2 March 2010

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Authorization and Evaluation Division
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FCCID: QRIPRIMUS

Biotronik is submitting this document in response to correspondence 38625 from the FCC.

Item 1:

1) Please note that for correspondence replies, besides any exhibits themselves we generally request also an item-by-item explanation for how each issue is resolved, i.e. either by details given in such item-by-item explanation, and/or explanation how each associated exhibit addresses each item. This reply can be in form of separate self-contained corresp. in the e-filing system, and/or a cover letter exhibit listing each question and answer. For the preceding corresp. in this filing, **38513/38514** and **38618/38619,** such item-by-item replies are not required at this stage - however we have repeated in the following some of the preceding info requests where it was unclear whether and how those were addressed.

Answer to Item 1:
An item-by-item explanation for the further information requests in this correspondence follows in question and answer format. Where another exhibit is needed, an explanation is given as to how that exhibit resolves the issue.

Item 2:

2) further to corresp. 38513/38514 item 5), if not in filing already please explain differences between the following models, and include photos and/or sketches if differences involve size, shape, properties etc of materials proximate to antenna: Evia SR, Evia SR coated, Evia SR-T, Evia SR-T coated, Evia DR, Evia DR coated, Evia DR-T, Evia DR-T coated, Entovis SR, Entovis SR coated, Entovis SR-T, Entovis SR-T coated, Entovis DR, Entovis DR coated, Entovis DR-T, Entovis DR-T coated.

Answer to Item 2:
Differences between models within the PRIMUS family are:

- The Evia models have a different (software-defined) medical therapy feature set than the Entovis models. These feature differences have no impact on RF, and do not involve differences in size, shape or properties of materials proximate to antenna.
- The –T models are capable of RF transmissions; the other models are not capable of RF transmissions. This does not involve differences in size, shape or properties of materials proximate to antenna.
- The coated models have a thin medical grade silicone rubber coating over most of the housing; this is not on the header or proximate to the antenna. This does not involve differences in size, shape or properties of materials proximate to antenna.
- The SR models both provide cardiac therapy; the DR models impact two chambers of the human heart; the SR models impact one chamber of the human heart.

- The SR-T models use a slightly smaller (and lower gain) antenna. The antennas are made of the same material and nearly identical shape.

These differences are summarized in the following table:

Model	Feature Set	Chambers	Small Antenna	RF Capable	Coated
Evia SR	Evia	1			
Evia SR-T	Evia	1	√	√	
Evia DR	Evia	2			
Evia DR-T	Evia	2		√	
Evia SR coated	Evia	1			√
Evia SR-T coated	Evia	1	√	√	√
Evia DR coated	Evia	2			√
Evia DR-T coated	Evia	2		√	√
Entovis SR	Entovis	1			
Entovis SR-T	Entovis	1	√	√	
Entovis DR	Entovis	2			
Entovis DR-T	Entovis	2		√	
Entovis SR coated	Entovis	1			√
Entovis SR-T coated	Entovis	1	√	√	√
Entovis DR coated	Entovis	2			√
Entovis DR-T coated	Entovis	2		√	√

Antenna Information and Specifications for each antenna are part of this filing.

The PRIMUS antenna is described in the following exhibits:
17_PRIMUS AntSpec.pdf

The PRIMUS small antenna is described in the following two files:
R5_PRIMUS Antenna Information small.pdf
R5_PRIMUS Antenna Specification small.pdf

These documents contain sketches and dimensions of the respective antennas, along with antenna gain, antenna materials and antenna header information.

Item 3:
3) At two places minimum, the SAR analysis considers 30-minute time interval and/or time averaging. Per 47 CFR 2.1093(d)(5) such time-averaging provisions may not be used in determining typical exposure levels for portable devices used by consumers. Please revise SAR analysis accordingly.

Answer to Item 3:
An updated SAR Report, **Primus SAR Analysis 3147205e.pdf** has been uploaded as part of this filing. This SAR Report removes any references to time-averaging. This SAR report shows that the Primus pacemaker's maximum worst-case SAR is **2.5218e-003 W/kg**, averaged over 1 gram of tissue. The regulatory limit specified in 47 CFR 2.1093 is **1.6 Watts/kg**, averaged over 1 gram of tissue. As such, the Primus pacemaker's SAR level complies with the FCC regulatory limit with a margin of **28 dB.**

Item 4:

4) if not in filing already, please amend to provide details about transmitter (feedpoint) impedance obtained from SAR computation; as part of this please include e.g. return loss data to demonstrate appropriate operating frequency for antenna as modelled, etc.

Answer to Item 4:

As described in Section 8.2 of the revised SAR Report (**Primus SAR Analysis 3147205e.pdf)**, the transmitter feedpoint impedance was obtained by the direct measurement of the transmitter's output impedance using an Agilent 8753ES RF Network Analyzer. For this measurement, the network analyzer was calibrated using an Agilent/HP 85033D calibration kit. The ultra-low power transmitter was active during the measurement of its output impedance, which was measured to be Z = 410 +j 63 Ohms at the transmitter's operating frequency.

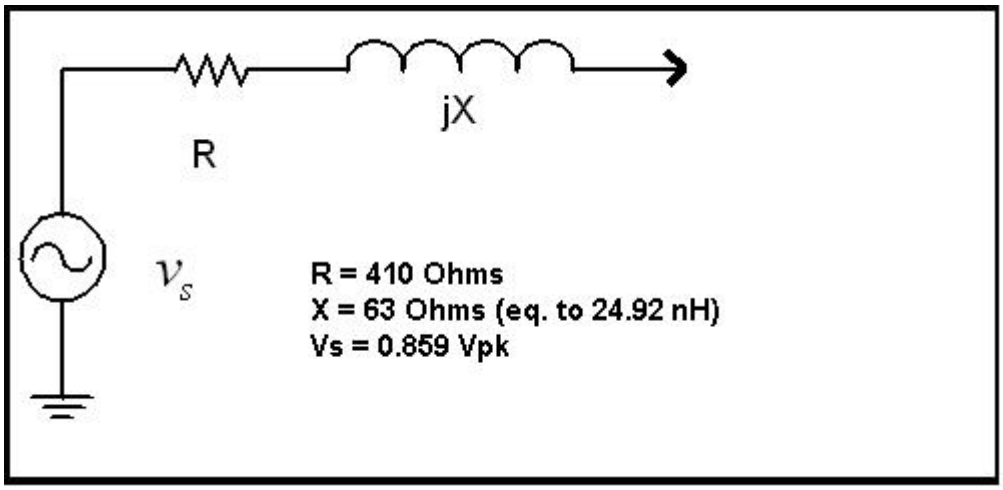
Item 5:

5) if not in filing already, please provide specific details for all model input source parameters and excitation signal type(s)

Answer to Item 5:

The specific details for all module input source parameters and excitation signal type(s) are shown in section 8.2 of the revised SAR report Report (**Primus SAR Analysis 3147205e.pdf)** . For the SAR analysis, the input source was modeled as a Thevenin equivalent circuit based upon measurements of the transmitter's output power and output impedance. The source model in the SAR analysis consisted of a sinusoidal continuous wave (CW) signal at 403.5 MHz with an amplitude of 0.859 Volts peak, and a source impedance of Z = 410 +j 63 Ohms.

The Thevenin equivalent model is shown below:



Primus SAR Analysis 3147205e.pdf replaces following exhibits:

18 PRIMUS RFEXp-MPE.pdf
R9_Primus SAR Analysis 3147205d_rev.pdf
R9_Primus SAR Analysis 3147205c.pdf