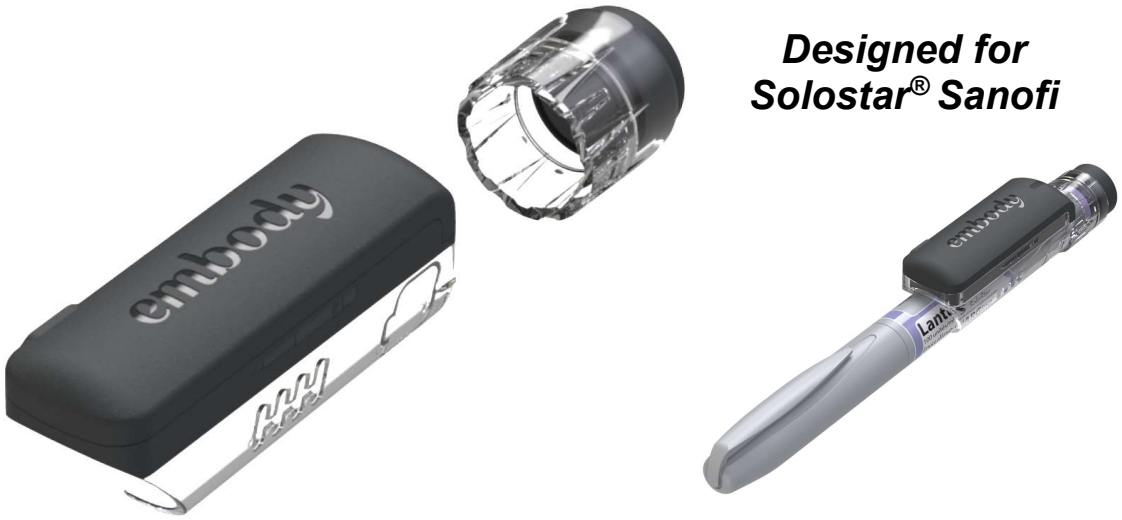
01-2021

Instructions For Use

embody



Designed for Solostar® Sanofi

Embedded software versions 3.6. and over

embody medical device

BIOCORP

Helping you keep track of your insulin doses

TABLE OF CONTENTS

TABLES LIST

SYMBOLS USED IN THIS MANUAL

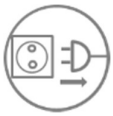
SYMBOL	MEANING	EXPLANATION
	**WARNING**	Improper operation may result in serious injury*1 or death to the user, patient
	CAUTION	Improper operation may result in bodily injury*2 or property damage*3
	**CAUTION**	Disconnect the device from power supply before servicing/cleaning
	NOTE	Important information for operation

Table 1 - Symbols used in IFU

*1 Serious injury means electrical shock or poisoning that causes a subsequent complication or requires hospitalization or long-term outpatient treatment.
*2 Bodily injury means an injury, burn, electrical shock and so on that will not necessitate hospitalization or long-term outpatient treatment.
*3 Damage to property means extensive damage to a house and/or household goods as well as a domestic animal and pet.

ABBREVIATIONS LIST

Abbreviation	Definition
PN	Part Number
SN	Serial Number
LED	Light indicator (Light Emitting Diode)
IP	Ingress Protection
BLE	Bluetooth Low Energy

Table 2 - Abbreviations list

FC STATEMENTS (US)

EMBODY
Model: 0273790-SLST
FCC ID: 2AYCW-EZL

CAUTION:

- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- The user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- This device complies with FCC radiation exposure limits set forth for general population. This device must not be co-located or operating in conjunction with any other antenna or transmitter.

NOTE:
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception which can be determined by turning the equipment off and on, the user is encouraged to try to correct interference by one or more of the following measures:
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

IC STATEMENTS (CANADA)

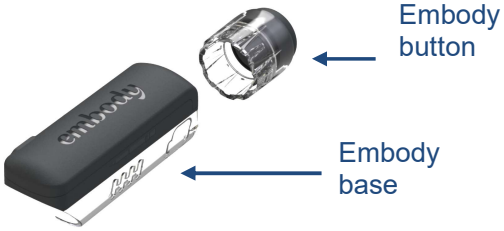
EMBODY
Model: 0273790-SLST
IC: 26747-EZL

CAUTION:

- This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) This device must accept any interference, including interference that may cause undesired operation of the device.
- This device complies with ISED radiation exposure limits set forth for general population. This device must not be co-located or operating in conjunction with any other antenna or transmitter.

Device features

The EMBODY device is composed of a base and a button that can be mounted on an insulin pen.



The EMBODY device allows you to:
- Signal the end of an injection,
- Record the injected selected increment (insulin dose),
- Record the day and time when each insulin dose was injected,
- Transmit the dose, day/time of when each insulin dose was injected, to a compatible mobile application on a smartphone, when the EMBODY device is paired to it, thanks to Bluetooth technology.

Pairing the EMBODY device with a compatible mobile application (autonomous software installed on a smartphone) will allow you to:
- Improve adherence to your insulin treatment. EMBODY will allow you to keep accurate records of your insulin injections (dose, day/time of the injection),
- Generate a report showing the injected doses for a given period,
- Store and share your data with a healthcare provider.

You can also use EMBODY in an autonomous mode (without a mobile application) to:
- Signal the end of your injections

In this case, data cannot be displayed and cannot be shared with another person.

Intended use

EMBODY is intended to be used for the capture and wireless transmission of dosing information from compatible pen injectors.

Intended users

The intended users of the EMBODY device are patients with type I and II diabetes. EMBODY is a reusable device intended for a single patient.

Usage environment

The EMBODY device is intended for use in a medical office or at home.

Healthcare data protection

The terms of the regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 may apply to the interactions between Biocorp Production and users of its products.
To this end, Biocorp Production agrees to comply with its obligations in accordance with the regulation applicable to Personal data protection and makes every effort to guarantee the security, confidentiality, and integrity of the Personal data that it may process.
A user has the right to access their data, rectify them, request their deletion, or exercise their right to limit the processing of such data. They may withdraw their consent to the processing of such data at any time; they may also object to the processing of their data and exercise their right to the portability of such data. To exercise these rights, please contact: gdpr@biocorp.fr
If a user considers, after having contacted Biocorp Production, that their Data Protection and Privacy rights have not been respected or that the access control provision does not comply with data protection rules, such user may file a claim online or by mail with the relevant national data protection authority.

1. GENERAL INFORMATION

BIOCORP PRODUCTION
ZI LAVAUR LA BECHADE
63500 ISSOIRE
CEDEX – FRANCE

DISTRIBUTOR:
See list at the end of leaflet

The user manual must be accessible to you at all times. You must read all instructions carefully before using the device.

If you have technical problems with our product, please contact a BIOCORP PRODUCTION authorized dealer.

The following information will be needed in order to provide you with the necessary assistance:

- **Serial Number of your EMBODY unit** (this **SN** number can be found on the device label)

2. EMBODY COMPATIBILITIES – MOLECULES AND CONCENTRATIONS

WARNING

Make sure EMBODY is compatible with your pen (insulin type and concentration).

The molecules and associated concentrations compatible with the EMBODY device are listed in the table below:

EMBODY MODEL	INSULINE INN	CONCENTRATION	WARNING EXCLUDED VERSIONS EMBODY IS NOT COMPATIBLE WITH THE FOLLOWING INSULIN PENS:
EMBODY designed for **SOLOSTAR®** **SANOFI** insulin pen	GLARGINE	100 IU/mL	
		300 IU/mL	Toujeo Max Toujeo Doublestar
	LISPRO	100 IU/mL	
	GLULISINE	100 IU/mL	
	GLARGINE AND LIXISENATIDE	100 IU/mL +33 mcg/mL	

Table 3 - EMBODY compatibilities – Molecules and concentrations

3. DEVICE DESCRIPTION AND EXAM ENVIRONMENT

3.1 DEVICE DESCRIPTION

3.1.1 EMBODY CHARACTERISTICS

The EMBODY device is composed of a base and a button:

BASE	BUTTON
	

3.1.2 ESSENTIAL PERFORMANCES OF THE SYSTEM (SIGNIFICANT OPERATING CHARACTERISTICS)

The essential performance characteristic for the EMBODY device has been defined as follows:
Provide reliable data dosage parameters of a drug to the patient and caregivers.
The device sends treatment information via Bluetooth (BLE) to the patient's smartphone:

- Injected Insulin Dosage (UI)
- Injection Date
- Injection Hour

A compatible mobile application allows the patient to securely display treatment information. This improves the patient's therapeutic adherence.

3.1.3 EMBODY PARTS REFERENCES

The references (Part Numbers) vary depending on the EMBODY model:

EMBODY MODEL	EMBODY BASE *APPLIED PART*	EMBODY BUTTON *APPLIED PART*
EMBODY designed for **SOLOSTAR® SANOFI** insulin pen	 **PN : 0273790**	 **PN: 0273710**

Table 4 - EMBODY parts numbers

The following parts are necessary to operate the EMBODY device:

USB CABLE	RESET KEY
	
PN: 0373707	PN: 0373708

Table 5 - Parts necessary for operation

3.2 WEIGHT AND SIZE OF THE MAIN ELEMENTS

ELEMENT	WEIGHT	INSULIN PEN	SIZE
EMBODY base	0,016 kg	SOLOSTAR®	**(60.8x26.9x21.3) mm**
EMBODY button	0,006 kg	SOLOSTAR®	**(24.4 x Ø20) mm**
EMBODY total weight	0,022 kg	-	-

Table 6 - Weight and size of the main elements

4. SAFETY INFORMATION

4.1 SYMBOLS ON THE DEVICE AND / OR ITS PACKAGING

SYMBOL	LOCATION	DESCRIPTION
	DEVICE AND PACKAGING	Refer to the instructions for use
	DEVICE AND PACKAGING	Manufacturer
	DEVICE AND PACKAGING	Serial Number
	DEVICE AND PACKAGING	Manufacturing date
	PACKAGING	Batch Number
	PACKAGING	International and unique item code (**G**lobal **T**rade **I**tem **N**umber)
	DEVICE AND PACKAGING	Product reference

Table 7 - Symbols on the device and its packaging

SYMBOL	LOCATION	DESCRIPTION
	DEVICE	**US** - Operation is subject to the following 2 conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
	DEVICE	**CANADA** - Innovation, Science and Economic Development Canada certification number (certification class A/B – intentional radiator)
	PACKAGING	Distributor reference
	PACKAGING	**Class II** device (double isolation)
	PACKAGING	**Type BF** applied part
	PACKAGING	Protection index IP22 (see ***section 9.3.: maintain water, dust and light resistance***)
	PACKAGING	For indoor use only
	PACKAGING	Moisture sensitive device
	PACKAGING	Temperature limits to which the device can be safely exposed.
	PACKAGING	Humidity limits to which the device can be safely exposed.
	PACKAGING	Pressure limits to which the device can be safely exposed.
	PACKAGING	Management of electrical and electronic waste.

Table 8 - Symbols on the device and its packaging (next)

4.2 WARNINGS AND CAUTIONS

NOTES:

- EMBODY must only be used for the **intended use** described in this manual.
- **Read these instructions before you use EMBODY** for the first time. Keep these instructions in a safe place.
- The device must be used in the **specified ambient conditions** (do not expose the device to temperatures above 40°C (104°F) or flames).
- If the device experiences an external **mechanical impact** (knocking, bumping, dropping, etc.), this may cause malfunctioning of the device. In case of malfunctioning, please contact a BIOCORP PRODUCTION authorized dealer for technical support.
- Never install a mobile application from **unofficial stores** on your phone.
- Using a phone of **unknown origin** causes risk and will invalidate the EMBODY warranty.
- Protect your **personal health data** by using a password on your smartphone.
- Periodic maintenance of EMBODY is not required, only **daily inspection** is recommended. Maintenance of the EMBODY is required when the device does not pass its functional testing. If the functional testing is not successful, you are prompted to contact a BIOCORP PRODUCTION authorized dealer.

WARNING

- **If you are not certain that you injected your insulin, do not start or repeat your injection. Monitor your blood glucose as instructed by your healthcare provider.**

- **Disconnect the USB cable from the USB charging port and disconnect EMBODY from the USB cable before using it.**

- EMBODY is supplied with a **USB cable.** Do not use any other cable. Use the cable supplied with the device to connect it to a USB power port.
- Do not attach or tighten cable to or around the head or neck. Cable can cause **strangulation**.
- Avoid using near **PACEMAKERS and DEFIBRILLATORS.**
- EMBODY contains a **magnet**, avoid contact with metallic parts during use.
- This device is not recommended for use by the **blind** or **visually impaired** without the help of someone trained to use the device.
- Do not disassemble, modify or repair the device by yourself. Otherwise, it may cause fire, electrical shock, bodily injury, or device malfunction. Refer all **servicing** to your authorized BIOCORP PRODUCTION dealer. The instrument disassembled, modified or repaired by anyone other than a BIOCORP PRODUCTION designated repair facility will invalidate the warranty.
- If there is any abnormal smell, sound, heat, or smoke when using the device, stop using EMBODY. Continued use may cause **fire** or device malfunction. Contact your authorized BIOCORP PRODUCTION dealer for inspection.
- EMBODY is **not waterproof** and will not be protected against the infiltration of water or moisture:
  - ✓ Do not immerse the device in water and do not clean it under running water.
  - ✓ Do not expose the device to moisture.
- Do not place EMBODY in a **microwave**.
- Do not operate the device in a hazardous environment: presenting a **risk of explosion**, or containing volatile solvents (alcohol, etc.) or flammable substances (anaesthetics, etc.); or do not place it in the vicinity of an environment rich in OXYGEN.
- **Small Children:** Do not leave your EMBODY and its accessories within the reach of small children or allow them to play with it. They could hurt themselves or others or could accidentally damage the device. Your EMBODY contains small parts with edges that may cause injuries or may detach and create a **choking** hazard.
- **Animals or insects:** Do not leave your EMBODY and its accessories within the reach of animals or insects. After use, your device must then be put away in its original packaging.
- The use of accessories other than those specified for the device is not recommended. They may result in increased emissions or decreased **electromagnetic immunity** of the device.

4.3 ELECTRICAL SAFETY

EMBODY is supplied with a USB cable. Do not use any other cable. Use the cable supplied with the device to connect it to a USB power port.

CAUTION

Connect the EMBODY USB cable to a power source compliant with the **IEC 60601-1.**

4.4 COMPLIANCE WITH STANDARDS / REGULATION AND CLASSIFICATIONS

COMPLIANT STANDARDS	DESCRIPTION	CLASSIFICATION
IEC 60601-1	• Protection type against electric shock	**Class II** (double isolation)
	• Degree of protection against electric shock	Type **BF**
	• Mode of operation	Continuous operation
IEC 60601-1-2	• Electromagnetic compatibility	* Refer to EMC ***section 11***
IEC 60529	• Type of protection against the access to hazardous parts and the infiltration of water as detailed in the current edition of IEC	**IP22**

Table 9 - Mains standards & classification

4.5 EMBODY BASE AND BUTTON LABELING

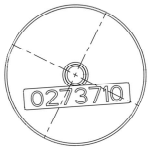
EMBODY TYPE	US / CA	BASE LABELING	BUTTON MARKINGS (INSIDE)
EMBODY designed for **SOLOSTAR® SANOFI** insulin pen	**US**		
	CA		

Table 10 - EMBODY base and button labeling

NOTE:
The part number and serial number of the device can also be found on the packaging accompanying the device.

4.6 TRANSPORT AND STORAGE CONDITIONS

	Temperature	Atmospheric pressure	Relative humidity
Transport	–10°C to +40°C **(14°F < T° < 104°F)**	500 hPa to 1060 hPa	10% to 90%
Storage	–10°C to +40°C **(14°F < T° < 104°F)**	800 hPa to 1060 hPa	10% to 90%

Table 11 - Transport and storage conditions

CAUTION

- The device must be transported and stored in its original packaging designed to protect it from damage.
- Storage and transport conditions must meet conditions described in the above table.

4.7 USAGE CONDITIONS

	Temperature	Atmospheric pressure	Relative humidity
Operating	+15°C to +35°C **(59°F < T° < 95°F)**	800 hPa to 1060 hPa	30% to 70%

Table 12 - Usage conditions

CAUTION

- Leave the device in a room for 30 minutes before unpacking to ensure there is no condensation.

4.8 DISPOSAL

Dispose of EMBODY according to your local guidelines.

According to Directives **2012/19/UE WEEE** and **2011/65/UE RoHS II** on the restriction of hazardous substances in electrical and electronic equipment on their disposal:
Public authorities adopt adequate measures to make sure that users, distributors and manufacturers contribute to the collection of electrical and electronic equipment, setting legal requirements to reuse, recover or recycle the said equipment.

CAUTION

You must take into account the potentially harmful effects to the environment or human health due to the improper disposal of the equipment or of parts of it.

The following graphic symbol is applied on the label of the equipment:

It reminds that all electrical and electronic equipment must be collected and disposed of separately from domestic waste at the end of life.

CAUTION

Before disposing of EMBODY: reset the device to delete all your personal health data (see ***section 8.2.***)

5. UNPACKING AND INSTALLING EMBODY (CHARGING / CALIBRATING / ASSEMBLING / PAIRING)

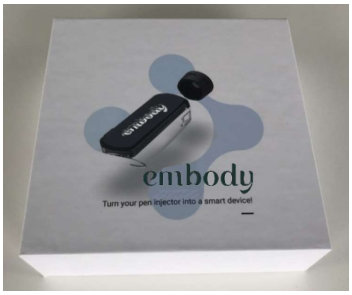
CAUTION

- **EMBODY can only be paired with a compatible mobile application.**
- **EMBODY is only compatible with the insulin pens:**
  - ✓ Solostar® **Sanofi** (except for **TOUJEO® MAX and TOUJEO® DOUBLESTAR**)

Refer to **section 2 – EMBODY compatibilities – Molecules and concentrations**

5.1 UNPACKING YOUR EMBODY AND ITS ACCESSORIES

5.1.1 PACKAGE CONTENTS



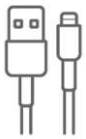
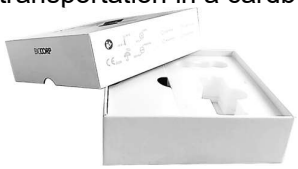
EMBODY base **(x1)**		EMBODY button **(x 2)**	
USB Cable **(x 1)**		Reset Key **(x 1)**	
Quick Start Guide with reference: **QSG_EMB_EN (x 1)**			

Table 13 - Package content

5.1.2 UNPACKING

➢ **STEP 1 – Open the EMBODY shipping box**

EMBODY is packed for shipping / transportation in a cardboard box:



The internal cardboard housing with special shaped forms and cardboard parts supports the EMBODY base and the button.

NOTES:

- After opening, keep all the original packaging for future use (in case of return or transport of the device). The device must always be transported in its original packaging, which has been specially designed to protect it from damage.
- Check whether the packaging is damaged. If damage is found, the device may also have been damaged. Please contact your distributor.

➢ **STEP 2 – Remove from the box: the base, the button and the accessories**

You can get EMBODY free support @ *my-EMBODY.com*

5.2 CHARGING AND CALIBRATING YOUR EMBODY

5.2.1 CHARGING YOUR EMBODY

NOTE:
EMBODY must be charged before first-time use.

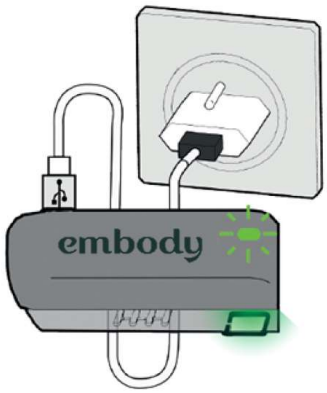
CAUTION

- EMBODY is supplied with a USB cable. Do not use any other cable. Use the cable supplied with the device to connect it to a USB power port.
- Never use your EMBODY for an injection while it is connected to a USB power port and charging.

5.2.1.1 Plug the powered USB cable into the EMBODY micro-USB port.

5.2.1.2 Check that the EMBODY LED is slowly flashing **green**.

5.2.1.3 Let the battery charge for at least **10 minutes.**



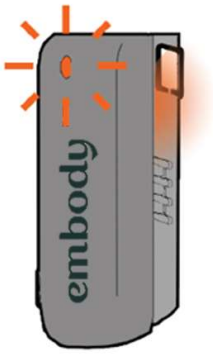
NOTES:

➢ Fully recharging the battery takes approximately 2 hours. When the battery is fully charged, the **green** LED will turn off. You can then unplug the USB power cable.

➢ Optimal autonomy is reached when EMBODY's battery is fully charged. You can then use EMBODY for at least 2 weeks.

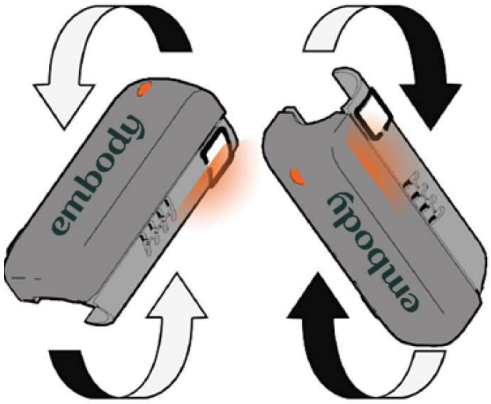
5.2.2 CALIBRATING YOUR EMBODY

5.2.2.1 Disconnect the USB cable from the EMBODY base.



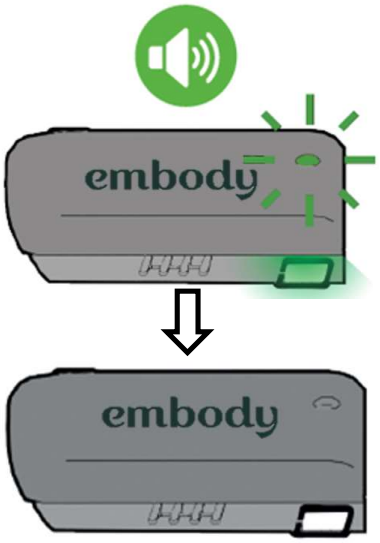
5.2.2.2 Check that the EMBODY LED is flashing **orange**.

5.2.2.3 **Slowly** tilt the EMBODY base side to side to **CALIBRATE**.



5.2.2.4 **Continue tilting until:**

- ✓ The base beeps and the LED light turns **green**.
- ✓ Then the light will turn off.



NOTE:
If the **orange** LED does not light up after disconnecting the USB cable from the EMBODY base, it means that the calibration was done automatically. You can go directly to the next section:
Section 5.3. Assembling your EMBODY to the insulin pen.

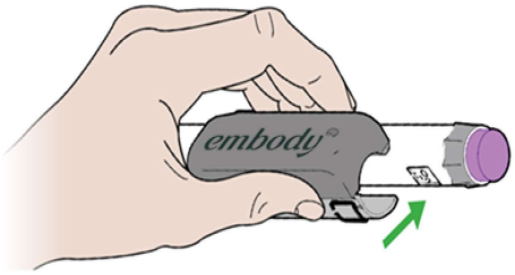
5.3 ASSEMBLING YOUR EMBODY TO THE INSULIN PEN

CAUTION

The EMBODY base and button must be correctly attached onto the pen, otherwise, data will not be transferred.

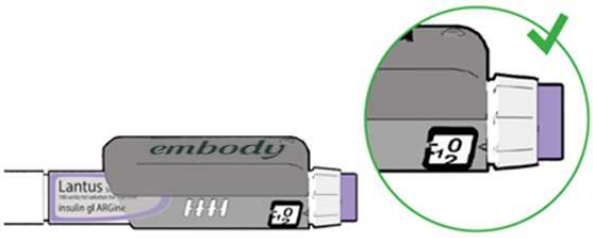
5.3.1 ATTACHING BASE TO PEN

5.3.1.1 Hold the EMBODY base so that the clear square plastic window is facing you



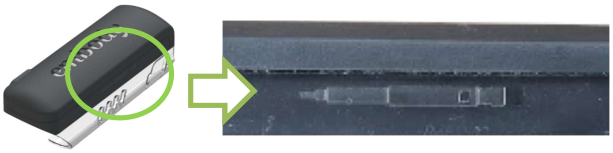
5.3.1.2 Align the EMBODY base clear square plastic window with the pen dose window, then snap the base onto the pen.

5.3.1.3 Make sure the EMBODY base window is perfectly aligned with the pen dose window.



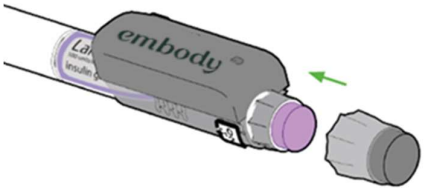
NOTE:

A pen symbol is represented on the side of the EMBODY base to help you position the pen in the correct orientation (square window oriented toward the top of the pen).

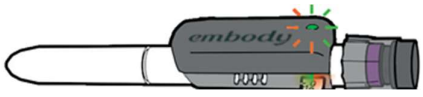


5.3.2 ATTACHING BUTTON TO PEN

5.3.2.1 Align the EMBODY button's grooves with the dose injection button's notches, then insert the EMBODY button onto the pen injection button. Make sure the button is properly attached and fully inserted.



5.3.2.2 The EMBODY base LED will flash orange and green when the button and base are properly mounted onto the pen and when the EMBODY device is not yet paired.



5.4 OPERATING IN AUTONOMOUS MODE OR IN PAIRING MODE

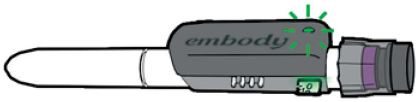
EMBODY can:

- **Either operate in autonomous mode**:
  In this case, data cannot be displayed and cannot be shared with another person.

Or

- **Be paired with a compatible mobile application** (an autonomous software installed on a smartphone).
  In this case, please follow the application manufacturer's instructions to pair EMBODY and use the application.

  When EMBODY is paired and correctly attached to the injector pen: the LED is **green.**



In pairing mode: EMBODY will track your activities

CAUTION

EMBODY must only be paired with a compatible application

6. OPERATING INSTRUCTIONS

NOTE:
Once EMBODY is attached to the insulin pen, the pen should be used just like a normal insulin pen. Refer to the manufacturer's injector pen user manual.

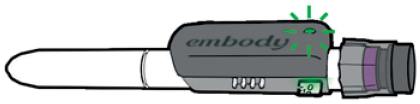
6.1 SECURITY TEST - PRIMING

WARNING
Always perform a priming (safety test) before each injection to ensure that:
✓ Your pen and the needle are working properly,
✓ The right dose of insulin will be injected.
If you do NOT perform the priming, you may receive too much or too little insulin (refer to the manufacturer's injector pen user manual).

IN AUTONOMOUS MODE OR PAIRING MODE => follow the steps indicated below:

6.1.1 Follow the injectable insulin pen instructions for use to carry out the priming step.

6.1.2 At the end of the priming step, hold the injection button pressed down:
- While EMBODY's **green** LED is flashing,
- Until EMBODY emits an audible signal (BEEP) signaling the end of the priming step.



WARNING
If the liquid does not come out of the needle tip during the safety test, do not use the pen and refer to the manufacturer's injector pen instructions for use for more information to solve the problem.

6.1.3 You can release the pressure on the button when the **green** LED stops flashing and the **"BEEP" signaling the end of priming is emitted.**

IN PAIRING MODE ONLY
When the device is coupled with a compatible mobile application installed on a smartphone:

The compatible application will automatically detect a "priming" if:
- You are priming 1 or 2 unit(s), AND
- You perform your insulin injection just after the priming step (within 2 minutes)

NOTE :
"Priming" will not be displayed in the application right away: it will be displayed once the insulin injection is done, within 2 minutes after priming.

Please refer to the application manufacturer's instructions.

CAUTION
If the time interval between the two consecutive injections exceeds 2 minutes, the application will automatically detect an injection instead of a priming.

6.2 INJECTION

WARNING

If you are not certain that you injected your insulin, do not start or repeat your injection. Monitor your blood glucose as instructed by your healthcare provider.

IN AUTONOMOUS MODE OR PAIRING MODE => follow the steps indicated below:

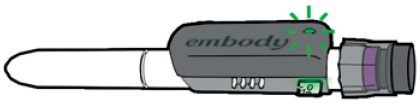
6.2.1 Check the insulin dose to inject according to the prescription and the type of medication.

6.2.2 Turn the button to select the number of units to inject. **The dose indicator should line up with the dose to inject.**

6.2.3 Press on the injection button with your thumb until you return to ZERO (complete dose injection)

6.2.4 **Keep the injection button pressed in** and the needle in the skin:

- While the EMBODY's **green** LED is flashing,
- Until EMBODY emits an audible signal (BEEP) signalling the end of the injection.



6.2.5 You can release the pressure on the button and then remove the needle from the skin when the **green** LED stops flashing and the **"BEEP" signaling the end of injection is emitted.**

WARNING

If you do not see ZERO ("0") in the pen dose window: it indicates that the full dose has not been injected.

IN PAIRING MODE ONLY

When the device is coupled with a compatible mobile application installed on a smartphone:

The application automatically detects an injection.

The information corresponding to the injected dose is displayed: **dose**, **day** and **time.**
Please refer to the application manufacturer's instructions.

COMPATIBLE MOBILE APP. SCREENS INFORMATION

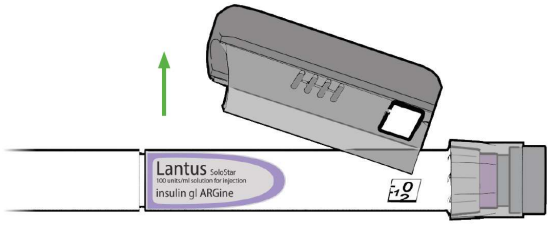
Refer to the manufacturer's application instructions for use for more information regarding the functionalities of the application you are using. More particularly:

- To display the selected and injected insulin dose
- To display the date and time of each injection.

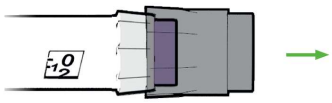
7. AFTER USE INSTRUCTIONS: DISASSEMBLE EMBODY FROM PEN

Follow the procedure indicated below to disassemble EMBODY from your pen:

7.1 Remove the EMBODY base from the insulin pen. Use your thumb to press on EMBODY and to remove it from the pen.



7.2 Then, remove the EMBODY button from the pen.



7.3 Follow ***section 5***. on assembling your EMBODY to the new insulin pen.

NOTE :
It is not necessary to pair your EMBODY again when changing the pen (unless your system has been reset - ***see section 8.2. Reset instructions***).

CAUTION

- EMBODY models are only compatible with the disposable insulin pens (Solostar, Kwikpen, Flexpen) they are designed for. Do not attach to, pair or use with any other insulin pen types.
- If you need to inject more than the number of units left in the pen, you may either:
  1) Inject the amount left in your pen and then use a new pen to deliver the rest of your dose: the EMBODY application will then display 2 successive injections, or
  2) Get a new pen and inject the full dose: the EMBODY application will display one full dose injection.

CAUTION

When EMBODY is transferred onto a new pen, the application automatically detects a ***"mounting event"*** (e.g..: your base and / or the button have / has been removed from the original pen).
In this situation, follow the application manufacturer's instructions to confirm the new pen type currently assembled with EMBODY.

8. TROUBLESHOOTING

CAUTION

- Never attempt to access the internal hardware of the device.
- When a functional testing is not successful and if the given recommendations do not solve the issue, you are prompted to contact a BIOCORP PRODUCTION authorized dealer.

8.1 TROUBLESHOOTING EMBODY: VISUAL AND AUDITIVE BASE SIGNALS

When a visual or audible signal occurs on your EMBODY, check the cause and follow the indications listed below to solve the issue:

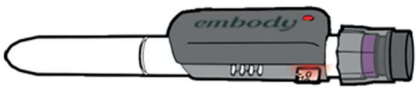
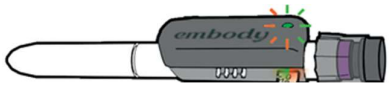
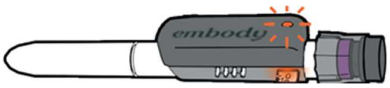
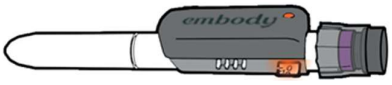
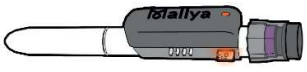
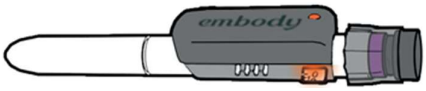
SIGNAL	CAUSE	TROUBLESHOOTING STEPS
Red LED 	EMBODY **error**	Remove EMBODY from pen. Re-calibrate EMBODY if the light indicator is flashing **orange** (*see **section 5.2.2.***) If the issue persists and the light is still **red:** reset the system (*see **section 8.2.***) Then, try to pair EMBODY to your smartphone (see **section 5.4**.) If the problem is not solved, please contact a BIOCORP PRODUCTION authorized dealer.
Orange LED (rapid flashing) 	**Calibration** in progress:	**Slowly** tilt the EMBODY side to side to calibrate (*see **section 5.2.2.***) A **green** light will appear for 2 seconds upon successful calibration (with a beep, then the **green** light will turn off).
Alternating **orange** and **green** flashing (rapid flashing) 	EMBODY device is correctly positioned onto the pen but must be **paired**.	Pair EMBODY to your smartphone (see ***section 5.4***.)
Orange LED (slow flashing) (every 15 seconds) 	**Battery** is low.	Plug in and charge the EMBODY base (see ***section 5.2.1.***)
Orange LED 	EMBODY **position error** on pen, **OR** The button is **not turned back to the dose "0"**	Make sure that: - the EMBODY window and the pen dose window are properly aligned, and - the EMBODY button is correctly pushed onto the pen *(please see the "cautions" recommendations below this table)* **OR** - the button is turned back to the dose "0".

Table 14 - Troubleshooting - Visual and auditive base signals

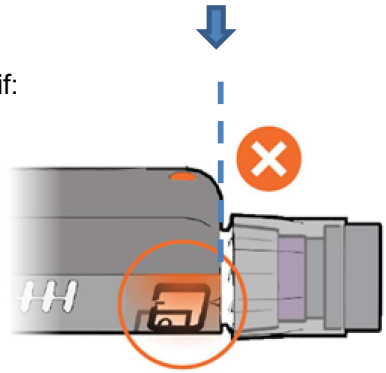
CAUTION



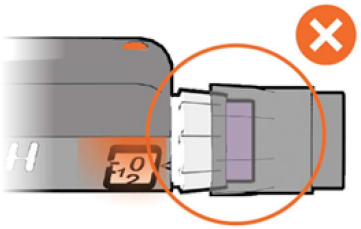
ORANGE LED – TROUBLESHOOTING RECOMMENDATIONS



The EMBODY base light indicator (LED) remains **orange** if:



- the clear square plastic window of the EMBODY base and the dose window of the pen are not correctly aligned, or
- if the base is mounted too low / too high (the top of the EMBODY base must be aligned with the top of the pen, at the base of the dose button on the pen), or



- if the EMBODY button is not pushed on enough.

In this case, it is necessary to:

- Adjust and align:
  - ⇨ the position of the windows:

  - ⇨ or raise or lower the position of the EMBODY base on the pen,

- Or, to push the EMBODY button onto the pen,

until the EMBODY base LED flashes **green** and **orange** if EMBODY is not paired (if EMBODY is paired, the light indicator is **green**).

8.2 RESET INSTRUCTIONS

The reset procedure of EMBODY may be necessary:
- If EMBODY is not working properly (no response, etc…),
- If you need to pair EMBODY with another mobile phone (smartphone),
- If you want to delete your personal health data from the device.

PROCEDURE:

8.2.1 Disassemble EMBODY as indicated ***section 7.***

8.2.2 Flip EMBODY over so that you can see the following indications:

8.2.3 Take the Reset Key: 

8.2.4 Insert the Reset Key into the hole shown below and WAIT until 3 beeps are emitted before removing the key.

3 BEEPS

8.2.5 Then follow ***section 5.*** to prepare your device for a new operation.

9. MAINTENANCE AND INSPECTION

9.1 EMBODY DEVICE LIFETIME

EMBODY and accessories' expected lifetime is 2 YEARS.
You are not required to perform a periodic maintenance of the device.

9.2 CLEANING YOUR EMBODY

When the surface of EMBODY is dirty, follow the steps indicated below to clean it:
- ✓ Disconnect the USB cable from EMBODY.
- ✓ Wipe the surface of the device with a slightly damp lint-free cloth.
- ✓ You can wipe off persistent dirt with a soft lint-free cloth slightly moistened with: water containing a small amount of neutral cleaning agent, or with ethanol 95%.
- ✓ Dry with a soft, lint-free cloth.
- ✓ Avoid moisture from reaching the micro-USB opening.

WARNING

Disconnect the USB cable before cleaning EMBODY.

CAUTION

- Do not wipe the surface of EMBODY with chemical products or solvents (e.g. acetone) other than those specified in this cleaning procedure as it could lead to discoloration or deterioration.
- Please remember that the EMBODY is **not waterproof:**
  - ✓ Do not immerse the device in water and do not clean it under running water.
  - ✓ Do not expose the device to moisture. Do not use the device in the bathroom or in areas with high temperature, humidity, dust or rain.
- Do not share EMBODY with other people to prevent infection.

9.3 MAINTAIN WATER, DUST AND LIGHT RESISTANCE

The device is rated **IP22** using the Ingress Protection rating system.
As defined in the IEC standard 60529, the IP code (or Ingress Protection code) classifies and rates the degree of protection provided by mechanical casing and electrical enclosure against the intrusion of solid objects, dust, accidental contact, and water.
EMBODY is rated **IP22** using this Ingress Protection rating system: your device has shown to be water and dust resistant in certain circumstances Despite this classification, your device is no manner impermeable to water damage.

NOTE:
If any liquid is found to have entered your device components (inside the sealed system): your device's warranty will be void.

Follow the next tips carefully to prevent damage to the device (operational or cosmetic issues):

- Whenever your device gets **wet**, dry it thoroughly with a soft, dry and clean cloth. You should dry the inside of the charging port before inserting a power connector to charge your device. If the charging port is not fully dry, your device may operate abnormally. For example, it may charge more slowly or overheat.
- Do not expose the device to direct **sunlight.**
- If the device is dropped or receives an **impact**, its water and dust resistance may be impaired.

10. TECHNICAL SPECIFICATIONS & PERFORMANCE

10.1 ELECTRICAL RATINGS

CAUTION

Make sure you connect the EMBODY USB cable to a power source compliant with the **IEC 60601-1.**

USB CHARACTERISTICS	
Input voltage	5V DC 2A
Min Current	500mA
Ingress Protection	IP 22
BATTERY CHARACTERISTICS	
Battery	Li-ion rechargeable : Li-ion 3,7V-130mAh
Model Number	GEB401730 / FT401235P
Operating time with fully charged battery	2 weeks
Charging time for fully charged battery	Full charge in 2.5 hours

Table 15 - EMBODY electrical information

You can connect the supplied USB cable to the USB port of your PC or to an AC adapter suitable for your region, with the following characteristics:

AC ADAPTOR (NOT PROVIDED)	
External Module with automatic adaptation of the voltage: no selection is required.	
Input voltage range	90-264 V
Frequencies range	47-63 Hz
Category	II (double insulation)
Output voltage	5V DC
Output current	500mA – 2A

Table 16 - Battery charging information

10.2 MATERIALS

EMBODY PART	MATERIALS
EMBODY base	PC/ABS (cover) Copolyester (body)
EMBODY button	Polypropylène and POM
	TPE

Table 17 - Materials

10.3 ACCURACY

MEASUREMENT ACCURACY	99%

Table 18 - Accuracy on test bench

CAUTION

External factors may affect the dose measurement accuracy.

Factors	Affect the measurement	Does not affect the measurement
Ambient Temperature		√
Magnetic disturbance	√	

Table 19 - External factors and accuracy of the displayed value

To display the accurate doses, please follow the recommended conditions of use.

11. ELECTROMAGNETIC COMPATIBILITY

11.1 GENERAL PRECAUTIONS AND WARNINGS

- ✓ Electrical medical devices and systems are subject to special measures concerning electromagnetic compatibility (EMC) and must be installed in accordance with the EMC instructions contained in this enclosed document.
- ✓ Portable and mobile radiofrequency communication systems may interfere with electrical medical devices.
- ✓ The use of accessories and cables other than those supplied with the devices, with the exception of the cable sold by the equipment manufacturer as spare parts, may result in increased emissions and reduced device or system immunity.
- ✓ The device must not be used when it is in contact with other electro-medical devices.

11.2 ELECTROMAGNETIC EMISSIONS

The device is intended for use in the following electromagnetic environment. You must ensure compliance with this guideline.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
The EMBODY is intended for use in the electromagnetic environment specified below. The operator of the EMBODY should ensure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - Guidance**
Radiated RF emission acc. to CISPR 11	Group 1 Class B	EMBODY uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to impair nearby electronic equipment.
Conducted RF emissions acc. to CISPR 11	Group 1 Class A	EMBODY is suitable in all establishments other than those in residential areas and those directly connected to the public low voltage power supply network that also supplies buildings used for residential purposes.
Harmonic emissions acc. to IEC 61000-3-2	compliant	
Voltage fluctuations / Flicker emissions acc. To IEC 61000-3-3	compliant	

Table 20 - Electromagnetic emissions

11.3 INTERFERENCE IMMUNITY

The device is intended for use in the following electromagnetic environment. You must ensure compliance with this guideline.

GUIDANCE AND MANUFACTURER DECLARATION – ELECTROMAGNETIC IMMUNITY			
The EMBODY is intended for use in the electromagnetic environment specified below. The operator of the EMBODY should ensure that it is used in such an environment.			
Immunity Test	**CEI 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of **EMBODY**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF disturbances according to IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	Not applicable	Recommended separation distance This test is not applicable since the equipment has not power or input/output line
Radiated RF disturbances according to IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	$d=1{,}2\sqrt{P}$ for 80 MHz to 800 MHz $d=2{,}3\sqrt{P}$ for 800 MHz to 2,5 GHz
			Where *P* is the maximum emission output power of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies. **NOTE 2: This guidance may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**			
[a] Field strength from fixed transmitters, such as base stations for radio (Cellular / cordless) and 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 device EMBODY is used exceeds the applicable RF compliance level above, additional measures may be necessary, such as reorientation or relocating the EMBODY In case unusual performance is witnessed, additional measures may be required such as change of orientation or location of the EMBODY **[b] Field strength should be less than 10 V/m in the range between 150 kHz and 80 MHz**			

Table 21 - Interference immunity

EMBODY is intended for use in an electromagnetic environment where radiated RF disturbances are under control. You can help prevent electromagnetic interference by maintaining a minimum distance between mobile and portable RF communication devices (transmitters) and the EMBODY device as recommended below, according to the maximum output power of the radio communications devices

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND EMBODY			
EMBODY is intended for use in an electromagnetic environment in which the radiated RF disturbances are controlled. The EMBODY user can help prevent electromagnetic interference by maintaining a minimal distance between portable and mobile RF communications equipment (transmitters) and the EMBODY as recommended below, according to the maximum output power of the communications equipment.			
Maximum transmitter power output (W)	**Separation distance according to the transmitter's frequency (m)**		
	150 kHz to 80 MHz $d=\left[\frac{3,5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d=\left[\frac{3,5}{E_1}\right]\sqrt{P}$	**800 MHz to 2,5GHz** $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum emission output power of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE 1: Between 80 MHz and 800 MHz, separation distance for the highest 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.**			

Table 22 - Recommended separation distance between portable & RF

Note: 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 this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this product.

11.4 ELECTROMAGNETIC IMMUNITY

The device is intended for use in the following electromagnetic environment. You must ensure compliance with this guideline.

GUIDANCE AND MANUFACTURER DECLARATION – ELECTROMAGNETIC IMMUNITY			
The EMBODY is intended for use in the electromagnetic environment specified below. The operator of the EMBODY must ensure that it is used in such an environment.			
Immunity test	**CEI 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidance**
Electrostatic discharge (ESD) acc. To IEC 61000-4-2	- ±8 kV contact discharge - ± 2 kV ,± 4 kV,± 6 kV,± 8 kV,± 15 kV air discharge	- ±8 kV contact discharge - ± 2 kV,± 4 kV,± 6 kV,± 8 kV,± 15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transients/ burst acc. To IEC 61000-4-4	- ±2 kV/100Hz for power supply lines	±2 kV/100Hz for power supply lines	The quality of the supply voltage should correspond with one characteristic for a typical commercial or hospital environment.
Surge acc. To IEC 61000-4-5	- ±0.5, ±1 kV differential mode	±0.5, ±1 kV differential mode	The quality of the supply voltage should correspond with one characteristic for a typical commercial or hospital environment.
Voltage dips, short-term interruptions and voltage variations on power supply input lines acc. to 61000-4-11	<5% U_T during 0,5 period 40% U_T during 5 periods 70% U_T during 25 periods <5% U_T during 5s	Compliant to the specified levels Compliant	The quality of the supply voltage should correspond to one characteristic for a typical commercial or hospital environment. If the user of the EMBODY requires a continuous function of the appliance also during interruptions of the power supply, it is recommended to power EMBODY out of an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic fields acc. to IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic for commercial or hospital environments.
NOTE: U_T is the voltage of the alternative supply voltage before the application of the test level			

Table 23 - Electromagnetic immunity

CAUTION

Interference may occur in the vicinity of equipment marked with the following symbol:

12. DISCLAIMER

The warranty is valid for twelve months from the date of purchase (unless a more advantageous period has been contractually agreed between the manufacturer and the distributor. Please check with your local distributor for more information).

The warranty covers any fault, material damage or manufacturing defect in products used in accordance with the instructions in this leaflet.

This warranty does not preclude the application of current legal guarantees under national legislation governing the sale of consumer goods.

BIOCORP PRODUCTION is not responsible for:

- Any damage resulting from disregarding the instructions described in this manual.
- Any damage resulting from malfunctioning caused by a combination of connected devices.
- Any damage resulting from transport, improper use or negligence, incorrect handling, modification of the system, poor maintenance, use of incorrect voltage, lightning, infiltration of sand or water, use of parts or accessories not provided or recommended in this manual by BIOCORP PRODUCTION.