

INOGENONE®G3 USER MANUAL







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1

Intended Use, Contraindications and General Precautions

Intended Use

The Inogen One® G₃ 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 One® G₃ may be used in home, institution, vehicle, on an airplane and various mobile environments.

The expected life for the Inogen One® G₃ 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.

| | 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 | Use of a cannula other than a high flow cannula (e.g. Salter 1600Q) may restrict oxygen delivery and/or attachment to nozzle fittings. |
| | | |
| <u>(i</u> | 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. |
| | | |

Contraindications

| <u> </u> | WARNING | This device is NOT INTENDED to be life sustaining or life supporting. |
|----------|---------|---|
| | 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 alarms or communicate discomfort. If the patient shows any signs of discomfort, a physician should be consulted immediately. |
| | CAUTION | The Inogen One® G3 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® G3 Concentrator. Any modifications performed on the equipment may impair performance or damage equipment and will void your warranty. |

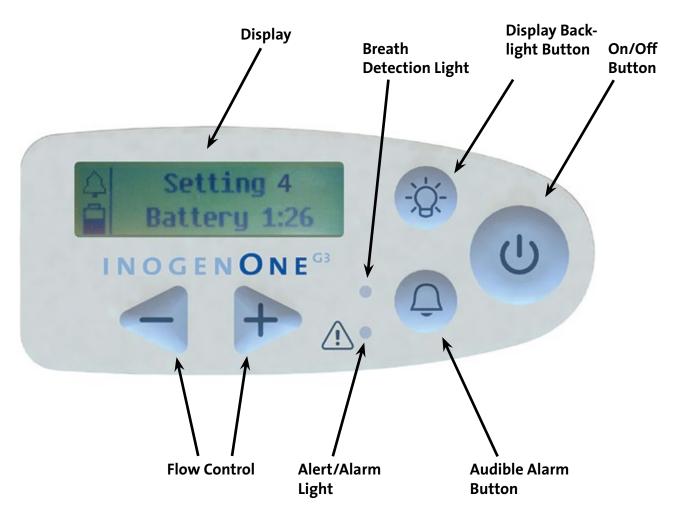
General Precautions

| 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 submerse the Inogen One® G ₃ 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® G3. |
| CAUTION | Never leave the Inogen One® G ₃ in an environment which can reach high temperatures, such as an unoccupied car in high temperature environments. This could damage the device. |

2

Description of the Inogen One® G₃ Oxygen Concentrator

Important Parts of the Inogen One® G₃ Oxygen Concentrator



Description of the Inogen One® G₃ Oxygen Concentrator Chapter 2

User Controls

ON / OFF Button

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

(U)

Audible Alarm Button

Pressing this button will toggle the Inogen One® G3's breath detection audible alert on and off:

- 1. Default Mode. When the Inogen One® G3 is powered up, the breath detection audible alert is disabled. The display's mode indication area will show a bell icon crossed out with an X in default mode.
- 2. Breath Detection Alert Mode. The Inogen One® G3 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 red light and display message when the alert is enabled.
- 3. If power is lost, breath detection alert mode resets to default mode.



Flow Setting Control Buttons

Use the – or + flow setting control buttons to select the setting as shown on the display. There are four settings, from 1 to 4.



Display Backlight Button

Push on; automatically turns off after 10 seconds.



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 Inogen Client Services.



User Interfaces (continued)

Indicator Lights

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

Input / Output Connections

Particle Filters

The filters 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® G3 output of oxygenated air.



DC Power In

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



USB Port

Used for servicing only.



Power Supply Options

Single and Double Rechargeable Lithium Ion Batteries

The battery will power the Inogen One® G3 without connection to an external power source. When fully charged, a single battery will provide up to 4 hours of operation; a double battery will provide up to 8 hours of operation. The battery recharges when properly installed in the Inogen One® G3 and the concentrator is connected



to AC or DC power. Recharging time is up to 4 hours for a single battery and 8 hours for a double battery. See information in the "Battery Care and Maintenance" section.

Power Supply

Overview

The Inogen One® G₃ AC power supply (BA-301) is used to power the Inogen One® G₃ concentrator from an AC power source.

Description

The Inogen One® G₃ AC power supply is specifically designed for use with the Inogen One® G₃ Oxygen Concentrator (IO-300). The AC power supply provides the precise current and voltage required to safely power the Inogen One® G₃ 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.

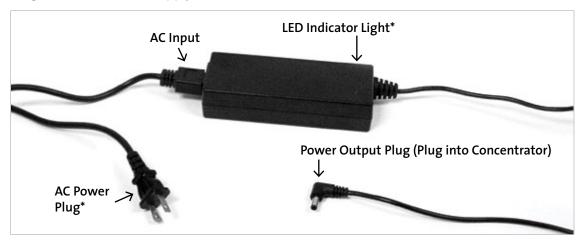
The AC power supply will charge the Inogen One® G₃ Batteries when used with AC input power. Due to aircraft power limitations, the AC Power Supply cannot be used to charge the Inogen One® G₃ Battery when used on an aircraft.

The AC power supply is used with the following components:

- Power supply with attached power output cable to connect to the Inogen One® G3
- AC power input cable

The DC power cable (BA-306) is specifically designed for use with the Inogen One® G3 Oxygen Concentrator (IO-300). 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-301



Inogen One G₃ DC Power Cable Model# BA-306



* Actual product appearance may vary.



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. Keep children and pets away from cord. Doing so may lead to damaged cords and a failure to provide power to the concentrator.

Inogen One® G₃ 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® G₃ 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 | children and pets. |
|----|---------|--|
| | | |
| | NOTE | Increasing the cannula length may reduce the perceived noise during oxygen bolus delivery. |
| | | |
| | NOTE | When using a cannula arff in length with the Inogen One® Ga an increase in |

Carry Bag (CA-300)

The Carry Bag provides a protective cover with a handle and adjustable shoulder strap to enable you to carry the Inogen One® G3. The Inogen One® G3 can be operated using battery power during transport with the Carry Bag. The carry bag is designed so that the Inogen One® G3 Concentrator is loaded into the carry bag from the bottom of the bag. The expandable zippered bottom is designed with an adjustable zipper for use with a single or double battery and easy access for changing battery. The expandable section is not intended for use as a storage compartment.

flow setting may be required.



Inogen One® G₃ Optional Accessory

External Battery Charger (BA-303)

- 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 G₃ 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. |

Inogen One G₃ Backpack

Alternative/optional way of carrying your Inogen One® G₃, hands free, more comfort, out of your way with extra pockets for additional accessories.

To order please call Inogen Client Services.





Operating Instructions

General Instructions

1. Place the Inogen One® G3 in a well ventilated location. Air intake and exhaust must have clear access. Locate the Inogen One® G₃ in such a way that any auditory alarms may be heard.



WARNING Avoid use of the Inogen One® G₃ in presence of pollutants, smoke or fumes. Do not use the Inogen One® G3 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.

2. Ensure both particle filters are in place.

CAUTION

Do not operate the Inogen One® G3 without both particle filters in place. Particles drawn into the system may damage the equipment.



3. Install the battery.

Insert the Inogen One® G₃ battery by sliding battery into place until the latch returns to the upper position.





Operating Instructions Chapter 3

| CAUTION | The Inogen One® G ₃ 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® G3 from an AC or DC external power supply, a |
| | properly inserted Inogen One® G ₃ battery should be maintained in the unit. |
| | This procedure will ensure uninterrupted operation and will operate all |
| | alarms 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® G3. 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® G3. 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® G3.

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® G₃ 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® G3 has been stored in extremely cold temperatures.



7. Set the Inogen One® G₃ Concentrator to the flow rate prescribed by your physician or clinician.

Use the + or – setting buttons to adjust the Inogen One® G3 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® G3 will sense the onset of inhalation and deliver a burst of oxygen at a precise time when you inhale. The Inogen One® G3 will sense each breath and continue to deliver oxygen in this manner. As your breathing rate changes, the Inogen One® G3 will sense these changes and deliver oxygen only as you need it. At times, if you inhale very quickly between breaths the Inogen One® G3 may ignore one of the breaths, giving the appearance of a missed breath. This may be normal as the Inogen One® G3 senses and monitors the changes in your breathing pattern. The Inogen One® G3 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.

| 1 | WARNING |
|----------|---------|
| | |

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

CAUTION

The Inogen One® G₃ is designed to provide a flow of high purity oxygen. An advisory alarm, "Oxygen Low", will inform you if oxygen concentration drops. If alarm 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).

CAUTION

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

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.
- Connect the AC power plug to the power source and connect the power output plug to the Inogen One® G3. The green LED will be illuminated, indicating the power supply has input power.

Traveling with your Inogen One® G₃ System

The Inogen One® G3 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® G3 at home. Here are some useful and important instructions for maximizing performance and convenience when using your Inogen One® G3 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® G₃.
- 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.

| <u>.</u> ! | WARNING | Ensure that the automobile power socket is adequately fused for the Inogen One® G3 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. |
|------------|---------|---|
| <u>[</u> | 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® G ₃ 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 FAA allows the Inogen One® G₃ onboard all U.S. aircraft, here are a few points to make air travel easy.

Planning Your Flight

When flying with the Inogen One® G₃, you must inform the airline that you will be using your Inogen One® G₃ onboard the aircraft. You must also keep a signed statement from your physician with you that includes:

- Your ability to see/hear alarms and appropriately respond.
- When oxygen use is necessary (all or a portion of the trip).
- Maximum flow rate corresponding to the pressure in the cabin under normal operating conditions.
- A new statement will not be necessary each time you fly, but the statement should be available during every flight.
- 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® G3. 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 the duration of your flight, plus a conservative estimate of unanticipated delays.
- 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 such as Magellan's Em Power Socket Connector Item #EA270.

Before Your Flight

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

- Ensure your Inogen One® G₃ 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® G3 for the 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, you will need sufficient battery power for the duration of the flight, plus a conservative estimate of unanticipated delays.

CAUTION Airlines may not be equipped to provide backup oxygen.

• Arrive at the airport early. Airport security screening personnel may require extra time to inspect your Inogen One® G3.

- 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® G₃ from an electrical outlet in the airport terminal if available.
- You should inform the airline you will be using your Inogen One® G3. Have your physician letter with you and ready for inspection if requested.

During Your Flight

- 1. If using airline power port, remove the Battery from the Inogen One® G₃ Oxygen Concentrator. Due to aircraft power limitations, the AC Power Supply cannot be used to charge the Inogen One® G₃ 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® G3 under the seat in front of you. Your Inogen One® G3 will fit upright under most airline seats. However, if it doesn't fit you may turn it on its side with vents facing up.
- It is not necessary to turn off your Inogen One® G3 during taxi, takeoff and landing if your physician's written statement requires you receive oxygen during these periods.

CAUTION

A change in altitude (for example, from sea level to mountains) may affect total oxygen available to the patient. The Inogen One® G3 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® G₃ from its power source. While the Inogen One® G₃ 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® G3 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® G3 (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® G₃ is being powered by the AC power supply or DC power, batteries will charge during operation. Leaving your Inogen One® G3 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® G₃ Lithium Ion Battery requires special care to ensure proper performance and long life. Use only Inogen One® G3 Batteries with your Inogen One® G3 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® G3 single battery powers the Inogen One® G3 Concentrator up to 4 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

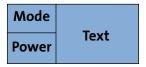
The Inogen One® G3 continuously displays battery time remaining. This displayed time is only an estimate and the actual time remaining may vary from this value.

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.

4

Inogen One® G3 Oxygen Concentrator Audible and Visible Signals



Display Icons

The Inogen One® G3 display is divided into three areas. The upper left corner of the display shows the breath detection alert status. The lower left corner indicates power source and battery charge level. The right side of the display contains text information, such as flow setting, battery time remaining and error notifications.

Power Status Icons

These icons are examples of those shown in the display's power status window when the Inogen One® G₃ is operating on battery power.

| lcon | 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 icons below are examples of those shown when the Inogen One® G₃ is operating from an external power supply and charging the battery. The lightning bolt indicates that an external power supply is connected.

| Icon | Meaning | |
|----------|--|--|
| 3 | Battery is charging with charge level between 60% and 70%. | |
| Ŧ | The battery is fully charged and is charging as necessary to maintain its charge. | |
| Z | Battery is charging with charge level less than 10%. | |
| # | The Inogen One® G3 is operating from an external power source with no battery present. | |

Mode Icons

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

| lcon | Meaning |
|------|--|
| | The breath detection audible alarm has been enabled. |
| | The breath detection audible alarm is disabled. This is the default condition. |

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 |
|--|---|
| ınogen | The Inogen logo is displayed at startup. |
| 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® G3 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.

The following notification messages are accompanied by a **single**, **short beep**.

| Message Display & Text | Condition/Action/Explanation |
|------------------------------|--|
| Inogen One® Shutting Down | On/Off button has been pressed for two seconds. Concentrator is performing system shut down. |
| HH:MM Vx.x:Serial Number | Audible Alarm 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 red 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. |
| O2 Service Soon | Column maintenance is required within 30 days. Press and hold the light button for 3 seconds to clear message from display. The message will be silenced for 72 hours. 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 See Manual | 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® G3. If the problem still persists, contact your equipment provider. |
| Comm Error See Manual | Concentrator is producing oxygen but cannot report battery status. Replace battery. If condition persists, contact your equipment provider. |
| Service Needed | 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. |
| O2 Sensor Fail See Manual | 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 red 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 Service Needed | 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. |
| System Error See Manual | Concentrator is experiencing an error but is capable of continued operation. Remove and re-insert battery and/ or check external power supply connections. If condition persists, contact your equipment provider. |
| 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. |

High Priority Alerts

CAUTION

If you are not near the Inogen One® G3 you may not be able to hear or see the high priority alerts. Make sure the Inogen One® G3 is in a location where the alerts and alarms 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 red 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 Shut Down | 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 Shut Down | 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. |

High Priority Alerts (continued)

| Message Display & Text | Condition/Action/Explanation |
|-------------------------------|--|
| System COLD Shut Down | This may result from the concentrator being stored in a cold environment (below o°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. |
| Error (###) Service Needed | Concentrator has stopped producing oxygen and is shutting down. You should: 1. Note error number 2. Switch to backup oxygen source 3. Contact your equipment provider |

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Troubleshooting

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

Inogen One® G₃ 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 | Battery is discharged or no battery is present | Use external power supply or replace battery with one that is fully charged |
| pressed | 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 |

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.

CAUTION

Use of a cannula other than a high flow cannula (e.g. Salter 1600Q) may restrict oxygen delivery and/or attachment to nozzle fittings.

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 submerse the Inogen One® G₃ 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 filters.

Filter Cleaning and Replacement

Both particle filters 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 $Dawn^{TM}$) and water; rinse in water and dry before reuse.



NOTE

It may be necessary to clean the particle filters 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® G3 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 owner using the Output Filter Replacement Kit (RP-107).

The Inogen One G₃ 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 G₃. 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® G₃ Column Change Procedure

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

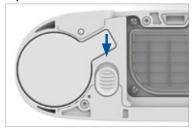
- 1. Turn off the Inogen One® G3 concentrator by pressing the power button to shut down the device.
- 2. Remove the Inogen One® G3 concentrator from the carry bag.
- 3. Remove the battery from the Inogen One® G3 concentrator.
- 4. Turn Inogen One® G3 over so that is standing in the upside down position where the display panel is facing down and the bottom of the Inogen One® G3 is facing up.
- 5. There are two columns (metal tubes) on the Inogen One® G3 concentrator and one is located on each side of the device.



Inogen One® G3 Column Change Procedure (continued)

6. Remove column by pressing the latch button with thumb or finger.

Open and unlocked



7. While holding the button open, slide the column (metal tube) out by gripping the exposed aluminum surface with other hand.



8. Remove the column (metal tube) completely from the Inogen One® G₃.



9. Repeat steps 6-8 to remove the other column (metal tube).

Column (metal tube) Installation

10. Remove dust caps of new column (metal tube). Make sure there is no dust or debris where the dust caps were located.



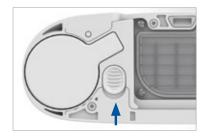
Inogen One® G3 Column Change Procedure (continued)

11. Insert column (metal tube) into the Inogen One® G3 concentrator. Do not leave the column exposed; it should be inserted into the Inogen One G3 as soon as the dust caps have been removed.



- 12. Push the column (metal tube) into the device such that the column (metal tube) is fully seated into the Inogen One® G3 concentrator. The spring loaded latch button should fully return to the closed position.
- 13. Repeat steps 10-12 to install the other column (metal tube).
- 14. Connect the AC power supply cord to the Inogen One® G₃ and plug the power supply AC cord into an electrical outlet. Do Not Power on the Inogen One® G₃ concentrator.
- 15. Press and hold the light button for 10 seconds and screen will display "sieve reset" message. Release button once message is displayed on screen.

Closed and locked





- 16. Press the bell button once and screen will display "sieve reset successful".
- 17. Press the power w button to turn on the Inogen One® G3, and use normally.

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.

Other Service and Maintenance

WARNING

Do not disassemble the Inogen One® G3 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® G₃ or its accessories.

Disposal of Equipment and Accessories

Follow your local governing ordinances for disposal and recycling of the Inogen One® G3 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® G3 single battery (model # BA- 300)
- Inogen One® G₃ double battery (model # BA- 316)
- Replacement intake particle filters (model # RP- 300)
- Output Filter Replacement Kit (model # RP-107)
- Inogen One® G3 columns (model # RP-320)

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

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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. |
| Ronly | 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. |
| Ti 🛄 | |

| Symbol | Meaning |
|------------|--|
| T | Keep Dry |
| | Indoor or Dry Location Use Only, Do Not Get Wet |
| | Use No Oil or Grease |
| 8 | Do Not Disassemble (contact your equipment provider for servicing by authorized personnel) |
| X | Do Not Dispose of In Unsorted Municipal Waste |
| † | Type BF Applied Part, Not Intended for Cardiac Application |
| | Class II Device |
| ⊕ ® | Electrical Safety Agency Certification Logo |
| CE | Complies With Applicable EU Directives Including Medical Device Directive |

User Interface Label

| Symbol | Meaning |
|--------|--------------------------|
| U | ON / OFF Button |
| | Display Backlight Button |
| + | Increase Flow Setting |
| 4 | Decrease Flow Setting |
| Q | Audible Alarm Button |

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Inogen One® G3 System Specifications

Inogen One® G₃ Concentrator

| Dimensions: | L / W / H: 8.75 in. (22.2 cm.) / 3.0 in. (7.6 cm.) / 7.25 in. (18.4 cm.) | | |
|---|--|--|--|
| With single battery | L / W / H : 8.75 in. (22.2 cm.) / 3.0 in. (7.6 cm.) / 8.25 in. (21 cm.) | | |
| Weight: | 4.8 pounds (2.2 Kg.) (includes single battery) | | |
| Noise: | Less than 42dBA (as packaged) on setting 2 | | |
| Warm-Up Time: | 2 minutes | | |
| Oxygen Concentration: | 90% - 3% /+ 6% at all settings | | |
| Flow Control Settings: | 4 settings: 1 to 4 | | |
| 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 4 hours with single battery Up to 8 hours with double battery | | |
| Battery Charging Time: | Up to 4 hours for a single battery Up to 8 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 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 | | |

Inogen One® G₃ Concentrator (continued)

| Tested by Independent | Safety: IEC 60601-1 |
|-----------------------|--------------------------------|
| Laboratory: | CAN/CSA C22.2 No. 60601-1 |
| | Electromagnetic Compatibility: |
| | IEC 60601-1-2 |
| | RTCA DO 160 |

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 While Used Outside of Carry Bag: | IP20 - Not protected from dripping water. Protected against ingress of solid objects ≥ 12.5 mm. |
| Degree of Protection to Concentrator Components Against Ingress of Water While Used Inside of Carry Bag: | 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 Protection to Concentrator Exterior Provided by the Carry Bag: | IPo2 - Vertically dripping water shall have no harmful effect 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 |

ELECTROMAGNETIC COMPATIBILITY

This CE Marked equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC [EN 55011 Class B and EN 60601-1-2]. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Inogen One® G₃ Oxygen Concentrator is intended for use in the electromagnetic environment specified below. The customer or the user of the Inogen One® G₃ Oxygen Concentrator should assure that it is used in such an environment.

| Emissions Test | Compliance | Electromagnetic Environment - Guidance |
|--|------------|---|
| RF emissions CISPR 11 | Group 1 | The Inogen One® G3 Oxygen 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 Inogen One® G3 Oxygen Concentrator is suitable for use in all |
| Harmonic Emissions IEC 61000-3-2 | Class A | establishments, including domestic establishments and those directly |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | Complies | connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |

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

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Inogen One® G3 Oxygen Concentrator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this Inogen One® G3 Oxygen Concentrator as recommended below, according to the maximum output power of the communications equipment.

| Rated Maximum Power | Separation Distance According to Frequency of Transmitter (M) | | | |
|---------------------------|---|------------------------------|-------------------------------|--|
| Output of Transmitter (W) | 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. |