

**REVISION HISTORY**

Rev.	Revised Section/Paragraph
<b>A</b>	<p>Creation. Enclosed: User manual Spider SAS U908E For approval of the document before launching the AM process.</p>
<b>B</b>	<p>Enclosed: User manual Spider SAS U908F Update for US/CAN submission. 4.5.           WARRANTY Updated from: All reusable sensors are guaranteed for 1 (one) year from the date of delivery. Belts and bags are eligible for a 3-month warranty.  To: All reusable sensors, in this case, oximeter and piezo sensors, are guaranteed for 1 year. All reusable accessories are guaranteed for 3 months including ECG cables, Bluetooth dongle, bags, pouches, blue and beige belts. The 1-year warranty applies neither to consumables nor to single-use devices.</p>
	<p>Replace the content of §4.7 with the text below: UNITED STATES This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:</p> <ul style="list-style-type: none"> <li>- Reorient or relocate the receiving antenna.</li> <li>- Increase the separation between the equipment and receiver.</li> <li>- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.</li> <li>- Consult the dealer or an experienced radio/TV technician for help.</li> </ul> <p>CAUTION: This equipment may not be modified, altered, or changed in any way without signed written permission from MicroPort CRM. Unauthorized modification may void the equipment authorization from the FCC and will void the MicroPort CRM warranty.</p> <p>This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines.</p>

	<p>This equipment has very low levels of RF energy that is deemed to comply without testing of specific absorption rate (SAR).</p> <p>CANADA</p> <p>This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.</p> <p>Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada.</p> <p>To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.</p> <p>This equipment complies with IC radiation exposure limits set forth for an uncontrolled environment and meets RSS-102 of the IC radio frequency (RF) Exposure rules.</p> <p>This equipment has very low levels of RF energy that is deemed to comply without testing of specific absorption rate (SAR).</p> <p><i>Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) il ne doit pas produire de brouillage, et (2) l'utilisateur du dispositif doit être prêt à accepter tout brouillage radioélectrique reçu, même si ce brouillage est susceptible de compromettre le fonctionnement du dispositif.</i></p> <p><i>Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada.</i></p> <p><i>Dans le but de réduire les risques de brouillage radioélectrique à l'intention d'autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.</i></p> <p><i>Cet équipement est conforme aux limites d'exposition aux rayonnements énoncées pour un environnement non contrôlé et respecte les règles d'exposition aux fréquences radioélectriques (RF) CNR-102 de l'IC.</i></p> <p><i>Cet équipement émet une énergie RF très faible qui est considérée comme conforme sans évaluation du débit d'absorption spécifique (DAS)</i></p>
<p><b>C</b></p>	<p>§4.7 US Federal communications commissions (FCC) and industry Canada</p> <p>Addition of the following text:</p> <p>This device complies with part 15 of the FCC rules.</p> <p>Operation is subject to the following two conditions:</p> <ol style="list-style-type: none"> <li>1. this device may not cause harmful interference, and</li> <li>2. this device must accept any interference received, including interference that may cause undesired operation of the device.</li> </ol>

# Spider SAS

Apnea & Rhythm recorder

USER MANUAL





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## 1. INTRODUCTION

### 1.1. TYPOGRAPHY CONVENTION












This manual often refers to screenshots, originated from the programming software HookUp RS used in its initial English version. The references to these screens are displayed in English and in the local language; they are identified by the following symbols:

[ ]: English (**original text in the screenshots - bold font**).



{ }: Local language of the labels displayed in the screenshots.

### 1.2. DESCRIPTION OF SYMBOLS ON THE CASE

The following pictograms are displayed on the Spider SAS packaging:

	This icon is used to draw your attention to a particularly important point.
	This icon alerts you to a hazard that may result in equipment damage or personal injury. Carefully read the instructions provided with this icon.
	Manufacturer
	Device classified as <b>type BF</b> (60601-1 IEC).
	Serial Number of device
	Refer to the user manual before handling.
	White symbol on a blue background. Consult the documentation and manual enclosed in the packaging.
	Instructions for use available on CD-ROM
	On/Off switch
	The equipment must be recycled according to European Directive 2012/19/EU.
	CE mark: product is compliant with directive 93/42/EEC.



	Medical equipment with respect to electric shock, fire, and mechanical hazards, only in: <ul style="list-style-type: none"><li>— AAMI/ES 60601-1(2006) / A2 (2010) and</li><li>— CSA 22.2 NO 60601-1 CAN/CSA:2008.</li></ul>
	This symbol confers the approval of the US Federal Communications Commission.

## 2. DEFINITIONS

### 2.1. ACRONYMS AND DEFINITIONS

<b>BT</b>	Bluetooth <sup>(1)</sup> : Generic term for naming all types of wireless interfaces according to Bluetooth consortium specifications (regardless of the Bluetooth protocol version).
<b>BTLE or BT 4.0</b>	Bluetooth <sup>(1)</sup> Low Energy, also called Bluetooth 4.0., enables HookUp RS to communicate with Spider SAS.
<b>ev</b>	Event button located on the front of Spider SAS. Intended for use by the patient when he/she wants to highlight a particular moment (symptom or relevant moment). When the button is pressed, Spider SAS creates a specific user mark which will be displayed in Synescope 3.30 or higher.
<b>HookUp RS</b>	Lets the users program the Spider SAS recorder and check the quality of signals from the connected sensors. R: Rhythm – S: Sleep.
<b>HR (bpm)</b>	Heart rate trend. A mean heart rate curve is calculated every minute (light line) and maximum and minimum values over the same period (dark line).
<b>μSD</b>	Micro SD Card: delivered in plastic box with SD card adapter.
<b>φ Hub</b>	Physio Hub.
<b>SAS Option</b>	Software option embedded in Synescope 3.30 to analyze Spider SAS recordings.
<b>Spider SAS</b>	SAS: Sleep Apnea System. Multi-settings recorder dedicated to sleep apnea (pauses in breathing or shallow breathing while the patient sleeps).

<sup>(1)</sup> The Bluetooth name and the Bluetooth trademark are owned by Bluetooth SIG.Inc

### 2.2. ABBREVIATIONS (RHYTHM)

<b>Brady</b>	Periods of bradycardia detected during a recording. Bradycardia threshold values can be defined in the rhythm protocol. Bradycardia can only be detected if the mean rate is lower than the threshold value for at least 10 seconds.
<b>MB</b>	Missed Beat period detected during a recording. Equal to a rate reduction of 75% (i.e. 175% of the previous RR) compared to the mean rate. Missed beats are not detected during segments of unstable rhythm.
<b>Pause</b>	Pauses detected during a recording. The minimum duration of a pause is defined in the rhythm protocol. Pauses between two artifacts are not detected.
<b>RR inst</b>	RR interval instability, periods of irregular supraventricular cardiac rhythm detected during a recording. These may be periods of atrial fibrillation, atrial flutter or sinus arrhythmia.
<b>SVPB</b>	All supraventricular premature beats detected during a recording. SVPB/1: one isolated supraventricular premature beat. SVPB/2: pair of consecutive supraventricular premature beats. SVPB/3: 3 or more consecutive supraventricular premature beats. All isolated, couplets or runs are indicated in red. Number of events detected per minute related to the trend bar's height. SVPB count during runs voluntarily stopped at 22 beats, necessary to minimize risk of misdetection of events during false positive SVPB runs. The "MaxHR" value indicated on the label of the run event is calculated on as many RR intervals as set for the calculation of Min/Max HR. If not enough RR values are available, 2 values are used.

<b>SVT</b>	Periods of supraventricular tachycardia detected during a recording. Tachycardia threshold's value defined in the rhythm protocol. Tachycardia only detected if the mean rate is higher than the threshold value for at least 5 seconds.
<b>VPB</b>	All ventricular premature beats detected during a recording. VPB/1: one isolated ventricular premature beat. VPB/2: pair of consecutive ventricular premature beats. VPB/3: 3 or more consecutive ventricular premature beats. All isolated, couplets or runs are indicated in red. Number of events detected per minute related to the trends bar height. VPB count during runs voluntarily stopped at 22 beats, necessary to minimize risk of misdetection of events during false positive VPB runs. The "Max HR" value indicated on the label of the run event is calculated on as many RR intervals as set for the calculation of Min/Max HR. If not enough RR values are available, 2 values are used.
<b>VT</b>	Periods of ventricular tachycardia detected during a recording. Tachycardia threshold's value can be defined in the rhythm protocol. Tachycardias are only detected if the mean rate is higher than the threshold value for at least 5 seconds.

### 2.3. ABBREVIATIONS (SLEEP APNEA)

<b>A</b>	Episode of apnea.
<b>AHI</b>	Apnea Hypopnea Index.
<b>H</b>	Episode of hypopnea.
<b>ODI</b>	Oxygen Desaturation Index (calculated from O <sub>2</sub> saturation values).
<b>SDB</b>	Sleep Disordered Breathing
<b>SaO<sub>2</sub></b>	Saturation of Oxygen in hemoglobin cell.
<b>SpO<sub>2</sub></b>	Peripheral capillary Oxygen Saturation (indirect measurement of SaO <sub>2</sub> ).

### 2.4. OTHER USEFUL ABBREVIATIONS

<b>AA</b>	Arrhythmia Assessment: part of CRM business line involved in development, manufacturing and selling of non-invasive products (Blood Pressure monitor, Event recorder, Holter recorder, Sleep Apnea recorder).
<b>MRI</b>	Magnetic Resonance Imaging
<b>RF</b>	Radio Frequency (disturbances)

## 3. SPIDER SAS OVERVIEW

### 3.1. PRESENTATION AND INTENDED USE

Spider SAS is an ECG and Apnea monitor able to record relevant physiologic signals for evaluating Sleep Apnea Syndrome.

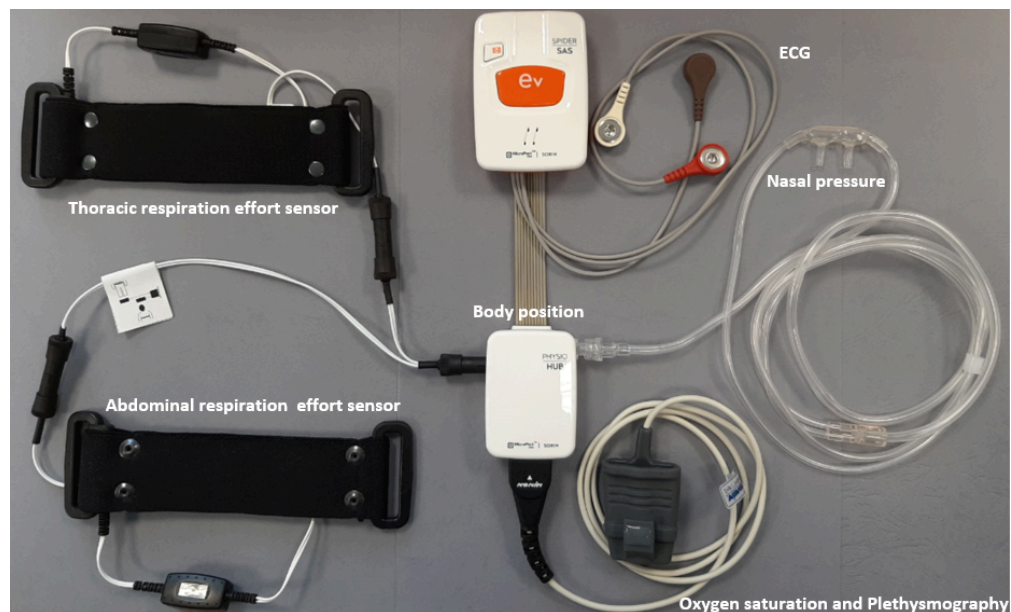
Spider SAS features a continuous 7-channel recording:

- ECG (2 channels)
- Thoracic respiratory effort
- Abdominal respiratory effort
- O2 Saturation
- Plethysmography
- Oral/Nasal Pressure
- Body position

The recorded data is stored on the  $\mu$ SD card, ready to be easily analyzed by Synescope software (version 3.30 or higher) with SAS option to provide reports of Sleep Apnea with ECG arrhythmia analysis.

Spider SAS is indicated for patients presenting (or suspected with) sleep apnea disease.

It can also record markers when the patient presses the “ev” button.



#### Data analysis

The SAS Synescope Option software is used to download, visualize and analyze the data recorded with Spider SAS. If necessary, the polygraph report can be modified and printed by the user.

### **3.2. PERFORMANCES**

Main performance of Spider SAS and PhysioHub is to record data from various sensors (see § 3.1).

### **3.3. CONTRAINDICATIONS AND SIDE EFFECTS**

There are no contraindications or side effects associated to the use of Spider SAS and its accessories.

## 4. PRECAUTIONS FOR USE AND MAINTENANCE

### 4.1. STORAGE AND TRANSPORTATION

The Spider SAS is packaged as outlined in the packaging chapter at time of delivery.

The following table shows the conditions of storage and transportation for Spider SAS:

Storage and transportation	Temperature	Humidity	Pressure
Recorder	-20° ~ 65°C	5% ~ 85% non condensing	500 hpa ~ 1060 hpa
µSD card	-20° ~ 65°C	8% ~ 95% non condensing	500 hpa ~ 1060 hpa
Electrode	5° ~ 30°C	NA	NA
Cable	10° ~ 40°C	25% ~ 90% non condensing	NA

A protective bag is needed in case of extremely humid environment.

Remove the battery before storing Spider SAS.



**CAUTION:** If stored over a prolonged period, **remove the battery** from Spider SAS. According to the duration and conditions of storage and the battery quality type, there is a **risk of electrolyte leak** into the Spider SAS's plastic case. In such a case the device must be returned to the MicroPort After Sales Department for repair. Repair is excluded from the warranty and a fee will be charged.



**CAUTION:** If a leak or a powdery deposit is visible on the battery, in the compartment or on the electrical contacts, remove the battery and dispose of it following local environmental legislation and/or the intended procedures. **If the leak is not significant (no oxidation on the electrical contacts of the battery), it is possible to clean it with a damp cloth, and then carefully dry the cleaned parts.** In the event of traces of significant oxidation, it is strongly recommended not to use the device (risk of recording failure) and return it to MicroPort After Sales. Repair is excluded from the warranty and a fee will be charged.

### 4.2. CONDITIONS FOR USE



**CAUTION:** If a patient carrying a Spider SAS recorder needs to be defibrillated, it is mandatory that the recorder's electrodes be removed before using the defibrillator. Spider SAS is not protected from the effects of external defibrillation shocks or against high frequency signals or strong electromagnetic disturbances.

The table below illustrates conditions for use for Spider SAS

Use	Temperature	Humidity	Pressure
Recorder and µSD card	0° ~ 38°C	10% ~ 95% no condensing	700 hpa ~ 1060 hpa

The correct operation of Spider SAS is only guaranteed when used with µSD cards provided by MicroPort.



**CAUTION:** Spider SAS does not start if a MicroPort SD card is not inserted.



**NOTE:**  $\mu$ SD cards designed for MicroPort devices cannot be used with other devices.

$\mu$ SD cards can be used up to 300 000 times. These cards resist electrostatic discharges of  $\pm 4$  kV maximum in the event of direct contact with the electrodes and  $\pm 8$  kV apart from the zone of the electrodes (flat contact). The  $\mu$ SD cards can resist a shock of 1 000 G maximum.



**CAUTION:** Spider SAS shall not be used in environments with flammable anesthetic mixtures containing oxygen or nitrous oxide.

### 4.3. ELECTROMAGNETIC ENVIRONMENT

The use of portable and mobile RF communication equipment (e.g. cellular phones) can affect the Spider SAS since the recorded signals may be disturbed due to electromagnetic interference.



**CAUTION: The device shall not be used** in the presence of ionizing radiations (x-rays, gamma rays...) or MRI System that could damage Spider SAS,  $\phi$  Hub and/or  $\mu$ SD card. Remove sensors and devices before starting any MRI procedure.

Concerning the electromagnetic emissions and the level of the immunity of the recorder, see Appendix 2: Electromagnetic compatibility.

### 4.4. CARE AND REPAIR OF THE DEVICE

No particular preventive maintenance is required for Spider SAS, Physio Hub and their accessories.

However, should the device fail to work properly or if plastic enclosure is broken after mechanical shock for example, contact your local MicroPort affiliate, or the MicroPort After-Sales Service. Do not unscrew the plastic case of the device under any circumstances and do not attempt to repair or modify mechanical or electrical parts since this may lead to malfunctions.

### 4.5. WARRANTY

The Spider SAS, Physio Hub and  $\mu$ SD card are guaranteed for two years from the date of delivery. After-Sales Service shall repair any faulty device within the warranty condition free of charge. After-Sales Service shall still be available after the warranty has expired but with a fee for repair.

All reusable sensors, in this case, oximeter and piezo sensors, are guaranteed for 1 year.

All reusable accessories are guaranteed for 3 months including ECG cables, Bluetooth dongle, bags, pouches, blue and beige belts.

The 1-year warranty applies neither to consumables nor to single-use devices.



**NOTE:** The warranty is only valid under the condition that no attempts have been made to open or repair the device. The warranty shall be void if devices or cards have been used contrary to this user manual's recommendation.

**Only  $\mu$ SD cards provided by MicroPort are under guarantee.**

Damaged, bent or dust-polluted  $\mu$ SD cards and sensors are not covered by warranty.

### 4.6. END OF SERVICE

When Spider SAS or Physio Hub reaches end of service, it should be returned to MicroPort for appropriate recycling. The batteries should be recycled according to the local regulation and/or procedures.

ECG cables, accessories and reusable holster bag should also be disposed of appropriately.

### 4.7. US FEDERAL COMMUNICATIONS COMMISSIONS (FCC) AND INDUSTRY CANADA

#### UNITED STATES

This device complies with part 15 of the FCC rules.

Operation is subject to the following two conditions:

1. this device may not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation of the device.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation distance between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.



**CAUTION:** This equipment may not be modified, altered, or changed in any way without signed written permission from MicroPort CRM. Unauthorized modification may void the equipment authorization from the FCC and will void the MicroPort CRM warranty.

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This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines.

This equipment has very low levels of RF energy that is deemed to comply without testing of specific absorption rate (SAR).

#### CANADA

This device complies with Industry Canada licence-exempt RSS standard(s).

Operation is subject to the following two conditions:

1. this device may not cause interference, and



2. this device must accept any interference, including interference that may cause undesired operation of the device.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada.

To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

This equipment complies with IC radiation exposure limits set forth for an uncontrolled environment and meets RSS-102 of the IC radio frequency (RF) Exposure rules.

This equipment has very low levels of RF energy that is deemed to comply without testing of specific absorption rate (SAR).

*Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :*

1. *il ne doit pas produire de brouillage, et*
2. *l'utilisateur du dispositif doit être prêt à accepter tout brouillage radioélectrique reçu, même si ce brouillage est susceptible de compromettre le fonctionnement du dispositif.*

*Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada.*

*Dans le but de réduire les risques de brouillage radioélectrique à l'intention d'autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.*

*Cet équipement est conforme aux limites d'exposition aux rayonnements énoncées pour un environnement non contrôlé et respecte les règles d'exposition aux fréquences radioélectriques (RF) CNR-102 de l'IC.*

*Cet équipement émet une énergie RF très faible qui est considérée comme conforme sans évaluation du débit d'absorption spécifique (DAS).*

## 5. CLEANING



**CAUTION:** A recently cleaned device must be dried carefully to avoid any oxidation of the electrical contacts before long term storage.

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### 5.1. SPIDER SAS AND PHYSIO HUB

The external case and the patient cable (including snap-on clips) must be cleaned with professional liquid soap and disinfectants.

Do not use detergents, alcohol or acetone.

The electrical parts and the connectors should be cleaned daily in order to avoid dysfunctions. After being cleaned, the materials must be carefully dried before storage and use. Spider SAS and Physio Hub are not waterproof devices, therefore they should not be immersed in liquid.

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**CAUTION:** Do not immerse the snap-on cable clips in a cleaning or disinfectant solution. This method considerably shortens the life of cables and causes an important internal oxidation between the clip and the wire of the cable. The quality of the ECG signal could be affected.

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### 5.2. SPO<sub>2</sub> SENSOR



Reusable PureLight® Sensor is manufactured by Nonin® Medical Inc. Cleaning instructions are available in the "Instructions for use" included with the sensor or on the Nonin website (<http://www.nonin.com/ProductCleaning>).

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**CAUTION:** Do not submerge or immerse sensor or connector plug. Do not place device in liquid or clean it with agents containing ammonium chloride or products that are not listed in the User's Guide supplied by Nonin Inc.

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Clean reusable sensors between patients or as needed:

1. Use a soft cloth with a 10% bleach/90% water solution (household bleach < 10% sodium hypochlorite).
2. Wipe away from connector plug. Do not turn Soft Sensors inside out.
3. Leave the Soft Sensors to dry completely before next use

### 5.3. PIEZO EFFORT SENSOR FOR RESPIRATION



This sensor is manufactured by SleepSense.

The Piezo Film Effort Sensor Kit requires a L or XL band (see § 13 Software, Hardware & Accessories). The bands can be wiped with a mild detergent or washed in a gentle machine cycle.

Wipe the cable with a non-corrosive (to plastic) cleanser to clean before use.

Make sure the bands and cable are thoroughly dry before reusing them.\*

\*(<http://www.sleepsense.com/resources.html>)

### 5.4. NASAL CANNULA AND FILTER

Nasal cannula, Oral & Nasal cannula and filter are disposable and single-use parts. After use, dispose of them according to local environmental recommendations.

### 5.5. BAG AND FABRIC PARTS

The Spider SAS holster bag (RG017) is reusable 10 times or more and can be washed at 30°C and/or disinfected.

### 5.6. DISINFECTION

Disinfectant product manufacturers provide specific indications for their appropriate use with medical devices. Their compatibility with medical devices is clearly mentioned on their packaging and needs to be respected.



**NOTE:** Quaternary ammonium associated with nonionic surfactants is the best solution (alcohol free cleaner) for preserving the duration of life and efficiency of Spider SAS and to guarantee a high level of hygiene for every patient. We recommend using wipes instead of liquid solution.



**CAUTION:** Do not use products if they are not CE approved according to directive 93 / 42 / EEC. CE is compulsory if the product is specifically intended for the disinfection of Medical Devices.

Disinfect the plastic case, cable and  $\mu$ SD card with a single-use disinfectant wipe which complies with the current standards:

- bactericide: EN1040, EN 1276
- virucide: NFT72-180, EN 14476
- fungicide: EN 1275
- levuricide: EN 1650

The solution used must be compatible with the disinfection of medical devices with fragile surfaces (screen, electrical contacts). The disinfectant concentration of products must be compliant with the appropriate hospitals' & clinics' standard practices.

To be efficient, the duration of contact with each element of Spider SAS must be strictly respected according to the instructions provided by the product manufacturer.



---

**CAUTION:** If the protocol used requires disinfection of the electrical contacts (battery contacts of the recorder and the contacts of  $\mu$ SD card), it is essential to carefully dry these contacts before reusing the Spider SAS and the  $\mu$ SD card.

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**CAUTION:** Never put Spider SAS, Physio Hub and active sensors in a liquid or a disinfectant solution. Never put Spider SAS and its accessories in an autoclave. Do not sterilize Spider SAS, Physio Hub, sensors, cables or cards.

---



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**NOTE:** In normal conditions of use, the disinfectant solution does not alter the functions and characteristics of our devices and accessories, however, the plastic case may discolor slightly in the long term. These modifications are essentially due to the presence of chloride ions and ethanol in some solutions.

---

## **6. USER PROFILE**

Any person who followed the required training based on the local regulation. Training completion and effectiveness are under his/her medical supervisor's responsibility.

## 7. GENERAL DESCRIPTION

### 7.1. SPIDER SAS PARTS

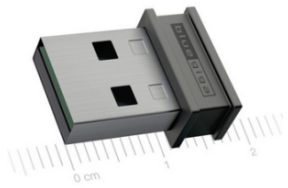


❶ Status LED (green/orange)	❺ μSD card	❾ Reset switch
❷ Send button	❻ Red writing led	❿ AAA Alkaline or Lithium battery
❸ Event Button	❼ On/Off button	⓫ Physio Hub connector
❹ Loudspeaker	❽ Open hood switch	⓬ ECG cable connector

### 7.2. PHYSIO HUB PARTS

	❶	Connector for belt(s)	
	❷	Sub 9D connector for pulse oxymeter sensor	
	❸	Luer lock connector for nasal cannula	
	❹	Spider SAS connection	

### 7.3. BLUETOOTH DONGLE



Before commencing the recording, Spider SAS must be prepared with HookUp RS software which requires a BTLE interface.

Bluetooth 4.0 Low Energy USB (BTLE) BlueGiga™ BLED112 is provided with Spider SAS.



**NOTE:** Hookup requires a BTLE interface for setting up Spider SAS. The embedded interface can be used if the laptop is equipped with a Bluetooth Low Energy interface which integrates a Broadcom, Intel or Texas Instruments chipset. In which case, the BLED112 dongle is not necessary.

### 7.4. HOOKUP RS SOFTWARE

HookUp RS software is provided in the Spider SAS packaging and must be installed before using the device.

### 7.5. HOW TO OPEN SPIDER SAS



The figure on the left shows how to open Spider SAS in order to access the battery,  $\mu$ SD card, on/off button, connectors for ECG cable and Physio Hub. The patient should be instructed not to remove the cover under any circumstances.

❶ Unlock the back side of the SpiderSAS (using a screwdriver or a coin), press where indicated with your right thumb, then hold Spider SAS securely with your other fingers on the other side.

❷ Open Spider SAS with the nail of your left thumb by applying a light pressure toward the back of the device.

## 7.6. HOW TO CLOSE SPIDER SAS



To close Spider SAS clip the right side of the back part into the orange plastic part then apply a light pressure (black arrows) on the left part with your thumb until the back cover is locked (with a click) onto the orange plastic part. Then lock the back side of the Spider SAS (using a screwdriver or a coin).

## 7.7. ECG CABLE INSERTION AND EXTRACTION



The insertion (① then ②) of the patient cable should be done as indicated in the picture.

① Take the ECG cable between your thumb and your index then pull the connector until the bottom stop ②.

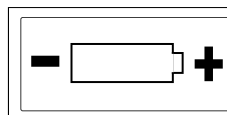
③ Gently press your thumb on the top of the connector until you hear a click.

④ To extract the ECG connector, use the upper lip. Gently press with the nail of your right index toward the top to remove the cable.



**NOTE:** When not in use, Spider SAS can be stored without disconnecting the patient cable and/or Physio Hub (φ Hub) from its connector.

## 7.8. BATTERIES



Open the recorder. Insert the AAA 1.5V battery in the battery compartment by respecting the polarity as marked in the compartment (see left).

### 7.8.1. Alkaline or Lithium batteries

Spider SAS is powered by an alkaline or a lithium battery AAA of 1.5 V depending on the duration required for the test. Maximum duration of recording is 48 hours.

A new alkaline battery ensures 1 day 2 channel ECG recording including an 8 hour nocturnal ventilation polygraph.



A new Lithium battery ensures 1 day 2 channel ECG recording including 2 nights of 8 hour nocturnal respiratory polygraph.



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**NOTE:** Place a new battery for each new recording in order to ensure the duration announced above.

---

#### 7.8.2. Internal memory battery

Spider SAS contains an internal battery recharged by the device's main AAA battery. This memory battery ensures the maintenance of the system's date and time and other parameters in the absence of the main battery for about 30 days.



---

**NOTE:** If the recorder has not been used for more than 1 month, it is recommended to remove the AAA battery to avoid electrolyte leak (See § 4.1). Consequently, if the device is stored for a very long period of time, the internal battery will run flat and therefore the recorder will not start when re-using. It is then necessary to insert a new battery in the recorder to recharge the internal memory battery before use. Depending on the level of discharge of the internal battery, it is necessary to wait from a few minutes up to a few hours to be able to start Spider SAS. The date and time of the recorder should be reset appropriately by using HookUp RS before starting a new recording.

---

## 8. PATIENT USE

### 8.1. DESCRIPTION



**NOTE:** Advise the patient to wear a T-shirt before setting up the recording. This way, Spider SAS, Physio Hub and belt(s) are not directly in contact with the skin. The long ECG cable (RC013) should be used instead of the short one (RC032).



**CAUTION:** Connect the patient to the SpiderSAS only when the back of the SpiderSAS is in place.

Before hooking up the patient, you need:

One Spider SAS recorder with:

- 1 new battery
- 1 µSD card
- 1 holster bag
- 1 long or 1 short ECG patient cable

One Physio Hub with:

- 1 SpO<sub>2</sub> Sensor
- 1 thoracic respiratory effort sensor or 1 abdominal respiratory effort sensor
- 2 belts
- 1 nasal cannula
- 1 transportation (Blue) pouch in which the patient will carry accessories.

### 8.2. RECOMMENDED POSITION

Recommended steps in order to obtain accurate and reliable results of the procedure:

- Connect the clips of the ECG cable RC013 (see § 8.3.1) or RC032 (see §8.3.2) to electrodes
- Apply the electrodes on the patient's chest as described in § 8.3
- Connect patient ECG cable to Spider SAS (see § 7.7)
- Switch on Spider SAS then check the color of the front LED is orange and is blinking every second
- Close the recorder with the back cover until you hear a click (see § 7.6)
- Connect Physio Hub to Spider SAS (see § 7.1 – part 11)
- Insert Spider SAS into its holster to be carried around the neck
- Connect nasal cannula, finger pulse oxymeter, thoracic (and abdominal) belt(s) to φ Hub (see § 7.2).



**NOTE:** Spider SAS is worn by the patient for at least one night. Both reusable and disposable neck holsters have been designed to guarantee maximum comfort and hygiene for the patient and to protect the recorder from sweat. Spider SAS is firmly maintained in the holster locked by a simple metal clip.

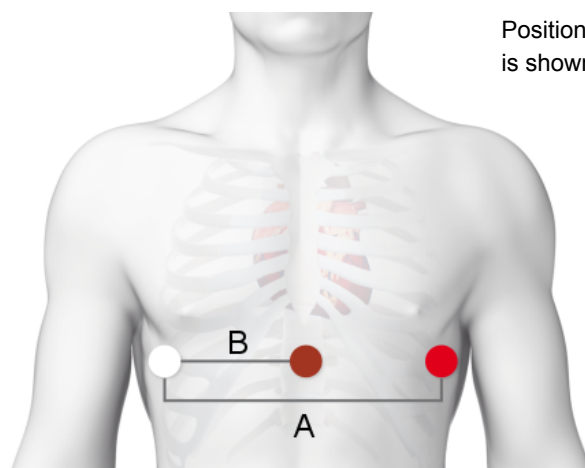
Place the holster around the neck following the picture (see §8.8). Adjust the cord length so that Spider SAS is located at the top of the patient's sternum. To stop the recording, Spider SAS must be paired and connected with the PC.

### 8.3. ELECTRODE PLACEMENT

*The information relating to the installation of the electrodes is provided as an indication only. It is advisable to check that the amplitude of the ECG is sufficient enough to allow a real time analysis of the ECG signal under the best possible conditions.*

The user can check the quality and the amplitude of the ECG using the HookUp RS software (see section 10.3.1).

To ensure a high quality ECG recording, the patient's skin must be prepared meticulously. The same rule applies for electrode placement and cable connection. Rub the skin gently and clean it thoroughly to obtain a proper contact with the electrode in order to minimize the effects generated by muscular movements and electromagnetic disturbances. The electrodes must be applied carefully in order to avoid air bubbles, which could prevent proper contact.



Positioning of electrodes for this configuration is shown in the figure on the left.

#### 8.3.1. 2 ECG channels / 3 electrodes – long cable (RC013)

This configuration is recommended when the recorder is carried at the belt as a Holter recorder.

Channel:	+ pole	Common – pole
A	2: red (112 cm)	1: white (122 cm)
B	3: brown (112 cm)	1: white (122 cm)

#### 8.3.2. 2 ECG channels / 3 electrodes – short cable (RC032)

This configuration is recommended when the recorder is carried around the neck.

Channel:	+ pole	Common – pole
A	2: red (35 cm)	1: white (25 cm)
B	3: brown (15 cm)	1: white (25 cm)



**WARNING:** Conductive parts of electrodes (including the neutral electrode), should not be put in contact with conductive parts or earthed parts.

---

#### 8.4. CHEST BELT PLACEMENT

Apply the thoracic belt on the patient's chest to measure the thoracic respiratory effort. The recommended placement of the thoracic belt is between the axillae (underarms) and above the lower part of the sternum (xiphoid). Depending on gender, the best results are obtained when the belt is located above or at the nipple line. If dual connector available, connect the thoracic sensor to the shortest part of the Y adaptor.

---



**NOTE:** The thoracic belt should be loose enough to stay comfortable and not be too tight; it should be tight enough to stay in place.

---

#### 8.5. ABDOMINAL BELT PLACEMENT

If available, apply the abdominal belt on the patient's abdomen to measure the abdominal respiratory effort. The recommended placement of the abdominal belt is just above the belly button. Connect the abdominal sensor to the longest part of the Y adaptor.

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**NOTE:** The abdominal belt should be loose enough to stay comfortable and not be too tight; it should be tight enough to stay in place.

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#### 8.6. NASAL CANNULA PLACEMENT



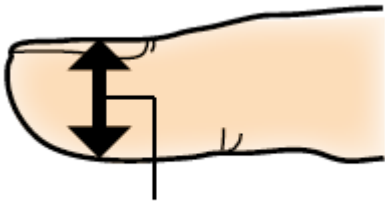
1. Place the tube coming from one side of the cannula behind one ear.
2. Line up the cannula with both nostrils.
3. Place the tube coming from the other side of the cannula around the other ear.
4. Slide the cannula clasp up to secure the cannula.
5. Screw the cannula into the Physio Hub dedicated Luer lock connector (See § 7.2).

#### 8.7. FINGER PULSE OXYMETER PLACEMENT

From Nonin Pulse Oxymeter Sensor Application Guide © 2013

##### 8.7.1. How to choose the proper size

Make sure you have the right size sensor for the finger. The table below is for reference only. Size, patient comfort and signal quality should be used to determine appropriate size.

 <p>measure nail to pad of finger</p>	8000S Sensor Digit Thickness		
	Type	Size (mm)	Size (in)
	S	7.5 - 12.5	0.3 - 0.5
	M	10.0 - 19.0	0.4 - 0.75
	L	12.5 - 25.5	0.5 - 1.0

### 8.7.2. How to place the sensor

The sensor can be positioned on index, middle or ring finger. The choice of finger does not affect accuracy of measurement; however thickness of the chosen finger must be related to the size of the sensor. For comfort reasons, the cable is placed on the top of the finger as shown below (3).



- 1 Gently squeeze the sides to open the sensor.
- 2 Slide onto the finger to the end of the sensor with cable on top of hand. Place fingertip at – but not pushed through – the end of sensor. Check that sensor gently hugs finger, and is not too tight or too loose.
- 3 Secure sensor to back of hand with medical tape to allow movement.



**NOTE:** Make sure you have the right size sensor for the finger which must be clean and dry. Heavy lotions, sunscreen, dirt, oils and nail polish may alter accuracy of measurement or secure placement.

### 8.8. POSITIONING OF SPIDER SAS & ACCESSORIES



Picture provided as an indication only. The position of each part can vary from case to case.

## 9. HOW TO PAIR SPIDER SAS (WINDOWS)



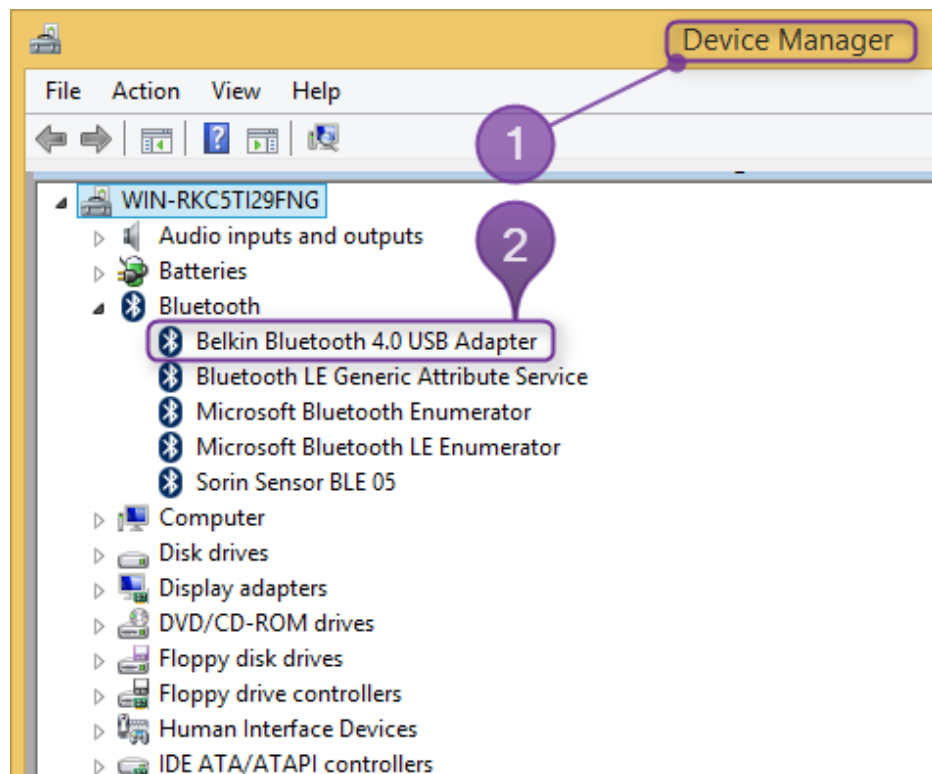
**NOTE:** Depending on provider, abbreviation of Bluetooth can be either BL, BLE, BTLE or BT 4.0

### 9.1. DESCRIPTION

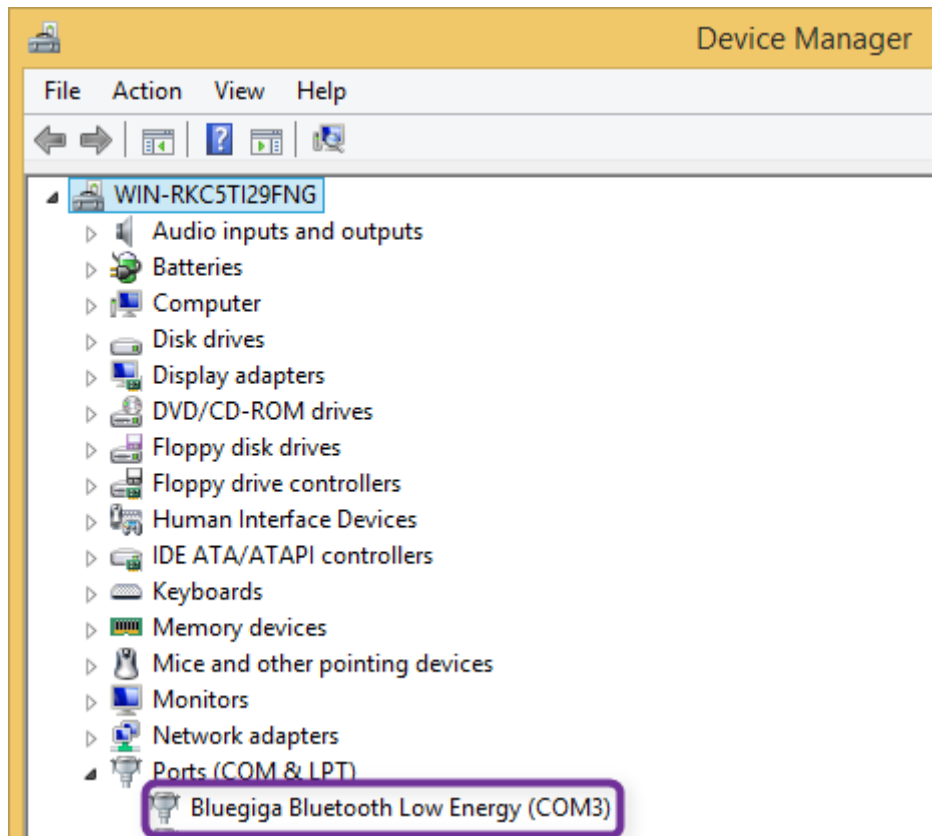


**NOTE:** The pairing operation or Bluetooth COM port emulation installation must be performed before using HookUp RS. The following pictures are issued from Windows 8.1 after successful installation of drivers and software by using Device Manager command from Windows Operating System.

Belkin interface uses the standard Bluetooth protocol with specific Belkin drivers. After installation, Spider SAS must be paired with the computer as any Bluetooth interface like a mouse.



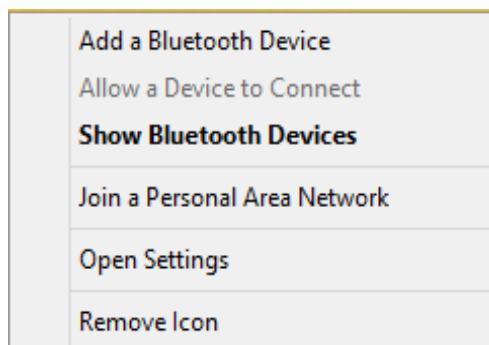
BlueGiga dongle is a BTLE device which creates a serial interface like a serial port named COMxxx. This port is automatically seen by HookUp RS (the COM port number is listed in HookUp RS settings).




## 9.2. BELKIN BLUETOOTH INTERFACE

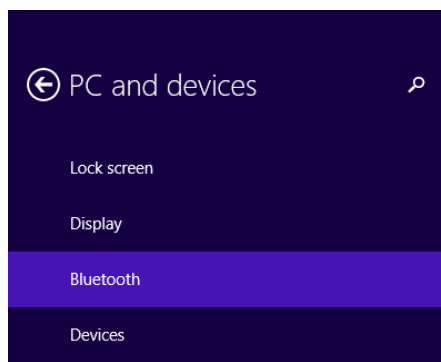


NOTE: The pairing operation is possible only after a successful installation of the BTLE interface Belkin with the CD Rom joined with the dongle. This operation must be done before using HookUp RS). Spider SAS must be switched on in order for pairing to be achieved successfully.



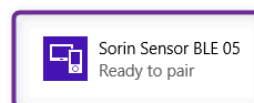
To proceed, use the CD Rom provided with the Belkin BTLE dongle. Follow the instructions displayed on the screens step by step. Once the installation has finished, open

Bluetooth manager by clicking on the  icon displayed on Windows desktop or Windows taskbar then select "Add a Bluetooth Device". The new installed BTLE interface will search all detectable devices close to the dongle (max 3 or 4 meters).



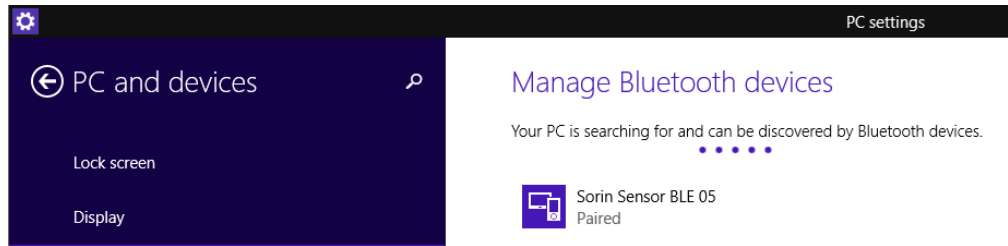
### Manage Bluetooth devices

Your PC is searching for and can be discovered by Bluetooth devices.

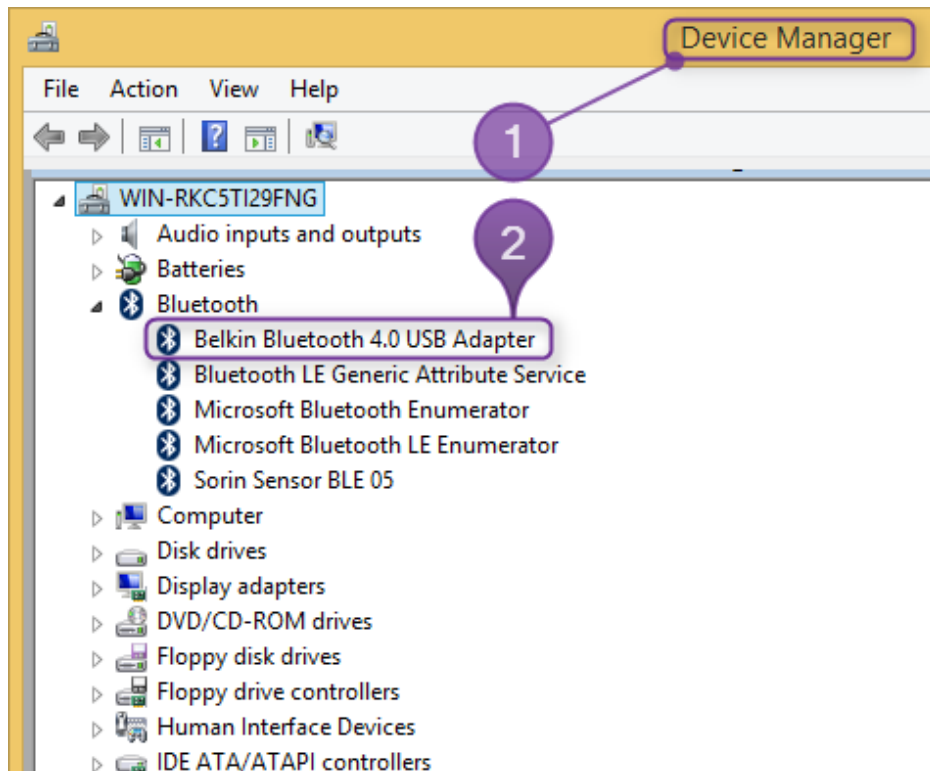




Spider SAS is recognized by the BTLE interface as {MicroPort Sensor BLE 05}. Click on the icon (framed in purple above) to pair Spider SAS with the computer. If a password is required type "0" or "000000".



Spider SAS paired successfully with the computer. Pairing can be checked with Device Manager (see below).



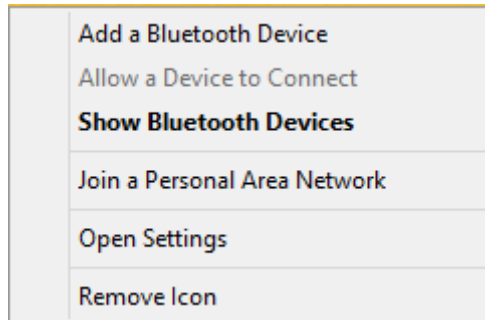
The Bluetooth key must be installed according to the instructions of the manufacturer of BTLE interface (see left). To check the BTLE adapter was correctly installed, on the desktop, right click on the icon {My computer} then select consecutively {Properties} ⇒ {Hardware} ⇒ {Device manager ❶} the BTLE adapter should be displayed ❷.


### 9.3. NATIVE BLUETOOTH INTERFACE

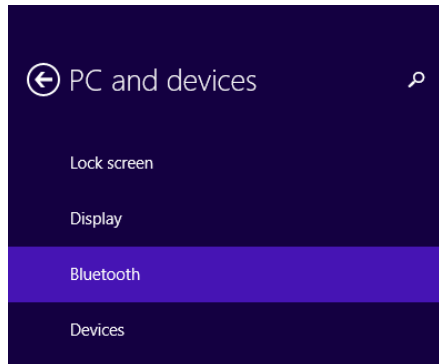
This interface is generally used for laptops equipped with BTLE embedded chipset.



**NOTE:** The pairing operation is similar to BTLE Belkin interface. Spider SAS must be switched on in order to pair successfully.

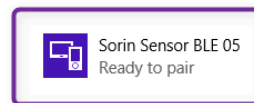


To proceed, open Bluetooth manager by clicking on the  icon displayed on Windows desktop or Windows taskbar then select "Add a Bluetooth Device".



### Manage Bluetooth devices

Your PC is searching for and can be discovered by Bluetooth devices.



Once BTLE is activated, the interface will search all detectable devices close to the PC (max 3 or 4 meters).

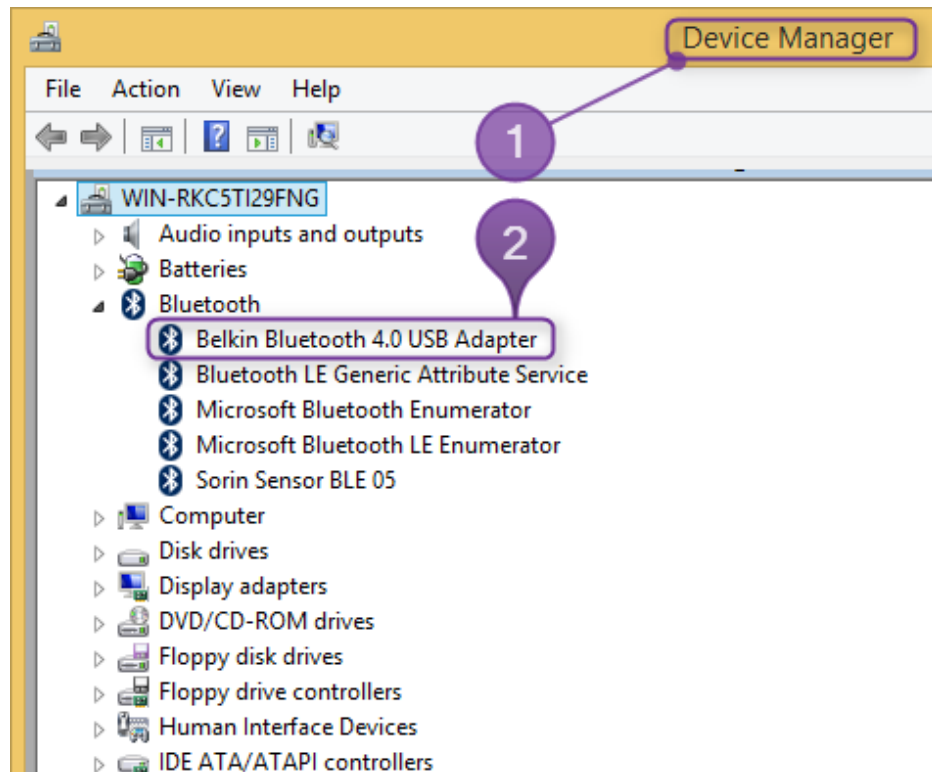
Spider SAS is recognized by the BTLE interface as {MicroPort Sensor BLE 05}.

## 9.4. BLUEGIGA BLUETOOTH INTERFACE



**NOTE:** BLED112 pairing operation must be done only after a successful installation of the BTLE interface and before using HookUp RS for the first time.

---



The Bluetooth key must be installed according to the instructions of the manufacturer of the BTLE interface (see left). To check the BTLE adapter was correctly installed, on the desktop, right click on the icon {My computer} then select consecutively {Properties} ⇒ {Hardware} ⇒ {Device manager ❶} the BTLE adapter should be displayed ❷.

## 9.5. INSTALLATION OF HOOKUP RS SOFTWARE

The software can be installed on Windows XP SP2 (minimum OS configuration), Windows 7, 8, 8.1 (32 & 64 bits platform).



**NOTE:** Installation screens can vary according to the OS and hardware (computer and BTLE interface). The following screenshots have been created on Windows 8.1 with 1680 x 1050 resolution of the screen and BTLE interface from Belkin).

Insert HookUp RS or Synescope 3.30 installation CD-ROM, wait for **[Autorun]** / {Autorun} or run HUESV2.EXE to start it manually. Select the option **[Install HookUp RS]** / {HookUp RS} to run the installation wizard and follow the instructions. Create a shortcut if necessary of the "HookUp RS.exe" executable file to the desktop in order to access the HookUp RS program more easily.

Switch on Spider SAS by pressing the On/Off button.

The Status LED flashes orange every 2 seconds, confirming device is on and recognized by a Bluetooth interface. As Bluetooth Low Energy devices are designed from an energy-saving technology; the range is 3 meters at the most.

After starting the software, press **[HookUp RS]** / {HookUp RS} button.



---

**NOTE:** Status LED (2) is a two-colored device:

- Orange and Green Orange for initialization mode
  - Green for functioning mode
  - Once Spider SAS is On (programming mode), status LED flashes orange every second.
-

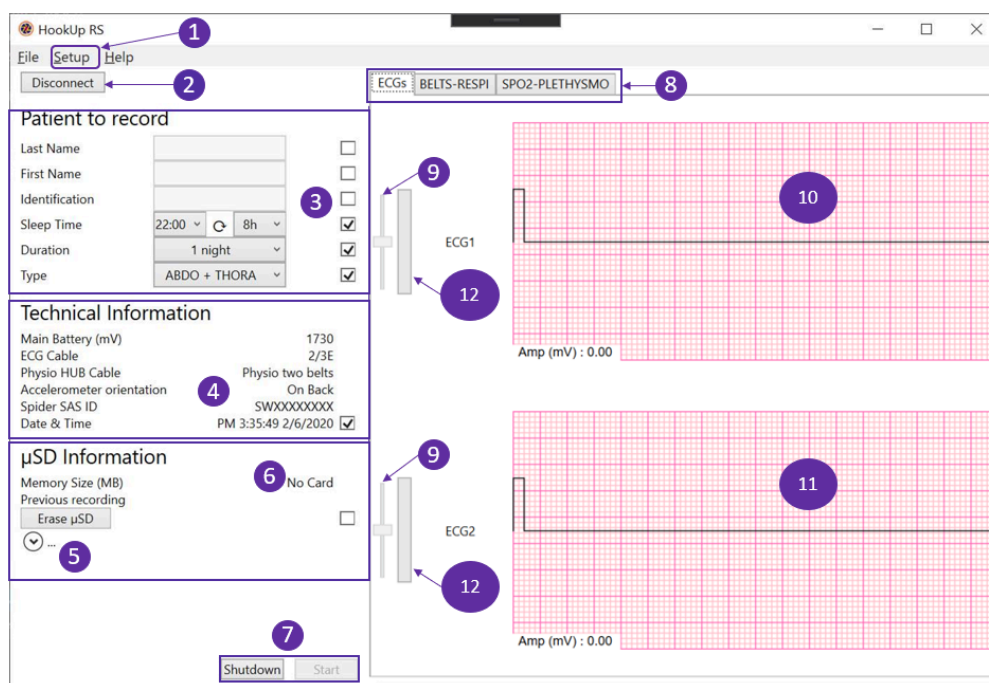
## 10. STARTING A RECORDING WITH HOOKUP RS

HookUp RS is the programming software to set-up, initialize and start Spider SAS. It allows to quickly review the parameters of the recording and the signal quality before starting the recording.

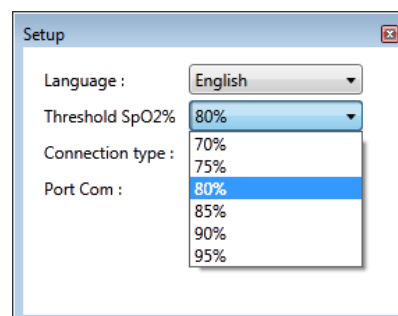
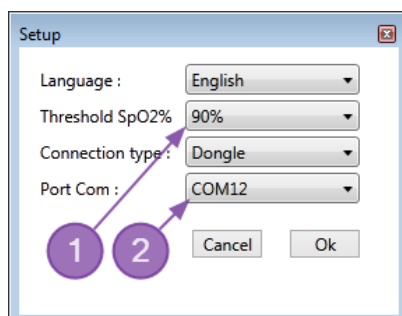
There are 2 recording modes:

- SAS mode: ECG + SAS recording for 1 or 2 nights if PhysioHub is connected to the Spider SAS when launching HookUp RS
- Holter mode: 24 or 48 hours continuous ECG only if PhysioHub is not connected to the Spider SAS when launching the HookUp RS

### 10.1. GENERAL DESCRIPTION



#### ① Setup Menu [Setup]



#### ① Threshold SpO<sub>2</sub> [Threshold SpO<sub>2</sub>]

Value can be adjusted by clicking on the dropdown list (see above). This function just modifies the position of the blue line of the [SpO<sub>2</sub> – Plethysmo] windows (see § 10.5).

② COM port number (BlueGiga dongle)

Automatically added to the list of COM ports but not selected by default.

③ Connection: Start BTLE communication with Spider SAS Recorder

④ Patient to record [**Patient to record**]:

- Surname of the patient (minimum required)
- First name
- ID number (max 256 characters)
- Sleep Time (By Default from 10:00 pm to 6:00 am):
  - Duration (1 or 2 night in SAS mode / 24h or 48h in Holter mode)
- Belt(s) Type(s):
  - None: must be selected when no belts are used
  - Thoracic: must be selected when only the thoracic belt is used
  - Abdominal: must be selected when only the abdominal belt is used
  - Abdominal + Thoracic: must be selected when the thoracic and abdominal belts are used

⑤ Technical Information [**Technical Information**]:

- Voltage battery
- Type of ECG cable
- Physio HUB Cable state – PhysioHub must be connected to allow SAS recording at night. If not, SpiderSAS will record in Holter mode (ECG only)
- Accelerometer Orientation: accelerometer is embedded in Spider SAS to indicate the spatial position of the body:

On the Back	On Stomach
Left Side	Right Side
Upright	Upside Down

- Spider SAS ID

Synchronization of Date and Time with PC Time. If synchronized the tick box is ON



⑥ Additional information: Click on  to display the following items:

Accelerometer detected (if yes = 1)

Firmware Version

⑦ μSD card Information [**μSD Information**]

Size displayed in MB

Previous Patient Name (if known)

Button [**Erase μSD**]: To delete data from the previous recording from the μSD card



**NOTE:** Spider SAS can be used without HookUp RS software (see chapter: Starting Recording: Anonymous Mode § 11.) In that case it is not possible to synchronize date and time. As the Surname, First name and ID fields cannot be filled out, the patient name will be "Anonymous" (see picture above).

---

⑦ **[Shutdown]** and **[Start]** buttons respectively for stopping the recording and beginning the recording



**NOTE:** To stop the recording, Spider SAS must be paired with and connected to the PC.

⑧ **Tabs:**

**[ECGs]:** 2 ECG channels collected with RC013 or RC032, respectively short and long patient cable

**[Belts – Respi]**

1st channel for nasal pressure (Respiration)

2nd channel for Thoracic effort (Belt)

3rd channel for Abdominal effort (Belt)

**[SpO<sub>2</sub> – Plethysmo]**

1st channel for Oxygen saturation (%)

2nd channel for plethysmography curve

⑨ Cursor to adjust the amplitude of the ECG signal displayed in graphic areas ⑩ and ⑪. The cursor does not modify the gain of the recorded signal.

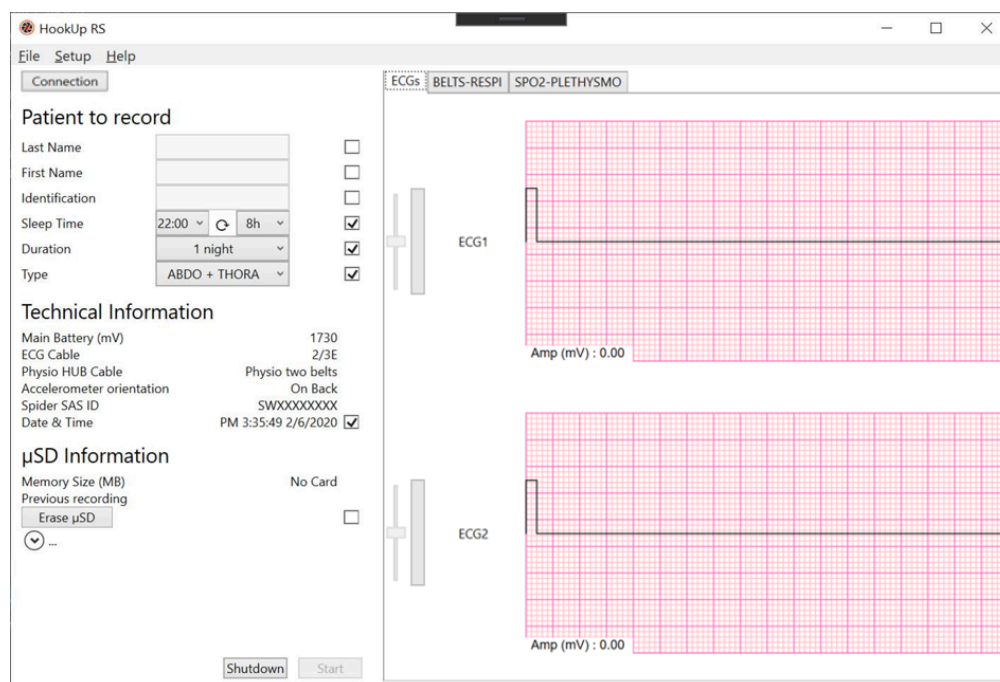
⑫ Colored bargraph to indicate quality of impedance of the signal displayed in graphic areas ⑩ and ⑪. (See § 10.3.1)

⑩ and ⑪ Graphic areas:

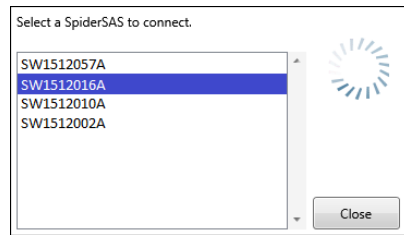
Display signals captured by electrodes and sensors depending on the tabs selected (see ⑧).

## 10.2. LAUNCHING HOOKUP RS

Click on the HookUp RS shortcut created on the desktop during the installation of the software. The screen shown below is then displayed.



Click on **[Connection]** / {Connection} button, HookUp RS initiates the BTLE communication with Spider SAS.



When the communication is successful, serial numbers of recorders detected by HookUp RS are listed in a popup window in order to select the Spider SAS. Select serial number (S/N) to connect to the recorder.

**[Connection]** / {Connection} button is renamed **[Disconnect]** / {Disconnect}.

All Technical Information fields and  $\mu$ SD card areas are completed with the current values of the recorder.

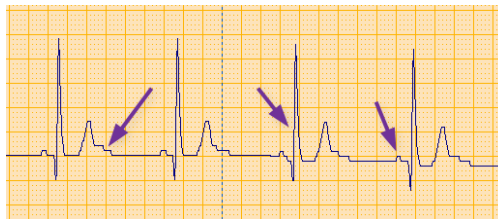
The button **[Erase  $\mu$ SD]** / {Erase  $\mu$ SD} must be used to delete all the data from the previous recording which could still be on the card.



**NOTE:** If the button is not pressed, the data will be deleted when the button **[Start]** / {Start} will be pressed.

**[Patient to record]** fields can now be filled up.

If the patient is connected to Spider SAS, ECG signal is displayed (see below).



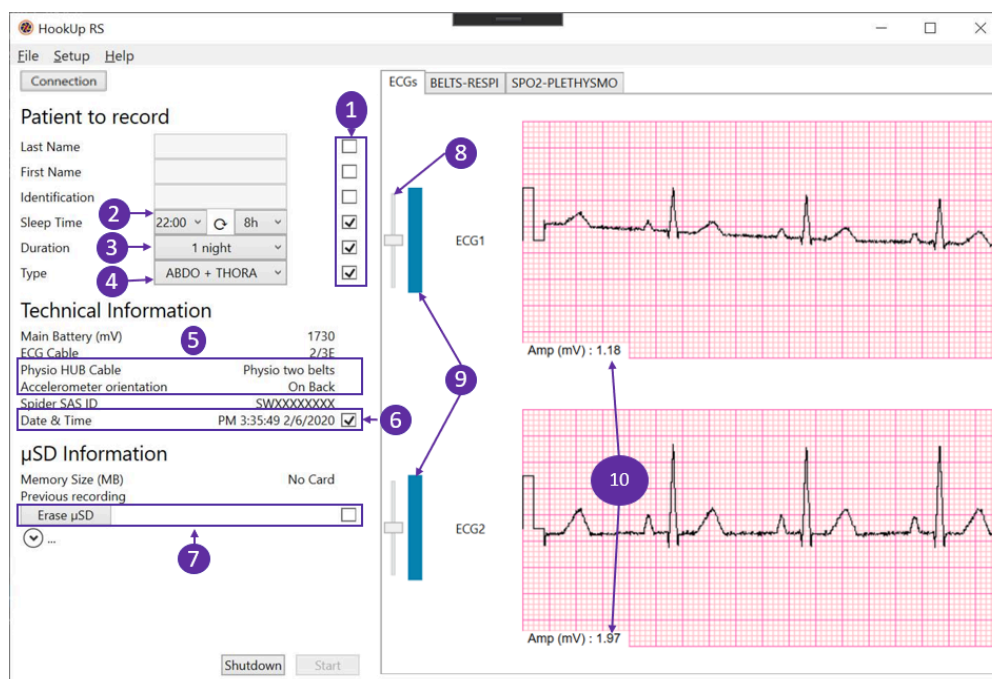
**CAUTION:** If the signal is aliased (see ECG signal above) then check contacts with electrodes, cable connections. This effect is due to a digitization problem of Spider SAS. This kind of problem can occur on Respiration and Plethysmography signals. Contact your representative to repair the device.

---

### 10.3. ECGS SCREEN

ECGs screen displays 2 ECG signals with QRS amplitude of each channel. Amplitude values are refreshed beat per beat and displayed at the bottom left corner of every graphic area.





### 10.3.1. ECG signal Quality

Make sure that the patient's skin has been properly cleaned and dried before electrodes are positioned. The upper channel displays lead A (red and white electrode), the lower channel displays lead B (brown and white electrode). If the QRS amplitude on the ECG is lower than 0.5 mV (10), you should check the positioning and the quality of the electrodes. Global quality of ECG acquisition is shown independently for every channel (ECG 1 and ECG 2).

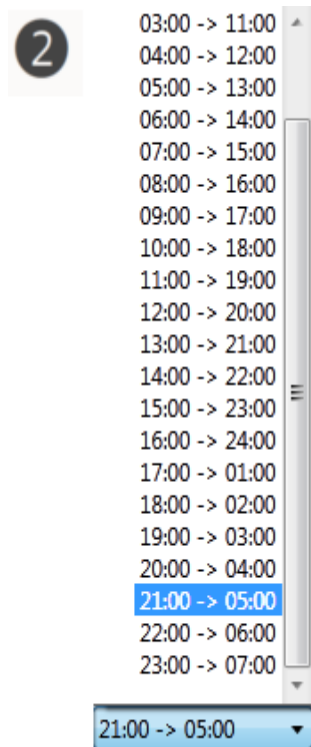
The bar graph color is fully blue when the quality of impedance is good enough (9).



**NOTE:** If the amplitude of the signal is not sufficient, do not hesitate to change the position of the electrode (red for channel A or brown for channel B). Cursor (8) is only for display and will not modify the measured amplitude of the ECG.

### 10.3.2. Other Parameters

1 Fill out the patient details. All boxes are ticked when information is sent and received by Spider SAS.



To evaluate sleep disordered breathing (SDB), it is necessary to activate all sensors during the nocturnal period. By default that period is activated between 10:00 pm and 06:00 am. According to patient's habits, it is possible to select another period from the drop down list shown on the left.

This time will not be taken into account if the Spider SAS is used in Holter recording mode.

⑤ **[Duration]** This box allows you to select the duration of the polygraph: 1 or 2 nights. If Spider SAS is used in Holter mode, this box allows you to select 24 h or 48h continuous ECG recording.

④ **[Types]** This box allows you to select the type of belt(s) used (None, Thoracic, Abdominal, Abdominal+Thoracic).

⑥ **[Physio Hub]** indicates if the Physio Hub is connected to Spider SAS. Spider SAS checks the quality of the connection then HookUp RS displays **[Physio]** on the right side. If there is no PhysioHub connected, the HookUp RS displays **[No cable]**: the recording will be launched in Holter mode (ECG only).

**[Accelerometer Orientation]** indicates in real time the position in space. Values displayed are based on the fact that Spider SAS is located and maintained on the patient as shown at § 8.8.

⑦ **[Date & Time]** This box is automatically ticked when the recorder is connected. It is possible to repeat the operation in order to (re)synchronize the PC Date/Time clock with Spider SAS clock.

⑧ **[Erase  $\mu$ SD]**. Press this button to delete data from the previous recording. When data are moved from the card the box is ticked.

⑨ Cursor to adjust the ECG signal amplitude.

#### 10.4. BELTS & RESPIRATION SCREEN

Click on **[Belts - Respi]** (tab ①) to display the belt(s) and respiration screen (see below).

If the sensors are connected, signals are displayed separately with indication of the amplitude in mV in real time. The curves come from:

- Nasal pressure ②
- Chest belt ③

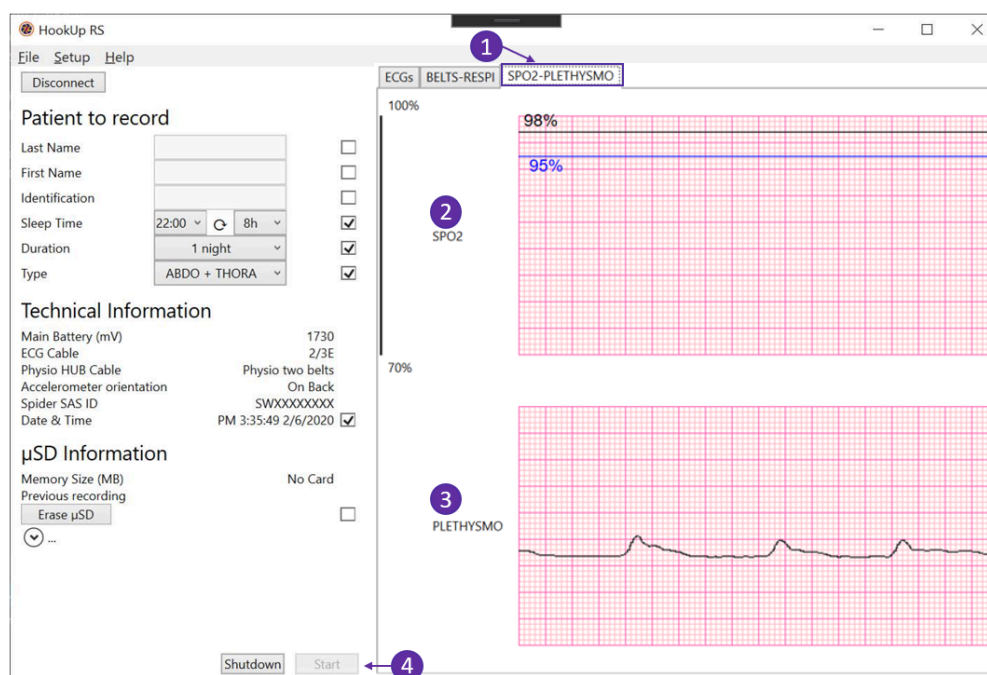
— Abdominal belt ④

Refer to § 8.4 and § 8.5 for the belt(s) and §8.6 for detailed information on placement of cannula.



## 10.5. OXYGEN SATURATION AND PLETHYSMOGRAPHY SCREEN

To display the screen below click on [SpO<sub>2</sub> - Plethysmo] tab ①.



② Oxygen saturation trend with the current value displayed on the left (96%).

The blue line indicates a threshold value selected in settings (see § 10.1). The black curve displays the level of peripheral oxygen saturation calculated from the signal coming from the pulse oxymeter sensor. There is no alarm or alert if the measured value is lower than the selected threshold value.

③ Plethysmography signal is provided for checking the quality of the current oxygen saturation signal captured by the sensor.

④ Click on the **[Start]** / {Start} button to begin recording. When done, Spider SAS beeps. Once the status led is flashing green, Spider SAS is recording all signals and Hookup RS can be closed.

Then status led flashes green every 2 seconds. Recording is ongoing.



**NOTE:** If the background becomes black and/or Plethysmography curve is flat, this means Spider SAS is no longer receiving a signal from the finger sensor. Check connections or sensor.

---

## 10.6. STEPS TO SETUP AND START A RECORDING WITH SPIDER SAS

1. Open the recorder (See § 7.5)
2. Insert  $\mu$ SD card (See § 7.1)
3. Insert a new battery in the recorder (See § 7.1)
4. Connect the clips of the ECG cable to electrodes
5. Apply the electrodes to the patient's chest (See § 8.3)
6. Ask the patient to put on his/her t-shirt
7. Connect the ECG patient cable to the recorder (See § 7.1).
8. Close Spider SAS (See § 7.6)
9. Open the cover of  $\phi$  Hub connector (check the cover is not locked)
10. Connect  $\phi$  Hub to Spider SAS (See § 7.1)
11. Close the cover then turn the lock with a screwdriver
12. Insert Spider SAS into holster (RG017) then secure it by closing the holster
13. Adjust the thoracic and abdominal belt(s) as described in § 8.4 and §8.5
14. Connect the thoracic and abdominal belt(s) to dedicated connector (see § 7.2)
15. Gently place the nasal cannula into the patient's nostrils (see § 8.6)
16. Lock the nasal cannula into Luer lock connector (see § 8.6)
17. Place the finger pulse sensor on the most convenient finger. The patient can choose whichever finger is the most comfortable (see §8.7)
18. Plug the SpO2 connector into  $\phi$  Hub (see § 7.2)
19. Check all is fine with HookUp RS
20. Adjust the position of the holster around the neck (see § 8.2)
21. In HookUp RS Click on Start button to start the recording (see § 10.1)



**NOTE:** Advise the patient how to connect and place sensors by himself/herself. If necessary, a patient transportation bag (RG018) is available to carry all accessories.

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**CAUTION:** Extraction of the card while ending the recording will immediately stop the recorder. Possibility of data loss.

---

## 10.7. STEPS TO SET UP AND START A HOLTER RECORDING WITH SPIDER SAS

1. Open the recorder (See § 7.5)

2. Insert  $\mu$ SD card (See § 7.1)
3. Insert a new battery in the recorder (See § 7.1)
4. Connect the clips of the ECG cable to electrodes
5. Apply the electrodes to the patient's chest (See § 8.3)
6. Ask the patient to put on his/her t-shirt
7. Connect the ECG patient cable to the recorder (See § 7.1).
8. Close Spider SAS (See § 7.6)
9. Insert Spider SAS into holster (RG017) then secure it by closing the holster
10. Check all is fine with HookUp RS
11. Adjust the position of the holster around the neck (see § 8.2)
12. In HookUp RS Click on Start button to start the recording (see § 10.1)

## 11. STARTING RECORDING: ANONYMOUS MODE

### 11.1. GENERAL DESCRIPTION

The procedure described in this chapter is named **[Anonymous]** / {Anonymous}. This naming comes from the ID automatically given by Spider SAS when that mode is used.

There are 2 recording modes:

- SAS mode: ECG + SAS recording for 1 or 2 nights if PhysioHub is connected when starting the recording
- Holter mode: 24 or 48 hours continuous ECG only if PhysioHub is not connected when starting the recording



**NOTE:** Spider SAS can start a holter recording and SAS monitoring without the help of HookUp RS. However, using this method means there is no control of quality signals.

This possibility is particularly interesting when there is no computer available at the location where Spider SAS would be used. However certain conditions, described below, must be fulfilled to activate Spider SAS.

### 11.2. LIMITATIONS OF USE

- No battery check
- No signal check
- No Date and Time update
- No duration selection: 2 nights in SAS mode and 48h in Holter mode
- No belt(s) type selection: 2 belts
- All ID fields are filled with **[Anonymous]** / {Anonymous}

### 11.3. CONDITIONS FOR STARTING A HOLTER RECORDING IN ANONYMOUS MODE

The recorder starts in holter mode on the following conditions:

- Empty  $\mu$ SD card
- ECG Cable and  $\mu$ SD card in place (see §8)
- No  $\phi$  Hub connected
- New battery.

### 11.4. CONDITIONS FOR STARTING THE MONITORING OF SAS IN ANONYMOUS MODE

The recorder starts on the following conditions:

- Empty  $\mu$ SD card
- All sensors, all cables and  $\mu$ SD card in place (see §8)
- New battery.



**NOTE:** If Spider SAS is started several times without the assistance of HookUp RS software, date and time are not the current one. To re-synchronize, launch a procedure with HookUp RS. (See §10.3.2) When the update is done the tick-box is "ON". You can then change the Time and Date with the function **[Adjust Time-Date]** / {Adjust Time-Date}.



**CAUTION:** It is strongly recommended not to use Windows formatting tools to erase the SD card.

## 11.5. STARTING THE RECORDER IN ANONYMOUS MODE

### 11.5.1. Holter + SAS Recording in Anonymous mode

1. Open the recorder (See § 7.5)
2. Insert an empty  $\mu$ SD card (See § 7.1)
3. Insert a new battery in the recorder (See § 7.1)
4. Switch on the recorder. Status LED flashes orange
5. Connect the clips of the ECG cable to electrodes
6. Apply the electrodes on the patient's chest (See § 8.3)
7. Ask the patient to put on his/her t-shirt
8. Connect the ECG patient cable to the recorder (See § 7.1).
9. Close Spider SAS (See § 7.6)
10. Open the cover of  $\phi$  Hub connector (check the cover is not locked)
11. Connect  $\phi$  Hub to Spider SAS (See § 7.1)
12. Close the cover then turn the lock with a screwdriver
13. Insert Spider SAS into holster (RG017) then secure it by closing the holster
14. Adjust the thoracic (and abdominal) belt(s) as described in § 8.4 and 8.5
15. Connect the thoracic (and abdominal) belt(s) into dedicated connector (see § 7.2)
16. Gently place the nasal cannula into the patient's nostrils (see § 8.6)
17. Lock the nasal cannula into Luer lock connector (see § 8.6)
18. Place the finger pulse sensor at the most convenient finger. The patient can choose whichever finger is the most comfortable (see § 8.7)
19. Plug the SpO<sub>2</sub> connector into  $\phi$  Hub (see § 7.2)
20. Adjust the position of the holster around the neck (see § 8.2)
21. Click on "ev" button (front face of Spider SAS recorder) to begin the recording (see § 7.1)

### 11.5.2. Holter recording in Anonymous mode

1. Open the recorder (See § 7.5)
2. Insert an empty  $\mu$ SD card (See § 7.1)
3. Insert a new battery in the recorder (See § 7.1)
4. Switch on the recorder. Status LED flashes orange
5. Connect the clips of the ECG cable to electrodes
6. Apply the electrodes on the patient's chest (See § 8.3)
7. Ask the patient to put on his/her t-shirt
8. Connect the ECG patient cable to the recorder (See § 7.1).
9. Close Spider SAS (See § 7.6)

10. Insert Spider SAS into holster (RG017) then secure it by closing the holster
11. Adjust the position of the holster around the neck (see § 8.2)
12. Click on "ev" button (front face of Spider SAS recorder) to begin the recording (see § 7.1)



**NOTE:** To ensure the recording has started properly, Spider SAS must be flashing green.

---



## 12. STOPPING A RECORDING



**CAUTION:** Extraction of the card while ending the recording will immediately stop the recorder. Possibility of data loss. There is a high risk of major errors during the download of the recording.

This chapter describes how to stop Spider SAS under the best conditions and to avoid the errors which could cause the loss of the recording.



**NOTE:** If the recorder no longer flashes green this means that Spider SAS has automatically stopped the recording due to low battery. This prevents data loss.

Spider SAS cannot be programmed to check for a precise date or time of ending. In general, the device is stopped after a period of monitoring defined between the physician and the patient.



**NOTE:** The recorder stops automatically in the event of insufficient space on the  $\mu$ SD card. This operation does not create data loss.

### 12.1. SPIDER SAS PAIRED WITH COMPUTER

When the patient is back, this possibility is available if Spider SAS is still flashing green and Bluetooth interface on the computer is activated

- Run HookUp RS then check click on [**Connection**] / {Connection} button. When Spider SAS is connected, check the Patient ID (see § 10.1 part 6).
- Then press on [**Shutdown**] / {Shutdown} button.
- Spider SAS Status led stops flashing and becomes fixed during 5 seconds before going out.
- Open the cover, then remove the  $\phi$  Hub cable from the connector
- There is a short beep when the operation ends.
- Open Spider SAS. The  $\mu$ SD card can then be removed and analyzed using the Synescope SAS software.

### 12.2. STOPPING SPIDER SAS WITHOUT HOOKUP RS

- Check if Spider SAS is still flashing green.
- Open the cover then remove the  $\phi$  Hub cable from the connector
- Open Spider SAS by removing the back cover (see § 7.5)
- Then press the On/Off button and wait for the red LED (6) to stop flashing (see § 7.1)
- Spider SAS Status LED stops flashing and becomes fixed for 5 seconds before going out, there is a short beep when the operation ends.  $\mu$ SD card can then be removed then analyzed using the Synescope SAS software.

## 13. SOFTWARE, HARDWARE AND ACCESSORIES

The following products, items and accessories are available for the Spider SAS recorder.

Code	Description	Qty / unit	AA Catalogue & spare parts
RE152	Pack of AAA Alkaline batteries	4	✓
RE153	Pack of AAA Lithium batteries	4	✓
LF001	Nasal Cannulae - 2 ft long (box of 50)	50	✓
LF002	Oral & Nasal Cannulae - 2 ft long (box of 50)	50	✓
LF010	Cannulae Disposable Filters (box of 50)	1	✓
LE001	Reusable Finger Pulse Oxymeter Sensor Size S	1	✓
LE003	Reusable Finger Pulse Oxymeter Sensor Size L	1	✓
LE004	1 m extension for LE001 to 3 & LE100	1	✓
LE100	Adult Reusable Flex Sensor 1m with 25 FlexiWrap	1+25	✓
LF020	Box of 25 FlexiWrap (Single patient)	25	✓
LA800	Spider SAS	1	✓
RC013	Long cable 3 leads / 2 Channels	1	✓
RC032	Short cable 3 leads / 2 Channels	1	✓
THLA0001B	Pack of 30 anallergic ECG electrodes	30	✓
LB001	µSD card for Spider SAS with SD adapter	1	✓
RG017	Neck & belt holster - reusable	1	✓
LB010	Bluetooth Dongle BLED112	1	✓
SMCV112	CD HookUp RS programming software	1	N/A
SMCV111	User Manual Spider SAS & HookUp RS (CD Rom)	1	N/A
LA801	Physio Hub	1	✓
RG018	Transport Bag: Blue Pouch	1	✓
LE002	Reusable Finger Pulse Oxymeter Sensor - Size M	1	✓
LE200	Piezo Film Effort Sensor 1ft long cable	1 or 2	✓
LE300	Y Adaptor	1	✓
LE210	Blue belt for piezo sensor - size L	1 or 2 depending on version	✓
LE211	Beige belt for piezo sensor - size XL	1 or 0 depending on version	✓
LK600, LK601, LK602	SyneScope Software V3.30	1	✓

## 14. TECHNICAL SPECIFICATIONS

### 14.1. DESCRIPTION

Spider SAS is a respiratory polygraph with O<sub>2</sub> saturation, thoracic and abdominal respiration effort, nasal pressure, 2 ECG channels, the body position and an event button. This recorder is a class IIA medical device (according to directive EEC 93/42).

### 14.2. ELECTRICAL CHARACTERISTICS

Frequency response:	0.05 - 80 Hz
Common-mode rejection:	94 dB
Input dynamic range:	± 16 mV ± 300 mV (low frequency)
Power supply:	1 AAA alkaline or lithium battery

### 14.3. MECHANICAL CHARACTERISTICS

Temperature, range of atmospheric pressure, humidity

Storage and transportation:	See § 4.1 - Storage and Transportation
Operation:	See § 4.2 - Conditions for use

Characteristics	Spider SAS	Physio Hub
Weight	50 g without battery (15 g for an AAA standard alkaline)	42 g
Dimensions	74 x 53 x 19.5 mm	42 x 58 x 18 mm w/o cables and connectors

### 14.4. CHARACTERISTICS OF ACQUISITION

Media:	µSD card
Mode:	No compression

Channel	Sampling rate (Hz)	Resolution
ECG	256	10 µV
O <sub>2</sub> Saturation	3	NA
Plethysmography signal	75	NA
Nasal pressure	256	NA
Respiration effort	256	NA
3D Accelerometer	64	NA

### 14.5. RADIO EQUIPMENT EMISSION

Radio Equipment	Transmitter Bands / Maximal Power	Receiver Frequency Bands
Spider SAS Bluetooth Low Energy	[2400 ; 2483.5] MHz ; ≤ 10 mW (0 dB)	[2400 ; 2483.5] MHz

## 15. APPENDIX 1: PATIENT RECOMMENDATIONS

### 15.1. PEDIATRIC USE

- In the case of pediatrics, it is highly recommended that a nurse or physician demonstrates the use to the parents.
- Such a recording must be operated under parental supervision.



**CAUTION:** If Spider SAS is not used, it must be placed in the blue transportation bag and out of reach of children and animals.

If Spider SAS is worn, do not let children and animals touch equipment, nasal cannula or sensors.

### 15.2. REMINDERS

- The patient shall be informed by a trained nurse or physician about the objectives of the recording.
- The patient should never take a shower or bath while the device is hooked up, since this will damage the device or make it completely unusable.
- In order to take a shower or bath, the patient should remove it and hook it up again using new electrodes. The nurse or technician shall therefore teach the patient how to position the electrodes according to the diagrams in §8.3 of this manual and provide him / her with spare electrodes. Switching the electrode position a little to the left or to the right will help prevent skin damage.
- Conductive parts of ELECTRODES (including the NEUTRAL ELECTRODE), should not be put in contact with conductive parts or earthed parts.
- Teach and repeat to the patient that he / she should not re-apply electrodes on irritated or injured areas (recent scars, wounds ...)
- If the patient does not carry the recorder, he / she should leave it inside the blue pouch provided to transport accessories and should not switch it off.
- If the recorder is not used, it passes automatically into sleep mode. The recorder "wakes up" as soon as electrodes are repositioned on the chest and the patient cable correctly connected.
- The patient must contact his/her physician immediately if electrodes or holster cause irritation of the skin.
- The patient sometimes checks that the LED (1) (§7.1) flashes green. It means that the recording is always in progress. In the case of a problem, he / she will get in touch with his / her physician or hospital department.
- The patient will immediately contact his / her physician in the case of unexpected symptoms which could require urgent analysis of the recording.

### 15.3. NASAL CANNULA

The tube of nasal or oral and nasal cannula ends by a female Luer lock connector.  $\varnothing$  Hub is equipped with a male connector located on the right side of the device (see § 7.2 Physio Hub Parts).

### 15.3.1. Connection to $\phi$ Hub



1. Insert the tube onto the connector
2. Gently screw clockwise a quarter turn to ensure a perfect connection with the pressure sensor.

Adjust the other end of the nasal cannula as described in § 8.6

### 15.3.2. Removal from $\phi$ Hub

After waking up, the patient shall remove the nasal cannula completely. In the case of a second night recording, the cannula must be reconnected as described above.

## 15.4. HOW TO CONNECT FINGER SENSOR TO $\Phi$ HUB

Put the sensor on the finger that the patient prefers according to comfort and recommendations given in § 8.7.



Connect the finger sensor (SpO<sub>2</sub>) cable to the connector located at the bottom of  $\phi$  Hub by pushing it at the maximum. The metal part of the connector is no longer visible and the cable is firmly maintained.

**15.5. PATIENT BOOKLET**

Before recording (steps ① and ④), after recording (steps ②, ③, ⑤ and ⑥).

## 16. APPENDIX 2: ELECTROMAGNETIC COMPATIBILITY

### 16.1. GUIDANCE AND MANUFACTURER'S DECLARATION

All information below is based on the normative requirements to which the manufacturers of electro-medical devices are subject, in the sense of IEC60601-1-2.

The medical device complies with applicable electromagnetic compatibility standards, however, the user will ensure that any electromagnetic interference does not create an additional hazard, such as radio frequency transmitters or other electronic devices.

In this chapter you will find information necessary to ensure the installation and commissioning of your medical device under the best conditions in terms of electromagnetic compatibility.

The different cords/cables of the medical device must be separated from each other.

Certain types of mobile telecommunication devices such as mobile phones are likely to interfere with the medical device. The separation distances recommended in this chapter must therefore be strictly observed.

The medical device must not be used near or on another device. If this cannot be avoided, it must be checked for proper operation under the conditions of use before use.

The use of accessories other than those specified or sold by MicroPort CRM as replacement parts, may result in an increase in the emission or a decrease in the immunity of the medical device.

### 16.2. GUIDANCE AND MANUFACTURER'S DECLARATION: CABLE LENGTH

Cables and accessories	Maximum length	Test type	In compliance with
Cables/Cords	< 3m	RF emission	CISPR 11, Class B
		Harmonic current emission	IEC61000-3-2
		Voltage fluctuation and flickers	IEC61000-3-3
		Electrostatic discharge immunity	IEC61000-4-2
		Radiated immunity – Electromagnetic fields	IEC61000-4-3
		Electrical fast transient/ burst immunity	IEC61000-4-4
		Surge immunity	IEC61000-4-5
		Immunity to conducted disturbances, induced by radio-frequency fields	IEC61000-4-6
		Radiated immunity - Magnetic fields	IEC61000-4-8
		Voltage dips, short interruptions and voltage variation immunity	IEC 61000-4-11



### 16.3. GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC EMISSIONS

The Spider SAS is intended for use in the electromagnetic environment specified below. The customer or the user of the Spider SAS should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
Electromagnetic radiation disturbance (radiated emissions) CISPR 11	Group 1	The Spider SAS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
Disturbing voltage at supply terminals conducted emissions CISPR 11	Class B	The Spider SAS is suitable for use in a professional health care establishment and home health care environment.
Harmonic current emissions IEC 61000-3-2	Non applicable	
Voltage variations, voltage fluctuations and flicker IEC 61000-3-3	Non applicable	

### 16.4. GUIDANCE AND MANUFACTURER'S DECLARATION: MAGNETIC AND ELECTROMAGNETIC IMMUNITY

Spider SAS is intended for use in the electromagnetic environment specified below. The customer or the user of the Spider SAS should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	± 8 kV contact ± 15 kV air	Professional health care establishment and home health care environment.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Non applicable	Professional health care establishment and home health care environment.
Surge IEC 61000-4-5	± 1 kV between phases ± 2 kV between line(s) to earth	Non applicable	Professional health care establishment.
Magnetic field at industrial rated frequency (IEC61000-4-8)	30 A/m	Non applicable	Professional health care establishment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips (IEC 61000-4-11)	0% $U_T$ for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% $U_T$ for 1 cycle and 70% $U_T$ for 25 cycles, 50Hz for 30 cycles, 60 Hz singlephase at 0°	Non applicable	Mains power quality should be that of a professional health care establishment.  If operation of the system requires continued use during power cuts, it is recommended that the medical device be powered by a separate power source (UPS, etc.).
Voltage Interruptions (IEC 61000-4-11)	0 % $U_T$ ; for 250 cycles at 50 Hz for 300 cycles at 60 Hz	Non applicable	Mains power quality should be that of a professional health care establishment.  If operation of the system requires continued use during power cuts, it is recommended that the medical device be powered by a separate power source (UPS, etc.).



NOTE:  $U_T$  is the a.c. mains voltage prior to application of the test level.

### 16.5. GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY, PORTABLE RF EQUIPMENT



**WARNING:** Portable RF communication devices (including peripherals such as antenna cables and external antennae) should not be used closer than 30 cm (12 inches) to any part of the Spider SAS, including the cables specified by the manufacturer. Otherwise, the performance of these devices may be impaired.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electromagnetic fields Radiated RF (IEC 61000-4-3)	10 V/m 80 MHz – 2.7 GHz 80 % MA at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80 % MA at 1 kHz	Professional health care establishment and home health care environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Proximity fields emitted by RF wireless communication devices IEC61000-4-3 (provisional method)	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	Professional health care establishment.
Conducted disturbances, induced by RF fields (IEC610004-6)	3 V 150 kHz at 80 MHz 80% MA at 1 KHz 6 V in ISM band between 0.15 MHz and 80 MHz, Radio Amateur band includes 80% MA at 1 KHz	Non applicable	Professional health care establishment and home health care environment.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>1</sup>, should be less than the compliance level in each frequency range.



Interference may occur in the vicinity of equipment marked with the following symbol:



**NOTE:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

1. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Spider SAS is used exceeds the applicable RF compliance level above, the Spider SAS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Spider SAS.

## **16.6. SPIDER SAS AND MOBILES (RECOMMENDATIONS)**

### 16.6.1. Guidance and manufacturer's declaration: electromagnetic immunity

Recommended separation distances between portable and mobile RF communications equipment and the Spider SAS.

The Spider SAS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

Portable RF communication devices (including peripherals such as antenna cables and external antennae) should not be used closer than 30 cm (12 inches) to any part of Spider SAS, including the specified cables. Otherwise, the performance of this device may be impaired.





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