emego®

Instructions for Use

Designed and Manufactured by gspk DESIGN

Contents

Emego: The Assistive Technology Switch

Emego is a small, wearable wireless, assistive technology switch. Emego uses advanced electromyography (EMG) technology to accurately detect even the smallest of muscle triggers and turn them into switches giving the user the ability to control everyday equipment such as phones, computers and much more.

Emego is easy to set up and will work effortlessly with your existing AAC equipment to give you greater control and independence for all your accessible switching needs.

Please read through these instructions carefully so that you fully understand all of the functions and safety information. If you have any questions, problems or suggestions then please contact us by visiting our website www.emego.co.uk for more information.

Title & Product Information

Brand Name: Emego

Product Name: Emego System

Model Number(s): E600204 / E600304

Classification: Class I Medical Device

Manufacturer: GSPK Design Ltd

Manufacturer Address:

GSPK Design Ltd
Knaresborough Technology Park
Manse Lane
Knaresborough
HG5 8LF
United Kingdom

TEL: +44 (0)1423 798 254
Email: hello@emego.co.uk

Statement of Intended Use

Product Description:

The Emego System is a Class I Medical device and consists of a body worn sensor (Patient Unit) and wireless receiver (Base Unit) that uses electromyography (EMG) technology to detect electric potential generated by muscles. The system enables the patient to trigger (in real time) a variety of ancillary devices from minimal muscle movement.

Intended Use:

The Emego System is intended to be used by patients with severe physical disabilities to give independence and control over a variety of ancillary 'assistive' devices. Small movements of targeted muscle groups are detected and translated directly into wireless signals. The wireless signal is sent to the Base Unit that is then used to control existing electronic assistive technology equipment (eAT). Emego is designed to control assistive applications including control of:

- Augmentative and alternative communication devices (AAC).
- Environmental control applications (EC).

Emego is not intended for use in safety critical applications.

Emego System Contents

[1x] Emego Patient Unit (E600204)

[1x] Emego Base Unit (E600304)

[1x] Holster Strap (E600224)

[1x] Silicone Patch (E600227)

[1x] UK Plug Adaptor (E600319)

[1x] USB Cable (E600320)

[1x] Carry Case (E600106)

[1x] Instructions for Use (E600108)

Please note additional accessories sold separately.

Warning & Safety Information

Statement: Product is NON-STERILE.

Contraindications: Do not use the product on areas of the body where the skin is damaged or broken.
Limitations: Only use on areas of the body where both sensors will make complete contact with the skin.

Warnings:
Do not use the device in or near environments with overly humid conditions such as; shower rooms, saunas, or swimming pools. (Should this occur allow the device to dry out completely before use).
Do not use this system in safety critical situations – For example; as a sole means of calling for attention, or where misuse of the device would potentially cause harm.
Do not administer the device in close proximity to a patient's eyes.
Do not over tighten device straps.
Do not attempt to use the Patient Unit while it is charging.
Choking Hazard not for use by children under 3 years.
WARNING: Some users may find prolonged contact could contribute to skin irritation or allergies. Discontinue use of product should this occur and if symptoms persist, consult your doctor.
WARNING: No modification of this equipment is allowed.
WARNING: Only connect items that have been specified as part of the Emego System.
WARNING: Not to be used in an oxygen rich environment.
WARNING: Do not disassemble the Emego Patient or Base Units or attempt to remove the embedded lithium-ion batteries. Attempting to replace the embedded batteries may result in damage and will void the warranty. If you are experiencing issues with either Emego battery please contact us.

Precautions:
Do not leave Patients unattended while using this product.
Intended for indoor use only.

Environmental Conditions:
The device should be operated in ambient room temperatures between 0°C and 30°C (32°F and 86°F).

Required Knowledge:
No special skills or training are needed for the operation of this unit.

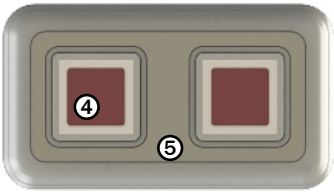
Equipment Description

Patient Unit:

① Power Switch

② LED Indicator (green/amber)

③ Wireless Power Receiver

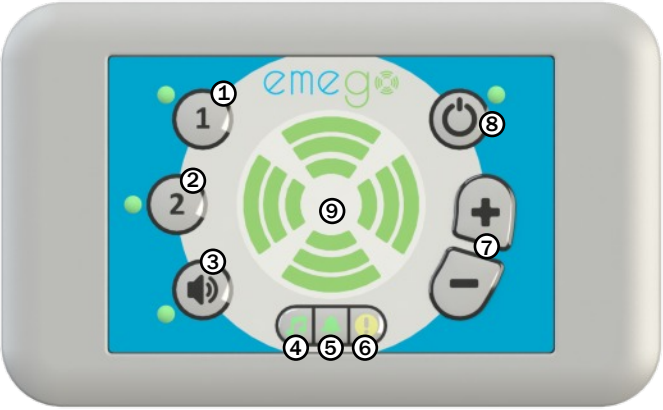


④ Sensor Contacts

⑤ Reference Electrode

Equipment Description

Base Unit Top View:



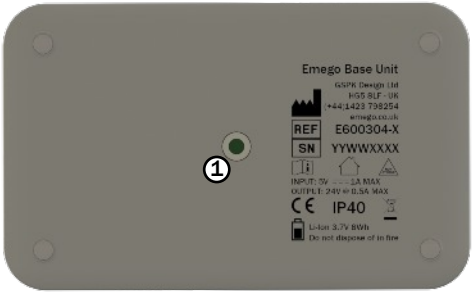
① Channel 1 Switch and LED
② Channel 2 Switch and LED
③ Audio Switch and LED
④ Data Audio Mode LED
⑤ Beep Audio Mode LED
⑥ Warning LED
⑦ Plus and Minus Switches
⑧ Power Switch & LED
⑨ Wireless Power Transmitter

Equipment Description

Base Unit Side View:

① USB Charging Port
② 3.5mm jack, AAC/EC Connection Ports

Base Unit Bottom View:



① 1/4'' - 20UNC Female Thread for Tripod Mounting

Directions for Use

Start-up Procedure:

Attach the Patient Unit; using hook and loop straps or the silicone patch (included in the kit). Take care not to over tighten the straps.

Press the Power Switch on the Patient Unit to turn on the device. The power LED will momentarily flash yellow, then periodically flash green to indicate the device is on.

Directions for Use

Press the Power Switch on the Base Unit to turn on the device. All LEDs will momentarily flash, then the green power LED will illuminate to indicate power on.

Press the Channel 1 or 2 Switch to connect the Patient Unit to the corresponding channel.
LEDs 1 or 2 flash (briefly) when connected.

The Patient and Base Units will come pre-paired and ready to connect to each other wirelessly. If you need to pair the units manually, then please refer to the pairing section on page 19 of this manual.

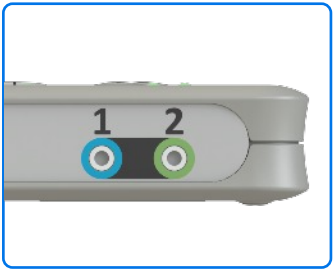
Directions for Use

Operating Instructions:

To adjust the trigger sensitivity for Channel 1 or 2, press the corresponding switch (1 or 2) then adjust using the Plus or Minus Switches.

Emego is now ready to use.

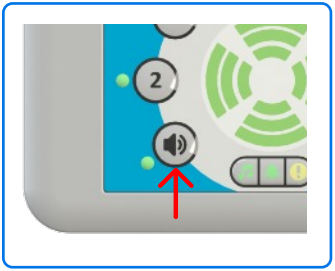
During non activation periods where the muscle is at rest, the Patient Unit LED for the corresponding channel (1 or 2) will be off. When the Patient Unit detects muscle activity the corresponding LED will be on. Adjust sensitivity accordingly, you may need to adjust the placement of the Patient Unit on the user to obtain the best signal.



Using the 3.5mm ports you can connect the desired AAC or EC device to be controlled. The 3.5mm ports connect a volt-free, 'normally open' relay output which can be used to control AAC or EC devices. The relay will close when the Emego Unit is triggered. The ports correspond to Channel 1 and Channel 2.

Directions for Use

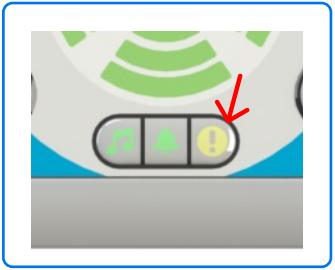
Operating Instructions:



If audio feedback is required whilst adjusting the sensitivity, press the audio button until the desired mode (data/beep/off) is selected. While the audio LED is illuminated the volume can be adjusted with the Plus and -Minus Switches.

Press 1 or 2 to return to adjusting sensitivity. The selected audio mode will stay as it is until turned off by the user.

Selection of audio control will timeout after 30 seconds of no activity and return to the previously selected channel adjust mode.



If the warning LED illuminates then please refer to the Messages and Indicators table on page 20 of this manual to troubleshoot.

Directions for Use

Charging:

The Base Unit is powered from an internal rechargeable battery. If low battery is indicated connect plug adapter and USB cable to recharge. To charge the Base Unit; ensure that it's plugged in using the supplied USB Power Cable and UK Plug Adaptor.

The Base Unit can still be used when on charge.

The Patient Unit is powered from an internal rechargeable battery. If low battery is indicated place the patient unit sensor side facing up, on the central point of the receiver unit (as pictured to the left). The base unit LED light will blink once a second to indicate charging and twice a second when fully charged.

The Patient Unit will only charge when the Base Unit is plugged in to an external USB power source, as described above.

The Patient Unit will not operate when being charged.

Directions for Use

Shut-Down Procedure:

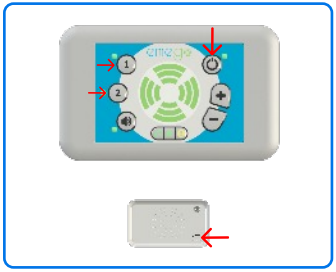
To turn off the Base Unit press the Power Switch then release. If the USB cable is plugged in, the Base Unit will be in stand-by mode and the Patient Unit can still be charged.

Base Unit will power down automatically if internal battery is too low, or there is no Patient Unit wirelessly connected for a period of 10 minutes.

To turn off the Patient Unit hold down the Power Switch for 1 second then release. Patient unit will power down automatically after 5 minutes if there is no wireless signal from the Base Unit, or if placed on the Base Unit wireless power transmitter, or if the internal battery is too low.

Directions for Use

Pairing:



Each Patient Unit is paired to only communicate with a specific Base Unit.

If you need to pair the units manually then turn on both Patient and Base Unit.

Hold Power Switch on the Patient Unit and Switch 1 or 2 on the Base Unit together for 15 seconds (both LED 1 and 2 will flash, the Base Unit will beep after 5 seconds, then again after the 15 seconds required.).

Release after 15 seconds.
This step must be completed successfully to allow re-pairing.

Hold the Power Switch on the Patient Unit and Channel 1 or 2 Switch on the Base Unit together for 5 seconds and release to create new pairing.

Pairing is now complete.

Directions for Use - Messages & Indicators:

Base Unit:

Indicator	What does it mean?	How to react
Channel 1 LED - on	Channel 1 is triggered or user has requested an event on this channel.	This is normal operation
Channel 2 LED - on	Channel 2 is triggered or user has requested an event on this channel.	This is normal operation
Audio mode LED	Audio mode is selected	Audio functions and volume can be adjusted
Power LED solid (green)	Base Unit is powered on	This is normal operation
Power LED flashing once a second (green)	Patient Unit is charging	This is normal operation
Power LED flashing twice a second (green)	Patient Unit is fully charged	Remove Patient Unit from Base Unit
Warning LED flashing with LED 1	Patient Unit on channel 1 battery is low	Charge Patient Unit
Warning LED flashing with LED 2	Patient Unit on channel 2 battery is low	Charge Patient Unit
Warning LED flashing with power LED	Base Unit battery is low	Charge Base Unit

Patient Unit:

Indicator	What does it mean?	How to react
Green flashing LED	Patient Unit is on	This is normal operation
Amber flashing LED	Battery is low	Charge Patient Unit

Instructions for Cleaning & Storage

Cleaning Procedure:

- Clean the surface of the Patient Unit and Base Unit with an alcohol-based wet wipe, soft dry tissue or cloth.
- Clean the silicone patch and silicone holster with an alcohol-based wet wipe or soft moist cloth.
- Store the Emego system in a cool dry place away from the reach of children.

Holster & Strap Cleaning:

- Straps are not cleanable. These should only be used by one patient and disposed of when no longer used.
- Wash Holster in warm soapy water

Silicone Patch Cleaning:

- Silicone Patch can be removed from Patient Unit and washed in warm soapy water. Dry thoroughly before use.
- Remove and replace adhesive patch after every session.

Storage:

- Store in carry case when not in use.

Maintenance

The Emego system contains no user serviceable parts. If any of the units are not functioning correctly, please send the product back to the manufacturer using the contact details found in the back of this manual.

Please contact us for:

- Advice.
- Failure of the device to meet its intended purpose.
- Adverse incidents involving the device.

Accessories, Supplementary Equipment & Used Materials

Emego Holster: (E600224)

- Holster Body: (E600218)
- Holster Strap: (E600223)

Emego Silicone Patch: (E600227)

- Silicone Patch Body: (E600219)
- Silicone Patch Adhesive: (E600226)

The silicone patches supplied with the Emego system are pre-loaded with an adhesive patch. The adhesive is a consumable item and will need to be replaced after every session.

For information on replacement patches and other accessories, please visit; www.emego.co.uk

Disposal

The Patient Unit, Base Unit and Plug Adapter should not be mixed with general household waste. For proper treatment, recovery and recycling, please take this product(s) to designated collection facilities. Please contact your local authority for further details of your nearest designated collection point.

The straps and the adhesive layer on the silicone patches can be disposed of in general waste.

Specification

Environmental Operating Limits:

- **Operating/ standby temperature:** 0 to 30°C (32 to 86°F)
- **Shipping/ storage temperature:** -10 to 50°C (14 to 122°F)
- **Relative humidity:** Non-condensing

Patient Unit (E600204):

- **Size:** 46 x 26 x 16mm
- **Weight:** 25g
- **Water resistance:** IP44
- **Battery type:** Li-ion (3.7V Nominal) rechargeable
- **Battery life:** 8 – 10 Hours
- **Frequency response:** 4 - 200Hz

Emego Base Unit (E600304):

- **Size:** 150 x 92 x 28mm
- **Weight:** 260g
- **Water resistance:** IP40
- **Battery type:** Li-ion (3.7V Nominal) rechargeable
- **Battery life:** 8 – 10 Hours

Technical Information

Emego Holster (E600224):
For use on patients where the target muscle groups are on arms, legs or around the forehead.

Size: 46mm x 48.2mm
Hook and loop straps: 25 x 300mm & 25 x 90mm

Emego Patch (E600227):
For use on patients where target muscles are on areas of the face.

Size: 130mm x 60mm
Shelf life: Check expiry date

Power Supply Limits
Input: 100-240VAC 50-60Hz
Output: 5VDC/1400mA

Graphic Symbols for Device Labelling

	Manufacturer		Non Sterile
	Consult Instructions for Use		Indoor Use Only
	Catalogue Number		Type BF Applied Part
	Serial Number		Direct Current
IP XX	Ingress Protection Rating		Do not dispose of along with household waste

Warranty

For a period of 12 months from delivery the Company will, free of charge, repair or, at the Company's option, replace Goods which are proved to the reasonable satisfaction of the Company to be damaged or defective due to faulty materials, workmanship or design.

This obligation will not apply:

• If the defect arises because the Customer has altered or repaired such Goods without the written consent of the Company; or

• Because the Customer did not follow the Company's instructions for storage, installation, use or maintenance of the Goods; or

• If the Customer has failed to notify the Company of any defect where the defect should have been reasonably apparent on reasonable inspection; or

• If the Customer fails to notify the Company of the defect within 12 months of the date of despatch of the Goods; or

• If the defect arises from fair wear and tear or wilful damage, negligence or abnormal working conditions.

Any replacement Goods or Goods repaired under this Condition will be guaranteed on these terms for any unexpired portion of the period of guarantee given on the original Goods. Any Goods which have been replaced will belong to the Company.

Glossary

Emego Patient Unit: Wireless body worn sensor
Emego Base Unit: Wireless receiver
Abbreviations:

- **EMG:** Electromyography
- **AAC:** Augmentative and alternative communication
- **LED:** Light-emitting diode
- **USB:** Universal Serial Bus
- **HID:** Human interface device
- **EC:** Environmental control

Version	Date	Author	Checked	Summary of changes
A	6/2/2017	JA	JN	First release
B	17/5/2017	JA	JN	Added in declaration of conformity
C	1/6/2017	JA	JN	Production release

Appendix A: Emego Declaration of Conformity

EU Declaration of Conformity

In accordance with ISO/IEC 17050-1

Manufacturer GSPK Design Ltd
Manse Lane
Knaresborough, North Yorkshire
HG5 8LF, England

Declares under their sole responsibility, that the product

Product Name: EMEGO
Model Number: E600204 Patient Unit
E600304 Base Unit
And accessories

Complies with the essential requirements of the following EU Directives and harmonised standards and carries the "CE" mark accordingly:

EMC Directive 2014/30/EU

BS EN 60601-1-2:2015
Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests.

Medical Devices Directive 93/42/EEC

Device Classification according to Annex IX: Class I
BS EN 60601-1:2006+A12:2014
Medical electrical equipment. General requirements for basic safety and essential performance.

Radio Equipment Directive 2014/53/EU

EN 301489-1 v1.9.2
EN 301489-17 v2.2.1
Electromagnetic compatibility and Radio Spectrum Matters: Electromagnetic compatibility standard for radio equipment and services.
Part 1: Common technical requirements.
Part 17: Specific conditions for Broadband Data Transmission Systems.
EN 300328 v2.1.1
Electromagnetic compatibility and Radio Spectrum Matters; Wideband transmission systems; Data transmission equipment operating in the 2.4GHz ISM band and using wideband modulation techniques.

RoHS-2 Directive 2011/65/EU

Paul Marsh
Managing Director
Knaresborough
15 May 2017

Appendix B: Plug Adapter Declaration of Conformity

FRIWO

Firma / Company: FRIWO
Gerätetyp / Typ FW8002/MUSB/05
Art.-Nr. / Part-No. 1898349
Zeichnungs-Nr. / Draw.-No. 15.4689.511-00

Liefervorschrift / Specification

7 CE-Konformitätserklärung / Declaration of Conformity

Wir, der Hersteller, erklären hiermit, dass das Produkt: /
We, the manufacturer, hereby confirm, that the product:

Gerätetyp / *Type:* FW8002MUSB/05

Artikel-Nr. / *Part-No.:* 1898349

Zeichnungs-Nr. / *Drawing-No.:* 15.4689.511-00

weitere Merkmale /
additional information:

mit der beiliegenden Beschreibung die Anforderungen der Niederspannungsrichtlinie 2006/95/EG, der EMV-Richtlinie 2004/108/EG und Öko-Design Richtlinie 2009/125/EG erfüllt.

Hiermit bestätigen und garantieren wir, dass unsere Produkte, unabhängig von der Produktionsstätte, RoHS-konform produziert werden und die Anforderungen der EU Richtlinie 2011/65/EU (Neufassung der Richtlinie 2002/95/EU) erfüllen.

with the enclosed description fulfils the requirements of the Low Voltage Directive 2006/95/EC, the regulations of the EMC Directive 2004/108/EC and the eco design Directive 2009/125/EC.

Hereby, we certify and guarantee that our products, regardless of the production location, RoHS compliant and fulfill the directive 2011/65/EC (revised version: directive 2002/95/EC).

Das Gerät entspricht der / *The unit corresponds to:*

a) Niederspannungsrichtlinie / *Low Voltage Directive*	b) EMV-Richtlinie / *EMC Directive*	c) Öko Design / *ECO Design*
▫ EN60601-1 Ed.3 07/2007	▫ EN 60601-1-2 12/2007	▫ Not applicable

Jendrik Moellers
Vice President Product Management & Marketing

Ausstelldatum / *Date of issue:* 2015-07-23

FRIWO Gerätebau GmbH
Von-Liebig-Straße 11
48346 Ostbevern

Firmenstempel / Company stamp

Armin Wegener
Vice President Research & Development

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