad for comfort and a sewn on velcro tab to wrap up that extra cannula tubing.



Carry Bag (CA-400)

The Carry Bag provides a protective cover with a handle and shoulder strap to enable you to carry the Inogen One® G4. The Inogen One® G4 can be operated using battery power during transport with the Carry Bag.

Inogen One® G4 Optional Accessories

External Battery Charger (BA-403)

The Inogen One® G4 external battery charger will charge the Inogen One® G4 single and double batteries.

1. Plug the External Battery Charger AC power supply cord into an electrical outlet.
2. Plug the External Battery Charger AC power supply into the battery charger.
3. Slide your charger onto the Inogen One G4 Battery by clicking and locking into the charger.
4. When the battery is in the correct position, a solid red light will indicate that the battery is charging.
5. When the green light illuminates, the battery is fully charged.



CAUTION Avoid touching the recessed electrical contacts of the External Battery Charger; damage to contacts may affect charger operation.

NOTE These contacts are not powered unless a battery is in place and charging.

NOTE To completely remove power from the External Battery Charger, remove the plug.



WARNING Do not repackage concentrator, accessories, or systems for shipment in packaging not provided by Inogen.

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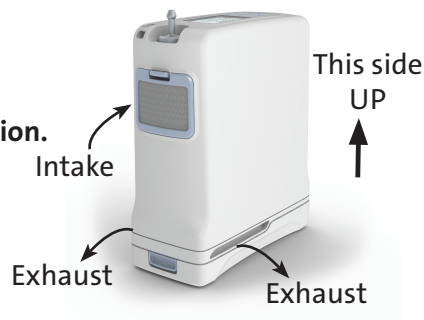
Operating Instructions

General Instructions

1. Place the Inogen One® G4 in a well ventilated location.

Air intake and exhaust must have clear access.

Locate the Inogen One® G4 in such a way that any auditory alerts may be heard. Always operate the Inogen One® G4 in an upright position (see image for proper orientation).



WARNING Avoid use of the Inogen One® G4 in presence of pollutants, smoke or fumes. Do not use the Inogen One® G4 in presence of flammable anesthetics, cleaning agents or other chemical vapors.

CAUTION Do not obstruct air intake or exhaust when operating the device. Blockage of air circulation or proximity to a heat source may lead to internal heat buildup and shutdown or damage to the concentrator.

CAUTION The Inogen One® G4 Concentrator is designed for continuous use. For optimal sieve bed (columns) life, the product should be used frequently.

2. Ensure particle filter is in place.

CAUTION Do not operate the Inogen One® G4 without the particle filter in place. Particles drawn into the system may damage the equipment.



3. Install the battery.

Insert the Inogen One® G4 battery by sliding battery into place until the latch returns to the upper position.



CAUTION The Inogen One® G4 battery acts as a secondary power supply in the event of a planned or unexpected loss of the AC or DC external power supply. When operating the Inogen One® G4 from an AC or DC external power supply, a properly inserted Inogen One® G4 battery should be maintained in the unit. This procedure will ensure uninterrupted operation and will operate all alerts and alerts in the event of a loss of the external power supply.

4. Connect the Power Supply.

Connect the AC input plug to the power supply. Connect the AC power plug to the power source and connect the power output plug to the Inogen One® G4. The green LED on the power supply will be illuminated and a beep will sound from the concentrator.



CAUTION Ensure the power supply is in a well ventilated location as it relies on air circulation for heat dissipation. The power supply may become hot during operation. Make sure the power supply cools down before handling.

CAUTION The power supply is not water resistant.

CAUTION Do not disassemble the power supply. This may lead to component failure and/or safety risk.

CAUTION Do not place anything in the power supply port other than the supplied wall cord. Avoid the use of electrical extension cords with the Inogen One® G4. 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 devices to the same extension cord.

NOTE Under certain conditions (see Technical Specifications) the power supply may shut down. The green LED will blink or will no longer be illuminated. If this occurs, disconnect the power supply for at least 10 seconds and reconnect.

NOTE When the power supply is disconnected from the AC outlet, also disconnect it from the concentrator to avoid unnecessary battery discharge.

5. Connect the nasal cannula tubing to the nozzle fitting.

Nozzle fitting is located on the top of the Inogen One® G4. Use of a single lumen cannula up to 25 feet in length is recommended to ensure proper breath detection and oxygen delivery. Additional titration may be needed to ensure proper oxygen delivery when using a particular cannula.



CAUTION To ensure oxygen flow, ensure that the nasal cannula is properly connected to the nozzle fitting and that the tubing is not kinked or pinched in any way.

CAUTION Replace the nasal cannula on a regular basis. Check with your equipment provider or physician to determine how often the cannula should be replaced.

6. Turn on your Inogen One® G4 by pressing the ON/OFF Button.

A single short beep will sound after the Inogen logo is displayed. "Please Wait" will appear while the concentrator starts up. The display will indicate the selected flow setting and power condition. Following a brief start-up sequence, a warm up period up to 2 minutes will initiate. During this time period the oxygen concentration is building to but may not have reached specification. Additional warm up time may be needed if your Inogen One® G4 has been stored in extremely cold temperatures.



7. Set the Inogen One® G4 Concentrator to the flow rate prescribed by your physician or clinician.

Use the + or – setting buttons to adjust the Inogen One® G4 to the desired setting. The current setting can be viewed on the display.

8. Position the nasal cannula on your face and breathe through your nose.

The Inogen One® G4 will sense the onset of inhalation and deliver a burst of oxygen at a precise time when you inhale. The Inogen One® G4 will sense each breath and continue to deliver oxygen in this manner. As your breathing rate changes, the Inogen One® G4 will sense these changes and deliver oxygen only as you need it. At times, if you inhale very quickly between breaths the Inogen One® G4 may ignore one of the breaths, giving the appearance of a missed breath. This may be normal as the Inogen One® G4 senses and monitors the changes in your breathing pattern. The Inogen One® G4 will normally sense the next breath and deliver oxygen accordingly.



A green light will flash each time a breath is detected. Make certain that the nasal cannula is properly aligned on your face and you are breathing through your nose.



WARNING If you begin to feel ill or are experiencing discomfort while using this device, consult your physician immediately.

CAUTION The Inogen One® G4 is designed to provide a flow of high purity oxygen. An advisory alert, “Oxygen Low”, will inform you if oxygen concentration drops. If alert persists, contact your equipment provider.

General

To remove power, unplug the input cord from its source (i.e., AC wall outlet, DC car cigarette lighter adapter) and disconnect it from the Inogen One® G4.

CAUTION Ensure the power supply is powered from only one power source (AC or DC) at any given time.



WARNING It is the responsibility of the patient to use only parts and accessories mentioned in these instructions for use. Parts and accessories used by the patient not recommended in these instructions for use are at the sole responsibility for the patient. Inogen assumes no liability for use of parts and accessories not mentioned in these instructions for use.

Additional Operating Instructions

For Use In Home with AC Power

For operation of the power supply using an AC power source, follow these instructions:

1. Connect the AC input to the power supply.
2. Connect the AC power plug to the power source and connect the power output plug to the Inogen One® G4. The green LED will be illuminated, indicating the power supply has input power.

Traveling with your Inogen One® G4 System

The Inogen One® G4 System makes travel by boat, car or train more convenient for oxygen users than ever before. Now you get the same quality performance and convenience while on the go that you're used to receiving from your Inogen One® G4 at home. Here are some useful and important instructions for maximizing performance and convenience when using your Inogen One® G4 while traveling.

You should begin planning for a trip with a checklist of items to remember. This checklist should include:

- ✓ AC power supply and DC power cable
- ✓ Extra Battery(s) if required
- ✓ Important phone numbers, such as those of your physician and home healthcare provider, or providers in the area you will be traveling
- ✓ Plan for backup oxygen in the event of a prolonged power outage or mechanical failure

For Use In Automobile/RV/Boat/Aircraft

For operation using a DC power source, follow these instructions:

1. Connect the DC power output plug to the Inogen One® G4.
2. Connect the DC power plug (Cigarette Lighter Adapter) to the power source.
3. The plug should insert into the socket without excessive force and securely remain in place.



4. Check the device display screen to confirm that an external power supply is connected. An icon of a battery with a lightning bolt or an AC power plug will be displayed on the screen, indicating that external power is connected and functioning properly.



WARNING Ensure that the automobile power socket is adequately fused for the Inogen One® G4 power requirements (minimum 15 Amp). If the power socket cannot support a 15 Amp load, the fuse may blow or the socket may be damaged.



WARNING The tip of the Cigarette Adapter Plug becomes HOT when in use. Do not touch the tip immediately after removal from an auto cigarette lighter socket.

CAUTION Ensure the automobile power socket is clean of cigarette ash and the adapter plug fits properly, otherwise overheating may occur.

CAUTION Do not use the power supply with a cigarette plug splitter or with an extension cable. This may cause overheating of the DC power input cable.

CAUTION Do not jump start the automobile with the DC power cable connected. This may lead to voltage spikes which could shut down and/or damage the DC power input cable.

CAUTION When powering the Inogen One® G4 in an automobile ensure the vehicle's engine is running first, before connecting DC cable into cigarette lighter adapter. Operating the device without the engine running may drain the vehicle's battery.

CAUTION A change in altitude (for example, from sea level to mountains) may affect total oxygen available to the patient. Consult your physician before traveling to higher or lower altitudes to determine if your flow settings should be changed.

Traveling By Air

The Inogen One® G4 conforms to all applicable FAA requirements for POC use on board an aircraft.

Planning Your Flight

When flying with the Inogen One® G4, you must inform the airline that you will be using your Inogen One® G4 on board the aircraft. You should contact the Special Assistance desk of the airline on which you will be traveling to learn of any paperwork, etc. that might be needed.

- Some airlines may equip their aircraft with onboard electrical power. You may have an opportunity to request a seat with a power port which can be used to power your Inogen One® G4. However, availability varies by airline, type of aircraft and class of service. You should check with your airlines for availability and always plan on having sufficient battery power for no less than 150% of the expected duration of the flight. Airlines may have specific requirements for battery life duration, so check with the airline before traveling.
- Your DC Power Cable is equipped with a commonly used cigarette lighter adapter. However, aircrafts use different power port configurations and it is difficult to determine which type of power port compatibility your aircraft may supply. It's a good idea to purchase an adapter, found at electronic and travel stores.

Before Your Flight

Here are some things to keep in mind the day your flight departs:

- Ensure your Inogen One® G4 is clean, in good condition and free from damage or other signs of excessive wear or abuse.
- Bring enough charged batteries with you to power your Inogen One® G4 for no less than 150% of the expected duration of the flight, plus a conservative estimate of unanticipated delays.
- Regional/Commuter airlines do not offer onboard electrical power. If your travel plans call for flights on regional airlines, bring enough charged batteries with you to power your Inogen One® G4 for no less than 150% of the expected duration of the flight, plus a conservative estimate of unanticipated delays.
- Arrive at the airport early. Airport security screening personnel may require extra time to inspect your Inogen One® G4.
- While waiting to board your flight, you may be able to conserve battery power by using the AC Power Supply to power your Inogen One® G4 from an electrical outlet in the airport terminal if available.

During Your Flight

1. If using airline power port, remove the Battery from the Inogen One® G4 Oxygen Concentrator. Due to aircraft power limitations, the AC Power Supply cannot be used to charge the Inogen One® G4 Battery when onboard aircraft.
 2. Connect the DC Power Plug for available airline power. Check with airline personnel to ensure compatibility.
- During taxi, takeoff and landing, stow your Inogen One® G4 under the seat in front of you. Your Inogen One® G4 will fit upright under most airline seats.
 - It is not necessary to turn off your Inogen One® G4 during taxi, takeoff and landing.

CAUTION A change in altitude (for example, from sea level to mountains) may affect total oxygen available to the patient. The Inogen One® G4 has been verified to provide oxygen to specification up to 10,000 ft. (3048 m). Consult your physician before traveling to higher or lower altitudes to determine if your flow settings should be changed.

After Your Flight

- Remember to recharge additional batteries you may have used prior to your next flight.

Traveling By Bus, Train or Boat

Contact your carrier to find out about power port availability.

Battery Operating Instructions

Ensure that the battery is in place and charged. Disconnect the Inogen One® G4 from its power source. While the Inogen One® G4 is operating on battery power, the battery will discharge. The display will indicate the estimated remaining percentage (%) or minutes of use.

When the concentrator detects that the battery life is low, with less than 10 minutes remaining, a low priority alert will sound. When the battery is empty, the alert will change to a high priority.

When battery life is low, do one of the following:

- Plug the Inogen One® G4 into an AC or DC power source using the AC power supply or DC cable.
- Replace the battery with a charged battery after turning off the Inogen One® G4 (by pressing the ON/OFF button). To remove battery press and hold the battery latch button and slide battery off the concentrator.
- If the battery is drained, charge the battery or remove it from the concentrator.

If the Inogen One® G4 is being powered by the AC power supply or DC power, batteries will charge during operation. Leaving your Inogen One® G4 plugged in past the full charge time will not harm the concentrator or the battery.



WARNING It is the responsibility of the patient to periodically check the battery and replace as necessary. Inogen assumes no liability for persons choosing not to adhere to manufacturers recommendations.

Normal Battery Charging

To ensure that your battery is properly charging, inspect that the correct AC and DC power output plug adapter is being used and that the adapter is properly inserted into the power outlet. Observe the display or lights that indicate charging status.

NOTE When starting to charge a fully discharged battery, the charging process may start and stop during the first few minutes.

Battery Care and Maintenance

Your Inogen One® G4 Lithium Ion Battery requires special care to ensure proper performance and long life. Use only Inogen One® G4 Batteries with your Inogen One® G4 Concentrator.

Keep Dry

Always keep liquids away from batteries. If batteries become wet, discontinue use immediately and dispose of battery properly.

Effect of Temperature on Battery Performance

The Inogen One® G4 single battery powers the Inogen One® G4 Concentrator up to 2.7 hours under most environmental conditions. To extend the run-time of your battery, avoid running in temperatures less than 41°F (5°C) or higher than 95°F (35°C) for extended periods of time.

Battery Time Remaining Clock

The Inogen One® G4 continuously displays battery time remaining. This displayed time is only an estimate and the actual time remaining may vary from this value.

Please Follow These Important Guidelines to Maximize Battery Performance and Life:

- Store battery in a cool, dry place. Store with a charge of 40-50%.
- If using multiple batteries, make sure that each battery is labeled (1, 2, 3 or A, B, C, etc.) and rotate on a regular basis. Batteries should not be left dormant for more than 90 days at a time.

Battery Charge Indicator Gauge

When the single or double battery is not attached to the Inogen® One G4 Concentrator, you can check the battery gauge on the battery to determine the amount of charge available. Determine the amount of battery charge available by pressing the green battery icon button and observing how many LEDs illuminate.

4 LEDs Light: 75% to 100% full

3 LEDs Light: 50% to 75% full

2 LEDs Light: 25% to 50% full

1 LED Lights: 10% to 25% full

1 LED Blinks: Battery is less than 10% full and needs to be recharged

4





Inogen One® G4 Oxygen Concentrator Audible and Visible Signals

Display

The Inogen One® G4 display contains power status icons, mode icons, text with informational messages and error notifications.





Power Status Icons

These icons are examples of those shown in the display's window when the Inogen One® G4 is operating on battery power.

Icon	Meaning
	Battery is empty.
	Battery has less than 10% charge remaining. This icon flashes.
	Battery has approximately 40% to 50% charge remaining.
	Battery is full.



Power Status Icons (continued)

The mode icons below are examples of those shown when the Inogen One® G4 is operating from an external power supply and charging the battery. The lightning bolt indicates that an external power supply is connected.

Icon	Meaning
	Battery is charging with charge level between 60% and 70%.
	The battery is fully charged and is charging as necessary to maintain its charge.
	Battery is charging with charge level less than 10%.
	The Inogen One® G4 is operating from an external power source with no battery present.





Mode Icons

These are the mode icons shown in the display's window.

Icon	Meaning
	The breath detection audible alert has been enabled.
	The breath detection audible alert is disabled. This is the default condition.

Display Icons

The icons below are examples of those shown when pertaining to Bluetooth functionality.


Icon	Meaning
	Bluetooth turned off.
	Bluetooth turned on.
	Pairing with Inogen Connect application.
	Concentrator unpaired from device.

Display Text

NOTE When two conditions occur simultaneously, the condition with the higher priority will be displayed.

Informational Messages

The following information displays are not accompanied by any audible feedback or any visual change in the indicator lights.

Message Display & Text	Condition/Action/Explanation
	The Inogen logo is displayed at startup.
Setting X Please Wait	Displayed during warm up. “X” represents the selected flow setting (eg., Setting 2).
Setting X Battery HH:MM	Default display when operating on battery power. “X” represents the selected flow setting (e.g., Setting 2). “HH:MM” represents the approximate time remaining on the battery charge (e.g., 1:45).
Setting X Charging xx (or) Battery Full	Default display when operating on an external power supply and the battery is charging. “xx%” represents the percent battery charge (e.g., 86%).
Setting X Battery xx%	Default display when the battery is not charging or when the time remaining is not available from the battery.
Charging xx% (Or) Battery Full	Displayed when the concentrator is plugged in and being used to charge a battery (not being used for oxygen production). It is normal to see a fully charged battery read between 95% and 100% when external power is removed. This feature maximizes the useful life of the battery.

Notifications



WARNING Audible notifications, ranging from 55dba to 65dba depending on the users position, are to warn the user of problems. To insure that audible notifications may be heard, the maximum distance that the user can move away from it must be determined to suit the surrounding noise level.

Notifications (continued)

The Inogen One® G4 monitors various parameters during operation and utilizes an intelligent alert system to indicate a malfunction of the concentrator. Mathematical algorithms and time delays are used to reduce the probability of false alerts while still ensuring proper notification of an alert condition.

If multiple alert conditions are detected, the highest priority alert will be displayed.

Note that failure to respond to the cause of an alert condition for low, medium and high priority alerts 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 a **single, short beep**.

Message Display & Text	Condition/Action/Explanation
Please Wait Shutting Down	On/Off button has been pressed for two seconds. Concentrator is performing system shut down.
HH:MM Vx.x:Serial Number	Audible Alert button has been pressed for five seconds.

Low Priority Alerts

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

Message Display & Text	Condition/Action/Explanation
Battery Low Attach Plug	Battery power is low, with less than 10 minutes remaining. Attach external power supply or power down and insert a fully charged battery.
Replace Columns	Column maintenance is required within 30 days. Contact your equipment provider to arrange for service.

Low Priority Alerts (continued)

Message Display & Text	Condition/Action/Explanation
Check Battery	Battery error has occurred. Check the connection of your battery and ensure that it is properly attached and latched on concentrator. If battery error recurs with same battery, stop using the battery and switch to a new battery or remove battery and operate concentrator using external power supply.
Oxygen Low	Concentrator is producing oxygen at a slightly low level (<82%) for a period of 10 minutes. If condition persists, contact your equipment provider.
Remove Battery to Cool	Battery has exceeded its charging temperature and charging has stopped. The battery will not charge while this alert is present but will begin to charge when the battery temperature returns to the normal operating range. If battery charging is desired sooner, remove the battery from the concentrator and allow it to cool in an open area for approximately 10-15 minutes. Then, re-insert the battery into the Inogen One® G4. If the problem still persists, contact your equipment provider.
Service Soon	The concentrator requires servicing at the earliest convenience. The concentrator is operating to specification and may continue to be used. Contact your equipment provider to arrange for service.
Sensor Fail	The concentrator's oxygen sensor has malfunctioned. You may continue to use the concentrator. If the condition persists, contact your equipment provider.

Medium Priority Alerts

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

Message Display & Text	Condition/Action/Explanation
No Breath Detect Check Cannula	Concentrator has not detected a breath for 60 seconds. Check that cannula is connected to concentrator, there are no kinks in tubing and cannula is positioned properly in your nose.
Oxygen Error	Oxygen output concentration has been below 50% for 10 minutes. If condition persists, switch to your backup oxygen source and contact your equipment provider to arrange for service.
O2 Delivery Error	A breath has been recognized, but proper oxygen delivery has not been detected.
Battery HOT Warning	Battery has exceeded temperature limit while concentrator is running on battery power. If possible, move concentrator to a cooler location or power unit with an external power supply and remove battery. If condition persists, contact your equipment provider.
System HOT Warning	Concentrator has exceeded temperature limit. If possible move concentrator to a cooler location. Ensure air intake and outlet vents have clear access and particle filters are clean. If condition persists, contact your equipment provider.

High Priority Alerts

CAUTION If you are not near the Inogen One® G4 you may not be able to hear or see the high priority alerts. Make sure the Inogen One® G4 is in a location where the alerts and alerts will be recognized if they occur.

The following high priority alert messages are accompanied by a **five beep pattern**, repeated every 10 seconds and a **flashing yellow light**.

Message Display & Text	Condition/Action/Explanation
Battery Empty Attach Plug	Concentrator has insufficient battery power to produce oxygen. Attach external power supply or exchange battery, then restart unit if necessary by pressing On/Off button.
Battery HOT	Battery has exceeded temperature limit while concentrator is running on battery power. Concentrator has stopped producing oxygen. If possible, move concentrator to a cooler location, then turn power off and back on. Ensure air intake and outlet vents have clear access and particle filters are clean. If condition persists, switch to a backup source of oxygen and contact your equipment provider.
System HOT	Concentrator temperature is too high and oxygen production is shutting down. Ensure air intake and outlet vents have clear access and particle filters are clean. If condition persists, switch to a backup source of oxygen and contact your equipment provider.
System COLD	This may result from the concentrator being stored in a cold environment (below 0°C (32°F)). Move to a warmer environment to allow the unit to warm up before starting it. If condition persists, switch to a backup source of oxygen and contact your equipment provider.
System Error	Concentrator has stopped producing oxygen and is shutting down. You should: <ol style="list-style-type: none">1. Switch to backup oxygen source2. Contact your equipment provider

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Troubleshooting

Solutions to some possible issues you may encounter are described in this section.

Inogen One® G4 Oxygen Concentrator

Problem	Possible Cause	Recommended Solution
Any problem accompanied by information on concentrator display, indicator lights and/or audible signals	Refer to Chapter 4	Refer to Chapter 4
Concentrator does not power on when On/Off button is pressed	Battery is discharged or no battery is present	Use external power supply or replace battery with one that is fully charged
	AC Power supply is not connected properly	Check power supply connection and verify green light is solid
	DC Cable is not connected properly	Check DC Cable connection at the Concentrator and at cigarette lighter or auxiliary DC power source
	Malfunction	Contact your equipment provider

Troubleshooting (continued)

Problem	Possible Cause	Recommended Solution
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 to concentrator nozzle

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Cleaning, Care and Maintenance

Cannula Replacement

Your nasal cannula should be replaced on a regular basis. Consult with your physician and/or equipment provider and/or cannula manufacturer's instructions for replacement information. A single lumen cannula up to 25 feet in length is recommended to ensure proper breath detection and oxygen delivery.



WARNING Oxygen is flammable. Do not leave the nasal cannula on bed coverings or chair cushions. Turn the oxygen concentrator off when not in use.

Case Cleaning

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



WARNING Do not submerge the Inogen One® G4 or its accessories in water or allow water to enter into the case; this may lead to electrical shock and/or damage.



WARNING Do not use cleaning agents other than those specified in this User Manual. Do not use alcohol, isopropyl alcohol, ethylene chloride or petroleum based cleaners on the cases or on the particle filter.

Filter Cleaning and Replacement

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



NOTE

It may be necessary to clean the particle filter more often in dusty environments.

To purchase additional particle filters contact your equipment provider or Inogen.

Output Filter

The output filter is intended to protect the user from inhalation of small particles in the product gas flow. The Inogen One® G4 includes an output filter conveniently located behind the removable cannula nozzle fitting.

The output filter may be replaced by the equipment provider or by the owner using the Output Filter Replacement Kit (RP-404).

The Inogen One G4 Concentrator must be cleaned and disinfected as per the above instructions for each new patient. No special maintenance needs to be carried out by the patient. Your equipment provider performs maintenance operations to assure continued reliable service from your Inogen One G4. The manufacturer's instructions for the preventative maintenance of the devices are defined in the service manual. All work must be performed by trained technicians certified by the manufacturer.

DC Input Cable Fuse Replacement

The Cigarette Lighter DC power plug contains a fuse. If the DC input cable is being used with a known good power source and the unit is not receiving power, the fuse may need to be replaced.

To replace the fuse, follow these instructions and refer to the photograph below.

1. Remove the tip by unscrewing the retainer. Use a tool if necessary.
2. Remove the retainer, tip and fuse.
3. The spring should remain inside the Cigarette Lighter Adapter housing. If the spring is removed, make sure to replace the spring first before inserting the replacement fuse.

4. Install a replacement fuse, Inogen RP#125 (BUSS MDA-12) and reassemble the tip. Ensure the retainer ring is properly seated and tightened.



CAUTION For continued protection against risk of fire, only use fuse specified.

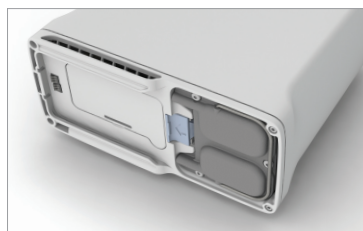
Inogen One® G4 Column Change Procedure

NOTE Column change instructions are only to be used when maintenance is required and are not intended for practice purpose.



WARNING 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 your warranty.

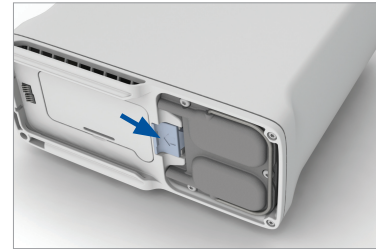
1. Turn off the Inogen One® G4 concentrator by pressing the power button to shut down the device.
2. Remove the Inogen One® G4 concentrator from the carry case, if applicable.
3. Remove the battery from the Inogen One® G4 concentrator.
4. Place the Inogen One® G4 concentrator on its side so that the underside is visible. The metal column assembly can be seen on one side of the device.



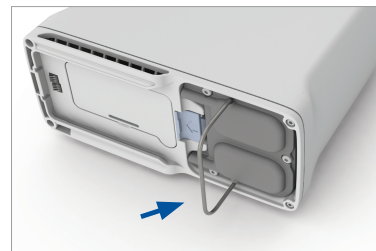
Inogen One® G4 Column Change Procedure (continued)

5. Unlock the column assembly by pushing the latch button away from the columns.

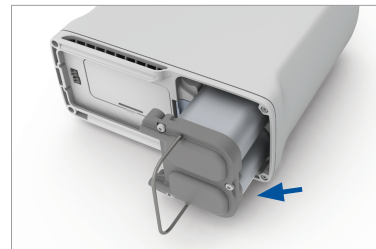
Open and unlocked



6. While holding the button open, slide the column assembly out of the device by pulling on the column pull handle.



7. Remove the columns completely from the Inogen One® G4. Both columns are removed as one piece.



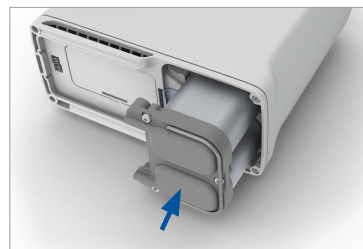
Column (metal tube) Installation

8. Remove dust caps of new column assembly. Make sure there is no dust or debris where the dust caps were located.



Inogen One® G4 Column Change Procedure (continued)

9. Insert column assembly into the Inogen One® G4 concentrator. Do not leave the column ends exposed; column assembly should be inserted into the Inogen One® G4 as soon as the dust caps have been removed.



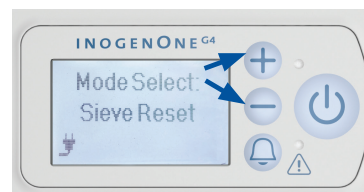
10. Push the column assembly into the device such that the columns are fully seated into the Inogen One® G4 concentrator. The spring loaded latch button should fully return to the closed position.


Closed and locked



11. Connect the AC power supply cord to the Inogen One® G4 and plug the power supply AC cord into an electrical outlet. Do Not Power on the Inogen One® G4 concentrator.

12. Press and hold the plus (+) and (-) minus button for 5 seconds. The screen will display “sieve reset” message. Release button once message is displayed on screen.



13. Press the alert  button once and screen will display “sieve reset success”.

14. Press the power  button to turn on the Inogen One® G4, and use normally.



15. If you are using Inogen Connect App, navigate to the Advanced screen, then to Additional Information screen and click on the Column Reset button.

Other Service and Maintenance



WARNING Do not disassemble the Inogen One® G4 or any of the accessories or attempt any maintenance other than tasks described in this user manual; disassembly creates a hazard of electrical shock and will void your warranty. Do not remove the tamper evident label. For events other than those described in this manual, contact your equipment provider for servicing by authorized personnel.

CAUTION Do not use lubricants on the Inogen One® G4 or its accessories.



WARNING Do not perform maintenance on the device while it is in use.

Disposal of Equipment and Accessories

Follow your local governing ordinances for disposal and recycling of the Inogen One® G4 and accessories. If WEEE regulations apply, do not dispose of in unsorted municipal waste. Within Europe, contact the EU Authorized Representative for disposal instructions. The battery contains lithium ion cells and should be recycled. The battery must not be incinerated.

Maintenance Items List

- Inogen One® G4 single battery (model # BA- 400)
- Inogen One® G4 double battery (model # BA- 408)
- Replacement intake particle filters (model # RP- 405)
- Output Filter Replacement Kit (model # RP-404)
- Inogen One® G4 columns (model # RP-406)








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

























WARNING It is the responsibility of the patient to use only parts and accessories mentioned in these instructions for use. Parts and accessories used by the patient not recommended in these instructions for use are at the sole responsibility for the patient. Inogen assumes no liability for use of parts and accessories not mentioned in these instructions for use.

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Symbols Used On Concentrator and Accessories

Symbol	Meaning
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.
	See User Manual for Instructions.
R _{ONLY}	U.S. Federal Regulation Restricts this Device to Sale by Order of Physician. May also be applicable in other Countries.
	AC Power
	DC Power
	No Smoking while device is in use.
	No Open Flames (Concentrator); Do not incinerate (Battery).
	Refer to instruction manual/booklet.
	Manufacturer

Symbol	Meaning
	Authorized Representative in the European Community
	Keep Dry
	Indoor or Dry Location Use Only, Do Not Get Wet
	Use No Oil or Grease
	Do Not Disassemble (contact your equipment provider for servicing by authorized personnel)
	Do Not Dispose of In Unsorted Municipal Waste
	Class II Device
	Electrical Safety Agency Certification Logo
	Complies With Applicable EU Directives Including Medical Device Directive
	UK Declaration of Conformity
	Importer
	Medical device
	Indicates the range of humidity to which the medical device can be safely exposed
	Date of Manufacture

Symbol	Meaning
	CH Authorized Representative
	Indicates not for use in MRI environment
	Unique Device Identification
	Serial Number
	Catalog Number
	Indicates the maximum and minimum temperature limits at which the item shall be stored, transported or used.
	Atmospheric pressure limitation to which the medical device can be safely exposed (operating)
	Type BF Applied Part

User Interface Label

Symbol	Meaning
	ON / OFF Button
	Increase Flow Setting
	Decrease Flow Setting
	Audible Alert Button

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Inogen One® G4 System Specifications

Inogen One® G4 Concentrator

Dimensions: With single battery	L / W / H : 5.91 in. (15.01 cm.) / 2.68 in. (6.8 cm.) / 6.5 in. (16.3 cm.) L / W / H : 5.91 in. (15.01 cm.) / 2.68 in. (6.8 cm.) / 7.2 in. (18.2 cm.)
Weight:	2.8 pounds (1.27 Kg.) (includes single battery)
Noise:	40 dBA (on setting 2)
Warm-Up Time:	2 minutes
Oxygen Concentration:	90% - 3% /+ 6% at all settings
Flow Control Settings:	3 settings: 1 to 3
Power: AC Power Supply:	AC Input: 100 to 240 VAC 50 to 60 Hz Auto-Sensing: 1.0A
DC Power Cable: Rechargeable Battery:	DC Input: 13.5-15.5VDC, 10A Max. Voltage: 12.0 to 16.8 VDC
Battery Duration*:	Up to 2.7 hours with single battery Up to 5 hours with double battery
Battery Charging Time:	Up to 3 hours for a single battery Up to 5 hours for a double battery
Environmental Ranges Intended for Use:	Temperature: 41 to 104°F (5 to 40°C) Humidity: 0% to 95%, non-condensing Altitude: 0 to 10,000 ft (0 to 3048 meters)
Environmental Ranges Intended for Shipping and Storage:	Temperature: -13 to 158°F (-25 to 70°C) Humidity: 0% to 95%, non-condensing Store in a dry environment
Transportation:	Keep Dry, Handle With Care
Tested by Independent Laboratory:	Safety: IEC 60601-1 CAN/CSA C22.2 No. 60601-1 Electromagnetic Compatibility: IEC 60601-1-2, RTCA DO 160

*Battery time varies with flow setting and environmental conditions.

Contains Transmitter Module IC: 12246A-BM71S2. Contains FCC ID: A8TBM71S2
This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: IT-network is a system composed of wireless (Bluetooth) transmission between the Inogen One® G4 and the Inogen Connect Application.

- Connection of the Inogen One® G4 to an IT-Network could result in previously unidentified risks to patients, operators or third parties.
- Subsequent changes to the IT-network could introduce new risks and require additional analysis
- Changes to the IT-network include:
 - Changes in the IT-network configuration;
 - Connection of additional items to the IT-network
 - Disconnecting items from the IT-network
 - Updating equipment connected to the IT-network


Classifications

Mode of Operation:	Continuous Duty
Type of Protection Against Electrical Shock:	Class II
Degree of Protection to Concentrator Components Against Electrical Shock:	Type BF Not intended for cardiac application
Degree of Protection to Concentrator Components Against Ingress of Water:	IP22 - Vertically dripping water shall have no harmful effect & protect against ingress of solid objects ≥ 12.5 mm. diameter when the enclosure is tilted at an angle up to 15° from its normal position*
Degree of Safety for Application in Presence of Anesthetic Gases:	Not suitable for such application

*Normal position of the Inogen One® G4 is upright with the user interface display facing upward.

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	<p>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.</p> <p>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</p> <p>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).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>
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 $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters 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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