INOGEN ONE G4 OXYGEN CONCENTRATOR SYSTEM

CE Technical File

Confidentiality Statement

The contents of this file and documents referenced in this file
are considered the confidential and proprietary information of Inogen.
The contents may not be disclosed to
anyone outside of Inogen without written permission.

Revision	Changes	Responsible	Date	DCR
A	Initial Release	A. Baduel	See DCR	2016-356
B	Revised file to include images of new G4 carry bag design and include G4 backpack (CA-450).	A. Baduel	13-Feb-2018	2018-009
C	Revised file to add Bluetooth capable version and update technical standards	B. Hedden	25-Sept-2020	2019-081

Table of Contents

1. Purpose and Scope 4
2. Primary References 4
3. Company Information 4
Name and address of Manufacturer 4
Name and address of EC Authorized Representative 4
Name and address of EU Notified Body 4
4. Device Description 5
4.1 Device Usage 5
4.2 Inogen Accessories 6
4.3 OEM Accessories 9
5 Device Classifications and Conformity Assessment 10
MDD Device Classification: 10
MDD Conformity Assessment Route: 10
Certificates Supporting CE Marking: 10
CE Marked Devices: 11
6 Device Specifications 11
6.1 Technical Description – Inogen One G4 Oxygen Concentrator 11
6.2 Technical Description – 4-Cell (Single Cell) Battery, (BA-400) 13
6.3 Technical Description – 8-Cell (Double Cell) Battery, (BA-408) 14
6.4 Technical Description – AC Power Supply (BA-401) 15
6.5 Technical Description – Carry Strap (CA-401) 16
6.6 Technical Description – Bag (CA-400) 17
6.7 Technical Description – Backpack (CA-450) 18
6.8 Technical Description – Inogen One G4 Oxygen Concentrator System 19
6.8 Catalog Numbers, Device Master Records, Bills of Material, Drawings, Component Specifications 20
6.9 Labeling and Instructions for Use 20
7 Applicable Technical Standards for Product Design 22
7.1 Standards Fully Applied: 22
7.2 Standards Partially Applied 23
7.3 Statements about standards not applicable or partially applied to the Inogen One G4 Oxygen Concentrator 24
8 Essential Requirements Checklist 24
9 Risk Analysis Summary 24
10 Design Validation Test Summary 25
For a listing of validation activities and associated protocols and reports, reference document DV-05237-00, Master Validation and Verification Matrix, Inogen One G4 and the design history records. 25
11 Clinical Data Summary 25
12 Manufacturing Information 25
12.1 Description of the manufacturing processes: 25
12.2 Manufacturing Process Validation 26
12.3 Quality Systems Certifications 26

12.4 Contracted Manufacturing Activities 26

1. Purpose and Scope

The purpose of this document is to demonstrate compliance of the Inogen One G4 Oxygen Concentrator System with the requirements of the European Medical Device Directive. Contents of this file and referenced documents support CE marking and marketing of the Inogen One G4 system in the European Union.

This document covers the Inogen One G4 Oxygen Concentrator System, and includes accessories listed below.

2. Primary References

- RG-07252-00, Inogen One G4 EC Technical File Essential Requirements Matrix
- RG-01058-02, Inogen Class IIa Devices EC Declaration of Conformity
- RG-01058-03, Inogen Class I Accessories EC Declaration of Conformity
- RG-01058-04, Inogen Oxygen Concentrator Systems EC Declaration of Conformity
- RG-01058-05, Inogen CE Marked Products

Other documents are specified below and/or in referenced files.

3. Company Information

Name and address of Manufacturer

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

Additional Site 1:
Inogen, Inc. (Customer Service)
1125 East Collins Boulevard, #200
Richardson, TX 75081
USA

Additional Site 2:
Inogen, Inc. (Manufacturing & Service)
1225 Commerce Drive
Richardson, TX 75081
USA

Name and address of EC Authorized Representative

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Name and address of EU Notified Body

BSI Group The Nethelands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam

4. Device Description

4.1 Device Usage

4.1.1. General:

The Inogen One G4 Oxygen Concentrator is used on a prescriptive basis by patients requiring supplemental oxygen. Patients may include, but are not restricted to, those with chronic obstructive pulmonary disease (COPD). Supplemental oxygen has been shown to increase the fraction of oxygen in the lungs to help prevent chronic and periodic hypoxemic conditions. The device is not intended to be life sustaining or to be life supporting. It is used with a nasal cannula to channel oxygen from the device to the patient. The concentrator and the nasal cannula are non-sterile.

The Inogen One G4 Oxygen Concentrator provides approximately 90% oxygen to the patient on a demand flow basis at a pulsed rate of 0.21 liters per minute to 0.63 liters per minute in increments of 0.21 liters per minute.

The Inogen One G4 Oxygen Concentrator is capable of continuous use in a home, institution, vehicle and various mobile environments. Power options include 100-240 VAC, 13.5-15.0 VDC or rechargeable batteries.

The Inogen One G4 Oxygen Concentrator is capable of Bluetooth functionality but will be disabled when shipped to EU countries.

4.1.2. Indications for Use:

The Inogen One G4 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 G4 may be used in a home, institution, vehicles and various mobile environments.

4.1.3. Primary Contraindications:

The Inogen One G4 Oxygen Concentrator is not intended to be life sustaining or life supporting.

See Owner Manual for additional information.

4.1.4. Primary Warnings and Cautions:

For use under direction of medical practitioner by prescription only (USA and other countries); prior to use patient should be evaluated by physician or clinician to determine ideal flow setting.

User is to: not operate while smoking or near open flame; operate only within specified environmental conditions; not obstruct air intake/ exhaust when operating; not submerse in liquid or expose to water or precipitation; not use cleaning agents other than those specified; not disassemble; use only recommended power supplies and accessories.

See Owner Manual for additional information.

4.1.5. Environmental Specifications:

Operation

- Temperature: 5 to 40°C
- Humidity: 0 to 95%, non-condensing
- Atmospheric Pressure: 70kPa to 106kPa

Storage

- Temperature: -25 to 70°C
- Humidity: 0 to 95%, non-condensing

4.2 Inogen Accessories

The accessories listed below are also covered by this Technical File and CE marked by Inogen.

4.2.1 4 Cell (Single-Cell) Battery (Lithium Ion), (BA-400)

- Required
- Provides approximately 2.6 hours of normal operation to the concentrator
- Recharges in approximately 2.6 hours
- Rechargeable in the concentrator using AC power supply or DC power cord
- Rechargeable in the External Battery Charger

4.2.2 8-Cell (Double-Cell) Battery (Lithium Ion), (BA-408)

- Optional
- Provides approximately 5 hours of normal operation to the concentrator
- Recharges in approximately 4.4hours
- Rechargeable in the concentrator using AC power supply or DC power cord
- Rechargeable in the External Battery Charger

4.2.3 External Battery Charger (BA-403)

- Optional
- Charges 4-cell and 8-cell batteries

"The External Battery Charger is not considered a medical device accessory because it is not required inorder for the concentrator to perform its intended function. The External Battery Charger simply recharges the batteries (which are considered medical device accessories). However, the batteries do not require the use of the External Battery Charger in order to be recharged and are able to be recharged by simply switching to A/C power with the batteries still attached to the device. The determination of the External Battery Chargers not being considered medical device accessories is consistent with the definition of a medical device accessory which is outlined in the EU Medical Device Guidance Document, MEDDEV 2.1/1."

4.2.4 Carry Strap (CA-401)

- Optional
- Designed to attach directy to the concentrator
- Allows easy transport and operation of the concentrator

4.2.5 Bag (CA-400)

- Optional
- Custom bag that serves as a protective cover for the Inogen One G4
- Allows easy transport and operation of the concentrator

4.2.6. Backpack (CA-450-01)

- Optional
- Custom bag that serves as a protective cover for the Inogen One G4
- Allows easy transport and operation of the concentrator

4.2.7. Backpack (CA-450-02)

- Optional
- Custom bag that serves as a protective cover for the Inogen One G4
- Allows easy transport and operation of the concentrator

4.3 OEM Accessories

These accessories are intended to be used with the Inogen One G4 and are CE marked by the supplier:

4.3.1 AC Power Supply

- When connected to AC power 100-240V, 50-60Hz, powers the concentrator and recharges the battery
- Provided with AC power cord

Supplied by Megmeet or Eurasia as a CE marked medical power supply per: IEC 60601-1:2005 and89/336/EEC, EMC Directive

4.3.2 DC Power Cord

- When connected to DC power 13.5-15.0V (e.g., car, RV, boat, airplane), powers the concentrator and recharges the battery
- Provided with DC power cord, automobile cigarette lighter adapter plug/ cord

4.3.3 Nasal Cannula

- Required
- Provides gas pathway from the concentrator to the patient's nostrils
- Supplied by Salter Labs as a CE marked device
- Equivalent cannula may be used

5 Device Classifications and Conformity Assessment

MDD Device Classification:

The Inogen One G4 Oxygen Concentrator is a Class IIa device per rule 11. It delivers substances (concentrated oxygen gas) to the patient. There are no unusual or significant hazards to the patient.

The Battery, External Battery Charger, Carry Strap, and Bag are accessories and Class I per rule 1.

MDD Conformity Assessment Route:

Inogen has selected EC Directive 93/42 EEC Annex II.3, Full Quality Assurance as the assessment route for class IIa devices.

Certificates Supporting CE Marking:

EC Annex II.3 certificate issued by BSI #CE 670456
ISO 13485:2016 certificate issued by BSI #FM 670059

CE Marked Devices:

See RG-01058-05, Inogen CE Marked Products for a listing.

6 Device Specifications

6.1 Technical Description – Inogen One G4 Oxygen Concentrator

6.1.1 Primary Functions:

- Produce a high concentration of oxygen from ambient air using pressure swing adsorption technology
- Detect onset of patient inhalation
- Deliver a specified volume of concentrated oxygen to the patient

6.1.2 Oxygen Concentrator Technology:

- The Inogen One G4 Oxygen Concentrator uses molecular sieve/ pressure swing adsorption technology. Ambient air is drawn through particle filters by a compressor and forced by pressure through molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. Oxygen is collected in an accumulator reservoir. The airflow is then changed and nitrogen is desorbed from the molecular sieve, allowing it to adsorb again during the next cycle. Waste nitrogen is exhausted back into the room. A series of sieve beds, a manifold with precision valves, sensors and embedded software to control the cycle are used to make the system function.

Oxygen is delivered to the patient on a demand flow basis in precise amounts during the inhalation part of the breathing cycle. This conserver technology eliminates waste of unused oxygen at other times in the breathing cycle when it is not needed. The Inogen One G4 Oxygen Concentrator senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas from the

accumulator reservoir, through a final filter, into the connected nasal cannula and onto the patient. Pressure sensors and embedded software are used to control the conserving function.

The design of the Inogen One G4 Oxygen Concentrator has focused on maximizing subsystem efficiencies and miniaturizing components to enable continuous duty use and to provide minimal weight and battery operation for mobile use.

6.1.3 Device Inputs/ Outputs:

- Input:13.5-15.5 VDC, ambient air
- Output: 90% purity bolus delivery oxygen
- Used with an AC Power Supply that converts 100-240VAC, 50-60Hz to 19.0VDC, or
- Used with a DC Power Cord with 13.5VDC to 15.5VDC, or
- Used with Battery that supplies 14.4 VDC nominal

6.1.4 Operator Controls:

- On/ Off
- Flow control
    - Audible alert
- Battery insertion/ removal
- Power cord connection
- Nasal Cannula/ tubing connection

6.1.5 Displays/ Indicators/ Alerts:

- Alphanumeric LCD display to communicate flow setting, battery life remaining, status messages, error messages, etc.
- Green and yellow LED indicators to communicate status and alert conditions
- Audible buzzer to communicate status and alert conditions

6.1.6 Primary Performance Specifications:

- The Inogen One G4 Oxygen Concentrator has three (3) flow settings and produces 0.21 LPM to 0.63 LPM (210 ml/min, 420 ml/min, & 630 ml/min) of 90% oxygen, -3% / +6% at STP.

The Inogen One G4 Oxygen Concentrator will deliver bolus volume that is dependent on the flow setting and the patient's breathing rate. Concentrator software calculates the bolus volume based on these factors so that the total amount of oxygen delivered each minute is held constant. When a patient takes an extended pause between breaths, the subsequent bolus is larger to compensate, and vice versa.

The gas temperature at the Oxygen Concentrator outlet does not exceed 41°C and does not exceed 6ºC above ambient temperature when operated within the recommended ambient temperature range.

For a more detailed list of performance specifications, see DS-05733-00, Performance and Service Specifications, Inogen One G4.

6.1.7 Mechanical, Electrical and Software Specifications:

See DM-IO-400, Inogen One G4 Oxygen Concentrator Device Master Record

6.1.8 Electrical Ratings when used with AC Power Supply:

Voltage: 100-240 VAC
Frequency: 50-60 Hz
Power: 65 W max

Construction: Portable
IEC 60601-1:2005 Protection Class: II
Supply Connection: Appliance Inlet
Operation: Continuous
Applied Part Type: BF
Use with Flammable Anesthetic: No

6.1.9 Safety Features:

Temperature control, current sensor, cooling fan, alarms, automatic shut-down

Oxygen flow control: oxygen sensor, breath sensor, automatic shut-down

Input air and output gas filtration

Pressure control: low level maximum pressurization, high pressure vessel safety factor

Electrical protection: medical grade power supply, over-current and voltage variation protection, dielectric spacing, well labeled connectors, alarms, automatic shut-down

Vibration and noise control: motor/ compressor design, vibration isolation mounting

6.2 Technical Description – 4-Cell (Single Cell) Battery, (BA-400)

6.2.1 Primary Function:

Provide power to the Oxygen Concentrator when other power is not available
Recharge when power is available

6.2.2 Technology:

Utilizes four 4.2V Volt Lithium Ion rechargeable cells
Utilizes system management bus (SMBUS) technology

6.2.3 Inputs/ Outputs:

Input: 16.8V-12.0V DC

Output: 14.4V VDC nominal

6.2.4 Operator Controls:

Concentrator insertion/ removal
Battery charger insertion/ removal

6.2.5 Indicators, Alerts:

Capacity with button push on battery

6.2.6 Device Specifications:

See DM-BA-400, Battery Device Master Record

6.2.7 Electrical Ratings:

Output Voltage: 12.0-16.8 VDC
Capacity: 3.5 Ah or 50.9 Wh
Charging Rate: 1.6 A max
Discharge Rate: 5.0 A max

6.2.8 Safety Features:

Double sealed lithium ion cells
Over-temperature protection
Over-charge protection

6.3 Technical Description – 8-Cell (Double Cell) Battery, (BA-408)

6.3.1 Primary Function:

Provide power to the Oxygen Concentrator when other power is not available
Recharge when power is available

6.3.2 Technology:

Utilizes eight 4.2 Volt Lithium Ion rechargeable cells
Utilizes system management bus (SMBUS) technology

6.3.3 Inputs/ Outputs:

Input: 16.8 VDC
Output: 14.4 VDC nominal

6.3.4 Operator Controls:

Concentrator insertion/ removal
Battery charger insertion/ removal

6.3.5 Indicators, Alerts:

Capacity with button push on battery

6.3.6 Device Specifications:

See DM-BA-408, Battery Device Master Record

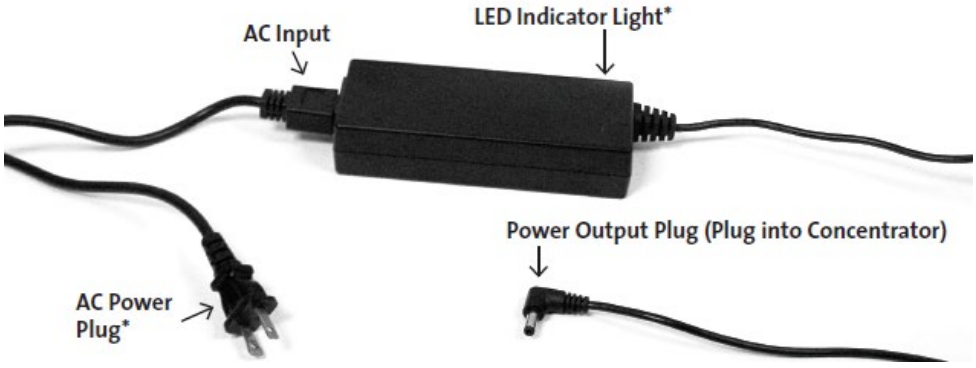
6.3.7 Electrical Ratings:

Output Voltage: 12.0-16.8 VDC
Capacity: 6.5 Ah or 93.6 Wh
Charging Rate: 2.5 A max
Discharge Rate: 5.0 A max

6.3.8 Safety Features:

Double sealed lithium ion cells
Over-temperature protection
Over-charge protection

6.4 Technical Description – AC Power Supply (BA-401)



6.4.1 Primary Function:

Provide power to the Oxygen Concentrator from AC power source

6.4.2 Inputs/ Outputs:

Input: 100-240 VAC, 50-60Hz

Output: 19 VDC

6.4.3 Operator Controls:

Power cord connections

6.4.4 Indicators, Alerts:

Green LED indicator to communicate operation condition

6.4.5 Device Specifications:

See DM-BA-401, AC Power Supply

6.4.6 Electrical Ratings:

AC
Input Voltage: 100-240 VAC, 50-60 Hz
Load Current: 1.0 A
Output Voltage: 19 VDC
Output Power: 65 W max

6.4.7 Safety Features:

Protection class II
Output overload protection
Over-temperature protection/ shutdown

6.5 Technical Description – Carry Strap (CA-401)

6.5.1 Primary Function:

Easy transport

6.5.2 Input/ Outputs:

None

6.5.3 Operator Controls:

Attachment to Oxygen Concentrator

6.5.4 Indicators, Alerts:

None

6.5.5 Device Specifications:

See DM-CA-401, Carry Bag Device Master Record

6.5.6 Electrical Ratings:

Not applicable

6.5.7 Safety Features:

None

6.6 Technical Description – Bag (CA-400)

6.6.1 Primary Function:

Protective cover for Oxygen Concentrator and accessories
Easy transport with bag shoulder strap

6.6.2 Input/ Outputs:

None

6.6.3 Operator Controls:

Placement of Oxygen Concentrator in bag

6.6.4 Indicators, Alerts:

None

6.6.5 Device Specifications:

See DM-CA-400, Carry Bag Device Master Record

6.6.6 Electrical Ratings:
Not applicable

6.6.7 Safety Features:
None

6.7 Technical Description – Backpack (CA-450-01)

6.7.1 Primary Function:
Protective cover for Oxygen Concentrator and accessories
Easy Transport

6.7.2 Inputs/ Outputs:
None

6.7.3 Operator Controls:
Placement of Oxygen Concentrator in the protective zippered compartment

6.7.4 Indicators, Alerts:
None

6.7.5 Device Specifications:
See DM-CA-450-01, Backpack Device Master Record

6.7.6 Electrical Ratings:
Not Applicable

6.7.7 Safety Features:
None

6.8 Technical Description – Backpack (CA-450-02)

6.8.1 Primary Function:
Protective cover for Oxygen Concentrator and accessories
Easy Transport

6.8.2 Inputs/ Outputs:
None

6.8.3 Operator Controls:
Placement of Oxygen Concentrator in the protective zippered compartment

6.8.4 Indicators, Alerts:
None

6.8.5 Device Specifications:
See DM-CA-450-02, Backpack Device Master Record

6.8.6 Electrical Ratings:
Not Applicable

6.8.7 Safety Features:
None

6.9 Technical Description – Inogen One G4 Oxygen Concentrator System

6.9.1 Primary Function:
Provide oxygen from a variety of power sources in a mobile environment

6.9.2 System Components:

Inogen One G4 Oxygen Concentrator
4-Cell and/or 8-Cell Battery
AC Power Supply
DC Power Cord
Carry Strap
Bag
Nasal Cannula

6.9.3 System Specifications:

See DM-IS-400, Inogen One G4 Oxygen Concentrator System Device Master Record

6.9.4 Catalog Numbers, Device Master Records, Bills of Material, Drawings, Component Specifications
The top level documents that define the Inogen One G4 Oxygen Concentrator System are:

Device/ Accessory	Catalog #	Device Master Record
Oxygen Concentrator	IO-400	DM-I0-400
4-Cell Battery	BA-400	DM-BA-400
8-Cell Battery	BA-408	DM-BA-408
AC Power Supply	BA-401	DM-BA-401
DC Power Cord	BA-306	DM-BA-306
Carry Strap	CA-401	DM-CA-401
Bag	CA-400	DM-CA-400
Backpack	CA-450-01	DM-CA-450-01
Backpack	CA-450-02	DM-CA-450-02
Inogen One G4 System	IS-400	DM-IS-400

All bills of materials, drawings, components, manufacturing procedures and quality procedures necessary to produce products are referenced in these documents.

6.10 Labeling and Instructions for Use

6.10.1 Device Labels:

Identification/ ratings labels are included on:
Oxygen Concentrator
Battery
AC Power Supply
DC Power Cord
Battery Charger and Power Supply
Bag
Backpack
Nasal Cannula

User Interface Labels are included on:
Oxygen Concentrator
Battery Charger

Package Labels are provided for each device, accessory and system.

See Product Labeling Specifications Inogen One G4, DS-05730-00, for label details.

6.10.2 Instructions for Use:

The Owner Manual, P/N 96-06728-00 (English) and 96-06729-00 (Multi-Language), contains all necessary instructions for the patient to set-up, operate and maintain the Inogen One G4 Oxygen Concentrator system, including accessories.

The Inogen One G4 Oxygen Concentrator includes an LCD screen that provides operational status messages.

The AC Power Supply instructions for use are included in the Inogen One G4 IFU, P/N 96-06728-00 and 96-06729-00.

The Inogen One G4 Backpack instructions for use are included in P/N, 96-08199-00-01.

The Salter Nasal Cannula includes identification and instructions for use, along with information available online. A summary of these instructions, as applicable to the Inogen One G4, for use is also included in the Inogen Owner Manual.

6.10.3 Language Translations:

Device labeling and instructions for use are initially approved in English. They are translated into appropriate languages prior to marketing the Inogen One G4 in EU countries requiring languages other than English.

Internationally recognized symbols and other defined symbols have been used wherever possible. Symbols are defined in the Owner Manual.

LCD screen message language can be set through an administrative menu.

At time of initial release, instructions for use and LCD screen messages are intended to be translated into English, French, Italian, German, Spanish, Dutch, Portuguese, Norwegian, Swedish, Danish and Finnish.

6.10.4 Application of CE marking

The following CE marking is included on the concentrator and accessory ratings labels, package labels, and instructions for use:

Oxygen Concentrator – CE2797
4-Cell Battery – CE (Totex)
8-Cell Battery – CE (Totex)
AC Power Supply – CE (Megmeet)
Carry Strap – CE (Case Concepts)

Bag – CE (Case Concepts)
Backpack (01)– CE (TetraFab)
Backpack (02) – CE (TetraFab)
Nasal Cannula – CE 2797 (Salter)
System – No additional CE marking appplied per Article 12 of MDD

7 7. Applicable Technical Standards for Product Design

7.1 Standards Fully Applied:

- Medical Device Directive 93/42/EEC (MDD)CAN/CSA-C22.2 No. 60601-1:08 Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance (Adopted IEC 60601-1:2005 + CORR.1)

- CAN/CSA-C22.2 No. 60601-1:08 TC 2:2011 (Corrigendum 2) Technical Corrigendum 2:2011 to CAN/CSA-C22.2 No. 60601-1:08 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005 - CORR.2)

- CAN/CSA-C22.2 No. 60601-1:14: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005 edition 3.0 + AMENDEMENT 1, 2012-07, MOD)

- CAN/CSA-C22.2 NO. 60601-1-6:11 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (Adopted IEC 60601-1-6:2010, third edition, 2010-01)

- CAN/CSA-C22.2 No. 60601-1-11:15 Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

- IEC 60529 B:2013, Edition 2.2, Degrees of Protection Provided by Enclosures (IP Code)

- IEC 62366 Ed 1.1 B:2014, Medical devices - Application of usability engineering to medical devices

- UL 1642 (2012), Lithium Batteries

- UL 2054 (2004), Household and Commercial Batteries

- IEC 62133 Ed. 2.0 B:2012, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

- EN-60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007)

- IEC 60601-1-8 Ed. 2.0:2012 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

- IEC 60601-1 Ed 3.0 B:2012Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-6 Ed 3.1 B:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

- IEC 60601-1-11 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- BS EN ISO 14971:2012, Medical devices. Application of risk management to medical devices
- ISTA 1A Non-Simulation Integrity Performance Tests
- ISTA 3A General Simulation Performance Tests

7.2 Standards Partially Applied:

- IEC 62304 Ed 1.1, EN:2015, Medical device software - Software life cycle processes
- RTCA 160E, Environmental Conditions and Test Procedures for Airborne Equipment
- BS EN ISO 8359:2009+A1:2012, Oxygen concentrators for medical use. Safety requirements
- IEC 60950-1: 2005, Information technology equipment –Safety
- UL94V-2 Flammability Standard
- UL94HF-1 Flammability Standard
- UL 1642 Standard for Lithium Batteries
- UL 2054 Standard for Household and Commercial Batteries
- UN38.3 Lithium Ion Battery Transportation Safety Testing Requirement
- BS EN ISO 80601-2-69:2014, Medical electrical equipment. Particular requirements for basic safety and essential performance of oxygen concentrator equipment
- BS EN ISO 10993-1: October 2009, Biological evaluation of medical devices. Evaluation and testing within a risk management process
- BS EN 1041:2008 + A1:2013, Information supplied by the manufacturer of medical devices
- IEC 60878 Ed 3.0 B:2015, Graphical symbols for electrical equipment in medical practice
- BS EN 980:2008, Symbols for the use in the labelling of medical devices
- BS EN ISO 15223-1:2016 , Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
- IEC 60417-1:2002, Graphical symbols for use on equipment
- ISO 7000:2012, Graphical symbols for use on equipment -- Registered symbols
- ISTA 2A (2011), Packaged-products weighing 150 lbs. (68kg) or less
  - Directive 2011/65/EU on EU RoHS 2
  - Directive 2012/19/EU on WEEE
  - RTCA/DO-160G Environmental Conditions and Test Procedure for Airborne Equipment
  - MIL-STD-461F MILITARY STANDARD: ELECTROMAGNETIC INTERFERENCE CHARACTERISTICS REQUIREMENTS FOR EQUIPMENT (31 JUL 1967)

- FCC, 47 CFR Part 15 Radio Frequency Devices
- 49 CFR 173 SHIPPERS-GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS (FAA SFAR)

7.3 Statements about standards not applicable or partially applied to the Inogen One G4 Oxygen Concentrator System:

- Sterility is not applicable to the Inogen One G4 Oxygen Concentrator and accessories are provided non-sterile.

- BS EN ISO 10993-1: October 2009, Biological evaluation of medical devices. Evaluation and testing within a risk management process is only partially applied to the Inogen One G4 Oxygen Concentrator and to Inogen CE marked accessories per Inogen's internal procedure, SOP-71-008, Biocompatibility, and TR-06609-00, Inogen One G4 Gas Output Analysis.

- BS EN ISO 8359:2009+A1:2012, Oxygen concentrators for medical use. This standard is written to test continuous flow output concentrators. As a result, there are test cases within this standard specific to continuous flow output accuracy and control, which is not applicable to the Inogen One G4 Concentrator, as it is a pulse-dose concentrator. The Inogen One G4 complies with BS EN ISO 8359:2009+A1:2012 to the extent it can be applied.

- BS EN 1041:2008 + A1:2013, Information supplied by the manufacturer of medical devices, IEC 60878 Ed 3.0 B:2015, Graphical symbols for electrical equipment in medical practice, BS EN ISO 15223-1:2012, Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements, ISO 7000:2012, Graphical symbols for use on equipment -- Registered symbols, IEC 60417-1:2002, Graphical symbols for use on equipment are broad in scope and applied partially as applicable to the Inogen One G4 Concentrator.

- IEC 60950-1, 2005, Information technology equipment – Safety, only Clause 4.7.3.4 & Clause 4.7.3.5 were applied to parts within the system.

- IEC 62304 Ed 1.1, EN:2015, Medical device software - Software life cycle processes is partially applied per Inogen's internal procedure, SOP-71-005, Product Software Development.

8 Essential Requirements Checklist

MDD Essential Requirements, application of standards, and compliance with requirements is detailed in matrix format in Inogen One G4 EC Technical File Essential Requirements Matrix, RG-06915-02. This document covers the Inogen One G4 Oxygen Concentrator System. The Inogen One G4 Oxygen Concentrator, Inogen CE marked accessories (Battery, Battery Charger, Carry Strap, and Bag), and Megmeet CE marked AC Power Supply are included.

9 Risk Analysis Summary

Risk Analysis has been performed both from a customer perspective to identify hazards to the patient/ user and utilizing FTA and FMEA techniques to identify potential component parts and sub-system failures and hazards that may occur.

Risk evaluation has identified potential hazards and quantified associated risks of the Inogen One G4 Oxygen Concentrator. Hazards have been categorized as follows: biological, energy (e.g., electrical), mechanical, device output (e.g., flow rate), use/ misuse and environmental.

Several hazards are associated with electrically powered devices. Product design has sought to minimize these risks. Electrical/ mechanical safety testing and electromagnetic compatibility testing have been conducted to demonstrate that such risks associated with the devices are minimal.

Several hazards associated with the device could lead to device failure/ shutdown and result in no supplemental oxygen to the patient. The resulting clinical affect to the patient would be some degree of hypoxia and the extent of harm would be dependent on the patient condition and amount of time without

oxygen. The Inogen One G4 is not intended to be life supporting or life sustaining. Hypoxia is a reversible condition that can be attended to by the patient. If the device malfunctions or fails, the unit will alarm, the patient will become aware of its failure and take appropriate action. A backup oxygen supply is recommended in case of device failure.

Risks that were found to be unacceptable are associated with misuse of the device around open flame or use of the device when smoking. To reduce these risks, a metal cannula fitting, which will act as a flame arrestor, has been integrated into the device. Labeling both on the device and in the Patient Manual warn the patient about this hazard.

Hazards and associated risks of the Inogen One G4 Oxygen Concentrator are acceptable for human use and release of the product to market. Any undesirable side-effect constitutes an acceptable risk when weighed against the performance intended, and the overall benefit versus risk of the device for its intended use is acceptable.

See Inogen One G4 Risk Analysis Report, RA-05234-01, for further details on design hazards and risks.

FMEA risk analysis of the manufacturing steps used to produce the Inogen One G4 are also contained therein. Risk Analysis will be reviewed post-market to identify and evaluate any unforeseen hazards and to review established risks. This will be done per the requirements of Inogen procedure, SOP 71-002, Risk Management. Risk Analysis will be updated as needed based on the post-market data.

10 Design Validation Test Summary

For a listing of validation activities and associated protocols and reports, reference document DV-05237-00, Master Validation and Verification Matrix, Inogen One G4 and the design history records.

11 Clinical Data Summary

Low flow oxygen therapy is not a life support treatment or therapy. The use of long term oxygen therapy (LTOT) in the home for the management of chronic hypoxemia is adjunctive and long term; LTOT is not considered an acute or short term therapy. The improvements in mortality seen in the NOTT and BMRC studies were not observed until patients remained on oxygen therapy of approximately 16 hours/day for 365 to 500 days. These data suggest the role of oxygen therapy in the treatment of hypoxemia is long term and dose related. Effective oxygen therapy is defined by the American Thoracic Society (ATS) as maintaining a SaO2 of ≥ 90% for 70% of the time. This recommendation is based in part on the evidence from the NOTT and BMRC studies that demonstrate improved clinical outcomes of LTOT based on average daily use of approximately 16 hours and suggests hypoxemic patients can safely tolerate short periods off their oxygen.

The Inogen One G4 portable oxygen concentrator (POC) is an effective low flow oxygen delivery system capable of meeting the clinical needs of appropriately prescribed users. The abundance of previously published science, along with Inogen One POC market experience, overwhelmingly supports the intended use, clinical applications and efficacy of the device. The risks associated with use of the Inogen One G4 POC are clearly outweighed by the long term clinical benefits of the device for prescribed users.

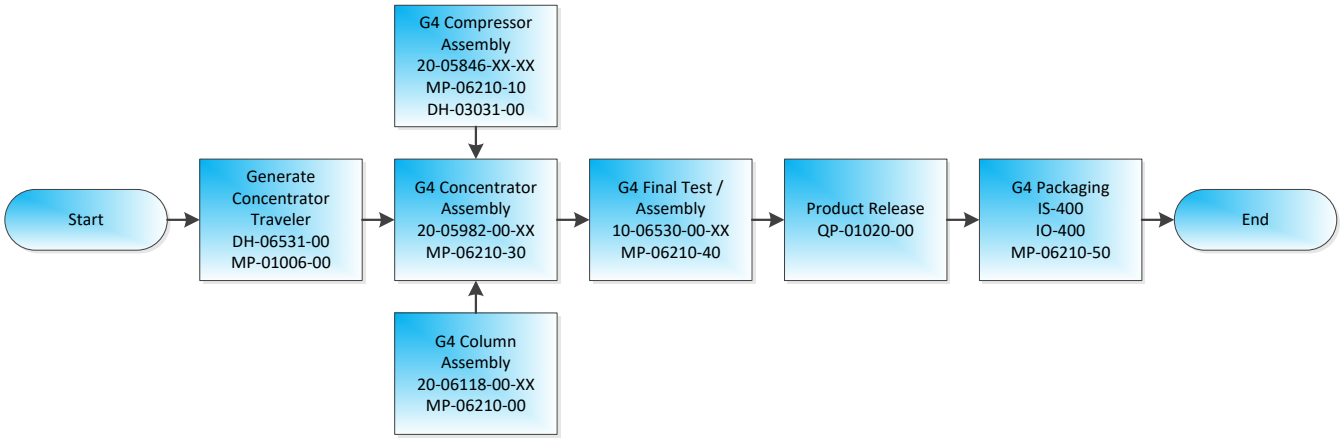
See CP-01424-00, Inogen One Clinical Evidence Report, CP-02651-00 Inogen One G2 Clinical Evaluation, CP-02651-01Inogen One and Inogen One G2 Clinical Evaluation, 2011, CP-02651-02 Inogen One Family Clinical Evaluation, Scientific Literature and Adverse Event Reports, Post Market Surveillance and Evaluation, 2012, CP-02651-03, Inogen Product Family Clinical Evaluation Scientific Literature and Adverse Event Reports Post Market Surveillance and Evaluation Report, and CP-07314-00, Inogen Product Family CER, for more details.

12 Manufacturing Information

12.1 Description of the manufacturing processes:

The Inogen One G4 Oxygen Concentrator is manufactured by Inogen at 1225 Commerce Drive, Richardson, TX (USA). Production operations consist of a series of assembly and test operations. Major sub-assemblies, such as the motor sub-assembly, housing sub-assemblies and circuit board assemblies,

are purchased components. The current overall manufacturing process is specified in the Inogen One G4 Manufacturing Flow Chart, QP-06529-00, and illustrated below:



12.2 Manufacturing Process Validation

VP-06616-00 Manufacturing Process Validation Plan, Inogen One G4

12.3 Quality Systems Certifications

Manufacture of the Inogen One G4 Oxygen Concentrator is covered by the Inogen quality system, which is certified to ISO 13485:2016 by BSI, as noted.

12.4 Contracted Manufacturing Activities

12.4.1 Oxygen Concentrator

There are no contracted or outsourced manufacturing activities for the Inogen One G4 Oxygen Concentrator other than purchased components, which are subject to incoming inspection.

Strategic suppliers (e.g., circuit board/ motor sub-assembly) are subject to supplier contracts and are evaluated and monitored for quality system compliance per Inogen procedure, SOP-74-001, Supplier Approval and Controls.

12.4.2 Accessories

The Batteries (BA-400 and BA-408) are manufactured by Totex Manufacturing of Torrance, CA. The Battery design is a collaborative effort between Inogen and Totex. Totex is certified to ISO 9001:2015 and ISO 13485:2016 by SARA.

The AC Power Supply (BA-401) is a standard CE marked medical grade power supply manufactured by Shenzhen Megmeet Electrical Company of China. Megmeet is certified to ISO 9001:2015 and ISO 14001:2015 by UCC, and to ISO 13485:2016 by SGS

The Carry Strap and Bag (CA-401 and CA-400, respectively) are designed by Inogen and contract manufactured by Case Concepts. Case Concepts is certified to ISO 13485:2016 by BSI.

The G4 Backpacks (CA-450-01 & CA-450-02) are designed by Inogen and contract manufactured by TetraFab. TetraFab abides by a Quality Management System standard which is in line with the standard, “MIL-STD 105E”..

The Nasal Cannula is an off-the-shelf CE marked device purchased from Salter Labs of Arvin, CA. Salter Labs is certified to ISO 13485:2016 by BSI.