EMFIT™

QS®

+CLINICAL

Installation & operating instructions

FOR WIFI (2.4 GHZ) MODEL:
EMD-9360-0656-30-P

REV. B
26.1.2018

Thank you for purchasing
EMFIT QS+CLINICAL™.

1. Product description

The EMFIT QS+CLINICAL™ (product hardware) consists of a plastic film sensor and a registering device to which the sensor is attached with a fixed cord. It is placed in bed, under the mattress (not a spring mattress) or mattress topper. The sensor is a very sensitive ferroelectret film sensor that reacts to dynamic changes of forces and it can sense even the slightest of changes caused by heart contractions, breathing and body movement of a person resting in bed.

The registering device consists of electronics and an embedded software that converts the electrical signal received from the sensor into a digital form. It also includes data transfer from the product to the cloud server of Emfit Ltd, which is based on 3G mobile phone technology. Data is available on the server in .edf (European data format) form and it is also available on a computer browser.

The user environment of the product is usually a bedroom and the user is usually an adult.

2. Indications for use

Without a patient contact to transform movement from a body, breathing and heart contractions into an electrical signal for the purpose of investigating physiological processes at rest. The signal data is intended for healthcare professionals to decide if further tests are needed to diagnose sleep disorders, such as sleep apnea.

In this use, the product is classified as grade 1 medical device according to EU directive 93/42/ETY rule 12.

3. Contraindications

The product and it's server software also registers (i) bed exits and returning to the mattress under which the sensor is placed; (ii) breathing and heart rate, sleep classes sleep time, heart rate variability (RMSSD) and autonomous nervous system balance. The manufacturer has not intended these above-mentioned qualities and the web application to be used for diagnosing, monitoring or alleviation of any disease, injury or deficiency or investigation of physiological processes. In regards these qualities manufacturer considers product and it's server software are not subject to meet the requirements of directive 93/42/ETY and directive 2007/47/EY of the European parliament and council.

4. Cautions

- The product shall not be used for any other purpose than what the manufacturer has intended it for
- The product shall not be connected to any other devices
- The product shall not be repaired by oneself.
- The product is only intended for use in warm indoor environments.
- Using the product with a pressure ulcer mattress adjusted with a compressor may disturb functioning of the product.
- The product shall not be sterilized in an autoclave or by irradiating/radiating it.
- The product shall not be used if it seems damaged or broken.

5. Warnings

- The product is not meant for self-diagnosis or self-treatment based on the results or analysis the product provides. Always consult a medical professional.
- When unplugging the power source, make sure the plug is not stuck in the power socket. If this has happened, touching the power socket or unplugging it may cause an electric shock
- The cables of the product have to be kept away from children (risk of choking). Attach the cables so that children will not be able to get a hold of them. For example use cable trunking or cable ties for attachment.
- The product is designed and tested for use with the power supply of Globtek Inc. (see further information from chapter Technical information). Any other power supply may affect the safety of the product.
- If the product gets wet or starts to heat up, immediately stop using it and unplug the power supply from the power socket.
- The product is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

6. Symbols used in these instructions for use

The following instructions are designed to ensure the personal safety of the user and protect this device or any device connected to it from damage. These instructions use symbols to draw the user's attention to the instructions at hand. The symbols act as safety and warning signs. The symbols and their explanations are as follows:

If the instructions are not adhered to, the situation may lead to a death or serious personal injury (in these instructions for use). ATTENTION - consult accompanying documents (i.e. these instructions for use)

Means that the section contains important information for the user (in these instructions for use).

Symbol of European Waste Electrical and Electronic Equipment Directive (WEEE Directive) 2002/96/EC on waste electrical and electronic equipment (in these instructions for use).

Indicates manufacturer's name and address (in the control unit).

Indicates polarity of d.c. power connector (In the external power supply).

Indicates alternating current (in the external power supply).

Indicates direct current (in the external power supply).

Indicates that product meets safety requirements specified in IEC 61140 for Class II equipment (In the external power supply).

Product is for indoor use only (in the external power supply).

Product is UL Demko certified (in the external power supply).

Product is China SJ/T 11363-2006 certified (in the external power supply).

Product is UL certified (in the external power supply).

Indicates that the product conforms with the relevant requirements of the Medical Device Directive 93/42/EEC.

Product is VCCI certified (in the external power supply).

Product is UKRSepro certified (in the external power supply).

Product is GOST-R certified (in the external power supply).

Product is C-TICK certified (in the external power supply).

Product is China RoHS 30 certified (in the external power supply).

Product is BSMI certified (in the external power supply).

Product is SIQ certified (in the external power supply).

Product is IRAM certified (in the external power supply).

Product is CCC certified (in the external power supply).

Product is CPSQ certified (in the external power supply).

Product is PSE to J60950 certified (in the external power supply).

7. Environmental conditions

Storage and transportation
- **Temperature:** -30°C - +50°C
- **Relative humidity:** ≤80%

Use
- **Temperature:** +10°C - +40°C
- **Relative humidity:** ≤75%
- **Altitude:** <3000 m

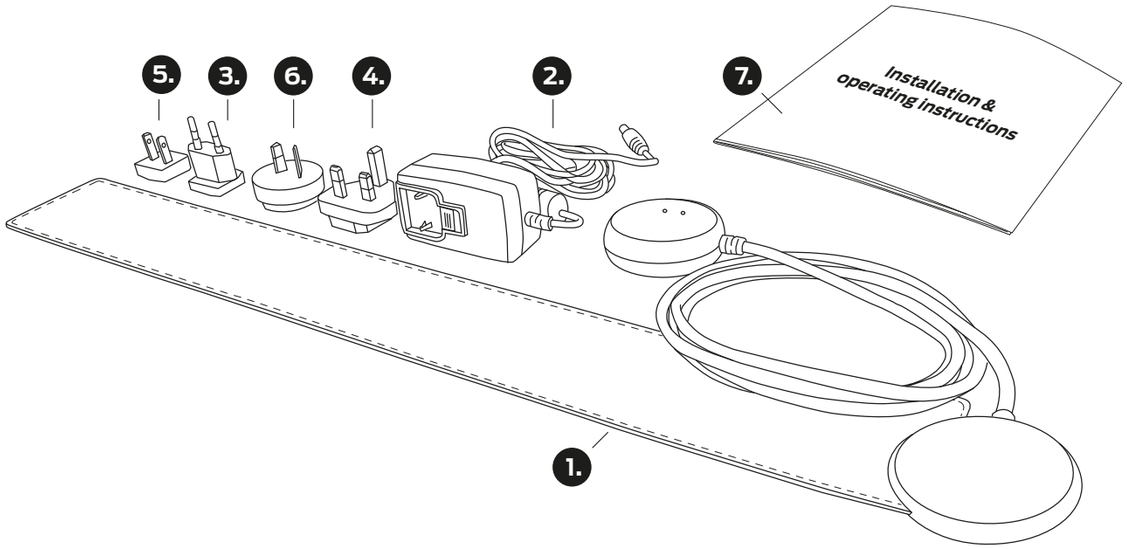
8. Cleaning

CAUTION Do not spray, pour or spill liquid onto the power supply, device, cables, or sensor.

The Emfit device may be surface-cleaned using a soft cloth dampened with either a commercial, nonabrasive cleaner or a solution of 70% alcohol in water. Lightly wipe the surfaces of the device, power supply, cables and sensor.

9. Package contents

1. Electronic unit with attached bed sensor
2. Power supply
3. Plug adapter for European countries
4. Plug adapter for United Kingdom
5. Plug adapter for United States of America
6. Plug adapter for Australia
7. User guide



10. Minimum requirements

- **2,4 GHz (802.11 b/g/n) home* Wi-Fi network with access to Internet. The 5 GHz Wi-Fi is not supported.**
- **Channels 1 - 11 in use (channels 12-14 are not supported)**
- **For Wi-Fi set up process, a computing device (for example laptop, desktop computer, smart phone) with internet browser.**
- **Electrical outlet (110 - 230V AC) for the included 5V power supply**

* In home Wi-Fi networks usually all outgoing ports are open. If you use professional (office, corporate) Wi-Fi you need to enable outgoing ports 35110 - 35121 open.

To operate, EMFIT QS needs Internet connection. It can be either:

A

Home Wi-Fi with Internet access
Your Wi-Fi network password

or

B

Mobile device as Wi-Fi hotspot
Your hotspot Wi-Fi network password

and then

for Wi-Fi set up you need (only during setup):

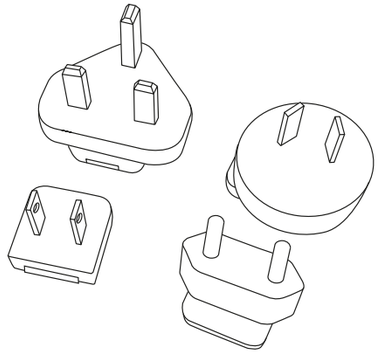
C

Computing device
(computer or tablet or smartphone with browser)

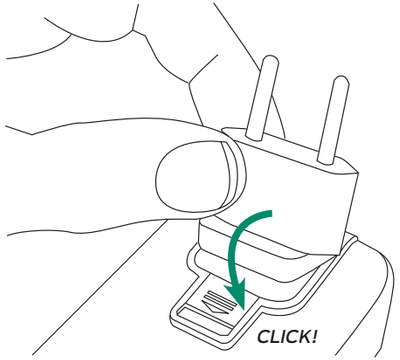
NOTE! If you choose method B,
please notice that you will need an additional computing device during setup:
- **Mobile device:** to create hotspot (Internet connection)
- **Computing device (laptop, mobile phone or tablet):** to set up your Emfit QS device to this hotspot

11. Setup

1 Select a suitable adapter from the four alternatives.

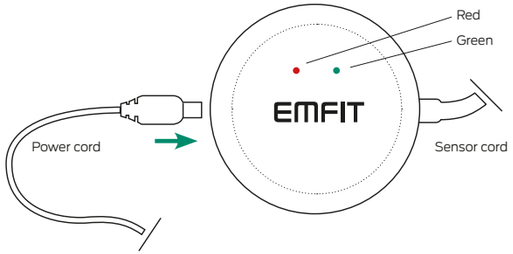


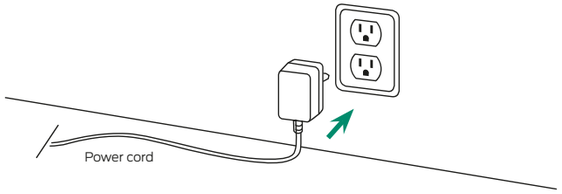
2 Connect the correct adapter to the power supply and ensure that it locks in its place.



3 Connect the power supply to an electrical outlet (110 - 230V AC) and connect the power cord to Emfit QS.

Green and red lights start to flash alternately and device makes beep sounds.

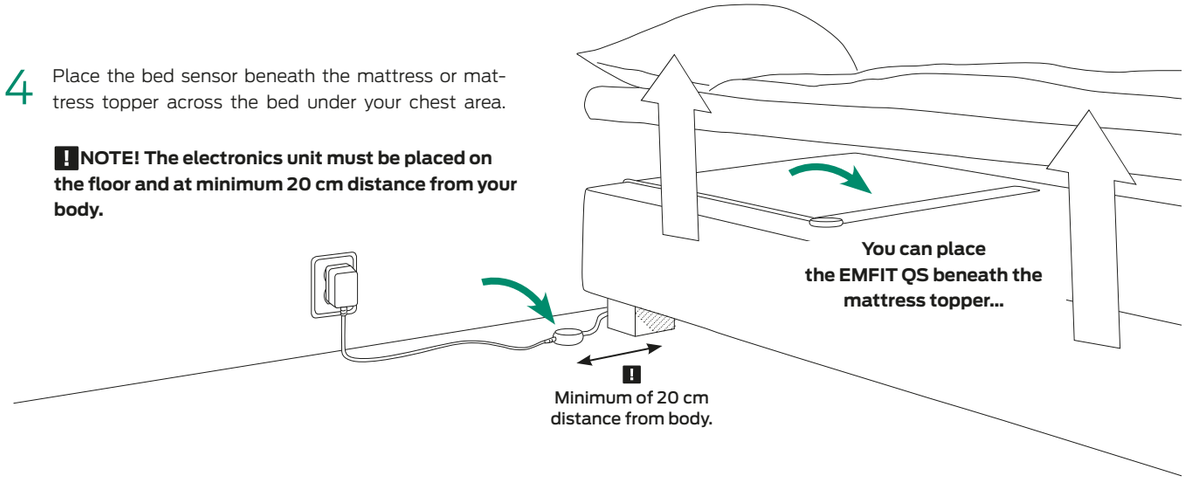


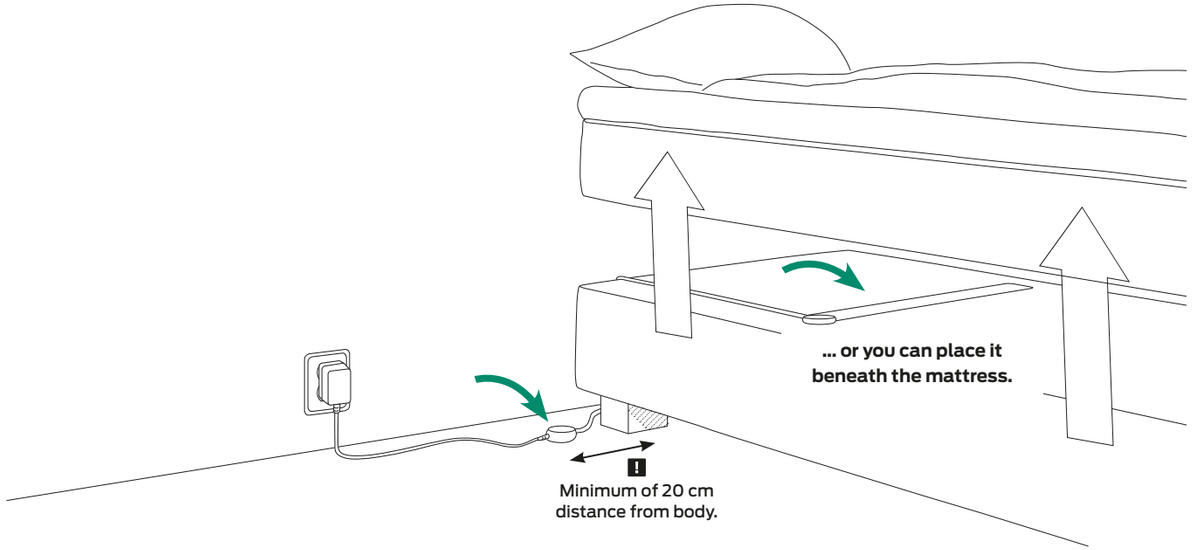


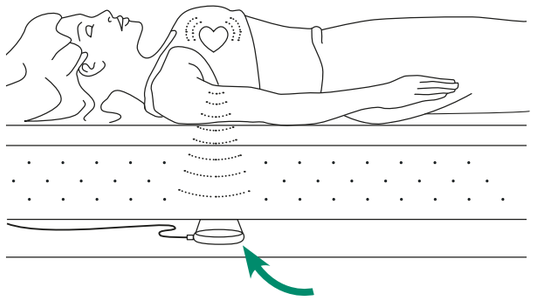
Note! If this is a new installation and only the red led flashes, you need to restore the device into AP mode. Please see chapter 14 on page 24.

4 Place the bed sensor beneath the mattress or mattress topper across the bed under your chest area.

NOTE! The electronics unit must be placed on the floor and at minimum 20 cm distance from your body.





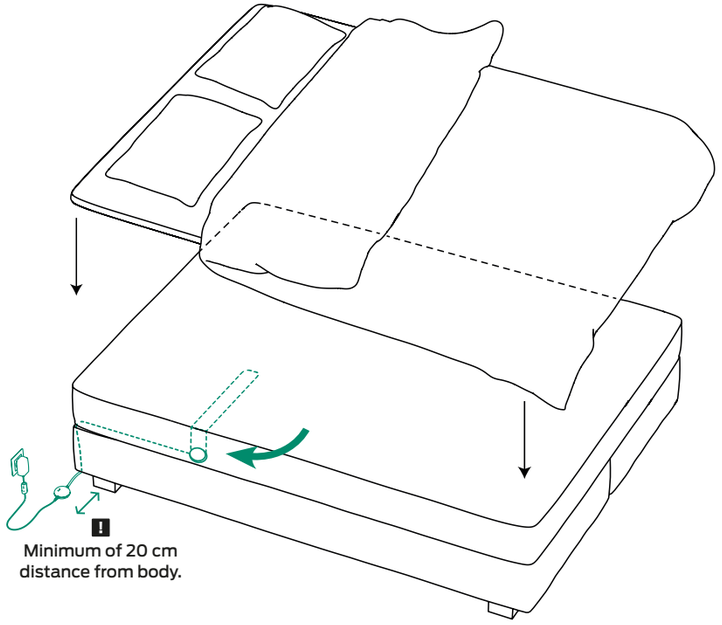


The device works most reliably when the sensor is located directly below your heart.

Placing EMFIT QS+CLINICAL in a double bed

If you sleep with a partner in a double bed, place the sensor on your side of the bed as far from your partner as possible. Make sure the sensor is still under your chest area.

You can bend the sensor over the corner of your mattress. This will help prevent sensing your partner's heart rate, especially when you leave the bed earlier than he/she.



12. Connecting to Wi-Fi network

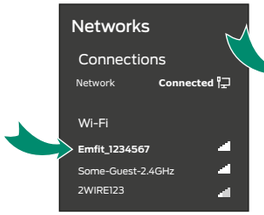
(without WPS button)

1 Search for wireless networks with your computing device.

2 Connect your computing device to the network: **Emfit_xxxxxx** (where xxxxxx is the serial number of your device).

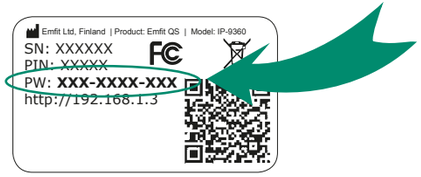
! Ignore possible "No internet connection".

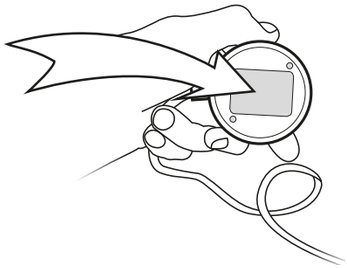
Windows



Mac OSX

3 Fill in the requested password (PW: XXX-XXXX-XXX).

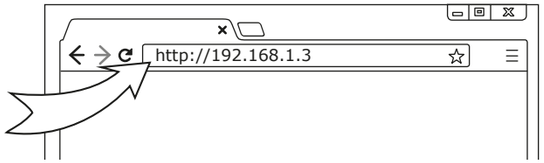




! Note! The password must be filled in with the hyphens.

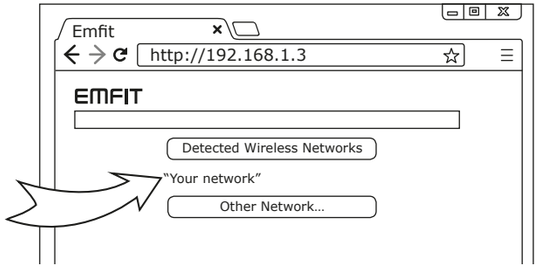
4 Open your computing devices' browser (Mozilla, Safari, Chrome, Internet Explorer etc.).

Type in address/url bar:
http://192.168.1.3 and hit enter.

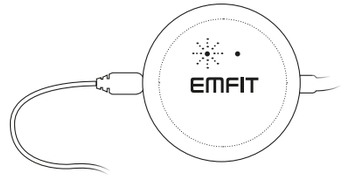


If you cannot access above-mentioned IP-address, check that your computing device did not disable itself from EMFIT QS+CLINICAL™ and is perhaps again connected to your own Wi-Fi. A problem may especially arise with a desktop computer and a connected LAN/ethernet cable. To solve this possible problem, simply remove the LAN/ethernet cable temporarily.

5 Select your own Wi-Fi network from the list and type its password.

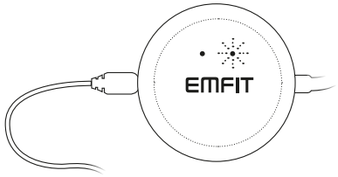


6 Press enter and EMFIT QS+CLINICAL™ will now try to connect to your Wi-Fi network. Thiscan take up to few minutes. You will hear short "beep" sounds and see the red led flashing.



Red light starts flashing two times (2x) between short pauses.

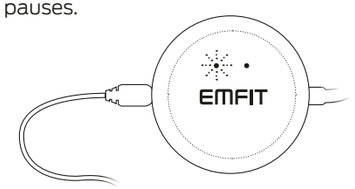
Successful connection type 1
The device will emit high tone sounds. In about 1-3 minutes, the red light will stop flashing and green light will start flashing.



Green light will start flashing.

You are done! Your device is now connected and ready to track your sleep.

Successful connection type 2
The device will emit high tone sounds. However, the red light will not stop flashing. It flashes one, two or three times between pauses.



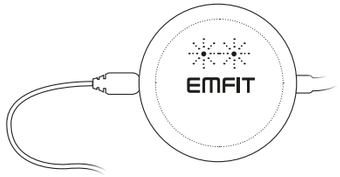
Only red light remain flashing.

Sorry, you are not done yet! Please see chapter Troubleshooting on page 21 in the Main Manual. This occurs usually in a hospital/corporate Wi-Fi network.

Unsuccessful connection
Red and green lights flash alternately again. This means that the device has returned to AP (Access Point) mode. This is common. You may have to try even 10-15 times, so please be patient. This is a common issue in Wi-Fi networks.

Please start again from step 1. Check that your computing device has automatically returned connection to your home Wi-Fi. You need to search for available Wi-Fi networks again and reconnect to EMFIT QS+CLINICAL™.

With your next attempt(s) you probably can skip step 3 as your laptop/tablet/smartphone remembers the EMFIT QS password.



Red and green lights are flashing alternately. Device is again at AP mode.

❗ *Please don't get confused if your browser says "http://192.168.1.3 is not replying." It is because your computer probably switched automatically to your home Wi-Fi and there is no device in that address on Internet.*

❗ *Check again that you have written your own home Wi-Fi network password correctly. Also, if after few attempts there is still no success, check that your router is not 5 GHz version only or operating at channels 12-13. For troubleshooting, see page 21.*

❗ *You may also get a reply from some other than EMFIT QS device, for example if you have an IP camera.*

After successful Wi-Fi connection, it is time to register your device.

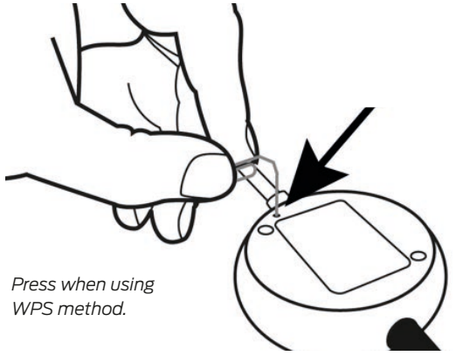
↓

Go to chapter 13.

12.1. Connecting through Wi-Fi Protected Setup (WPS) button

1) Enable your home Wi-Fi router's WPS button. Depending on your router, you may need to push the button for 2-3 seconds or more. After you have pressed the WPS push button of your router, it will be in pairing mode usually for 1-2 minutes.

2) Press and hold your EMFIT QS device WPS button for 2-3 seconds until you hear a sound. The button is accessible via the tiny hole in the back. Use a paper clip, for example. Lights of the device will flash. After you have pressed both your router and EMFIT QS device WPS buttons, pairing of the devices begins.



Press when using WPS method.

Examples of WPS button in router.

Pairing of the devices can take up to few minutes. Usually it takes less though. During this time, the device will keep emitting short sounds and red light is blinking.

Successful pairing
If pairing of the devices is successful and Wi-Fi connection is enabled, EMFIT QS device will emit 3 short notes with rising tone and red light will go off wihin 2 minutes and green light starts to blink.

Unsuccessful pairing
If the pairing fails, you will hear three quick tones - low high low - and red light will keep blinking. EMFIT QS device will automatically return to the state it was in at the beginning of this chapter i.e. AP (access point). Check again that your router goes into pairing mode and make sure its WPS push button is enabled. Try to pair the devices again. It is worth to try this at least three times.

If the pairing still fails, you will need to connect manually. See next chapter 8.2.2. on page 14.

NOTE: Videos that will help you to understand how the WPS pairing is done are available in the User's Guide at **qs.emfit.com** after you have logged in.

After successful Wi-Fi connection, it is time to register your device.
Go to chapter 13.

12.1.1. MY NETWORK IS HIDDEN

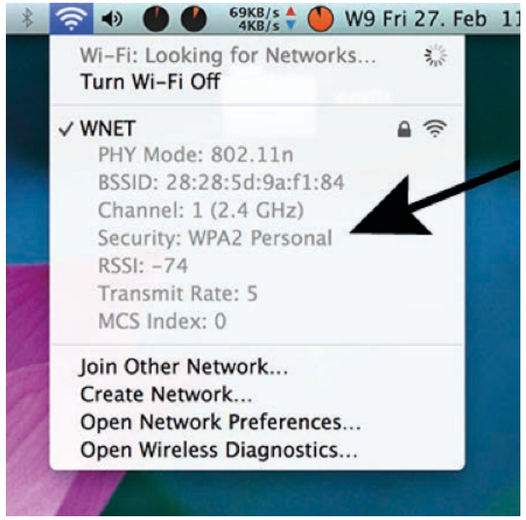
First, you will need to find out what type of encryption your home Wi-Fi network uses.

With Windows OS computer, move the cursor over the network. WPA2 is a common encryption.

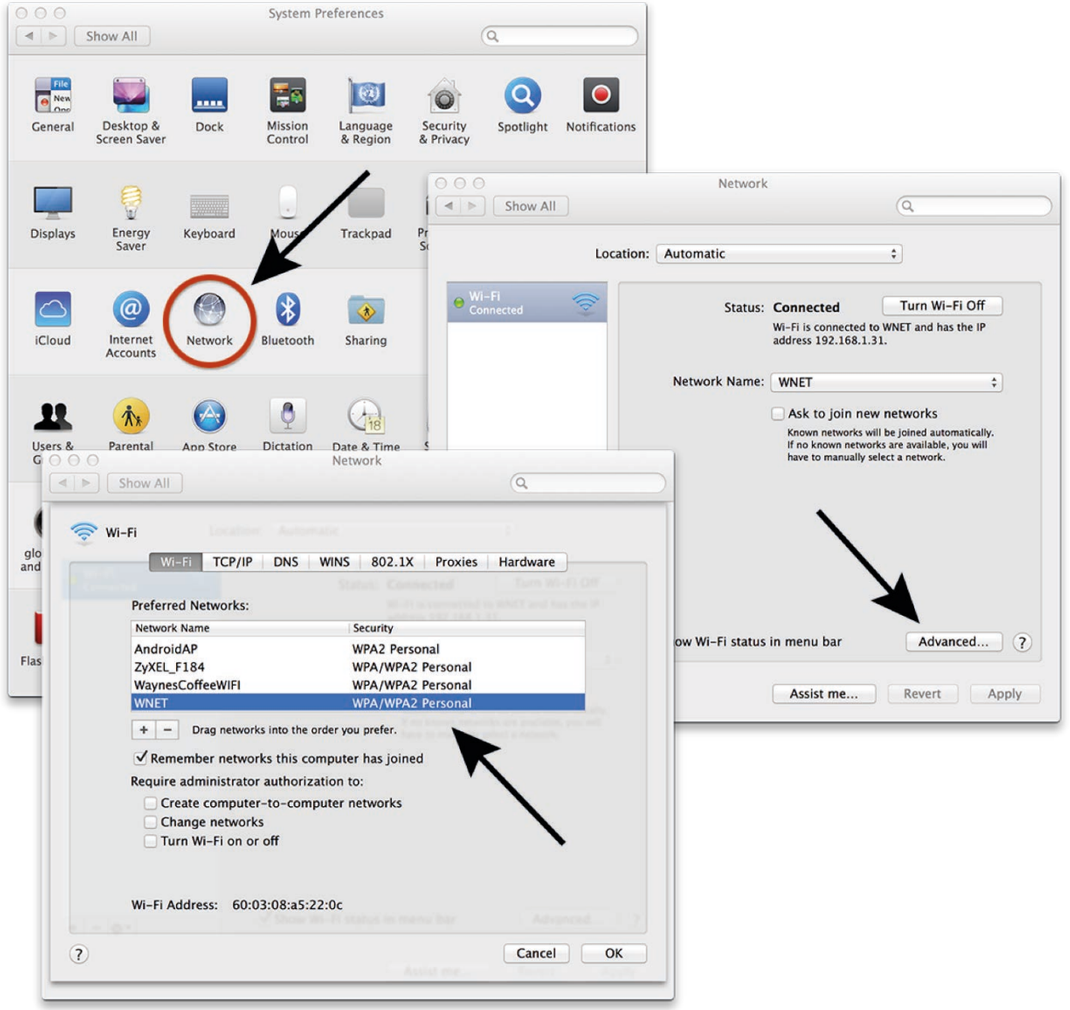
Remember this security method's name as you will use it on next actionstep.

On Windows see network listing and hover mouse over your network:

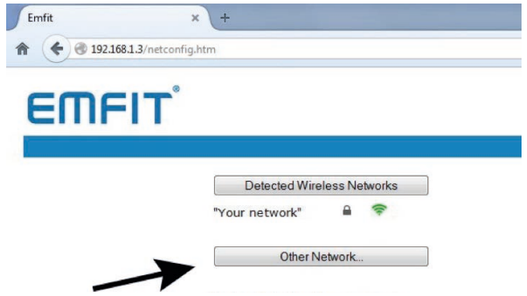
On Mac, click the top right toolbar icon while pressing down the ALT key. This lists networks with additional details:



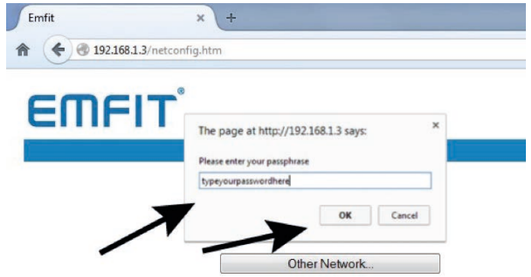
If you don't have the toolbar icon enabled, you can alternatively view it here:



Next, on the web page in your browser, click “Other network” button and type your network’s name and choose the correct encryption method. Press join.



Type your Wi-Fi network password and click OK. The password you type is visible on purpose because you must ensure that you type it correctly. The field is case sensitive. If you don’t have a password for your network (your network is open), leave the password field empty and click OK.



When you click OK, the device will start connecting to your selected network. Connection in progress page will appear. Notification sounds emit indicating that connection attempt has begun. During the connection attempt the device will emit continuous sounds. After successful connection you will hear three short notes with rising tone. Red light goes off and green will keep blinking.

! NOTE! If connecting fails, you will hear three quick tones of low-high-low and red light will keep blinking. The EMFIT QS device will automatically return to access point (AP). Try again and make sure you have typed the Wi-Fi network’s password correctly.

Red light will stop blinking. Your EMFIT QS device has now been configured.

! NOTE! When the device is connected to the selected wireless network, you will not be able to access your device from this page anymore without resetting your device to Access Point (AP) again. But, you have no need for it unless you wish to connect to a different wireless network or if you have changed the password of your home network’s.

! NOTE! If red light is still blinking after 2 minutes, something went wrong and your device is not connected to our server. Try once more by restoring to factory settings. See chapter 9. on page 23 for instructions for instructions on Restoring EMFIT QS device to Access Point (AP) mode and factory settings

12.2. Checking the data flow of the device to server’s database

The system begins to gather data after one minute of detected presence in the bed (green light will turn on as the system has noticed that you are lying on the bed).

To check this, lie on the bed until green light stops blinking and turns on. “Monitor” section of qs.emfit.com should now start showing graphs. Then leave the bed. After a short while, the “Monitor” section should say “Absent”.

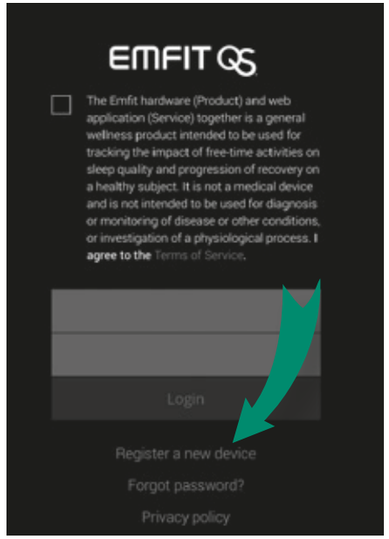
Please note that Sleep Period data will not be available until at least one hour of sleep. Sleep classification however needs a minimum of two hours of presence in bed.

! NOTE! Trends are not available until four nights of sleep.

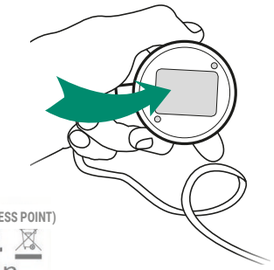
13. Register the device

After successful Wi-Fi connection, it is time to register your device.

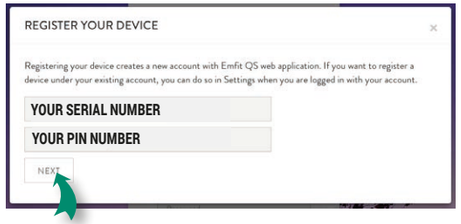
1 Go to **https://qs.emfit.com** and click “Register your device”.



2 Locate your serial and PIN numbers on the back of the device.

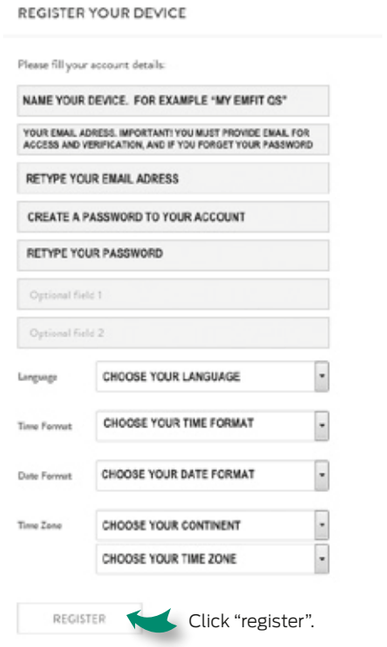


3 Insert serial number and PIN number of your device.



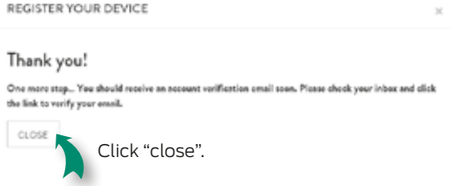
Click “next”.

4 Fill in/choose the details.



Click “register”.

5 This will open.

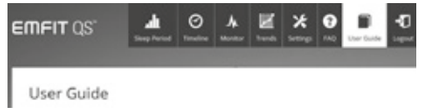


Click “close”.

6 Go check your email for our verification email. Open it and click on the link in it.

(If you do not receive the confirmation message within a few minutes of signing up, please check your Spam folder just in case the confirmation email got delivered there instead of your inbox.)

7 You will be directed to the Emfit QS web application.



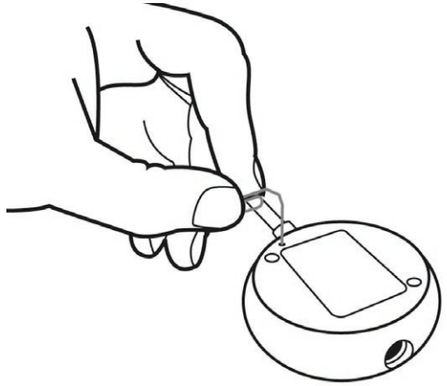
14. Restoring EMFIT QS+CLINICAL™ to Access Point (AP) mode

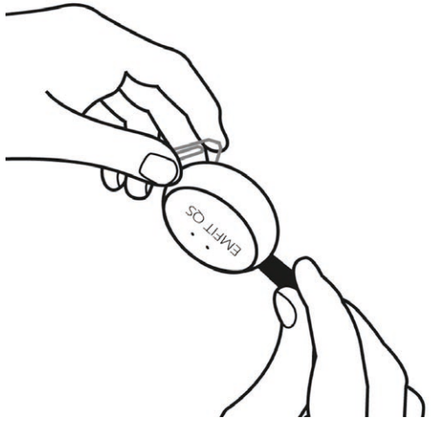
Follow these steps if you need to connect EMFIT QS+CLINICAL™ to a different wireless network that has Internet access, or if you experience any problems with setting up your device. This action restores the device back to factory default settings (NOTE: Sleep data or registration details will not be deleted), and returns the device back in Access Point (AP) mode:

A) Remove the power supply cord from the device.

B) With using a paperclip or a needle, press and hold down the WPS / multifunction button at the back of the device:

C) Connect the power supply cord while keeping the button pressed down. Keep the button pressed down.





D) As the red light starts flashing, press the button down for about 10 seconds until the red light stops flashing and turns on.

E) Release the button. Green and red light will start blinking alternately. Factory settings have been restored.

NOTE: Videos that will help you to understand how the restoring is done are available in the User's Guide at **qs.emfit.com** after you have logged in.

15. Meanings of lights and sounds

How the LED lights and sound notifications of the EMFIT QS+CLINICAL™ behave in different situations. Sound signals are used only during setup to help the user interpret the status of the device.

During Setup

When everything goes well:

Case	Red LED light (light on the right)	Green LED light (light on the left)	Sound description
The device is powered and it is an AP (access point)	Flashing alternately with green LED (about once per second)	Flashing alternately with red LED (about once per second)	Beep - beep (two short beeps)
You connect to the device while it is an AP	No change. Green LED flashing alternately (about once per second)	No change. Flashing alternately with red LED (about once per second)	Beep (one short beep)
You went to the device's internal html-page at IP address: 192.168.1.3., choosed your own home Wi-Fi network and clicked to establish connection to it.	Flashes three times fast, then about 3 seconds pause, again 3 fast flashes, and pause, and so on...	No flashing light	Several low short beeps while establishing connection
Successfully connected to your home Wi-Fi network and Emfit server	Stops flashing	Starts flashing every 3 seconds (slowly). Lit when you are in bed for longer than one minute.	Two times short beep and one long beep (something like beep-beep-beeeeep)
Connects to your home Wi-Fi network but router is not connected to the Internet	After connection to Wi-Fi network remains flashing once every three seconds. QS is no longer in AP mode.	Stops flashing when connecting to Wi-Fi, but does not start flashing after connection: no connection to the Internet.	Two short beeps and one long beep ("beep-beep-beeeeep").

Fault cases:

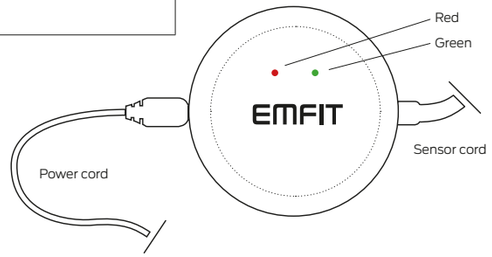
Case	Red LED light (light on the right)	Green LED light (light on the left)	Sound description
Wrong password for your home Wi-Fi network or unknown connectivity issue between your router and EMFIT QS	Flashes in cycles of three ●●● ●●● ●●● ●●● Connection could not be established. The device usually returns back to the AP mode (red and green flash alternately). If not, you should reboot the router. If this does not help, then return the device manually back to the AP mode (see page 24).	Stops flashing during connection attempt. When the device notices that connection cannot be established it returns to AP mode and red and green start flashing alternately.	Several long beeps when establishing connection. Low pitched beep and beep-beep indicate return to AP mode.

During use

Network problems:

Your home Wi-Fi network has no Internet connection (for example temporary loss of Internet connection)	Flashes in cycles of three ●●● ●●● ●●● ●●●	Does not flash (person out of bed) or stays on (person in bed)
Emfit server does not respond (temporarily)	Flashes once (person out of bed) ● ● ● ● Does not flash (person in bed)	Does not flash (person out of bed)

NOTE! When there is person in bed, green LED is always on and no fault situations are informed.



Data buffering, network connection is lost:

EMFIT QS+CARE has an internal memory where sleep data is stored if network or server connection is lost. Blinking LED lights are used to inform user when device is buffering sleep data to memory and when sleep data is released from memory to Emfit server.

Data buffering release, network connection up again:

Case	Red LED light (light on the right)	Green LED light (light on the left)
Person is sleeping or lying in bed. Wi-Fi network or connection to Emfit server reverts.	Flashes in parallel with green led in every 2 seconds	Flashes in parallel with red led in every 2 seconds

16. Using the device

After you have registered your device, installed it to your bed and hooked it up to your wireless network, the device is ready to track your sleep.

If possible, please keep the device powered on at all times (even during the day when you are not using it). If this is not possible please read the following carefully:

In the evening, power the device up before you go to bed. It is okay if red light flashes at that moment. It should however stop flashing within a few minutes when connection to cellular network and Emfit cloud server is established. Sometimes establishing server connection can take more than few minutes.

- BUT, if the red keep flashing and it flashes 3x between pauses (it does at power up for a moment), it is a problem. The cellular network does not connect.
- BUT if the red keep flashing 2x between pause (it does at power for moment), it is a problem too. There is no internet. However, this is usually temporary and/or rare.

In the morning when you get out of bed, do not remove the power supply until green light is flashing (flashing green light means that device has detected bed exit). This should not take more than 10-20 seconds. This is very important: otherwise the sleep period will not be registered correctly (bed exit event is not registered).

When you get out of bed; the red light may start flashing. This indicates that there have been cut offs at cellular connection during the night and there is data at the device's internal memory. Red light flashing after bed exit means that the device is uploading this data to cloud server. Please wait until red light is no longer flashing before removing power supply.

17. Using the product in case of a suspection of sleep apnea

EMFIT QS+CLINICAL™ (later bed sensor) is aimed for healthcare professionals who investigate and treat patients, whose history and/or status suggest that she/he might suffer from sleep related breathing disorders.

The bed sensor is used for registering sleep related apneas and hypopneas at patient's home.
Apnea considers of regular, at least of 10 seconds lasting periods, where occurs no breathing. This is caused by obstructed upper airways. During hypopneas, upper airways are partially obstructed. Hypopnea periods last over one minute of time, where constricted inhaling does not lead to apnea or awakening, but tempts to breath, loud snoring and carbon dioxide saturation increases slowly. (Source: käypähoitosuositus, uniapnea (obstruktiivinen uniapnea aikuisilla)).

Medical doctor should make a decision of a use of bed sensor, diagnosing of patients and possibly needed further investigations. Other health care personnel (eg. nurses, hospital physicians) may participate in using the bed sensor, helping to guide of use and handling of the collected information.

Patient will carry out the home measurement according to the instructions, in order to collect the sleep recording by using the sleep sensor.

Interpreting registered information

The bed sensor can be used for registering breathing movements to see the fluctuation of breathing in and out and movements caused by the mechanical pumping of the heart (ballistocardiography, BCG). Disturbances in breathing cause identifiable changes in registered data, such as central or obstructive apneas or so called periodic breathing (partial intensifying and weakening of breathing). This often includes simultaneous snoring, which can be seen as increased vibration in data registered by the bed sensor. Increased vibration is also known as "spiking".

Central sleep apnea can also be detected from data registered by the bed sensor, which means that the automatic regulation of breathing transmitted by the brain momentarily ceases and only movements caused by heart beats can be observed from data gathered by the bed sensor.

NOTE! – It is not possible to register blood oxygen levels or breathing flow with the Emfit bed sensor.

The information registered with sleep sensor

EMFIT QS+CLINICAL™ can visualize on how different kinds of breathing disturbances can be detected from data gathered with the bed sensor. Here are examples of the normal breathing of a healthy person and examples presenting breathing disturbance situations during sleep.

In the first chapter, there is an example of the normal breathing of a healthy person. In each example, there are two curves that are measured with the sleep sensor. Each curve represents registered data with different filterings of the raw BCG signal. Respiration flow nor saturation cannot be measured with the bed sensor.

In the following figures, there are sleep registering in different situations. In the figure 1, normal breathing is represented and in the figures following that, there are descriptions of the sleep related breathing disorders.

1) Normal breathing

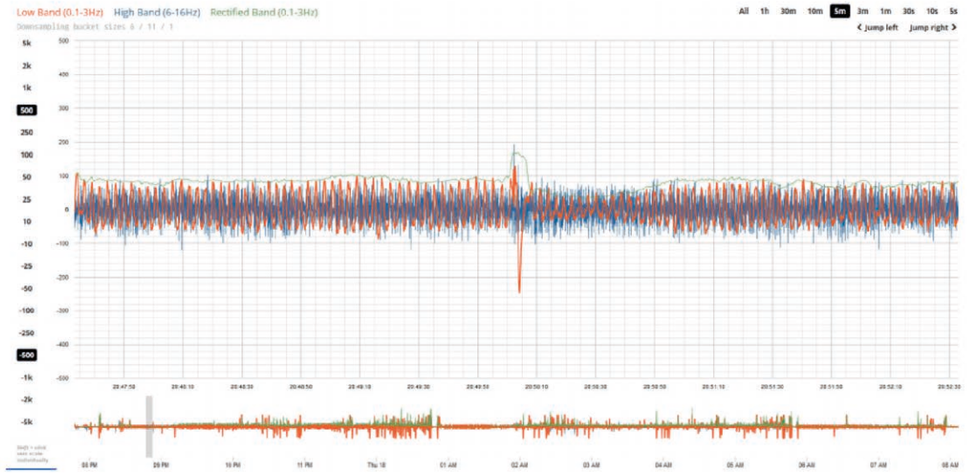


Figure 1: *The amplitude of the normal breathing with a healhty person stays quite constant during the whole sleep period. Breathing is regular and BCG is quite stable. Some irregular spiking is normal. This can be observed from the both signals derived from the bed sensor.*

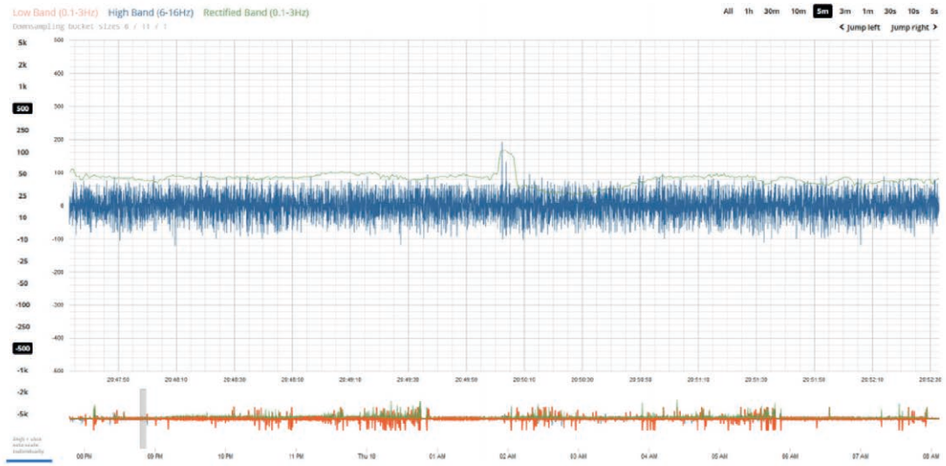


Figure 2: *Curve of respiration effort of normal breathing*

Figure 3:: *Curve of normal breathing*

2) Periodic obstructive breathing (POB)

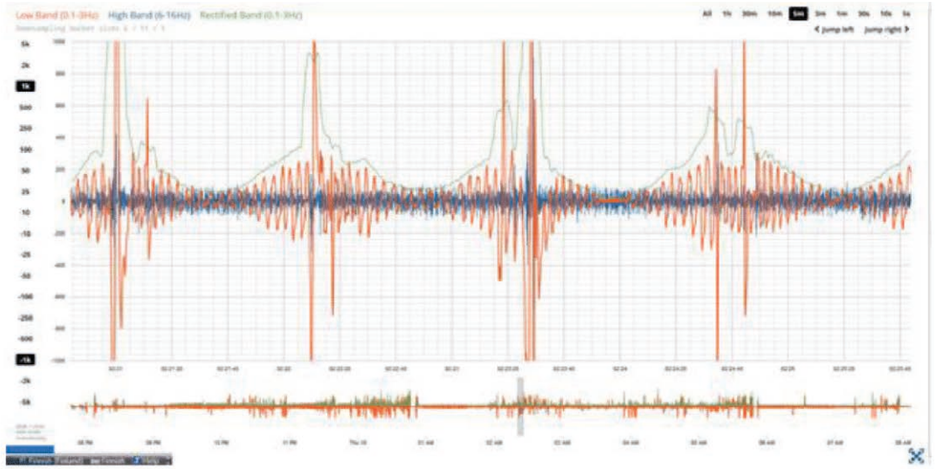


Figure 4: *Periodic obstructive breathing (POB) consists of hypopnea and apnea periods. When the airways open after apnea, there are spiking and the amplitude of the curve changes periodically.*

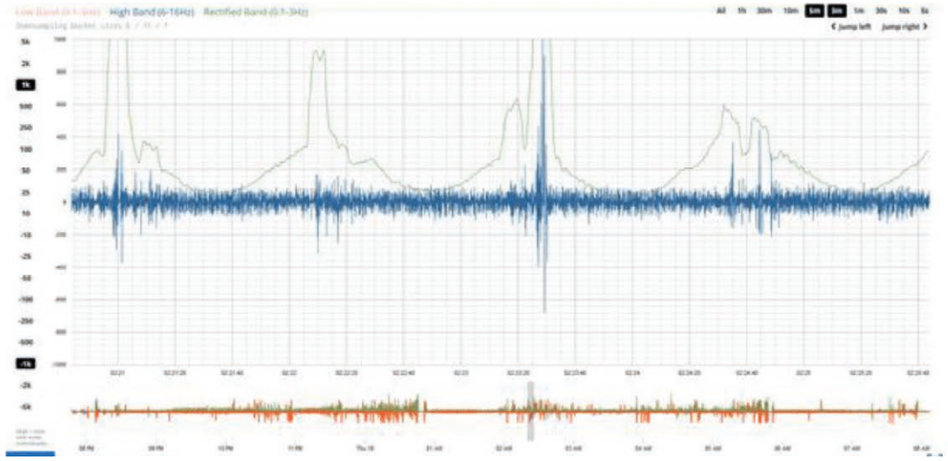


Figure 5: *Curve of respiratory effort during periodic obstructive breathing.*

3) Prolonged partial obstruction or increased respitatory resistance (PPO/IRR)

The upper airways of the patient are obstruced caused by the increased level of thoracic cavity. Breating is laboured and the intrathoracic negative pressure is greater than -8 CmH_2O. This causes spiking in he curve in relation to the base line.

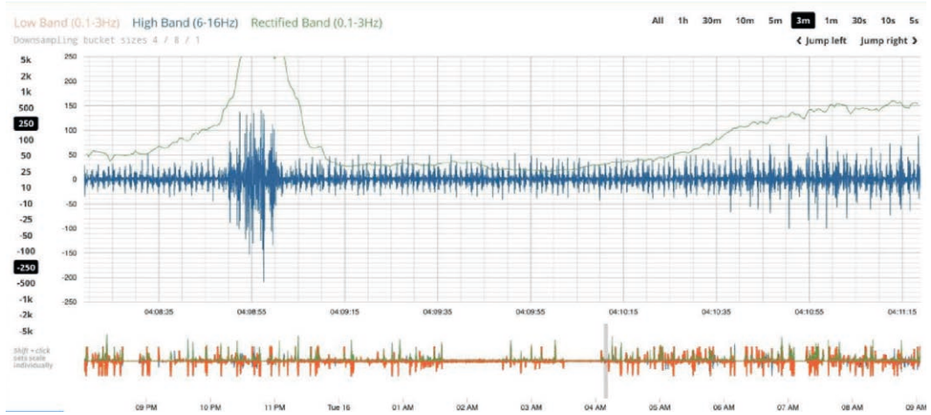


Figure 6: *Partial prolonged obstruction can be seen from the curve at the 6-16 Hz channel. Respitatory effort starts to intensify which leads to increase in the respitatory amplitude.*

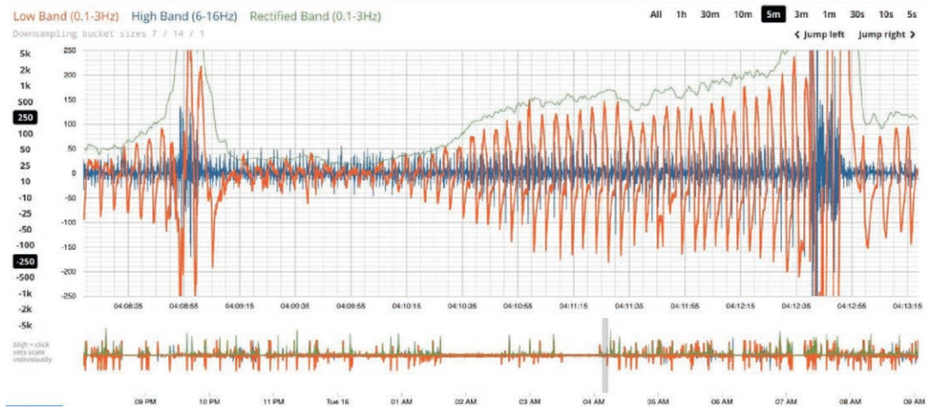


Figure 7: *Breathing can be seen from the same situation*

4) Central apnea

Figure 8: *In the left side of the curve, one can see an apnea period when the breathing stops completely. One can also see that there are no attemps to breathe neither. These are features of central sleep apnea.*

5) Cheyne-Stokes breathing

Cheyne-Stokes breathing is a periodic sleep disorder, which has crescendo-diminuendo pattern in the signal. These patterns repeat themselves from apnea to hypopnea.

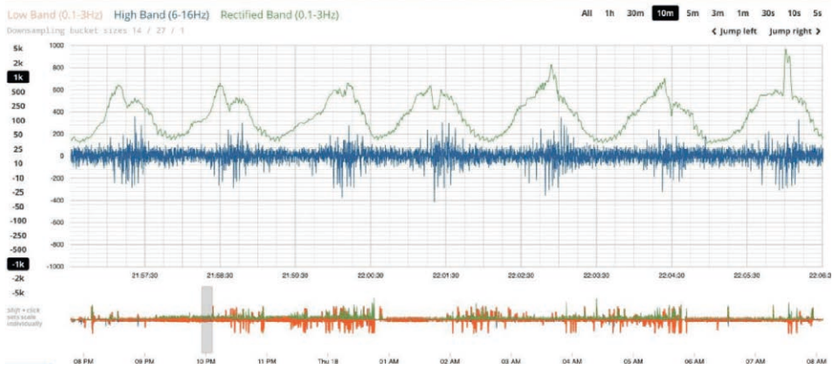


Figure 9: *In Cheyne-Stokes crescendo-diminuendo pattern can be seen in the curve of respitatory work load*

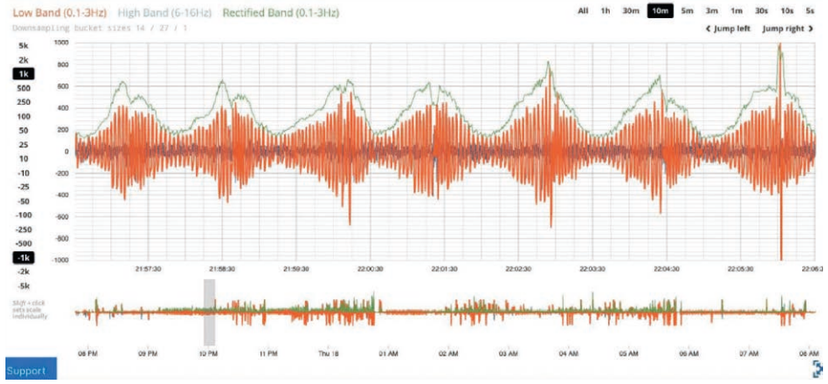


Figure 10: *Cheyne-Stokes phenomena in the respitatory curve*

Conclusions

Assumption of the possible breathing disorder can be made visually by using the sleep registering with the bed sensor.

If in the 5 minutes of a time window:

- Breathing is regular and stable, presumably it is not sleep related sleep order, if the history of the patient or symptoms do not suggest otherwise
- Periodic breathing can be seen, it might suggest for periodic obstructive apnea or hypopnea
- Continuous spiking can be seen that can be related in prolonged partial obstruction (3 mins to hour)
- Central apnea might be possible if one see only pumping of the heart and no efforts to breathe
- Cheyne-Stokes breathing is possible if crescendo-diminuen do pattern can be seen in the curve
- Mixed: if there are central apnea periods following eith the opening of the airways and breathing movements can be seen and spiking, too.

18. Troubleshooting

• EMFIT QS can't find my wireless network during setup
EMFIT QS searches for open network when powered up in AP mode (after factory reset or taken first time out from the sales Box). Make sure that wireless network is available and it is not hidden. For connecting to hidden networks please see chapter 8.2.4.

• EMFIT QS fails to connect to my wireless network (fail sound after connecting attempt)
EMFIT QS supports only Wi-Fi 802.11 b/g/n (2,4 Ghz only). Wi-Fi channels 11-13 are not supported. Make sure your router is not set to these channels and that speed is 2,4 Ghz. Refer to your router's user manual for help.

Make sure you have typed the Wi-Fi password correctly.

If you can't get it connected after another attempt, please contact customer support.

• Red light keeps blinking even though I have connected QS to my wireless network successfully (success sound after connecting attempt)
Red light should stop flashing completely within 2 minutes after successfully hooking EMFIT QS up to your Wi-Fi. This means that EMFIT QS is communicating with Emfit cloud server.

There is nothing that the user can do to speed up this process. Occasionally, red light may flash when the device is being used. There may be a temporary error that prevents the device from communicating with the cloud server.

You can leave it be even though the red light is flashing. If red light does not stop flashing within 24, hours please contact customer service.

• Red light is constantly on
There may be something wrong with your sensor. Please contact customer support.

• My sleep period is too long
Too long sleep periods are usually caused by the device not registering that you have left the bed. If you need to remove power supply after waking up, please wait until green turns from being continuous on to blinking. This happens usually within 10 seconds after getting up and means that the device has registered a bed exit. Too long sleep periods can also be edited manually at the user interface.

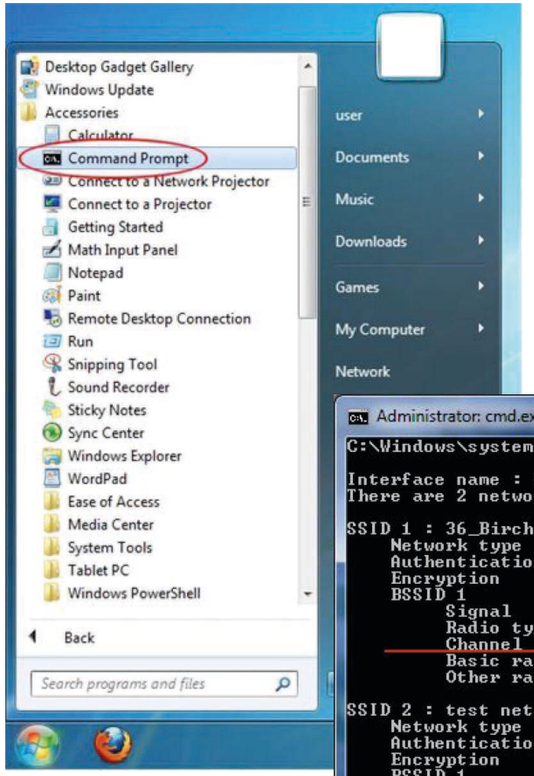
• My sleep period is not registered or data is missing
Usually sleep periods will be available within one hour after getting up from bed. Connection cutoffs (either with your wireless network or at Emfit server) may however prolong this time. If you continue to have this issue, please contact customer support.

• My sleep data is inaccurate
The device may (every now and then) make false assumptions about your sleep. For example, the device may interpret that you were asleep while in reality you were awake but completely still. We are constantly working on improving our sleep algorithms to make sleep detection as precise as possible.

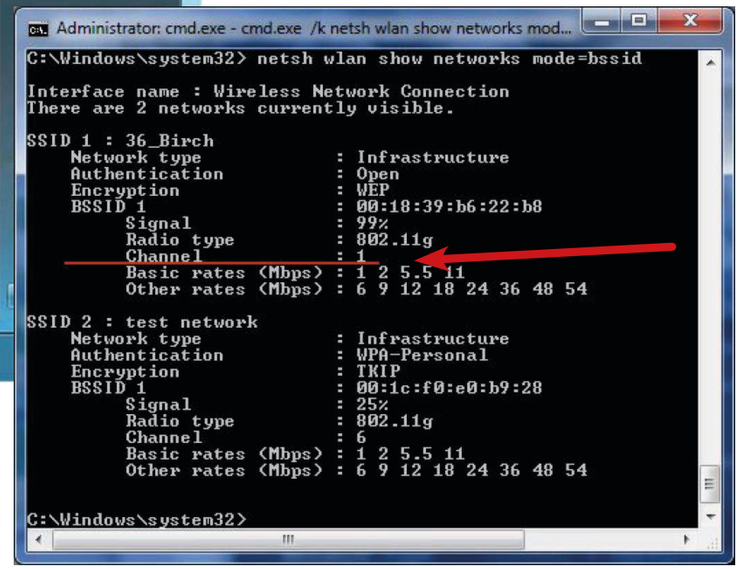
Your EMFIT QS will always be automatically updated to the newest possible firmware with newest improvements.

• Green light stays on even if I have left the bed or green light keeps blinking when I'm on bed
If you have just recently taken the device into use please wait for a couple of days. During the first days sensitivity adjustments are being made and most likely the problem settles on its own over time. If you continue having this problem after a few days of use, please contact customer support.

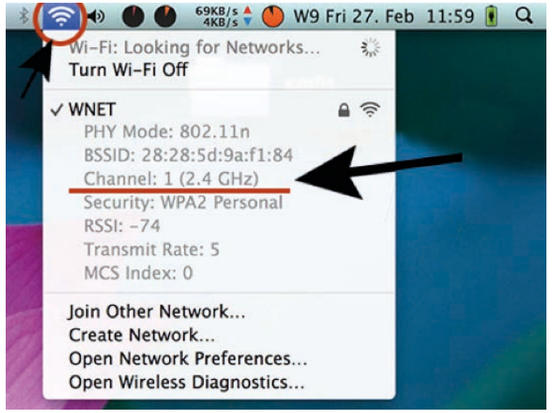
• I don't know which Wi-Fi frequency and channel my router uses
You can find it out:
On Windows open Command Prompt:



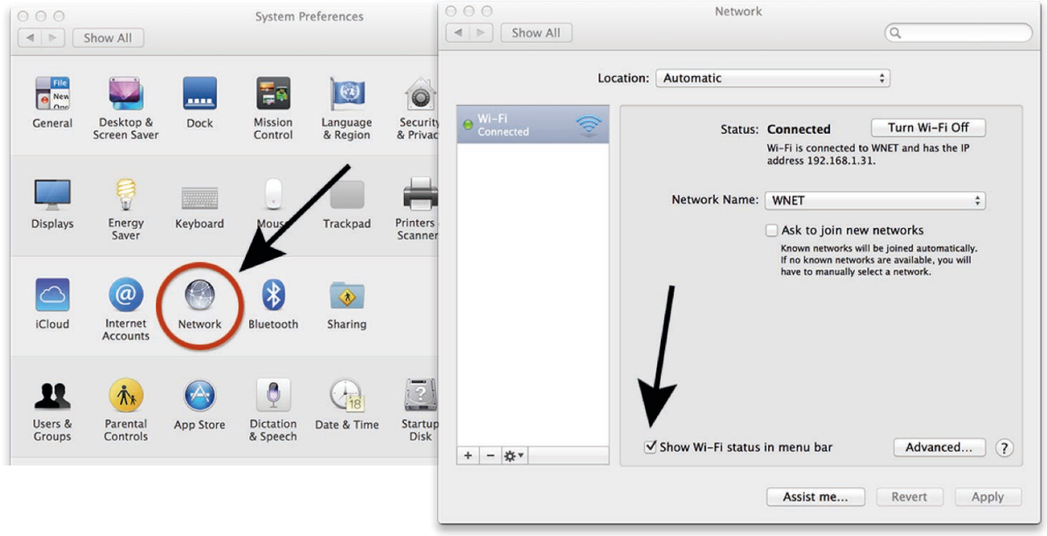
Type in "netsh wlan show networks mode=bssid" and hit enter:



On Mac, click the top right toolbar icon while holding ALT key pressed down. This lists networks with additional details:



If you don't have the toolbar icon enabled you can enabled it here:



19. Periodic Safety Checks

We recommend that the following checks be performed **every month**:
- Equipment inspection for mechanical and functional damage.
- Inspection of safety labels for legibility.

20. Service

The device should only be opened by Emfit service personnel. It contains no user serviceable parts. It does not require routine servicing or calibration. If servicing is necessary, contact Emfit service personnel or your local Emfit representative

21. Disposal of the device after use

In conformity with the Waste Electrical and Electronic Equipment Directive (WEEE Directive), the device must be collected separately and returned to an authorised collection facility. The owner must take the device to the waste collection point specified by local authorities.

For more information on how to dispose of the device, please contact the relevant authorities.

22. Declaration of conformity (EU)

CE The manufacturer, Emfit Ltd, hereby declares that the product fulfills the essential requirements of the Medical Device Directive 93/42/ETY and its modified directive 2007/47/EY. A signed, full declaration of conformity can be found in the attachments of this user manual.

23. Emfit warranty, its terms of condition and technical support

The warranty of Emfit products is valid for 24 months from the purchase date. The warranty covers structural, material and manufacturing defects. The warranty does not cover normal wear or defects caused by it. Emfit can demand a purchase invoice, receipt or other verification for deliveries to warranty services.

The warranty does not cover damages or problems caused by use of other additional devices, such as routers. The warranty also does not cover self-inflicted problems, such as careless use.

The warranty does not cover damages caused by external matters (such as thunder or water leakage). The warranty does not cover any indirect ramification damages such as person damages, decrease of production, decrease of revenue, etc. Emfit Ltd is not liable for such consequences in any way.

Emfit Ltd has a right to exchange a defected product to another equivalent product. The exchanged product becomes ownership of Emfit Ltd. Exchanging a product does not elongate the original warranty.

Actions in warranty repairs
The customer has to contact the vendor or Emfit Ltd and agree upon sending the device to warranty repair. Tell the serial number (found at the back of the electronics device), purchase date, defect description and your own contact information. After this, you will receive instructions for sending the device.

When the product is shipped, it has to be carefully packed and the power source has to be shipped with the device. Personal contact information, including phone number and defect description, must be included as well.

Actions when contacting technical support
Free of charge technical service is available from 9 am to 4 pm on business days (Finnish time, GMT+2) at +358 20 778 0879. Questions for technical support can also be sent to qs@emfit.com. Be prepared to give technical support the serial number of your device.

24. Technical specifications

Model:	**IP-9360 (sensor attached is model L-0656)**
Wi-Fi	IEEE 802.11 b/g Wi-Fi Transceiver Module. Compatible with IEEE 802.11b/g/n networks. Channels 1-11.
Internal memory:	128 Mbit (16Mbyte)
Operating voltage:	5V DC external power supply
Power supply:	Manufacturer: Globtek Inc. Model Nr: GTM41076-0605 Input: 100-240V~, 50-60 Hz, Output: 5V, 1.2A
Input and output connectors:	Power supply input
Switches and controls:	Reset switch for returning to AP
Signal lights:	2 LEDs: green and red
Mounting:	Sensor: under bed mattress, electronic unit: floor
Measurements (electronic unit):	ø 63mm x 20mm
Measurements (sensor):	542mm x 70mm x 1,4mm (without cable connection part)
Cable length:	3.0 meters
Total weight with cable:	278 grams
Surface material and color (sensor):	PVC
Surface material (casing):	ABS plastic
IP rating:	IP20

Ambient conditions	
Operating temperature:	10°C ... 40°C
Storage and transport temperature:	-30C ... 50°C
Relative humidity	20% ... 75%

Product class	
Product class in accordance with the Directive 93/42/EEC:	Class 1
Electrical safety class:	Class II device

25. EMC declaration

Device description:
A 6 x 56 cm size bed sensor and a round, puck-like electronics, that is permanently connected to the sensor with a 3 meter long shielded cable. Power supply made by Globtek (see further info in chapter Technical Information).

Guidance and manufacturer's declaration – electromagnetic emissions		
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
RF emissions CISPR 11	Group 1	The product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity			
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 Ed. 4.0 test level**	**Compliance level**	**Electromagnetic environment**
Electrostatic discharge (ESD): IEC 61000-4-2	±8 kV contact ±2, ±4, ±8 ja ±15 kV air	±8 kV contact ±2, ±4, ±8 ja ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst: IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Immunity to electro-magnetic fields: IEC 61000-4-3 (2006 + A1 + A2) IEC 60601-1-2:2014	80 – 1000 MHz 10 V/m with 80 % AM @ 2 Hz 1,0 – 2,7 GHz 10 V/m with 80 % AM @ 2 Hz Table 9 (≤28 V/m pulssi modulaatio ISM kanavil-la)	IEC-60601-1-2 test level	
Surge: IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the product enquires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	N/A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity			
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz – 80 MHz 3 V/m 80 MHz – 2,5 GHz	3 Vrms 150 kHz – 80 MHz 3 V/m 80 MHz – 2,5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz - 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz - 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Cable specification:
Power cable (non-shielded) max. Length 2 m
Sensor cable (shielded) max. length 3 m

Note! RF communications equipment can effect medical electrical equipment!

NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] 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 Emfit Tonic-Clonic Seizure Monitor is used exceeds the applicable RF compliance level above, the Emfit Tonic-Clonic Seizure Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Emfit Tonic-Clonic Seizure Monitor.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Emfit device.			
The product is intended for use in an electromagnetic environment where RF disturbances are controlled. The customer or user can help block electromagnetic disturbances by keeping the greatest power output of the telecommunications device under the recommended minimum limit between mobile and moving RF communication technologies devices (routers) and the Emfit device.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz - 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz - 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz - 2,5 GHz $d = 2{,}3\sqrt{P}$
0,01	0,12 m	0,12 m	0,23 m
0,1	0,38 m	0,38 m	0,73 m
1	1,2 m	1,2 m	2,3 m
10	3,8 m	3,8 m	7,3 m
100	12 m	12 m	23 m
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

26. Declaration of Conformity CE

We, Emfit Ltd, Konttisentie 8, 40800 Vaajakoski, Finland, declare under our sole responsibility that the following product family,

Product trade name:	EMFIT QS+CLINICAL
Model numbers:	EMD-9260-xxxx-xx-x, EMD-9360-xxxx-xx-x
Risk class:	Class 1 medical device

to which this declaration relates, satisfies the provisions of Directives:

93/42/EEC	*Medical Devices*
2014/53/EU	*Radio Equipment (RE) Directive*
2011/65/EU	*Restriction of the use of certain hazardous substances (RoHS)*

and is in conformity with the essential requirements of the following standards:

Standard	*Version*	*Title*
Directive 93/42/EEC		
EN 60601-1	2005 Ed.3	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	2014 Ed.4	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
Directive 2014/53/EU		
EN 300 328	2.1.1	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 489-01	2.1.1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-17	3.1.1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 60950-1	2006+A2:2013	Information technology equipment - Safety - Part 1: General requirements
EN 62311	2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz – 300 GHz)

(IEC 62311:2007, modified)

The Technical Construction File is maintained at Konttisentie 8, 40800 Vaajakoski, Finland.

Place and date of issue: Vaajakoski, 14.07.2017

Authorized signature:

Heikki Räisänen

Heikki Räisänen
Managing director

27. Disposal of the device after use

In EU: 

In conformity with the Waste Electrical and Electronic Equipment Directive (WEEE Directive 2002/96/EC), the device must be collected separately and returned to an authorized collection facility. The owner must take the device to the waste collection point specified by local authorities. For more information on how to dispose of the device, please contact the relevant authorities.

28. Restrictions of this radio equipment

 NO

Norway:

Use of this radio equipment is not allowed in the geographical area within a radius of 20 km from the centre of Ny-Ålesund, Svalbard, Norway.

29. Manufacturer’s contact information

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Release date	Revision
05.06.2017	0
28.12.2017	A
26.1.2018	B