

eConnect

Instructions to Use EN



eConnect



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1 Introduction

Thank you for choosing the data transfer solution **eConnect**.

The **eConnect** is a supplementary device for remotely operated medical systems. It is used to receive measurement data via Bluetooth® from certain measuring devices and to transfer it to an external database via a mobile communications network.

Read this operating manual carefully before use and keep it in a suitable place so that the information is available when required.

If you have any questions about services or products, feel free to contact I.E.M. GmbH.

1.1 Contents

Base set:

- 1x **eConnect** (including SIM card)
- 1x mains PSU
- 1x operating manual

Optional accessories:

- 1x SIM card

Contact details for the manufacturer

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2 eConnect

2.1 Technical description

The **eConnect** works similar to a mobile telephone, using a mobile connection based on the international GSM standard to transfer data.

The **eConnect** receives measurement data from certain measuring devices via a Bluetooth® connection and automatically transfers it to an external database via a mobile communication link. Data transfer is performed wirelessly.

The eConnect as shipped is entirely pre-configured and ready to use.

2.2 eConnect – Front

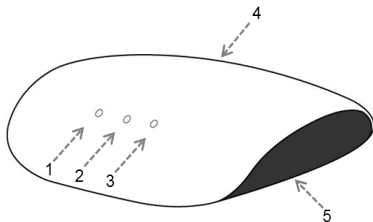


Fig. 1: eConnect – Front

- | | | | |
|---|----------------------------|---|-----------------------|
| 1 | “BT” LED | 4 | Upper part of housing |
| 2 | “Mobile communication” LED | 5 | Lower part of housing |
| 3 | “System” LED | | |

2.3 eConnect – Rear side

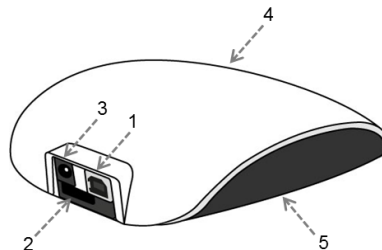


Fig. 2: eConnect – Rear

- | | | | |
|---|-----------------------------------|---|-----------------------|
| 1 | USB connector (only for service!) | 4 | Upper part of housing |
| 2 | SIM card holder | 5 | Lower part of housing |
| 3 | Mains PSU connector | | |

2.4 Conformity

The **eConnect** meets the requirements of the following directives:

- MDD (93/42/EEC)
- RED (2014/53/EU)
- RoHS (2002/95/EU)

The **eConnect** bears the CE mark.



3 For your safety

This chapter provides all of the safety information relating to the device.

Read this chapter carefully before using the **eConnect**

3.1 Symbols used in this manual



WARNING!

... indicates a possible risk of death or serious injury if not avoided.



NOTE!

... indicates a potential risk of damage to property or loss of product function if not avoided.



... provides additional information or instructions that should be taken into consideration in relation to a given chapter of this operating manual.

3.2 Intended use

The I.E.M.-Terminal, also referred to as the eConnect, is an additional device for telemedical systems. It is used to receive measurement data from external Bluetooth® devices and forward them to a database anywhere in the world via GPRS.

This product can be used as a component in a telemetric application. I.E.M. GmbH points out that to transfer data completely and correctly to a telemetric application, services, performance characteristics and infrastructure ('Services') have to be contracted from external providers, e.g. telecommunication companies. I.E.M. GmbH cannot guarantee the punctual and local availability of the Services or the completeness,

accuracy and availability of the medical data that are recorded and forwarded with our products.

3.3 Indication and contraindication



Note the indications and contraindications of the medical products (measuring devices) that are connected to the **eConnect**.

As the **eConnect** is only a supplementary device for remote medical systems, it does not have any inherent medical indications or contraindications.

3.4 Power supply



WARNING!

Risk of fire if power supply defective or connected improperly!

- The use of other power supply units than the one supplied with the product may present a greater risk of fire!



NOTE!

Damage to **eConnect**!

- Only use the power supply unit supplied to avoid damage to the **eConnect**.
- To supply the **eConnect** with power, only use the 12V power supply unit (AC/DC adapter) included with the product.
- The use of any other power supply unit not included with the product will invalidate any warranty entitlements relating to the **eConnect**.

3.5 Electric fields



WARNING!

Danger presented by electric fields!

- The use of a power supply unit other than that supplied may result in elevated electromagnetic radiation and impair electrical safety!

Errors may arise in the data transfer if the device is operated in the vicinity of strong electrical fields. Do not perform any data transfers near:

- High-voltage power lines
- Microwave devices

For your safety

Portable and mobile high frequency transmitters, such as mobile phones, may affect data transmission.

Transmission of data via mobile communication networks may be disrupted by other devices, even if those devices comply with the applicable transmission requirements specified by CISPR.

3.6 Operation



WARNING!

Danger as a result of humidity!

- Only use the **eConnect** in dry locations and avoid direct contact with water. The **eConnect** is not watertight.



WARNING!

Risk of data loss if power supply is disconnected!

- The **eConnect** should remain constantly connected to the power supply.



WARNING!

Danger caused by delayed data transmission

- Successful data transmission is dependent on external providers. A delayed transmission can therefore never be ruled out. Do **not** use **eConnect** with life preserving or life supporting medical products, as delayed data transmission might directly endanger the patient.



WARNING!

Risk of data loss if data connection is lost!

- The relevant source measuring device should always be relatively close to the **eConnect** to avoid data transmission errors.
- Please also note that the ranges of the measuring devices might differ.



NOTE!

Damage to **eConnect!**

- Only use the power supply unit supplied to avoid damage to the **eConnect**.

3.7 Ambient conditions



WARNING!

Risk of data loss where ambient conditions are not as specified!

- The operation of the **eConnect** under ambient conditions different to those specified may result in loss of data.
- Note the ambient conditions in the operating manual.
- The **eConnect** is designed to be used for domestic healthcare. It is not designed to be used in clinics, and its use near other medical devices, especially HF equipment, is forbidden. It is also not designed to be used in cars or aircraft, as no tests to this end have been conducted.
- Do not store or transport the **eConnect** outside a temperature range of +5 °C to +50 °C.

- Do not use the **eConnect** outside a temperature range of +5 °C to +40 °C.
- Only store, transport or use the **eConnect** at an air humidity (non-condensing) of 15% to 90%.
- Extreme temperatures or air humidity values may affect the performance of the **eConnect**.

4 Installation and initial operation

4.1 Unpacking



WARNING!

Risk of suffocation by the packaging material!

- Keep the packaging material out of the reach of children!
- 1) Unpack the entire shipment and check that everything is present.
 - 2) Inspect the **eConnect** to ensure there is no visible damage on the outside. In case of damage, have the **eConnect** repaired before use.
 - 3) Keep the packaging so that it can be used to safely package the **eConnect** at a later date.

4.2 Setting up

 **WARNING!**

Risk of injury by the PSU cable!

- Set up the **eConnect** so that there is no risk of injury from a PSU cable lying around!
- 1) Select a suitable installation location for the **eConnect**, ideally near a window.
 - 2) Alternatively, set up the **eConnect** at a location at which your mobile telephone has good reception.
 - 3) Select an installation location at which the **eConnect** is not exposed to any strong electric fields.
 - 4) Keep moisture away from the **eConnect**.
 - 5) Set up the **eConnect** so that it can be isolated from the mains and power supply voltage at any time.

4.3 Installation and preparation for use

 **WARNING!**

Danger presented by improper preparation for use

- The **eConnect** must not be operated directly adjacently to other devices or stacked on top of each other, as doing so may result in malfunction! However, if it becomes necessary to operate the device in the manner described above, this device and the other devices should be monitored to ensure that they are functioning correctly.

 **WARNING!**

Danger presented by improper preparation for use

- Keep the **eConnect** at least 30 cm (12 inches) away from other devices that emit radio waves (e.g. mobile telephones).
- Portable HF communication devices (radios, including accessories thereof such as antenna cables and external antennas) should not be used within a range of 30 cm (12 inches) of the **eConnect's** parts and cables as identified by the manufacturer. Failure to comply with this may result in impairment of the device's performance.

The **eConnect** as shipped is pre-configured and ready to use.

- 1) First connect the supplied power supply unit to the PSU connector on the **eConnect**.
- 2) Then connect the power supply unit to a corresponding power source (wall socket).
- 3) During initialisation, the LEDs "**BT**", "**Mobile communication**" and "**System**" will light up yellow simultaneously in succession.
- 4) The **eConnect** is ready to use as soon as the "**System**" LED is continuously lit green and the LEDs "**BT**" and "**Mobile communication**" go out.

4.4 Bluetooth®

The **eConnect** and the measuring devices communicate with one another via a Bluetooth® connection.

The measuring device connects automatically to the **eConnect**.

i

The one-time acquisition of the default settings required for communication ("pairing") will normally already have been performed before the products are shipped.

However, should it become necessary to perform the pairing anew, this must only be done with the guidance and support of a service provider or the manufacturer

5 Operation

5.1 LED status information

The three LEDs "**BT**", "**Mobile communication**" and "**System**" show you different information on the status of the **eConnect**.

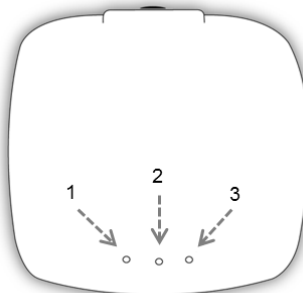


Fig.. 3: eConnect – Top

1 BT 2 Mobile comm. 3 System

Operation

The following information is indicated by the relevant LED:

LED	Colour	Status information
BT	Yellow, flashing	Initialisation when started
	Blue	Bluetooth® connection/ data transmission
	Yellow	Warning
	Red	Error in Bluetooth® module
Mobile communications network	Yellow, flashing	Initialisation when started
	Green	Mobile connection/ data transmission
	Yellow	Warning
	Red	Error in mobile communication module
System	Yellow, flashing	Initialisation when started
	Green	System ready for operation
	Yellow	Warning
	Red	Error

5.2 Transferring the measurement values

The **eConnect** is functional as soon as the “**System**” LED lights up green.

The regular data transmission procedure from the measuring device to the **eConnect** and the process of forwarding data from there is as follows:

- 1) Check whether the “**System**” LED on the **eConnect** is lit green.
- 2) Start a measurement with your measuring device.
- 3) After the measurement, a Bluetooth® connection between the measuring device and the **eConnect** is established.
- 4) The “**BT**” LED on the **eConnect** is lit blue.
- 5) The measurement data is transferred from the measuring device to the **eConnect**.
- 6) The **eConnect** establishes a connection to the mobile communication network.
- 7) The “**Mobile communication**” LED lights up green.
- 8) Your measurement data is being transferred to the external database by the **eConnect**.
- 9) After data transmission, the “**BT**” and “**Mobile communication**” LEDs go out.

- 10) The “**System**” LED lights up green. The **eConnect** is ready for the next measurement. The **eConnect** remains in operation.

5.3 Malfunctions

If there is a malfunction during operation, the malfunction will be indicated via the corresponding LED on the **eConnect**.

The “**BT**”, “**Mobile communication**” and “**System**” LEDs indicate malfunctions with the colours yellow or red.

The colour yellow indicates a warning. Warnings are errors deemed to be temporary. Example: The mobile communication reception is poor. Data transmission is taking too long.

The colour red indicates specific errors deemed to be permanent. Example: The Bluetooth® module is not responding.

Please refer to chapter 6 “Error descriptions” for detailed descriptions of errors, possible causes and remedies.

5.4 SIM card



WARNING!

Risk of data loss when changing SIM card!

- Changing the SIM card without being instructed to do so may cause data transmission problems and result in data loss!

The SIM card is usually included in the shipment. It contains information needed to establish a connection with the mobile communications network, which is required to transfer measurement data.

The SIM card is normally already inserted into the terminal when the **eConnect** is shipped and ordinarily should not need to be removed or replaced by the customer.

However, should it become necessary to replace the SIM card, this must only be done with the guidance and support of a service provider or the manufacturer.

5.5 Transferring the measured values via mobile communications network

If the **eConnect** is configured for transmission of the measured values via a mobile communications network, the measured values will be automatically transferred to an external database.

Operation

If previous measurement transmissions have not yet been completed, all data not yet sent will be sent together.

6 Error descriptions

Where a malfunction arises, the following table may be useful to you for troubleshooting purposes:

Error description	Cause	Remedy
<p>The eConnect does not start up.</p> <p>The "BT", "Mobile communication" and "System" LEDs do not light up.</p>	<p>The power supply unit is not connected or has been improperly connected.</p>	<p>Check whether the power supply unit is correctly connected to the eConnect and the power supply.</p> <p>Reconnect the eConnect to the power supply unit before inserting the power supply unit into the mains socket.</p>
<p>Once switched on, the LEDs do not stay lit.</p>	<p>Problem with the electronics or internal software</p>	<p>Pull the power supply unit out of the mains socket, wait for 10 seconds, then insert the power supply unit back into the mains socket.</p> <p>If the error still occurs, cease using the eConnect. Contact your service provider or specialist dealership.</p>
<p>A connection between the measuring device and eConnect cannot be established.</p> <p>The "BT" LED does not light up blue.</p>	<p>Error connecting via Bluetooth®</p>	<p>Pull the power supply unit out of the mains socket, wait for 10 seconds, then insert the power supply unit back into the mains socket.</p> <p>Perform another measurement.</p> <p>If the error still occurs, cease using the eConnect. Contact your service provider or specialist dealership.</p>

Error descriptions

Error description	Cause	Remedy
<p>The eConnect cannot establish a connection to the mobile communications network.</p> <p>The “Mobile communication” LED lights up yellow.</p>	<p>Error connecting via mobile communications network</p>	<p>Select another location to operate the eConnect at. Set up the eConnect elsewhere, for instance in another room, near a window. Perform another measurement. If the error still occurs, cease using the eConnect. Contact your service provider or specialist dealership.</p>
<p>The eConnect shows a warning. The “BT” or “System” LED lights up yellow.</p>	<p>Problem with data transmission, the electronics or internal software</p>	<p>Pull the power supply unit out of the mains socket, wait for 10 seconds, then insert the power supply unit back into the mains socket.</p> <p>Perform another measurement.</p> <p>If the error still occurs, cease using the eConnect. Contact your service provider or specialist dealership.</p>
<p>The eConnect shows an error. The “BT”, “Mobile communication” or “System” LED lights up red.</p>	<p>Problems with the electronics or internal software.</p>	<p>Pull the power supply unit out of the mains socket, wait for 10 seconds, then insert the power supply unit back into the mains socket.</p> <p>If the error still occurs, cease using the eConnect. Contact your service provider or specialist dealership.</p>

If the above remedies do not help to eliminate the malfunction, please contact your service provider or specialist dealership.

7 Care and maintenance

WARNING!

Risk of damage from water penetration!

- Switch the device off and disconnect the power supply unit.

Only clean the **eConnect** when it is switched off. To do this, remove the power supply unit. Liquid must not penetrate the device. If liquids do happen to enter the **eConnect**, contact your retailer or the manufacturer without delay.

Use a damp cotton cloth to wipe off the **eConnect** as necessary. Dampen the cotton cloth with lukewarm water only, possibly adding a mild detergent. Never use chemical solvents or detergents, as these can damage the surface of the **eConnect**.

The **eConnect** and the power supply unit should be submitted for a safety inspection at least every two years. In this case, disconnect the **eConnect** from the power source to safely shut it down. Send the device with the power supply unit back to the manufacturer in the original packaging.


8 Disposal

NOTE!

Environmental damage if disposed of incorrectly!

- Electrical scrap and electronic components have to be treated as hazardous waste.



The  symbol on the product or packaging means that this product should not be treated as normal domestic waste, but has to be passed to a recycling point for electric and electronic devices.

You can find out more about this from your local authority, the communal disposal companies or the shop in which you bought the product.

9 Technical data and symbols

Technical data:

Specification	Value	Unit
Memory	30	records
Power supply	12V mains PSU	
Data connection (1)	Mobile communications network	
Data transmission (1)	GSM, GPRS	
Data connection (2)	Bluetooth®	
Data transmission (2)	Bluetooth Classic, Bluetooth Low Energy	
Dimensions (L x W x H)	104 x 107 x 36	mm
Weight	111	g
Material	ABS (acrylonitrile-butadiene-styrene)	
IP protection class	20	
Operating temperature	+5 to +40	°C
Transport temperature	+5 to +50	°C
Storage temperature	+5 to +50	°C
Air humidity, not condensing (operation, transport and storage)	15 to 90	%
Air pressure (operation, transport and storage)	700 to 1060	hPa

The **eConnect** is compliant with the EMC guidelines, see chapter 12 "Manufacturer's EMC guidelines".

Power supply:












NOTE!

Damage to **eConnect!**

- Only use the power supply unit supplied to avoid damage to the **eConnect**.
-
- **Type:** Mains PSU
 - **Primary (AC):** Standard 230 V ~50 Hz / Universal Version 90–264 V, 47–63 Hz
 - **Secondary (DC):** 7–12 V, 6 W

Symbols

Symbol	Meaning
	Manufacturer in accordance with Directive 93/42/EEC
	Date of manufacture (YYYY-MM)
	CE: Labelling of a medical device in accordance with Directive 93/42/EEC
	Bluetooth designation. Bluetooth is a registered trademark of Bluetooth SIG, Inc.
	Protect from rain and moisture
	Comply with the operating manual
	The symbol on the product or packaging means that this product should not be treated as normal domestic waste, but should be passed to a recycling point for electric and electronic devices. You can find out more about this from your local authority, the communal disposal companies or the shop in which you bought the product.
	Non-ionizing electromagnetic radiation
	Mandatory – Consult Directions for Use

10 Standards

The device complies with the specifications of EU Directive 93/42/EEC for medical products and with the national laws on medical products.

The requirements of the directives 2014/53/EU (RED) and 2002/95/EG (RoHS) have been complied with.

The **eConnect** visibly bears the CE mark.

11 Warranty and repairs

Warranty information

- **I.E.M. GmbH** provides a two-year warranty on the **eConnect** from the date of sale. The date of sale must be demonstrated using the invoice or receipt.
- Faults due to material or production defects shall be remedied free of charge within the warranty period by way of repair or replacement.
- A warranty claim does not result in an extension of the warranty period, neither for the product nor for the replaced components.
- The following are excluded from the warranty:
 - All damage caused by improper handling, e.g. as a result of failing to comply with the operating manual.

- Damage resulting from maintenance or intervention by the purchaser or unauthorised third parties.
- Accessories subject to normal wear and tear.
- Liability for direct or indirect consequential damages caused by the device is excluded even in the event that the damage to the device is acknowledged as a warranty case.
- Any further claims, irrespective of the cause, are excluded.

I.E.M. GmbH does not grant any warranty on the power supply unit provided.

Repair conditions

When claiming on the warranty, please contact our customer service, which will inform you about the terms of repair and shipment procedure.

12 Manufacturer's EMC guidelines

Electromagnetic interference emissions

The **eConnect** is designed for operation in an electromagnetic environment as specified below. Only use the **eConnect** in such an environment.

Measurement of interference emissions	Compliance	Electromagnetic environment – guidelines
HF interference emissions according to CISPR 11	Group 1	The eConnect utilises HF power for its internal function only. Its HF emission is therefore very low and it is improbable that any neighbouring electronic devices will experience any interference.
HF interference emissions according to CISPR 11	Class B	The eConnect is designed to be used in areas where healthcare is administered at home, where there is a direct connection to a public mains power supply that also supplies buildings used for residential purposes.
IEC 61000-3-2	Class A	
IEC 61000-3-3	Compliant	

Electromagnetic immunity

The **eConnect** is designed for operation in an electromagnetic environment as specified below. Only use the **eConnect** in such an environment.

Measurement of interference emissions	IEC 60601-1 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) in accordance with IEC 61000-4-2	±/- 8kV contact discharge ±/- 15kV air discharge	±/- 8kV contact discharge ±/- 15kV air discharge	Floors should consist of wood or cement or ceramic tiles. If the floor consists of synthetic materials, relative humidity must be at least 30%.
IEC 61000-4-4		Not applicable	
IEC 61000-4-5		Not applicable	
IEC 61000-4-11		Not applicable	
Magnetic field at supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at mains frequency should match the typical values found in business and hospital environments.
Radiated RF interference in accordance with IEC 61000-4-3	380 - 390 MHz 27 V/m; PM 50%; 18 Hz 430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz Sinus) PM; 18 Hz	380 - 390 MHz 27 V/m; PM 50%; 18 Hz 430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz Sinus) PM; 18 Hz	

Manufacturer's EMC guidelines

Measurement of interference emissions	IEC 60601-1 test level	Compliance level	Electromagnetic environment – guidelines
	704 - 787 MHz 9 V/m; PM 50%; 217 Hz	704 - 787 MHz 9 V/m; PM 50%; 217 Hz	
	800 - 960 MHz 28 V/m; PM 50%; 18 Hz	800 - 960 MHz 28 V/m; PM 50%; 18 Hz	
	1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz	1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz	
	2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz	2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz	
	5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	

NOTE 1: The higher frequency range applies to 80 MHz and 800 MHz.

NOTE 2: These guidelines may not apply in all cases. The distribution of electromagnetic variables is influenced by the absorption and reflection of buildings, objects and people.

The field intensity of stationary transmitters such as base stations of wireless telephones and mobile terrestrial radios, amateur radio stations, AM and FM radio and TV transmitters cannot be accurately theoretically determined in advance.

In order to determine the electromagnetic environment in relation to stationary transmitters, a study of the location should be considered. If the measured field strength at the location where the **eConnect** is used exceeds the upper compliance level, the **eConnect** should be kept under observation to ensure that it functions correctly. If it is observed to be performing unusually, additional action may be necessary, such as changing the orientation or location of the **eConnect**.

Recommended safety distances between portable and mobile HF telecommunication devices and the eConnect

The **eConnect** is designed for operation in an electromagnetic environment in which disturbance variables are controlled. Maintain the minimum distances between portable and mobile telecommunication devices (transmitters) and the measuring device as specified below, depending on the output of the communication device.

Frequency bands

Safety distance in relation to transmission frequency in m			
Nominal output of transmitter P in W	80 MHz to 800 MHz $d = 1.2 * \sqrt{P(W)}$	800 MHz to 2.5 GHz $d = 2.3 * \sqrt{P(W)}$	150 kHz to 80 MHz
0.01	0.12	0.23	Not applicable
0.1	0.38	0.73	Not applicable
1	1.2	2.3	Not applicable
10	3.8	7.3	Not applicable
100	12	23	Not applicable

The recommended protection distance (d) can be calculated in metres (m) for transmitters whose maximum rated output is not specified in the table above. To do so, use the equation for the column in question, where P is the maximum rated output of the transmitter.

NOTE 1: The higher frequency range applies to 80 MHz and 800 MHz.

NOTE 2: These guidelines may not apply in all cases. The distribution of electromagnetic variables is influenced by the absorption and reflection of buildings, objects and people.

13 Frequency bands

The mobile communication module of the **eConnect** uses the following frequency bands:

Band designation	Range (transmission)	Range (reception)	Maximum transmission power
GSM 850	824 to 849 MHz	869 to 894 MHz	2 Watt GSM and GPRS
E-GSM 900	880 to 915 MHz	925 to 960 MHz	2 Watt GSM and GPRS
DCS 1800	1710 to 1785 MHz	1805 to 1880 MHz	1 Watt GSM and GPRS
PCS 1900	1850 to 1910 MHz	1930 to 1990 MHz	1 Watt GSM and GPRS