

SpotLite EEG Device Instructions for Use

LB-10001 Rev A -DRAFT 27APR2023

Current Issues to Resolve:

Distribution: Per Jean, digital is satisfactory for 510K submission, but physical copies could be needed. That need is based on the preference of the hospitals. Should we plan to include a physical copy within the SpotLite System box?

References

- [Peer IFUs and FDA Guidance](#)
- [Draft SpotLite User manual for compliance testing](#)
- [STAT Hardware Manual](#)
- [Byteflies Kit](#)

Table of Contents

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Getting Started

What's in the box completed

Your box includes:

- SpotLite EEG Device
- Charging Dock
- Power Adapter
- USB-C Cable

You should also have received

- A number of patch envelopes which contain
 - The patch with SpotLite cradle attached
 - 2 skin prep wipes

You should also have

- A mobile device with the SpotLite app installed and it is connected to the Wi-Fi

Descriptions

Ready for Review The Beacon SpotLite System is a wearable self-contained EEG system designed to amplify and digitize and record the electroencephalogram (EEG) from a patient's scalp. The recorded EEG signals are acquired by the SpotLite Device, transmitted to a mobile device in real time, and uploaded to the cloud storage after a recording session is completed. The recorded data is available for access for viewing on the Beacon Platform (not included in the SpotLite system). The Beacon platform provides the recorded signals for post-hoc review ONLY.

Indications for Use

Ready for Review The SpotLite EEG System is intended to record, store, and display EEG signals.

A reusable SpotLite Device is intended to amplify, capture and wirelessly transmit the signals to the cloud storage via a mobile device. A single use, disposable SpotLite Patch is an EEG electrode array to be used with the SpotLite Device to record up to 8 channels of EEG signals.

The Beacon SpotLite EEG System does not provide any diagnostic conclusion about the subject's condition and does not provide any automated alerts of an adverse clinical event. It is intended for prescription use in the home, healthcare facility or clinical site where reduced montage EEG monitoring may be desired.

Contraindications

completed



- The SpotLite EEG System should not be used when real time EEG monitoring is required.
- The SpotLite EEG System does not provide real time alarms and should not be used to make life saving decisions.
- The SpotLite System should not be used on children under the age of 6
- The SpotLite Patch is manufactured with medical grade adhesives containing silicones, acrylics and conductive hydrogels. The Patch should not be used on patients with a suspected or known allergy to skin adhesives, acrylics, hydrogels, or silicones.

Warnings

@@Ready for Review

- The SpotLite Device and SpotLite Patch have not been evaluated for safety in the MR environment. The SpotLite Device and SpotLite Patch have not been tested for heating or unwanted movement in the MR environment. The safety of the SpotLite Device within the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.
- Only place the Patch on intact skin, do not place the Patch on open wounds or abrasions.
- Depending on wireless connectivity, a temporary interruption of data transmission is possible. Data will be stored on the device for transfer once connectivity is reestablished.
- Do not use the SpotLite EEG Device or Patch in conjunction with defibrillation devices

PrecautionsIn Progress

- Wireless electronic devices may cause signal interference during data transmission. Avoid close proximity with interfering devices.
- The Patch is single use only. Do not reapply or reuse the patch once it is removed.
- Do not use the SpotLite EEG Device or Patch if the package has been opened, or appears used, damaged, or expired.
- If prolonged discomfort or irritation occurs, the Patch should be removed. If mild soreness or redness is experienced after removing the Patch, take care to let the area heal prior to applying another Patch.
- Incorrect handling, excessive force, or dropping the SpotLite EEG Device may cause malfunction or permanent damage
- The SpotLite Device and Patch are not intended to be used in a wet environment; do not use the device while showering or under water.
- Keep the SpotLite EEG Device away from children and pets. The device may be a choking hazard, and may be harmful if swallowed.
- If the SpotLite EEG Device fails to operate, contact your healthcare provider immediately.
- This device has not been evaluated for use in a HF surgical environment.

System Overview

System Components@@Ready for Review

- SpotLite EEG Device
The device is electrically connected to the Patch, samples the EEG signals, monitors the impedance of each Patch electrode, and wirelessly transmits the data to a connected mobile device.
- Charging Dock
A wireless charging dock used to both charge and protect the SpotLite EEG Device when not in use. When

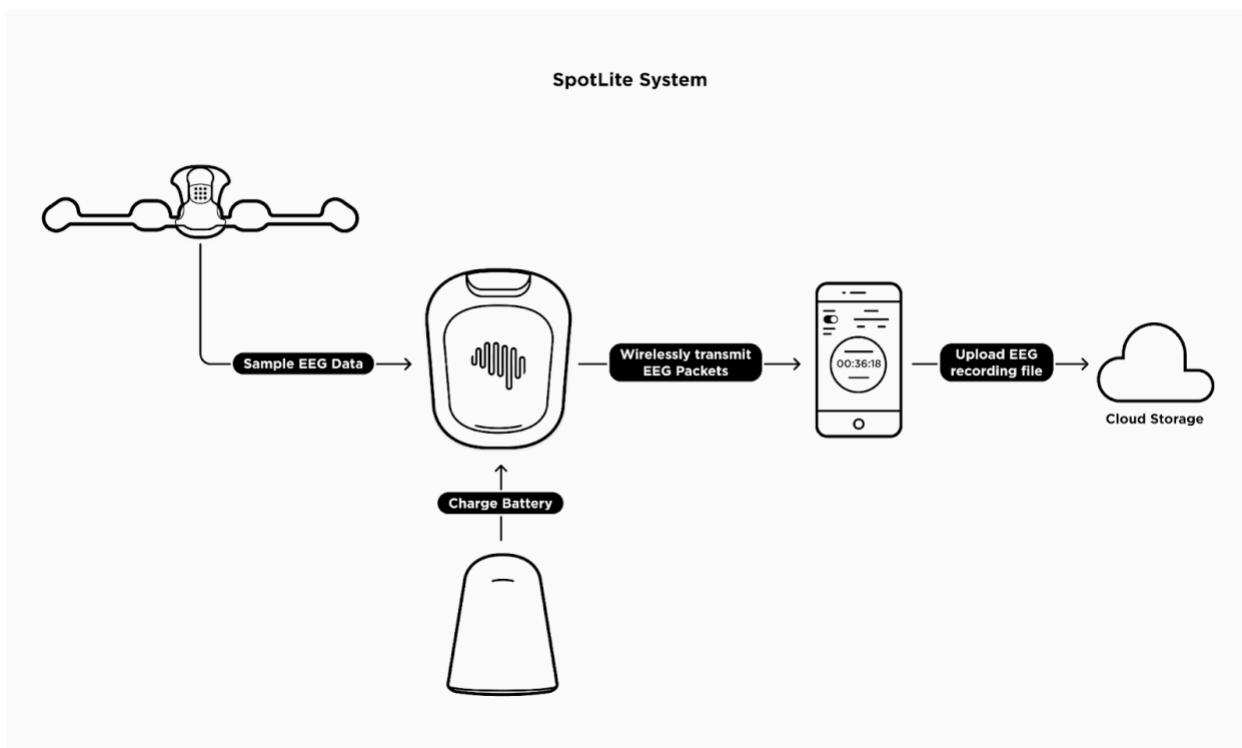
the SpotLite EEG Device is placed within the charging dock, all EEG acquisition functions are automatically disabled.

- **Patch**
Multiple electrodes are attached to the forehead with adhesive on each electrode. Each Patch has a cradle to securely mount the EEG device. The conductive pads allow the EEG device to electrically connect to the Patch.
- **Power Adaptor**
100-240 V AC power adapter used to charge the SpotLite EEG Device. Only use the included power adapter to charge the SpotLite EEG Device.
- **USB-C Cable**
Cable used to connect the SpotLite EEG Device to the power adapter for charging.
- **Mobile Device**
A user interacts with the SpotLite system with a mobile device. The app installed on the device will guide the user on how to set up, start and stop the EEG recording.
- **Cloud Storage**
When the EEG recording is completed on the mobile device, the data is uploaded to the cloud storage for retrieval and analysis.

System Description

@@Ready for Review

The EEG device is connected to a wearable patch attached to the forehead that acquires brain wave signals continuously. The EEG device, the patch, the wireless charger, the companion mobile app and the cloud storage, collectively known as the SpotLite System, are custom designed by Beacon.



Phone Requirements Ready for Review

Supported phones and OS versions

OS	Phone model	OS version
iOS	Apple iPhone 14	16.2.X
iOS	Apple iPhone 13	16.2.X
iOS	Apple iPhone 12	16.2.X
iOS	Apple iPhone 11	16.2.X
iOS	Apple iPhone XR	16.2.X
Android	Google Pixel 6, 7	12, 13, 14
Android	Samsung Galaxy S2x	12, 13, 14

Charging the BatteryReady for Review

The SpotLite EEG Device is powered by a rechargeable battery.

To charge the battery, align the front of the SpotLite EEG Device (with logo) with the front of the Charging Dock (the opposite side of the charging cable).



Gently push the device all the way into the charging dock.



During the charging, the light in the front of the charging dock is blinking. When the charging is complete, the light turns solid. The charging time should be less than 90 minutes.

If you notice longer charging time or significant reduction in the duration of the SpotLite EEG Device operating time, the device may need to be replaced.

Powering On and Off the SpotLite EEG Device

To turn on the SpotLite EEG Device, press the green power button on the back of the device. To turn off the SpotLite EEG Device, press and hold the green power button for 5 seconds.

Quick Start Guide

For Self-Application

Author: Elliott Munoz Stephen Johnson Laura Edinger, in draft state In Progress

Step 1

Confirm the LED on the SpotLite Device is green. This means the Device is on and paired with the SpotLite App.

Step 2

Remove a SpotLite EEG Patch from an envelope.

Step 3

Carefully place the SpotLite Device, bottom first, into the Cradle of the SpotLite Patch and listen for a click.

Step 4

Turn the Patch over and, using the plastic tab, remove the backing from the center of the Patch.

Step 5

Use a mirror to help place the patch about $\frac{1}{2}$ an inch above the eyebrows with the Device centered between the eyes. Firmly press the Device against your forehead.

Step 6

Use the plastic tab to remove the backing from the left sensor and, taking care to avoid the hairline, place the sensor along the left side of the forehead.

Step 7

1. Plug in and ensure you have access to your phone
2. Be in the place where you plan to relax or sleep.
3. If you need to get up at any time while recording, please take your phone with you and keep your patch on until you're able to return to where you plan to relax or sleep.

Step 8: Monitoring

1. When you are ready to begin, press "Start Monitoring"
2. If there is an issue with a sensor during the monitoring, the screen will go red and direct you on how to address the issue

Step 9: Stop the EEG Monitoring

1. Press the "Stop" button to end monitoring

For Assisted-Application

Author: Elliott Munoz Stephen Johnson Laura Edinger, in draft stateIn Progress

Step 1

Assist the user in turning on the device and confirm the LED on the SpotLite Device is green. This means the Device is on and paired with the SpotLite App.

Step 2

Assist the user in removing a SpotLite Patch from an envelope.

Step 3

Place SpotLite Device, bottom first, into the cradle until you hear a click.

Step 4

Turn the Patch over and use the plastic tab to remove the backing from the center of the Patch.

Step 5

Place the patch about $\frac{1}{2}$ an inch above the eyebrows with the Device centered between the user's eyes. Firmly press the Device against their forehead.

Step 6

Use the plastic tab to remove the backing from the left sensor and, taking care to avoid the hairline, place the sensor along the left side of the forehead.

Step 7

4. Plug in and ensure the participant has access to their phone
5. Be in the place where the participant plans to relax or sleep.
6. If the participant needs to get up at any time while recording, instruct them to take their phone with them and keep the patch on until they're able to return to where they plan to relax or sleep.

Step 8: Monitoring

3. When they are ready to begin, press "Start Monitoring"
4. If there is an issue with a sensor during the monitoring, the screen will go red and direct you on how to address the issue

Step 9: Stop the EEG Monitoring

2. Press the "Stop" button to end monitoring

SpotLite App

Signing in

Author: Jean Wheeler Elliott Munoz, in draft state locked

After you receive your SpotLite EEG Device, you should receive a welcome email to the email address you provided your administrator. If you have not received the welcome email, please first check any junk or spam folders prior to contacting your administrator.

The welcome email will include a link to finish setting up your [SpotLite] account. Click the link and follow the instructions on how to update your account password. This password, along with your email address will be the credentials used for signing into the SpotLite app.

To access the SpotLite app, log in using the credentials provided to you by your health care network administrator.

Home Screen

Author: Elliott Munoz In Progress

The home screen is divided into two sections. The top section contains an Overview carousel that orients the participant to the contents of the SpotLite System. The bottom section contains a button to start a recording.

Navigation

Author: Elliott Munoz In Progress

The Navigation consists of 3 menu items: Home, Record, and More. Each Menu item contains a representative icon and a label.

Home

Pressing "Home" will take you back to the Home Screen.

Record

Pressing "Record" will initiate a monitoring session.

Menu

Author: Elliott Munoz Not Started  Ready for Review

Pressing "Menu" will display five submenu items:

1. Account

Pressing "Account" will display "Sign Out" and five additional submenu items:

- a. Notification Preferences
- b. Consent Documents
- c. Legal Notices
- d. License Agreement
- e. Privacy Policy

2. The SpotLite System

3. Instructions

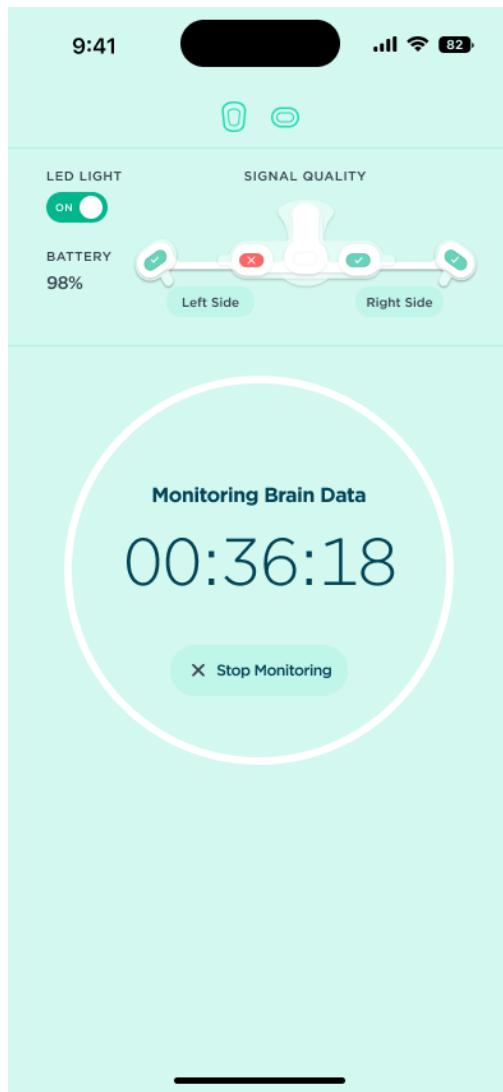
4. Contact

5. About

Starting an EEG Recording

Author: Elliott Munoz  Ready for Review

Once you click Start Monitoring from the "Monitoring Tips" screen, the Monitoring screen will appear as shown below. The Monitoring screen is composed of two sections. The top section displays LED Light settings, Battery life, and Signal Quality. The bottom section displays the elapsed time of the Monitoring session and the "Stop Monitoring" button.



If there are issues with a sensor during the monitoring session, a sheet will appear with instructions for addressing the issue. A monitoring session will not be stopped unless more than one sensor has an issue.

A user may end a monitoring session by clicking and confirming "Stop Monitoring." See the **Stop Monitoring** section of this manual on how to end a recording.

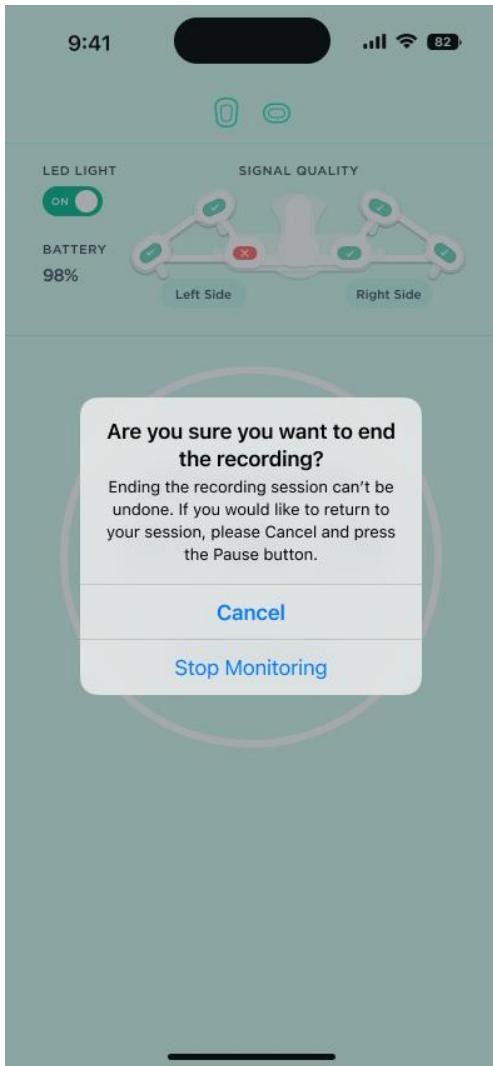
Stopping an EEG Recording

Author: Elliott Munoz  Ready for Review

It is possible to end a recording from the Monitoring screen by clicking on "Stop Monitoring."

An alert — as shown below — will appear asking you to either "Cancel" which will send you back to the Monitoring screen or "Stop Monitoring" which will end your monitoring session. Click "Stop Monitoring" to end your monitoring session.

Ending your monitoring session will begin the file transfer process. See the **Uploading EEG Monitoring via Wi-Fi** section of this manual for more information.



Uploading EEG Monitoring via Wi-Fi

Author: David Klaffenbach Elliott Munoz Not Started

Maintenance

Cleaning SpotLite and the Charger

Author: David Klaffenbach Not Started

Disposing of patches

Author: Jean Wheeler Not Started

Disposing of SpotLite

Author: Jean Wheeler

Not Started

EEG Device Product Specifications  Ready for Review

Parameter	Value/Description	Comments
Battery	Li-poly, 3.85V, 220mAh	
Dimensions	41 x 32 x 13 mm	H x W x D [1]
Mass	approx. 14 g	
Wireless Protocol	BLE 5.0	
Operating Temperature	15 - 40 °C	
Operating Humidity	25 - 95 %RH w/o condensation	
Shipping Temperature	-20 - 60 °C	
Shipping Humidity	15 - 95 %RH	
Battery Life	> 12 hours, all features on	
Number of Channels	6	
Minimum Bandwidth	0 - 70 Hz	[2]
EEG Sample Rate	250 sps	
Input range	±300.0 mV	
Impedance measurement	Continuous	[3]
Resolution	35.8 nV	
Common Mode Rejection Ratio (CMRR)	< 100µV pk-valley for 1Vrms	
Crosstalk rejection	40 dB	
Noise	< 1.0 µVrms	
Charging interface	Qi (inductive) 5 W	
Charger	Proprietary	

Charger dimensions	51 x 43 x 47 mm	H x W x D
Charger mass	approx. 70 g	
EEG connection to Patch	Proprietary	

[1] Not including protrusions of pogo pins or the latch feature.

[2] The SpotLite does not high-pass filter the data.

[3] Continuous, out of band (125Hz), AC impedance measurements.

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.

Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: 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 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 a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/TV technician for help.

1* WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.”

2* WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.”

3* WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.”

4* RF Exposure Compliance

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. This equipment should be installed and operated with minimum distance 00cm between the radiator and your body.

Table 1

FCC Declaration - Electromagnetic Emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Clause 5

Table 2

Declaration - Electromagnetic Immunity		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_{UT} ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % U_{UT} ; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % U_{UT} ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % U_{UT} ; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

Table 3

Declaration - Electromagnetic Immunity		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz

	6 V in ISM bands between 0.15 MHz and 80 MHz	3Vrms (emf), 6Vrms (emf) in ISM bands between 0.15 MHz and 80 MHz 80%, 1 kHz
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m
Immunity to proximity magnetic fields in the frequency range IEC 61000-4-39	Immunity to proximity magnetic fields in the frequency range 9 kHz to 13.56	See table 11 of standard Any one of its nominal input voltages and frequencies

Table 4

Declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m

Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.

1. Verdict summary section

IEC 60601-1-2 referenced emission standards			
Clause	Requirement – Test case	Basic standard	Verdict
7.1	Terminal disturbance voltages	CISPR 11:2015 +A1:2016 + A2:2019	P
7.1	Radiation disturbance	CISPR 11:2015 +A1:2016 + A2:2019	P
7.2.1	AC-Mains Harmonics	IEC 61000-3-2:2005 +A1:2008 +A2:2009	P
7.2.2	AC-Mains Voltage fluctuations and flicker	IEC 61000-3-3:2013	P
IEC 60601-1-2 referenced immunity standards			
Clause	Requirement – Test case	Basic standard	Verdict
8.9	ELECTROSTATIC DISCHARGE	IEC 61000-4-2:2008	P
8.9	Radiated RF EM fields	IEC 61000-4-3:2006 +A1:2007 +A2:2010	P
8.9	Electrical fast transients / bursts	IEC 61000-4-4:2012	P
8.9	Surges	IEC 61000-4-5:2014+A1:2017	P
8.9	Conducted disturbances induced by RF fields	IEC 61000-4-6:2013	P
8.9	RATED power frequency magnetic fields	IEC 61000-4-8:2009	P
8.9	Voltage dips	IEC 61000-4-11:2004 + A1:2017	P
8.9	Voltage interruptions	IEC 61000-4-11:2004 + A1:2017	P
8.10	IMMUNITY to proximity fields from RF wireless communications equipment	IEC 60601-1-2:2014 + A1:2020 Table 9	P
8.11	Immunity to proximity magnetic fields	IEC 61000-4-39:2017	P
Supplementary information: None.			

Clause 5

Troubleshooting

Author: Yongbo Wang Not Started

Contact Information

Author: Jean Wheeler In Progress

For [questions/issues] related to SpotLite, please email spotlite@beacon.bio

For more information on Beacon Biosignals and SpotLite, visit www.beacon.bio

Glossary

Meaning of Symbols



Single Use Only



Not made with latex



Non-Sterile



Consult Instructions for use



Upper limit of temperature



Batch Code



Manufacture Date



Expiration Date



Manufactured by



Quantity



Prescription Only

Addendum