Response to Issues Raised by the FCC Regarding the Computational SAR Report for PG6CYLOS

As highlighted in our initial submission, the Biotronik Cylos DR-T pacemaker (FCC ID: PG6CYLOS) is essentially similar to the Biotronik Philos DR-T pacemaker (FCC ID: PG6BA0T), whose SAR analysis was accepted by the FCC on March 25, 2003. The Philos DR-T pacemaker complies with the SAR limit of 1.6 W/kg with a margin of 25.5 dB. To support our claim that the Cylos DR-T pacemaker, which is essentially similar to the Philos DR-T pacemaker, also complies with the SAR Limits of 1.6 W/kg, please refer to the additional data and information provided below.

Issue (1): Transmitter and Model Validations

The Philos DR-T pacemaker (FCC ID: PG6BA0T) SAR analysis is on file with the FCC, and a summary of its SAR analysis is stated below:

(a) SAR computation software: Remcom XFDTD Ver. 5.1.0.5 Bio-Pro, Calc FDTD 5.1, Remesher Ver. 5.1
(b) SAR analysis mesh size: $2mm^3$
(c) Region of SAR analysis: Human torso, Remcom HIFI body model
(d) Pacemaker model location: typical location in upper chest
(e) Pacemaker physical model: includes titanium can, loop antenna, epoxy antenna header, pacing leads.
(f) Pacemaker transmitter characteristics: Output power measured with a calibrated HP8595E RF spectrum analyzer, output impedance measured with a calibrated HP8753ES RF network analyzer. Modeled with Eagleware Superstar Pro Ver. 6.5b and MicroSim PSPICE Ver. 8.0 simulation software.
(g) SAR analysis results:
Maximum SAR: 4.54 mW/kg
Maximum 1g averaged SAR 1.11 mW/kg
Average SAR 427 nW/kg
SAR margin between maximum SAR and ANSI/IEEE spec. limit: 25.5 dB
SAR expressed as a percent of ANSII/IEEE spec. limit: 0.28%

As outlined in Exhibit S – SAR Analysis, the Cylos DR-T pacemaker (FCC ID: PG6CYLOS) is essentially similar to the Philos DR-T pacemaker (FCC ID: PG6BA0T) with respect to the following areas:

(a) RF transmitter circuitry
(b) RF transmitter antenna and housing
(c) Acceptance Test Procedure/Specification
(d) Measured Radiated Emissions Levels

Based upon the relative similarity of the pacemakers, and the very low SAR levels computed for the Philos DR-T pacemaker, the Cylos DR-T pacemaker would be in compliance with the ANSII/IEEE SAR limits.

Issue (2): Antenna-terminal Measured Conducted Output Power and Related Testing Details

The RF output power measured at the Cylos DR-T implant antenna terminals (output of the RF amplifier) was -8.04 dBm at 403.623 MHz. The measurement was made on July 1, 2005 with an HP8595E spectrum analyzer (calibrated on May 11, 2005 with a one year calibration cycle) with the following instrument settings:

- Ref Level: 0 dBm
- Center Frequency: 403.623 MHz (same as device transmit frequency)
- Span: 200 kHz
- RF Atten: 10 dB
- Resolution BW: 3 kHz
- Video BW: 3 kHz
- Sweep Time: 100ms

For the spectrum analyzer settings shown above, the RF power measurement error was verified to be less than +/- 0.2 dB. The RF power measurement accuracy was verified by comparing the spectrum analyzer measurement against a calibrated RF power meter and signal source.

Additional Information: Transmitter Duty Cycle Factor

The Cylos DR-T transmitter does not transmit RF energy continuously. By design, the transmitter will normally transmit 7 times daily, at the power level noted above, for a duration of approximately 80 milliseconds. Thus the implant will transmit for a total duration of approximately 0.56 seconds per day. This gives a daily transmission duty cycle of 0.00065%.

Under extraordinary conditions (when there is a device failure or extraordinary medical event), the Cylos DR-T will transmit up to 24 additional times per day, for a total of 31 messages. Thus it will transmit for 2.48 seconds per day at the above noted power level. This corresponds to a daily transmission duty cycle of 0.0029%. These low duty cycle factors were not included in the above SAR analysis (which assumed continuous steady-state RF transmission – a scenario not possible in pacemaker). Considering the extremely low RF transmitter duty cycle, the already low SAR levels will be reduced by an additional factor of 0.0000065 or -51.9 dB (0.000029 or -45.4 dB for a device failure or extraordinary medical event) if duty cycle averaging is taken into account.

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