

THE REVEAL LINQ™

DETECTION OF AF AND QUANTIFICATION OF ITS
BURDEN USING IMPLANTABLE LOOP RECORDER :
ALGORITHM AND TECHNICAL ASPECTS

REVEAL LINQ™
IMPLANTABLE LOOP RECORDER
2018/12/08
MEDTRONIC
JOO, SANG YOUNG



Medtronic
Further, Together

REVEAL LINQ™

1. Reveal LINQ introduction
2. Reveal LINQ AT/AF Detection Algorithm
3. Aspects for Using ILR(Implantable Loop Recorder)
4. Case Study
5. Q&A

REVEAL LINQ SYSTEM ADVANTAGES

REVOLUTIONIZING CARDIAC MONITORING

The smallest, most powerful insertable cardiac monitor

SMALL

One-third the size of a AAA battery (1.2 cc)

3

YEAR

Up to a 3-year longevity for long-term monitoring⁵



MR Conditional at 1.5 and 3.0 Tesla

EASY

Minimally invasive, simplified insertion procedure⁶

96.7%

96.7% of patients very satisfied or satisfied with Reveal LINQ ICM after insertion⁷



References:

5. Reference the Reveal LINQ ICM Clinician Manual for usage parameters.

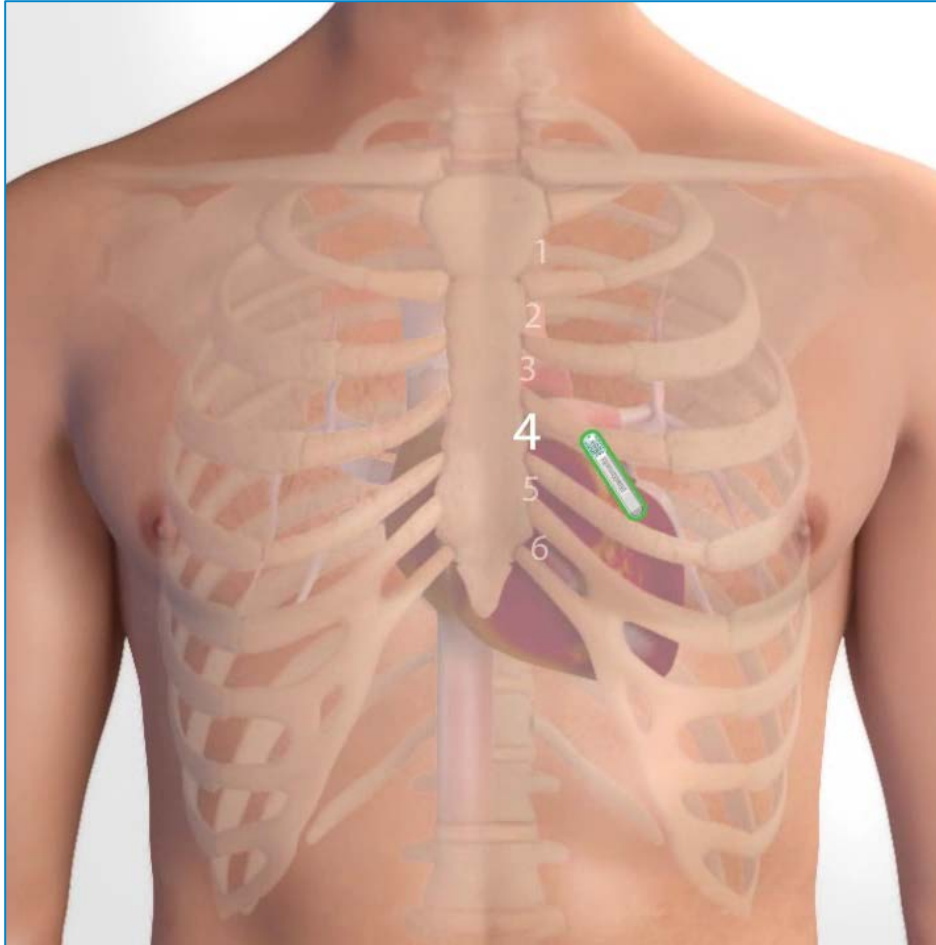
6. Reveal LINQ Usability Study. Medtronic data on file. 2013.

7. Pürerfellner H, Prashanthan S, Pokushalov E, et al. Miniaturized Reveal LINQ insertable cardiac monitoring system: First-in-human experience. *Heart Rhythm*. June 2015;12(6):1113–1119.

Medtronic

REVEAL LINQ SYSTEM ADVANTAGES

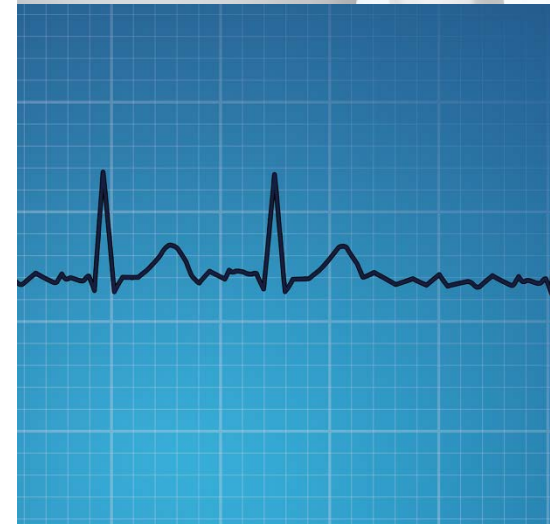
SIMPLE INSERTION PROCEDURE



Best location:
45 degrees to
sternum over 4th
intercostal space,
2 cm from left
edge of sternum

97%
of physicians
found the
insertion tool
simple and
intuitive.⁶

Requires minimal
procedure time and
clinical resources



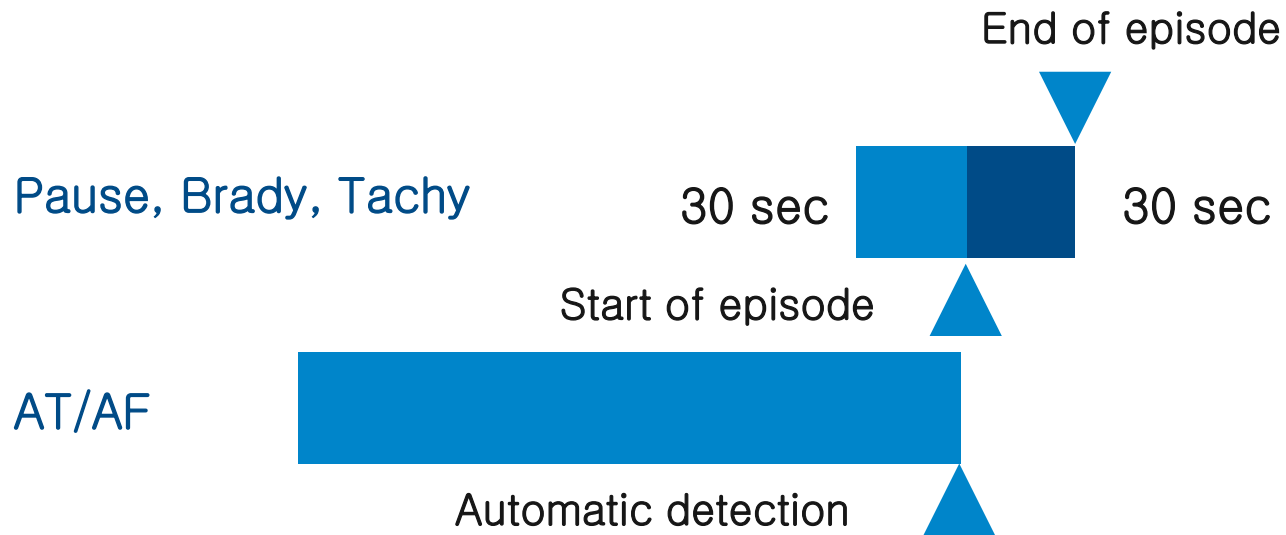
References:
6. Reveal LINQ Usability Study. Medtronic data on file. 2013.

REVEAL LINQ SYSTEM ADVANTAGES

SMART ECG DATA STORAGE

ECG data storage: **59 minutes total**

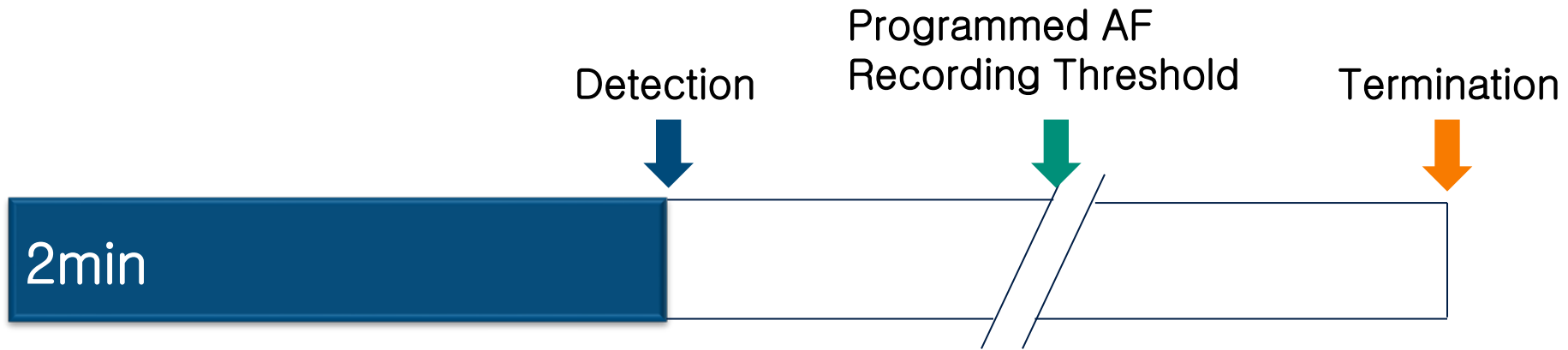
Automatically detected: **29 minutes**



2 minutes of longest AF episode stored since last interrogation in addition to the 27 minutes of automatically detected episodes.

DETECTION/TERMINATION MEMORY STORAGE

ATRIAL EPISODES




ECG only stored if the episode is longer than the Programmed AF Recording Threshold.


DETECTION EPISODES & DIAGNOSTICS

72 bpm / 830 ms
0.51 mV

ECG Lead II



ECG Reveal



Freeze

Strips...

Adjust...

FullView™
Software

Parameters

Symptom

| | Detection | Interval (Rate) | Duration |
|----------|--------------------------------------|---|---------------------------------------|
| Tachy | <input type="text" value="On"/> | <input type="text" value="350 ms (171 bpm)"/> | <input type="text" value="16 beats"/> |
| Brady | <input type="text" value="On"/> | <input type="text" value="2000 ms (30 bpm)"/> | <input type="text" value="4 beats"/> |
| Pause | <input type="text" value="On"/> | | <input type="text" value="3 sec"/> |
| AT/AF... | <input type="text" value="AF Only"/> | | |

Additional Settings

Sensing...

Device Data Collection...

Save...

Get...

Undo Pending


Print...


i


PROGRAM


Interrogate...


End Session...


 Quick Look

 Episodes

 Params

 < Reports

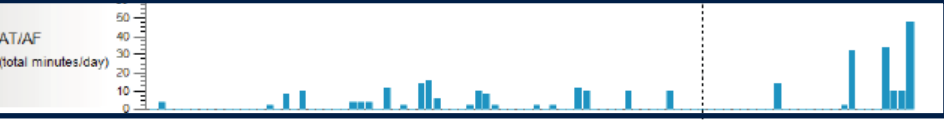
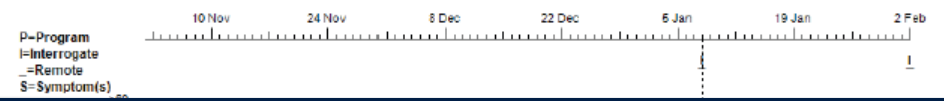
 Patient

 < Session

CARDIAC COMPASS® REPORT

TRENDED DIAGNOSTICS

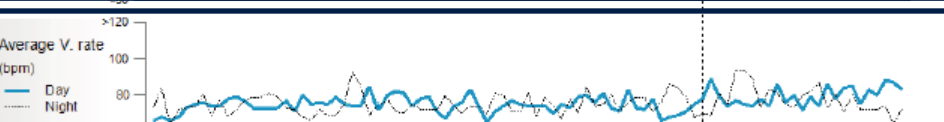
Daily AF Burden



Ventricular Rate during AF



Day & Night Heart Rate



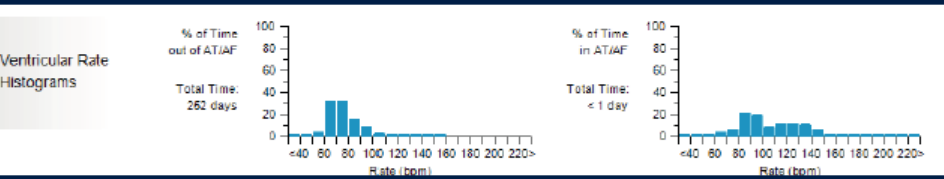
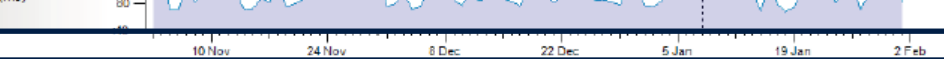
Patient Activity



Heart Rate Variability



Ventricular Rate Histograms



10 seconds of Longest AF In the past 90 days



REVEAL LINQ SYSTEM ADVANTAGES

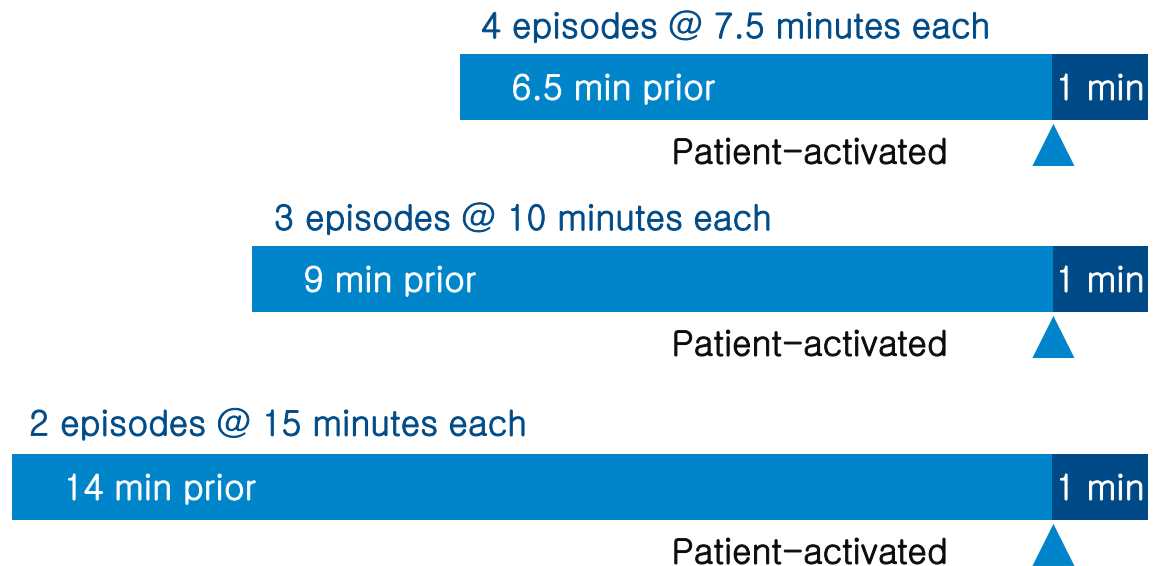
SMART ECG DATA STORAGE

ECG data storage: **59 minutes total**

Patient-activated: **up to 30 minutes**



Patient Assistant



SMART ECG DATA STORAGE

■ Patient-activated

----- Last Medtronic CareLink Monitor Session 27-Apr-2014 -----

| | | | | | | |
|----|---------|-------------|-------|-----|--------------|------------------|
| 37 | Brady | 21-Apr-2014 | 20:30 | :19 | Min = 36 bpm | 37 bpm (1630 ms) |
| 36 | Brady | 21-Apr-2014 | 20:30 | :09 | Min = 38 bpm | 38 bpm (1570 ms) |
| 35 | Brady | 19-Apr-2014 | 15:50 | :14 | Min = 40 bpm | 48 bpm (1260 ms) |
| 34 | Brady | 19-Apr-2014 | 15:49 | :06 | Min = 40 bpm | 43 bpm (1390 ms) |
| 33 | Brady | 19-Apr-2014 | 14:27 | :07 | Min = 40 bpm | 43 bpm (1380 ms) |
| 32 | Brady | 19-Apr-2014 | 14:18 | :07 | Min = 40 bpm | 47 bpm (1280 ms) |
| 31 | Brady | 19-Apr-2014 | 10:47 | :06 | Min = 41 bpm | 42 bpm (1440 ms) |
| 30 | Brady | 18-Apr-2014 | 14:37 | :16 | Min = 39 bpm | 41 bpm (1470 ms) |
| 29 | Brady | 18-Apr-2014 | 14:33 | :08 | Min = 40 bpm | 43 bpm (1410 ms) |
| 28 | Brady | 18-Apr-2014 | 14:28 | :07 | Min = 40 bpm | 41 bpm (1450 ms) |
| 27 | Brady | 18-Apr-2014 | 13:44 | :08 | Min = 40 bpm | 41 bpm (1470 ms) |
| 26 | Brady | 17-Apr-2014 | 15:44 | :06 | Min = 40 bpm | 41 bpm (1450 ms) |
| 25 | Brady | 17-Apr-2014 | 15:26 | :06 | Min = 40 bpm | 42 bpm (1420 ms) |
| 24 | Brady | 17-Apr-2014 | 15:25 | :07 | Min = 40 bpm | 41 bpm (1460 ms) |
| 23 | Brady | 17-Apr-2014 | 15:20 | :14 | Min = 39 bpm | 42 bpm (1430 ms) |
| 22 | Brady | 17-Apr-2014 | 15:19 | :18 | Min = 40 bpm | 40 bpm (1500 ms) |
| 21 | Brady | 17-Apr-2014 | 15:14 | :15 | Min = 39 bpm | 49 bpm (1230 ms) |
| 20 | Brady | 17-Apr-2014 | 15:13 | :09 | Min = 40 bpm | 40 bpm (1500 ms) |
| 19 | Brady | 17-Apr-2014 | 15:13 | :06 | Min = 40 bpm | 40 bpm (1500 ms) |
| 18 | Brady | 17-Apr-2014 | 15:12 | :11 | Min = 40 bpm | 40 bpm (1510 ms) |
| 17 | Brady | 17-Apr-2014 | 15:12 | :07 | Min = 39 bpm | 40 bpm (1490 ms) |
| 16 | Brady | 17-Apr-2014 | 15:00 | :06 | Min = 41 bpm | 41 bpm (1450 ms) |
| 15 | Brady | 17-Apr-2014 | 14:12 | :11 | Min = 39 bpm | 39 bpm (1520 ms) |
| 14 | Brady | 17-Apr-2014 | 14:12 | :06 | Min = 40 bpm | 40 bpm (1510 ms) |
| 13 | Brady | 12-Apr-2014 | 19:01 | :20 | Min = 35 bpm | 65 bpm (920 ms) |
| 12 | SYMPTOM | 12-Apr-2014 | 18:44 | | | |
| 11 | Brady | 12-Apr-2014 | 18:42 | :59 | Min = 34 bpm | 63 bpm (960 ms) |
| 2 | SYMPTOM | 25-Mar-2014 | 22:25 | | | |

----- Last Programmer Session 21-Mar-2014 -----

Multiple true Brady episodes detected and 2 Patient Activated episodes recorded

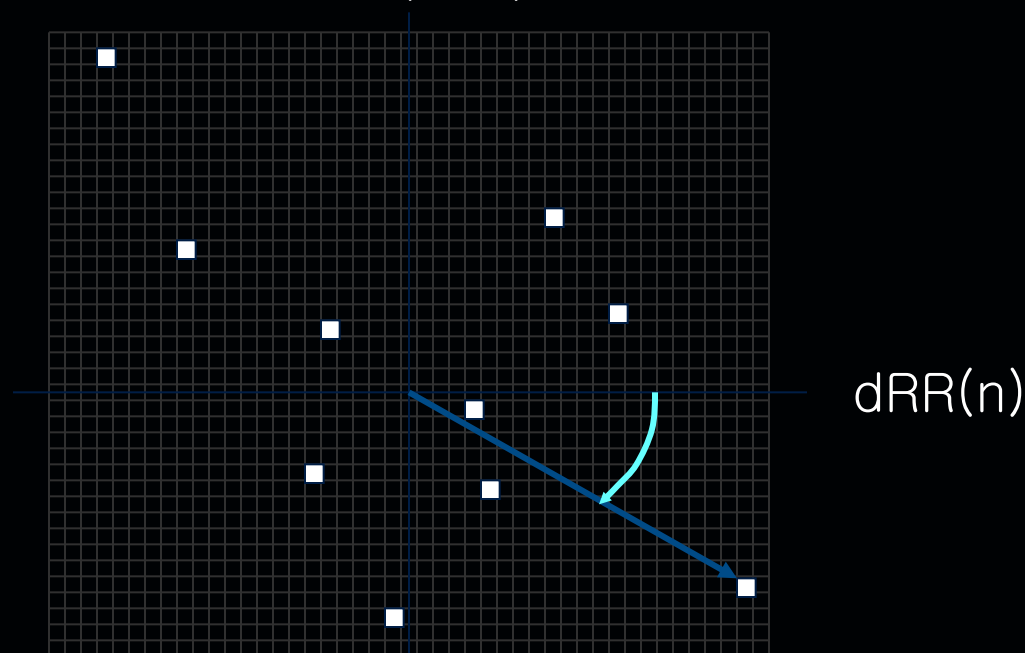
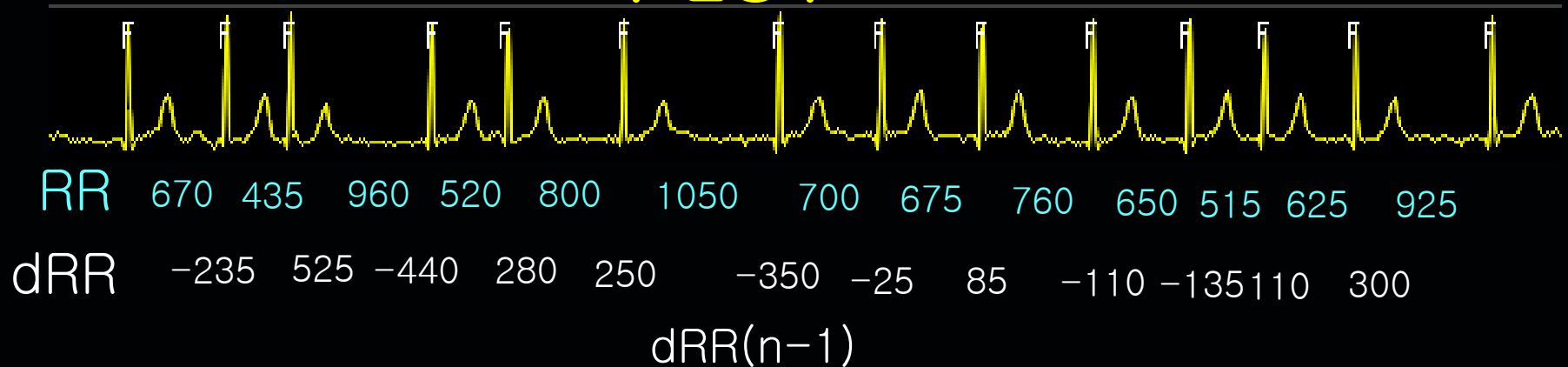
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DETECTING AF IN LINQ

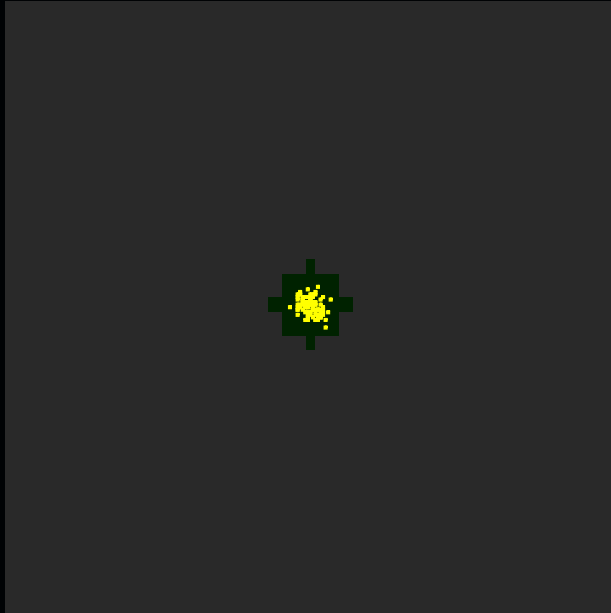
- Define how LINQ detects AF
 - The patterns of R–R variability are analyzed using the Lorenz plot over a two minute period of time
- It is not a rolling two minutes, it starts over

DETECTOR PRINCIPLE: LORENZ PLOT

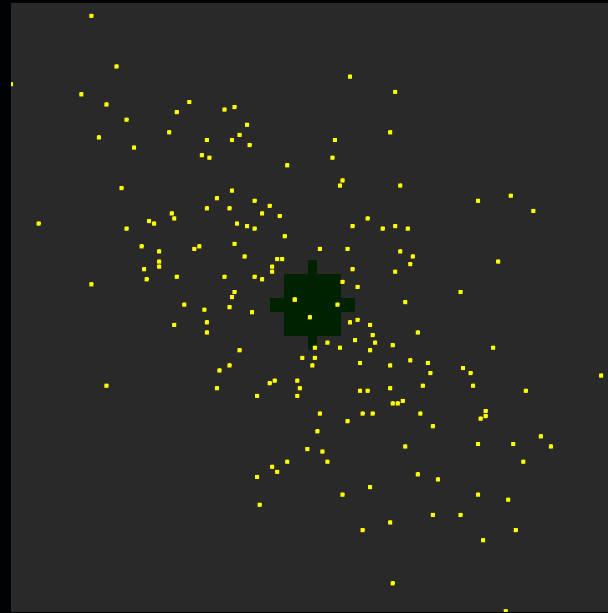


CLUSTER SIGNATURES IN LORENZ PLOT

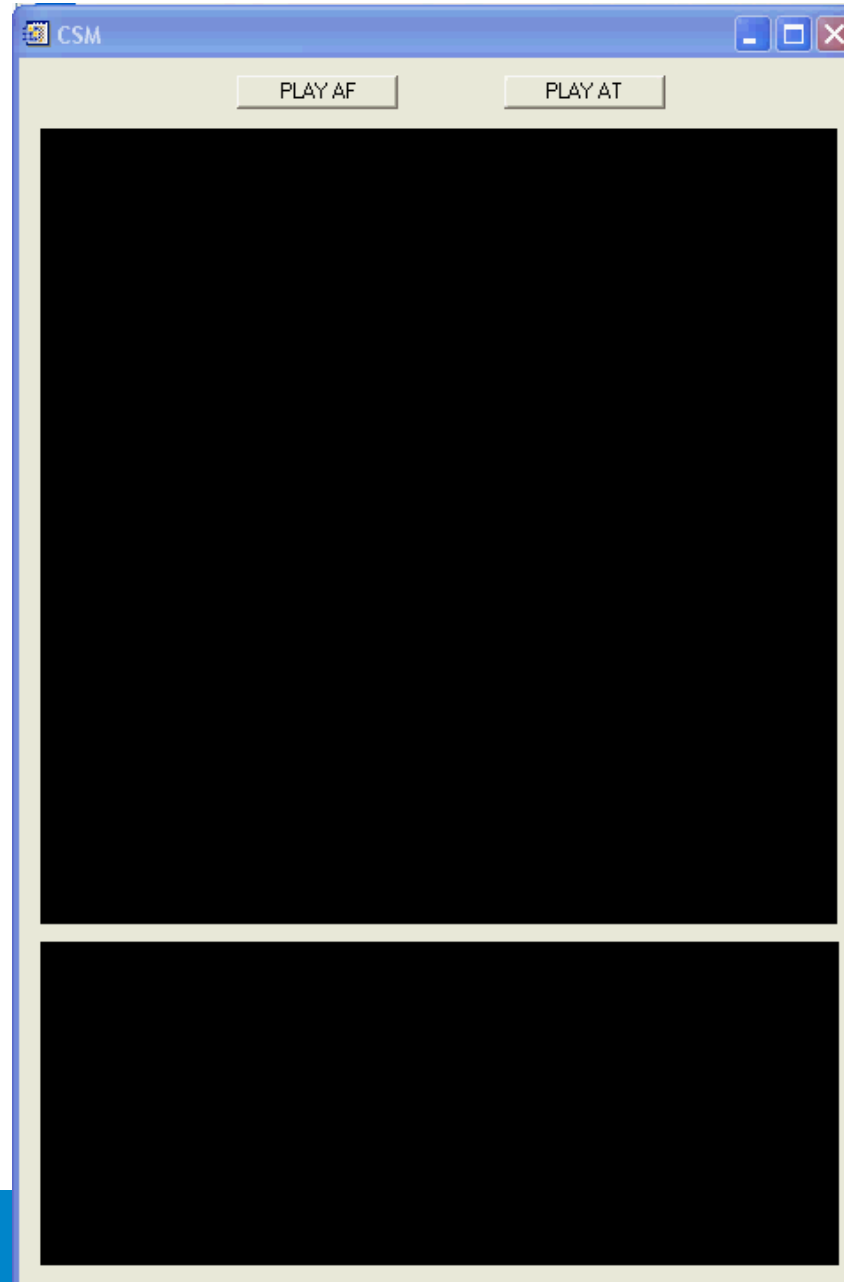
Sinus



AF



24 HOURS OF RHYTHM SHOWING AF ON THE LORENZ PLOT



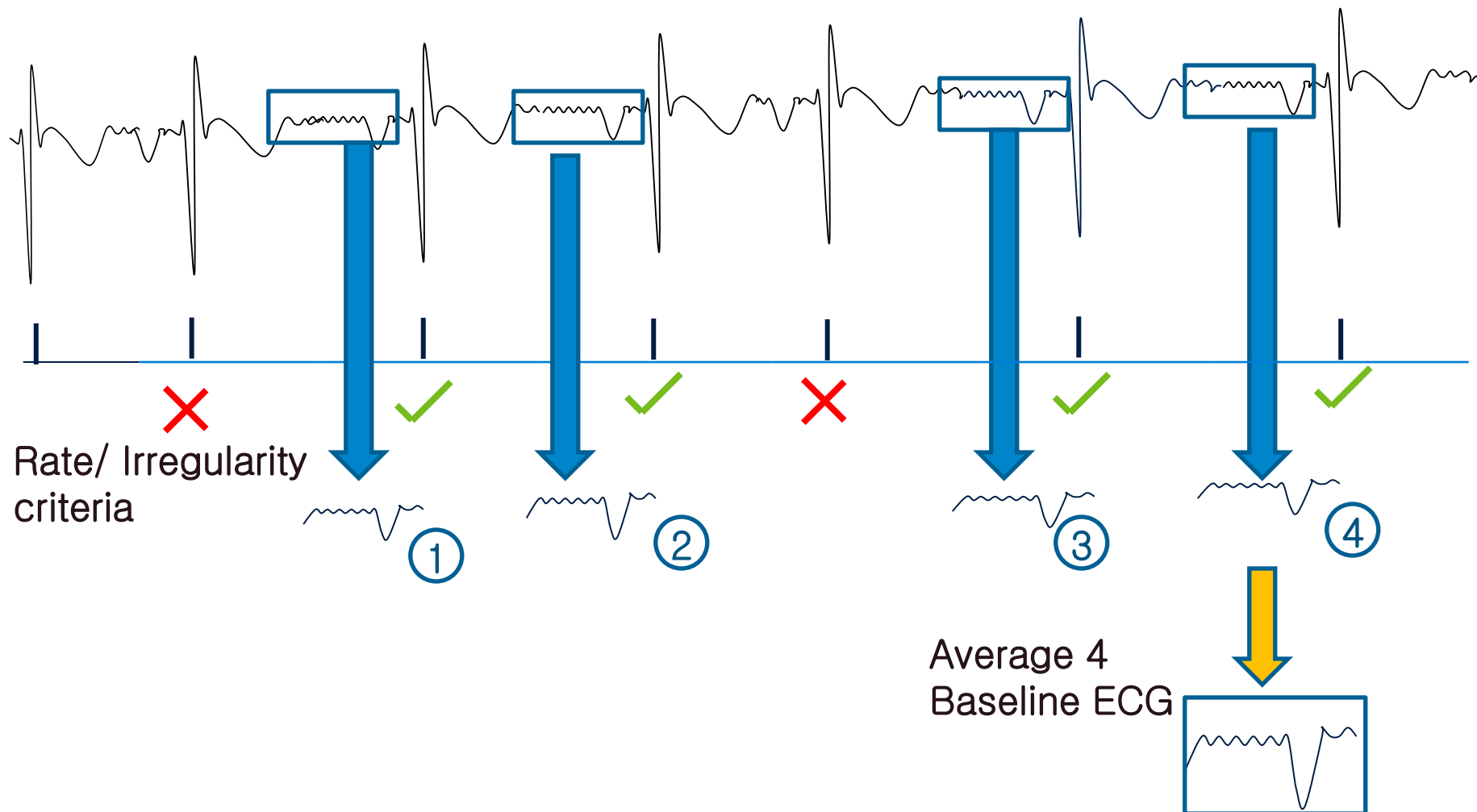
P-SENSE DETAILS

Finding the presence of single P-wave between two R-waves

1. P-wave Averaging
2. P-wave feature extraction algorithm
3. P-wave evidence accumulation
4. Modify AF evidence

P-SENSE

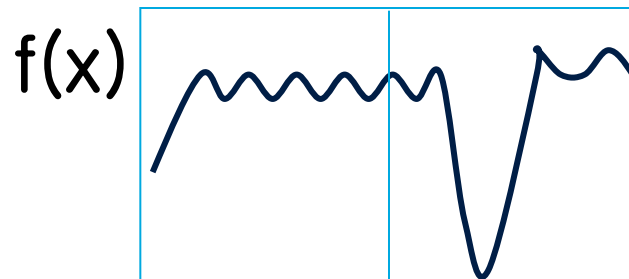
P-WAVE AVERAGING



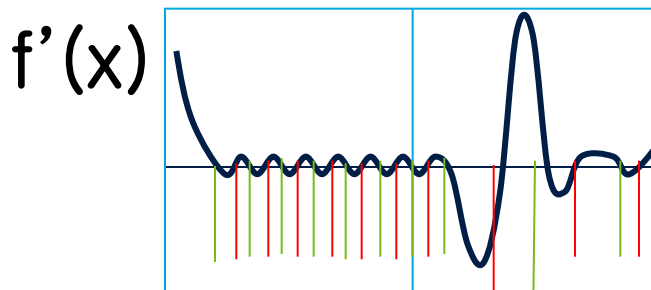
P-SENSE ALGORITHM DESCRIPTION

P-WAVE FEATURE EXTRACTION – EVIDENCE OF 1P BETWEEN 2RS

Function (average of 4 windows)

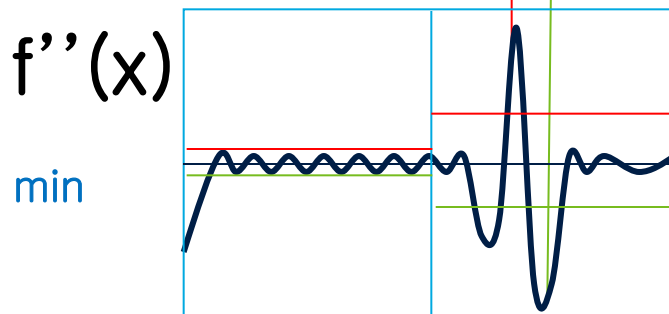


First Derivative
Measures the rate of change of y to x



In the first derivative, we extract P-wave features using zero crossings

Second Derivative
Determines whether a point is a local max or min



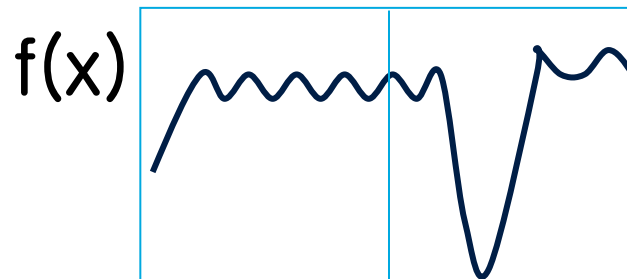
In the second derivative we extract P-wave features by looking at the amplitude of the signal at the zero crossings

← Baseline Window | P-wave Window →

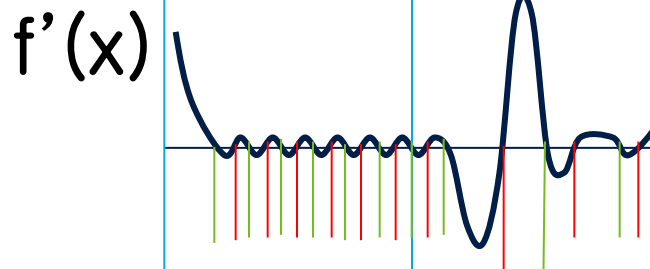
P-SENSE ALGORITHM DESCRIPTION

P-WAVE FEATURE EXTRACTION – EVIDENCE OF 1P BETWEEN 2RS

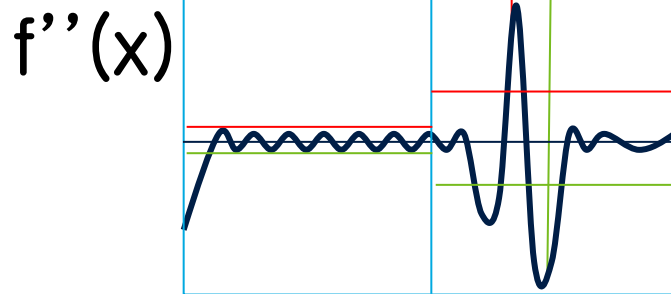
Function
(average of 4
windows)



First Derivative



Second Derivative



Baseline Window | P-wave Window

Evidence of P-wave

- 2X baseline amplitude at zero crossings
- One pos / one neg or one of each

DURATION BASED OR TOTAL AF BURDEN

SENSITIVITY

98.4%

If a patient has 100 hours of AF, LINQ will detect 98.4 hours

SPECIFICITY

99.5%

If a patient has 100 hours of non-AF, LINQ will inappropriately detect half hour of AF that isn't AF

POSITIVE PREDICTIVE VALUE

97.2%

If LINQ identifies 100 hours of AF, 97.2 hours of the 100 hours will be true AF

NEGATIVE PREDICTIVE VALUE

99.7%

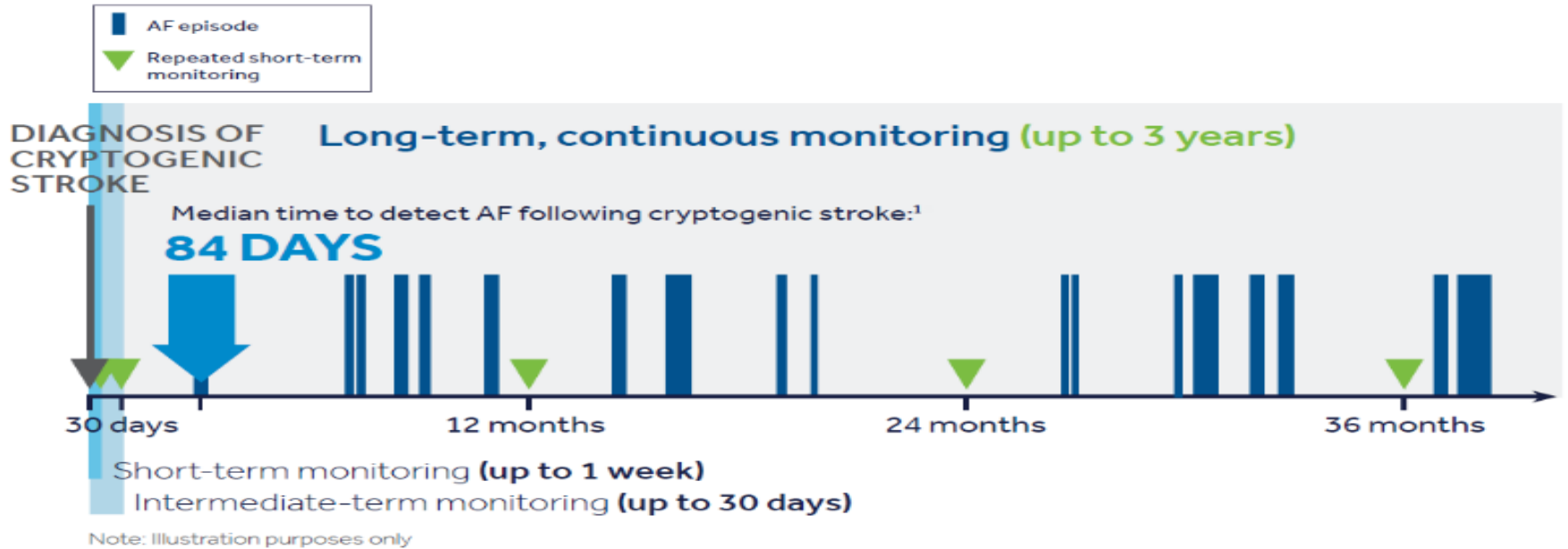
If LINQ did not identify any AF in 100 hours, only 0.3 hours was there AF

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Are You Monitoring Cryptogenic Stroke Patients Long Enough?

Short- and intermediate-term cardiac monitoring may miss many patients with paroxysmal AF²



84 DAYS

is the median time to AF detection in cryptogenic stroke patients

79%

of first AF episodes were asymptomatic at 12 months

88%

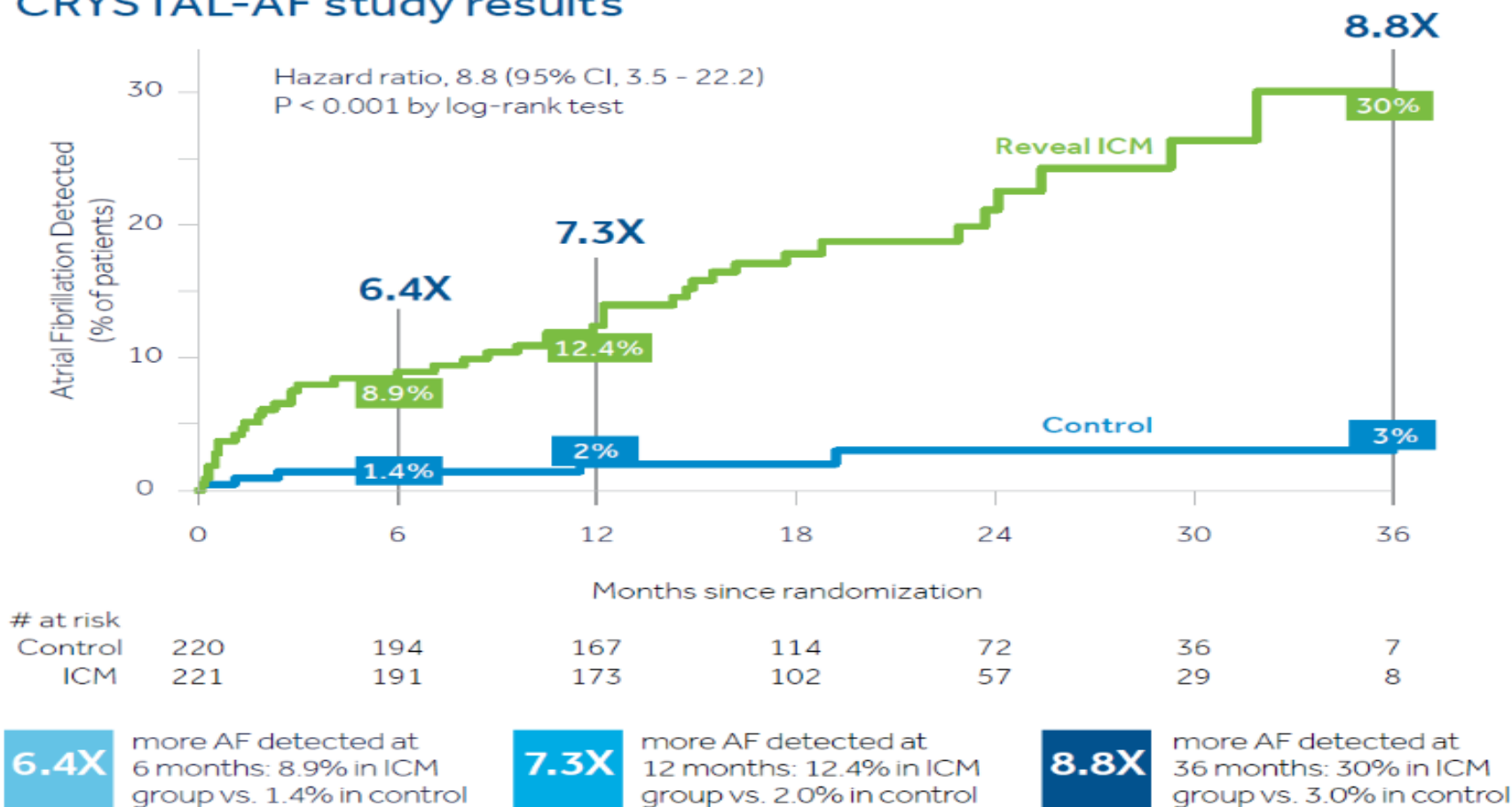
of patients who had AF would have been missed if only monitored for 30 days*

*Based on Kaplan Meier estimates.

Continuous monitoring with Reveal™ Insertable Cardiac Monitoring (ICM) is superior to standard medical care for AF detection in patients with a cryptogenic stroke¹

As published in the *New England Journal of Medicine*

CRYSTAL-AF study results



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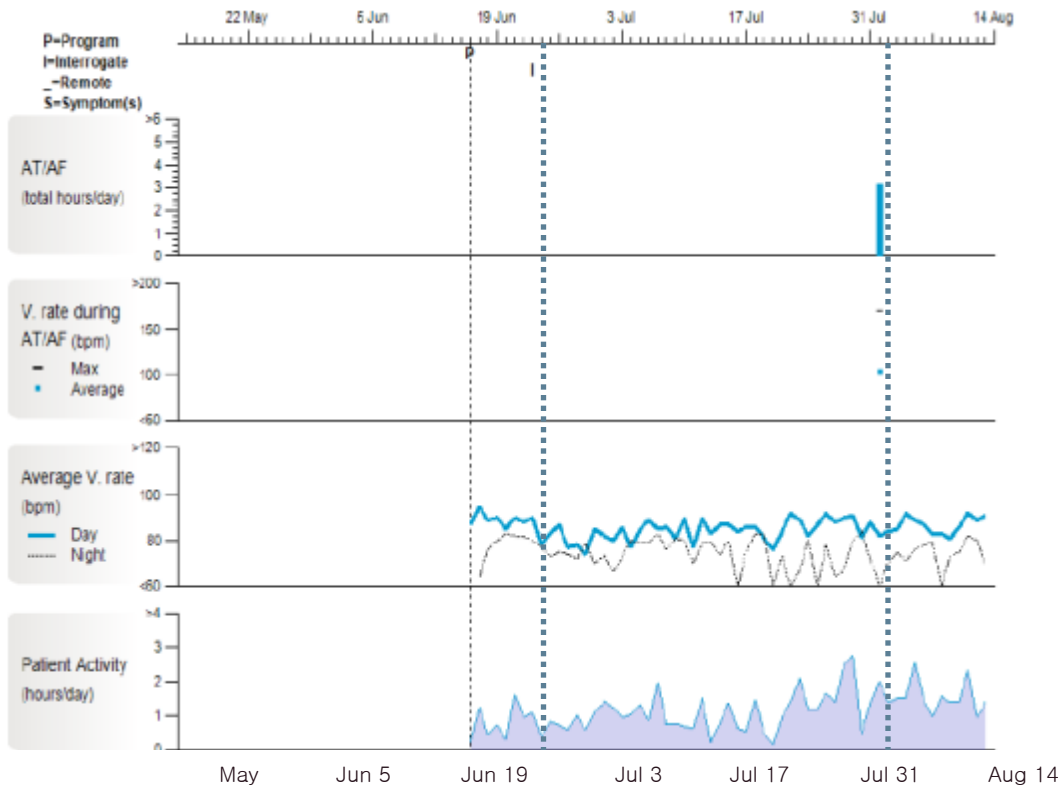
LINQ ICM CASE STUDY

- Pertinent Patient History
 - 61-year old female with ischemic stroke of unknown cause on June 13, 2014.
 - History of HTN, Hyperlipidemia, & DM
 - Medications: lisinopril, pravastatin, metformin, & nifedipine
- Stroke Hospitalization Workup
 - CT and MRI of head
 - Carotid Ultrasound
 - Echo – Normal
 - ECG – Normal Sinus Rhythm, no AF on telemetry

LINQ ICM CASE STUDY

- Cardiology Consult
 - No AF detected on ECG or telemetry during hospitalization
 - LINQ ICM device implanted
 - LINQ device programmed to detect AF
 - Patient discharged to home

47 DAYS LATER... LINQ DOCUMENTS AF



First Interrogation - No AF

Remote Interrogation - AF Documented

Cardiac Compass[®] Report

- AT/AF Summary shows:
 - Patient's first episode of AF detected
 - 0.2% of time spent in AT/AF

Counters

| | Since 16-Jun-2014 | Lifetime |
|--------------------|----------------------|----------|
| Symptom | 0 | 0 |
| Tachy | 0 | 0 |
| Pause | 290 | 290 |
| Brady | 61 | 61 |
| AT | 0 | 0 |
| AF | 1 | 1 |
| % of Time in AT/AF | 0.2% | 0.2% |

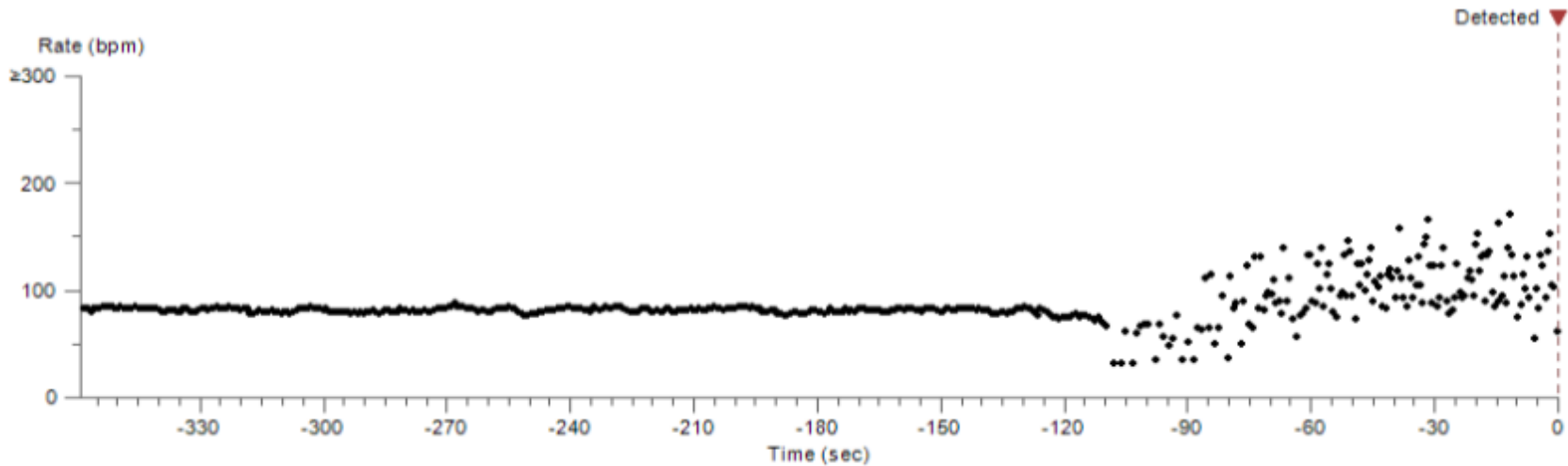
47 DAYS AFTER IMPLANT... AF DETECTED

| ID# | Type | Date | Detected hh:mm | Duration hh:mm:ss | Max V. Rate | Median V. Rate |
|-----|------|-------------|-------------------|----------------------|----------------|-------------------|
| 261 | AF | 01-Aug-2014 | 09:46 | 03:10:00 | 171 bpm | 102 bpm |

Other Details

Activity Level:

Inactive

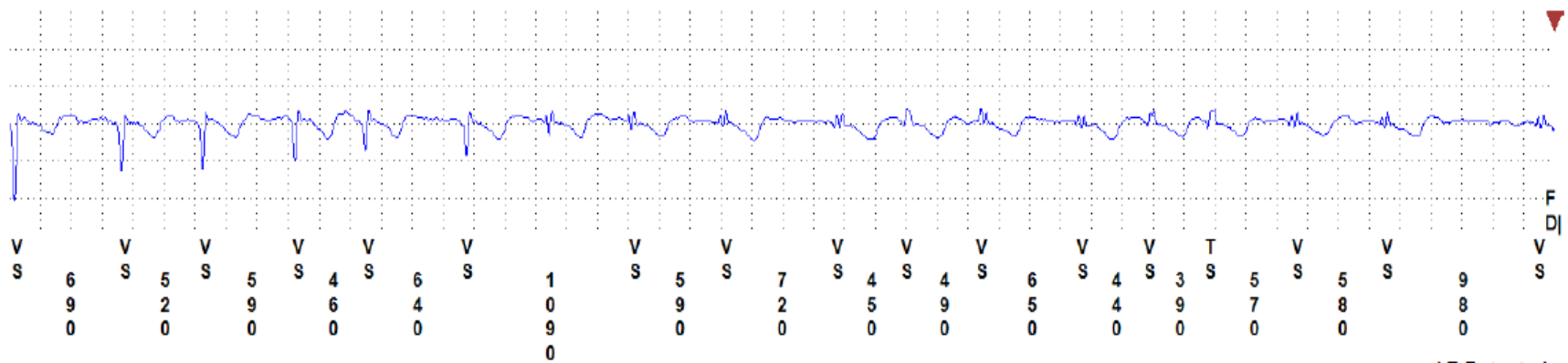
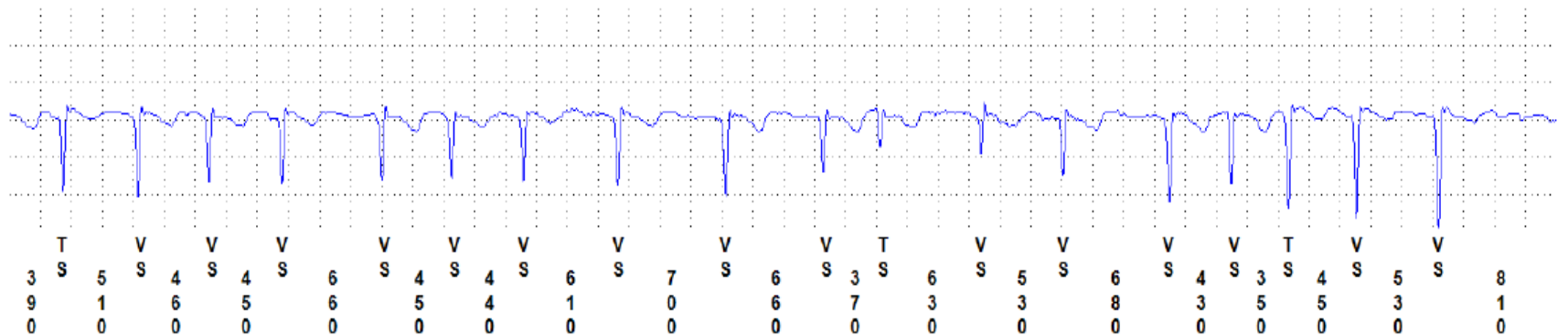


47 DAYS AFTER IMPLANT... AF DETECTED



Reveal LINQ™

ECG Detail: AF (ID# 261), 01-Aug-2014 ▼ Detected: 09:46:00



AF Detected

CASE SUMMARY

- LINQ ICM documented AF that previous workups could not prove
- Patient put on Eliquis 5 mg BID to prevent recurrent stroke
- LINQ ICM remains implanted to continuously monitor the patient's AF Burden

이식형 사건 기록기 검사 급여기준 (ILR, Implantable Loop Recorder)

나725-3 이식형 사건 기록기(Implantable Loop Recorder, ILR) 검사는 다른 검사로 원인이 진단되지 않는 다음의 경우에 요양급여함.

다 음

가. 재발성 실신

다만, 구조적 심장질환을 가진 환자의 경우에는 실신이 1회 발생한 경우에도 요양급여함.

나. 재발성 두근거림(Palpitations)

다. 심방세동이 의심되는 원인불명의 뇌졸중(Cryptogenic Stroke)으로 아래의 1) ~ 4)를 모두 만족하는 경우

- 아 래 -

- 1) 비열공성 뇌경색
- 2) 심전도 검사와 24시간 홀터기록 등의 비침습적 심전도 검사를 통해 심방세동이 발견되지 않은 경우
- 3) 뇌혈관의 뇌경색을 유발할 수 있는 의미있는 협착이나 폐색이 없는 경우
- 4) 신경과(또는 신경외과) 전문의의 진료 소견에 따라 기타 색전성 뇌경색의 원인이 없는 경우

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