

```
→Backlight Delay  
Backlight Level
```

8. The change is now effective. Press the ↵ key to enter the display backlight delay menu. The display reads:

```
BackLight Delay  
130 [s]
```

9. Press the key C to exit from the menu. The display reads:

```
→Backlight Delay  
Backlight Level
```

10. Press the C key to exit from the configuration menu. The display reads:

```
User Menu  
→ Config Menu
```

11. Press the C key to exit from the special menus. The display returns to its initial display.

7.2 User Menu

7.2.1 Battery Status

This menu displays the battery charge level represented on a 5 bar scale:

```
BATTERY LEVEL  
■■■■■
```

7.2.2 Implant ID

This menu displays the implant identification number recorded in the implant. This is a manufacturer code and it is not the same as the serial number.

```
EASYBAND  
ID: XXXXXXXX
```

7.2.3 No Card Mode

This mode is used to make an adjustment without a microchip card. Its use is described in chapter 7.4.

7.2.4 Firmw. Version

This menu indicates the firmware version implemented on the Easyband[®] Control Unit:

```
FCU X.XXX / 200X  
(c) ENDOART - CH
```

7.3 Configuration Menu

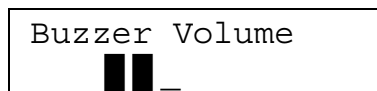
7.3.1 LCD Contrast

This menu is used to change the display contrast. This parameter corresponds by default to 3 bars out of 5:



7.3.2 Buzzer Volume

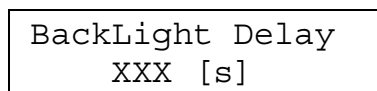
This menu is used to change the sound level of the buzzer signals. By default, this parameter corresponds to 2 bars out of 3:



The user should set these buzzer signals to an audible level.

7.3.3 Backlight Off Delay

The display backlight switches off after a certain time to preserve the battery level. This menu is used to change this time delay, see 7.1.5 (example of use of special menus). By default the time is 20 seconds. It can be adjusted between 1 second and 999 seconds:



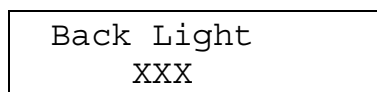
7.3.4 Backlight Level

This menu is used to change the display backlight intensity. By default this parameter corresponds to 5 bars out of 10:



7.3.5 Backlight On/Off

This menu is used to switch ON or to force OFF the display backlight. By default this parameter is set to "ON":



7.3.6 Power Off Delay

This menu is used to set the automatic power off time of the Easyband[®] Control Unit. This is the time after which the device switches off automatically when operating on a battery (or the time after which the device automatically goes into standby when operating on the external power supply). By default this time is 15 minutes. It is adjustable between 5 minutes and 300 minutes:

Power Off Delay XXX [min]

7.3.7 Set Default Value

This menu is used to reinitialize all the default parameters of the Easyband[®] Control Unit configuration menu:

PUSH ENTER TO SET DEFAULT VAL

7.4 No Card Mode

The no card mode is used to adjust an Easyband[®] implant when the corresponding microchip card is no longer available (lost, damaged, etc.).

7.4.1 Warnings

Because of the greater risk of incorrect use in this mode and to limit access to it, this mode is protected by an access code available only from EndoArt.

In this special mode, the operation of the Easyband[®] Control Unit differs from normal operation and certain safety functions are no longer active:

- As the band diameter is indicated only on the microchip card, the control unit can no longer display the absolute band diameter but only a relative position. This relative position is indicated in the form $\pm XX.X$ mm. The + sign indicates the closing of the band and the – sign the opening of the band relative to the band diameter at the time the no card mode was entered. The absolute position is obtained by adding or subtracting the relative position indicated on the display to the position at the time the no card mode was entered, which is typically the last position recorded in the patient's file.
- Once an adjustment has been carried out on a Easyband[®] implant in the no card mode, it will no longer be possible to carry out any further adjustments using its microchip card even if the card is inserted again. When a subsequent adjustment of the implant is attempted, the display will read temporarily:

IMPLANT USED IN
NO CARD MODE

and then:

STOPPED @
UNKNOWN DIAM.

These messages mean that the microchip card is not being taken into account and it is therefore necessary to enter the no card mode as described in the following procedure. To avoid putting other implants into this configuration, once the no card mode adjustment has been completed, **switch off the control unit before adjusting another implant.**

- To exit the no card mode, the Easyband[®] Control Unit must be switched off.
- The control unit allows adjustment even if the coupling level is not correct (see point 3, chapter 5.3). Band diameter indications on the control unit display may be inaccurate when compared to the actual band diameter. For these reasons, patient monitoring (see chapter 5.1) is very important in no card mode.
- In no card mode, the Easyband[®] Control Unit is not designed to detect the precise instant when the band reaches its minimum diameter of 20.0 mm. So, when the minimum diameter is reached in the no card mode, the display continues to indicate that the band is closing, even when it is in fact stopped at its minimum diameter of 20.0 mm.

7.4.2 Adjustment in no card mode

Preparing the control unit:

- 1) Connect the external antenna to the antenna connector of the Easyband[®] Control Unit.
- 2) Switch on the control unit by pressing the ON/OFF key. The display indicates briefly the battery status and then prompts the insertion of a microchip card:

PLEASE INSERT
CARD

- 3) Access the special menus: press the ↵ key (see chapter 7.1).
- 4) Enter the user menu: press the ↵ key.

- 5) Access the no card mode: press the ↓ key 2 times and then the ↵ key once. The display then prompts you to enter the access code (note: the code can be obtained only from EndoArt):

```
NO CARD MODE
ENTER CODE: XXXX
```

- 6) Enter the code digit by digit using the ↑ and ↓ keys to select the numbers and confirming each digit by pressing the ↵ key. When the code is accepted, the device goes into the no card mode and indicates temporarily:

```
NO CARD MODE
ENABLED
```

The device then indicates the band diameter in the relative mode:

```
STOPPED @±XX.Xmm
CHANGE IN DIAM.
```

- 7) The rest of the adjustment procedure is identical in all respects to the procedure described in chapters 5.3 and 5.4 with the exception of the following important points:

- During the coupling procedure, there is of course no check on the matching between the microchip card and the implant.
- All the adjustment indications are relative. During band closure, the display reads:

```
RELATIVE CLOSING
DIAM. ±XX.X
```

or, during band opening:

```
RELATIVE OPENING
DIAM. ±XX.X
```

The + sign indicates a larger diameter and the – sign a smaller diameter compared to the diameter at the time the no card mode was entered

Example: If the no card mode was selected when the diameter was 26.6 mm, at the time when the no card mode is entered the display reads temporarily:

```
NO CARD MODE
ENABLED
```

Then the display reads:

```
STOPPED @±0.0mm
CHANGE IN DIAM.
```

After a 1.5 mm diameter closure, the display reads:

STOPPED @ -1.5mm CHANGE IN DIAM.

which means that the actual diameter is 25.1 mm.

- 8) Once the adjustment in the no card mode has been completed, switch off the control unit before adjusting another implant. This is to exit the control unit from the no card mode.

IMPORTANT:

If the maximum diameter of 29.0 mm is reached, the control unit displays temporarily the message:

DEVICE FULLY OPEN

Then, the diameter indication is displayed in absolute value:

STOPPED @ 29.0mm DIAM.

8 MEANING OF LCD DISPLAYS

Screen display	Meaning	Description-action
ANTENNA PROBLEM OR NOT CONNECTED	The external antenna is malfunctioning or is not or badly connected.	Try to reconnect the external antenna. If the message remains unchanged, the electrical circuit of the antenna is probably damaged. Contact EndoArt.
Back Light (ON ou OFF)	Display backlight is ON or OFF. See chapter 7.3.5.	Switch the backlight ON or OFF using the ↑ and ↓ keys, and then confirm using the ↵ key.
BackLight Delay XXX [s]	Setting the display backlight switch off delay. See chapter 7.3.3.	Adjust this parameter digit by digit using the ↑ and ↓ keys, and confirm each digit using the ↵ key.
BacklightLevel ■■■■■	Setting the display backlight intensity. See chapter 7.3.4.	Adjust this parameter using the ↑ et ↓ keys, and then confirm using the ↵ key.
Backlight Delay Backlight Level	Prompts to access one of the two menus.	Select a menu by moving the → arrow using the ↑ and ↓ keys, and then confirm using the ↵ key.
Backlight OnOff Power Off Delay	Prompts to access one of the two menus.	Select a menu by moving the → arrow using the ↑ and ↓ keys, and then confirm using the ↵ key.
BATTERY FULLY CHARGED	The battery is completely charged.	Disconnect the external power supply
BATTERY LEVEL ■■■■■	Battery charge level.	The charge level is indicated on a scale of 5 black bars.

Screen display	Meaning	Description-action
Battery Status Implant ID	Prompts to access one of the two menus.	Select a menu by moving the → arrow using the ↑ and ↓ keys, and then confirm using the ↵ key.
Buzzer Volume ■■_	Setting the buzzer alarm volume. See chapter 7.3.2.	Adjust this parameter using the ↑ et ↓ keys, and then confirm using the ↵ key.
CARD & IMPLANT MATCHED	The microchip card serial number corresponds to the implant serial number.	
CARD & IMPLANT NOT MATCHED	The microchip card serial number does not correspond to the implant serial number.	Check the card label to make sure that the correct card is used. If the correct card is indeed in use, this message may be produced by an interference: repeat the coupling procedure.
CHARGING ■■■■■	Battery being charged.	The charge level is indicated on a scale of 5 black bars.
CLOSING DIAM XX.Xmm	The band is closing. The band diameter is XX.X mm.	See chapter 5.4.
Connecting...	Establishing a communication between the control unit and the implant antenna.	Try to find a better position. If necessary, restart the coupling procedure.
COUPLING CORRECT	Correct coupling level.	
Coupling Mode :	Coupling mode.	Coupling under way.

Screen display	Meaning	Description-action
DEVICE @ MINIMUM DIAM.	The band has reached its minimum diameter of 20.0 mm.	
DEVICE BLOCKED ERROR DETECTED	The implant is mechanically blocked or there is an implant failure.	Try again to adjust the band, opening and closing. If the message persists contact EndoArt.
DEVICE FULLY OPEN	The band is completely open.	
Disconnecting...	Disconnecting ...	Disconnection from the implant.
FCU X.XXX / 200X (c) ENDOART - CH	Identification of the firmware implemented on the device.	
FIRMW. CORRUPTED Inform ENDOART	The control unit firmware is damaged.	The control unit is no longer usable. Contact EndoArt.
EASYBAND SN: XXXXXXXX	Easyband [®] implant serial number XXXXXXXX.	Information contained in the microchip card.
IMPLANT UNRECOGNISED	Implant memory is damaged.	Start the coupling procedure again trying to find a better position. If this procedure does not work, enter the no card mode, see chapter 7.4.
EASYBAND ID: XXXXXXXX	Easyband [®] implant identification number XXXXXXXX.	Manufacturer code contained in the implant.









Screen display	Meaning	Description-action
IMPLANT USED IN NO CARD MODE	The implant has been used in no card mode.	Because this message may be produced by an interference, start the coupling procedure again. If this message lasts, enter the no card mode, see chapter 7.4.
LCD Contrast Buzzer Volume	Prompts to access one of the two menus.	Select a menu by moving the → arrow using the ↑ and ↓ keys, and then confirm using the ↵ key.
LCD Contrast ■■■ — —	Setting the display contrast level. See chapter 7.3.1.	Adjust this parameter using the ↑ et ↓ keys, and then confirm using the ↵ key.
LOW BATTERY PLEASE RECHARGE	Battery charge level low. Please recharge.	Recharge the device using the external power supply. When this message is displayed, it is necessary to connect the external power supply to be able to use the device.
No Card Mode Firmw. Version	Prompts to access one of the two menus.	Select a menu by moving the → arrow using the ↑ and ↓ keys, and then confirm using the ↵ key.
MICROCHIP CARD BAD FORMAT	The microchip card is not formatted properly	Check the card label to make sure that the correct card is used. If the message persists, this means that the card is not the correct one.
MICROCHIP CARD CORRUPTED	The microchip card contains damaged data.	Check the card label to make sure that the correct card is used. If the message remains unchanged, it means the card is not usable.




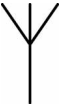



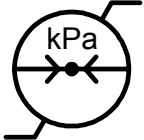
Screen display	Meaning	Description-action
MICROCHIP CARD NOT FORMATTED	The microchip card contains no data.	Check the card label to make sure that the correct card is used. If the message remains unchanged, it means the card is not usable.
MICROCHIP CARD NOT FOUND	The microchip card cannot be found.	The card has been removed during adjustment. Insert the card again.
MICROCHIP CARD UNRECOGNISED	The device does not recognize the microchip card.	The type of card inserted is different from the one supplied with the implant or the microchip card has been inserted the wrong way.
NO CARD MODE ENABLED	No card mode selected.	See chapter 7.4.
NO CARD MODE ENTER CODE: XXXX	No card mode. Enter the code. See chapter 7.4.	To use this mode a code is required. The code can be obtained from EndoArt. Enter the code digit by digit using the ↑ and ↓ keys and confirm each digit using ↵.
NO CARD MODE WRONG CODE	no card mode. Incorrect code.	Enter the correct code.
NO SIGNAL MOVE ANTENNA	No implant. Position the antenna.	No coupling between the implant and the external antenna. Reposition the external antenna.
OPENING DIAM XX.Xmm	The band is opening. The band diameter is XX.X mm.	See chapter 5.4.
PLEASE INSERT CARD	Please insert the patient's microchip card.	Insert the microchip card supplied with the implant to be adjusted.

Screen display	Meaning	Description-action
Power Off Delay XXX [min]	Setting the automatic device switch off time. See chapter 7.3.6.	Adjust this parameter digit by digit using the ↑ and ↓ keys, and confirm each digit using the ↵ key.
PUSH ENTER TO SET DEFAULT VAL	Press the ↵ key to restore the default values. See chapter 7.3.7.	Select a menu by moving the → arrow using the ↑ and ↓ keys, and then confirm using the ↵ key.
RELATIVE CLOSING DIAM. ±XX.Xmm	The band is closing in no card mode. The band diameter is ±XX.X mm compared to its value at the beginning of the adjustment.	See chapter 7.4.
RELATIVE OPENING DIAM. ±XX.Xmm	The band is opening in no card mode. The band diameter is ±XX.X mm to its value at the beginning of the adjustment.	See chapter 7.4.
Set Default Val -----	Prompts to access the “Restore default values” menu.	Select a menu by moving the → arrow using the ↑ and ↓ keys, and then confirm using the ↵ key.
STOPPED @ UNKNOWN DIAM.	Adjustment stopped at an unknown diameter.	The implant was used in no card mode. In order to be able to adjust the band, enter the no card mode.
STOPPED @ XX.Xmm DIAM.	Adjustment stopped. The band diameter is XX.X mm.	See chapter 5.4.
STOPPED @ ±XX.Xmm CHANGE IN DIAM.	Adjustment stopped in no card mode. The band diameter is ±XX.X mm compared to its value at the beginning of the adjustment.	See chapter 7.4.

Screen display	Meaning	Description-action
User Menu Config Menu	Prompts to access one of the two menus.	Select a menu moving the → arrows using the ↑ and ↓ keys, and then confirm using the ↵ key.
VOLTAGE SOURCE INAPPROPRIATE	Unsuitable voltage source.	Use the external power supply delivered with the device.
WEAK SIGNAL MOVE ANTENNA	Insufficient coupling level. Move the antenna.	The coupling level between the external antenna and the implant is insufficient. Move the external antenna to obtain better coupling.
WRONG CONFIG FOR THIS DEVICE	The control unit is badly configured.	The device is no longer configured for adjusting Easyband [®] type.

9 DEFINITION OF SYMBOLS

	Caution, refer to accompanying documents
	CE marking of conformity showing conformity with the European directives 90/385/EEC & 99/5/EEC
	Equipment class identifier (class 2) according to European directive 99/5/EEC
	CSA mark of conformity showing compliance with the applicable US and Canadian electrical safety regulations
	The device is subject to a separate collection for recycling. It was placed on the market after August 13, 2005
	Catalogue number
	Serial number
	Direct current

	<p>AC to DC power supply: use only the model “Mascot 9920”.</p>
	<p>Type BF equipment (degree of protection against electric shock)</p>
	<p>Non-ionizing radiation</p>
	<p>Antenna</p>
	<p>Keep dry</p>
	<p>Temperature range (for storage and transport)</p>
	<p>Humidity range (for storage and transport)</p>
	<p>Atmospheric pressure range (for storage and transport)</p>

10 ANNEX: TECHNICAL DESCRIPTION

Compliance with European directives	
Applicable directives	90/385/EEC & 99/5/EEC
CE marking authorization year	2005
Technical data	
Easyband [®] Control Unit	Rated input: 12Vdc, 20VA; also internally powered by rechargeable NiMH battery pack rated 7.2V, 1500mAh
External power supply Mascot 9920	Rated input: 100-240Vac, 50-60Hz, max. 0.9A. Rated output: 12Vdc, 3A or 13.2Vdc, 3A/40W.
Electrical safety	
Applied standards	IEC 60601-1 & US and Canadian national deviations
Type of protection against electric shocks	Power supply: class I device Control unit: internal electrical source device
Degree of protection against electric shocks	Type BF
Degree of protection against penetration of liquids	Ordinary protection (IPX0)
Cleaning method	Clean with a cloth slightly moistened with alcohol. The device cannot be sterilized
Degree of safe use in the presence of a flammable anaesthetic mixture with air or oxygen or nitrous oxide	Device not suitable
Mode of operation	Continuous use
Electromagnetic compatibility	
Applied standards	IEC 60601-1-2 & EN 301489-3
Indications	The indications according to IEC 60601-1-2 are listed in tables 201, 202, 204 and 206. These indications are not applicable if the device is used in the immediate vicinity of another electrical device. In this case, carefully check the correct working of the Easyband [®] Control Unit.
Radio characteristics	
Applied standards/regulations	Europe: EN 300 330-2 (class 3) USA: 47 CFR Part 15 Canada: RSS-310
Carrier frequency	27.000 ± 0.005 MHz
Band	ISM 26.957-27.283 MHz
Maximum emission level	18 dB μ A/m at 10 m
Environmental conditions for transport	
Temperature range	- 20°C to +50°C
Humidity range	10% - 90% RH
Pressure range	500 - 1060 hPA (375 - 795 mmHg)
Environmental conditions for storage	
Temperature range	+ 10°C to + 35°C
Humidity range	20% - 70% RH
Pressure range	500 - 1060 hPA (375 - 795 mmHg)

Guidance and manufacturer’s declaration – electromagnetic emissions		
<p>The Easyband[®] Control Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Easyband[®] Control Unit should assure that it is used in such an environment.</p>		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	<p>The Easyband[®] Control Unit must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</p> <p>The Easyband[®] Control Unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</p>
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 201, IEC 60601-1-2.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Easyband [®] Control Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Easyband [®] Control Unit should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV ± 1 kV	AC power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV ± 2 kV	AC power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec	AC power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 202, IEC 60601-1-2.


Guidance and manufacturer's declaration – electromagnetic immunity			
The Easyband [®] Control Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Easyband [®] Control Unit should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Portable and mobile RF communications equipment should be used no closer to any part of the Easyband [®] Control Unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
<p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>			
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Fields strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Easyband[®] Control Unit is used exceeds the applicable RF compliance level above, the Easyband[®] Control Unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Easyband[®] Control Unit.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Table 204, IEC 60601-1-2.

Recommended separation distance between portable and mobile RF communications equipment and the Easyband[®] Control Unit			
<p>The Easyband[®] Control Unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Easyband[®] Control Unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Easyband[®] Control Unit as recommended below, according to the output power of the communications equipment.</p>			
Rated maximum output power of transmitter W	Separation distance according to frequency or transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
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
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

Table 206, IEC 60601-1-2.

We

EndoArt SA
PSE-B
CH-1015 Lausanne

Declare under our sole responsibility that the product
Easyband[®] - Control Unit

1. Conforms to the essential requirements of the European Council Directive 90/385/EEC on Active Implantable Medical Devices,

Conformity assessment procedure: annex 2.3 (quality system) and annex 2.4 (examination of the design of the product),

Notified body: TÜV Product Service GmbH, Germany, number 0123,

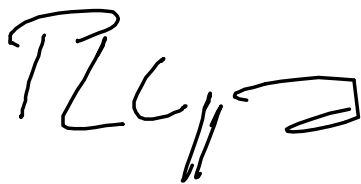
Applied standards: EN 45502-1
IEC 60601-1
IEC 60601-1-2.

2. Conforms to the essential requirements of the European Council Directive 99/5/EEC on Radio & Telecommunication Terminal Equipment,

Conformity assessment procedure: annex III, internal production control plus specific apparatus tests,

Applied standards: EN 300 330-2
EN 301 489-3.

Lausanne, June 23, 2006.



P. Dro, CEO



N. Stergiopoulos, CSO

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