I N O G E N O N E





Introduction

Introduction

This Owner Manual will familiarize you with the Inogen One Oxygen Concentrator and its accessories. Be sure to thoroughly read all of the information in this manual in its entirety.

Application

This Manual applies to the following Inogen, Inc. products:

Inogen One Oxygen Concentrator, model # IO-100 AC Power Supply, model # BA-101 Mobile Power Charger, model # BA-106 Inogen One Battery, model # BA-100 Inogen One Carry Bag, model # CA-102 Inogen One Cart and Carry Bag, model # CA-100 * Satellite Conserver, model # SC-100 * External Battery Charger, model # BA-103

* Additional Accessories

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Intended Use, Contraindications and General Precautions

Intended Use

The Inogen One 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 may be used in home, institution, vehicle and various mobile environments.

	CAUTION	JTION USA Federal law restricts this device to sale by or on the order of a physician. May also be applicable in other countries.		
<u>^</u>	WARNING	Availability of an alternate source of oxygen is recommended in case of power outage or mechanical failure. Consult your physician for type of back-up system required.		
<u>\</u>	WARNING	Flow setting selection is relative to physician prescription. Inogen has labeled each of the five settings (1-5) to provide a guideline for matching the setting of the device to the continuous flow oxygen prescription issued by the physician. Actual correlation is dependent upon the patient's breathing rates, inspiratory tidal volume, and other physiologic factors. Inogen suggests that prior to use, you be evaluated by your physician or clinician to determine the ideal setting.		
	NOTE	It is the responsibility of the patient and/or provider to make back-up arrangements for alternative oxygen supply when traveling; Inogen assumes no liability for persons choosing not to adhere to manufacturer recommendations.		

NOTE Comments regarding use in pediatric oxygen applications. The Inogen One is cleared for use by all patients meeting the general indications for use. The term "pediatric use" is broad and may define a diverse population of patients ranging from very small and low weight infants to larger adolescents.

> All oxygen patients, including pediatric patients, using the Inogen One must be capable of tolerating and receiving oxygen as delivered by the Inogen One oxygen conserver. The device setting, type of cannula used and the patient's respiratory rate will affect oxygen delivery; therefore it is prudent to be evaluated by your physician before using the Inogen One.

Contraindications

$\overline{\mathbf{N}}$	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 is not designed or specified to be used with a humidifier or nebulizer. Use of this device with a humidifier or nebulizer may impair performance and/or damage the equipment.
	CAUTION	The Inogen One is designed to provide a flow of high purity oxygen. Patients with a fast breathing rate, requiring high oxygen flow, may require more oxygen than the Inogen One can produce, and therefore may not be suited for the Inogen One.

General Precautions

WARNING	Comments regarding transtracheal catheter applications.
	The use of the Inogen One in conjunction with any oxygen delivery other
	than a nasal cannula has not been validated. Inogen currently has no clinical or technical data supporting the use of the Inogen One with TTO
	catheters.

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 or any of the accessories in liquid. Do not expose to water or precipitation. Do not operate in 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.

CAUTION Never leave the Inogen One 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 Oxygen Concentrator Important Parts of the Inogen One Oxygen Concentrator



User Controls

CAUTION	The user controls on the Inogen One are specifically designed to be pressed by a finger. Never press any of the buttons with a pen, screwdriver, stylus, or any other object.

NOTE	Pressing the buttons with any hard, sharp and/or small object can
	damage the user controls.

ON / OFF Button

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

Mode Button

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

- 1. Default Mode. When the Inogen One is powered up, the breath detection alert is disabled. The display's mode indication area is empty in Default Mode.
- 2. Breath Detection Alert Mode. The Inogen One 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.

The display's mode indication area will show a bell icon when the alert is enabled.

Pressing and holding the button for five seconds will display the Inogen One life clock.

Flow Setting Control Buttons

Use the up and down flow setting control buttons to select the setting as shown on the display. There are five settings, from 1 to 5. A sixth setting, "Satellite", may be enabled if you have a Satellite Conserver. The Satellite Flow setting is designed to be used only with the Inogen Satellite Conserver. Contact your equipment provider if you have a Satellite Conserver and wish to enable the Satellite setting.

Display Backlight Button

Push on; automatically turns off.







ON / OFF

IN E

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.

Indicator Lights

Colored lights indicate either a change in operating status or a condition that may need response (alarm). Priority by color is red, yellow, then green. 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 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 output of oxygenated air.

DC Power In

Connection for DC power connection from the AC Power Supply or Mobile Power Charger.











Infrared Data Port

Stored operation data can be transmitted to an external infrared communications port (located within the ratings label) by service personnel. This feature is not intended for patient use.

Power Supply Options

Inogen One AC Power Supply

The AC Power Supply enables the Inogen One to be connected to a normal U.S. standard (110V) electrical outlet (globally compatible: 100 to 240V, 50 to 60Hz with appropriate foreign outlet adapter). The Power Supply senses the AC electrical current and converts it into DC voltage, which powers the concentrator. When the Inogen One is connected to AC power, the battery will charge.

Rechargeable Lithium Ion Battery

The battery will power the Inogen One without connection to an external power source. When fully charged, the battery will provide 2 to 3 hours of operation. The battery recharges when properly installed in the Inogen One and the concentrator is connected to AC power. Recharging time is approximately 3 hours. See information in the "Battery Care and Maintenance" section. The battery can also be recharged using the External Battery Charger.

Mobile Power Charger

The Mobile Power Charger enables the Inogen One to be operated in an automobile or other vehicle with a DC output or a cigarette lighter adapter. The Mobile Power Charger supplies 18VDC power to operate the concentrator and to charge the onboard battery. When the Inogen One is connected to DC power, the battery will charge. See additional instructions included in the System for using the Mobile Power Charger.









WARNING Do not use power supplies/adapters or accessories other than those specified in this Owner 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 to provide oxygen from the concentrator. A single lumen cannula seven feet in length or less must be used to ensure proper breath detection and oxygen delivery.



Carry Bag

The Carry Bag provides a protective cover and shoulder strap to enable you to carry the Inogen One. Pockets are provided for carrying accessories. The Inogen One can be operated using battery power during transport with the Carry Bag.

Cart

The Cart has wheels and a telescoping handle to provide easy transport of the Inogen One. The Inogen One can be operated using battery power during transport.

* Actual appearance of accessories may vary.





Satellite Conserver

The Satellite Conserver enables use up to distances of 100 feet from the Inogen One Oxygen Concentrator.

External Battery Charger

The External Battery Charger allows you to charge additional batteries. This is especially useful if you are planning an extended outing away from electrical power and have more than one battery.

External Battery Charger Power Supply

The External Battery Charger Power Supply plugs into an AC outlet and powers your External Battery Charger.









WARNING Do not use the External Battery Charger Power Supply to power your Inogen One. This may create a safety hazard and/or impair equipment performance.

* Accessories included in your system may vary.

3

Operating Instructions

General Instructions

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



<u>î </u>	WARNING	Avoid use of the Inogen One in presence of pollutants, smoke or fumes. Do not use the Inogen One in presence of flammable anesthetics, cleaning agents or other chemical vapors.
	CAUTION	Do not operate in temperatures below 41°F (5°C) or above 104°F (40°C) for extended amounts of time.
	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	Be aware that electrical cord and/or tubing on the floor could present a tripping hazard.
	NOTE	It is recommended the Inogen One be used in an upright position whenever possible.

- 2. Ensure the particle filter is in place.
- **CAUTION** Do not operate the Inogen One without the particle filter in place. Particles drawn into the system may damage the equipment.
- **CAUTION** The particle filter is placed ONLY in the front end of the Inogen One where air is drawn into the unit. Do not place a filter in the other end of the unit; this will restrict exhaust and may lead to overheating.



3. Install the battery.

Open the battery door and insert the Inogen One Battery with the handle of the battery up. Press firmly to make sure the battery is in the correct position. Close the battery door.

CAUTION The Inogen One 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 from an AC or DC external power supply, a properly inserted Inogen One 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.

CAUTION Do not put hand or foreign objects into the battery well.

NOTE The battery requires an initial AC charging of 3 hours to condition the battery. Do not run the Inogen One on battery power alone until this initial charging has been completed.

4. Connect the AC Power Supply.

Connect the AC Power Cord to the AC Power Supply. Connect the AC Power Supply to the Inogen One. Plug into a nearby AC outlet. (A beep will sound.)





CAUTION Do not place anything in the AC Power Supply port other than the supplied wall cord. Avoid the use of electrical extension cords with the Inogen One. 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 When the AC 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 next to the handle of the Inogen One. Use only a single lumen cannula with a length of 7 feet or less.

CAUTION	To ensure oxygen flow, ensure that the nasal can-
	nula 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.

CAUTION To ensure proper breath detection and oxygen delivery, do not use additional tubing length exceeding 7 feet.

6. Turn on your Inogen One 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 30 minutes will initiate. During this time period the oxygen concentration is building to, but may not have reached, specification. However, the Inogen One can and should be used immediately. Additional warm up time may be needed if your Inogen One has been stored in extremely cold temperatures.







NOTE	Following a change in flow setting, the concentrator will adjust to the new conditions. Alerts and some error messages will be temporarily disabled. Continue to use the Inogen One normally.
NOTE	When the Inogen One is turned on, it will be set to the same flow setting that it was in when it was turned off. However, if the Inogen One was in the Satellite setting when turned off or if no setting was detected, the Inogen One will start in Setting 3 when turned on.

7. Set the Inogen One Concentrator to the flow rate prescribed by your physician. Use the up or down setting buttons to adjust the Inogen One to the desired setting. The current setting can be viewed on the display.

WARNING Flow setting selection is relative to physician prescription. Inogen has labeled each of the five settings (1-5) to provide a guideline for matching the setting of the device to the continuous flow oxygen prescription issued by the physician. Actual correlation is dependent upon the patient's breathing rates, inspiratory tidal volume, and other physiologic factors. Inogen suggests that prior to use, you be evaluated by your physician or clinician to determine the ideal setting.

CAUTION The Inogen One must not be operated in the "Satellite" flow setting without use of the Satellite Conserver. Operation at this setting without the conserver will lead to reduced oxygen concentration and a system error.

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

The Inogen One will sense the onset of inhalation and deliver a burst of oxygen at a precise time when you inhale. The Inogen One will sense each breath and continue to deliver oxygen in this manner. As your breathing rate changes, the Inogen One will sense these changes and deliver oxygen only as you need it. At times, if you inhale very quickly between breaths the Inogen One may ignore one of the breaths, giving the appearance of a missed breath. This may be normal as the Inogen One senses and monitors the changes in your breathing pattern. The Inogen One 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 Inhale through your nose for the concentrator to work most effectively. Inhaling through your mouth may result in less effective oxygen therapy.

CAUTION The Inogen One 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.

Additional Operating Instructions

Mobile Power Charger – for Auto/RV/Boat travel

To use the Inogen One while traveling in an automobile, plug the Mobile Power Charger into the cigarette lighter outlet or DC outlet, then plug in the Inogen One. Make sure the Inogen One is secure before operating the automobile or other vehicle.



See additional instructions included in the system for using the Mobile Power Charger.

Battery Operation

Battery operation allows you to be away from a power source (if the Inogen One is being powered by any of the external power options, a battery does not need to be installed for use).

Ensure that the battery is in place and charged. Disconnect the Inogen One from its power source. While the Inogen One 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 below 10% 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 into an AC power source
- Replace the battery with a charged battery after turning off the Inogen One (by pressing the ON/OFF button)
- Attach the Mobile Power Charger
- If the battery is drained, charge the battery or remove it from the concentrator. Leaving a deeply drained battery in the Inogen One for extended periods may cause the battery to not function properly

If the Inogen One is being powered by the AC Power Supply or Mobile Power Charger, batteries will charge during operation. Leaving your Inogen One plugged in past the 3 hour charge time will not harm the concentrator or the battery. The Inogen One battery run time in Satellite mode is similar to setting 5: approximately 2 hours.

Initial Battery Charging

The Inogen One Battery requires an initial 3 hours of uninterrupted charging from an empty state using either the Inogen One or the External Battery Charger. Do not run the Inogen One on battery power until this initial charging has been completed.

Normal Battery Charging

To ensure that your battery is properly charging, inspect that the correct AC power adapter is being used and that the adapter is properly inserted into the power outlet. Observe the display or lights that indicate charging status. Normal battery charging time is approximately 3 hours.

NOTE	Battery charging times noted above are with the concentrator not running. Add 1 to 3 hours of charging time with concentrator running depending on flow setting.
NOTE	When starting to charge a fully discharged battery, the charging process may start and stop during the first few minutes.
NOTE	Attempting to charge a battery while running the Inogen One in elevated temperatures may lead to a "Remove Battery To Cool" message on the display and termination of battery charging. This will not affect operation of the Inogen One.
NOTE	If the Inogen One has been operated on battery power only, the battery may be too hot to charge immediately. Remove the battery from the concentrator and let it cool for 10 minutes prior to charging.

Battery Run Time Management

Independence can be achieved through proper battery run time management. By combining the use of the AC Power Supply, the Mobile Power Charger, and the Inogen One Battery, you may stay away from your home almost indefinitely, when other types of devices require returning home to replace or refill the oxygen supply. You are never further from a supplemental supply of oxygen with your Inogen One than you are from a source of electric power.

As an illustration of Battery Run Time Management, imagine a day in the life of oxygen user "Mae":

Time Period	Activity	Power Source	Battery Level *
6:00-8:30 AM	Wake Up / Breakfast	AC Power Supply	100%
8:30-8:50 AM	Drive to store	Mobile Power Charger	100%
8:50-9:30 AM	Shopping	Battery Power	65%

Battery Run Time Management (continued)

Time Period	Activity	Power Source	Battery Level *
9:30-9:50 AM	Drive to friend's home	Mobile Power Charger	70%
9:50-12:00 PM	Visit with friend	AC Power Supply	100%
12:00-12:15 PM	Drive to lunch date	Mobile Power Charger	100%
12:15-1:30 PM	Leisurely lunch	Battery Power**	40%
1:30-4:00 PM	Drive to visit family	Mobile Power Charger	80%
4:00-5:00 PM	Play with grandson	Battery Power	30%
5:00-7:00 PM	Dinner with family	AC Power Supply	75%
7:00-9:00 PM	Visit with family	AC Power Supply	100%
9:00 PM - 6:00 AM	Sleep at family's house	AC Power Supply	100%
6:00-8:30 AM Wake Up / Breakfast		AC Power Supply	100%
8:30-8:50 AM	Drive to church	Mobile Power Charger	100%
8:50-10:30 AM	Church service	Battery Power	15%
10:30-1:00 PM	Drive back home	Mobile Power Charger	55%
1:00-5:00 PM	Bridge game & lunch with friends	AC Power Supply	100%
5:00-5:30 PM	Get mail & chat with neighbor outside	Battery Power	75%
5:30-6:30 PM	5:30-6:30 PM Spontaneous dinner at neighbor's home		25%
6:30 - Read & watch TV before going to bed		AC Power Supply	100%

* Assuming high power usage rate (setting 4); conservative battery level at end of time period

** Many restaurants may make AC power accessible upon request

As can be seen from the previous table, proper battery management can, in many cases, allow you to remain away from home for entire days or longer without stress or concern of running out of oxygen. Users who require lower flow settings or who carry a second charged battery may experience even greater flexibility than seen in the above example.

Travel

When traveling with the Inogen One Oxygen Concentrator, be sure to bring the AC Power Supply and the Mobile Power Charger. If you have extra Inogen One batteries or the External Battery Charger, bring those with you. It is advisable to use external power whenever it is available to keep the internal battery in the Inogen One fully charged.

Consider use of the Carry Bag and Cart for transporting the Inogen One.

CAUTION A change in altitude (for example, from sea level to mountains) may affect total oxygen available to the patient. The Inogen One 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.

Satellite Conserver

Contact your equipment provider to configure the Inogen One for use with the Satellite Conserver. The Satellite Conserver enables use of the Inogen One by placing the concentrator in one location and connecting additional lengths of tubing. Place the concentrator in the desired location and power with the AC Power Supply.

Attach the desired length of supply tubing (25 to 100 ft (7.62 m to 30.48 m)) to the hose nozzle on the Inogen One and to the "SUPPLY" hose nozzle on the Satellite Conserver. Inogen recommends that you do not use swivel connectors or extensions in your tubing while using the Satellite Conserver as this may cause a breach in pressure and cause a leak.

Attach the cannula to the "CANNULA" hose nozzle on the Satellite Conserver.





Turn the concentrator "ON" and adjust the flow control dial on the concentrator to "Satellite". Turn the Satellite Conserver "ON" by turning the rotary switch to the prescribed flow setting. A brief beep will sound and the indicator light will come on briefly.

Place the Satellite Conserver in your pocket, around your shoulder or neck with the provided strap or attach to your belt.

The light during startup indicates battery status: green if the battery is good; yellow when marginal; red when it should be immediately replaced. The light will show no light during normal operation, when the conserver is turned "OFF" or when the battery is completely dead.

If more than 30 seconds elapses between breath detections, the Satellite Conserver will produce a single beep. This may indicate a tubing connection problem.

NOTE Unlike the concentrator, the green light does not flash each time a breath is detected.

The Satellite Conserver uses a "C" size alkaline battery, which may last up to 4 weeks when used 8 hours per day. It can be replaced by turning "OFF" the conserver, sliding open the battery panel on the back of the conserver, removing the old battery and installing the new battery using the orientation shown inside the battery compartment. When it is likely that the Satellite Conserver will not be used for some time, remove the battery.

 CAUTION
 It is suggested that an extra "C" size battery is kept available for the Satellite Conserver.

 CAUTION
 Avoid using the Satellite Conserver with extended tubing lengths in

CAUTION Avoid using the Satellite Conserver with extended tubing lengths in any setting where the tubing may be unexpected to others and may present a tripping hazard.





External Battery Charger – to charge an extra battery.

Plug the External Battery Charger into an electrical outlet. A solid red light indicates that it is plugged in and is ready to begin charging. Charging time is approximately 3 hours. Slide the battery down and then firmly press into place to ensure a good connection. A flashing green light means the battery is charging. A solid green light indicates the battery is fully charged. A flashing red light indicates an error.



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 remain neuror from the External Dattery Charger remain
NOTE	to completely remove power from the External Battery Charger, remove
	the plug.

4

Inogen One Oxygen Concentrator Audible and Visible Signals

Display Icons

The Inogen One 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 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 is operating from an external power supply and charging the battery. The lightning bolt indicates that an external power supply is connected.

lcon	Meaning
F	Battery is charging with charge level between 60% and 70%.
F	The battery is fully charged and is charging as necessary to maintain its charge.
Ţ	Battery is charging with charge level less than 10%.
€	The Inogen One 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
4	The breath detection alarm has been enabled.
[blank]	The concentrator is in the standard breath detect mode, and the breath detection alert 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
inogen	The Inogen logo is displayed at startup.
Setting X (or) Satellite Battery HH:MM	Default display when operating on battery power. "X.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 (or) Satellite 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 (or) Satellite 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	Display when the concentrator is plugged in and being used to charge a battery (not being used for oxygen production).

Notifications

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 Vxx.x ########	Mode button has been pressed for five seconds. Display shows the unit life clock, the software version, and the eight digit serial number (display will revert to the default in 10 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
External Power Low	External power supply is too low to run the unit, which is running on battery power despite being plugged in. Check external power supply connections. If condition persists, contact your equipment provider.
External Power High	External power supply is too high. Check external power supply connections. If condition persists, contact your equipment provider.
Battery Low Attach Plug	Battery power is low, with less than 10% remaining. Attach external power supply or power down and insert a fully charged battery.
Battery Error See Manual	Battery error has occurred. Switch to a new battery or remove battery and operate concentrator using external power supply. If battery error recurs with same battery, stop using the battery and contact your equipment provider.
Oxygen Low See Manual	Concentrator is producing oxygen at a slightly low level (<82%). If condition persists, contact your equipment provider.

Low Priority Alerts (continued)

Message Display & Text	Condition/Action/Explanation
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 lnogen One. If the problem still persists, contact your equipment provider.
Maximum Flow Exceeded	Satellite Conserver is being used and oxygen concentration is below desired level. If shortness of breath occurs, reduce activity level or change to a backup oxygen source. If condition 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 yellow light**.

Message Display & Text	Condition/Action/Explanation
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.
No Breath Detect Check Cannula	Concentrator is not detecting a breath. Check that: cannula is connected to concentrator, there are no kinks in tubing, and cannula is positioned properly in your nose. If Satellite Conserver is attached, make sure flow control on concentrator is set to Satellite Mode. This alert may be enabled or disabled through use of the mode button.
Check Tubing Connections	Check tubing and cannula connections. Assure proper flow setting if Satellite Conserver is not being used.
System Error See Manual	Concentrator is experiencing an error, but is capable of continued operation. As soon as you are able: • Remove and re-insert battery, and/or • Check external power supply connections. If condition persists, contact your equipment provider.
Oxygen Error Service Needed	Oxygen output concentrator is below 50%. If condition persists, switch to your backup oxygen source and contact your equipment provider to arrange for service.

High Priority Alerts

CAUTION If you are not near the Inogen One you may not be able to hear or see the high priority alerts. Make sure the Inogen One 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 filter is 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 filter is 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 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.
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 Oxygen Concentrator

Problem	Possible Cause	Recommended Solution
Any problem accompanied by information on concentrator display, indicator lights, and/or audible signals.	Refer to Section 4	Refer to Section 4
Scrambled LCD Screen	External power added (plugged in) or removed (unplugged) when concentrator is starting up and "please wait" message is displayed.	Remove battery and unplug power supply from the concentrator, wait a few moments. Plug power supply into the Inogen One, re-insert battery, and then power the Inogen One on. This process may need to be repeated. If the scrambled LCD persists and becomes an annoyance, contact your equipment provider.

Inogen One Oxygen Concentrator (continued)

Problem	Possible Cause	Recommended Solution
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
	Malfunction	Contact your equipment provider
No oxygen	Concentrator is not powered on	Press On/Off button to power concentrator
	Cannula is not connected properly or is kinked or obstructed	Check cannula and its connection to concentrator nozzle

Satellite Conserver

Problem	Possible Cause	Recommended Solution
No oxygen	Inogen One is not turned on or is not set to Satellite mode	Check Inogen One settings
	Tubing or cannula is not connected properly or is kinked or obstructed	Check tubing, cannula and connections
	Battery is discharged or no battery is present	Check battery and battery connections. Replace battery if necessary
	Malfunction	Contact your equipment provider

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Cleaning, Care and Maintenance

Cannula Replacement

Your nasal cannula should be cleaned or replaced on a regular basis. Consult with your physician and/or equipment provider and/or cannula manufacturer's instructions for cleaning and replacement information. A single lumen cannula of seven feet in length or less must be used.

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 and water.

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

CAUTION Do not use cleaning agents other than those specified in this Owner Manual. Do not use alcohol, ethylene chloride or petroleum based cleaners on the cases or on the particle filters.

Filter Cleaning and Replacement

The particle filter must be cleaned at least weekly to ensure the ease of air flow. Remove filter. Clean the particle filter with a mild liquid detergent and water; rinse in water and allow to air dry before reuse.



CAUTION	The particle filter must be dry before reuse. Moisture from a wet filter will negatively impact performance of the Inogen One.
NOTE	It may be necessary to clean the particle filter more often in dusty environments

Additional particle filters are provided with the Inogen One. Contact your equipment provider if you need additional filters.

Output Filter

The output filter is intended to protect the user from inhalation of small particles in the product gas flow. The Inogen One includes an output filter, conveniently located behind the removable cannula nozzle fitting. Inogen suggests that this filter be inspected and replaced on an annual basis.

The output filter may be replaced by the equipment provider or by the owner using the Output Filter Replacement Kit (RP-107).

Other Service and Maintenance

WARNING Do not disassemble the Inogen One or any of the accessories or attempt any maintenance other than tasks described in the troubleshooting section; disassembly creates a hazard of electrical shock and will void your warranty. Do not remove 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 or its accessories.

Battery Care and Maintenance

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

Effect of Temperature on Battery Performance

The Inogen One Battery powers the Inogen One Concentrator from 2 to 3 hours under most environmental conditions. To extend the run-time of your battery, avoid running in temperatures less than $41^{\circ}F(5^{\circ}C)$ or higher than $95^{\circ}F(35^{\circ}C)$ for extended periods of time.

Battery Time Remaining Clock

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

Periodic Conditioning

Under some conditions, battery time remaining indicator may become inaccurate. To reduce this risk: fully charge the battery, then fully discharge the battery by running the concentrator on battery power (no AC) until the concentrator displays "Battery Low Attach Plug", or automatically shuts down (do not charge the battery during this discharge cycle); then completely recharge the battery on AC power using the concentrator or External Battery Charger.

Storage

CAUTION	Do not store your Inogen One or accessories in extreme temperatures,
	below -4°F (-20°C) or above 140°F (60°C).

Battery Storage

Remove your battery from the Inogen One when it is not in use to avoid inadvertent discharge. Storage of your Inogen One Battery in a cool, dry location will help to assure the longevity of your battery.

Disposal of Equipment and Accessories

Follow your local governing ordinances for disposal and recycling of the Inogen One 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 Battery (model # BA- 100)
- Replacement intake particle filters (model # RP- 100)
- Output Filter Replacement Kit (model # RP-107)

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 Owner Manual for Instructions
${ m R}_{ m only}$	U.S. Federal Regulation Restricts this Device to Sale by Order of Physician. May also be applicable in other Countries.
~	AC Power
	DC Power
\bigotimes	No Smoking while device is in use
\bigotimes	No Open Flames (Concentrator, Satellite Conserver); Do not incinerate (Battery)

Symbol	Meaning
	Keep Dry
仚	Indoor or Dry Location Use Only, Do Not Get Wet
	Use No Oil or Grease
\otimes	Do Not Disassemble
X	Do Not Dispose of In Unsorted Municipal Waste.
X	Type BF Applied Part, Not Intended for Cardiac Application
	Class II Device
S₽ °	Electrical Safety Agency Certification Logo
CE	Complies With Applicable EU Directives Including Medical Device Directive

User Interface Label

Symbol	Meaning
	ON / OFF Button
	Display Backlight Button
	Increase Flow Setting
	Decrease Flow Setting
Μ	Mode

Inogen One System Specifications

Inogen One Concentrator

Dimensions:	L / W / H : 11.6 in (29.5cm) / 6.0 in (15.2cm) / 10.7 in (27.3cm) (no handle) 11.6 in (29.5cm) / 6.0 in (15.2cm) / 12.4 in (31.5cm) (with handle)	
Weight:	Approximately 9.8 pounds (4.4kg) (includes battery)	
Noise:	Less than 4odBA (as packaged)	
Warm-Up Time:	Less than 30 minutes	
Oxygen Concentration:	90 ± 3% at all settings	
Flow Control Settings:	5 settings: 1 to 5 and one setting of "Satellite"	
Power:	AC Power Supply: Input: 100 to 240 VAC 50 to 60 Hz Output: 18 VDC, up to 90 W Mobile Power Charger: Input: 0.6- 6.0VDC Output: 19 VDC, up to 90W Rechargeable Battery: Voltage: 2.0 to 6.8 VDC	
Battery Duration:	Approximately 2 to 3 hours; Duration varies with user flow setting on battery power.	
Battery Charging Time:	Approximately 3 hours.	
Environmental Ranges Intended for Use:	Temperature: 4 to 104°F (4 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: -4 to 140°F (-20 to 60°C) Humidity: 0% to 95%, non-condensing. Store in a dry environment.	

Inogen One Concentrator (continued)

Transportation:	Keep Dry, Handle With Care
Tested by Independent Laboratory:	Safety: UL 60601 -1 CAN/CSA C22.2 No. 601 .1 -M-90 with supplement and amendment IEC 601 - : 1988 with amendments Electromagnetic Compatibility: EN 60601 - :2002, RTCA DO 160D

Classifications

Mode of Operation:	Continuous Duty
Type of Protection Against Electrical Shock:	Class II
Degree of Protection Against Electrical Shock:	Type BF Not intended for cardiac application
Degree of Protection Against Ingress of Water:	IPX1
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.

The equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- 1. Reorient or relocate the receiving device.
- 2. Increase the separation between the equipment.
- 3. Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected.
- 4. Consult Inogen or your equipment provider for assistance.

CAUTION	Portable and mobile RF communications equipment can affect medical electrical equipment.
CAUTION	Stacking or placing equipment adjacent to other devices is not recommended, where such configurations are necessary, all equipment in question should be carefully observed to ensure that EMI does not degrade performance.
CAUTION	Use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the equipment as replacement parts for internal components, may result in

increased emissions and decreased immunity of the equipment or system.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Inogen One Oxygen Concentrator is intended for use in the electromagnetic environment specified below. The customer or the user of the Inogen One 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 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 Oxygen 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	

Inogen One Oxygen Concentrator Limited Warranty Statement

INOGEN Inc. ("INOGEN") warrants that each new Inogen One Oxygen Concentrator ("Concentrator"), components for the Concentrator ("Components") and accessories and replacement parts for the Concentrator ("Accessories and Parts" and, together with the Concentrator and Components, the "Products") shall be free from defects in materials and workmanship under normal use and service and when correctly maintained for the periods shown from the date of shipment, except as provided below:

Description	Period
Concentrator	
Inogen One Oxygen Concentrator	3 years
Accessories	
Satellite Conserver	2 years
Accessories	1 year

Purchaser agrees that before this limited warranty shall become effective, Purchaser shall fully inspect each Product within two (2) days of delivery and before such Product is put to use. Purchaser also agrees to operate the Product in accordance with INOGEN's operating instructions as provided and that failure to do so shall void this limited warranty. Purchaser further agrees that any claim for breach of warranty must be made in writing promptly following the discovery of a purported defect and within the warranty period. INOGEN will not be responsible for any alleged breach of warranty, which, as a result of INOGEN's inspection, INOGEN determines to have arisen from a cause not covered by this limited warranty.

This limited warranty does not apply to: (A) normal routine service items; (B) repair or replacement of Products necessitated by misuse, abuse, accident, or repairs made by persons other than INOGEN or persons expressly authorized by INOGEN; (C) use of Components or Accessories and Parts with the Concentrator other than those expressly approved by INOGEN; (D) defects caused by the effects of normal wear and tear; (E) Acts of God, or other causes not within the control of INOGEN.

If Purchaser believes that a Product does not comply with the limited warranty stated above, Purchaser should contact the distributor, describing the problem and providing proof of the date of purchase. If directed by the distributor, Purchaser shall return the Products, freight prepaid, properly packaged in an INOGEN approved shipping container and properly identified by a Return Material Authorization Number issued by the distributor. Products returned without a Return Material Authorization Number will be refused and returned at Purchaser's expense.

The sole and exclusive remedy for any breach of this limited warranty is limited to repair or replacement of the defective Product or refund of the purchase price, at the sole discretion of INOGEN. INOGEN shall pay for shipment back to the Customer for repairs or replacements of Products under warranty. For Products returned for repair that are not covered under warranty, INOGEN's standard repair charges shall be applicable in addition to all shipping expenses.

THIS LIMITED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES OR REPRESENTATIONS, EXPRESSED, OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT. NO REPRESENTATION OR STATEMENT OF INOGEN MAY CHANGE OR ALTER THIS LIMITED WARRANTY.

INOGEN SHALL HAVE NO FURTHER LIABILITY FOR DAMAGES, LOSSES, COST OR FEES OF ANY KIND OR NATURE, WHETHER FORESEEABLE OR NOT, INCLUDING BUT NOT LIMITED TO ATTORNEY'S FEES AND CONSEQUENTIAL, GENERAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, REGARDLESS OF THE FORM OF ANY CLAIM, WHETHER IN CONTRACT, TORT OR OTHERWISE, ARISING OUT OF OR RELATED TO THE USE OF INOGEN PRODUCTS EVEN IF INOGEN HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, LOSSES, COST OR FEES. INOGEN'S LIABILITY FOR LOSS OR DAMAGES SHALL NOT EXCEED THE PURCHASE PRICE PAID FOR THE PARTICULAR PRODUCT.

Any claims for breach of this limited warranty shall be governed by California law and must be brought in a state or United States of America federal court in California.