

This supplemental insert MUST be given to the user of the product. Before using the product, read the user manual and this insert. Save this insert with the user manual.

The information in this insert is a supplement to the information provided in the user manual that came with your product. Refer to the user manual for more information.

1. General

1.1 Intended Use

POC1-CONNECT, to allow patients via their Android* or iOS mobile phone or tablet to display device settings, and to collect device performance and usage information for maintenance/servicing purposes only.

1.2 Indications for Use

The Invacare Mobile Medical Application Accessory POC1-CONNECT is intended for use with the Invacare Platinum Mobile Oxygen Concentrator POC1-100B device, to allow patients via their Android* or iOS mobile phone or tablet to display device settings, and to collect device performance and usage information for maintenance/servicing purposes only.

1.3 Dongle

The USB Dongle (A) is a USB connectivity device that is designed to allow the Platinum Mobile oxygen concentrator (“product”) to communicate via Bluetooth® with the Invacare Piccolo O₂ App. The App displays battery time remaining of the product, provides the user with self-directed help, and access to other resources. The App also delivers product diagnostic information to the cloud platform accessible by participating providers via the Invacare O₂ Provider Portal.

The latest version of the user manual can be downloaded from Invacare website at www.invacare.com.

For information on the Piccolo O₂ App, please visit www.invacare.com/BreatheSmartBreatheEasy.



2. Wireless Technology

2.1 Summary

The product, via the dongle, makes use of Bluetooth wireless technology. Bluetooth is a wireless communications system that is designed to operate in short-range wireless personal area networks (WPAN).

The product supports the Smart (low energy) Bluetooth protocol. It operates in the spectrum range 2.400 GHz to 2.4835 GHz industrial, scientific and medical (ISM) band. Smart Bluetooth uses 40 x 2 Mhz channels. Within a channel, data is transmitted using Gaussian frequency shift modulation. The bit rate is 1 Mbit/s and the maximum transmit power is 5 mW. The Smart Bluetooth protocol uses frequency hopping to counteract narrowband and interference problems.

*Android app available in November 2017

Technical Specification	Smart (low energy) Bluetooth
Class	Class 2
Distance/Range (theoretical max.)	10m (33ft)
Over the Air Data Rate	1 Mbit/s
Application Throughput	0.27 Mbit/s
Security	128-bit AES with Counter Mode CBCMAC and application layer user defined
Robustness	Adaptive frequency hopping, Lazy Acknowledgement, 24-bit CRC, 32-bit Message Integrity Check
Latency (from a non-connected state)	6 ms
Network Topology	Scatternet
Power Consumption	5 mW
Service Discovery	Yes
Profile Concept	Yes

2.2 Intended Wireless Environment

The intended environments are defined as the user's home, public settings, assisted living facilities, nursing homes, vocational settings and healthcare facilities. Across these environments, there may be numerous different items of both medical and non-medical equipment that may also operate on similar wireless technologies.

2.3 Quality of Service (QoS)

The wireless QoS needed for to assure effective product communication/display in the Piccolo O₂ App is optimized for Bluetooth when the product and connected device (i.e. iOS or Android*, phone or tablet) are within 10m (33ft). The wireless QoS needed for to assure effective product communication for transfer of data to the cloud platform is optimized when the connected device has sufficient cellular signal and/or adequate Wi-Fi connection.

If the wireless signal is lost, the remote display of product on the Piccolo O₂ App and delivery of diagnostic information to the cloud platform may be interrupted. Data latency and/or the probability of loss of service creates an inconvenience only and does not affect operation of the product and cannot inhibit the user's therapy or treatment.

2.4 Wireless Security

The product and Piccolo O₂ App include a cipher block chaining message authentication code (CBC-MAC) from a block cipher to protect data. Wi-Fi connections are recommended to include Wi-Fi Protected Access II (WPA2) security protocols. The security measures taken address:

- Embedded software
- Diagnostic software
- Bluetooth wireless technology

Users should not share their login details to the Piccolo O₂ App. Errors in the display or integrity of the data transmitted are a nuisance and will not interrupt function of the product.

2.5 Wireless Connection Issues

Users who experience connection problems should first verify Bluetooth connectivity functions are evident on both the product and connected device. Consult the Piccolo O₂ App Quick Start Guide and/or the product's user manual at www.invacare.com for further information.

2.6 Wireless Coexistence

Wireless coexistence testing has been conducted in line with ANSI C63.27:2017 and IEC 60601-1-2 4th edition.

The function of the product is not impacted if disruption of the dongle wireless communication occurs. If the dongle becomes disconnected from the product during use, remove the product from the radio frequency (RF) field and wirelessly reconnect to their device.

2.7 User Actions

Should the user be concerned about the Bluetooth connection for any reason, the user can:

1. Switch off the Smart Bluetooth functionality by simultaneously depressing the product's Display Backlight and Flow Selection buttons to disable the product's Bluetooth signal.
2. Close the App on the connected device.

3.0 Limited Product Warranty

See the user manual for information regarding product warranty.

3.1 Limited Dongle Warranty

Except as otherwise set forth below, Invacare warrants that the Dongle will be free from defects in materials and workmanship for a period of three (3) months from the date Invacare ships the product to the original purchaser or provider (“Dongle Warranty”). A copy of the original product invoice is required for coverage under the Dongle Warranty.

Invacare’s sole obligation and the original purchaser’s exclusive remedy under the Dongle Warranty is limited to Invacare’s repair and/or replacement, at Invacare’s option, of a defective Dongle accessory covered by the Dongle Warranty. Such repair or replacement does not include any labor or shipping charges incurred by Invacare in the replacement and/or repair of any such Dongle accessory. For Dongle Warranty service, please contact the provider from whom you purchased your product. In the event you do not receive satisfactory Dongle Warranty service, please write directly to Invacare at the address provided below.

Provide provider’s name, address, date of purchase, indicate nature of the defect and, if the product is serialized, indicate the serial number. Do not return the Dongle or products to Invacare without Invacare’s prior written authorization.

3.2 Limitations and Exclusions

The Dongle Warranty is extended only to the original purchaser who purchases the product new and unused from Invacare or a provider. The Dongle Warranty is not extended to any other person or entity and is not transferable or assignable to any subsequent purchaser or owner. Coverage under the Dongle Warranty will end upon any such subsequent sale or other transfer of title to any other person. The Dongle Warranty does not apply to problems arising from normal wear and tear or failure to adhere to the product instructions.

3.3 Disclaimers

The Dongle Warranty may not be modified or waived in any manner whatsoever without Invacare’s express written authorization.

THE DONGLE WARRANTY IS EXCLUSIVE AND IN LIEU OF ANY OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. EXCEPT AND TO THE EXTENT AS MAY BE PROHIBITED BY STATE OR PROVINCIAL LAW, IN NO EVENT SHALL INVACARE BE LIABLE FOR ANY DIRECT, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM OR ARISING OUT OF OR RELATED TO A DEFECT IN ANY PRODUCT, OR INVACARE’S PERFORMANCE OR FAILURE TO PERFORM ANY OF ITS OBLIGATIONS UNDER THIS WARRANTY, WHETHER OR NOT INVACARE HAS BEEN ADVISED, KNEW OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES, INCLUDING, BUT NOT LIMITED TO, LOST PROFITS.

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