EMFIT®

NOCTURNAL EPILEPTIC TONIC-CLONIC SEIZURE MONITOR

User's Manual with Operation and installation instructions and Warranty terms

WARNING! MUST NOT BE USED IN SITUATIONS WHERE A MALFUNCTION OR A LATENT DESIGN FLAW IN THE PRODUCT COULD LEAD TO A DELAY IN DELIVERY OF APPROPRIATE MEDICAL CARE OR THAT WOULD LIKELY LEAD TO A POTENTIALLY LIFE THREATENING SITUATION

Applicable model numbers:
Control Unit D-1090-2G, version t43 v.1.0.10. (50Hz) or newer
Under Mattress Bed Sensor L-4060SL

Date June 27th, 2008. V2.2.

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DANGER NOTES

THE FOLLOWING NOTES ARE PROVIDED BOTH FOR YOUR PERSONAL SAFETY AND TO PROTECT THE DESCRIBED PRODUCT OR ATTACHED DEVICES FROM DAMAGE.

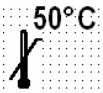
SAFETY NOTES AND WARNINGS FOR THE PREVENTION OF DANGER TO THE LIVES AND HEALTH OF USERS OR MAINTENANCE PERSONNEL AND/OR FOR THE AVOIDANCE OF DAMAGE TO PROPERTY ARE EMPHASISED IN THESE INSTRUCTIONS BY THE PICTOGRAMS DEFINED HERE. THE PICTOGRAMS USED HAVE THE FOLLOWING MEANINGS FOR THESE INSTRUCTIONS:

Means that death, serious personal injury or substantial damage to property can occur if the appropriate precautionary measures are not taken.

Means important information about the product or a part of the instructions that particular attention should be paid to.

OTHER SYMBOLS USED

Use by



Upper storage temperature limit

1. GENERAL INFORMATION

Intended Use

The Emfit Nocturnal Epileptic Tonic-Clonic Seizure Monitor (device model D-1090-2G and sensor model L-4060SL) is intended to be used for monitoring a person with epilepsy in a bed or on a chair and notifying caregiver of an over preset continued tonic-clonic seizure, with muscle jerkings. The product consists of a bed sensor and a control unit. The control unit has an audible notification sound and a dry-contact output for connecting it to a nurse-call system or to a safety phone.

Control Unit

The control unit D-1090-2G activates for monitoring after it has noticed movements or micro movements, such as caused by respiratory movements or heart beating, for over 40 seconds. Notification is triggered if movements are faster than preset frequency threshold (2Hz or 3 Hz) and continue over preset delay time or all the movements disappear.

The control unit processes a low voltage (from about 1 mV up to about 1 V), high impedance signal from the dynamic, quasi-piezoelectric type (i.e. self-biased) flexible film-like sensor.

The control unit operates with 2 pcs AA size 1.5 V alkaline batteries. An optional AC adapter is available (5 VDC). AC ADAPTERS OTHER THAN ORIGINAL ACCESSORIES FROM EMFIT MUST NOT BE USED. (MODEL: NO GTM41060-1505 AND P/N:WR9QA3000LCP-N-MNK)

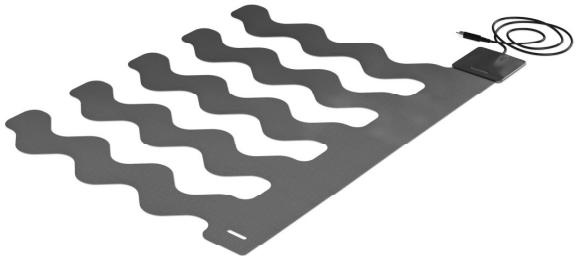
The control unit has input connectors for the sensor (marked as X3) and optional AC adapter (marked as X1). There is also a connector marked as X2 for connecting the device to other systems for transferring the notification via dry-contact opto-coupler.

A reset switch for turning off the notification sound is to the right of the sensor input (marked as SW1).

Inside the device there is a place for 2 pcs AA size 1.5 V batteries, and mini-switches (DIP and rotary) for program settings.

Under Mattress Bed Sensor

The Emfit under mattress bed sensor model L-4060SL is a quasi-piezoelectric, dynamic sensor that has no embedded wires or switches. This specially formulated plastic sheet sensor is placed below mattress, crosswise to the bed, below the chest area.



The sensor produces signals from even the slightest micro-movements created when a person is in bed. When there is no movement, it recognizes this as the individual being absent. When there is continued movements with frequency from 3 Hz (or 2 Hz, see 3. DIP switch #3) or more and up to 20 Hz, an internal time counter activates. If these movements continue over the preset delay (10, 13, 16, or 20 seconds), it gives a notification by sound and by dry-contact output.

There are no particular size or weight limitations, but sensitivity and ability to recognize user presence as well as those movements that should trigger notification, need to be tested in each case.

2. PACKAGE CONTENTS

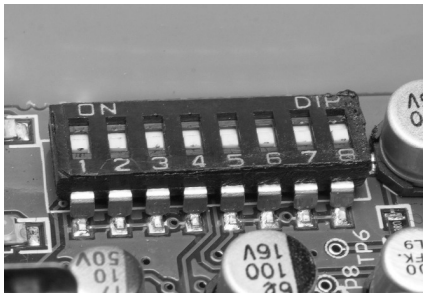
- Control unit
- Bed sensor
- Wall mounting clip
- 2 screws
- 2 locking anchors
- This user's manual
- Optionally a power supply

3. BEFORE USE SELECT THE RIGHT DIP SWITCH SETTINGS

Inside the device there is a DIP switch with 8 small switches. These are used for various program settings.

See the following table and set up the switches for your preferred use.

To open the device cover, see the picture on right.



Open the cover by lifting from one side

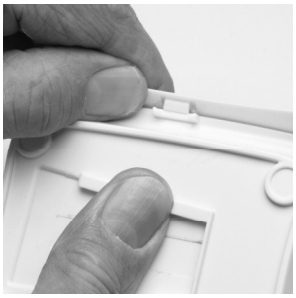


Table of DIP Switch Settings

Switch #	OFF (down)	ON (up)
#1	Movement continuation time delay setting, see next chapter after volume settings	Movement continuation time delay setting, see next chapter after volume settings
#2	Movement continuation time delay setting, see next chapter after volume settings	Movement continuation time delay setting, see next chapter after volume settings
#3	Movement frequency threshold 3 Hz (default)	Movement frequency threshold lowered to 2 Hz. Use only if device does not notice person's movements (that the caregiver should be notified of) at OFF position.
#4	Normal sensitivity for noticing micro movements; use when sensor is installed below foam mattress or mattress pad	Increased sensitivity for noticing micro movements. Recommended use only when sensor needs to be installed below spring mattress (no mattress pad in use). NOTE! Consumes more power and shortens battery life! Blued LED light blinks slightly faster.
#5	"No movements" notification is enabled	"No movements" notification is disabled
#6	Power switch function at SW1 is enabled (device can be shut down and turned on by pressing SW1 for about 3 seconds)	Power switch function at SW1 disabled (device is always on).
#7	Notification sound volume setting, see below	Notification sound volume setting, see below
#8	Notification sound volume setting, see below	Notification sound volume setting, see below

Setting the Notification Sound Volume

The notification sound is useful only when caregiver is in close proximity to the control unit. The volume can be adjusted at 4 levels: no sound, quiet, loud, and very loud.

Volume level	Switch # 7	Switch #8
Very Loud	OFF (down)	OFF (down)
Loud	ON (up)	OFF (down)
Quiet	OFF (down)	ON (up)
No sound / mute	ON (up)	ON (up)

The sound stops when both the reset switch is pressed and when the event is over. In case of person's absence from the bed, the sound will stop once person has returned or reset is pressed.

Setting the Movement Notifications

Continued Faster Movements Notification Time Delay Setting

This notification is triggered when the device senses movements in frequency range between 3 Hz – 20 Hz (or 2 – 20 Hz if switch #3 is ON) that continue longer than the preset delay. The alarm delay can be set at 10, 13, 16 or 20 seconds.

Set the preferred delay according to the following table. If false alarms become a problem, extend the delay.

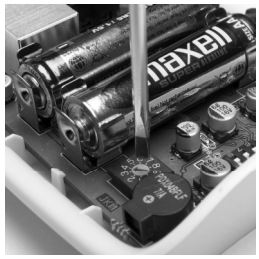
Movements to continue to trigger a notification	Switch # 1	Switch #2
10 seconds	ON(up)	ON (up)
13 seconds (default)	OFF (down)	OFF (down)
16 seconds	ON (up)	OFF (down)
20 seconds	OFF (down)	ON (up)

No Movements Notification / Switch #5

The device can be set to trigger notification when system does not notice any movements or micro movements (for example when person leaves the bed). As factory default this switch is at OFF position ie. notification is enabled.

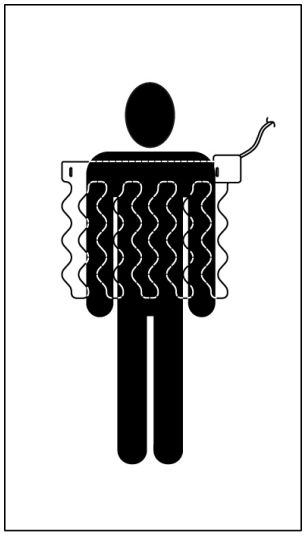
ALWAYS REMOVE BATTERIES AND UNPLUG THE AC ADAPTER (IF IN USE) BEFORE MAKING CHANGES TO THE DIP SWITCH POSITIONS. OTHERWISE THE NEW SETTINGS WILL NOT TAKE EFFECT.

4. SETTING THE SENSITIVITY



Sensitivity can be adjusted with 10 position rotary switch inside. Factory default setting is the pointer pointing to #3. In case device does not notice individual's micro movements, adjust sensitivity higher by turning the pointer clock-wise one position per time. If the device notices movements even though no one is in bed, lower sensitivity by turning the screw counter-clockwise one position per time. Always test after every change before putting into use.

5. INSTALLING THE BED SENSOR BELOW MATTRESS



ALWAYS INSTALL THE SENSOR CROSSWISE TO THE BED AT THE POSITION BELOW THE CHEST.

CHECK THE CORRECT PLACEMENT OF THE SENSOR AT LEAST ONCE A WEEK.

IF YOU USE THE SENSOR ON A SPRING MATTRESS, PLACE THE SENSOR BETWEEN THE MATTRESS PAD AND THE SPRING MATTRESS!

IF THE BED HAS A SPRING MATTRESS, WITHOUT MATTRESS PAD, AND A BOX-SPRING BELOW SPRING MATTRESS, SENSOR CAN BE INSTALLED BETWEEN THE SPRING MATTRESS AND THE BOX. IN THAT CASE INSTALL SOME DURABLE (ABOUT 2-3 MM), THICK PLASTIC OR PLYWOOD SHEET ON TOP AND BELOW OF THE SENSOR TO AVOID SPRINGS DAMAGING THE SENSOR. THIN SOFT CUSHION BETWEEN THE SHEETS AND SENSOR IS PREFERRED. SET THE DIP SWITCH #4 UP.

THE SENSOR MUST ALWAYS BE PLACED BENEATH A MATTRESS OR MATTRESS PAD. THE SENSOR MUST NOT BE IN DIRECT CONTACT WITH A PERSON!

THE EMFIT BED SENSOR IS DESIGNED TO WITHSTAND USE BELOW THE MATTRESS, AGAINST A HARD BED BOTTOM FOR 4 – 5 YEARS OF USE. MANUFACTURER RECOMMENDS REPLACING IT AFTER 6 YEARS FROM MANUFACTURING DATE OR AFTER 5 YEARS OF USE, WHICHEVER COMES FIRST.

WHEN USED ON TOP OF A SPRING MATTRESS, THE USE TIME IS MUCH SHORTER DUE TO MORE WEAR AND TEAR CAUSED WHEN PERSON IS IN BED. THIS WEAR AND TEAR CAUSES THE SENSOR TO WRINKLE. WITH SPRING MATTRESSES, A PERSON'S WEIGHT AND RESTLESSNESS CAN AFFECT THE USE TIME. THE ESTIMATED USE TIME IN A SPRING MATTRESS BED IS 1–2 YEARS. IF USED IN SUCH CIRCUMSTANCES, MANUFACTURER RECOMMENDS REPLACING THE SENSOR WHEN IT LOOKS WEAR OUT AND LATEST AFTER 3 YEARS OF USE. WARRANTY DOES NOT APPLY IF BED SENSOR IS DAMAGED DUE TO NORMAL WEAR AND TEAR!

DO NOT USE WITH ANTI-DECUBITUS MATTRESS (USED FOR PREVENTING BED-SORES), WHERE AIR PRESSURE IS CONTROLLED WITH COMPRESSOR.

6. CONNECTORS AND WIRING

Connectors are marked with X1, X2 and X3. These are:

X1 - Power supply connector. Use only GlobTek Inc. power supply, model no: GTM41060-1505 and P/N:WR9QA3000LCP-N-MNK, available as original acessory from Emfit.

X2 - Aux connector for connecting the device to some other system (cable not included) for transferring the notification via a dry-contact opto-coupler. DRY-CONTACT OUTPUT OF THE X2 (AUX) CONNECTOR CAN ONLY BE CONNECTED TO A SYSTEM SAFETY VOLTAGE INPUT WITH MAX VOLTAGE BELOW 25V (AC) / 60V (DC), WHERE BOTH POLES HAVE BEEN SEPARATED FROM THE ELECTRICAL NETWORK (SO CALLED FLOATING APPLIED PART). MAX LOAD CURRENT 100 mA!

X3 - Sensor connector (use only Emfit bed sensor model L-4060SL)

Connect the under mattress sensor, optional AC adapter and possible connection wire to other system as follows:

Connect the sensor wire plug to the control unit X3 marked connector.

If you need to connect the dry-contact output to another system, plug the suitable connection wire to the X2 marked connector

Connect the optional AC adapter cord to the X1 marked connector

X2 (AUX) Connector Pin Order

From left to right

Pin #1	Common return
Pin #2	Normally Open (NO) send
Pin #3	Normally Closed (NC) send
Pin #4	Low Battery send
Pin #5	Not in use, do not connect
Pin #6	Not in use, do not connect
Pin #7	Not in use, do not connect
Pin #8	Not in use, do not connect

DRY-CONTACT OUTPUT OF THE X2 (AUX) CONNECTOR CAN ONLY BE CONNECTED TO A SYSTEM SAFETY VOLTAGE INPUT WITH MAX VOLTAGE BELOW 25V (AC) / 60V (DC), WHERE BOTH POLES HAVE BEEN SEPARATED FROM THE ELECTRICAL NETWORK (SO CALLED FLOATING APPLIED PART). MAX LOAD CURRENT 100 mA!

7. INSTALLING THE WALL MOUNT AND DEVICE

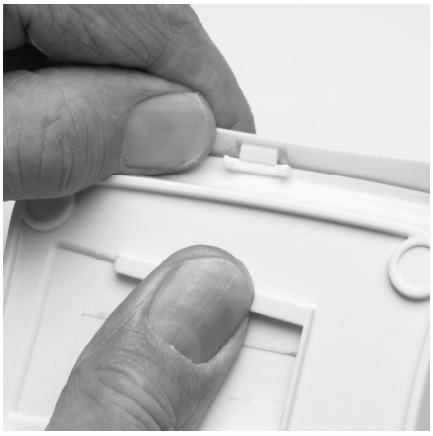
Attach the wall mount with the included two anchors and screws

Slide the device into the mount

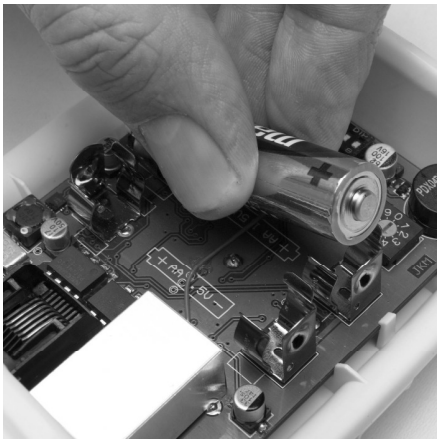
Press the device downwards so you hear a "click" sound

8. INSTALLING BATTERIES AND BATTERY CONSUMPTION

Product operates with 2 pcs AA size 1.5 V batteries. Install and remove the batteries as follows:



Open the cover by lifting from one side



Install 2 pcs good quality alkaline AA size 1,5 V alkaline batteries according the polarity drawings on the circuit board

When removing old batteries, they are easiest to remove by lifting from + ends

Estimated battery life is 6 months, when using high quality alkaline batteries, with 2800 mAh capacity (2pcs). Estimation is based on measured battery consumption in various conditions and then a calculation where device is on 50% of time (shut down 50% of time) and of that 50% of time there is someone in bed 75% of that time, there are two notifications per day and sound notification is on 30 seconds each time.

WHEN THE BATTERIES ARE GETTING LOW, THE RED LED BEGINS TO FLASH SLOWLY, A "BEEP" SOUND WILL BE HEARD AFTER EVERY 1,5 HOURS AND THE DRY-CONTACT OUTPUT GIVES LOW BATTERY NOTIFICATION AFTER EVERY 3 HOURS.

9. ABOUT THE OPTIONAL 5V AC ADAPTER

For preparing the optional power supply for use, do the following:

Remove the plastic cover

Pick up suitable adapter from the included 4 pcs

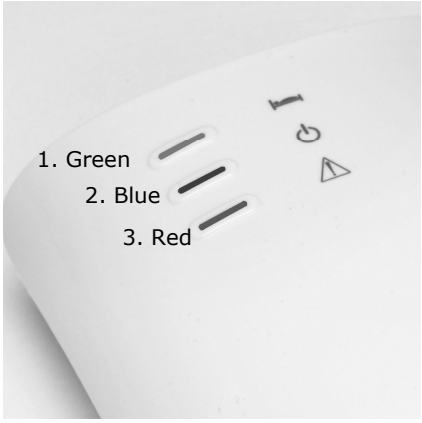
Install the adapter and make sure it stays in place

THE EMFIT EPILEPTIC TONIC-CLONIC SEIZURE ALARM IS DESIGNED AND TESTED TO BE USED ONLY WITH GLOBTEK INC. POWER SUPPLY MODEL: NO GTM41060-1505 AND P/N:WR9QA3000LCP-N-MNK. ANY OTHER TYPE OF AC ADAPTER MAY AFFECT THE PRODUCT'S SAFETY.

The power supply is equipped with a blue indicator light; when the light is on the power supply is in use. If the light is off and the power supply is connected to the mains outlet, the power supply is probably damaged and should be replaced.

WHEN THE AC ADAPTER IS CONNECTED TO THE POWER INPUT, THE BATTERIES ARE ELECTRICALLY DISCONNECTED. IN CASE OF NO MAINS POWER AND AC ADAPTER CORD IS CONNECTED TO X1, THE BATTERIES INSIDE WILL NOT OPERATE AS BACK UP POWER SUPPLY.

10. LED-LIGHT INDICATORS



1. Green LED / Presence

- The green light starts blinking slowly (half the speed of blue light) when the device notices micro or other movements (person goes to bed)
- The green light starts blinking same speed with blue light when the device has noticed micro and/or other movements (person in bed) for 40 seconds and it activates for presence monitoring.
- The green light blinks rapidly when device notices movements with frequency between 3-20 Hz (2-20 Hz if DIP switch #3 is ON)
- The green light blinks every 4th time of the blue light after device has triggered no movement notification, until SW1 is pressed shortly or there is movements or micro movements (person has returned to the bed) for at least 40 seconds.

2. Blue LED / Power ON - Standby

- The blue light blinks slowly when the device is ON
- The blue light blinks fast for a short moment when the device triggers a notification

3. Red LED / Fault

- The red light blinking quickly means the sensor is not connected or sensor is broken. A notification sound is heard first time 10 seconds after device notices sensor fault, and then after every 45 seconds. Dry-contact output gives notification first time after 30 seconds and then after every 30 minutes, until proper sensor is plugged.
- The red light blinking slowly means replace the batteries. A notification sound is after every 1 ½ hours and dry-contact output gives low battery notification after every 3 hours until batteries are replaced.

11. SW1 - RESET SWITCH / ON-OFF SWITCH / BY-PASS SWITCH

SW1 As a Reset Switch

When the notification sound is activated, it can be silenced by briefly pressing the the SW1 switch (see picture). A beep-beep sound is also heard.

In case of faster continued movements, when the faster movements have stopped the sound will also stop.

In case of no movement notification, when person returns to the bed the sound will stop after about 40 seconds.

SW1 As a On-Off Switch

When the ON-OFF switch function is enabled from DIP-switch #5, the SW1 switch functions also as ON-OFF switch. To turn the device ON or OFF, just press the SW1 switch for about 3 seconds. A "beep" sound is heard when turning the device ON. A beep-beep-buup sound is heard when turning the device OFF.

SW1 As a No Movement Notification By-Pass Switch

The no movement notification can be bypassed if a person wants to leave the bed without causing a notification. This means that the person can be away from the bed without time limits. Exit-delay will not be activated until the person is back on the bed and then leaves again.

When the no movement notification is enabled from DIP-switch #4, to bypass the notification, press the SW1 switch before the exit-delay time is up. Control-unit informs of a successful by-pass by beep-beep sound. The SW1 switch can also be pressed just before getting up off the bed to by-pass the notification.

After pressing the SW1 switch, person has 20 seconds to completely exit the bed. If this is not done, device re-activates automatically.

12. TESTING AND INSPECTIONS

Weekly Inspection

1. Inspect that all wires are in good condition.

2. Check that the sensor is positioned correctly below chest position, across the bed.

Tests When Taking into Use and Every Month

Do the following tests at least once a month and when putting into use, to ensure the system's proper operation!

Testing the "no movements" notification

1. Check to see if system is turned on. If disabled, set on the "no movement" notification function (DIP switch 5 at OFF position). Check that the device is ON (blue LED-light is blinking slowly).

2. Have the person lay still on the bed on his/her right side for at least 2 minutes. System should notice person's micro movements immediately, and the green occupancy LED indicator will start to blink slowly, every second time the blue LED blinks. Green LED should blink continuously the entire time person is in bed. System activates after noticing movements or micro movements for 40 seconds. At that time the green LED starts blinking at same time with blue LED. If the device won't detect the presence of a person (green LED light is not blinking) move to chapter 12 troubleshooting. If the green light goes off for long periods of time and the no movement notification is triggered, adjust sensitivity higher (see 4, setting the sensitivity). If the green light blinks continuously, while the person is laying still on their right side, the sensitivity level is correct.

3. Now ask the person to leave the bed. The no movement notification should be triggered after about 5 - 10 seconds, when person has left the bed and no one is touching the bed, sensor or wires. If the notification doesn't work and the green light continues blinking, see chapter 13 troubleshooting.

Testing the faster movements notification

1. Simulate continued fast movements, for example, by tapping the mattress just above the sensor.

2. During the tapping, the green light should start blinking faster.

3. The device should make the notification sound after the delay time (10, 13 16 or 20 sec) has passed.

13. TROUBLESHOOTING

ALWAYS CHECK FIRST THAT INSTALLATION IS CORRECT AND TEST THE DEVICE PROPERLY AFTER EVERY ADJUSTMENT.

Notification is not getting forward via the other system the device is connected to;

- Check that the connection cable is connected correctly and it is in good condition. Often the wire uses at both ends same connector but wiring order is not the same. Make sure it is connected the right way!

Notification sound does not operate;

- Check the volume level.

False notifications without reason:

- Check the condition, positioning and connection of the bed sensor.
- Is the no movement notification in use? If yes, check the sensitivity according to chapters 4 and 11. It may be that sensitivity is not set properly and device cannot occasionally detect any micro-movements.

Notice! Any movements that are between 3 Hz (or 2 Hz if enabled) and 20 Hz frequency and have continued over preset delay time will trigger the notification.

The device does not trigger no movements notification and the green light is blinking even if there is no one on the bed

- Check for possible external disturbances on the bed sensor and its cable. Remove any external disturbances causing vibrations.
- Check the sensor and its cable. A broken sensor or cable may cause disturbances to the signal so that the green light blinks all the time. Usually this is detected by the device itself and red light starts blinking. Also, sensor cable should be away from any main outlet cables and should not be hooked to the AC adapter cable.
- If the cable and the sensor seem to be in order, try reducing the sensitivity as some external vibrations may cause this. See also chapters 4 and 11.

The device does not trigger no movement notification and the green light is off when there is no one on the bed:

- Is the green light blinking when there is someone in bed? If not, check the sensor and its cable.
- Check that the device is switched ON. It is ON if the blue LED light is blinking slowly. If it is not blinking, press the SW1 switch for about 4 seconds.
- Check the sensitivity setting of the device when a person remains still on the bed. Green light should be blinking and system activate after person has been in bed for 40 seconds. If necessary increase the sensitivity.

Please never hesitate to contact manufacturer for any problems with use! All feedback is highly appreciated!

14. CLEANING

The bed sensor can be cleaned with water and, when necessary, neutral general-purpose or mild antiseptic detergents. Always dry the sensor after cleaning. Use a moist cloth for cleaning the control unit.

THE CONTROL UNIT MUST NOT GET WET! DO NOT CLEAN THE AC ADAPTER OR THE CONTROL UNIT WHEN IT IS CONNECTED TO THE MAINS OUTLET. ALWAYS DRY IT WELL AFTER CLEANING.

15. IMPORTANT SAFETY PRECAUTIONS

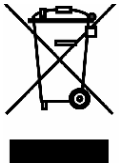
TO AVOID POSSIBLE INJURY OR DEATH:

- READ INSTRUCTIONS PRIOR TO USE
- ALWAYS TEST THE SYSTEM PER INSTRUCTIONS PRIOR TO USE
- THIS PRODUCT MAY NOT BE SUITABLE FOR ALL PERSONS
- THIS PRODUCT SHOULD NOT BE A SUBSTITUTE FOR MAINTAINING THE ROUTINE VISUAL MONITORING PROTOCOL BY CAREGIVER.
- MUST NOT BE USED IN SITUATIONS WHERE A DELAY IN THE ARRIVAL OF APPROPRIATE MEDICAL CARE COULD LEAD TO A POTENTIALLY LIFE-THREATENING SITUATION.
- NEVER USE EMFIT SENSOR WITH OTHER MANUFACTURERS' DEVICES.
- THE NOTIFICATION MAY FAIL TO SOUND IF THE SENSOR OR ITS WIRE IS DAMAGED OR IMPROPERLY POSITIONED.
- PETS CAN CAUSE FALSE NOTIFICATIONS OR MAY CAUSE THE DEVICE NOT TO TRIGGER NOTIFICATION.
- SENSOR MUST NOT BE SCRATCHED, SLIT OR CUT.
- CHECK SENSOR AND WIRES CONDITION AND IN USE TIME AT LEAST WEEKLY AND REPLACE WHEN NECESSARY.
- DO NOT INTEGRATE TO OTHER SYSTEM OTHERWISE THAN SPECIFIED IN THIS MANUAL.
- TO AVOID RISK OF ELECTRICAL SHOCK, AVOID GETTING THE SENSOR SYSTEM GET WET.
- DO NOT OPEN THE PARTS OR ATTEMPT TO REPAIR IT YOURSELF.
- ALWAYS KEEP THE CONTROL UNIT AND SENSOR DRY. EXPOSURE TO EXCESSIVE MOISTURE CAN CAUSE IT TO MALFUNCTION.
- THE PRODUCT FULLFILLS THE REQUIREMENTS OF THE EMC-DIRECTIVE FOR MEDICAL DEVICES- IT DOES NOT CAUSE ANY ELECTROMAGNETIC DISTURBANCE IN NORMAL WORKING CONDITIONS.
- THE PRODUCT CAN BE STACKED OR PLACED NEAR OTHER PRODUCTS OR DEVICES AS LONG AS MECHANICAL VIBRATION IS NOT PRESENT.
- ALWAYS CHECK THE FUNCTION OF THE PRODUCT AFTER MAKING ADJUSTMENTS.

ACCIDENTIAL OR INTENTIONAL ADJUSTMENT OF KNOBS AND SWITCHES BY THE USER OR SUBJECT MAY CAUSE:

- THE NOTIFICATION SOUND TO NOT ACTIVATE WHEN ADJUSTING THE VOLUME CONTROL TO THE OFF POSITION.
- FALSE NOTIFICATIONS (INCREASE) OR MALFUCTION (DECREASE) WHEN ADJUSTING THE SENSITIVITY.
- THE PRODUCT MAY NOT GIVE NOTIFICATION WHEN NECESSARY WHEN PRESSING THE ON/OFF/RESET SWITCH.
- THE PRODUCT MAY NOT GIVE NOTIFICATION WHEN NECESSARY WHEN SWITCHING DIP SWITCHES.

16. MATERIALS DISPOSAL



At the end of the product's use life, please dispose of it at appropriate collection points provided in your country. For disposal or recycling information, please contact your local authorities or the Electronic Industries Alliance (EIA, www.eiae.org).

In the European Union, this label indicates that this product should not be disposed of with household waste. It should be deposited at an appropriate facility to enable recovery and recycling.

17. EU / DECLARATION OF CONFORMITY

Emfit Epileptic Seizure Alarm (device model D-1090-2G and bed sensor model L-4060SL) complies with the essential requirements of EMC directive 2004/108/EC, CE mark directive 93/68/EEC and Medical Device Directive 93/42/EC and carries the CE marking accordingly.

18. EMFIT LIMITED WARRANTY STATEMENT

In the unlikely event that your product needs guarantee service, please contact your dealer, distributor or manufacturer. To avoid any unnecessary inconvenience on your part, we recommend you read this instruction manual carefully before seeking guarantee service.

YOUR GUARANTEE

By this Guarantee, Emfit guarantees the product to be free from defects in materials and workmanship at the date of original purchase for a period of two (2) years from that date.

If within the guarantee period the product is determined to be defective (at the date of original purchase) due to improper materials or workmanship, Emfit will, without charge for labour or parts, repair or (at Emfit's discretion) replace the product or its defective parts subject to the terms and limitations below. Emfit may replace defective products or parts with new or refurbished products or parts. All products and parts replaced become the property of Emfit.

TERMS

Guarantee services will be provided only if the original invoice or sales receipt (indicating the date of purchase, model name and dealer's name) is presented with the defective product within the guarantee period. Emfit may refuse free-of-charge guarantee service if these documents are not presented or if they are incomplete or illegible. This Guarantee will not apply if the model name or serial number on the product has been altered, deleted, removed or made illegible.

This Guarantee does not cover transport costs and risks associated with transport of your product to and from Emfit.

This Guarantee does not cover:
a) periodic maintenance and repair or parts replacement due to wear and tear. Notice! Emfit bed-sensor wears and tears significantly faster when installed on soft base like spring mattress.
b) consumables (components that are expected to require periodic replacement during the lifetime of a product such as non-rechargeable batteries)
c) damage or defects caused by use, operation or treatment of the product inconsistent with normal use
d) damage or changes to the product as a result of:
i. misuse, including:
- treatment resulting in physical, cosmetic or surface damage or changes to the product
- failure to install or use the product for its normal purpose or in accordance with Emfit’s instructions on installation or use
- failure to maintain the product in accordance with Emfit’s instructions on proper maintenance
- installation or use of the product in a manner inconsistent with the technical or safety laws or standards in the country where it is installed or used
ii. the condition of or defects in systems with which the product is used or incorporated except other Emfit’s products designed to be used with the product
iii. use of the product with accessories, peripheral equipment and other products of a type, condition and standard other than prescribed by Emfit
iv. repair or attempted repair by persons who are not Emfit employees
v. adjustments or adaptations without Emfit’s prior written consent, including:
- upgrading the product beyond specifications or features described in the instruction manual, or
- modifications to the product to conform it to national or local technical or safety standards in countries other than those for which the product was specifically designed and manufactured
vi. neglect
vii. accidents, fire, liquids, chemicals, other substances, flooding, vibrations, excessive heat, improper ventilation, power surges, excess or incorrect supply or input voltage, radiation, electrostatic discharges including lighting, other external forces and impacts.

This guarantee covers only hardware components of the product.

EXCLUSIONS AND LIMITATIONS

EXCEPT AS STATED ABOVE, EMFIT MAKES NO WARRANTIES (EXPRESS, IMPLIED, STATUTORY OR OTHERWISE) REGARDING PRODUCT OR ACCOMPANYING OR CONSTITUENT SOFTWARE QUALITY, PERFORMANCE, ACCURACY, RELIABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR OTHERWISE. If this exclusion is not permitted or fully permitted by applicable law, Emfit excludes or limits its warranties only to the maximum extent permitted by applicable law. Any warranty that cannot be fully excluded will be limited (as far as permitted by applicable law) to the duration of this Guarantee.

EMFIT’S ONLY OBLIGATION UNDER THIS GUARANTEE IS TO REPAIR OR REPLACE PRODUCTS SUBJECT TO THESE GUARANTEE TERMS AND CONDITIONS. EMFIT IS NOT LIABLE FOR ANY LOSS OR DAMAGE RELATING TO PRODUCTS, SERVICE, THIS GUARANTEE OR OTHERWISE, INCLUDING - ECONOMIC OR INTANGIBLE LOSSES - THE PRICE PAID FOR THE PRODUCT - LOSS OF PROFITS, REVENUE, DATA, ENJOYMENT OR USE OF THE PRODUCT OR ANY ASSOCIATED PRODUCTS - INDIRECT, INCIDENTAL OR CONSEQUENTIAL LOSS OR DAMAGE. THIS APPLIES WHETHER THAT LOSS OR DAMAGE RELATES TO: IMPAIRED OR NON-OPERATION OF THE PRODUCT OR ASSOCIATED PRODUCTS THROUGH DEFECTS OR UNAVAILABILITY WHILE WITH EMFIT, WHICH CAUSED DOWNTIME, LOSS OF USER TIME OR BUSINESS INTERRUPTION INACCURACY OF OUTPUT FROM THE PRODUCT OR ASSOCIATED PRODUCTS.

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Where applicable law prohibits or limits these liability exclusions, Emfit excludes or limits its liability only to the maximum extent permitted by applicable law. For example, some countries prohibit the exclusion or limitation of damages resulting from negligence, gross negligence, wilful misconduct, deceit and similar acts. Emfit’s liability under this guarantee will in no case exceed the price paid for the product, but if applicable law permits only higher liability limitations, the higher limitations apply.

YOUR LEGAL RIGHTS RESERVED

Consumers have legal (statutory) rights under applicable national laws relating to the sale of consumer products. This guarantee does not affect statutory rights you may have nor those rights that cannot be excluded or limited, nor rights against the person from whom you purchased the product. You may assert any rights you have at your sole discretion.

19. TECHNICAL SPECIFICATIONS

Control Unit

Model:	D-1090-2G
Operating voltage:	5 V DC
Input / output connectors:	Power, AUX and Sensor
Dry-contact outputs:	Max. 100 mA A, <60 V DC, <25 V AC
Switches and controls:	SW1 (On/Off/Reset switch), 8 DIP switches for program settings, 1 pcs 10 position rotary switch for sensitivity adjustment
Light indicators:	3 LEDs, green, blue and red
Notification delays:	Faster movements threshold delay adjustable: 10, 13, 16 or 20 sec; no movement notification threshold delay about 5 seconds
Mounting:	On the wall with included bracket or on the table
Dimensions mm	96 x 127 x 34 mm
Weight:	110 g
Color:	White
Enclosure protection:	IP20
Case:	Plastic

Bed Sensor

Model:	L-4060SL
Type:	Bed sensor
Placing:	Under the mattress
Portability:	Yes
Dimension mm (L x W):	400 x 580 mm
Thickness:	0,4 mm
Weight:	110 g
Color:	Blue
Surface material:	Polyester
Cable length:	3m

Environment conditions

Operating temperature:	10°C TO 40°C
Storage and transportation temperature:	-30°C TO 50°C
Humidity:	20%… 75% Relative humidity

Product classification

93/42/EEC	Medical device class **1**
Electrical safety:	Class **II** equipment
Enclosure protection:	IP20

20. ELECTROMAGNETIC CONDITIONS

System specification:
- D-1090-2G monitor
- L-4060SL bed sensor
- GlobTek power supply model: no GTM41060-1505 and P/N:WR9QA3000LCP-N-MNK.

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!

Electromagnetic emissions		
The Emfit Emfit Nocturnal Epileptic Tonic-Clonic Seizure Monitor 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 Emfit Nocturnal Epileptic Tonic-Clonic Seizure Monitor 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 Emfit Emfit Nocturnal Epileptic Tonic-Clonic Seizure Monitor 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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	IEC-60601-1-2 test level	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 ±1 kV for input/output lines	IEC-60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	IEC-60601-1-2 test level	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 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	IEC-60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment. If the user of the The Emfit epileptic seizure alarm enquires continued operation during power mains interruptions, it is recommended that the Emfit Nocturnal Epileptic Tonic-Clonic Seizure Monitor be powered from an uninterruptible power supply or battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	IEC-60601-1-2 test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[V_1] = 3 V 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the The Emfit Nocturnal Epileptic Tonic-Clonic Seizure Monitor , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	[E_1] = 3 V/m 80 MHz to 2,5 GHz	$d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 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 [EQUIPMENT or SYSTEM] is used exceeds the applicable RF compliance level above, the [EQUIPMENT or SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the [EQUIPMENT or SYSTEM]. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the [EQUIPMENT or SYSTEM]

The Emfit Nocturnal Epileptic Tonic-Clonic Seizure Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Emfit epileptic seizure alarm can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Emfit Nocturnal Epileptic Tonic-Clonic Seizure Monitor alarm as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E_1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0,01	0,12 m	0,12 m	0,23 m
0,1	0,37 m	0,37 m	0,73 m
1	1,17 m	1,17 m	2,33 m
10	3,69 m	3,69 m	7,38 m
100	11,67 m	11,67 m	23,33 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 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

21. MANUFACTURER´S CONTACT INFORMATION

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