The BIO|CONCEPT.BIOMONITOR III study: Performance of implanted Biomonitor IIITM for detection of baseline electrocardiogram (ECG) parameters

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Introduction: Implantable loop recorders (ILR) are employed to establish a rhythm symptom correlation or diagnose occult arrhythmias and rely on adequate P wave and R wave detection to achieve this. Current devices aim for a benchmark of R wave amplitude >0.2mV which was obtained in one series in 96.7% of patients at implantation and 93.3% at 1 month follow up. Stability of signal over time and accuracy of identification of both P and R wave is important for arrhythmia detection. In this study we sought to assess BIOMONITOR III P and R wave amplitude in the BIO|CONCEPT.BIOMONITOR III study in comparison with that measured in the approximating surface ECG lead at implantation and 1 month follow-up.

Methods: ECGs from five patients (>10% of the study population) representing a single site subpopulation of the BIO|CONCEPT.BIOMONITOR III study have currently been analysed. All patients had an indication for an implantable loop recorder (unexplained syncope or cryptogenic stroke). Management of these patients was as per the existing study protocol. P and R wave amplitude of the surface 12 lead ECG was assessed in the vector best approximating the vector of implantation (in all cases lead II). This was compared to the signal transmitted from the Biomonitor IIITM at first transmission and at 1 month post-implantation. In all cases the signal was measured to the nearest 1mm and averaged over five cardiac cycles. All values were grouped and are reported as mean ± standard error and assessed for statistical significance by paired two tailed t-tests.

Result: The amplitude of the R waves transmitted by the BIOMONITOR III was 1.0±0.3mV compared to the surface ECG of 0.6±0.1mV. The R wave signal was not significantly different at one month with an amplitude of 1.1±0.3mV (p=0.57). P wave amplitude was also stable over time at 0.03±0.01mV at first transmission and 0.03±0.01mV at one month (p=0.82) compared to the surface ECG of 0.10±0.00mV. Visualisation of P waves on the transmitted ECGs was aided by viewing the ECG using the standard BiotronikTM home monitoring interface at a gain of 50mm/mV yielding P waves of 1.5±0.4mm and 1.6±0.5mm (at first transmission and one month respectively, see Figure 1) compared to
Conclusion: Our current assessment demonstrates the BIOMONITOR III is capable of recording ECGs with P and R wave amplitudes comparable to those recorded on a gold standard 12 lead ECG in a similar vector. Visualisation of P waves can be further aided by simply adjusting the gain on the home monitoring interface. This assessment of P and R wave amplitude in comparison to the surface ECG will be applied to entire BIOICONCEPT.BIOMONITOR III study population.