Information to Support the Use of
Inogen One Onboard Commercial Aircraft

Technical Description

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Technical Description

The Inogen One Oxygen Concentrator has been designed to meet the full time home and mobile needs of oxygen patients. The Inogen One severs the tie between these patients and their liquid oxygen systems or compressed gas cylinders.

Principles of Oxygen Generation in the Inogen One

The Inogen One utilizes a pressure swing adsorption (PSA) system employing zeolite filled sieve beds. The sieve beds are connected to a series of valves through which ambient

air is filtered in a process that results in separation of the oxygen component of the air from other components allowing purified oxygen to be delivered to the patient. Zeolite is a clay-like material with adsorption properties that result in faster uptake of nitrogen than oxygen, resulting in oxygen purification. The device employs a small compressor which pressurizes ambient gas by a factor of 2.6 (39 psia maximum with input air at STP – below the hazardous material thresholds set by FAA). The compressed gas is applied sequentially to the collection of sieve beds to produce a maximum of approximately 750ml/min of 90% pure oxygen product. This product is stored in a 175cm^3 accumulator at approximately 2.0 to 2.3 times ambient pressure (30-34 psia with input air at STP). The actual volume of oxygen produced is reduced as the user flow setting is turned down to correspond to reduced demand. The device neither stores nor contains liquid oxygen or any other FAA classified Hazardous Material.

Oxygen Delivery with a Conserver

The Inogen One utilizes a conserving device, delivering oxygen only at the onset of inhalation, when oxygen is most beneficial.

The Inogen One provides oxygen in nine incremental flow settings. These user-selectable flow settings, marked 1 through 5 in increments of 0.5, are guidelines intended to correspond to continuous liter per minute flow rates. These settings may not be representative for all patients. Inogen recommends that each patient be titrated by their physician or respiratory care provider.

Major Components

Sieve Beds. The device contains three zeolite filled cylinders. The granular zeolite is contained within the system by a series of filters, and each column is held in compression.

Compressor. The device employs a motor-driven compressor that provides compressed air to the system.

Cooling Blower. The blower is applied to the compressor to provide for adequate cooling of the device.

Valves. The flow within the device is metered by nine independent solenoid valves.

Battery. The device may be powered by a 12 cell Lithium Ion battery pack (7.92g equivalent Lithium – therefore not a Class 9 Hazardous Material) utilizing standard 18650 cells, similar to those used in laptop computers. The pack is rated at 14.8V with a range of 12.0V to 16.8V and a capacity of 6.6A-h. The battery has multiple levels of circuit protection and over-temperature protection, and is robustly packaged for durability. It communicates its status to the device via SMBus communication protocol. It has been tested by a third party agency to comply with UN travel regulations for lithium batteries.

Printed Circuit Boards. The device uses two circuit board assemblies inter-linked by a communication cable and by a power cable. These circuit boards provide for the controlled function of the PSA system, alert and alarm determination from the array of on-board status sensors, battery communication and power management, and user interface communications.

AC Power Input. The device may be powered by an 18V 90W medical grade power supply. This supply connects to an AC power supply jack (50-60Hz, 90-260VAC auto-switching) and to the DC power input on the Inogen One using the 2.5mm barrel type connector.

DC Power Input. Alternatively, the device may be powered using one of several types of DC power inputs, including car cigarette lighter adapters and airplane adapters. The device is rated for DC inputs from 12-24V using the power adapters supplied with the concentrator. The battery will charge when connected to DC power input.

Certifications. Inogen, Inc. is an ISO-13485 certified company. The Inogen One is manufactured in a certified ISO-9002 and ISO-13485 environment. The device has been tested and certified by an outside agency (CSA) for compliance with applicable electrical and oxygen concentrator safety standards exceeding those required by FDA or FAA. The Inogen One Battery has been certified to comply with UN standards for Lithium Ion batteries. The Inogen One has been certified by a third party test agency to comply with RTCA DO-160D commercial airline industry standards for

radiated emissions, and therefore does not require any further radiated emissions testing or certification aboard commercial aircraft per FAA regulation.

Power Supply

The Inogen One may be powered by any of three options:

- AC power (100 to 240 Volts, 50 to 60 Hz, Auto-switching) from most wall sockets worldwide using the AC Power Supply
- DC power from an automobile, aircraft power port, boat or similar power source (12 to 24 Volts)
- Rechargeable Battery

The device requires 30-46 Watts of electric power to operate, plus up to an additional 40Watts to charge the battery.

Battery Operation

The battery pack will last from 2-3 hours, depending on flow setting, and will take approximately 3 hours to recharge using the AC power input. The battery will not charge when it is overheated, as can happen in ambient temperatures above 25^{o}C. An external AC (100 to 240 Volts, 50 to 60 Hz) powered battery charger is available from Inogen if the patient wishes to charge batteries in higher temperature environments (up to 45^{o}C). Extra battery packs are also available from Inogen.

Power Considerations On Commercial Aircraft

While users will be able to power the device from DC power supplies onboard most commercial aircraft, it is suggested that either (a) patients carry sufficient battery packs with them to power the device through any single leg of air travel, or (b) airlines support patients by maintaining an adequate backup supply of charged batteries on hand. This battery power reserve will allow patients to complete a flight without aircraft power supply in case of aircraft power bus failure or necessitated shut-down. Because the Inogen One’s battery is expected to last 2-3 hours, most domestic flights would necessitate no more than 1 reserve battery pack (2 total). It is recommended that the battery be removed from the Inogen One when the device is powered by onboard power outlets (not available on many flights – patients are directed to check with airlines for

availability and special accommodations 48 hours before travel).

Sensed Operating Parameters

The Inogen One employs an array of sensors which monitor product oxygen concentration, pressures in the PSA system, temperatures in the device, ambient pressures, patient inspiratory pressure, power input status, battery status, and internal DC power supply current draw. These inputs allow the Inogen One to detect emerging conditions, to notify the user of appropriate corrective action where applicable, or to shut down to protect the safety of the patient and the device. The Inogen One is a “smart device,” in that it continuously monitors its operating condition; it will alert the user with audible, visual (LEDs), and text (LCD), directing the user to take appropriate corrective actions when possible. The system is designed to be fail-safe, meaning that when the device is not showing an alert, it is operating normally.

Operation at Reduced Ambient Pressure

The Inogen One is rated to operate at altitudes up to 10,000 ft (3050 m). Most commercial airplane cabins are pressurized to 8000 ft (2400 m) or 10.9 psia (750 mbar).

Because the Inogen One takes in air at ambient pressure and delivers it to the patient (at nearly ambient pressure), the device intakes a lower molar flow of air and produces a lower molar flow of oxygen at reduced ambient pressures. A patient who normally uses the device at setting 2 while at rest at sea level may need to turn the device up to setting 2.5-3.0 while in an aircraft. For this reason, the Inogen One may not be suitable for patients who normally use the device at the highest settings (4-5) while resting at sea level. Inogen suggests that it is prudent that patients confer with their physician before attempting to travel by air using any supplemental oxygen supply. Roughly speaking, the following flow settings are approximately equal in molar delivery of supplemental oxygen:

Sea Level Inogen One Flow Setting	Approximate Setting in Pressurized Aircraft Cabin (8000 ft equivalent)
1.0	1.0 - 1.5
1.5	2.0
2.0	2.5 - 3.0

2.5	3.0 - 3.5
3.0	4.0
3.5	4.5 - 5.0
4.0	5.0 +
4.5	---
5.0	---

The Inogen One monitors its oxygen concentration during operation, and adjusts its measurements for ambient pressure using an embedded ambient pressure sensor. This sensor allows the device to recognize the conditions under which it is operating and to respond accordingly.

Maintenance

The Inogen One is designed to be a highly reliable and low maintenance device intended for continuous duty usage. The company recommends that the home health care provider visit the patient 2-4 times per year to check on the state of the device and to ensure proper use by the patient. Patients are required to remove and clean a coarse intake filter on a weekly basis to assure unobstructed air intake. Standards presently suggest the providers visually inspect the product line bacteria filter annually. On the Inogen One, this is done by simply unscrewing the cannula hose barb – the outer case of the device need not be removed. The compressor is rated for 18,000 hours between overhauls. Devices used by patients at lower flow settings may require less frequent overhauls.

The Lithium Ion battery packs for the Inogen One have been demonstrated through life testing to be highly durable. Replacement packs may be ordered from Inogen. The battery pack communicates all errors to the concentrator.

Device Durability

The Inogen One has undergone significant durability testing, and will continue to be evaluated for durability in the coming months. Inogen's test program includes (a) high cycle life testing (moving parts), (b) drop / shock testing, (c) user evaluation / testing, and (d) Highly Accelerated Life Testing (HALT). The company believes that the Inogen One will prove to be both durable and reliable.

Other Concerns or Issues

Inogen believes that the Inogen One presents no risk to either patients or other passengers on board commercial aircraft. As with any mechanical device (such as pressure

regulators on compressed gas cylinders), some risk always exists of mechanical failures. Inogen believes this risk to be very small for the Inogen One.

The Inogen One is designed for efficacy, reliability, and ease of transport. The combination of these three characteristics not only enables patient activity, but it also provides a level of freedom that previously did not exist. The ability of a patient to continue living an active life, including travel, is extremely important to the patient's health and life expectancy.

The device is small enough to fit under aircraft seats, and should not present any impediment to motion throughout the cabin in the case of emergency. It may be stowed safely on its base or side without risk to function. Additionally, special precautions have been taken with the device to reduce its radiated emissions. The DOT has recommended, and the ATA has acknowledged, that medical devices complying with radiated emissions standard RTCA DO-160D (Section 21, Category M) be deemed safe for operation on all commercial airlines. The Inogen One has been tested and certified to comply with this standard.