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Subject: changes to BIOMONITOR III family of devices

Herewith we like to inform about proposed hardware changes of BIOTRONIK's BIOMONITOR III family of implantable cardiac monitors. Changes are driven by product design improvement. This results in addition of D301 and therefore slight PCB layout adjustments which also improve manufacturability. Due to the layout adjustments some BOM positions need to be adjusted in their values. This also included an adjustment of an antenna matching component in C807. The hardware changes that have been made are listed in the following table:

Component	C804	C813	C814	C815	C807	D301
Old Value	10uF	10uF	22uF	22uF	39pF	Not Present
New Value	22uF	Not Populated	10uF	10uF	27pF	CDBQR0230R

In addition to the above mentioned PCB hardware changes it was decided to add a new model number to the device family.

	Model	Hardware	ROM	RAM
Existing model	BIOMONITOR III	BOM-0428_02 SCH-0295_03	7848ROMRev_01.03	7848RAMRev_04.06
Additional model	BIOMONITOR IIIIm	ASM-0929_06		7183RamRev_02.02

Both models share the identical RF antenna and electronics included the PCB changes mentioned above. The only differences are BIOMONITOR IIIIm owns an extended battery capacity which results in an extended service lifetime and extended therapeutic features which result in a different RAM firmware version as mentioned above. The RAM firmware differences do not alter the radio transceiver parameters.

Sincerely,


 Dirk König
 Regulatory Affairs Senior Manager
 BIOTRONIK SE & CO. KG