Miniaturized implantable cardiac monitor with a long sensing vector (BIOMONITOR III): Insertion procedure assessment, sensing performance, and home monitoring transmission success

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ABSTRACT

Keywords: Implantable cardiac monitor, Implantable loop recorder, Remote monitoring, Syncope, Cardiac arrhythmia

Background: Implantable Cardiac Monitors (ICMs) are used for long-term monitoring of arrhythmias. BIOMONITOR III is a novel ICM with a miniaturized profile, long sensing vector due to a flexible antenna, simplified implantation with a dedicated insertion tool for pocket formation and ICM placement in a single step, and daily automatic Home Monitoring (HM) function.

Methods: In 47 patients undergoing BIOMONITOR III insertion for any ICM indication, 16 investigators at 10 Australian sites assessed handling characteristics of the insertion tool, R-wave amplitudes, noise burden, P-wave visibility, and HM transmission success. Patients were followed for 1 month.

Results: All 47 attempted insertions were successful. Median time from skin incision to removal of the insertion tool after ICM insertion was 39 s (IQR 19–65) and to wound closure and cleaning was 4.7 min (IQR 3.5–7.8). All aspects of the insertion tool were rated as "good" or "excellent" in ≥97.9% and "fair" in ≤2.1% of patients, except for "force needed for tunnelling" (91.5% good/excellent, 8.5% fair). Based on HM data, R-waves in the first month were stable at 0.70 ± 0.37 mV. Median noise burden (disabling automatic rhythm evaluation) was 0.19% (IQR 0.00–0.93), equivalent to 2.7 min (IQR 0.0–13.4) per day. In HM-transmitted ECG strips with regular sinus rhythm, P-waves were visible in 89 ± 24% of heart cycles. Patient-individual automatic Home Monitoring transmission success was 98.0% ± 5.5%.

Conclusions: The novel ICM performed well in all aspects studied, including fast insertion, reliable R-wave sensing, good P-wave visibility, and highly successful HM transmissions.

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**Introduction**

Implantable Cardiac Monitors (ICMs) are used to detect bradycardia, asystole (pause), atrial fibrillation, or other heart rhythm disturbances in patients with unexplained recurrent syncpe, cryptogenic stroke, palpitations or pre-syncope, or in patients undergoing catheter ablation or other management of atrial fibrillation [1–8]. However, arrhythmia detection by ICMs is hampered by misdetections and artefacts, requiring technological advancement to enhance the diagnostic yield [7,9–11]. A larger electrode spacing (longer sensing vector) can increase sensed signal amplitudes and consequently reduce undersensing and noise artefacts [7,12,13]. On the other hand, further ICM miniaturization and simplification of the implantation procedure is desired to increase ICM acceptance among patients and physicians [7,14,15].

BIOMONITOR III (Biotronik, Berlin, Germany) is a novel ICM combining a long sensing vector with a miniaturized profile. It promises a simple implantation procedure with a specially designed Fast Insertion Tool for pocket formation and ICM placement in a single step. We report the results of the first-in-human study, in which we assessed the insertion procedure, R-wave amplitudes, noise burden, P-wave visibility, and the remote monitoring performance of BIOMONITOR III.

**Material and methods**

**Study design**

The BIO|CONCEPT.BIOMONITOR III study was a first-in-human investigation of the novel ICM, involving 16 operators at ten sites across Australia. Data were collected at insertion and during a clinical visit at 1 week. One month after the ICM insertion, patients were contacted by telephone and remote monitoring data were evaluated.

This non-randomized, prospective, observational, single-arm clinical study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Institutional ethics committee approvals were obtained and the Australian Therapeutic Goods Administration (TGA) was notified for all investigational sites. The study is registered at ClinicalTrials.gov under NCT03850327. All patients provided written informed consent.

**Patient selection**

To be enrolled, patients had to be at least 18 years old; to have one of the following indications for ICM: (1) symptoms of palpitations, pre-syncope, or syncope suggestive of an underlying cardiac arrhythmia; (2) cryptogenic stroke; (3) high risk of developing a clinically important cardiac arrhythmia; or (4) having undergone or awaiting catheter ablation of atrial fibrillation; to be able and willing to complete the planned follow-up; and to consent to remote monitoring. Exclusion criteria were an existing cardiac implantable electronic device, participation in another interventional clinical investigation, pregnancy or breast feeding, and a life expectancy <6 months.

**Investigational device**

BIOMONITOR III is an ICM with a 47.5-mm long rigid component and a 30.5-mm long flexible antenna. This antenna follows to the body’s curvature and movements. It has been designed to solve the conflict between a large sensing vector to increase the signal amplitude and a small palpable device under the patient’s skin (Fig. 1A). With a cross-section of 8.3 mm × 4.3 mm, total volume of 1.97 cm³, and weight of 5 g, the novel ICM has a similar cross-sectional profile to the Reveal LINQ (Medtronic Inc., Minneapolis, MN, USA; 7 × 4 mm) [7] and the Confirm Rx (Abbott Medical, Plymouth, MN, USA; 9.4 × 3.1 mm) [7].

On the other hand, the sensing vector of ≈70 mm is about 50% longer, promising larger R-wave amplitudes. A dedicated insertion tool set, consisting of the Incision Tool and the Fast Insertion Tool “FIT OneStep” (Fig. 1B), has been developed to enable injection-like implantation procedure (Fig. 2).

BIOMONITOR III classifies the rhythm according to the rate and regularity of R-waves [13,16]. Five different types of heart rhythm disturbances can be detected automatically based on programmable criteria: pause, bradycardia, atrial fibrillation, high ventricular rate, and sudden ventricular rate drop [16]. The subcutaneous ECG (sECG) of 56 arrhythmia episodes (~60 s per episode) and four patient-triggered recordings (7.5 min per recording) can be stored in the ICM memory. To quantify the amount of noise and artefacts, the device records “noise burden” as the proportion of a 24-hour period, during which very fast signals (~180 ms) prevent the evaluation of the rhythm. BIOMONITOR III features simplified programming by indication-based program sets and enhanced signal quality by improved filtering and data compression. It has a projected battery life of 4 years and is compatible with Magnetic Resonance Imaging for full-body scans at 1.5 and 3 Tesla.

The ICM uses the established Biotronik Home Monitoring® system to transmit daily messages that contain arrhythmia detection statistics, data on device sensing performance, and up to six sECG episodes [17]. If more than six sECGs have been stored, the device transmits at least one episode of each arrhythmia type [17]. The transmission of a periodic sECG strip of 60 s can be scheduled at programmed intervals to assist with data interpretation [17,18]. The responsible physician is automatically alerted after pre-specified events and can access the data using a secure internet-based platform at any time.

**Insertion procedure**

The study protocol recommended three insertion positions. These were either parallel to the heart’s long axis (position A), parasternal (position B), or inframammary (position C) (Fig. 1D), wherever minimal device movement due to positional changes or body and arm movement was expected. In other positions, the orientation of the antenna was recorded according to the hand of a clock. After selection of the position and injection of a local anaesthetic agent, an incision through the skin was made by the Incision Tool. The ICM was then inserted into subcutaneous tissue with the FIT OneStep tool that forms the pocket and delivers the device in a simple single-step procedure (Fig. 2). Incision closure and wound protection were done according to the standard procedures of the respective hospitals.

The time was recorded at the time of skin incision, tool removal, wound closure and after cleaning. For each procedure, the implanting physician rated seven criteria related to the insertion tool set on a five-step scale: very poor, poor, fair, good and excellent. To avoid undue influence of single investigators on rating results, the maximum number of insertions per investigator was limited to five.

**Study protocol**

After ICM insertion, all patients received a CardioMessenger® mobile device for Home Monitoring with instructions on its use. Devices were programmed to transmit a daily periodic sECG. Follow-up involved Home Monitoring with automatic transmissions of ICM data every 24 h, a clinic appointment at 1 week, and examination of Home Monitoring data combined with a telephone interview at 1 month post-insertion. Serious adverse events related to the procedure or study device were reported throughout the study.

**Study objectives and data evaluation**

The main objective of the study was a controlled assessment of the safety and efficacy of the new insertion procedure with dedicated tools. The endpoints were insertion success, assessment of handling characteristics of both tools, duration of insertion procedure, wound closure methods, and adverse events.
The second objective was to investigate the sensing quality of BIOMONITOR III. The R-wave amplitudes and noise burden obtained via Home Monitoring during 1 month were therefore analysed for different positions. Additionally, P-wave visibility was evaluated in periodic sECG strips transmitted by Home Monitoring.

We also analysed Home Monitoring transmission success defined as the percentage of days with a Home Monitoring message after the first message. The patients’ view of the BIOMONITOR III was recorded at one month by them rating their comfort with the device.

**Statistical analysis**

Results are presented with standard summary statistics. No study hypotheses or statistical endpoints were predefined. The planned
sample size of 45 patients was determined based on the rationale that it would allow with 95% confidence to observe at least one event of a certain type assuming 15% probability for this event type to occur within the respective population. R-wave amplitudes and noise burden were imported from the Home Monitoring database for all patients who had at least one week of data. The transmitted values over 1 month of Home Monitoring were averaged per patient and the individual means were summarized. Amplitudes “at insertion” and “at 30 days” were averaged for days 1, 2, 3 and 28, 29, 30 after insertion, resp., and summarized for patients with at least one data point in both periods. For the evaluation of P-wave visibility, the investigators analysed the first and the last periodic sECG sent by Home Monitoring until the 1-week clinical visit, and the most recent one the 1-month data check. After excluding sECGs not showing sinus rhythm with a regular 1:1 conduction, the investigators counted the number of clearly identifiable P-waves and the number of heart cycles. The ratio between the two counts represented the proportion of QRS complexes preceded by a visible P-wave in the given sECG strip. These proportions were averaged per patient and then summarized for the population.

Results

Patients

Between 8 March 2019 and 14 May 2019, 48 patients were enrolled. Indications for ICM implantation were syncope in 28 (58.3%), atrial fibrillation monitoring in 14 (29.2%), 5 post-catheter ablation, 5 planned ablation, and cryptogenic stroke in six patients (12.5%).

Twenty-five patients were male (52.1%) and 23 were female (47.9%). The mean age was 64.0 ± 14.0 years (range 20–87) and the body mass index was 26.8 ± 4.6 kg/m² (16–37). Fifteen patients had a history of atrial fibrillation (31.3%), eight patients had other atrial or supraventricular arrhythmias (16.7%), and a single patient had a known history of ventricular arrhythmia (2.1%). The most frequent comorbidities were hypertension (50.0%), dyslipidaemia (47.9%), and coronary artery disease (14.6%). Heart failure was infrequent (6.3%).

Of the 48 patients, 47 had a study device inserted. One patient terminated the study before ICM insertion due to a concern of the hospital staff that no valid consent existed. However, as the consent had in fact been signed, the patient contributed to baseline data.

Insertion procedure

The insertion success rate was 100%. All 47 insertions were performed in cardiac catheterization laboratories and succeeded on the first attempt. Sixteen investigators inserted between one and five study devices. Twenty-two devices were inserted in position A (46.8%) and 15 in position B (31.9%) (Fig. 1D). The remaining ten devices (21.3%) were inserted in positions D (n = 1), E (n = 6), and F (n = 3), with the antenna pointing to 3 o’clock (D and F) or 4 or 5 o’clock (E).

The investigators rated handling characteristics of both tools as “good” or “excellent” in 97.9% to 100% of cases for each criterion and “fair” in 0% to 2.1% of cases, with the exception of “force needed for tunnelling” (good/excellent 91.5%; fair 8.5%) (Table 1). In all cases, the ICM was well-placed in the intended target position.

The median time from skin cut to removal of the insertion tool was 39 s (interquartile range [IQR] 19–65), from skin cut to wound closure was 3.6 min (IQR 2.3–5.3, range 0.5–9.5), and from skin cut to wound cleaning was 4.7 min (IQR 3.5–7.8, range 1.0–12.9). In 32 insertions (69.6% of 46 patients with available data) the wound was closed in a single layer (i.e., superficially) by adhesive tape (n = 17), stitches (n = 10), or skin glue (n = 5). In the remaining 14 insertions (30.4%) the wound was closed in double or triple layers by the combination of stitches and adhesive tape.

Systemic antibiotics were used peri-operatively in 23 of 47 patients; local antibiotics were not applied. There were no pocket infections during the study. The type of anaesthesia for the insertion procedure was local in 43 patients and general in nine patients (e.g. when the ICM insertion was done during a catheter ablation).

Follow-up and serious adverse events

The mean follow-up duration was 35.2 ± 18.5 days (cumulatively 4.6 patient-years). The study participation of the last patient ended on 6 August 2019. Eight of the 47 patients with an inserted study device terminated the study prematurely: Four patients received a permanent pacemaker after ICM documented bradycardia or pause, one patient was lost to follow-up, and one ICM was permanently damaged by a 200 joule electrical cardioversion via a paddle placed directly over the device. Furthermore, in two patients from one investigational site the ICM protruded shortly after insertion. In both cases, the incision of the skin had not been carried out as per intended design (Fig. 2), resulting in a length exceeding the device’s width. Additionally, the devices were inserted into a substantial subcutaneous fatty tissue layer without suture. All cases were concluded without sequel.

Throughout the trial, the only serious adverse device effect was a permanent ICM damage by external cardioversion, requiring device replacement with a new one. In one case, difficulty to remove the ICM in order to implant a permanent pacemaker was classified as device deficiency that could not have led to a serious adverse event. The two cases of ICM protrusion through the wound were classified as procedure-related serious adverse events.

Signal amplitudes

Forty-three patients contributed to the R-wave and noise burden analysis. The mean R-wave amplitude was 0.70 ± 0.37 mV, ranging from 0.22 mV (minimum) to 1.82 mV (maximum) in the individual patients (Table 2). The median noise burden was 0.19% (IQR 0–0.93), equivalent to 2.7 min in a 24-hour period (IQR 0–13.4). Within this

Table 1

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<tr>
<th>Table 1</th>
<th>Investigators’ assessments of the insertion tool set (N = 47).</th>
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<tbody>
<tr>
<td>Incision tool</td>
<td>Excellent N (%)</td>
</tr>
<tr>
<td>Blade sharpness</td>
<td>42 (89.4%)</td>
</tr>
<tr>
<td>Grip on tool</td>
<td>41 (87.2%)</td>
</tr>
<tr>
<td>Overall rating of the incision tool</td>
<td>39 (83.0%)</td>
</tr>
<tr>
<td>Fast Insertion Tool “FIT OneStep”</td>
<td>27 (57.4%)</td>
</tr>
<tr>
<td>Force needed for tunnelling</td>
<td>38 (80.9%)</td>
</tr>
<tr>
<td>Unlocking</td>
<td>43 (91.5%)</td>
</tr>
<tr>
<td>How easy was it to use FIT OneStep</td>
<td>40 (85.1%)</td>
</tr>
</tbody>
</table>

*a Excellent = very low force; Good = low force; Fair = medium force; Poor = high force; Very poor = very high force. |  
*b Excellent = very easy; Good = easy; Fair = fair; Poor = somewhat difficult; Very poor = very difficult. |
study sample, neither R-wave amplitude nor noise burden was clearly dependent on the insertion position (P > 0.15, post-hoc t-test).

There was no trend in the R-wave amplitudes between insertion and the one-month time point (Table 3).

P-wave visibility

Of 129 periodic sECGs, 39 did not show sinus rhythm with a regular 1:1 conduction and were excluded. In the remaining 90 sECG strips with regular sinus rhythm, involving 39 patients, P-waves were visible in 89 ± 24% of all heart cycles (median 100, IQR 85–100). In 20 of 39 patients, all P-waves in all periodic sECG strips were visible (up to 3 strips per patient). P-wave visibility did not vary with time (88 ± 26/89 ± 25/91 ± 23% for the first/1-week/1-month periodic sECGs).

Home monitoring transmission

Of the 47 patients with an inserted study device, two dropped out of the study before discharge. The remaining 45 patients used Home Monitoring. The first data transmission occurred on the day of ICM insertion in 34 patients (75.6%). The remaining patients sent the first message 1 day later (n = 9) or up to 8 days later (n = 2). The mean delay from the insertion to the first message was 1.0 ± 1.1 days.

Of all days between the first message and study termination in the individual patients, messages were received on 98.0% ± 5.5% days (median 100, IQR 100–100). Only nine of 45 patients did not transmit every day.

Patient comfort with the device

At 1 month, 40 patients rated their comfort with the device. Excellent comfort was reported by 50.0% (n = 20), good by 35.0% (n = 14), fair by 12.5% (n = 5), poor by 0%, and very poor by 2.5% (n = 1; “sore device site”). In the majority of patients, the ICM did not interfere with daily activities in any way (77.5%; n = 31) or it interfered rarely (15.0%; n = 6). Other patients reported more frequent (5.0%; n = 2) or very frequent (2.5%; n = 1) interference.

Discussion

In this first-in-human study, we have successfully inserted the novel ICM BIOMONITOR III in 47 patients. The newly designed insertion tools allowed a simple and short procedure.

Due to a growing recognition of the value of the ICM in patients with suspected arrhythmias, such as embolic stroke of unclear origin, post-myocardial infarction, post-transcatheter aortic valve replacement, and in other conditions, the use of ICMs is expected to double over the next 5 years [4–8,19–21]. This expansion has also been driven by device miniaturization, simplified implantation procedure, improved diagnostic power, and remote monitoring to avoid the loss of information due to device memory overflow and shorten the time to diagnosis and targeted treatment [4–8,14].

The primary aim of our study was to investigate the specially designed tool for pocket formation and ICM insertion in a single step. The median time from skin cut to final ICM positioning was a mere 39 s, and the median time to wound closure was 3.6 min. The investigators’ ratings of the insertion procedure were generally favourable. In particular, the most critical aspect “force needed for tunnelling” was rated “good/excellent” in 91.5% and “acceptable/fair” in 8.5% of cases. All other aspects of the insertion procedure were rated “good/excellent” in 97.9% to 100% of patients.

The cross-section of BIOMONITOR III is similar to other contemporary ICM models, but it has a longer sensing vector and offers a longer battery duration (4 years, vs. 2–3 years in other ICMs) [7,8]. The wearing comfort during 1 month after device insertion was classified as good or excellent by 85% of patients. However, in one patient (2.5%), the device continued to cause significant pain and permanent discomfort one month after insertion. These rare cases should be taken seriously by implanting physicians and industry alike because they pose a threat to the expansion of this otherwise low-risk technology. In 92.5% of patients, the ICM interfered rarely or never with daily activities in any way. These findings are similar to those with the larger predecessor device [22,23], implying that further device size reduction may have little influence on patient comfort.

In two patients from one investigational site, the ICM protruded shortly after insertion. Careful examination revealed that the skin fold had been cut in the compressed side, resulting in a cut exceeding the normal length that is otherwise determined by the design of the cutting tool. Additionally, both patients were females with high body mass index, which generally constitute a challenge for proper ICM placement and fixation. Early or late spontaneous device extrusions through the insertion site have also been observed with other miniaturized ICM models [24–26].

The “antenna” of the BIOMONITOR III and the resulting extended sensing vector are intended to guarantee large R-wave amplitudes, which was on average 0.70 mV. Importantly, it ranged from 0.22 mV to 1.82 mV across patients, and even the lowest measured values are sufficient for reliable sensing. Within the admittedly short scope of our study, we did not recognize a decline of the signal. With other contemporary ICM models, characterized by a shorter sensing vector (<50 mm), the reported mean R-wave amplitudes did not exceed 0.60 mV [27,28]. The advantage of long sensing vector in terms of R-wave amplitudes has been well recognized [7]. Improved sensing performance can help avoid signal dropout and undersensing that might otherwise lead to missed true arrhythmia and excessive false positive detections requiring time commitment from electrophysiologists and device clinic personnel to adjudicate these detections [29,30].

Noise such as electromagnetic interference or muscle potentials requires the suspension of rhythm classification to reduce false positive detections and avoid data overflow [29,30]. To the best of our

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<td>R-wave amplitudes and noise burden. a</td>
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<tr>
<td>R-wave amplitude [mV]</td>
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<td>All insertion positions b</td>
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<tr>
<td>Position A: Along the heart’s long axis</td>
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<td>Position B: Parasternal</td>
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<tr>
<td>Positions D, E, F</td>
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<tr>
<td>Noise burden [% of day]</td>
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<td>All insertion positions b</td>
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<tr>
<td>Position A: Along the heart’s long axis</td>
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<td>Position B: Parasternal</td>
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<td>Positions D, E, F</td>
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IQR, interquartile range; SD, standard deviation.

a R-wave amplitudes and noise burden were derived from Home Monitoring data in patients who were followed for at least 1 week.

b See Fig. 1D for definitions of insertion positions. Position C was not used.
knowledge, the amount of noise is reported only by BIOMONITOR devices, while other ICM models suspend heart rhythm classification in the presence of noise without quantifying it. We found a mean “noise burden” value of 0.94%, which is close to the range reported from the predecessor device (1.0–3.4%) [13,16,22,23]. Noteworthy, in half of our patients the average noise burden per day was ≤0.19% (median value), and in three quarters of patients it was ≤14 min.

Within this study sample, neither noise burden nor R-wave amplitude depended significantly on the insertion position. However, the number of patients was low and further studies are needed to confirm this hypothesis. The recommended positions A (along the heart axis) and B (parasternal) are most proximal to the heart and should therefore remain the first choice until solid proof of sufficient sensing in other positions is generated. It is worth noting that one non-randomized study of 55 patients implanted with the BioMonitor 2 ICM suggested that axillary insertion (similar to our position F) may result in equivalent sensing performance to the prepectoral insertion (positions A and B), while improving aesthetic result by avoiding the pectoral scar in concerned patients [22].

In our study, 89% of all heart cycles in periodic sECGs showing regular sinus rhythm had visible P-waves. P-wave visibility is an increasingly recognized ICM parameter of clinical relevance [22,28,31]. In case of arrhythmia detection, the physician usually has only a single, short, one-lead sECG to make a clinical decision. An example of a Wenckebach block incidentally captured in a periodic sECG may illustrate the argument (Fig. 3).

The sECG strip and recorded signals have therefore to be of excellent quality, including P-wave visibility, to allow the right medical decision. To our knowledge, three previous studies reported P-wave visibility in sECG strips obtained from ICMs, demonstrating that P-waves were well visible in 58% of patients (Reveal LINQ; Medtronic Inc., Minneapolis, MN, USA) [28], and 67% to 72% of patients (BioMonitor 2) [22,31].

The present study confirms the high success rate of Home Monitoring transmissions (98.0%) previously reported [13,16,17,31], outperforming competitor ICM devices with different remote monitoring technology (≈80% transmission success [7,27], causing delays impacting patient care [32]). A recent publication demonstrated that transmission of up to six sECG strips per day by Home Monitoring prevents loss of relevant sECGs in case of multiple detections, in contrast to systems capable of transmitting only one sECG strip per day [17]. A reliable remote monitoring technology is especially important in ICM patients, who are otherwise well suited for exclusive remote follow-up [16]. Compared to the well-recognized and much studied field of detection performance (few false positive episodes with high sensitivity for true arrhythmia), the question of delays in clinical decision-making once an arrhythmia is detected is a field that has received little attention in studies of ICMs to date.

**Study limitations**

The main limitations of the study were the small patient cohort size and short follow-up time. Furthermore, the study protocol did not request a summary of the ICM-detected arrhythmia episodes and

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**Table 3**

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<th>Insertion</th>
<th>1 month</th>
<th>12 months</th>
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<tr>
<td></td>
<td>Mean ± SD</td>
<td>Median (IQR)</td>
</tr>
<tr>
<td>This study⁶</td>
<td>0.73 ± 0.39</td>
<td>0.64 (0.45–0.91)</td>
</tr>
<tr>
<td>BioMonitor 2 [13]</td>
<td>0.85 ± 0.37</td>
<td>n.a.</td>
</tr>
<tr>
<td>Medtronic LINQ [27,28]</td>
<td>0.58 ± 0.33</td>
<td>n.a.</td>
</tr>
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IQR, interquartile range; SD, standard deviation.

* R-wave amplitudes and noise burden were derived from Home Monitoring data in patients who had data in the first three days after insertion and in the days 28 to 30 (N = 30).

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**Fig. 3.** An episode of a second degree AV block type Wenckebach was captured in a study patient in a periodic subcutaneous ECG.
adjudication of related sEEGs due to anticipation that the limited number of patients, the short follow-up, and the heterogeneous study population would preclude clinically valid conclusions. The diagnostic performance of BIOMONITOR III will be evaluated in ongoing studies [21].

Conclusions
The newly developed insertion tools and insertion procedure for the BIOMONITOR III ICM achieved convincing results in terms of implantation success, procedure duration, and the operators’ assessment of the utility of the tools and techniques. R-wave amplitudes afforded by the novel ICM are very large and allow reliable sensing in all patients. P-waves were regularly visible in most sinus rhythm ECGs. This is essential to support the diagnosis entirely based on the arrhythmia sEEG obtained from the device. The reliable Home Monitoring option allows for complete remote patient management.

CRediT authorship contribution statement
Justin A. Mariani: Conceptualization, Writing - original draft, Investigation, Formal analysis, Writing - review & editing. Rukshen Weerasooriya: Investigation, Writing - review & editing. Olivier van den Brink: Investigation, Writing - review & editing. Paul A. Gould: Investigation, Writing - review & editing. Rajeev K. Pathak: Investigation, Writing - review & editing. Tina Lin: Investigation, Writing - review & editing. Andre Conradie: Investigation, Writing - review & editing. Peter Illés: Investigation, Writing - review & editing. Stephen Pavia: Investigation, Writing - review & editing. Ian Matthews: Investigation, Writing - review & editing. Deepak Arumugam: Investigation, Writing - review & editing. Dennis H. Lau: Investigation, Writing - review & editing.

Declaration of competing interest
JM, RW, UM, PG, RP, TL, AC, PL and SP have received honoraria and/or non-financial support from Biotronik in the context of this study, JS is a full-time employee of Biotronik. PG, DHL and UW has received honoraria from Biotronik outside the context of this study.

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