SPYDER BLUETOOTH USER MANUAL

SPBT20A

SPYDER
Wireless ECG Monitoring System

At WEB Biotechnology, we take the responsibility to provide the best medical products to our users. This User Manual, although sufficient, will be constantly updated as our products are improved. Do keep a look out at:

www.web-biotech.com/downloads/spyderBT/usermanuals

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Introduction:
Intended use of Spyder Bluetooth

Spyder Blutooth Intended Use:
Spyder Bluetooth is a ECG sensor for monitoring of heart rhythm with bluetooth devices. It is attached to the chest with an electrode pad. The device is practically inconspicuous when worn, providing remarkable quality of life to user. Spyder Bluetooth continuously measures and transmits ECG signal to a computer server programmed to identify abnormal heart rhythm patterns. It is easy to administer and hassle-free to use. Spyder Bluetooth truly simplifies the life of user and medical professionals."

Spyder Bluetooth is intended to be used in the mobile healthcare environment accessed with mobile phone application. Information provided are intended only for information to the user.

Complementary Products

Android Smartphone:
All smartphones running on Android OS with minimum specifications of v2.1 Eclair are suitable for hosting the Spyder App. The smartphone is provided as accessory by agent representing the product in respective territories.

Spyder App:
The Spyder Android App must be installed on the Android smartphone. The most updated Spyder App shall be updated by authorized distributor or can be requested to WEB Biotechnology directly (info@web-biotech.com). Healthcare professional and agents installing the Spyder Android App will receive training from WEB Biotechnology Pte Ltd or its authorized representatives.

Doctor Spyder (Server)
The Doctor Spyder is our server which stores the encrypted ECG data. The server can be accessed by authorized medical professionals at the url www.doctorspyder.com.

For information on how to login and use, please refer to Doctor Spyder User Guide. Users of Doctor Spyder (server) will receive training from WEB Biotechnology Pte Ltd or its authorized representatives.

Electrode Pad:
For users' safety, we advise users to use CE certified electrode pad or pads recommended by certified physician. User is advised to read the instructions and warning statements of the related electrode pad product for safe operation.

Detachable Parts

Cover:
The cover can be removed for easy changing of batteries by sliding the cover upwards gently.

Product Technical Specifications

Function:	Real-time ECG monitoring with Bluetooth devices
Acquisition:	3 leads
Sample Rate:	250 per second
Dynamic Range:	-2.5 to 7.7mV
Resolution:	10µV
Heart Rate Accuracy:	+/- 1 bpm
Freq. Response:	0.5 to 25 Hz
Common Mode Rejection:	> 100dB @ 50Hz
Input Impedence:	> 10MΩ @ 10HzΩ
Patient Leakage:	< 10µA
Battery Type:	2 x AAA
Battery Voltage:	3V
Battery Life:	3 days per pair
Battery Included:	No
Data Transfer Method:	Bluetooth 2.0
Weight:	26g (without batteries)
Dimensions:	60 x 55 x 18mm
Operating Temperature:	5 to 42°C

Product Technical Specifications

Operating Relative Humidity:	15 to 93%
Operating Pressure:	Atmospheric pressure of 700-1060 hPa
Data Analysis:	Signal Measurements & Arrhythmia Detection Doctor Spyder Website
Data Access:	User Manual, Spyder App for mobile devices
Accessories:	
Firmware version:	SPBT20A_V1.1
Product Life:	5 years
Heart Rate Calculation	Heart rate is calculated with the averaging of 8 beats.
Pause Calculation	PAUSE is determine by continuously comparing the detected RR interval with a preset threshold.

Safety Precautions and Warnings

Please remove batteries inside Spyder Bluetooth when the device is not likely to be used for some time, during transport and before storage to avoid the risk of leakage from batteries.

Avoid having Spyder Bluetooth in contact with water.

Spyder does not require to operate in a sterile environment and does not require any deliberate cleaning or maintenance routine under normal use. However, user may clean the external surfaces of the device in case of contamination due to lint or dust using a lint free cloth.

This equipment needs to be installed and put into service in accordance with the information provided in this document. No modification of Spyder Bluetooth is allowed.

This product must be disposed properly according to local laws and regulations. Since this product contains a battery, the battery must be disposed separately from household waste.

Spyder Bluetooth was not evaluated for use in an oxygen rich environment.

Spyder Bluetooth is not intended for use with flammable anesthetics.

Safety Precautions and Warnings

Spyder Bluetooth is not intended for use in conjunction with flammable agents.

If the product is received in a damage state, do not use. Return the product according to service information section in user manual.

If the on/off switch does not work, or if the cover of Spyder Bluetooth becomes loose, there is no risk to the patient. However, return the parts according to service information section in user manual.

In case of Spyder Bluetooth failing to function normally or appearance of phenomenon like, Spyder Apps screen goes blank, no waveform is seen on phone, the notification alarm on the phone ring or the green indicator lights fails to turn on/off, please follow the instructions in troubleshooting section of the user manual.

Spyder Bluetooth is intended to be used with biocompatible electrodes with CE mark only.

The mobile phone with the Spyder Apps must be kept within "10 metre" direct line of sight with the equipment. In case of exceeding this distance, an alarm will sound and user simply need to move the equipment within range and connections will automatically re-establish.

Safety Precautions and Warnings

Spyder Bluetooth is not intended for use in an environment with stronger than normal magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration. If Spyder Bluetooth is expose under the above unintended operating environment, move the Spyder Bluetooth away and normal operating functions should resume without problem. In case of uncertainty, you may refer to the troubleshooting section of the user manual or consult the manufacturer for guidance.

Wireless communications equipment like wireless home network devices, mobile phones, cordless telephones and their base stations, walkie talkies can affect this equipment and interfere Spyder Bluetooth equipment. For optimum performance, Spyder Bluetooth should be kept at least a distance of 0.163m away from the interfering source equipment.

This equipment is to be operated away from direct light source that will result in an operating environment out of the stated specification in the manual.

Spyder Bluetooth is not design for ST segment analysis.

Spyder Bluetooth is not intended for use in conjunction of a pacemaker.

Spyder Bluetooth is not intended for use on infants weighing less than 10 kg.

Storage Conditions

Temperature: -25 to 70°C

Relative Humidity: Up to 93%

Pressure: Atmospheric pressure of 700–1060
                                hPa

Users are advised to store Spyder Bluetooth in a cool and dry place.

Using Spyder Bluetooth

If Spyder Bluetooth is used for the first time, follow the instructions below:

1) The following accessories are required to complete the set up

    a) Spyder Bluetooth SPBT20A

    b) 2 x AAA alkaline batteries

    c) Pre-loaded Spyder Apps mobile phone with paired connections to Spyder Bluetooth (This task must be performed by agent/distributor at the point of purchase).

2) Load the batteries according to "Replacing the batteries" Page 17.

3) Turn on the Spyder according to Page 14 – 16.

Using Spyder Bluetooth

4) Turn on the Paired-Spyder mobile phone with preloaded Spyder apps.

5) Follow the instructions of "Using Spyder Apps" on page 19-21.

To Turn "On" Spyder Bluetooth

Step 1:
Turn on Spyder Bluetooth by pushing the switch to the "ON" position.
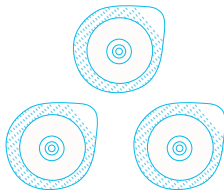
Using Spyder Bluetooth

Step 2:
A green light will illuminate for 2 seconds to indicate that Spyder Bluetooth has been successfully switched on.
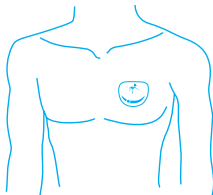
Step 3:
Attach the electrode pads to Spyder Bluetooth by securing the pads to each of the buttons.

Using Spyder Bluetooth

Step 4:
Peel off the plastic cover from the elec-
trode pad and affix Spyder Bluetooth on
chest.

To Turn "Off" Spyder Bluetooth

Step 1:
Switch Spyder Bluetooth off by pushing
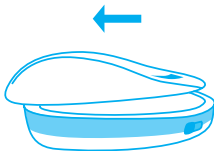the switch to the "OFF" position.
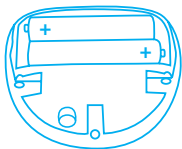
Replacing the Batteries

Step 1:
A red light will flash once every 5 seconds to indicate that the batteries need to be replaced soon.

Step 2:
Push open the top cover of Spyder Bluetooth.

Replacing the Batteries

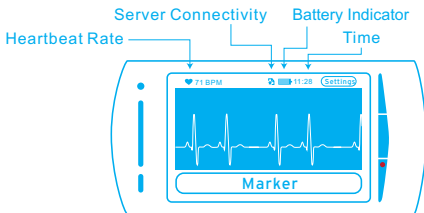**Step 3:**
Replace 2 AAA batteries as shown.

Step 4:
Replace the top cover of Spyder Bluetooth.

Using Spyder App

Step 1:
Launch the Spyder App. The Application displays the following information.

Server Connectivity   Battery Indicator

Heartbeat Rate   Time
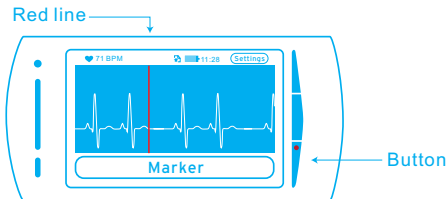
❤ 71 BPM   11:28   Settings

Marker

Step 2:
The 🔖 server connectivity icon will turn red if there is a problem with the server connection. Restart the phone or application if the problem persists.

Using Spyder App

Red line

Button

Step 3:
A marker can be sent to the server by tapping the screen at the area labelled 'Marker'. A red line will appear on the screen to indicate successful creation of the marker.

Step 4:
Do not exit the application or the detected ECG may not be transmitted to the phone and server. Simply 'hide' the application while the Spyder Bluetooth is in use.

Using Spyder App

Step 5:
The phone will sound when Bluetooth connection with the Spyder Bluetooth device is lost.

Step 6:
Start or re-enter the application by tapping on the ♥ Spyder Application.

Step 7:
To terminate the session, simply exit the application.

Troubleshooting

What should I do when the app screen goes blank, no waveform is seen or the notification alarm on the phone rings?

Check the Bluetooth connection between your android smartphone and Spyder Bluetooth.

Ensure the Spyder Bluetooth has working batteries.

Restart the application by exiting and launching it again.

The notification alarm will stop ringing when the waveform appears on the phone screen.

If the waveform does not appear, the screen is blank or notification ring tone continues to ring after action (1), (2) & (3), please return the product according to service information section in user manual.

Troubleshooting

What should I do, if the green indicator light fail to turn on for 2-3 seconds after switching on the Spyder.

Ensure the Spyder Bluetooth has working batteries.Make sure that the phone apps is receiving constant signal from Spyder Bluetooth.

Ensure that the batteries are inserted according to the indicated polarities."

If Spyder Bluetooth indicator light still does not turn on after checking with point (1) & (2), please return the product according to service information section in user manual.

Troubleshooting

What should I do, if the green indicator light on the Spyder Bluetooth turn off after lighting up for 2-3 seconds when the switch is in "on" position?

Do Not do anything. This indicate Spyder Bluetooth in normal operating condition. [Refer to user manual – Using SPYDER Bluetooth Step 2 highlighted the indicator light is design to turn off after 2~3 seconds.

Make sure that the phone apps is receiving constant signal from Spyder Bluetooth.

If there is no waveform seen and notification ringtone rings, please refer to user manual troubleshoot section.

Service Information

In the case where the device is not functioning as it should be, inform your doctor immediately or otherwise, contact WEB Biotechnology Pte Ltd at:

Tel: +65 6223 2723
Fax: +65 6220 0833
Email: info@web-biotech.com

Certification Statements

FCC Statement For Spyder Bluetooth:

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. 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 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 radio or television off and on, the user is encouraged to try to correct interference by one or more of the following measures:
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on another circuit.
- Consult the dealer or an experienced radio/TV technician for help.

CAUTION: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment

Certification Statements

CE Statement For Spyder Bluetooth:

CE 1304 2280 ⓪

FCC ID: CD9SPBT20A

EN 300 328 V1.7.1 -- Electromagnetic compatibility and Radio spectrum Matters (ERM); Wide-band transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide-band modulation techniques; Harmonised EN covering essential requirements under Article 3.2 of the R&TTE Directive.

EN 301 489-17 V2.1.1 -- Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for broadband data transmission systems high performance RLAN equipment and 5,8 GHz broadband data transmitting systems.

Complies with
IDA Standard
DB105540

Certification Statements

IP22 – is International Protection Rating, which classifies and rates the degree of protection provided against the intrusion (including body parts such as hands and fingers), dust, accidental contact, and water by mechanical casings and electrical enclosures. Spyder is rated as IP22 and is protected against insertion by object larger than 12.5mm in diameter (including fingers) and vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position.

Legend For Logos

An applied part that includes a patient connection that is intended to deliver electrical energy or an electrophysiological signal to or from the patient.

Refer to User Manual for operating instructions

Turn "On"

Turn "Off"

Direct current

In 2002 the European Union introduced the Directive on Waste Electrical and Electronic Equipment (WEEE). The directive requires you as end-user to dispose of any WEEE with the label separately.

Legal Information

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