EXHIBIT O – User Manual

FCC ID# PG6BA0T

Using the BA03 DDDR Pacemaker

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF, A PHYSICIAN (OR PROPERLY LICENSED PRACTITIONER).

Software SWM 1000/B-KT0.0

This software must only be used for follow-ups involving BA03 DDDR pacemakers.

The BA03 DDDR and Actros DR pacemakers are handled almost the same way.

➤ Please consult the Actros DR^{+} or the SWM 1000/B-K00.0 manual for a description of Actros DR features

In addition to the description in the SWM 1000/B-K00.0 manual, the following special features are included in the B-KT0.0 software:

- The list of pacemakers contains only the BA03 DDDR Home Monitoring device.
- The Home Monitoring functions and parameters are only available with the B-KT0.0 software.
- All statistical functions can be used simultaneously. No preselection is necessary.
- Both the rate trend and the sensor trend can be displayed.
- The trend for the gain monitor is not available.

This software can be ordered by using the following Catalog No.:

SWM 1000/B-KT0.0.A 332 076

Note: This software can only be used with the BIOTRONIK programmers EPR 1000^{Plus} and TMS 1000^{Plus}.

Home Monitoring - Introduction

The pacemaker BA03 DDDR is the newest member of the Actros^{+} family, that consists of pacemakers for treatment of bradycardia arrhythmia. The pacemaker is identical to the Actros DR^{+} in that it is a rate adaptive, dual chamber system with separate atrial and ventricular leads and is suited for patients who need AV synchronous pacing. BA03 DDDR has the functionality of a current DDDR pacemaker and is additionally equipped with the Home Monitoring function

Home Monitoring

This function is part of a complete Home Monitoring system, in which information about the cardiac condition of the patient can be transmitted using wireless technology between implant, patient and physician. The Home Monitoring function is used to obtain messages from the implant and to compile these messages into tables and graphs. Thus, the course of the therapy can be optimzied by setting up an additional follow-up between regularly scheduled visits, if necessary.

The implants' Home Monitoring function can be used during the entire service time of the implant or in shorter periods, e.g., a few weeks or months.

Transmission of message

For the transmission of the message, the implant is equipped with a small transmitter that has a range of approx. 2 m. The patients' implant data is transmitted to the respective patient device in certain, adjustable periods. The minimum distance between implant and patient device is 15 cm. The patient can activate the transmission himself by application and immediate removal of a magnet over the implant .

Patient device with components

The patient device (Fig.1) is developed for home use and consists of a mobile unit and the respective charging station. The patient can also carry the mobile unit with them in their normal daily activities.

The patient device rechargeable batteries that make an operating time of about 24 h possible. The patient device receives messages from the implant and for-

wards them to a BIOTRONIK Service Center via mobile communications.

Fig.1
Patient Device with Charging Station RUC 200

Cardio Report The service center compiles the messages into a comprehensive report (Cardio Report). This Cardio Report is tailored to the individual needs of the patient and is sent to the attending physician via fax.

- For further information about the patient device, please refer to the respective Users Manual.
- The standard functions are described in the Actros^{+} family techncial manua .
- The additional Home Monitoring functions of the BA03 DDDR are found in this manual

Indications and Contraindications

For the general indications and contraindications please refer to the Actros^{+} Family technical manual. Basically, the indications and contraindications of the BA03 DDDR are identical to that for the rate adaptive dual chamber pacemaker Actros DR^{+}. The special criteria for the Home Monitoring Function are described as follows:

Criteria for using Home Monitoring

There are no contraindications for use of the Home Monitoring function. This function has no influence on the diagnostic or therapeutic functionality of the pacemaker. The patient must be capable and willing to manage certain tasks associated with Home Monitoring. Usage of the Home Monitoring system is inappropriate in the following cases:

- The patient can not handle the system as intended, because of their physical or psychological condition.
- There is no GSM cellular service available in the local area of the patient's home.
- The patient often stays (i.e. works) in areas where it is not permitted to use mobile phones.

Note: Home Monitoring does not replace the regular follow-up examination.
When using the Home Monitoring function, the time interval between the follow-ups must not be prolonged.

Caution: The data transmitted by Home Monitoring are not suitable for diagnosis, because not all information available in the implant is being transmitted.

Transmission of Message

The Home Monitoring function can be switched ON or OFF with the programming device. If the Home Monitoring function is active, the transmission of the implant data can be triggered as follows:

- Periodic message at predefined time intervals
- Message activated by the patient

The attending physician himself decides if the patient should trigger a transmission by programming this paramater ON or OFF. The patient activated message does not effect the programmed periodic message.

Note: Please note that with the BA03 DDDR, the Home Monitoring function is only possible in following pacing modes: DDD, DDDR, DDI, DDIR.

Periodic Message

The time and interval (Monitoring Interval) of the periodic message are programmable. For the periodic message, a time between 0:00 and 24:00 can be set. Generally, it is recommended to select a time between 0:00 and 4:00. For every Monitoring Interval, a data string is generated in the implant and the transmission is activated.

Patient Activated Message

Application of a magnet over the implant activates a transmission. The attending physician should inform the patient in detail about the handling and the physical symptoms that suggest a magnet application by the patient.

Caution: The magnet effect must be programmed "synchronous" if the attending physician enables the patient to transmit messages.

Diagnostic Memory Functions

BA03 DDDR has the same standard functions as the Actros DR+, with the exception that the Gain Monitor is unavailable. Contrary to the Actros DR+, the BA03 DDDR has the ability to use all memory functions simultanously.

When the Home Monitoring function is activated, the following diagnostic memory functions are recorded automatically and transmitted by the Home Monitoring System:

Event Counter

The function Event Counter can record the following events:

- As percentage
- Vs percentage

Event sequences:

- As - Vs percentage
- As - Vp percentage
- Ap - Vs percentage
- Ap - Vp percentage

With every periodic message, the counter is reset.

Arrhythmia

VES Classifications

The VES events are classified according to their complexity. The following classifications are available:

1. Number of Single-VES

   Event sequence A-V-VES-A...

2. Number of VES Couplets:

   Event sequence A-V-VES-VES-A.

3. Number of VES Triplets:

   Event sequence A-V-VES-VES-VES-A.

4. Number of VES Runs

   Sequence of 4...8 consecutive VES.

   Event sequence A-V-VES-VES-...-A.

5. Maximum number of VES /h

6. Number of Ventricular Tachycardias:

   VT with duration > 8 VES and ≥ 120 bpm

Activity Chart

This function records data, that are characteristic for the activities of patient and pacemaker system:

- Mean value of actual ventricular heart rate
- Maximum value of actual ventricular heart rate
- Activity duration at maximum sensor rate

Functions of Home Monitoring

Programmable Parameters

The functions of Home Monitoring and their parameters can be set with the programmers EPR 1000^{plus} and TMS 1000^{plus}. Therefore, the corresponding software SWM 1000/B-KT0.0 is necessary

The functions of Home Monitoring are available only in following pacing modes:
DDD, DDDR, DDI, DDIR.

When using the Home Monitoring system, the transmission interval must be selected. This monitoring interval can be from one to 30 days. If the standard setting is selected, data will be transmitted daily. For the periodic message, a time between 0:00 and 24:00 is programmed. It is recommended that a time between 0:00 and 4:00 is selected, as preset in the standard program.

The patient activated message can also be programmed ON or OFF. This option is deactivated in the standard program

Technical Data

Modes

Valid when Home Monitoring function is activated:

DDD, DDDR, DDI, DDIR

Valid when Home Monitoring function is deactivated:

DDD, DDDR, DDI, DDIR, DVI, DVIR, VDD, VDDR, DOO, DOOR, VVI, VVIR, AAI, AAIR, VOO, VOOR, AOO, AOOR, DDI/T, DDI/TR, DDT, DDTR, DVT, DVTR, VDT, VDTR, VVT, VVTR, AAT, AATR, VDI, OFF

Home Monitoring parameters

Home Monitoring	Off, On
Monitoring interval	1...(1) ...30 days
Time of transmission	0:00...23:50 h:min
Patient activated data transmission	Off, On

Pulse and Timing Data[1)]

Basic rate[2)]	30 ... (1) ... 88 ... (2) ... 122 ... (3) ... 140 ... (5) ... 180 ppm
Hysteresis[2)]	Off; -5 ... (5) ... -50 bpm
Repetitive Hyster.	Off; 1 ... (1) ... 10
Scan Hysteresis	Off; 1 ... (1) ... 10
Upper rate (UTR)[2)]	100; 110; 120; 130; 140; 160; 185 ppm
Night Rate	Off; (and basic rate settings)
Tachycardia mode	2:1; WKB (automatic setting)
Rate limitation[2)3)]	190 ... 220 ppm
Dynamic AV delay	low; medium; high; individual; fixed
AV delay values	15; 50; 75; 100; 120 ... (10) ... 200; 225; 250; 300 ms (programmable in 5 ranges)
AV safety interval	100 ms
Ventricular Blanking time	12; 16; 24; 32; 40; 48; 56; 72 ms
Magnet effect	Auto; asynchronous; synchronous
Pulse amplitude A	0,1 ... (0,1) ... 4,8 ... (1,2) ... 8,4 V
V	0,1 ... (0,1) ... 4,8 ... (1,2) ... 8,4 V
Pulse width A	0,1; 0,2; 0,3; 0,4; 0,5; 0,75; 1,0; 1,5 ms
V	0,1; 0,2; 0,3; 0,4; 0,5; 0,75; 1,0; 1,5 ms
Sensitivity A	0,1 ... (0,1) ... 1,5 ... (0,5) ... 7,5 mV
V	0,5 ... (0,5) ... 7,5 mV
Refractory period A	200 ... (25) ... 775 mV
V	250; 300; 350; 400 ms

1) 37°C, 500 Ω
2) The respective intervals result from the rate f in the formula t = 60.000 / f (t in ms, f in ppm)
3) In the case of an electronic failure

ARP extension	0 ... (50) ... 350 ms
Automatic mode conversion	Off; On (in the modes DDD(R) and VDD(R))
Lead polarity	
Pace A/V	unipolar; bipolar / unipolar; bipolar
Sense A/V	unipolar; bipolar / unipolar; bipolar

Rate Adaption

Sensor gain	1 ... 40 (in 32 steps)
Autom. s. gain	Off; On
Sensor threshold	very low; low; medium; high; very high
Rate increase	1; 2; 4; 8 ppm/s
Max. Sensor rate[1)]	80 ... (5) ... 180 ppm/s
Rate decrease	0,1; 0,2; 0,4; 0,8 ppm/s

1) In the modes DDIR-, DVIR-, VVIR-and VOOR, lower maximum sensor rates result than indicated here (partly depending on the selected AV interval). The respective values are displayed by the programmer.

Parameter at Replacement Indication

Basic rate programmed value decreased by 11%
(in the modes DVI(R), DDI(R), DVT(R), DDI/T(R), decreases by 4,5–11%, depending on the programmed AV delay)

Magnet rate Pulse generator behavior after reaching ERI

Magnet Mode	Cycles 1-10 after magnet application	After Cycle 11
Automatic	Asynch. at 80 ppm	Synch. with basic rate reduced by 4.5 - 11%
Asynchronous	Asynch. at 80 ppm	Asynch. with basic rate reduced by 4.5 - 11%
Synchronous	Synch. with basic rate reduced by 4.5 - 11%	Synch. with basic rate reduced by 4.5 - 11%

Pulse amplitudes programmed values

sensitivity programmed values

Home Monitoring after ERI 0 ...(1)...14 days

Default 14 days

Features

- Home Monitoring

Additional functions conform with Actros DR

- Automatic sensor gain
- Extensive VES analysis
- External pulse control up to 800 ppm
- Dual chamber IEGM with event marker
- 24 hour trend with pacing part in %
- Sensor test trend with rate forecast
- Automatic mode conversion
- High definition threshold test in the range of 0,1 up to 4,8 V with 0,1 V resolution
- P/R wave test
- Retrograde conduction test
- Reaction to vasovagal syncopes
- Night program
- Heart rate histogram
- Sensor rate histogram
- Assisted follow-up
- Activity chart
- Event counter
- Patient data memory
- Analog telemetry
- Temporary program activation
- Controlled impulse amplitudes

Default Programs

Parameter/Function	Factory-Settings	Standard-Program	Safe Program
Home Monitoring	Off	Off	Off
Mode	DDD	DDDR	VVI
Autom. m. conversion	Off	Off	—
Basic rate	60 ppm	60 ppm	70 ppm
Hysteresis	Off	Off	Off
Repetitive hysteres.	—	—	Off
Scan hysteresis	—	—	Off
Night program	Off	Off	Off
Upper rate (UTR)	160 ppm	160 ppm	—
Dynamic AV delay	medium	medium	—
Ventric. blanking time	24 ms	24 ms	—
Magnet effect	Auto	Auto	Auto
Pulse amplitude A	3,6 V	3,6 V	—
V	3,6 V	3,6 V	4,8 V
Pulse width A	0,4 ms	0,4 ms	—
V	0,4 ms	0,4 ms	1,0 ms
Sensitivity A	1,5 mV	1,5 mV	—
V	2,5 mV	2,5 mV	2,5 mV
Refractory time A	425 ms	425 ms	—
V	250 ms	250 ms	300 ms
ARP	0 ms	0 ms	—

Parameter/Function	Factory Settings	Standard-Program	Save Program
Sensor threshold	—	medium	—
Sensor gain	—	6	—
Auto. Sensor gain.	—	Off	—
Rate increase	—	2 ppm/s	—
Max. sensor rate	—	120 ppm	—
Rate decrease	—	0,4 ppm/s	—
Lead polarity			
Pace A/V	unipolar	unipolar	unipolar
Sense A/V	unipolar	unipolar	unipolar
Statistics	standard	standard	standard

Materials in Contact to Human Tissue

Housing	Titanium
Grommet	Silicone
Connector Receptacle	Epoxy resin
Coating (for unipolar devices)	Silicone (if used)

Programmer

EPR 1000^{plus}, and TMS 1000^{plus}

Electrical Data[1)]

Circuit	Hybrid electronics with VLSI-CMOS-Chip
Input impedance A	270 kΩ
V	330 kΩ
Pulse form	biphasic, asymmetric
Polarity	cathodic
Current drain	
BOS, inhibited	12 µA
BOS, 100 % stimul.	24 µA
Conducting surface	36 cm^2
Conducting shape	flattened ellipsoidal

1) 37°C, 500 Ω

Battery

Power Source	Li/J
Manufacturer	Wilson Greatbatch
Type	WG 8431
Voltage	2,8 V
Voltage at ERI	2,5 V
Nominal Capacity[1)]	1,3 Ah

Service Times

Nominal service time[2)]	6,7 years at pulse amplitudes 3,6 V
Expected service time[3)]	5,1 years at pulse amplitudes 3,6 V
Remaining capacity at ERI in Ah	0,13

Mechanical Data

Lead connection	IS-1 (accepts unipolar and bipolar)
Mass	30 g
Volume	13 cm^3
Dimensions	6 x 45 x 57 mm
X-Ray Identification	EE

1) Data from battery manufacturer
2) Calculated with formula: T= 2740 x C_{bat} /(I_{BOS}+ I_{EOS})
3) Expected service time based on all avialable data as provided from the battery manufacturer

Tolerances of Factory Settings[1)]

Data according to EN 50 061

Basic rate				
Interference rate	60 ± 1 min-1			
Basic interval	1000 ± 3 ms			
Escape interval	1000 ± 5 ms			
Magnet rate	90 ± 1 min^{-1} (for 10 cycles)			
Magnet Interval	664 ± 2 ms (for 10 cycles)			
AV delay				
Basic rate	180	+3/-1 ms		
≤70 ppm	180	+3/-1 ms		
70-90 ppm	160	+15/-5 ms		
91-110 ppm	140	+15/-5 ms		
111-130 ppm	120	+15/-5 ms		
≥130 ppm	100	+15/-5 ms		
	Atrium		**Ventricle**	
Pulse amplitude				
Peak value	3,6	+0,25 V/ -0,45 V	3,6	+0,25 V/ -0,45 V
EN 50061 mean	3,3	+0,25 V / -0,45 V	3,3	+0,25 V / -0,45 V
Pulse width	0,43	±0,02 ms	0,43	±0,02 ms
Sensitivity				
15 ms sin^2	1,5	±0,5 mV		
40 ms sin^2			2,5	±0,5 mV
EN 50061 Triangle	1,8	±0,5 mV	2,5	±0,5 mV
Refractory period	425	+5 / -20 ms	250	+5 / -20 ms
Run-away protection	210	±20 min^{-1}	210	±20 min^{-1}

1) 37°C, 500 Ω

Order Information

Model	Lead Connection	Order Number
BA03 DDDR		
uncoated	IS-1	122 126

Federal Communications Commission Disclosure

The BA03 DDDR pacemaker is equipped with an RF transmitter for wireless communications. This transmitter is authorized by rule under the Medical Implant Communications Service (47 CFR Part 95) and must not cause harmful interference to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

The FCC ID number for this device is: PG6BA0T.