

## Rhaeos® FlowSense® Technical Data

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## Wireless Specifications

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

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment. The device complies with IEC EN 60601-1-2:2014.

- All medical electrical equipment must be put into service in accordance with the EMC information provided in these tables and in the Directions for use.
- Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The device complies with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- However, it is good practice to avoid using the device in extremely close proximity to other equipment.

**Note** The FlowSense<sup>®</sup> shunt monitor is intended for use in professional healthcare environments.

**Note** The FlowSense<sup>®</sup> shunt monitor uses Bluetooth Low Energy ( $\geq 4.2$ ) to transmit thermal flow data to the mobile application for processing and displaying calculated shunt flow measurement results. The FlowSense<sup>®</sup> shunt monitor may experience an interruption in Bluetooth connection to the mobile application in the presence of EM disturbances. An interruption in Bluetooth connection will result in an error

code displayed on the mobile application of the lost connection and any active measurement will not be completed. Once the EM disturbances stop, the user will be able to reconnect to the FlowSense<sup>®</sup> shunt monitor through the mobile application and begin a new measurement.

**Warning** Maintain a minimum separation distance of 12 inches (30 cm) between the FlowSense<sup>®</sup> shunt monitor and portable RF communication equipment (including peripherals such as antenna cables and external antenna). Performance the FlowSense<sup>®</sup> shunt monitor might degrade if proper distance is not maintained.

**Warning** The FlowSense<sup>®</sup> shunt monitor has not been tested in the presence of diathermy equipment and should not be used in close proximity to active diathermy equipment.

**Warning** The FlowSense<sup>®</sup> shunt monitor has not been tested in the presence of electrocautery equipment and should not be used in close proximity to active electrocautery equipment.

**Warning** The FlowSense<sup>®</sup> shunt monitor is not compatible with Magnetic Resonance Imaging (MRI) equipment and should not be used during MRI procedures.

**Caution** The FlowSense<sup>®</sup> shunt monitor has not been tested for use in proximity to wireless power transmit devices.

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

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

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

Emissions Test	Compliance	Electromagnetic Environment Guidance
<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	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
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.