INOGEN ONE

Technical Manual

inogen

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

- Inogen One Oxygen Concentrator, model # IO-100
- Inogen One AC Power Supply, model # BA-101
- Inogen One Lithium Ion Battery, model # BA-100
- Inogen One Satellite Conserver, model # SC-100
- Inogen One Mobile Power Charger, model # BA-106
- Inogen One External Battery Charger with Power Supply, model # BA-103

This manual will be updated periodically. The latest version may be found at: http://www.inogen.net/providerlogin

Contents

Information for Providers of the Inogen One

Thank you for choosing to provide your patients with the Inogen One. We are pleased to offer you and your patients one solution for your many oxygen needs.

This Technical Manual will familiarize you with provider-specific information regarding the Inogen One Oxygen Concentrator and accessories. Before reading this Technical Manual, *please read and review the* ***Inogen One Patient Manual*** *for directions and indications for use of the device.*

Be sure to thoroughly read all of the information in this manual in its entirety. If you have any additional questions, please see the list of contacts at the end of this Technical Manual.

Instructions included in this Technical Manual are intended to ensure that Providers instruct patients on the proper use and function of the Inogen One and its accessories. Proper care in relaying this information will not only enhance your patients' experience with the Inogen One, but will also protect the patients, prolong the life of the device, and help you avoid unnecessary service calls and complaints.

Caution and Warning Statements

You will see Warnings and Cautions throughout this Technical Manual and the Patient Manual. To ensure effective oxygen therapy and proper operation of the Inogen One Oxygen Concentrator, you should observe them carefully.

WARNING	A WARNING indicates that the personal SAFETY of the Patient may be involved. Disregarding a WARNING could result in a significant injury. Be sure that patients understand all WARNING statements.

CAUTION	A CAUTION indicates that a precaution or a service procedure must be followed. Disregarding a caution could lead to a minor injury or to damage to the equipment. Be sure that patients understand all CAUTION statements.

NOTE	A NOTE indicates specific information to improve ease of use or maintenance of the equipment.

DESIGN NOTE	A DESIGN NOTE indicates specific information regarding the design of the Inogen One and/or accessories. This information is included in this manual to provide you with a greater working understanding of the device. This information is not required to operate or maintain the Inogen One.

In many cases, Warnings and Cautions have been included in the Inogen One Patient Manual.

Inogen One System Specifications

Inogen One Concentrator

Dimensions:	L / W / H :	11.62 in. / 6.00 in. / 10.74 in. (no handle) 11.62 in. / 6.00 in. / 12.39 in. (w/ handle)	
Weight:	Approximately 9.8 pounds (includes battery)		
Noise:	Less than 40dBA (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"		
OCD Trigger Sensitivity:	0.12 cm water (12Pa)		
Power:	Inogen One:	46W (max setting, not charging) Up to 86W when charging	
	AC Power Supply:	Input:	100 to 240 VAC 50 to 60 Hz
		Output:	18 VDC, up to 90 W
	Mobile Power Charger:	Input:	10.6-16.0VDC
		Output:	18VDC, up to 90W
	Rechargeable Battery:	Voltage:	12.0 to 16.8 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: Humidity:	41 to 104˚F (5 to 40˚C) 0% to 95%, non-condensing	
Environmental Ranges Intended for Storage:	Temperature: Humidity: Store in a dry environment	-4 to 140˚F (-20 to 60˚C) 0% to 95%, non-condensing	
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 601-1:1988 with amendments	
	Electromagnetic Compatibility: EN 60601-1:2002, 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:	IPXO
Degree of Safety for Application in Presence of Anesthetic Gases:	Not suitable for such application

Satellite Conserver

Dimensions:	5.5" high x 2.9" wide x 1.3" thick
Weight:	9.0 oz. (0.56 lbs, 254g) (including battery)
Flow Control Settings:	5 settings from 1 to 5
Power:	One "C" alkaline battery
Battery Life:	Up to 4 weeks at 8 hours usage per day

External Battery Charger

Power:	AC Power Supply Input: AC Power Supply Output:	100 to 240 VAC, 50 to 60 Hz 18 VDC, 50 W
Battery Charging Time:	Approximately 3 hours	

NOTE Technical drawings and internal parts lists are available only to Inogen One Certified Service Providers. Contact Inogen about how to become an Inogen One Certified Service Provider.

Setting Up a Patient On the Inogen One

Indications for 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 Oxygen Concentrator may be used in a home, institution, vehicles and various mobile environments.

WARNING It is the responsibility of the Home Healthcare Provider, licensed Respiratory Therapist, or Physician supplying the Inogen One to the patient to ensure that the device is used in a safe and effective manner in keeping with the physician's prescription for supplemental oxygen use. While this Technical Manual and the Patient Manual are intended to support this goal, ultimate determination of the patient's safety resides with the patient's care giver.

WARNING Availability of an alternate source of oxygen is required in case of power outage or mechanical failure. Several certifying bodies for Home Healthcare Providers require back-up oxygen be available to the patient. Supplemental oxygen cylinders may satisfy these requirements.

CAUTION Oxygen demand of some patients, particularly those with high breathing rates and high flow settings, may exceed the design specifications of the Inogen One.

NOTE Inogen suggests you consider titrating the flow setting of each patient upon the initial delivery / setup to assure that the Inogen One is an appropriate oxygen delivery solution for their individual needs.

Inogen One Oxygen Delivery

The Inogen One incorporates an electronic oxygen conserving device (OCD), which delivers a predetermined bolus of oxygen in response to a patient's inspiratory trigger/demand. The unit has five oxygen delivery settings, ranging from 1 to 5. The Inogen One promotes a unique OCD technology that offers breath sensing sensitivity of - 0.12cm H_2O.

The Inogen One OCD has been calibrated and validated for use with a single lumen cannula. Inogen has tested its performance data with the Salter Labs 1600Q cannula, which is an adult cannula. Higher flow cannulas (e.g., those rated for 8 LPM or greater) are preferred as they offer less flow restriction. Low flow and small diameter cannulas may offer greater resistance to flow. Such flow resistance may impact the accuracy of the oxygen bolus volume and flow delivered by the Inogen One.

Comments Regarding Use in Pediatric Oxygen Applications

The Inogen One is cleared for use by *all* patients meeting the above noted "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. Respiratory rates, tidal volumes and inspiratory flow demand can vary greatly depending on the age, size and medical condition of the patient. Use of low flow and/or small diameter pediatric/infant cannulas may also impact bolus volume flow delivered by the Inogen One.

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 the fraction of inspired oxygen (FiO_2); therefore it is prudent to evaluate and titrate all patients for use and tolerance of any oxygen conserving device, including the Inogen One.

We strongly recommend as a good standard of clinical practice that providers ensure all patients are appropriately evaluated and titrated to determine individual tolerance and the best clinical effect.

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. Transtracheal oxygen (TTO) catheters are single lumen, very small diameter tubes (typically 9-13 cm in length and 9 french in diameter) that are surgically placed directly into the airway via stoma. The catheter tip resides inside the patient's upper airway, normally resting a few centimeters above the carina.

Inogen currently has no clinical or technical data supporting the use of the Inogen One with TTO catheters.

Using the Inogen One

Patient Set-Up. To properly set up a patient on the Inogen One System, you may need to provide:

- Extra cannulas (not included)
- Satellite Tubing – up to 100 ft. (not included)

For quick start instructions on how to configure the Inogen One System for first use, please reference the Patient Manual.

Under some conditions, particularly upon start-up of the unit and upon return to flow settings 1 through 5 from operating in satellite mode, the Inogen One may require 30-45 seconds to reset internal electronics. During this period, the conserver will not function and "Please Wait" will appear on the display. The Inogen One may require up to 30 minutes for oxygen concentration to reach full specification. The device will otherwise function normally during this period.

For further information regarding the use of the Inogen One, please consult the Patient Manual.

DESIGN NOTE	It is recommended that the Inogen One be used in an upright position whenever possible. The Inogen One employs an internal vibration isolation system which is most effective when the device is upright. This system helps to protect internal components from wear while reducing the noise and external vibration of the device. Operating the device in another orientation may lead to increased vibration which, if sustained for long periods of time, may reduce life expectancy of the Inogen One.

Selecting the Proper Flow Setting

Bolus Volume Specification

All oxygen conserving devices (OCD's) function differently, and therefore it is prudent to titrate patients for any new conserving device. Delivery timing, bolus volume, and oxygen concentration all contribute to a patient's fraction of inspired oxygen (FiO2), and therefore to the OCD's efficacy at maintaining the patient's blood oxygen saturation.

As an oxygen concentrator, the Inogen One does not contain a finite stored volume of oxygen, such as with compressed gas or liquid cryogenic systems. The Inogen One provides oxygen to the patient as long as a power source is available. However, because the oxygen is being produced as it is used, supply of oxygen is *rate-limited*. That is, delivery rate of oxygen has an upper limit, while total volume to be delivered over time is constrained only by availability of electric power. The Inogen One delivers up to 750 ml/min of 90% oxygen.

At each flow setting, the Inogen One generates a specific amount of oxygen (150ml per setting), and the on-board OCD delivers this entire product flow to the patient. The Inogen One is designed to deliver the total amount of oxygen per setting, regardless of the patient's respiratory rate. To accomplish this, slower breathing patients will receive larger boluses, and faster breathing patients will receive smaller boluses, with the net result yielding the same total volume of oxygen delivered per setting per minute.

NOTE	The audible breath detection alarm is turned off by default at each startup. Note that all other audible and visual notifications and alarms remain active at all times. Patients may elect to remove their cannula for a short period of time while leaving the concentrator running and may not want to hear the breath detection alarm during these periods. You may elect to instruct patients how to enable and disable the breath detection alarm.

DESIGN NOTE	Breath detection sensitivity is particularly important to patients who exert low inspiratory effort and may have difficulty using conserving devices. This is often exacerbated when these patients are inactive, when breathing efforts may be weaker. It may also be exacerbated when patients mouth breathe or have difficulty with nose-only inhalation. The Inogen One is equipped with a conserver technology designed to respond to very low inspiratory signals.

DESIGN NOTE Breath detection sensitivity is also important to the speed at which the conserver is able to recognize and respond to an inhalation. Many presently used breathing models indicate that only the first half of a patient's inspiratory volume reaches the lungs' alveoli, where oxygen is exchanged. These models suggest that when an oxygen bolus (or a portion of a bolus) is delivered too late in the inspiratory effort, the blood oxygenation efficacy may be reduced. Inogen's breath detection technology allows for high sensitivity and fast response.

DESIGN NOTE Because the Inogen One employs a single lumen cannula, the same tubing that transmits the inspiratory signal to the OCD delivers the oxygen to the patient. The OCD employs a very brief "Blind Time" following each bolus delivery. During the Blind Time, the OCD's breath sensing is disabled while the system resets in preparation for the next breath. Patients who are "huffing" or who breathe in quick succession (faster than 30 breaths per minute or less than 2 seconds between breaths) may not receive a bolus on every breath. The Inogen One Satellite Conserver has a similar function.

In general, the Inogen One delivers 10ml per bolus per flow setting at 15 breaths per minute (150ml/min per flow setting). The following table summarizes the bolus volumes delivered by the Inogen One OCD:

Inogen One OCD Bolus Volumes (ml)

Flow Setting	Production Rate (ml/min)	Breathing Rate (BPM) 10	15	20	25
1	150	15.0	10.0	7.5	6.0
2	300	30.0	20.0	15.0	12.0
3	450	45.0	30.0	22.5	18.0
4	600	60.0	40.0	30.0	24.0
5	750	75.0	50.0	37.5	30.0
Satellite	750				

Flow Setting Selection 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 patient use, you consider titrating each patient.

NOTE	If you do not know or you are uncertain how to perform titration on a patient, please consult a licensed Respiratory Therapist or a Physician.

Use with the Inogen Satellite Conserver

When shipped, the Inogen One is not set up for use with the Satellite Conserver. If the patient receives a Satellite Conserver, please call Inogen Customer Care at 1-877-4-Inogen (1-877-446-6436) to configure the Inogen One for use with the satellite conserver. The Inogen Satellite Conserver receives pressurized oxygen from the concentrator and is similar in function to the Inogen One OCD, sensing breaths and delivering boluses. In general, the Satellite Conserver is best employed when a user is not highly ambulatory – when the Inogen One concentrator can be left in one place for a period of time, plugged into an external source of electricity.

The concentrator, when used in this mode, generates its maximum amount of oxygen, 750ml/min. The Satellite Conserver delivers a fixed volume of 8.75ml of oxygen per breath per flow setting. For higher flow settings, and higher breathing rates, the Satellite Conserver may deliver more volume per minute than the concentrator can produce, resulting in slightly lower oxygen concentrations. In these cases, the device will continue to function normally; an alert will appear on the concentrator's display informing the user that the demand is exceeding production ("Maximum Flow Exceeded"). In this state, the oxygen concentration of the device may be reduced, but the concentrator is operating normally and may continue to be used. For many patients, the device will still meet their supplemental oxygen supply needs, but Inogen suggests you consider titrating each patient under a variety of conditions for assurance.

The following table summarizes the bolus delivery of the Inogen Satellite Conserver:

Satellite OCD Bolus Volumes (ml)					
Flow Setting	Production Rate (ml/min)	Breathing Rate (BPM) 10	15	20	25
1	750	8.8	8.8	8.8	8.8
2	750	17.5	17.5	17.5	17.5
3	750	26.3	26.3	26.3	26.3
4	750	35.0	35.0	35.0	35.0
5	750	43.8	43.8	43.8	43.8

Shaded boxes indicate combinations of settings and breathing rates at which the Satellite Conserver's delivery may exceed the production of the Inogen One. In these conditions, the oxygen concentration may be below specification.

Some patients may be sensitive to the sound of the concentrator when at home and when background noise is very low. Use of the Satellite Conserver on a long hose (25 to 100 feet) while the concentrator is placed in another room may alleviate some of this sensitivity.

NOTE	It is recommended that the Inogen One be physically located in such a manner that the audible alarms can effectively alert the user and/or a caregiver.

Selecting the Proper Breath Detect Alarm Mode

Pressing and releasing the Mode Button will toggle between enabling and disabling the breath detect alarms. A bell is shown on the display when the breath detect alarm is enabled. When the Inogen One is powered up, the breath detect alarm is disabled.

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Servicing the Inogen One

Patient Maintenance

Instruct your patient on proper maintenance of the Inogen One.

Cannula Replacement

The nasal cannula should be replaced on a regular basis. A single lumen cannula can be used. Inogen has tested its performance data with the Salter Laboratories 1600Q cannula. Higher flow cannulas (e.g., those rated for 8LPM or greater) are preferred as they offer less flow restriction.

Providers should advise patients as to the proper cleaning and replacement of cannulas.

CAUTION	Do not use cannula tubing length exceeding 7 feet total with the Inogen One or the Satellite Conserver. The breath detection system may not function properly.

Intake Filter Cleaning

Under the front (intake) vent of the Inogen One, ambient air passes through a particle filter that removes dust fragments. The intake particle filter must be cleaned at least weekly to ensure ease of air flow. This filter should be disposed of and replaced periodically. No particle filter is used at the exhaust vent, which is located above the ratings label.

Patients should understand how to properly clean the particle filter using a mild detergent (e.g., dishwashing solution, such as Dawn™) and water solution; they should be sure to rinse the filter in water and allow to air dry before reuse. Spare filters are provided with the Inogen One to enable use of the device while the filter is drying. Additional replacement filters may be obtained from Inogen. There are other types of filters inside the Inogen One that provide additional filtration. Maintenance of these filters is performed during internal servicing.

NOTE	When setting up a patient on the Inogen One, it is recommended that you observe the operating environment and instruct the patient about the negative effects of dirt and dust on device function. It may be necessary to instruct patients to clean the intake particle filter more often in dusty environments or in homes with shedding animals. In some cases, you may elect to contact or visit the patient more frequently to assure that they are properly caring for their equipment.

DESIGN NOTE	Care has been taken in the design of the Inogen One to protect the functional components from dust, particulates, and other contaminants that may enter the device. The Inogen One contains 15 filters in total. Only the intake particle filter and the product filter require field maintenance.

Surface Cleaning

Patients should understand how to clean the outside case using a cloth dampened with a solution of mild detergent (e.g., dishwashing detergent) and water.

Battery Care and Maintenance

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

DESIGN NOTE	The Inogen One Lithium Ion Battery employs smart battery technology to communicate its status and protect the battery and concentrator from potential hazards. This battery chemistry and technology is similar to that used in laptop computer and cell phone batteries.

DESIGN NOTE	The Inogen One Oxygen Concentrator adjusts its oxygen production rate to match the oxygen demand specified by the user flow setting. When the device is used in lower settings, its battery run time is extended. Additionally, at lower flow settings, the concentrator does not generate as much heat and noise, draw as much electric current from external power supplies, and many system components do not wear as quickly.

Initial 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 in order to condition the battery. Batteries may arrive partially charged, requiring less time to achieve full charge.

Patients should avoid running the Inogen One on battery power until this initial charging has been completed.

Normal Charging

The patient should understand how to ensure that the 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. Patients should be made aware that the Inogen One battery will take longer to charge when the concentrator is operating, and will take longer when operating at higher flow settings.

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 maintain maximum runtime of the battery, users should avoid running on battery in temperatures less than 40˚F (4˚C) or higher than 95˚F (35˚C) for extended periods of time.

The number of cycles that the battery will last is highly dependent upon the temperature at which the battery is charged. Inogen recommends that batteries not be charged inside of a running concentrator at ambient temperatures exceeding 85˚F (30˚C).

DESIGN NOTE	The Inogen One Battery has been cycle life tested at its maximum charge and discharge rates while held at elevated temperature. In general, the capacity of the battery gradually decreases as the number of cycles increases. Exposure of the battery to elevated temperatures may result in fewer cycles, decreased capacity, or both.

Patients should be aware that attempting to charge their battery in a running Inogen One concentrator in elevated temperatures, particularly if they are using higher flow settings, may result in a charging error and termination of the battery charge. In this case, they may (a) place the concentrator into a cooler environment, (b) charge the battery while the Inogen One is turned off and plugged into an AC power outlet, or (c) remove the battery

and charge on the External Battery Charger (optional accessory). Improper charging may also result in decreased run time on a single battery charge and in reduced life expectancy of the battery.

DESIGN NOTE	The Inogen One Battery can discharge at higher temperatures than it can be charged. When the concentrator is used at high ambient temperatures, it is possible that the battery will need to cool for a period of time following a deep discharge. In this case the concentrator may be run from AC power or another battery. To accelerate cooling, remove the battery from the concentrator.

Battery Time Remaining Clock

The Inogen One continuously displays battery time remaining. Explain to the user that this displayed time is *only an estimate*, and the actual time remaining may vary from this value. In some conditions, the concentrator may display battery time remaining as a percentage, and not as hours and minutes. In most cases, the display will revert to time remaining within several minutes.

To avoid running out of battery power unexpectedly, users should regularly monitor the displayed battery levels and/or carry a back-up power supply (extra charged battery, AC Power Supply, or Mobile Power Charger).

Conditioning the Battery

Under some conditions, the battery time remaining indicator may indicate that the battery's remaining energy is less than it actually is. This can result in premature low battery level alarms and perceived reduction in battery run time. To reduce the risk of this:

- Users should fully charge the battery
- Users should then fully discharge the battery by running the concentrator on battery power until the concentrator displays "Battery Low, Attach Plug", or automatically shuts down. Do not attempt to charge the battery early during this discharge cycle. Doing so will negate the correction algorithm.
- Users should then completely recharge the battery using either the concentrator on AC power or the External Battery Charger.

Battery Run Time Management

The Inogen One opens new approaches to ambulatory oxygen management by putting the patients in control of their supply. In essence, they are never

further from a supplemental supply of oxygen with their Inogen One than they are from a source of electric power.

In setting up a patient on the Inogen One, you may choose to inform them about the freedom and independence they can achieve through battery run time management. By combining the use of the AC Power Supply, the Mobile Power Charger, and the Inogen One Battery, patients may stay away from their homes almost indefinitely, when other types of devices require returning home to replace or refill their oxygen supply.

As an illustration of Battery Run Time Management, imagine a day in the life of oxygen patient "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%
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	Spontaneous dinner at neighbor's home	Battery Power	25%
6:30 PM -	Read & watch TV before going to bed	AC Power Supply	100%

* Assumes 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 illustration above, proper battery management can, in many cases, allow users to remain away from home for entire days or longer without stress or concern of running out of oxygen. Patients who use lower flow settings or who carry a second charged battery may experience even greater flexibility than seen in the above example.

Storage

Patients should remove the battery from the Inogen One when it is not in use to avoid inadvertent discharge. Leaving a battery in an unused Inogen One for prolonged periods will result in battery discharge. Additionally, leaving a warm fully charged battery in an Inogen One may result in reduced battery capacity.

DESIGN NOTE

When the concentrator is off but the battery is installed, the battery will continue to provide a small amount of power to the concentrator's microprocessor. This power draw will empty a full battery in approximately 20 days.

If an external power supply is plugged into the power port on the concentrator but not plugged into an outlet or other power source, the turned-off concentrator will maintain activity in a much larger portion of its electronics while battery power is available. Under these conditions, the battery may go from full to empty in less than 5 days.

Patients should avoid storing the Inogen One battery in extreme temperatures, below -4˚F (-20˚C) or above 140˚F (60˚C), for any amount of time. They should avoid leaving batteries in automobiles, where these temperatures can be regularly exceeded. Storage of the Inogen One battery in a cool, dry location will help to assure the longevity of the battery.

Battery Disposal

Lithium ion batteries, like all rechargeable batteries, are recyclable and should never be incinerated. Contact your local Hazardous Waste disposal center for information on proper disposal and recycling.

Maintenance by the Provider

Expected Maintenance Intervals

It is suggested that the Inogen One Oxygen Concentrator be field-serviced at least annually by a trained technician. At the time of service, it is recommended that the amount of usage be checked. To do so, press and hold the

Mode Button for 5 seconds. The concentrator's display will show the non-resettable hour meter, the unit's serial number, and the software version installed on the device. It is suggested that you maintain a service log for the Inogen One and accessories (see the sample Service Record template included at the end of this Technical Manual).

CAUTION	Do not disassemble the Inogen One or any of the accessories or attempt any maintenance other than tasks described in this Technical Manual. **DISASSEMBLY OF THE INOGEN ONE OR ANY OF THE ACCESSORIES WITHOUT PROPER TRAINING CERTIFICATION WILL VOID THE PRODUCT WARRANTIES.** Contact your distributor for information about receiving proper training and certification for service of the Inogen One and accessories.

NOTE	While Inogen recommends field service of the Inogen One on an annual basis, it may be advisable to visit the patient more frequently to monitor the patient's proper maintenance and usage of the device.

DESIGN NOTE	For the ease of providers, the device has been designed with maintenance and service requirements in mind. The concentrator requires periodic field maintenance which requires very little training, and can be done without opening the outer case. Service, which typically involves opening the device and is more equipment intensive, is intended to be performed by Inogen Certified Service Centers. For information about becoming certified in servicing the device, please contact your distributor.

Suggested Materials for Regular Maintenance

To perform regular field maintenance (by a technician) on the Inogen One System, you may need:

- Replacement Inogen One Batteries (model # BA-100)
- Replacement intake particle filters (model # RP-100)
- Replacement output filters (model # RP-101)
- Spanner Wrench for Output Filter (model # RP-102)
- Replacement "C" batteries for Satellite Conserver
- Replacement cannulas
- Personal Data Assistant (PDA, Palm OS) for collection of usage data

- Equipment service log
- Extra oxygen supply (for temporary use by the patient while concentrator is being serviced)

NOTE	During a normal field maintenance visit, the technician may elect to turn off the concentrator for approximately 30 minutes. If the patient requires oxygen during this period, Inogen recommends making arrangements to bring an extra oxygen supply (such as a supplemental Inogen One Concentrator).

System Inspection

At the start of each maintenance visit:

1. Ask the patient if they have experienced any difficulties in operating the equipment.
2. Ask the patient if they have observed any malfunctions or changes in characteristics of the equipment.
3. Visually inspect the device, batteries, and accessories for cracks or other damage.
4. Feel the sides of the device for vibration and listen for unusual noises, rattles, or other signs that the device requires more attention or extensive service.

CAUTION	Discovery of cracks or other types of external damage may be indicative of other internal damage that may not be visible. If such external damage is discovered, be certain to inquire as to how it occurred, and whether any changes in the device have been noticed since its occurrence. If you have any concern over the safety of the device, repair it (if possible) or arrange for equipment servicing.

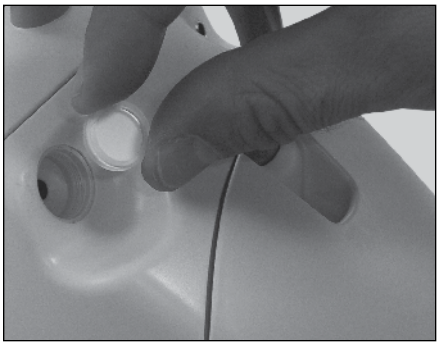
To arrange for more extensive equipment servicing, please contact your customer care representative (evo Medical Solutions: 800-759-3038). Do not attempt to ship equipment without an RMA number.

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 during a provider maintenance visit.

To replace the Product Filter:

1. Use the Spanner Wrench for the Output Filter (available from your distributor) to access the product filter. The tool has two prongs which mate with two indentations located on the surface of the metal nozzle fitting on the Inogen One.
2. Carefully remove the nozzle fitting by unscrewing it in a counter-clockwise direction.
3. The filter, a hard plastic disk with a silicone gasket on its outer edge, will be visible in the recess once the hose barb is removed.



4. Remove the filter, and inspect the recess to make sure it is free of debris. You may require a pointed object to aid in removing the filter.
5. Install a replacement filter.
6. Carefully screw the nozzle fitting back into the recess (clockwise) until it bottoms out on the filter gasket. Take care to squarely screw the nozzle fitting into the threads. Do not over tighten.

CAUTION	Failure to inspect and replace the product filter may result in the filter becoming clogged or obstructed over time, and in reduced delivery of oxygen to the patient.

CAUTION	Take care not to over tighten the cannula nozzle fitting during re-installation. Over tightening may cause the concentrator case to break or crack, or may cause the filter to break. This may result in hazards to the user.

CAUTION	Take care not to cross-thread the cannula nozzle fitting during re-installation. Cross-threading may result in the development of leaks, in reduced delivery of oxygen to the patient, or in system malfunction.

Administrative Functions and Modes

The Inogen One is equipped with several Administrative Modes and Functions, designed for use by providers and service personnel. These features facilitate controlled testing of the Inogen One, and monitoring of past system performance.

To enter into the administrative modes:

1. Make sure the concentrator is turned off and plugged into an AC Power Supply connected to a wall outlet.
2. With the unit off, depress and hold the Light and Mode buttons simultaneously for 5 seconds.
3. A text message will appear on the display indicating the administrative mode has been entered.
4. Use the (+) and (-) buttons to cycle through available options until you see the desired mode displayed.
5. Some modes contain sub-menus. These are indicated by a ">". To enter the sub-menu, press Mode. To navigate within the sub-menu, press "-" or "+". To navigate back up in the menu structure, press Light.
6. Depress the Mode button to enter the desired administrative function.
7. To cancel this process during selection, or to exit a mode, depress the off button.

CAUTION	Take care not to select a function that is not intended.

Auto Pulse Mode

This mode starts up the Inogen One with all functions normal, except that boluses are automatically delivered at a regular interval and the breath detection circuitry is disabled. Several auto pulse options may be available with different bolus delivery rates. These may be selected by navigating to this administrative mode and by depressing the Mode button to select the desired option.

This mode may be used to establish if a concentrator is working properly (i.e., via a simple bench test) by entering auto pulse mode and allowing the concentrator to run for at least 40 minutes uninterrupted. Because the device monitors its own systems actively and reports errors (exception reporting), if the device does not show any notifications or alerts after this period, then the device is operating normally. In summary, if after 40 minutes of uninterrupted operation in the auto-pulse mode there are no alerts or alarms, the unit is operating to specification.

Data Logging

Inogen One operating data are periodically recorded to flash memory located within the concentrator as an administrative function. Data is stored for a period of approximately 1-2 months; new data replaces the oldest data as it is collected.

DESIGN NOTE	This data collection function is designed to provide information regarding the operation and use of the Inogen One. This data may be uploaded to the Inogen web site and then used by Inogen to assist in diagnosing and correcting errors, should they occur. After uploading data to the Inogen web site, providers may view records of each upload, including the serial number of the concentrator, its life clock reading, and the date and time of the upload.

Data Download

You may collect stored data at your discretion.

To download data from the Inogen One, you will need a Personal Digital Assistant (PDA) equipped with an infrared communications port and operating on Palm OS (operating system 5.0 or higher). Consult the Inogen web site (http://www.inogen.net/providerlogin) for more information.

To collect data:

1. Turn the Inogen One off, but leave it plugged into an external power supply.
2. Turn on the PDA and position it such that its infrared port points at the Inogen One's infrared port (located in a clear window on the ratings label on the rear of the device).

3. Simultaneously depress the Light and Mode buttons for 5 seconds.
4. Using the (+) and (-) buttons, cycle through the administrative options. Select the Data Log mode by depressing the Mode button. Press Mode and when you see "Transfer", press Mode again to initiate transfer.
5. The display will show "Data Transfer in Process", and then will show "Data Transfer Complete". This process may take up to 10 minutes. The transfer process may be stopped by pressing the ON/OFF button.
6. If the transfer is interrupted, the display will indicate "Data Transfer Failure." In this case, you may elect to re-start the transfer process. If the problem persists, contact your distributor for assistance.

Data files are saved on the PDA in a .PDB file with a name that is unique to the concentrator from which the data was retrieved. While files from multiple concentrators may be held on the PDA without problem, subsequent downloads of data from a particular concentrator will overwrite older files on the PDA. It is recommended that you remove files to a computer as soon as possible following download.

Data Upload

Once a data file has been received by the PDA, this file may be transferred to a personal computer and uploaded to the password protected Provider area of the Inogen web site (http://www.inogen.net/providerlogin). From there, Inogen technical service personnel can view the data and use it to assist with troubleshooting.

For information about transferring files from the PDA to a PC, and about uploading the files from the PC to the provider website, please visit the web address above.

Expected Service Requirements

Inogen One Concentrator

Life expectancy of many parts of the Inogen One Oxygen Concentrator is affected by patient usage patterns. Devices that are used at higher flow settings and/or for more hours each day will require more frequent service. Service of internal components of the Inogen One may only be performed by certified service centers. Contact Inogen about how to become a certified service center.

Inogen One Accessories

The Inogen One AC Power Supply, Mobile Power Charger, and External Battery Charger are not expected to require service. The Satellite Conserver is not expected to require service beyond periodic battery changes.

NOTE	Regular maintenance of the Inogen One and accessories, as described in this manual, is a key contributor to prolonging product life. Failure to provide proper maintenance may adversely affect component and system life expectancy.

DESIGN NOTE	Inogen has submitted the Inogen One to an extensive series of tests designed to uncover potential design and manufacturing flaws. These tests included accelerated component life testing, Highly Accelerated Life Testing (HALT), drop testing, high cycle life testing, and environmental stress testing. The Inogen One is safety certified by CSA. To receive this certification, the products have undergone extensive third-party electrical safety qualification. Additional product reliability testing has been performed. Manufacturing processes have been validated, and are regularly third-party audited. The Inogen One is manufactured in an ISO 9002 and ISo 13485 certified system. Inogen believes that these tests reflect our commitment to the durability and longevity of the Inogen One. We have attempted to build reasonable safety margins and controls into our products.

Inogen One
Error Code Table

These codes are supplemental to the text alarm and alerts listed in the Patient Manual.

Error Code Number	Explanation
1	Low voltage on power supply
2	Software error
4	Accumulator pressure sensor signal out of specification
16	System electric current out of specification
128	Signal or reading out of specification. Applies to signals from user interface and other internal connections.

Limited Warranty

Inogen One™ Oxygen Concentrator - Limited Warranty Statement

Inogen, Inc. 326 Bollay Drive, Goleta, CA 93117

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 and Parts	
Satellite Conserver	2 years
All other accessories and replacement parts	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 federal court in California.

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Contacts for More Information

Inogen Websites:	http://www.inogenone.com http://www.inogen.net http://www.OxygeNation.com
Inogen Customer Care:	326 Bollay Drive Goleta, CA 93117 805-562-0515 1-877-4-Inogen (Toll-Free Customer Care) 1-877-446-6436 (Toll-Free Customer Care) E-mail: care@inogen.net

Device Service Record

Concentrator S/N:	
Life Clock Hours:	

Service Event Date:	
Group / Company:	
Technician Name:	

Patient Name / ID:	

Service Checklist:

Concentrator:

	Interview the patient
	Inspect for external damage / wear
	Operational inspection
	Replace intake / exhaust filters
	Replace product filter
	Inspect Satellite Conserver & tubing
	Download operational data file
	Provide replacement filters
	Provide replacement cannulas
	Other:

Accessories:

	Check battery on Satellite Conserver
	Inspect power supplies & cords
	Inspect mobile power adapter
	Inspect carry bag and cart

Service Location:

	Patient's residence
	Service center / office
	Other:

Service Type:

	Set up equipment
	Scheduled visit
	Patient call / complaint
	Other:

Notes:

Notes