

New Features in the Philos II Dual-Chamber Pacemaker for Improved Patient Monitoring and Efficient Therapy

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Summary

The purpose of the clinical study was to evaluate the new features implemented in the Philos II dual-chamber pacemaker, including Automatic Implant Detection (AID), Active Capture Control (ACC), and wideband IEGM snapshots. The device was implanted in seven patients (four male, three female; mean age 72.4 ± 2.9 years). The performance of the new features was tested during the implantation and at the pre-discharge, 1-week, 2-month, and 4-month follow-up examinations. The AID feature functioned appropriately in all seven patients. In addition, ACC was activated successfully in all patients. The manual and automatic threshold tests resulted in the same threshold values. All IEGM snapshots were triggered correctly according to their triggers, which included mode switch window (22), high ventricular rate (71), Pacemaker-Mediated Tachycardia (PMT) termination (24), and patient trigger (7). Due to the snapshots, both the pacemaker timing and the medication were adjusted in order to improve the therapy in two patients. The new features of the Philos II pacemaker system performed very well in this small group of patients. AID and ACC reduce the programming effort of the pacemaker and make the therapy more efficient. Furthermore, the IEGM snapshots provide a highly effective tool for improved patient monitoring between follow-up visits.

Key Words

IEGM snapshots, Active Capture Control (ACC), Automatic Implant Detection (AID)

Introduction

A look back at the history of implantable cardiac pacemakers reveals that the functionality of these devices has changed dramatically over the last 30 years [1]. Beginning as simple lifesaving units, implants have evolved over the years into highly sophisticated devices by adding and more functionality. On the other hand, these additional features also require more and more time to perform the follow-up of the device and to adjust all parameters in order to optimize the therapy for the patient as well as increase the longevity of the implant. These requirements are the major challenges for a modern implant to address. The device should work as automatically as possible, and the diagnostic functions should point the physician to special events that may require the start or the adjustment of an additional therapy.

We present the first results of the new Philos II (Biotronik, Germany) pacemaker, which fulfills these needs by providing automaticity with functions such as Automatic Implant Detection (AID) and Active Capture Control (ACC), and support the physician by storing high-resolution intracardiac electrograms (IEGMs).

Materials and Methods

The purpose of the study was to evaluate several new features implemented in the Philos II device, including AID, ACC, automatic ventricular threshold test, broadband IEGM snapshots, and follow-up data storage. These features are described briefly in the following sections.

Automatic Implant Detection

AID detects when a pacing lead is connected to the Philos II pacemaker at implantation and determines the polarity of the connected lead. Upon successful lead detection, Philos II automatically initiates several features, including mode switching, Pacemaker-Mediated Tachycardia (PMT) management, Automatic Threshold Monitoring (ATM) mode based on ACC, and statistics. AID consists of the following three phases.

Lead detection

In order to detect a lead, the Philos II delivers unipolar pacing pulses in the ventricle and in the atrium at the factory programmed amplitude. The device measures the lead impedance at each paced event and assumes that a lead is connected when the measured impedance falls in the range between 200 and 3000 Ω . Immediately after the lead is detected, the Philos II switches the pacing polarity to bipolar. If the lead impedance remains between 200 and 3000 Ω , the lead is classified as bipolar and the sense and pace polarities are set to bipolar. The device switches back to the unipolar pacing and sensing configuration if the lead impedance falls outside this range.

30-min confirmation phase

A 30-min confirmation phase is initiated after detection of the lead and its polarity, during which time the previously measured lead impedances are confirmed. The lead impedance is again measured at each paced event and must fall in the range of 200 to 3000 Ω . Lead detection is confirmed after 30 min, when all impedance measurements fall within the range of 200 to 3000 Ω .

Activation of pulse generator features

After the confirmation phase has been successfully completed, the following features are activated:

- Mode switching
- PMT management
- ATM mode
- Statistics

When the pulse generator is interrogated, the status of AID is displayed, as well as the following information:

- Atrial and ventricular lead polarity detected
- Date and time of the first lead detection for each chamber
- Date and time when the confirmation phase was completed

Active Capture Control

ACC is an algorithm that periodically determines the capture threshold, automatically adjusts the pacing output, and provides a programmable safety margin. In addition, this feature accesses ventricular pacing capture on a continuous, beat-to-beat basis and responds to loss of capture with a safety backup pulse. Differences in the signal morphology following the ventricular pacing pulse distinguish capture events from non-capture events. Besides the continuous monitoring of the evoked response, additional searches for the current pacing threshold occurs at programmable time intervals. In case of a loss of capture, the algorithm responds with a safety backup pulse and initiates a threshold search.

ACC consists of three primary components: Signal Quality Check (SQC), Capture Threshold Search (CTS), and Continuous Capture Confirmation (CCC). The SQC analyzes the amplitude of myocardium response to the pacing pulse and the amplitude of the polarization artifact following the pacing pulse. The CTS measures the ventricular pacing threshold by stepping down the output until non-capture occurs; the pacing amplitude is then set to the pacing threshold as well as a programmable safety margin. The CCC provides beat-to-beat capture verification. Details about this ACC feature have been provided elsewhere [2].

IEGM Snapshots

IEGM recording provides a means of capture IEGMs as wideband snapshots for the atrial and ventricular channels as well as event marker information under certain trigger conditions. Philos II is capable of storing 15 IEGM snapshots with a sampling rate of 128 samples/s each with a fixed length of 10 s. Each recording consists of 7.5 s of pre-trigger data and 2.5 s of post-trigger data. The following events can trigger an IEGM recording; each of them is independently programmable, and they are all mutually exclusive:

- High atrial rate: This trigger is initiated when the atrial rate exceeds a programmable rate limit for at least four consecutive events. The high atrial rate trigger can only be activated when the mode switch feature is disabled.
- High ventricular rate: This trigger is initiated when the ventricular rate exceeds a programmable rate limit for at least four consecutive ventricular events.
- Mode switching: Initiation occurs when the x-out-of-8 detection criterion is fulfilled.

- PMT termination: This trigger will be initiated upon any attempted conversion of PMT.
- Patient using magnet: The patient trigger occurs when a magnet is temporarily placed over the pacemaker, and the snapshot is committed when a magnet is no longer detected and no programmer interaction was detected.

With each wideband snapshot, additional information is recorded: trigger type, time and date, trigger position, markers, and the peak atrial and ventricular rates during the episode.

Storage of Follow-up Data

With Philos II, the pacemaker programmer allows the storage of follow-up data in the device from the current follow-up and recalls the data during future follow-ups. The following information is available for storage in Philos II and can be selected individually, similar to the automatic tests on the follow-up screen:

- Date of follow-up
- Lead impedance in both chambers
- P- and R-wave amplitudes
- Pacing thresholds in both chambers
- Retrograde conduction time
- Lead polarities
- Battery status

Data from up to four separate follow-ups can be stored. Afterwards, new data overwrites the first follow-up data stored.

Patients

Within our clinical investigation, the Philos II dual-chamber pacemaker was implanted in seven patients

(four male, three female; mean age 72.4 ± 2.9 years). The indication for use followed the recommendation of Class I indications for rate-responsive, dual-chamber pacing. In Table 1, the patient and implant characteristics are summarized. The investigation was conducted according to the Declaration of Helsinki for Good Clinical Practice, and all patients signed an informed consent document.

Follow-up Procedure

An investigational device was implanted in each patient using a standard procedure. The performance of the new features of the Philos II were tested during the implantation and at the pre-discharge, 1-week, 2-month, and 4-month follow-up examinations. Pacemaker printouts before and after implantation were generated to recognize the success of the AID. Manual and automatic ventricular threshold tests (at 0.4 ms pulse width) were compared in subsequent follow-up examinations to test the accuracy of the threshold test. The performance of ACC and IEGM recording was verified during all follow-up sessions. To this end, all IEGM triggers were switched on. During the first follow-up the patient trigger for IEGM recordings was tested. At the end of each follow-up, the data were stored to test the follow-up data storage. The following endpoints were set:

- Endpoint 1: Appropriate AID
- Endpoint 2: Appropriate ACC initialization
- Endpoint 3: Effective automatic ventricular threshold test
- Endpoint 4: Appropriate IEGM recording function
- Endpoint 5: Appropriate follow-up data storage function

Patient ID	Implant Date	Age (years)	Gender	Primary cardiac disease	Atrial Lead	Ventricular Lead
1	July 16, 2003	72	M	AVB III	PX 53 JBP	PX 53/15 BP
2	July 17, 2003	71	M	SSS Brady	YP 53 BP	PX 53/15 BP
3	July 17, 2003	71	M	SSS Brady	YP 53 BP	PX 53 BP
4	July 16, 2003	70	F	AVB III	SX 45 JBP	PX 53/15 BP
5	July 17, 2003	70	F	SSS Brady, AVB III	YP 53 BP	PX 53 BP
6	July 18, 2003	78	F	SSS Brady, AVB	YP 53 BP	PX 53 BP
7	July 18, 2003	71	M	SSS Brady, AVB III	ELOX 53 BP	YP 53 BP

Table 1. Characteristics of study patients and the lead models implanted (all leads are manufactured by Biotronik, Germany). AVB = atrioventricular block, SSS = sick sinus syndrome.

Results

All investigations could be performed successfully in all patients. One patient was not compliant for the 2-month follow-up, and three were not compliant for the 4-month follow-up; no data are available from these devices for the corresponding follow-up investigations. In Table 2, the average values of measured lead parameters are provided for all follow-up procedures except for the ventricular threshold, which is discussed later in more detail. The following results are discussed in accordance with the endpoints mentioned.

Automatic Implant Detection

The AID feature was tested by comparing the programmer printouts prior to and after the implantation. The AID worked appropriately in all seven patients (Table 3). In all devices, the lead polarities were detected appropriately, and the pacing and sensing polarities were set to bipolar. The mode switch functionality and PMT protection were turned on, the collection of statistical data was activated, and ACC was initialized.

Active Capture Control Initialization

ACC could be activated in all patients. Activation was completed in six patients at implantation and in all patients at the pre-discharge follow-up. At the begin-

ning of each follow-up, the current ACC status was reported. In all but two cases, ACC was enabled and was working fine. Only at the 1-week follow-up in one patient and at the 2-month follow-up in another patient, the ACC was disabled. In both cases, the pacing amplitude was set to a safe value of 4.8 V; this information could be obtained from the ventricular pacing amplitude trend. In the first case, disabling of the ACC was caused by undersensing in the atrial channel. After adjusting the sensitivity, ACC was activated successfully and was not disabled until study end. The reason for ACC disabling in the second case remained unclear; however, ACC was later activated successfully.

Automatic Ventricular Threshold Test

Ventricular threshold measurements were performed manually and automatically during each follow-up examination (Figure 1). The manual and automatic threshold tests resulted in the same threshold values, indicating reliability of the ACC algorithm. A detailed analysis of data in each individual patient, the manually and automatically determined threshold values differed by a maximum of 0.1 V.

The printouts of statistical pacemaker data also provided the information on the functionality of the ACC. The ventricular threshold and pacing amplitude trends show the time course of the values. Examples of these

	P-wave (mV)	Atrial threshold (V)	Atrial impedance (Ω)	R-wave (mV)	Ventricular impedance (Ω)
Implantation	3.5 \pm 1.5	0.5 \pm 0.1	590.7 \pm 151.1	17.1 \pm 4.8	747.6 \pm 155.7
Discharge follow-up	3.2 \pm 0.7	0.4 \pm 0.1	527.9 \pm 90.5	17.7 \pm 3.4	688.0 \pm 93.6
1-week follow-up	2.0 \pm 0.8	1.5 \pm 1.0	429.9 \pm 75.6	17.2 \pm 3.4	518.4 \pm 77.1
2-month follow-up	2.9 \pm 1.0	1.1 \pm 0.4	442.5 \pm 100.4	17.6 \pm 1.5	634.5 \pm 152.4
4-month follow-up	2.7 \pm 0.7	1.1 \pm 0.6	465.3 \pm 99.8	16.2 \pm 2.4	691.3 \pm 149.7

Table 2. Average lead measurements for all follow-up points. Only six and four data sets contributed to the mean values at the 2- and 4-month follow-ups, respectively.

Trigger	Discharge follow-up	1-week follow-up	2-month follow-up	4-month follow-up
High atrial rate	0	0	0	0
Mode switch	0	7	3	12
High ventricular rate (set to 100 ppm)	1	22	48	0
Pacemaker-mediated tachycardia termination	0	1	1	21

Table 3. Distribution of the recorded IEGM snapshots with respect to the different triggers. The large number of high ventricular rate triggers is due to the low trigger rate of 100 bpm. Only six and four data sets contributed to the distributions at the 2- and 4-month follow-ups, respectively.

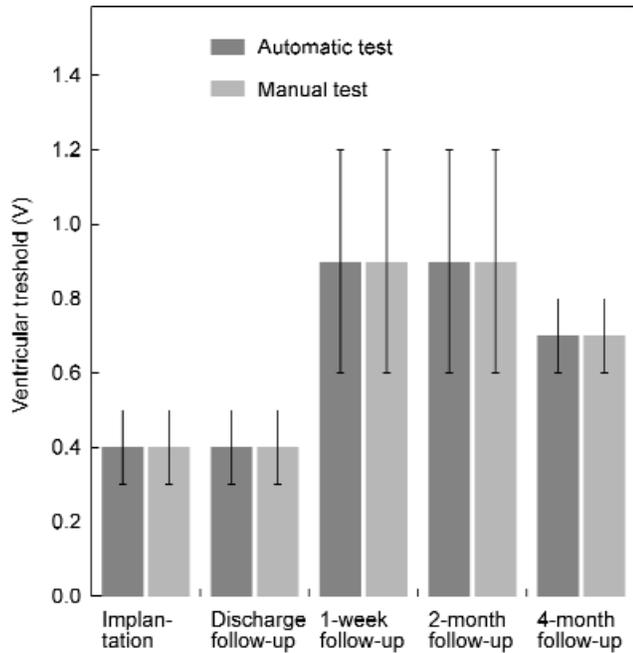


Figure 1. Comparison of mean ventricular threshold values from manual and automatic threshold tests.

trends are illustrated in Figure 2. The 1-week follow-up shows the expected slight increase of the ventricular threshold during the first week after implantation.

IEGM Snapshots

In Table 3, the distribution of the recorded snapshots in all patients is provided for each follow-up. All IEGM recordings triggered by patients were performed successfully. Additionally, all other recorded IEGMs were triggered correctly. As the trigger rate for the high ventricular rate was programmed to 100 bpm, many snapshots of this type were recorded. All high ventricular rate snapshots were triggered by ventricular rates between 100 and 115 bpm. In some cases, an initiated PMT was the reason for the high ventricular rate. As illustrated in Figure 3, there were also snapshots when PMTs were terminated. Due to these snapshots, the pacemaker timing parameters were readjusted, to prevent further occurrence of PMTs. Mode switch triggered snapshots provided information about short-term

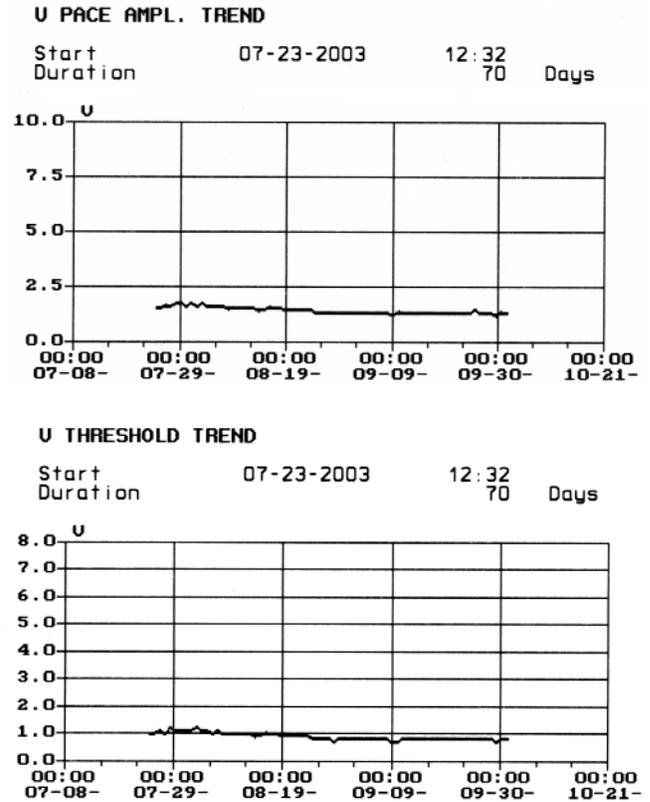
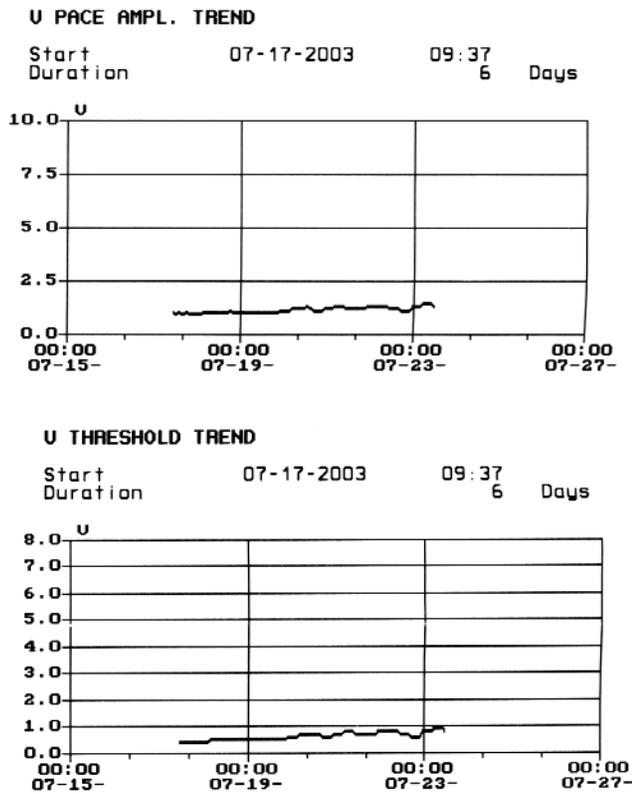


Figure 2. Ventricular pace amplitude and ventricular threshold trends printed at the 1-week (left) and 2-month follow-ups (right). The typical threshold increase during the lead in-growth phase is seen, as well as the reduction of the threshold after a short time. The pacing amplitude followed this behavior.

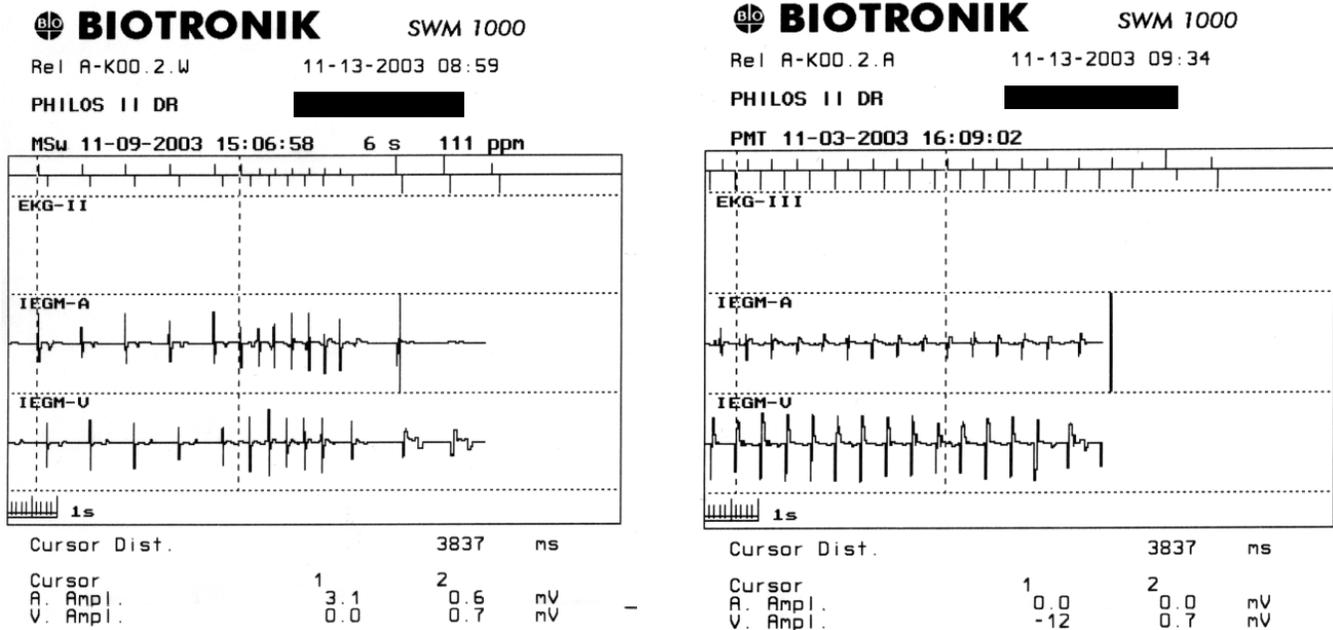


Figure 3. Two exemplary printouts from stored IEGM snapshots. In one case, an atrial arrhythmia caused a mode switch event, which triggered the IEGM recording (left). The other printout shows the successful termination of a pacemaker-mediated tachycardia (right).

arrhythmias (Figure 3), which resulted in changed drug therapy in order to treat the atrial arrhythmias.

Storage of Follow-up Data

At the end of each follow-up, the follow-up data were stored in the device. The data were stored correctly in the device in all patients and for all investigations. In Figure 4, a sample printout shows the data from the last two follow-up sessions.

Discussion

The results demonstrate that the new features of the Philos II pacemaker performed very well during all follow-up investigations. The implants detected their implantation appropriately in all cases and switched on several functionalities as anticipated. The AID prevents automatically an unintended maladjustment of the lead polarities and, therefore, the pacemaker features relying on the adjusted polarity function appropriately without any readjustments. The AID simplifies the programming of the device after implantation, so that the physician can concentrate on the more important parameter settings.

During the AID, the ACC is initialized automatically to a passive mode (ATM). With the ACC algorithm,

the right ventricular threshold is monitored on a beat-to-beat basis. Threshold changes are responded to with a corresponding amplitude change by the ACC algo-

BIOTRONIK SWM 1000		11-13-2003 09:36	
PHILOS II DR			
Status	11-13-	10-02-	-----
Date	2003	2003	-----
Lead Imp. A	489	426	-----
	BIPL	BIPL	-----
Lead Imp. V	841	841	-----
	BIPL	BIPL	-----
Atr. Sensing	2.0	2.2	-----
	BIPL	BIPL	-----
Ven. Sensing	17.4	17.1	-----
	BIPL	BIPL	-----
Atr. Threshold	0.9	1.0	-----
	0.40	0.40	-----
	BIPL	BIPL	-----
Ven. Threshold	0.6	0.7	-----
	0.40	0.40	-----
	BIPL	BIPL	-----
Retrograde test	225	213	-----
	BIPL	BIPL	-----
Batt. Status	OK	OK	-----

Figure 4. Sample printout of the stored follow-up data. In this specific device, two more data sets can be stored before the very first becomes overwritten by the data of a fifth follow-up.

rhythm, so that safe and energy-efficient ventricular pacing is always guaranteed. The monitored threshold and pacing amplitude values are reported in the statistics of Philos II. Therefore, the physician receives information about the in-growth behavior of the lead and its long term stability. Many factors affecting the myocardial pacing threshold [3,4], such as short-term, pathophysiological changes in the myocardium, will be recognized in the provided trends. The automatic ventricular threshold test as part of the "fast follow-up" not only determines the ventricular threshold with high accuracy but also makes the follow-up faster and less interactive.

The IEGM snapshots were all recorded correctly based on the trigger that was programmed. The occurrence of PMTs was revealed, and their successful termination was reported. IEGMs are a highly effective tool for adjusting timing parameters to prevent further PMTs. The early detection and treatment of atrial and ventricular tachycardia is important to slow or even prevent the progress of those diseases. IEGM snapshots triggered by high ventricular rates, high atrial rates and mode switching led to a change in the medical treatment in two of those patients. These examples prove that IEGM snapshots are a perfect tool for better patient monitoring and improved therapy. The storage of the follow-up data in the device allows the attending physician to compare the results of all lead measurements from the last four follow-up investigations. Long-term changes can be analyzed much easier, so that slow developing instabilities could be detected.

Conclusion

The new features of the Philos II pacemaker system performed very well in this small group of patients. They simplified the process and reduced the effort for parameter adjustment, and, therefore, these improvements leave more time for the physician to concentrate on the patient's disease and its treatment. Here the IEGM snapshots provide a highly effective tool for improved patient monitoring between follow-ups, which allows the detection and recording of rhythm disturbances leading to an improved patient therapy. The recording of IEGMs triggered by the patient in the case of symptomatic events supports the identification of cardiac diseases. Clearly, the functionality of "Home Monitoring" paired with the recording of IEGM snapshots will provide a definite possibility for improved patient monitoring between follow-up sessions.

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