# Instructions for Use

## Emfit Tonic-Clonic Seizure Monitor

**NOTE!**

THE DEVICE MUST NOT BE USED IF AN OPERATIONAL FAILURE OF THE DEVICE MIGHT LEAD TO A DELAY IN GETTING THE APPROPRIATE TREATMENT OR MEDICATION FOR THE PATIENT, WHICH COULD PUT THE PATIENTS LIFE AT RISK.

Applicable to products:
Control unit D-1090-2G, t73 v.1.0.15
Bed sensor L-4060SL
17 December 2013, ENG ver. 4.2

ENGLISH

# TABLE OF CONTENTS

# 1. WARNINGS

## 1.1. Important information. Read before use.

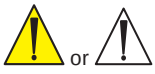
- Must not be used in situations where a delay in the arrival of appropriate medical care, could lead to a potentially life-threatening situation.
- This device is designed only to be used as an aid for a caregiver.
- Pets can cause false notifications or prevent a notification when needed if they walk or lie on a bed fitted with this device.
- Do not use this device for any purpose other than that specified by the manufacturer.
- Do not connect the device to any other devices other than those specified by the manufacturer.
- Do not try to repair the device yourself.
- The device is designed to be used in the electromagnetic environment and conditions specified on chapter “Electromagnetic conditions”. The client or user of the device must ensure that it is only used in the specified ambient conditions.
- Do not install this device near or on top of another device. However, if this cannot be avoided, the user must ensure that the device functions in the normal manner.
- Do not use X1, X2 or X3 connectors for any purpose other than that specified by the manufacturer. Do not connect the connectors to e.g. telecommunications or local area networks.
- If this device is used with a pressure care mattress filled using a compression pump, the device may not function normally in some cases.
- Equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- Do not let the device get wet.
- Remove the batteries when the device is not in use or when it is stored for an extended period. Alkaline batteries may become self-discharged, start leaking and contaminate the device.
- Do not use any rechargeable batteries or lithium-ion batteries! Rechargeable or lithium-ion batteries carry the risk of melting, ruining the device and causing possible danger to the user.
- The device is not diagnostic and cannot differentiate between a tonic-clonic seizure and other fast movements.
- When removing the power supply from the socket, ensure that the plug part is not left in the socket. If the plug part is left in the socket, touching or trying to remove it carries the risk of an electric shock.

## 1.2. Unintended adjustment of control unit settings:

- Adjusting the volume may lead to the notification sound not being heard.
- Increasing sensitivity may lead to false notifications while decreasing sensitivity may lead to the notification not becoming activated when needed.
- Incorrect positioning of the DIP switches may interfere with the normal operation of the device.
- Pressing the ON/OFF/Reset (SW1) press switch for too long will switch off the device.

# 2. SYMBOLS USED IN THIS MANUAL

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 this User’s Guide). ATTENTION - consult accompanying documents (i.e. this User’s Guide)

Means that the section contains important information for the user (in this User’s Guide).


Indicates the maximum use and storage temperature (of the sensor).

When LED next to this is on it indicates person is in bed (on the control device)

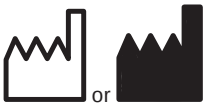
When LED next to this is on it indicates product is in stand-by mode (on the control device).

Non-ionizing radiation (in this User's Guide, chapter "Electromagnetic conditions")

Symbol of European Waste Electrical and Electronic Equipment Directive (WEEE Directive) 2002/96/EC on waste electrical and electronic equipment (in this User's Guide, chapter "Disposal of the device after use" and on bed sensor).

RoHS

Indicates that the product is in compliance with the European directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (commonly referred to as the Restriction of Hazardous Substances Directive or RoHS).




Indicates manufacturer name and address.

Indicates positioning of battery cell. + is positive terminal and - is negative terminal

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

In the external power supply indicates it is for indoor use only

In the external power supply indicates it is UL Demko certified


In the external power supply indicates it is China SJ/T 11363-2006 certified


In the external power supply indicates it is UL Certified

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

In the external power supply indicates it is VCCI certified

In the external power supply indicates it is UKRSepro certified

In the external power supply indicates it is GOST-R certified


In the external power supply indicates it is C-TICK certified

In the external power supply indicates it is China RoHS 30 certified

In the external power supply indicates it is BSMI certified

In the external power supply indicates it is SIQ certified

In the external power supply indicates it is IRAM certified

In the external power supply indicates it is CCC certified

In the external power supply indicates it is CPSQ certified

In the external power supply indicates it is PSE to J60950 certified

# 3. INTRODUCTION

- These instructions describe the use of the Emfit Tonic-Clonic Seizure Monitor. The exact version number on the first page of this manual should be referred to and compared against the number on the sticker found on your device.
- Use the device only in the ambient conditions specified by the manufacturer. For detailed information, refer to "Technical Specifications" in this manual.
- Follow all instructions provided in this document concerning the installation, use and cleaning of the device.
- In accordance with the intended use defined in Section 3.1 below, the Emfit Tonic-Clonic Seizure Monitor is a medical device as defined in the Medical Device Directive 93/42/EEC.
- The device is a Class I medical device in accordance with the Medical Device Directive 93/42/EEC and carries the CE marking accordingly.

## 3.1. Intended use

The Emfit Tonic-Clonic Seizure Monitor is intended to be used to assist in sensory monitoring and to notify the user of the body movements of a person lying on a mattress equipped with the under-mattress sensor due to a tonic-clonic seizure while sleeping

**NOTE 1**
The manufacturer cannot guarantee that the device will detect all episodes of tonic-clonic seizure-induced body movements in the monitored person.

**NOTE 2**
The device may trigger a false body movement notification, especially if the person recumbent on the mattress fitted with the under-mattress bed sensor is awake.

**NOTE 3**
The device cannot be used to verify whether the alerted body movement was caused by a tonic-clonic seizure. The occurrence of a tonic-clonic epileptic seizure can be verified, among other things, against electroencephalogram (EEG) data interpreted by a healthcare professional. The Emfit Tonic-Clonic Seizure Monitor cannot replace an EEG recording system.

**NOTE 4**
Always ensure the suitability of the device - particularly for small children - by conducting a test run. There are no weight or age restrictions for the use of the device.

## 3.2. Liability of the manufacturer

Emfit Ltd. is liable to ensure the safety, reliability and performance of the device, provided that:
- the device is installed, used and cleaned in accordance with the instructions in this manual
- any changes to the product, maintenance and repairs are conducted by a person trained by Emfit Ltd. or its representative
- any spare parts or accessories used have been approved by Emfit Ltd.

## 3.3. About this manual

Read all warnings and reminders in this manual with care to avoid any hazardous situations and damage.

# 4. PACKAGE CONTENTS

- A control unit and two screws to attach the lid (D-1090-2G) ***(picture 1)***
- A bed sensor (L-4060SL) ***(picture 6)***
- Two pieces 3M double-sided tape to fix the sensor ***(picture 26)***
- A wall mounting bracket with two screws and two plugs ***(picture 7)***
- Clip for bed side attachment (**picture 16)**
- This manual
- A power supply (see chapter Technical Specifications for details) ***(picture 2)***
- Two AA batteries
- An optional accessory, such as an approved wireless transmitter ***(picture 8)***

# 5. GENERAL

## 5.1. Control unit *(picture 1)*

The control unit emits a notification sound when the sensor detects fast-paced movement (frequency 3–20Hz) in the bed for the duration of the preset time (10, 13, 16 or 20 sec.).

The control unit has a separate power supply. Do not use any power supply other than that provided by Emfit Ltd. (see chapter Technical Specifications for details) ***(picture 2)***. In the event of a power failure, two high-quality 1.5V AA alkaline batteries can be used as an emergency power supply.

The control unit has an input connector for the bed sensor (X3) and power supply (X1). The device also has a connector (X2) to transfer the notification via an external wireless transmitter to e.g. a nurse call system or a personal emergency phone.

Next to the input connector, there is a push button (SW1) that can be used to acknowledge a notification or as an on/off switch. ***(picture 3)***

The control unit has 8 DIP switches ***(picture 4)*** to select the settings and a rotary switch to adjust the sensitivity of the device. ***(picture 5)***

## 5.2. Bed sensor *(picture 6)*

The bed sensor produces a millivolt alternating current when detecting movement. The control unit calculates the frequency and scale of the movement from this signal and, on this basis, detects the person's presence in the bed or a possible tonic-clonic seizure. Normal vital functions (heartbeat, breathing) cause micro-movement that allow the device to detect the person's presence.

# 6. SETTING UP THE DIP SWITCHES

Open the lid of the control unit by lifting it from the side ***(picture 9).*** Inside, you will find eight DIP switches that are used to select the desired functions ***(picture 4)***. Remember to select the desired settings using the DIP switches before using the device.

Disconnect the device from the power supply before opening the lid.

Remove the batteries and disconnect the power supply before setting up the DIP switches in order to implement the new settings.

The control unit has the following factory settings. DIP 1, 2, 3, 4 and 6 OFF (down). DIP 5, 7, 8 ON (up). With these settings:

- Movement notification delay is 13 seconds.
- The SW1 switch acts as the On/Off switch which means that the device can be switched on or off by pressing the switch for three (3) seconds.
- The notification sound is turned down.

## 6.1. Adjusting the tonic-clonic seizure notification delay (switches #1 and #2)

When the device detects faster movement (between 3–20Hz), its internal timer switches on. The device gives a notification if the movement continues for longer than the preset time. The desired delay should be set up according to the table below. The factory setting is 13 seconds. If the user makes other habitual movements, such as rocking, scratching or restlessness, a longer delay time can be selected to avoid false notifications.

| **Setting the fast movements duration after which the notification goes off** | **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) |

Switches #3 and #4 must be kept down (OFF).
Switch #5 must be kept up (ON)

### 6.2. SW 1 switch function (switch #6)

| SW 1 switch function | Switch #6 |
|---|---|
| The SW1 switch acts as the On/Off switch which means that the device can be switched on or off by pressing the switch for three (3) seconds. | OFF (down) |
| The SW1 switch does not act as the On/Off switch. The device is always on when it is connected to the power supply or when the batteries are in. | ON (up) |

### 6.3. Adjusting the notification sound volume (switches #7 and #8)

There are four volume levels: Very loud, loud, quiet and mute. The factory setting is mute.

| Level | Switch #7 | Switch #8 |
|---|---|---|
| Loud | OFF (down) | OFF (down) |
| Normal | ON (up) | OFF (down) |
| Quiet | OFF (down) | ON (up) |
| Mute | ON (up) | ON (up) |

The notification sound stops when the SW1 switch is pressed or when the seizure stops.

Remove the batteries and disconnect the power supply before setting up the DIP switches.
If the power supply is not disconnected, the new settings will not take effect.

## 7. INSERTING BATTERIES AND BATTERY SERVICE LIFE

In the event of a power failure, you can fit the device with two high-quality AA size 1.5V alkaline batteries (operating voltage 2x1.5V = 3V).

Disconnect the device from the power supply before opening the lid.

1) Open the lid by removing the screws and lifting it from one side (for first-time assembly: the screws for the lid can be found in the pouch containing wall mounting parts). ***(picture 9)***

2) Insert two high-quality AA size 1.5V alkaline batteries into the device following the polarity symbols at the bottom of the device. Close the lid and screw the screws back on. ***(picture 10)***

The easiest way to remove a battery is by lifting it from the + end. ***(picture 11)***

NOTE! All alkaline batteries start to leak when empty, and a leak will contaminate the device. Remember to replace the batteries at least once a year to avoid any leaks. Remove the batteries when the device is not being used or when it is being stored for an extended period. Disconnect the power supply briefly to test the batteries. If the batteries are empty, the red light on the control unit will light up. The X2 connector and the connected system will also trigger a notification. Replace the batteries when necessary.

Do not use any rechargeable batteries or lithium-ion batteries! Rechargeable or lithium-ion batteries carry the risk of melting, ruining the device and causing possible danger to the user.

## 8. EXTERNAL POWER SUPPLY

Set up the power supply in the following manner:

1) Remove the plastic cover (if applicable). ***(picture 23)***

2) Select a suitable plug from the four alternatives. ***(picture 24)***

3) Plug in the plug and ensure that it is not loose. ***(picture 25)***

The control unit has been designed and tested to be used with the Globtek inc. power supply (see chapter Technical Specifications for details). Using any other power supply may interfere with the safe use of the device.

The power supply is fitted with a light which lights up when the power supply is connected. If the light is not on while the power supply is connected to the mains, the power supply is probably faulty and needs to be replaced.

When the power supply is connected, the batteries act as backup power supply in the event of a power failure. All alkaline batteries self-discharge and start to leak when empty, contaminating the device. Ensure that batteries are replaced at least once a year.

When removing the power supply from the socket, ensure that the plug part is not left in the socket. If the plug part is left in the socket, touching or trying to remove it carries the risk of an electric shock.

# 9. CONNECTORS AND CABLES

Connector symbols can be found at the bottom of the control unit. ***(picture 3)***

X1 / connector for an external power supply. Only use Globtek Inc. power supply (see chapter Technical Specifications for details) which can be obtained as an original accessory from Emfit Ltd.

X2 / AUX connector to connect the device to an external battery-operated wireless transmitter to send the notification to another system. The connector may only be connected to a system safety voltage input with max. voltage below 25V(AC) / 60 (DC), where both poles have been separated from the electrical network. Max. load current 100mA.

X3 / sensor connector. Only use the Emfit bed sensor.

Connect the bed sensor ***(picture 13)***, the power supply delivered as an accessory ***(picture 14)*** and any connector cables ***(picture 15)*** according to the pictures.

# 10. INSTALLATION OF THE CONTROL UNIT

## 10.1. With wall mounting bracket

1) Fix the mounting bracket onto a wall with the plugs and screws supplied. ***(picture 17)***

2) Slide the control unit onto the wall mounting bracket. ***(picture 18)***

3) Press the control unit down until you hear a click. ***(picture 19)***

## 10.1. With bed side clip

1) Press the control unit down to the clip ***(picture 20)***

# 11. INSTALLATION OF THE BED SENSOR

- Place the bed sensor across the bed, under the mattress at approximately chest height. ***(picture 12)***
- To prevent the bed sensor from moving, fix the sensor to the bed using e.g. cable ties.
- Check at least once a week that the bed sensor is properly positioned.
- If you are using the bed sensor with a spring mattress, always place the bed sensor between the mattress and the mattress topper!
- Always place the bed sensor under the mattress or mattress topper, never just under the sheet. The bed sensor must not come into direct contact with a person!
- The bed sensor is designed to last for a minimum of two (2) years placed under a foam mattress and against the hard base of a bed frame.
- With a spring mattress, the service life of the bed sensor may be considerably shorter. When the bed sensor is placed on a spring

mattress, the user's weight and movement will cause the sensor to crumple, which may affect the sensor's performance. The manufacturer recommends that users replace the sensor when it starts to look crumpled. When used with a spring mattress, the sensor should be replaced every year. The warranty does not cover damage caused by crumpling.

- If the bed sensor is used with a pressure care mattress that is adjusted using a compressor pump, the mattress may interfere with the sensor's performance. If you are unsure about the suitability of your mattress, please contact the manufacturer.

# 12. SW1 PRESS SWITCH *(PICTURE 21)*

## 12.1. ON/OFF switch

The SW1 switch acts as the on/off switch if this function is activated (DIP switch #6 is down).

Press the SW1 switch for three (3) seconds in order to activate or deactivate the control unit. When the control unit is switched on, you will hear a beep and the blue LED light will turn on. When the device is switched off, you will hear a "beep-beep-boop" (high-high-low) sound. The blue LED light will go off.

## 12.2. Acknowledgement switch

The notification sound (if activated) can be muted by pressing the SW1 switch shortly. The device will make a "beep-beep" sound. NOTE! If you press the switch for too long, you might accidentally switch off the device. The notification sound will also stop when the fast-paced movements stop.

# 13. SIGNAL LIGHTS *(PICTURE 22)*

## 13.1. Green – Presence

| | |
|---|---|
| Slow flash. | A person is on the bed or other movement is being made. |
| Light is on continuously. | A person has been on the bed for 40 seconds and the device has become activated. |
| Light flashes. | Fast-paced movement on the bed detected. |
| Light is off. | No one is on the bed. |

## 13.2. Blue – Device on/standby

| | |
|---|---|
| Light is off. | Device is switched off. |
| Light is on. | Device is switched on. |
| Light flashes a few times. | Device triggers a notification. |

## 13.3. Red – Malfunction

| | |
|---|---|
| Light is on (power supply connected). | Bed sensor is defective or disconnected. Signal alarm sounds after 10 seconds and then every 45 seconds. There is also an alarm sent through the X2 connector after 30 seconds and then every 30 minutes. |
| Light is on (power supply disconnected). | Batteries are empty. Replace batteries. |

# 14. ADJUSTING SENSITIVITY

The sensitivity of the device can be adjusted through a 10-position rotary switch. The factory setting is position 3.

To test the sensitivity of the sensor, ask another person to lie on the bed completely still and without talking. Wait at least 1–2 minutes. If the green light does not light up, adjust the rotary switch up one position at a time until the green light lights up. If the green LED lights up when no one is on the bed, adjust the rotary switch down one position at a time until the green light is no longer on.

If you experience any problems, please contact the manufacturer.

Adjust the sensitivity of the device every time the sensor is re-installed, if the user or the sensor changes.

# 15. CHECKS

## 15.1. Weekly checks

**1. Condition of the cables**
Check the condition of the cables

**2. Position of the bed sensor**
Check the position of the bed sensor under the mattress. The correct position is at the chest height of the user and across the bed.

## 15.2. Start-up and monthly checks

To ensure faultless performance, conduct the following tests at least once a month and when ever the device is re-installed.

**1. Testing sensitivity**
To test the sensitivity of the sensor, ask another person to lie on the bed completely still and without talking. Wait at least 1–2 minutes. If the green light does not light up, adjust the rotary switch up one position at a time until the green light lights up. If the green LED lights up when no one is on the bed, adjust the rotary switch down one position at a time until the green light is no longer on.

**2. Testing the movement notification**
Make fast-paced movements (e.g. tapping the mattress repeatedly around the bed sensor). The device should trigger a notification after the preset delay time has passed (10–20 seconds depending on the position of DIP switches #1 and #2). The green light should start flashing when you tap the mattress.

# 16. TROUBLESHOOTING

Ensure that the device is properly installed. Test the device carefully every time its settings are adjusted.

| | |
|---|---|
| The device triggers a notification but the nurse call system does not. | Ensure that the external wireless transmitter is connected to the X2 connector. Check the battery of the external wireless transmitter. |
| Notification sound is inaudible. | Check the volume. |
| The device triggers a notification even if there is no unusual movement. | Check the condition, installation and position of the bed sensor.<br><br>Check that the sensitivity setting of the sensor is not too high. The green light should not be on if no one is on the bed.<br><br>The device may interpret normal movements (scratching, rocking, etc.) as a seizure. Adjust the delay time longer if necessary. Some people are restless before they fall asleep, and this might cause false notifications. Try switching the device on only after the person has fallen asleep. |
| The green light is on even if no one is on the bed. | Ensure that the bed sensor and its cables are not affected by external movement and remove any distractions.<br><br>Check the condition of the bed sensor and its cables. Faulty sensor or cable may cause distractions so that the green light is on all the time.<br><br>Adjust sensitivity. |
| The device does not trigger a notification, and the green light is on even if no one is on the bed. | Check the condition of the bed sensor and its cables. Faulty sensor or cable may cause distractions so that the green light is on all the time. This means that the device cannot necessarily detect a seizure due to constant distraction. |
| The device does not trigger a notification, and the green light is not on even if someone is on the bed. | Check the condition of the bed sensor and its cables. Check the sensitivity of the device by having someone lie on the bed completely still. The green light should be on. |

See also the “Troubleshooting Flow Chart” ***(picture 27)***.

If you experience any problems with the use of the device, please contact the manufacturer.

## 17. CLEANING

You can wipe the bed sensor and cables, control unit and external power supply with a damp cloth, neutral cleaning product or mild disinfectant.

Disconnect the external power supply always before cleaning the device. Dry all parts well after cleaning.

## 18. 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.

## 19. DECLARATION OF CONFORMITY (EU)

The manufacturer, Emfit Ltd., hereby declares that the Emfit Tonic-Clonic Seizure Monitor conforms with the relevant requirements of the Medical Device Directive 93/42/EEC.

## 20. 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.
This applies to loss and damages under any legal theory, including negligence and other torts, breach of contract, express or implied warranty, and strict liability (even where Emfit has been advised of the possibility of such damages).
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.

# 21. TECHNICAL SPECIFICATIONS

Equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

## 21.1. Control unit

| | |
|---|---|
| Model: | D-1090-2G |
| Operating voltage: | 3V DC with batteries/ 5V DC with external power supply |

| | |
|---|---|
| Input and output connectors: | Power supply, AUX and bed sensor |
| Dry-contact output: | Max. 100mA A, <60V DC, <25V AC |
| Switches and controls: | SW1 (On/Off/Reset switch), 8 pcs DIP switches for settings (volume, delay), one 10-position rotary switch for adjusting sensitivity. |
| Signal lights: | 3 LEDs: green, blue and red |
| Delays: | Movement notification delay alternatives: 10s, 13s, 16s or 20s. |
| Mounting: | Wall mounting, bed-side or table |
| Measurements: | 96 x 127 x 34mm |
| Weight (g): | 120g |
| Colour: | White |
| IP rating: | IP20 |
| Casing: | Plastic |

### 21.2. Sensor

| | |
|---|---|
| Model: | L-4060SL |
| Type: | Bed sensor |
| Placing: | Under a mattress |
| Portability: | Yes |
| Measurements mm (length x width): | 400 x 580mm |
| Thickness: | 0.4mm |
| Weight: | 235g |
| Colour: | Blue |
| Surface material: | Polyester |
| Cable length: | 3m |
| IP rating: | IP20 |

### 21.3. External Power Supply

| | |
|---|---|
| Manufacturer | GlobTek Inc. |
| Model | GTM41076-0605 (WR9QA1200L9PNMNK2813) or GTM41060-1505 (WR9QA3000LCP-N-MNK) |
| Input voltage | 100-240 V |
| Input current | <0,6 A RMS MAX |
| Input frequency | 50 - 60 Hz |
| Watts | 6.0 W / 15 W |
| Output voltage | 5 VDC |
| Output current | 1.2 A / 3.0 A |
| Electrical safety class | Class II |

### 21.4. Ambient conditions

| | |
|---|---|
| Operating temperature: | 10–40°C |
| Storage and transport temperature: | -30–50°C |
| Relative humidity: | 20–75% |

### 21.5. Product class

| | |
|---|---|
| Product class in accordance with the Directive 93/42/EEC: | Class I |
| Electrical safety class: | Internal and external power supply / Class II device |

# 22. ELECTROMAGNETIC CONDITIONS



### System specification:

D-1090-2G monitor

L-4060SL bed sensor

GlobTek power supply (see chapter Technical Specifications for details)

### 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!**

| **Guidance and manufacturer's declaration – electromagnetic emissions** | | |
|---|---|---|
| The Emfit 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<br>CISPR 11 | Group 1 | The Emfit 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<br>CISPR 11 | Class B | The Emfit 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<br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3 | Complies | |

| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The Emfit 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. | | | |
| **Immunity test** | **IEC 60601<br>test level** | **Compliance level** | **Electromagnetic environment** |
| Electrostatic<br>discharge (ESD)<br>IEC 61000-4-2 | ±6 kV contact<br>±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<br>transient/burst<br>IEC 61000-4-4 | ±2 kV for power<br>supply lines<br>±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<br>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 % 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 | IEC-60601-1-2 test level | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Emfit Tonic-Clonic Seizure Monitor enquires continued operation during power mains interruptions, it is recommended that the Emfit 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 UT is the a.c. mains voltage prior to application of the test level.** | | | |

This space was left blank on purpose

## Guidance and manufacturer's declaration – electromagnetic immunity

The Emfit 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.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
|---|---|---|---|
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the The Emfit Tonic-Clonic Seizure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 V 150 kHz to 80 MHz | $d = 1{,}2\sqrt{P}$ |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m 80 MHz to 2.5 GHz | $d = 1{,}2\sqrt{P}$ 80 MHz – 800 MHz<br><br>$d = 2{,}3\sqrt{P}$ 800 MHz – 2.5 GHz<br><br>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).<br><br>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]<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br>  |

**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 Tonic-Clonic Seizure Monitor.**

The Emfit 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 Tonic-Clonic Seizure Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Emfit 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 – 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.

## 23. MANUFACTURER

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Fax: +358 20 778 0871
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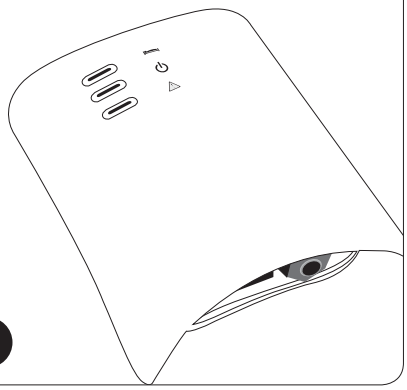
## 24. APPENDIX - RELATED PICTURES

1



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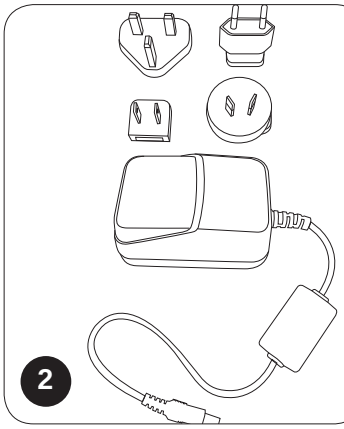

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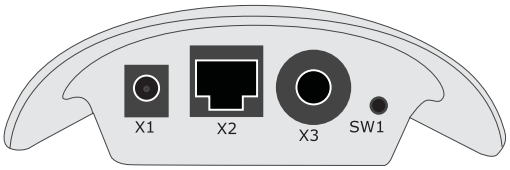


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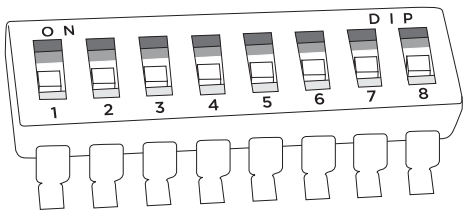


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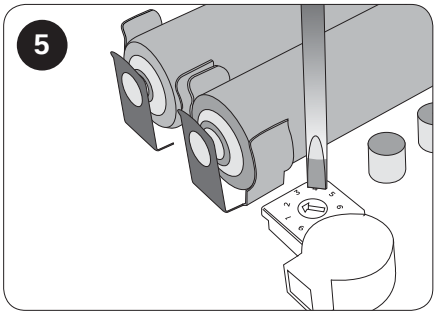

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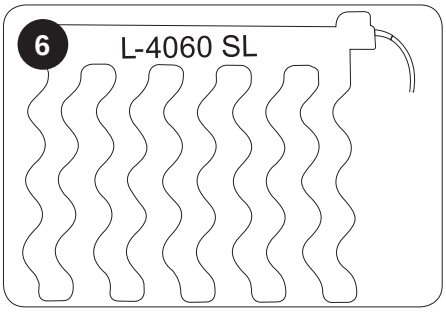


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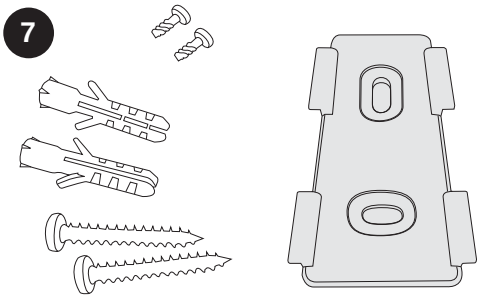

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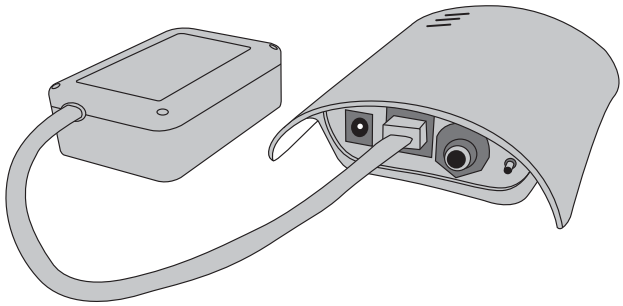

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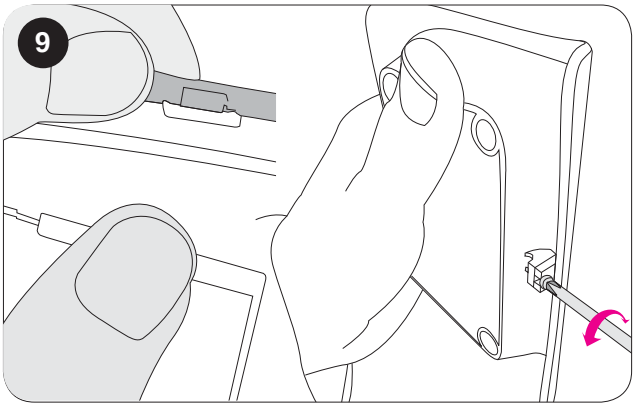

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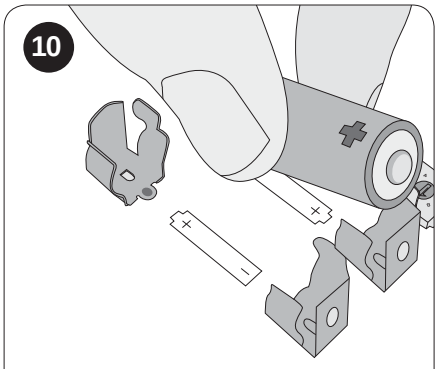

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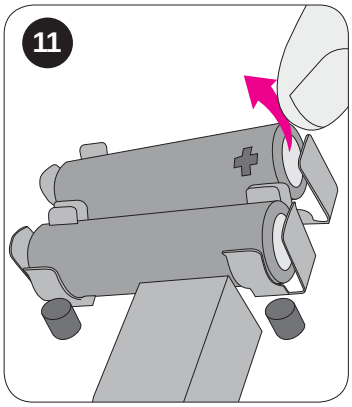

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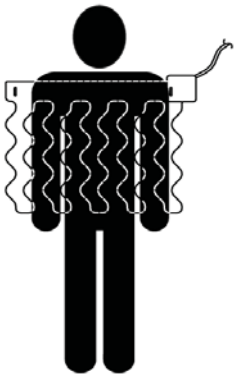

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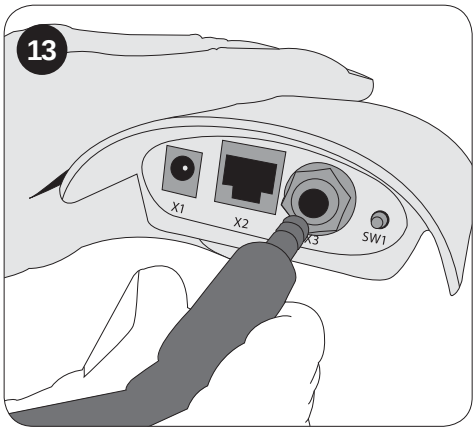


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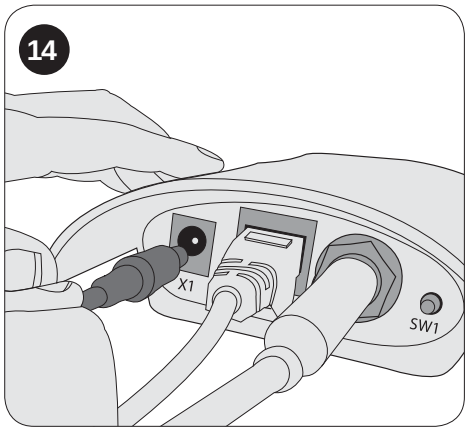

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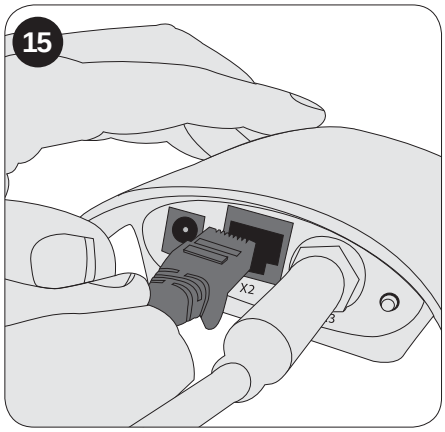


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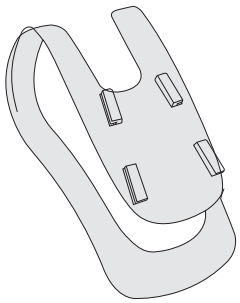

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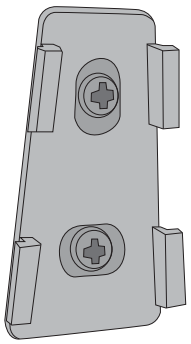

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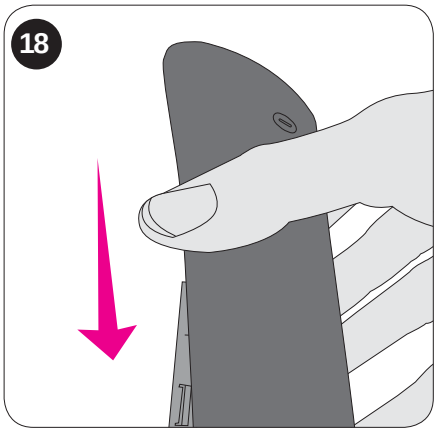

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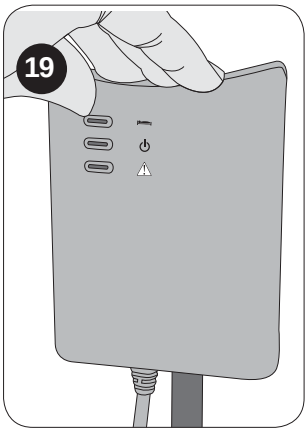

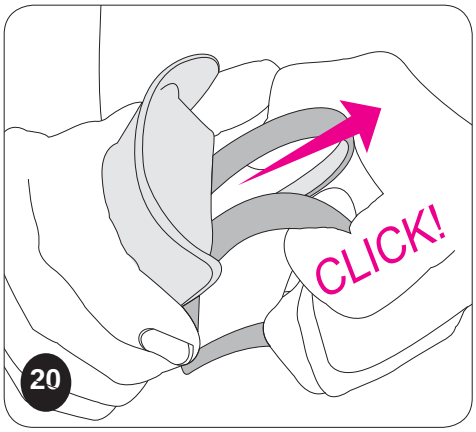


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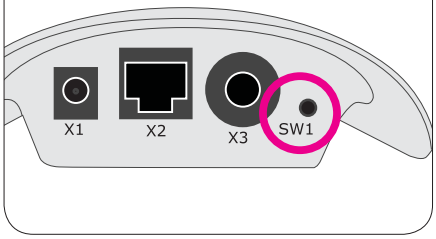


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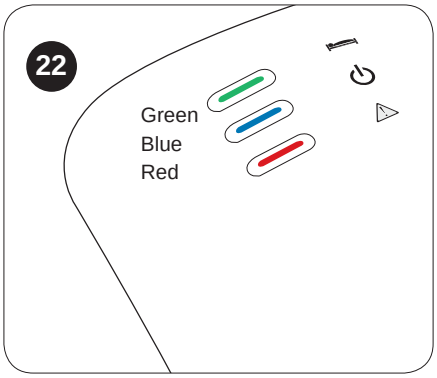


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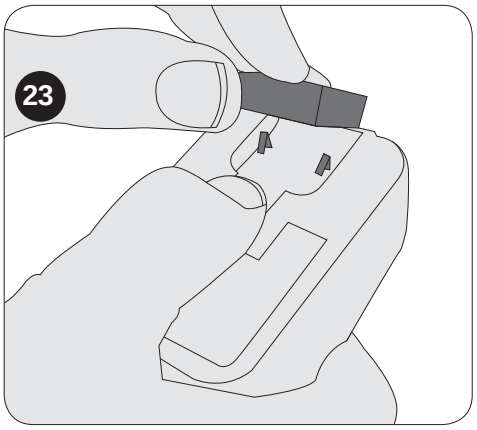

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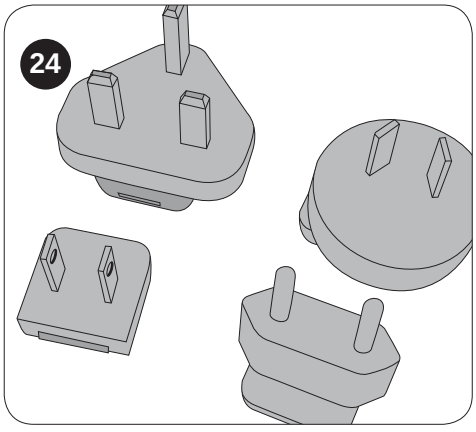

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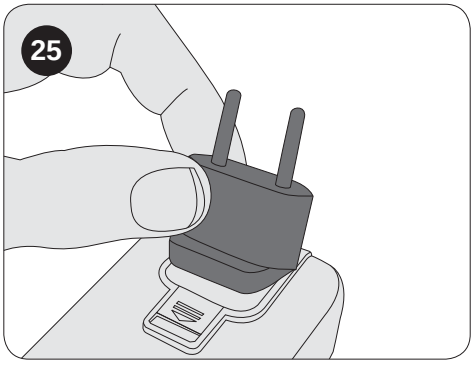
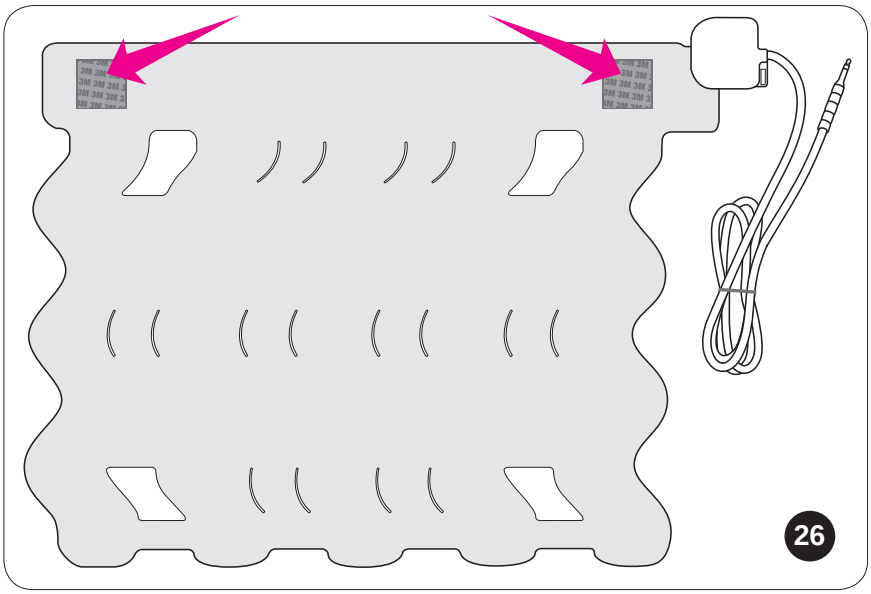
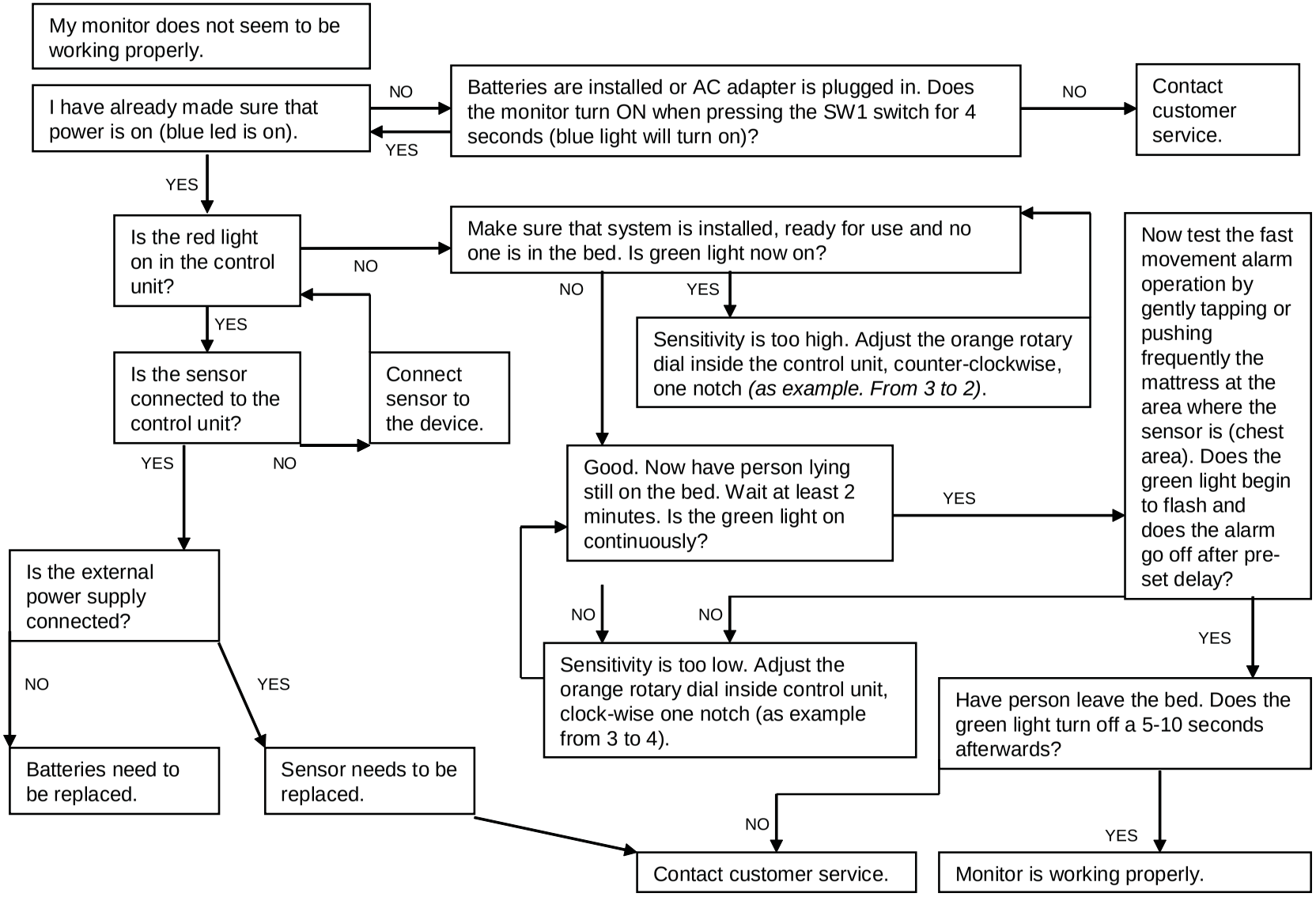




27

# Emfit Tonic-Clonic Seizure Monitor Troubleshooting Flow Chart



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