INOGEN ONE G2 OXYGEN CONCENTRATOR

TECHNICAL MANUAL

96-02735-00-01

Revision C

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

- Inogen One G2 Oxygen Concentrator, model # IO-200
- Inogen Universal Power Supply, model # BA-107 & BA-207
- Battery, model # BA 200
- Battery, model # BA-224

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1. INFORMATION FOR PROVIDERS OF THE INOGEN ONE G2

Thank you for choosing to provide your patients with the Inogen One G2 oxygen concentrator. 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 G2 Oxygen Concentrator and its accessories. Before reading this Technical Manual, *please read and review the Inogen One G2 Patient Manual for description 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 help assure that patients are given proper guidance in the use and function of the Inogen One G2 and its accessories. Proper care in relaying this information will not only enhance the user's experience with the Inogen One G2, but will also protect the patient, prolong the life of the device, and help you avoid unnecessary service calls and complaints from users.

1.1. Caution and Warning Statements

You will see Warnings and Cautions throughout this Technical Manual. To ensure effective Oxygen Therapy and proper operation of the Inogen One G2 Oxygen Concentrator, you must 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 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 G2 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 G2.

The Inogen One G2 User Manual contains additional cautions and warnings.

2. SETTING UP A PATIENT ON INOGEN ONE

2.1. Recommendations for Use

The Inogen One G2 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. You may choose to equip your patients with the Inogen One G2 so it may be used in home, institution, vehicle and various mobile environments.

NOTE	Availability of an alternate source of oxygen is recommended in case of power outage. Several certifying bodies for Home Health Care Providers require that back-up oxygen be available to the patient. Supplemental oxygen cylinders or extra Inogen One G2 Batteries may satisfy these requirements.

CAUTION	Oxygen demand of some patients, particularly those with high breathing rates and high flow settings, may exceed the capabilities of the Inogen One G2. Inogen suggests that each patient be titrated to assure that the Inogen One G2 is an appropriate solution for their needs.

2.2. System Components

The following are standard components of the Inogen One system:

- Inogen One G2 Oxygen Concentrator
- 12 cell Battery
- AC/DC Power Supply
- Cart
- Carry Bag
- Cannula

Patient Set-Up. To properly set up a patient on the Inogen One G2 System, you may need to provide:

- Pulse Oximeter (for titration, not included)

- Extra cannulas (not included)

2.3. Using the Inogen One G2

To quickly configure the Inogen One G2 for patient use:

1. Slide the battery onto the bottom of the system until the latch clicks into place.
2. Connect AC or DC power cord to the power supply.
3. Connect the power supply to the Inogen One G2.
4. Plug into closest AC or DC outlet.
5. Turn on the Inogen One G2 by pressing the on/off button.
6. Set the Inogen One G2 to correct flow setting prescribed by the physician or clinician by pressing the + (increase flow) or – (decrease flow) button.
7. Attach cannula to the metal hose barb located next to the handle of the Inogen One G2.

For further information regarding the use of the Inogen One G2, please consult the User Manual.

2.4. Selecting the Proper Flow Setting

2.4.1. Bolus Volumes 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 (FiO_2), and therefore to the OCD's efficacy at maintaining the patient's blood oxygen saturation.

As an oxygen concentrator, the Inogen One G2 does not contain a finite stored volume of oxygen, such as with compressed gas or liquid cryogenic systems. The Inogen One G2 can provide oxygen to the patient as long as a source of electricity is available. However, because the oxygen is being produced as it is used, supply of oxygen is *rate-limited*. The Inogen One G2 delivers up to 900 ml/min of 90% oxygen.

At each flow setting, the Inogen One generates a specific amount of oxygen (180ml per setting), and the on-board OCD attempts to deliver all of this product to the patient. This is equivalent to a conserving ratio of 5.6 at all flow settings and breathing rates.

Slower breathing patients will receive larger boluses, and faster breathing patients will receive smaller boluses.

DESIGN NOTE	This method of bolus volume determination is similar to what is experienced by a patient using a continuous flow concentrator – actual alveolar oxygen inspiration is more closely linked to flow setting than to breathing rate.

In general, the Inogen One G2 delivers 12ml per bolus per flow setting at 15 breaths per minute (180ml/min per flow setting). The following table summarizes the bolus volumes delivered by the Inogen One OCD at 20C and Sea Level:

Flow setting	Flow Rate (ml +/- 10%)	10 BPM (ml +/- 10%)			20 BPM (ml +/- 10%)			25 BPM (ml +/- 10%)		
		min	nominal	max	min	nominal	max	min	nominal	max
1.0	180	16.2	18.0	19.8	8.1	9.0	11.6	6.5	7.2	7.9
2.0	360	32.4	36.0	39.6	16.2	18.0	23.3	13.0	14.4	15.8
3.0	540	48.6	54.0	59.4	24.3	27.0	34.9	19.4	21.6	23.8
4.0	720	64.8	72.0	79.2	32.4	36.0	46.6	25.9	28.8	31.7
5.0	900	81.0	90.0	99.0	40.5	45.0	58.2	32.4	36.0	39.6

DESIGN NOTE	Bolus Volume is tuned to provide the correct bolus volume when delivered through a nasal cannula such as the Salter Labs 1600Q. If bolus volumes are measured without a cannula or with a different type of nasal cannula, bolus volumes will vary from values stated in the table above.

2.4.2. Trigger sensitivity

The conserver will trigger when the negative pressure at the internal sensor reaches approximately -0.12 cm H_2O. This low trigger sensitivity allows for breath detection of very shallow breathing, but may also result in the occasional trigger due to motion of the cannula or motion of the concentrator.

2.4.3. Flow Setting Selection Relative to Physician Prescription

Inogen has labeled each of the five settings to provide a *guideline* for matching the setting of the device to the continuous flow 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 each patient be titrated (a) while sedentary, (b) while active or ambulatory.

2.4.4. Use with the Inogen Satellite Conserver

The Inogen One G2 is not compatible with the Inogen One Satellite Conserver

3. SERVICING THE INOGEN ONE G2

3.1. Maintenance by the Provider

3.1.1. The Inogen One G2 is only intended to be repaired by authorized repair centers. If a repair is required, please contact Inogen to locate your nearest authorized repair center. If you would like to become an authorized repair center, please contact Inogen for access to certification training, service instructions, component part lists and the necessary repair equipment.

3.1.2. Checking Life Clock, Serial #, and SW version

To check usage, press and hold the Alarm Bell Button for 5 seconds. The concentrator's display will show the hour meter, the unit's serial number, and the software version installed on the device.

NOTE	Do not disassemble the Inogen One G2 or any of the accessories or attempt any maintenance other than tasks described in this Technical Manual unless you have completed a training course through Inogen. Disassembly of the Inogen One G2 or any of the accessories without proper training certification will void the product warranties. Contact Inogen for information about receiving proper training and certification for service of the Inogen One G2 and accessories.

3.1.3. Suggested Materials for Regular Maintenance

To perform regular field maintenance (by a technician) on the Inogen One G2 System, you may need:

- Replacement cannulas (RP-128)
- Replacement intake screens (RP-200)
- Replacement Inogen One G2 Batteries (BA-200 or BA-224)
- Hose barb removal tool (Spanner Wrench, RP-102)

- Replacement product filters (RP-101)
- USB storage drive for data log transfers (such as PNY PN# P-FD2GBATT2-SF)

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 G2 Concentrator).

3.1.4. System Inspection

At the start of any maintenance visit:

1. Be sure to ask the patient if they have experienced any difficulties in operating the equipment.
2. Be sure to 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 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 noticeable since its occurrence. If you have any concern over the safety of the device, arrange for equipment servicing.

3.1.5. Product (Bacterial) Filter

Oxygen concentrator safety standards (ISO 8359) require use of a filter in the product line capable of removing particles larger than 10 microns. This filter is intended to protect the user from bacterial infection, and from inhalation of small particles in the product gas flow. The Inogen One G2 includes a product filter, conveniently located behind the removable cannula nozzle fitting. Inogen suggests that this filter be replaced between patients.

To replace the Product Filter:

1. Use the Cannula Nozzle Fitting Tool (available from Inogen as RP-102) 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 G2.
2. Carefully remove the nozzle fitting by unscrewing it in the 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.
5. Install a new 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, and not to over tighten.

WARNING	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.

3.1.6. Data Logging

Operating data from your Inogen One G2 concentrator are periodically recorded to flash memory located within the device. Data is stored for a period of approximately 6-12 months; new data replaces the oldest data as it is collected.

Additionally, the device records errors and system information at the time of the error which is useful in diagnostics.

3.1.6.1. The following information is a list of recorded parameters that can be used to evaluate the device and its usage:

- Real Time Clock
- Life Clock
- Flow Setting
- Breaths per Minute
- Low, Medium , and High Priority Errors
- Ambient Pressure
- System Temperature
- Battery Status
- Charging Status

3.1.7. Data Download

To download data from the Inogen One G2, you will need a USB mass storage device. If one of the following drives cannot be obtained, the drive must be less than 2GB in capacity and have a native file format of FAT32. The capacity of the drive and the file system alone do not ensure compatibility with the Inogen One G2.

Compatible USB drives include:

- PNY Attache 2GB PN: P-FD2GBATT2-SF
- SanDisk Cruzer Micro 2GB PN:SDCZ6-2048RB
- Kingston Data Traveler G3 2GB PN:DTIG3/2GBZ
- Kingston DataTraveler 102 2GB PN:DT102/2GB
- Kingston DataTraveler DT101 2GB PN: DT101G2/2GB
- Dane-Elec DNL 2GB PN:DNLDAZMP02GCAW
- Transcend JetFlash V30 2GB PN:TS2GJFV30
- Patriot Signature 2GB PN: PSF2GUSB

To collect data:

a) With the Inogen One G2 off, insert the USB mass storage device into the USB port behind the Gross Particle Screen
b) Plug in external power to the concentrator
c) Press the “alarm bell” and the “light” buttons for 5 seconds

d) The administrative mode menu will show normal. Press the "+" or "-" buttons until the LCD reads "Data Log"
e) Press the "alarm bell" button twice and the LCD will read "Transferring"
f) When the data is transferred, the LCD will read "Success"
g) If the LCD screen reads "Failure" try a different type of USB mass storage device

3.2. Maintenance by the Patient

3.2.1. Cannula Replacement

The nasal cannula should be replaced on a regular basis. A single lumen cannula of four to 25 feet in length must be used. Inogen has certified its performance data with the Salter Laboratories 1600Q cannula.

CAUTION	Do not use total cannula tubing length exceeding 25 feet with the Inogen One G2 unless proper saturation has been verified by a clinician.

3.2.2. Intake Filter Cleaning

At the front of the Inogen One G2, ambient air passes through a gross particle screen that removes dust fragments. This particle screen must be cleaned on a weekly basis to ensure adequate air flow through the device. If the particle screen is not cleaned frequently, the life expectancy of the concentrator will be shortened due to higher internal operating temperatures.

Particle screens should be cleaned using a mild detergent (e.g., dishwashing solution, such as Dawn™) and water solution; be sure the filter is rinsed in water and allowed to air dry before reuse. Additional replacement filters may be obtained from Inogen (RP-200). There are other types of filters inside the Inogen One G2 that provide additional filtration. Maintenance of these filters is not required under normal operating conditions.

3.2.3. Surface Cleaning

The outside case should be cleaned using a cloth dampened with a solution of mild detergent (e.g., dishwashing detergent, such as Dawn™) and water or disinfecting towelettes (e.g., DisCide Ultra).

3.2.4. Battery Care and Maintenance

The Inogen One G2 Lithium Ion Battery requires special care to ensure proper performance and long life. Use only Inogen One G2 Batteries with the Inogen One G2 Oxygen Concentrator.

DESIGN NOTE	The Inogen One G2 Oxygen Concentrator adjusts its oxygen production rate to match the oxygen demand specified by the user flow setting. When the device is used at lower settings, its battery life 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 and subsequent charging

The Inogen One G2 battery requires an initial charge to full capacity before use.

Instruct the patient to avoid running the Inogen One G2 on battery power until this initial charging has been completed. This charge typically takes 2 hours depending on the flow setting.

The Inogen One G2 may be run on AC or DC power and used by the patient during this initial charging period

Normal Charging

The battery is operating properly when a battery icon is displayed on the LCD screen.

The Inogen One G2 batteries do not have a "memory" like older NiCad battery packs. The Inogen One G2 batteries can be partially charged and discharged without damaging the battery packs.

Effect of Temperature on Battery Performance

The Inogen One G2 battery powers the Inogen One G2 Oxygen Concentrator from 2 to 4 hours using the standard 12 cell pack (BA-200) under most environmental conditions. To maintain maximum run-time of the battery, users should avoid running 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 at room temperatures exceeding 75°F (24°C).

DESIGN NOTE	The BA-200 and BA-224 will typically achieve 500 charge/discharge cycles while retaining 80% of their original capacity if proper battery care is taken.

The BA-200 and BA-224 will typically achieve 500 charge/discharge cycles while retaining 80% of their original capacity if proper battery care is taken.

Instruct the user that attempting to charge their battery while attached to a running Inogen One G2 concentrator at elevated temperatures may result in a charging error and termination of the battery charge. In this case, they may either (a) place the concentrator into a cooler environment, (b) charge the battery while the Inogen One G2 is turned off and plugged into an AC power outlet, or (c) remove the battery and charge using the External Battery Charger (optional accessory). Improper charging may also result in decreased run time on a single battery charge and reduced life expectancy of the battery.

Battery Time Remaining Clock

The Inogen One G2 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.

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

Storage

Instruct patients to remove the battery from the Inogen One G2 when it is not in use to avoid inadvertent discharge. Leaving a battery attached to an idle Inogen One G2 for prolonged periods will result in battery damage that will severely shorten the expected life of the battery.

DESIGN NOTE	When the concentrator is off but the battery 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.

CAUTION	Leaving a Battery in the Inogen One G2 while the device is unused will irreversibly damage the battery. After such storage, the battery may not be able to recharge or its life cycle and/or capacity will be greatly diminished. A full battery can be damaged in as little as 20 days if left in the concentrator while not plugged in.

Instruct users to avoid storing the Inogen One G2 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 G2 battery in a cool, dry location will help to maximize the longevity of the battery.

3.3. Expected Service Requirements

The following table is provided as an estimate only and assumes typical environmental conditions for temperature, humidity, and air pollution. Any smoking around the device will severely shorten its life expectancy. Please refer to product warranty coverage terms.

Service Item	Estimated Service Requirement Frequency
Battery	500 full charge/discharge cycles (to approximately 80% capacity)
Compressor	Function of flow setting and time
	17,000 run hours @ flow setting 5 20,000 run hours @ flow setting 2
Oxygen Sensor	No Service Requirement
Molecular Sieve	36 to 60 months depending on usage
Valves	20,000 run hours
Intake Filter	20,000 run hours
Cooling Fan	20,000 run hours

4. INOGEN ONE G2 SYSTEM SPECIFICATIONS

INOGEN ONE G2 CONCENTRATOR

Dimensions:

	Length		Width		Height	
	Cm	In	Cm	In	Cm	In
No battery	27.2	10.7	9.9	3.9	22.2	8.75
12 cell battery	27.2	10.7	9.9	3.9	24.1	9.50
24 cell battery	27.2	10.7	9.9	3.9	26.0	10.25
In Bag	27.2	10.7	11.4	4.50	25.4	10.00
On Cart	34.3	13.5	20.3	8.00	40.6	16.00

Weight:	Approximately 7.25 pounds (includes 12 cell battery)
Noise:	<38 dB on flow setting 2
Warm-Up Time:	Approximately 2 minutes
Oxygen Concentration:	90 ± 6/-3%
Flow Control Settings:	1,2,3,4,5
Power:	AC/DC Power Supply AC Input: 100 to 240 VAC, 50 to 60 Hz, 1.0A to 0.5A DC Input: 13.5 to 15 VDC, 10A Output 19 VDC, 90 W

	Rechargeable Battery: Voltage: 12.0 to 16.8 VDC,
Battery Duration:	Approximately 2 to 3.5 hours for 12 cell battery Approximately 4 to 7 hours for 24 cell battery
Battery Charging Time:	Approximately 2.25 to 4.25 hours for 12 cell battery Approximately 4.25 to 8.00 hours for 24 cell battery
Environmental Ranges Intended for Use:	Temperature: 40 – 104°F (4 – 40°C) Humidity: 0% to 95%, non-condensing

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:	Concentrator: IP 20 Carry bag: IP 22
Degree of Safety for Application in Presence of Anesthetic Gases:	Not suitable for such applications

5. INOGEN ONE G2 ERROR CODE TABLE

If more than one alarm is triggered simultaneously, the error code number will be the sum of the error codes given below.

Error Code Number	Explanation	Possible Causes & Troubleshooting Instructions
001	Low voltage on power supply	Replace the power supply or remove the battery to see if the concentrator was running on battery power
002	Software error	Unplug the external power and remove the battery to clear the error and then restart the concentrator
004 B/C	Pressure Error	The concentrator was shut down due to a pressure error. Ensure that the

		battery is sufficiently charged. If the error persists, return the concentrator for service..
016	System electric current out of specifications	There may be a fault with the motor or the battery communication. If the problem occurs at the end of a battery discharge, recharge the battery. If the error is persistent, return the concentrator for service.
128	Signal or reading out of spec. Applies to signals from user interface and other internal connections.	A sensor has given an out of range reading and might need to be serviced if the error persists after restarting the concentrator.
System Hot System Cold	temperature out of specifications	Remove the concentrator from the carry bag and restart the concentrator after 10 minutes to cool down. If the error persists, the fan may have failed. If the System Cold message appears, allow the concentrator to warm up for 15 minutes in a room temperature environment and then restart the concentrator.
Battery Hot Warning Battery Hot Shutdown	Battery over temperature during discharge	The concentrator might need to be moved to a cooler location with improved ventilation
Oxygen Low	The Oxygen purity is < 82% for 30 minutes	The sieve beds may require servicing
Oxygen Error	The Oxygen purity is < 50% for 10 minutes	The concentrator has a malfunction such as a leak or a failed valve
O2 Sensor Failure	The oxygen sensor is returning false readings	If the problem persists, return the concentrator for service
O2 Delivery Error	A breath is detected, but no bolus is delivered	Check for kinks or blockages in the tubing between the product manifold

		and the cannula barb. If the problem persists, return the concentrator for service.
Battery Error	The system is not properly communicating with the battery	Remove and reinsert the battery to clear the error. If the error persists, replace the battery
Service Needed	The compressor has reached maximum speed	The compressor is at its end of life or there is a leak in the concentrator
External Power Low	The input voltage is less than 17V	Remove power to the concentrator and remove and reinsert the battery. Try another external power source such as DC power

6. CONTACTS FOR MORE INFORMATION

Inogen Website: Patient Issues: http://www.inogenone.com
Corporate: http://www.inogen.net

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