

## Easyband<sup>®</sup> Control Unit



CE 0123 Ⓢ



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# 1 GENERAL INFORMATION

## 1.1 Contents of the Carrying Case

The Easyband® Control Unit is delivered in a plastic carrying case, together with its 3 accessories. The contents of this case are shown below (note: illustrations are not contractually binding).



**Easyband® control unit**



**External antenna**



**External power supply**



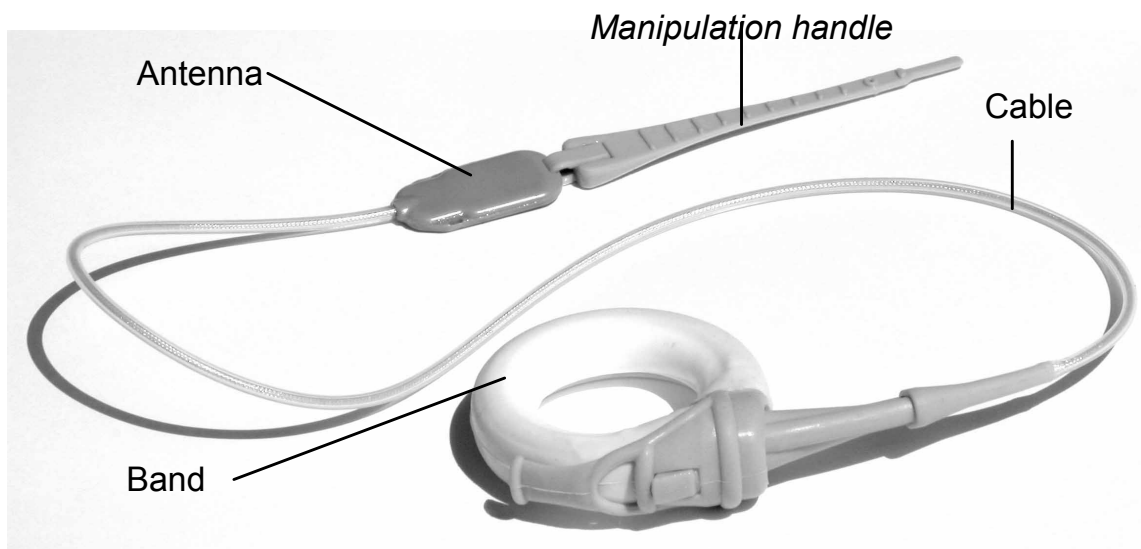
**Power supply cord**

## 1.2 Aim of the Device

The Easyband® Control Unit is used for adjusting Easyband® implants. The Easyband® is a device for the surgical treatment of obesity. It is implanted in morbidly obese patients in order to perform a gastric banding. Gastric banding consists of placing a band around the stomach in order to create a small pouch in its superior part. The presence of this small pouch induces a satiety feeling so that the patient eats only a limited quantity of food in a single meal.

The Easyband® (Figure 1) consists of a band, which is implanted around the stomach, connected by a cable to a small flat antenna, that is placed under the skin over the base of the sternum. The Easyband® Control Unit allows the physician to adjust the band diameter during the patient's post-operative follow-up. The band can be closed to help the patient progress in a medically supervised weight loss program or opened in case of complications, such as an obstruction to the passage of food through the band or in case of undesirable side-effects such as excessive vomiting.

The band adjustment is performed in a noninvasive way from outside the body. The external antenna is connected to the control unit and applied on the patient chest just on top of the implanted Easyband® antenna (Figure 2).



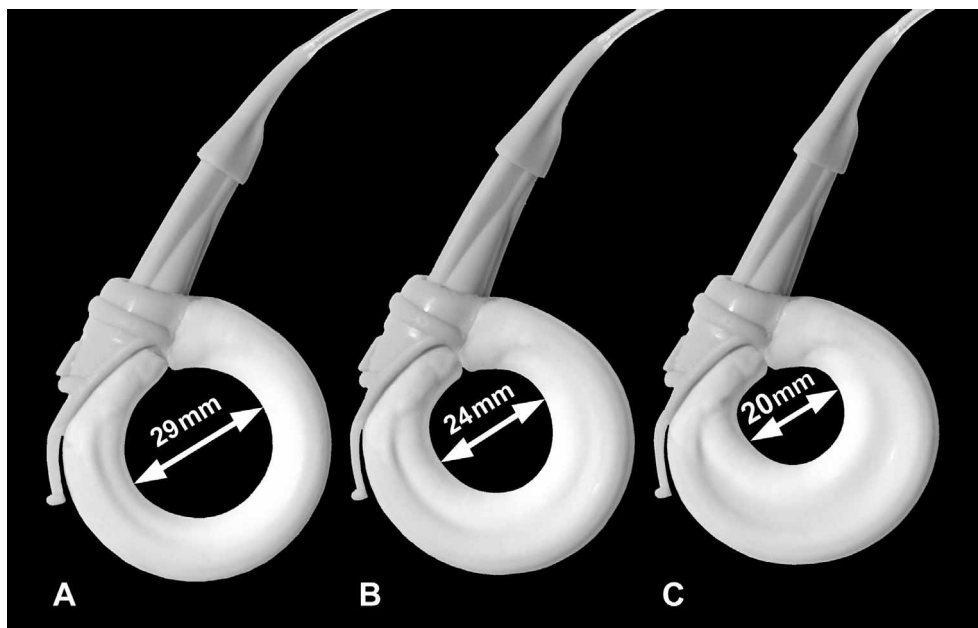
**Figure 1: Easyband® implant.** Note: the manipulation handle attached to the antenna is useful for the implantation procedure but does not remain implanted.

## 2 GENERAL PRINCIPLES OF ADJUSTMENT

Figure 3 shows the Easyband® band at three different settings. The inner diameter of the band can vary from 29 to 20 mm while the outer diameter remains constant.



**Figure 2: adjusting the Easyband® with the Easyband® Control Unit.** The external antenna is placed just on top of the implanted Easyband® antenna.



**Figure 3: Easyband® implant in three adjustment positions.**

From a technical point of view, the adjustment is performed by a flexible screw that runs all along the inside of the body of the band. One end of the screw is fixed and the other passes through an electrical micro-motor. When the motor turns the screw is pulled or pushed, changing the inner diameter of the band. For more information on the Easyband<sup>®</sup> implant (technical description, indications and contra-indications, implantation and extraction procedures, etc.), please refer to the instructions for use supplied with the device.

Before adjusting a specific implant, connect the external antenna to the Easyband<sup>®</sup> Control Unit and insert the microchip card supplied with the implant (see Figure 4), in the appropriate slot of the control unit.



**Figure 4: Easyband<sup>®</sup> microchip card.**  
*The card is patient specific and assigned to the implant with which it was delivered.*

The external antenna is positioned on the patient's chest just over the implanted antenna. The correct positioning of the external antenna is guided by the coupling indications given by the control unit (see chapter 5.3). Once the antenna has been correctly positioned, the adjustment can take place (see chapter 5.4). The control unit transmits to the band the energy and commands necessary to make the adjustment. During adjustment, the control unit displays the actual band diameter and records this value in the microchip card memory.

**Note:** if the card is lost or damaged, it is still possible to adjust the implant using a special no card mode. This is described in chapter 7.4.



## 3 PRECAUTIONS AND WARNINGS

### 3.1 User Training

The Easyband<sup>®</sup> Control Unit should be used only by competent medical personnel. It is not permitted to deliver the Easyband<sup>®</sup> Control Unit to a patient.

The instructions for use contain all the necessary information required to use the Easyband<sup>®</sup> Control Unit correctly. However, **EndoArt also offers training for the users of the Easyband<sup>®</sup> Control Unit.** It is recommended that all users of the Easyband<sup>®</sup> Control Unit receive this training to guarantee its optimal use.

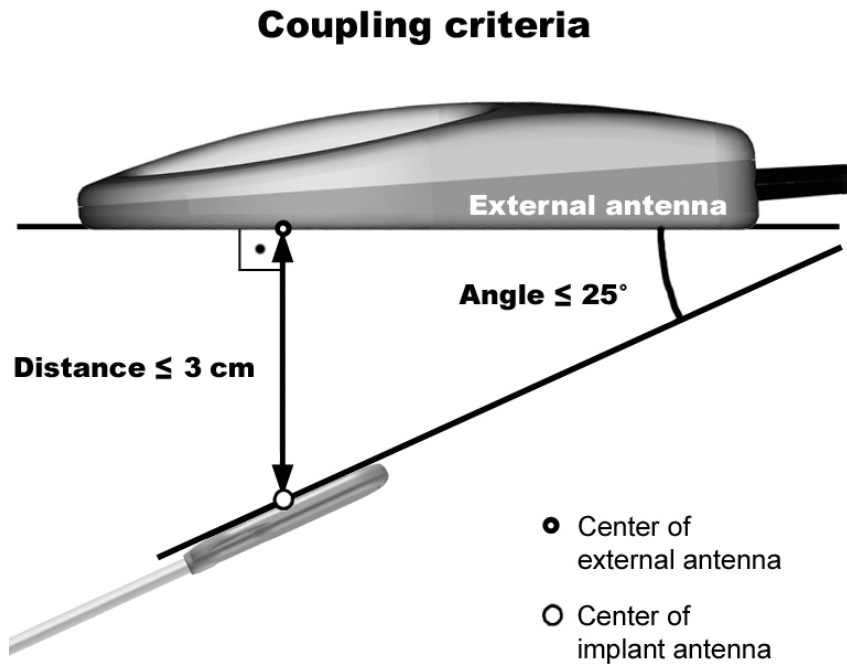
### 3.2 Band Adjustment

During the band adjustment, the Easyband<sup>®</sup> Control Unit indicates the gastric band diameter. The effects of the adjustment are evidently not comparable between different patients so this information is only indicative and **the effects of adjustment on the patient's digestive system should always be measured by appropriate clinical examinations.**

Adjustment of the Easyband<sup>®</sup>, by means of passive telemetry, is **only possible if the coupling criteria defined in Figure 5 are met.** During adjustment, it is necessary to place the external antenna directly over the implanted antenna.

During adjustment, the band diameter is recorded on the microchip card. **However, at the end of the adjustment procedure, record the final diameter in the patient's file.** This ensures complete documentation of patient's treatment history and allows safe adjustment of the band in case the microchip card is lost or damaged (see chapter 7.4).

**IMPORTANT:** if the adjustment is carried out after the fibrous capsule around the band is formed (> 2 months), the band diameter should be adjusted gradually and by not more than 3 mm during the same day. This is to allow this fibrous capsule to adapt gradually to the new band diameter. Please note that especially when opening the band after a long period, the total effects may not be immediate. Due to tissue adaptation, some of the opening effects may appear a certain period after the actual adjustment.



**Figure 5: definition of coupling criteria.** The criteria are defined in terms of

- a) the distance between the center of external antenna and the center of the Easyband<sup>®</sup> antenna ,
- b) the angle between the plane of the external antenna and the plane of the Easyband<sup>®</sup> antenna,

as indicated in the Figure above. Coupling is sufficient if the distance is less than 3 cm and, at the same time the angle does not surpass 25°.

### 3.3 Electromagnetic Interactions

As the Easyband<sup>®</sup> Control Unit is a device emitting electromagnetic waves, it may interfere with other devices and this can jeopardize their correct operation. Detailed indications on this subject are given in the technical description (chapter 10). A summary of the essential points follows:

**When in operation, the Easyband<sup>®</sup> Control Unit emits electromagnetic waves, mainly at radio frequencies, which can affect nearby electrical devices.** Although the levels of these emissions are in compliance with international standards, it is necessary to pay particular attention to the correct operation of any devices close to the external antenna during adjustment. This is especially important for electrical devices whose correct operation is vital for the patient, the control unit user or a third party. Some examples of such devices are: external or implantable pacemaker, external or implantable defibrillator, external or implantable drug delivery pump, respirator, etc.

The correct working of the Easyband<sup>®</sup> Control Unit can be affected by an inappropriate electrical environment (metallic surfaces, static electricity, high electrical voltage, etc.) and by portable or mobile telecommunication or medical devices using radio frequencies and bearing the symbol ((⚡)), even if these devices are in compliance with international standards. In the event of incorrect operation of the control unit, it is advisable to change position in the room or to change room in order to reduce electromagnetic interference to acceptable levels.

## 3.4 Control Unit Handling

**Do not use the Easyband<sup>®</sup> Control Unit in case of room temperatures higher than 35°C.**

**Do not use the Easyband<sup>®</sup> Control Unit in presence of a flammable mixture of gas, such as an anaesthetic with air, oxygen or nitrogen monoxide.**

**Use exclusively the external power supply contained in the carrying case.** The performance of the device related to electrical safety (electric shock risk, for example) and electromagnetic interactions (interference with other electrical devices) may be affected if another power supply is used.

**In the US and Canada: the delivery package contains a hospital grade power cord with a 5-15P plug and shall be connected to a 120V receptacle marked “hospital grade” or “hospital only”. In case the equipment is intended to be connected to a 240V supply, an approved hospital grade power cord with a 6-15P plug shall be used.**

**Handle the Easyband<sup>®</sup> Control Unit with care.** The device can be damaged by violent shocks.

**Do not expose the Easyband<sup>®</sup> Control Unit or its accessories to liquids.** For cleaning, refer to chapter 4.2.2.

Do not expose the Easyband<sup>®</sup> Control Unit or its accessories to direct sunlight for a long time.

Do not bring the Easyband<sup>®</sup> Control Unit or its accessories into contact with sources of heat (radiator, oven, etc.).

## 3.5 Sterility

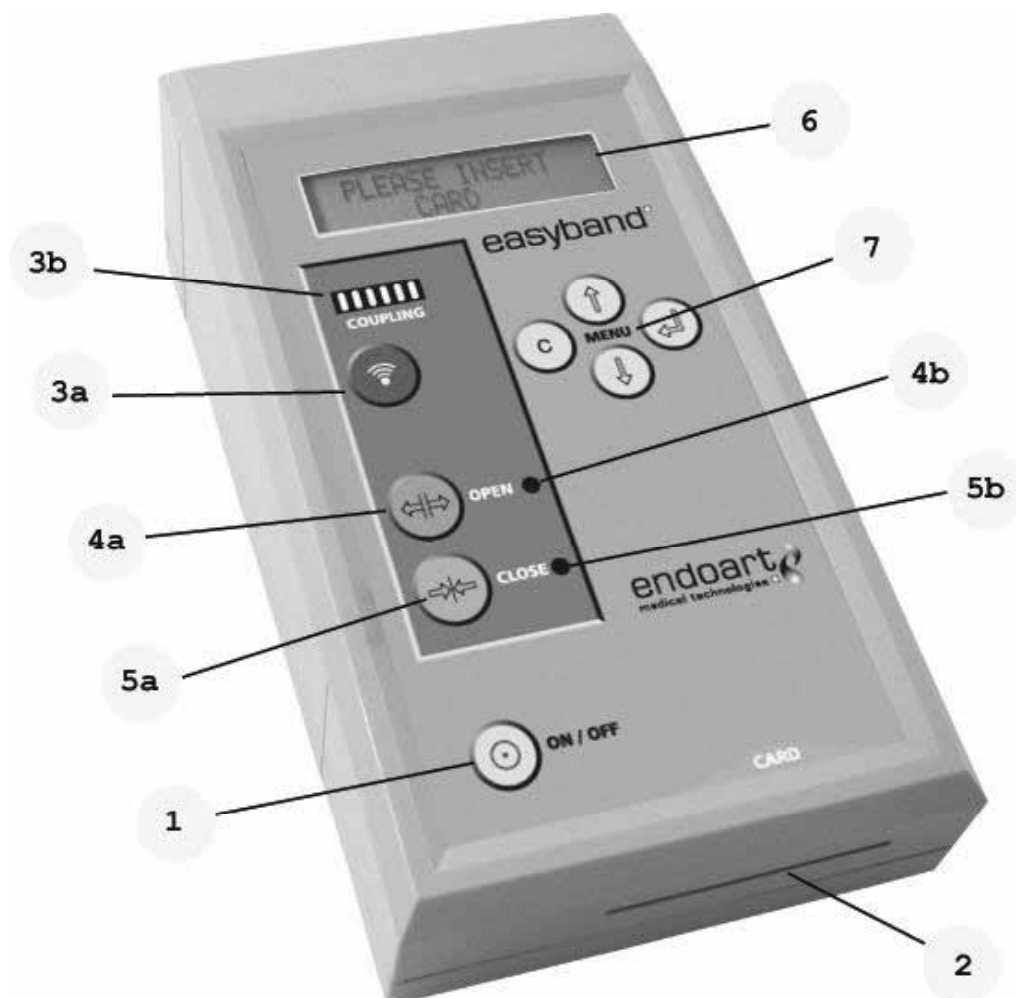
The Easyband<sup>®</sup> Control Unit and its accessories are not delivered in a sterile state and **cannot be sterilized.**

Any attempt to sterilize the Easyband<sup>®</sup> Control Unit or its accessories could lead to irreversible damages to these devices.

## 4 DEVICE HANDLING

### 4.1 Description

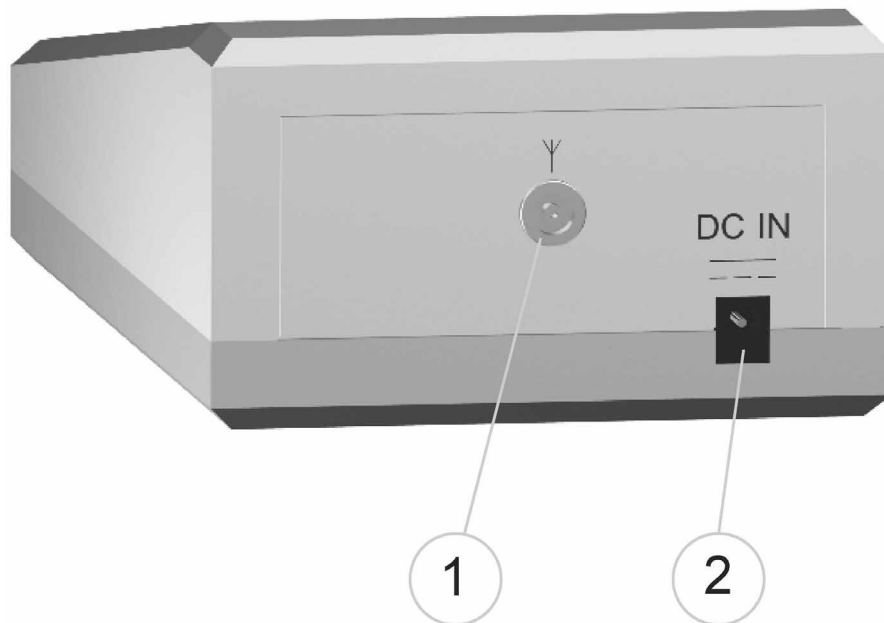
#### 4.1.1 Description of front face



**Figure 6: Easyband® Control Unit front face.**

1. ON/OFF key
2. Microchip card insertion slot (CARD)
- 3a. Coupling key (COUPLING)
- 3b. Coupling luminous scale
- 4a. Open key (OPEN)
- 4b. Opening indicator light
- 5a. Close key (CLOSE)
- 5b. Closing indicator light
6. Liquid crystal display
7. Menu keys

### 4.1.2 Description of connection face



**Figure 7: Easyband<sup>®</sup> Control Unit connection face.**

1. External antenna connector
2. External power supply connector

### 4.1.3 Information given to the user

The control unit gives information to the user through indicator lights, messages on the liquid crystal display and acoustic signals ("bips").

Chapters 5 to 6 describe the normal operation of the device as well as the corresponding messages appearing on the liquid crystal display. If other messages appear, refer to chapter 8, which contains an alphabetic list of all messages as well as a description of their meaning.

Acoustic signals are heard when the control unit has performed a specific operation or to attract the user attention.

## 4.2 Storage, Cleaning, Maintenance and Disposal

### 4.2.1 Storage

Store the device in a dry place at room temperature.

The control unit and its accessories are protected in an optimal manner in their original packaging (carrying case).

### 4.2.2 Cleaning

To clean the Easyband<sup>®</sup> Control Unit or its accessories, use a cloth slightly moistened with alcohol. Contact with liquids can damage these devices. The Easyband<sup>®</sup> Control Unit and its accessories cannot be sterilized.

### 4.2.3 Maintenance and repair

Maintenance or repairs of the Easyband<sup>®</sup> Control Unit or its accessories cannot be performed by the user. If necessary, contact EndoArt.

**CAUTION:** any change or modification to the Easyband<sup>®</sup> Control Unit or its accessories not expressly approved by EndoArt could void the user's authority to operate the equipment.

### 4.2.4 Disposal

The Easyband<sup>®</sup> Control Unit and its accessories should not be discarded in normal urban refuse but are subject to a separate collection for recycling. For the disposal of the Easyband<sup>®</sup> Control Unit or of its accessories, send the devices back to EndoArt.

## 5 ADJUSTMENT PROCEDURE

### 5.1 Patient Monitoring

The band diameter displayed on the control unit is not an indicator of clinical parameters, and it is not sufficient to use it as a clinical monitor for adjustments. This information is only indicative and **the clinical effects of adjustment on the patient's should always be measured by appropriate clinical examinations.**

### 5.2 Control Unit Preparation

**Preliminary remark:** the control unit can function either on its internal battery or on its external power supply. For the purpose of these instructions, battery operation of the device is used. For information on the battery charge level and the working on the external power supply, see chapter 6.

**CAUTION:** for each of the following steps, allow enough time to the control unit to display the described messages before passing to the next step. This guarantees that the control unit performs each operation correctly.

#### Preparation of the control unit:

- 1) Connect the external antenna to the antenna connector on the Easyband<sup>®</sup> Control Unit.
- 2) Switch on the control unit by pressing the ON/OFF key. There is a brief display of the battery status and then a message prompting the insertion of the microchip card:

PLEASE INSERT  
CARD

- 3) Insert the microchip card for the Easyband<sup>®</sup> implant to be adjusted. There is a brief display of the serial number of the corresponding implant, which is recorded on the microchip card:

EASYBAND  
SN: XXXXXXXX

The display then indicates the actual band diameter in mm:

STOPPED @ XX.Xmm DIAM
--------------------------

- 4) Everything is now ready to proceed with the next step: verifying the level of coupling to the implanted device antenna.

#### IMPORTANT:

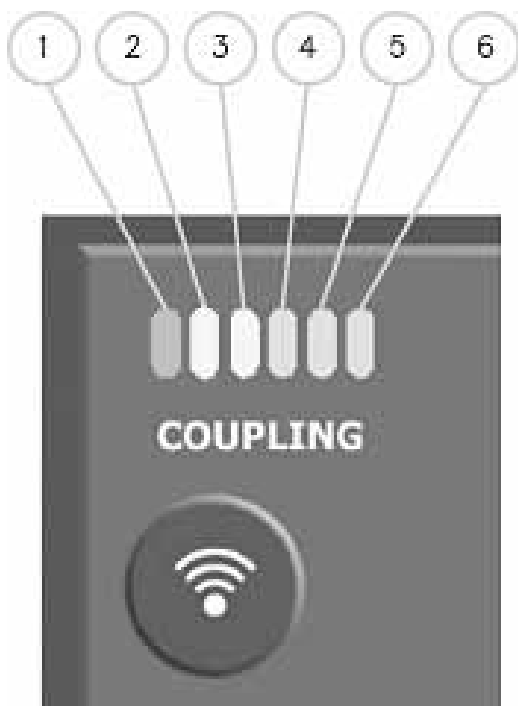
- **The microchip card penetrates only half way into its slot on the control unit: do not force the microchip card when inserting it.**
- The microchip card should be kept in a safe place (for example in the patient's file or in the control unit carrying case). If the card is lost or damaged, please refer to chapter 7.4. The microchip card contains, among other things, two items of information in its memory:
  - 1) ***The serial number of the associated implant***
  - 2) ***The current band diameter in mm***
- If the control unit is not used for a certain period of time, it automatically switches off to preserve the battery level (automatic power off delay, see chapter 7.3.6).

## 5.3 Coupling with the Implant Antenna

The purpose of the coupling procedure is to determine the optimal position of the external antenna in order to be able to perform the adjustment of the band diameter. Optimal positioning of the external antenna is guided by the level of coupling indicators. The level of coupling measures the capacity of the control unit to adjust the implant. It is necessary to have a sufficient level of coupling to perform the adjustment.

The coupling indications given by the control unit are presented in the following.





**Figure 8: detail of the coupling area.** Above the coupling key (illustrated) there is a luminous coupling scale. The meaning of the indicator lights is given in the table "Coupling Indications".

Table: coupling indications		
Level of coupling	Luminous scale of coupling	Indication on the display
1	red indicator light is lit	NO SIGNAL MOVE ANTENNA
2	1 <sup>st</sup> yellow indicator light is lit	WEAK SIGNAL MOVE ANTENNA
3	2 <sup>nd</sup> yellow indicator light is lit	WEAK SIGNAL MOVE ANTENNA
4	1 <sup>st</sup> green indicator light is lit	COUPLING CORRECT
5	1 <sup>st</sup> and 2 <sup>nd</sup> green indicator lights are lit	COUPLING CORRECT
6	The three green indicator lights are lit	COUPLING CORRECT

### Coupling procedure:

- 1) Place the external antenna on the patient's chest just on top of the implant antenna. The external antenna should always be placed with the dark grey side of the antenna in contact with the patient's chest.

- 2) Press briefly on the coupling key (COUPLING). The device then indicates the level of electromagnetic coupling between the external antenna and the implant antenna as described in the table “Coupling Indications”.
- 3) Move the external antenna to obtain the best possible coupling level.

**Three(3) green lights indicate optimal coupling, however, it is possible to proceed with a minimum of one(1) green bar.** Changes in the patient’s position or in the location of the external antenna may change the coupling indications.

- 4) During the coupling phase, the control unit indicates, temporarily, that coupling with the implant is being performed:

Coupling mode :

The first time a sufficient coupling level is obtained, the control unit first checks that the microchip card corresponds to the implant and, if this is the case, the following message appears temporarily on the display:

CARD & IMPLANT  
MATCHED

The display then indicates the coupling level again. However, if the microchip card does not correspond to the implant, the following message appears temporarily on the display:

CARD & IMPLANT  
NOT MATCHED

In this case, check that the correct card has been inserted. If this is the case, restart the coupling procedure and try to find a better position. It is possible that the control unit may accidentally display a message indicating that the card does not correspond to the implant due to interference if the coupling is barely sufficient.

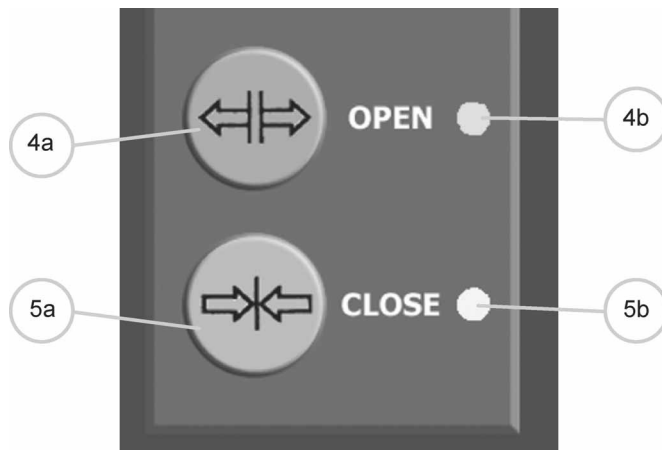
- 5) Once the optimal position for the external antenna has been found, press briefly on the coupling key again and hold the external antenna position steady. Everything is now ready to adjust the band.

## 5.4 Band Adjustment

The band diameter adjustment is performed simply by using the two keys OPEN and CLOSE:

**OPEN:** to open the band, the band diameter increases

**CLOSE:** to close the band, the band diameter decreases



**Figure 9: details of the adjustment area.**

4a) OPEN key

4b) green opening indicator light

5a) CLOSE key

5b) yellow closing indicator light

### Adjustment procedure:

Do not move the external antenna during the coupling or adjustment procedure.

Band adjustment is performed using the OPEN or CLOSE keys: press briefly on the key to start the adjustment and press on the **same** key a second time to stop the adjustment. In order to avoid unexpected adjustments, in case the user's attention is diverted, the adjustment stops automatically after a 1.5mm diameter change.

When the OPEN or CLOSE keys are pressed, the control unit establishes the connection with the implant and then the display reads:

Connecting...

When the band is closing, the display reads:

CLOSING  
DIAM XX.Xmm

This means that the band diameter decreases. The word "closing" flashes during adjustment and the closing indicator light is lit.

When the band is opening, the display reads:

OPENING DIAM      XX.Xmm
-----------------------------

This means that the band diameter increases. The word “opening” flashes during adjustment and the opening indicator light is lit.

Once the OPEN or CLOSE key is pressed a second time, the display indicates that the control unit is disconnecting from the implant:

Disconnecting...
------------------

**Do not move the antenna as long as this message reads on display and as long as the coupling indicator light is lit, to allow the disconnection to be performed correctly.**

#### IMPORTANT:

- It takes around 40 seconds for the diameter to vary by 1mm. While the band is being adjusted, the corresponding coupling indicator light remains lit, which means that it is possible to check at all times the coupling level and to reposition the external antenna slightly, if necessary.
- In case the connection is difficult to establish, the message:

Connecting...
---------------

may last over some time. Beyond 3 seconds, it is advisable to improve coupling by moving the external antenna according to the indications of the luminous coupling scale or to repeat the coupling procedure.

- When the band reaches its minimum diameter of 20.0 mm, the adjustment is automatically interrupted and the display reads:

DEVICE @ MINIMUM DIAM.
---------------------------

The display then indicates the value of the minimum diameter (20.0 mm).

- When the band reaches its maximum diameter of 29.0 mm, the adjustment is automatically interrupted and the display reads:

DEVICE FULLY OPEN
----------------------

The display then indicates the value of the maximum diameter (29.0 mm).

In presence of interference (for example, inappropriate electromagnetic environment), it is possible that the maximum diameter may not correspond exactly to 29.0 mm on the control unit display. In such case, it is recommended to continue opening the band until "DEVICE FULLY OPEN" is displayed. The implant has reached its full opening only when this latter message is displayed.

- Once the band has reached its minimum diameter or its maximum diameter, do not move the antenna as long as the corresponding message reads on display and as long as the coupling indicator light is lit, to allow the disconnection to be performed correctly.
- If, during adjustment, the coupling level is no longer sufficient, the adjustment is interrupted. Try to establish a sufficient coupling level by repeating the coupling procedure described in chapter 5.3.
- If the adjustment is carried out after the fibrous capsule around the band is formed (> 2 months), the band diameter should be adjusted gradually and by not more than 3 mm during the same day. This is to allow this fibrous capsule to adapt gradually to the new band diameter. Please note that especially when opening the band after a long period, the total effects may not be immediate. Due to tissue adaptation, some of the opening effects may appear a certain period after the actual adjustment.

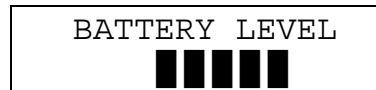
## 5.5 End of Adjustment Procedure

- 1) Record the band diameter in the patient's file.
- 2) Remove the microchip card and keep it in a safe place (for example in the patient's file or in the control unit carrying case).
- 3) Switch off the control unit by keeping the ON/OFF key pressed for at least 3 seconds.
- 4) Disconnect the external antenna.
- 5) If necessary, recharge the battery as indicated in chapter 6.

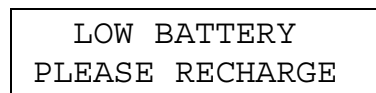
## 6 BATTERY

### 6.1 Battery Level Indications

When the control unit is switched on, the display briefly indicates the battery charge level on a 5 bar scale:



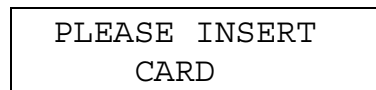
If a single bar is displayed, it is advisable to recharge the device before carrying out the adjustment procedure. If the device is used without being recharged, the following reminder message is displayed repeatedly:



When the battery charge level is really too low for the device to be used, the above message is displayed permanently. It is then necessary to connect the external power supply to be able to use the device.

### 6.2 Recharging the Battery, Using with the External Power Supply

Connect the control unit (DC IN) connector to the AC power using the external power supply and the power supply cord. The display then briefly indicates the battery status and then prompts the insertion of a microchip card:



- It is then possible to perform the adjustment procedure as described in chapter 5.3 and also to recharge the battery. To do so, put the device into standby by keeping the ON/OFF key pressed for 3 seconds.
- The device then charges the battery and the display reads:



- The current battery level is represented on a 5 bar scale. When the battery is completely charged, the control unit reads:

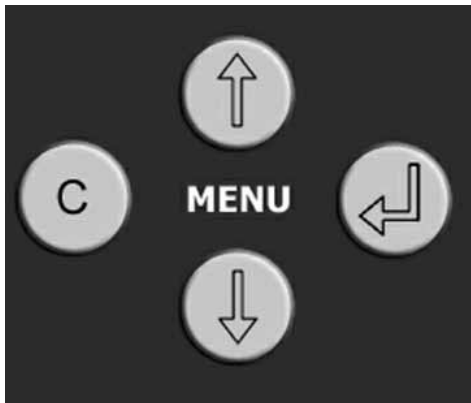


- Once the battery charging has been completed, disconnect the external power supply and the power supply cord.

## 7 SPECIAL MENUS

### 7.1 Navigation in the Menus

The special menus are used to change or to consult some parameters of the Easyband® Control Unit or of the corresponding Easyband® implant.



**Figure 10: details of the menu area.**

↵ : *ENTER* key  
C : *CORRECTION* key  
↑ : *UP* key  
↓ : *DOWN* key

These menus are accessed by pressing the ENTER key (↵). From this point on, navigation is simple using the 4 menu keys. The effect of these keys is described below and a detailed example of the use of a special menu follows. Chapter 8 contains an exhaustive description of the Easyband® Control Unit menus.

#### 7.1.1 ↵ key (*ENTER* key)

- Gives access to menus and sub-menus.
- Allows data entry confirmation.
- Allows selection and scrolling towards the right in a function containing a variables field to be initialized.

#### 7.1.2 C key (*CORRECTION* key)

- Allows exit from menus or sub-menus.
- Allows selection and scrolling towards the left in a function containing a variables field to be initialized.

#### 7.1.3 ↑ key (*UP* key)

- Allows scrolling upwards in a menu.
- To increase a value.

### 7.1.4 ↓ key (**DOWN** key)

- Allows scrolling downwards in a menu.
- To decrease a value.

### 7.1.5 **Example of use of special menus**

The display backlight off delay is the time after which, in case of inactivity, the display light goes off to preserve battery level. The default value is 20 seconds. To increase the display backlight off delay, for example, to 2 minutes and 10 seconds, proceed as follows:

1. When the control unit is on, press the ↓ key to enter the special menus. The display reads:

```
→ User Menu
   Config Menu
```

2. Press the key ↓ to select the configuration menu. The display reads:

```
User Menu
→ Config Menu
```

3. Press the ↓ key to enter the configuration menu. The display reads:

```
→LCD Contrast
   Buzzer Volume
```

4. Press the ↓ key twice to select the display backlight delay menu. The display reads:

```
→Backlight Delay
   Backlight Level
```

5. Press the ↓ key to enter the display backlight delay menu. The display reads (for a control unit set to the default value):

```
BackLight Delay
   020 [s]
```

6. Press the ↑ key to set the first digit to 1 (2 minutes and 10 seconds, corresponding to 130 seconds). Confirm the selection by pressing the ↓ key. The display reads:

```
BackLight Delay
   120 [s]
```

7. Press the ↑ key to set the second figure to 3. Confirm the selection by pressing the ↓ key. Press the ↓ key again to confirm the value of the last digit (0). The display then returns to the upper level: