



**Rhaeos® FlowSense® Technical Data**

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## Wireless Specifications

Wireless performance	
Wireless protocol	Bluetooth Low Energy version 5.0
Minimum Bluetooth requirements for service	Version 4.2
Wireless frequency	2.4 GHz
Power	3.7 V Li-ion battery
Operating distance	10 feet
Security	Bluetooth Low Energy Secure Connection

## EMC Guidance and Manufacturer's Declarations

This system complies with part 15 of the FCC Rules. Operation is subject to the follow two conditions: (1) this system may not cause harmful interference, and (2) this system must not accept any interference received, including interference that may cause undesired operation.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions	
Emissions Test	
RF emissions	CISPR 11:2015 +A1:2016 +A2:2019
Harmonic emissions	N/A battery powered
Voltage fluctuations/flicker emissions	N/A battery powered

Guidance and Manufacturer's Declaration – Electromagnetic Immunity	
Immunity Test	
Electrostatic discharge (ESD)	IEC 61000-4-2:2008
Electrical fast transient/burst	N/A battery powered with no cables
Surge	N/A battery powered
Voltage dips, short interruptions and voltage variations on power supply input lines	N/A battery powered
Power frequency (60 Hz) magnetic field	IEC 61000-4-8:2009

Guidance and Manufacturer's Declaration – Radiofrequency Electromagnetic Immunity	
Conducted RF	N/A battery powered with no cables
Radiated RF	IEC 61000-4-3:2020

Emissions Test	Compliance	Electromagnetic Environment Guidance
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<b>RF radiated emissions CISPR 11</b>	Class B	The FlowSense system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
<b>RF conducted emissions CISPR 11</b>	Not applicable	The FlowSense system is suitable for use in all hospital and clinical environments.
<b>Harmonic emissions IEC 61000-3-2</b>	Not applicable	
<b>Voltage fluctuations/ flicker emissions IEC 61000-3-3</b>	Not applicable	

<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment Guidance</b>
Electrostatic discharge (ESD) IEC 60601-1-2 : 2014 levels	±8 kV contact  ±2, 4, 8, 15 kV air	±8 kV contact  ±2, 4, 8, 15 kV air	Floors should be wood, concrete, or ceramic tile. Synthetic materials and low humidity may cause higher levels of ESD .
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable	Not applicable

<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment Guidance</b>
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Surge IEC 61000-4-5	N/A battery powered	N/A battery powered	Not applicable
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	N/A battery powered	N/A battery powered	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

## Cybersecurity Guidance

- This product communicates sensor data using Bluetooth Low Energy and requires a minimum of Bluetooth Low Energy 4.2 to support data encryption.
- The Bluetooth Low Energy communications shall use the native Bluetooth Low Energy Over the Air encryption Level 1 Mode 2, which is AES-128 CCM mode.
- Always confirm the LED indicator light pattern as described in the mobile application during use.
- If the application indicates the shunt monitor has been used before, confirm that this is expected for the shunt monitor in use. If unexpected, disconnect from the shunt monitor and confirm proper connection.
- The mobile application is digitally signed to enforce integrity.
- FlowSense shunt monitors should remain in their packaging until use to disable wireless access.
- Unexpected shunt monitor function will be indicated as an error to the user during use.
- The software within shunt monitor units is not updateable. The manufacturer will communicate any identification of critical security vulnerabilities identified that require use to be halted.
- Updates to the FlowSense mobile application will be distributed via the associated application store for the mobile device. Critical updates will be communicated by the manufacturer.
- This product does not contain any user configuration options.
- The shunt monitor does not store any patient or operating data beyond its operational life span. No decommissioning activities are needed.
- Any available measurement logs on the mobile device used to host the mobile application should be deleted upon decommissioning.