

BIO|CONCEPT.BIOMONITOR III Study

BIO|CONCEPT.BIOMONITOR III STUDY
CLINICALTRIALS.GOV IDENTIFIER: NCT03850327

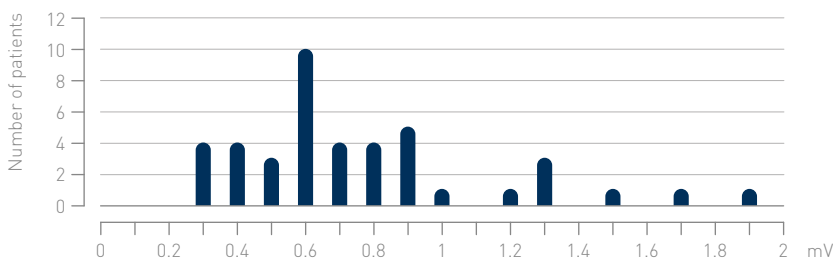
Study Design¹

- Prospective, open-label, non-randomized, multicenter study
- 48 patients implanted with a BIOMONITOR III, using the FIT OneStep insertion tool at 10 sites in Australia
- Monitoring of developing cardiac arrhythmia, syncope and AF following cryptogenic stroke or monitoring of AF prior to or following AF ablation
- Follow-up one week (on-site) and one month (Home Monitoring) after implantation
- To confirm the safety and efficacy of the insertion procedure and of the use and handling of the incision/insertion tools, and to assess the sensing quality of BIOMONITOR III

Main Results

BIOMONITOR III shows a high and stable R-wave amplitude²

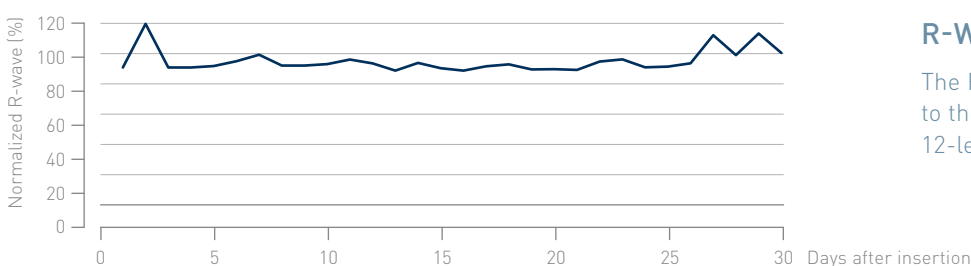
Mean R-wave amplitude per patient



LARGE R-WAVE AMPLITUDE

The mean R-wave amplitude per patient was 0.7 mV.

Mean R-wave amplitude trend



R-WAVE AMPLITUDE IS STABLE

The R-waves are comparable to those recorded on a gold standard 12-lead ECG.³

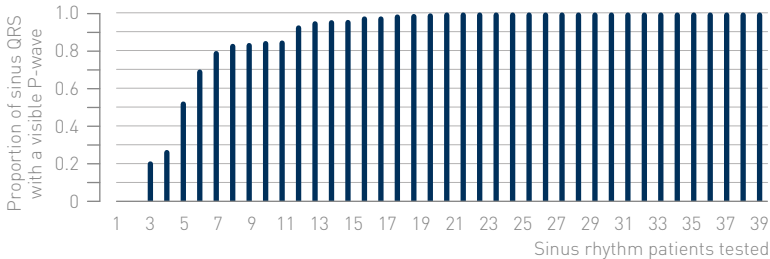
Patient-specific normalized R-wave values per day were averaged to generate the mean normalized R-wave value per day of the cohort.

Clinical Relevance

- Implantable Cardiac Monitors (ICM) are helpful in the diagnosis of a wide range of rare disorders and pathologies.
- Remote monitoring capabilities of ICMs improve the time to diagnosis and the follow-up strategy and offer a potential reduction of health care costs.
- The Bio|Concept study data confirmed the safety, efficacy and sensing quality of BIOMONITOR III.
- Visualization of P- and R-waves is comparable to those recorded on a gold standard 12-lead ECG.
- Clear P-wave visibility contributed to reliable rhythm diagnosis in a relevant number of cases.

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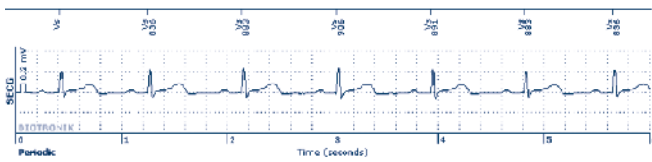
Clearly visible P-waves in the vast majority of patients²



HIGH RATE OF SENSED P-WAVES

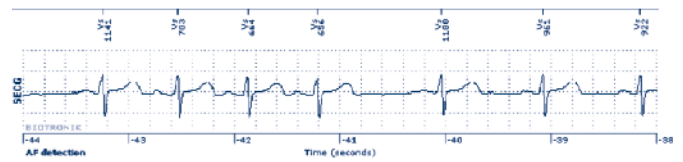
P-waves were visible in 89% of the heart cycles.

P-waves are comparable to those recorded on a gold standard 12-lead ECG³



BIOMONITOR III periodic ECG strip showing sinus rhythm²

P-waves contribute to reliable rhythm identification in device-detected arrhythmia episodes⁴



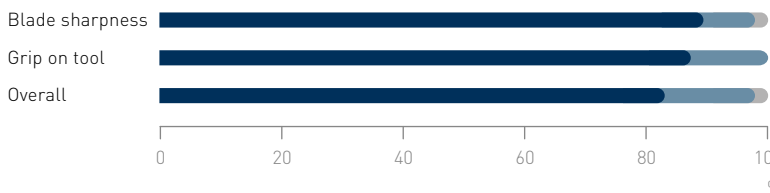
BIOMONITOR III-detected episode of arrhythmia. The presence of P-waves helps to distinguish this irregular rhythm from atrial fibrillation.

BIOMONITOR III shows good usability and is easy to handle⁵

FIT One Step insertion tool



Incision tool



- Excellent
- Good
- Fair

SUPERIOR CONVENIENCE

100% of the users rated BIOMONITOR III usage 'excellent' or 'good'.

QUICK INSERTION

The median time from incision to tool removal was 39 sec.

1 BIO|CONCEPT.BIOMONITOR III study; ClinicalTrials.gov identifier: NCT03850327. 2 Lovibond S et al. The BIO|CONCEPT.BIOMONITOR III study: Sensing performance and Home Monitoring transmission success of a new miniaturized Implantable Cardiac Monitor. Poster AP19-00775; APHRS 2019. 3 McDowall L et al. The BIO|CONCEPT.BIOMONITOR III study: Performance of implanted BIOMONITOR III™ for detection of baseline electrocardiogram (ECG) parameters. Poster AP19-01240; APHRS 2019. 4 Lovibond S et al. The BIO|CONCEPT.BIOMONITOR III study: P-wave visibility and utility during recorded arrhythmia in the BIOMONITOR III Loop Recorder. Poster AP19-00531; APHRS 2019. 5 Lovibond S et al. The BIO|CONCEPT.BIOMONITOR III study: Insertion success and procedure assessment of a new miniaturized Implantable Cardiac Monitor; Poster AP19-00776; APHRS 2019.