EXHIBIT D – FCC ID Label

FCC ID# PG6BA0T

FCC ID Labeling Scheme

Per 47 CFR 2.926 (e),

> "Where it is shown that a permanently affixed nameplate is not desirable or is not feasible, an alternative method of positively identifying the equipment may be used if approved by the Commission. The proposed alternative method of identification and the justification for its use must be included with the application for equipment authorization.
>
> Note: As an example, a device intended to be implanted within the body of a test animal or person would probably require an alternate method of identification."

Since the EUT is implanted in the human body, the FCC ID will not be applied to outside of the device. Instead, the applicant is proposing the following alternate method of applying the FCC ID number to two locations:

1. The FCC ID, along with the disclosure statement required by 95.1215(a), is in the User Manual (page 19 – see excerpt below).

2. The FCC ID also appears on the package label (see below), which is affixed to outside of the shipping box for the EUT.

Packaging Label

BA03 DDDR

DUAL CHAMBER,
RATE ADAPTIVE PACEMAKER
IS-1, UNI/BIPOLAR
ISO 5841-3:1992(E)
DDDR Uncoated

Order No.: 122 126
Serial No.: *****
Use Before: *****
Rate: **60 ppm**
Pulse: **(A) 3.6 V; 0.4 ms**
(V) 3.6 V; 0.4 ms

NOTE: This unit is designed for use with two (2) Unipolar or Bipolar **IS-1** leads meeting the International Standard ISO 5841-3:1992(E).

Mode	DDD*
Lower Rate	60 ppm
Home Monitoring	OFF
Hysteresis	OFF
Upper Tracking Rate	160 ppm
UTR Response	2:1
Dynamic AV Delay	MEDIUM
ARP Extension	0 ms
Safety AV Delay	100 ms
Ventricular Blanking Period	24 ms
Automatic Mode Conversion	OFF
Magnet Rate	Async
Pulse Amplitude	(A) 3.6 V; (V) 3.6 V
Pulse Width	(A) 0.4 ms; (V) 0.4 ms
Sensitivity	(A) 1.5 mV; (V) 2.5 mV
Refractory Period	(A) 425 ms; (V) 250 ms
Polarity Sense	Unipolar
Polarity Pace	Unipolar

*See enclosed Technical Manual for programmable values.

CAUTION: Because of the numerous available 3.2 mm configurations, e.g., the IS-1 and the VS-1 standards, lead/pulse generator compatibility should be confirmed with the pulse generator and/or lead manufacturer prior to the implantation of a pacing system.

STERILE: Pacemaker as identified and accessories
NON-STERILE: Package Inserts

STERILIZATION: This unit has been gas sterilized with ethylene oxide. Sterility cannot be guaranteed if the package has been damaged during transportation. Please examine the package carefully before opening. If it shows any evidence of damage or mishandling, it should be returned immediately to BIOTRONIK. Once the box seal has been broken, title passes to the hospital and a purchase order is required.

CAUTION: Recommended Storage Temperature: 5° C - 55° C (41° F - 131° F).

Federal (U.S.A.) law restricts this device to sale by, or on the order of, a physician.

FCC Statement: (FCC ID PG6BA0T) This pacemaker is equipped with an RF transmitter for wireless communications. This device must not interfere with stations operating in the 400.150 - 406.000 MHz band in the Meteorological Satellite or Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

Made in Germany B1112-A 02/01

Device / No.:	BA03 DDDR / 122 126	Device / No.:	BA03 DDDR / 122 126
Serial No.:	*	Serial No.:	*
Manufacturer Name/No.:	BIOTRONIK / 004	Manufacturer Name/No.:	BIOTRONIK / 004
Device / No.:	BA03 DDDR / 122 126	Device / No.:	BA03 DDDR / 122 126
Serial No.:	*	Serial No.:	*
Manufacturer Name/No.:	BIOTRONIK / 004	Manufacturer Name/No.:	BIOTRONIK / 004
Device / No.:	BA03 DDDR / 122 126	Device / No.:	BA03 DDDR / 122 126
Serial No.:	*	Serial No.:	*
Manufacturer Name/No.:	BIOTRONIK / 004	Manufacturer Name/No.:	BIOTRONIK / 004
Device / No.:	BA03 DDDR / 122 126	Device / No.:	BA03 DDDR / 122 126
Serial No.:	*	Serial No.:	*
Manufacturer Name/No.:	BIOTRONIK / 004	Manufacturer Name/No.:	BIOTRONIK / 004
Device / No.:	BA03 DDDR / 122 126	Device / No.:	BA03 DDDR / 122 126
Serial No.:	*	Serial No.:	*
Manufacturer Name/No.:	BIOTRONIK / 004	Manufacturer Name/No.:	BIOTRONIK / 004

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.