AF monitoring and stroke: XPECT & REVEAL LINQ

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EUROPEAN Heart Rhythm ASSOCIATION
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EHRA POSITION PAPER

Indications for the use of diagnostic implantable and external ECG loop recorders

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Part II: Non-established indications

3. Atrial fibrillation: therapy guided by loop recorder observations

Key points

- There is a poor correlation of symptoms with atrial fibrillation (AF), especially after rhythm control therapy is started, which makes subjective evaluation of the effect of any therapy unreliable
- There are two main potential reasons for accurate arrhythmia monitoring: in clinical practice to determine the efficacy of rhythm control therapy; in rhythm control trials when freedom from AF is the outcome parameter
- Owing to the unpredictable nature of recurrences, AF is significantly underdetected by intermittent monitoring systems
- Continuous monitoring by implantable devices further increases the detection of AF, but it is hampered by misdetections and artefacts.
- Technological improvements are required for significant reduction of maldetection. Manual analysis can improve diagnostic yield if stored electrograms are provided. The results of some on-going studies with new generation devices are awaited
- The clinical relevance of Loop Recorders to guide medical and device therapy has yet to be demonstrated

Circ Arrhythm Electrophysiol 2010;3:141-47

Performance of a New Leadless Implantable Cardiac Monitor in Detecting and Quantifying Atrial Fibrillation Results of the XPECT Trial

Gerhard Hindricks, MD, PhD; Evgueny Pokushalov, MD; Lubos Urban, MD;
Milos Taborsky, MD, PhD; Karl-Heinz Kuck, MD, PhD; Dmitry Lebedev, MD, PhD;
Guido Rieger, MD; Helmut Pürerfellner, MD; on behalf of the XPECT Trial Investigators

Reveal XT versus LINQ

Parameter	Reveal XT	Reveal LINQ™
Longevity	3 years	3 years
Electrode Spacing (inside-to-inside)	41 mm	38 mm
Volume	9 cc	1.18 cc
Mass	15 g	~2.5 g
Episode Storage	49 min	57 min
Patient Symptom Mark	Patient Assistant	Patient Assistant
Cardiac Compass	Same	Same
MRI Compatibility	MR Conditional	MR Conditional
Clinician Notification	No	Nightly Transmission / CareAlerts
Bi-Directional Telemetry	B	B
Detection Algorithms	Full View	Full View + P-wave detection
CareLink®	Yes	Yes *New CL Full reports, online episode viewer, online trends viewer, episode rollup since implant, 31-day summary report, CareAlert event reports, FullView zoom capability*
Wireless Telemetry	No	1-Way, Transmit Only

XPECT

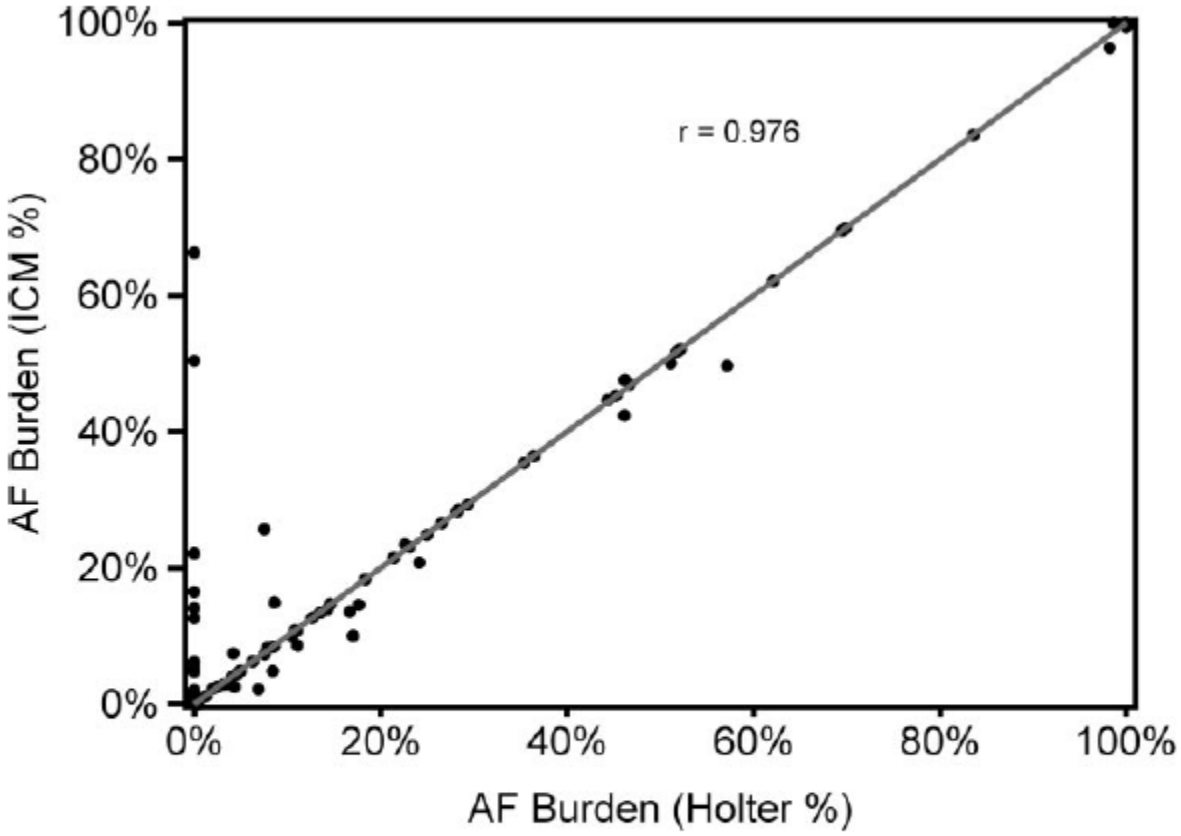


Figure 3. AF burden measured by the ICM compared with AF burden calculated from the core laboratory–annotated Holter recording for all patients (r indicates Pearson correlation coefficient).

XPECT

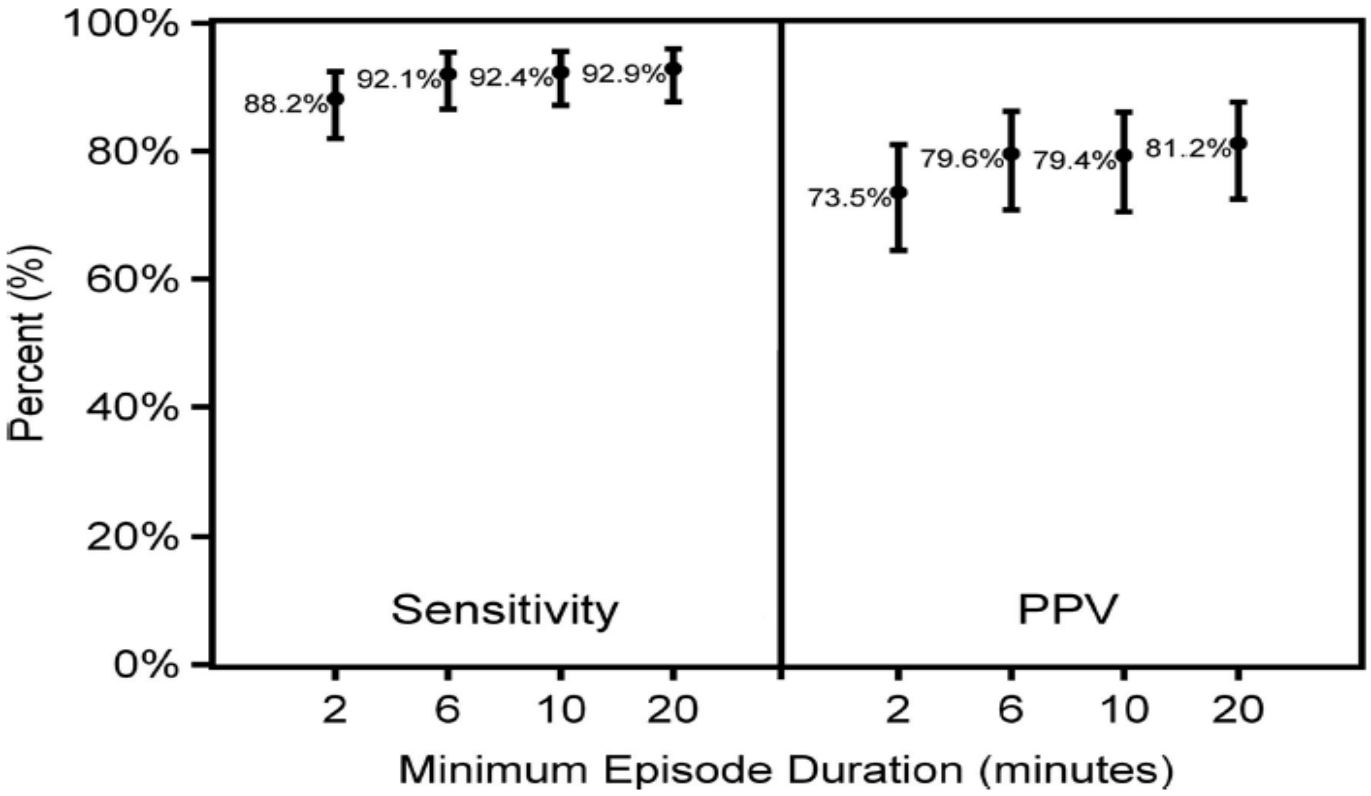
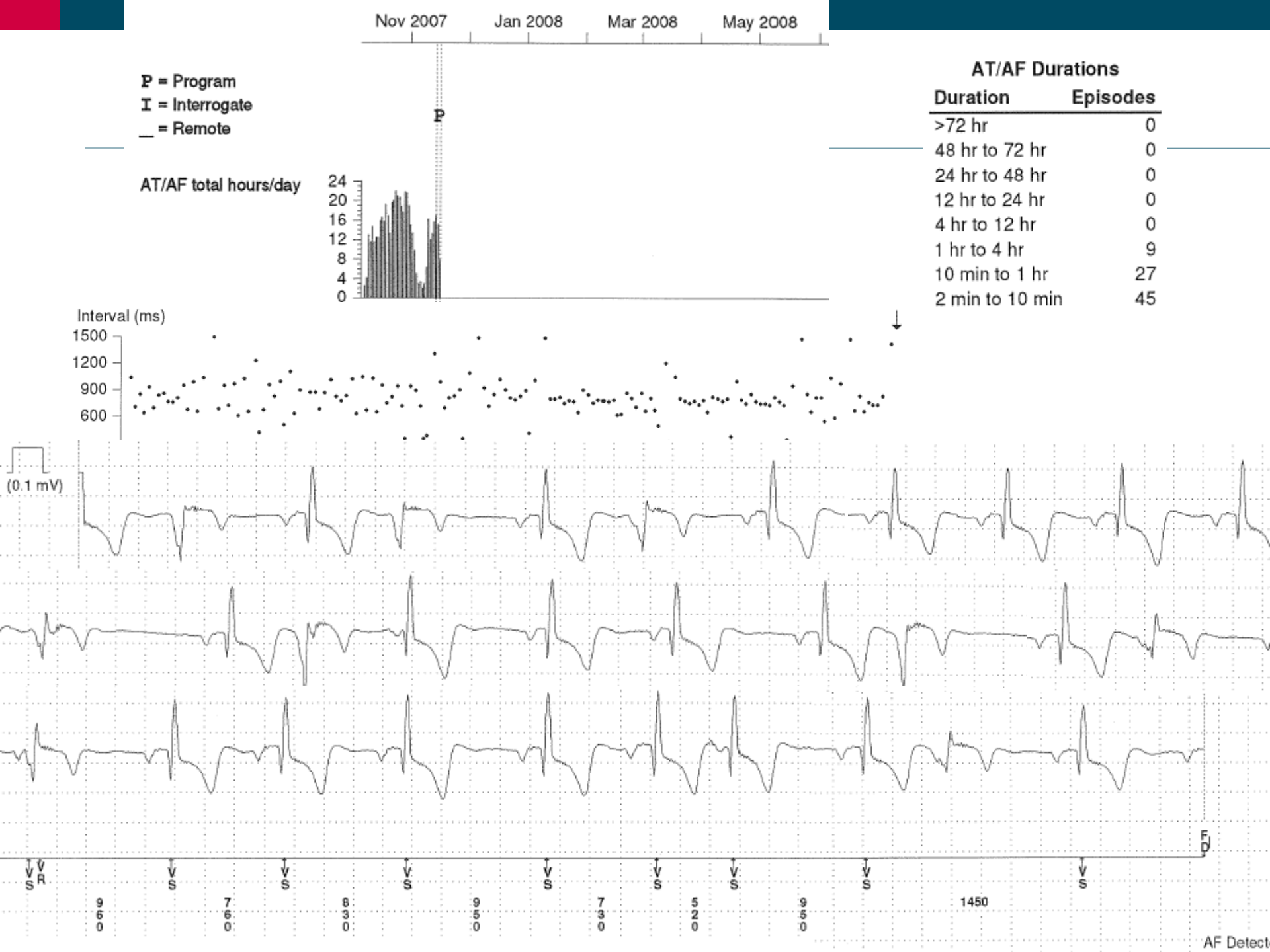


Figure 4. AF episode detection sensitivity (left) and PPV (right), depending on episode duration. Episodes longer than the minimum duration are included in the analysis for each result. Bars denote confidence intervals.

Causes for Inappropriate AF Detection

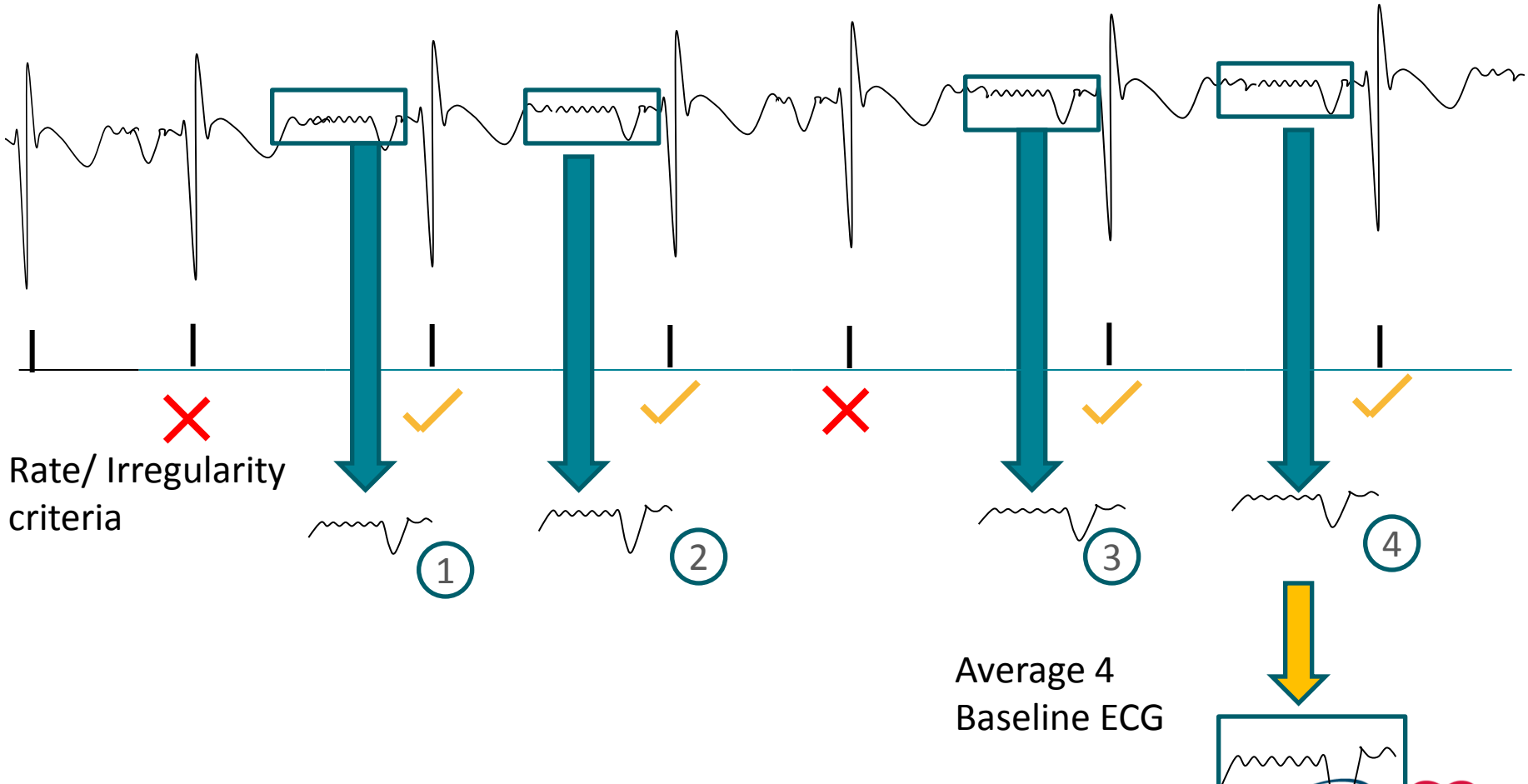
- ~~Over-sensing due to noise~~
- ~~Bigeminy and trigeminy~~
- Frequent ectopy with irregular coupling interval
- Sick sinus: brady-tachy syndrome
- Sinus tachycardia with RR variability
- Under-sensing due to small amplitude or wide R-waves
- T-wave over-sensing or p-waves over-sensing


Nov 2007
Jan 2008
Mar 2008
May 2008
P = Program
I = Interrogate
_ = Remote
P
AT/AF total hours/day
24
20
16
12
8
4
0
AT/AF Durations
Duration Episodes
>72 hr 0
48 hr to 72 hr 0
24 hr to 48 hr 0
12 hr to 24 hr 0
4 hr to 12 hr 0
1 hr to 4 hr 9
10 min to 1 hr 27
2 min to 10 min 45
Interval (ms)
1500
1200
900
600
(0.1 mV)
1450
AF Detect

Goal for AF detection in Reveal LinQ

- **Reduce episode review burden**
  - Algorithm enhancements in Reveal LinQ
  - Nominal programming based on patient type
  - Enhanced episode storage scheme
- **Preserve AF burden accuracy**
  - Preserve Sensitivity to AF detection

P-SENSE: *P-wave Averaging*

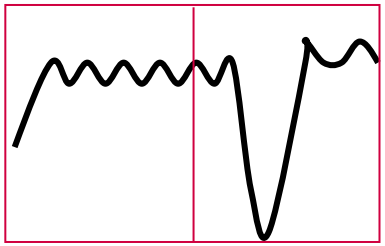


P-SENSE: *P-wave feature extraction*

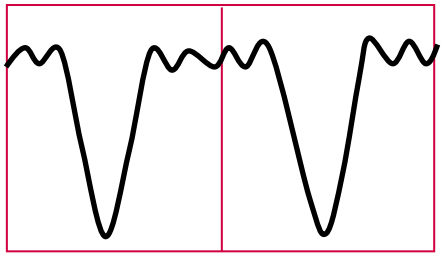
Morphology of Averaged ECG is used to identify

- Presence of P-wave
- Absence of atrial flutter waves
- Absence of baseline noise

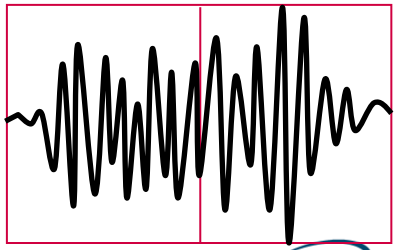
P-wave



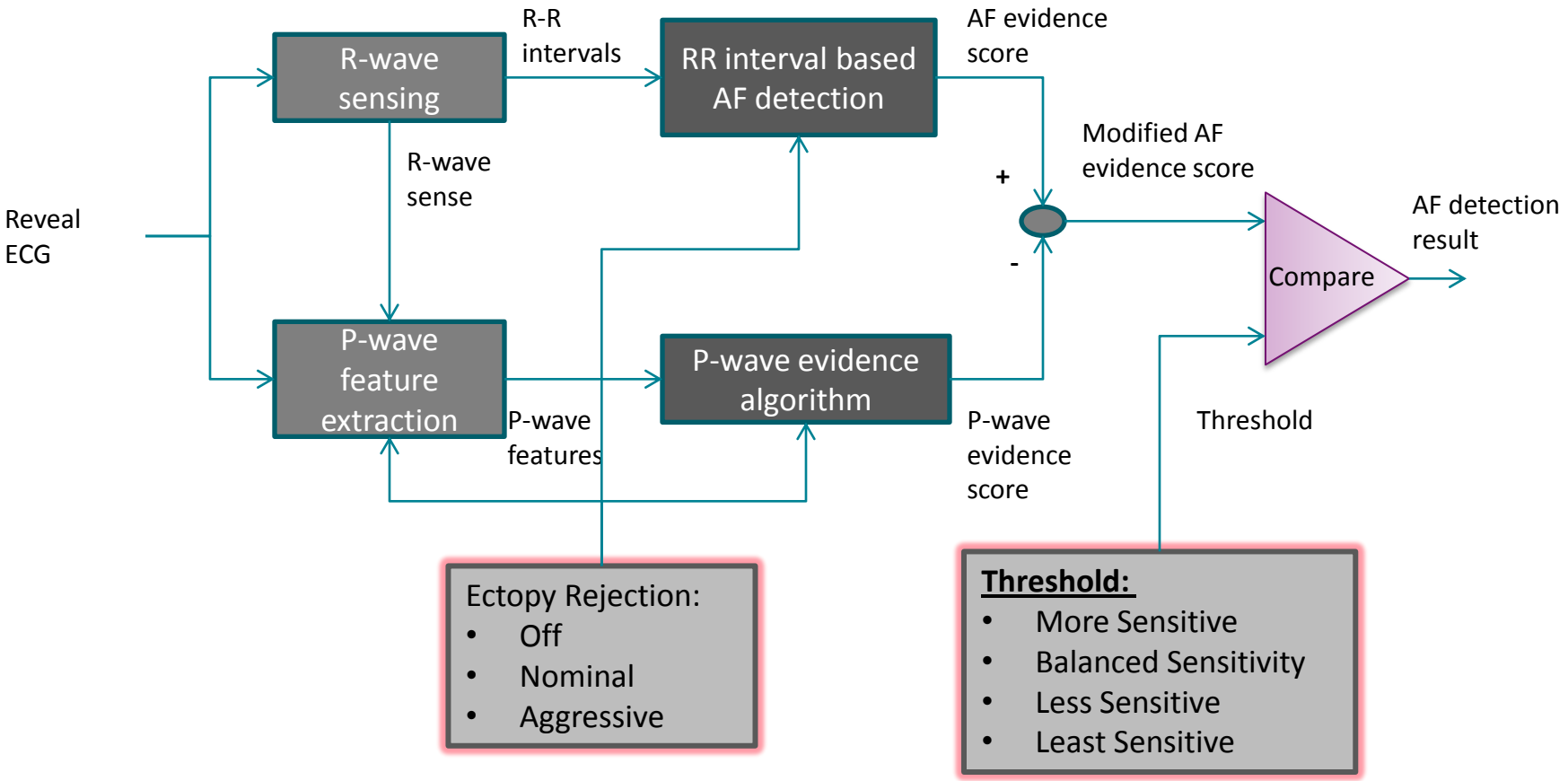
Flutter



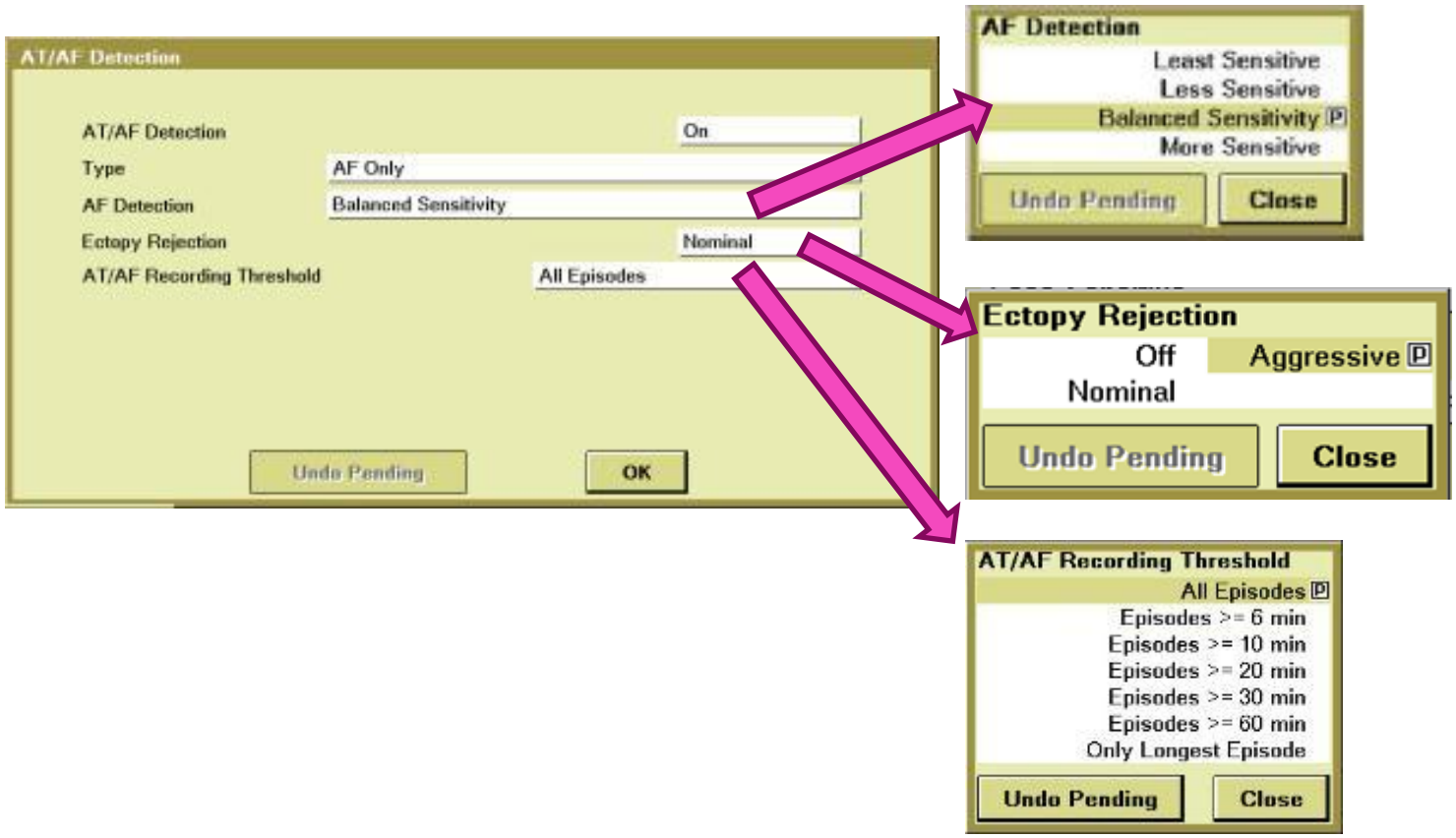
Noise



P-SENSE: *Modify AF evidence*



AF detection in Reveal LinQ: *Programming options*



Optimizing AF Detection for Patient Type
Reduce burden of episode review

Reason for Monitoring	Parameters		
	AF Detection Threshold	Ectopy Rejection	Episode Storage Threshold
Syncope	Least	Aggressive	Longest Episode Only
Seizures	Least	Aggressive	≥ 10 min
Ventricular Tachycardia	Least	Aggressive	≥ 10 min
Palpitations	Less	Aggressive	≥ 6 min
Suspected AF	Less	Aggressive	≥ 6 min
Cryptogenic Stroke	Balanced	Aggressive	All
AF Ablation	Balanced	Nominal	All
AF Management	Balanced	Nominal	All
Other	Less	Aggressive	≥ 10 min

AF detection 'nice to have'

Does patient have AF ?

Does patient have AF ?
How much AF ?

Heart Rhythm 2014;11:1575-1583

P-wave evidence as a method for improving algorithm to detect atrial fibrillation in insertable cardiac monitors

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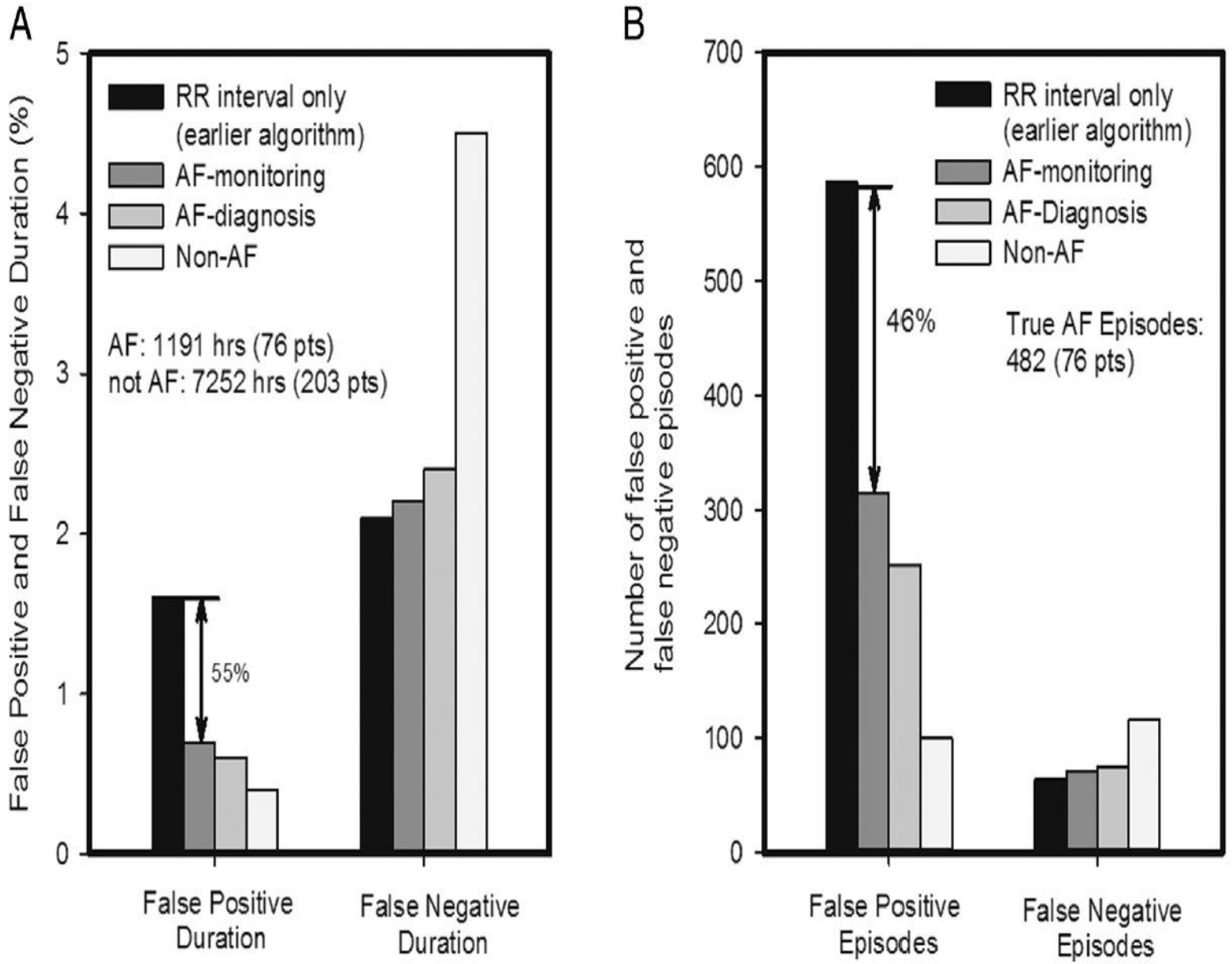
From the [*]Department of Cardiology, Krankenhaus der Elisabethinen, Linz, Austria, [†]State Research Institute of Circulation Pathology, Novosibirsk, Russia, [‡]Medtronic Incorporated, Mounds View, Minnesota, [§]The National Institute of Cardiovascular Diseases, Bratislava, Slovakia, and [‖]Heart Center, University of Leipzig, Leipzig, Germany.

P-SENSE *Performance summary*

- **False episodes reduced by 46% with 2% reduction in true episodes**
- **False duration reduced by 55% with 0.1% reduction in true duration**

- **Detected 97.8% of total AF duration**
- **Detected 99.3% of total sinus or non-AF rhythm duration**

- **Detected 85% (90% patient average) of all AF episodes ≥2 minutes**
- **55% (78% patient average) of detected episodes had AF**
  - 95% of detected episodes >1 hour had AF
  - 14% of patients had false detects
  - 7% of patients with only false detects
  - 3 patients account for 70% of false detects


A
False Positive and False Negative Duration (%)
0
1
2
3
4
5
RR interval only
(earlier algorithm)
AF-monitoring
AF-diagnosis
Non-AF
AF: 1191 hrs (76 pts)
not AF: 7252 hrs (203 pts)
55%
False Positive
Duration
False Negative
Duration
B
Number of false positive and
false negative episodes
0
100
200
300
400
500
600
700
RR interval only
(earlier algorithm)
AF-monitoring
AF-Diagnosis
Non-AF
46%
True AF Episodes:
482 (76 pts)
False Positive
Episodes
False Negative
Episodes

Reveal XT versus LINQ

Parameter	Reveal XT	Reveal LINQ™
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LINQ™ System Components

Devices

Reveal LINQ™

Incision Tool

Insertion Tool

Patient Assistant

MyCareLink® Home Monitor

Programmer

2090 Programmer

CareLink®

Reports & notifications

Heart Rhythm 2015 (in press)

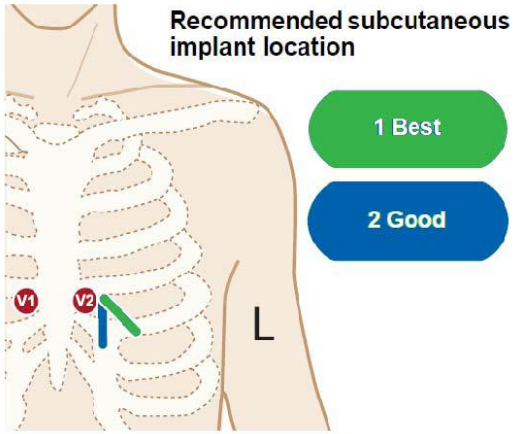
Miniaturized Reveal LINQ™ Insertable Cardiac Monitoring (ICM) System: First in Man Experience

Pürerfellner, Helmut, MD, FHRS[1], Sanders, Prashanthan, MBBS, PhD, FHRS[2], Pokushalov, Evgeny, MD[3], Di Bacco, Marco, PharmD[4], Bergemann, Tracy, PhD[5], Dekker, Lukas R.C., MD, PhD[6] for the Reveal LINQ™ Usability Study Investigators

Insertion Procedure: Insertion

- **Procedure Location:**
  - Cath Lab: n=25 (83.3%)
  - Clean Room: n=5 (16.7%)

- Insertion Location:



28 (93.3%)

2 (6.7%)

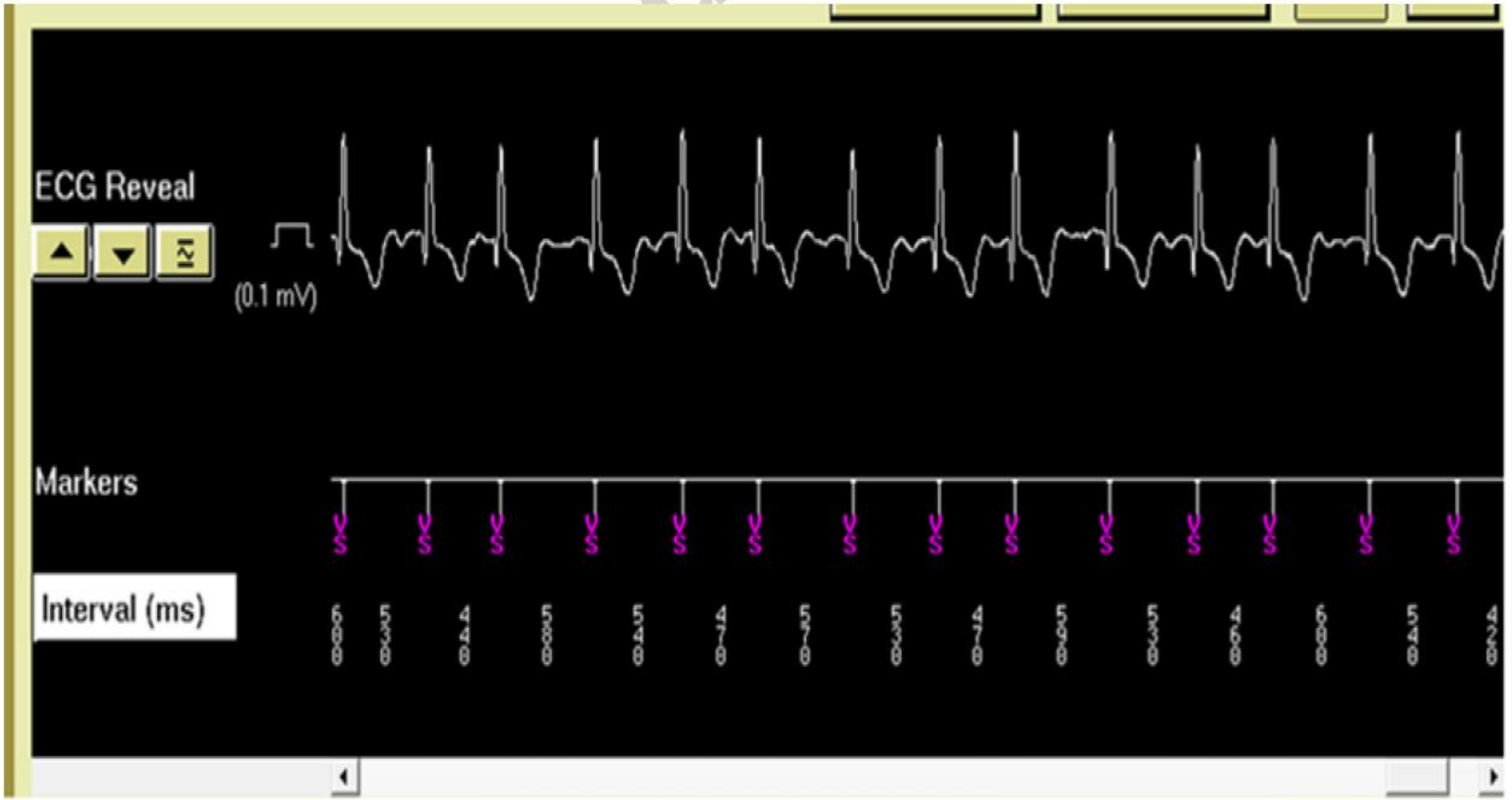
Primary Indication	Implanted Subjects (n=30)
Syncope	19 (63.3%)
Palpitations	3 (10.0%)
Seizures	0 (0.0%)
Suspected AF	2 (6.7%)
AF Ablation Monitoring	2 (6.7%)
AF Management	2 (6.7%)
Cryptogenic Stroke	1 (3.3%)
Ventricular Tachycardia	0 (0.0%)
Other	1 (3.3%)

Results

- 100% (n=30) implant success for Phase I
- Successful transmissions in 79,5%
- R-wave amplitude ≥200µV at implant for 96.7% of subjects
- High physician and patient acceptance
- No significant migration
- No reportable system or procedure adverse events

Note: The Reveal LINQ System has received CE Mark and TGA Approval and is Pending FDA 510K Clearance

Reveal LINQ



AF diagnosis and monitoring: *Clinical Applications*

- **Secondary stroke prevention (post cryptogenic stroke)**
  - Sinha AM et al Am Heart J. 2010;160(1):36-41.
  - Ritter MA et al Stroke. 2013;44(5):1449-52.
  - Etgen T et al. Stroke. 2013;44(7):2007-9.
- **Pre and post PV ablation**
  - Pokuslalov E et al. J Cardiovasc Electrophysiol. 2011;22(4):369-75.
  - Verma A et al. JAMA Intern Med. 2013;173(2):149-56.
  - Kapa S et al. J Cardiovasc Electrophysiol. 2013;24(8):875-81.
- **Post surgical AF ablation**
  - Hanke T et al. Circulation. 2009;120(11 Suppl):S177-84.
- **Selection of patients for redo ablation**
  - Pokushalov E et al. Circ Arrhythm Electrophysiol. 2011;4(6):823-31.
  - Pokushalov E et al. Circ Arrhythm Electrophysiol. 2013;6(4):754-60.
- **Post atrial flutter ablation**
  - Mittal S et al Heart Rhythm. 2013. doi: 10.1016/j.hrthm.2013.07.044.
- **Primary stroke prevention (high risk of stroke)**
  - Reveal AF study (enrolling)