Medical and Consumer Wearables for Arrhythmia Detection, Diagnosis, and Management:

Examining the Opportunities & Challenges

May 9, 2019 | InterContinental San Francisco | San Francisco, CA

AGENDA

6:00 PM	Registration and Buffet Dinner
6:30 PM	Program Overview *Nassir F. Marrouche, MD, Chair*
6:40 PM	Impact of Study Duration on Ability to Detect Duration and Burden of AF Using Ambulatory ECG Monitoring Tools *Suneet Mittal, MD*
6:55 PM	Consumer Wearables: Ready for Prime Time? *Mintu Turakhia, MD, MAS*
7:10 PM	Wearables and the Transformation of Care of the Arrhythmia Patient *Khaldoun G. Tarakji, MD, MPH*
7:25 PM	Practical Applications of Machine Learning and Artificial Intelligence (AI) in Wearable Cardiac Monitoring Technology *Hamid Ghanbari, MD, MPH*
7:40 PM	Discussion and Q&A *Faculty and Participants*
8:25 PM	Closing Comments *Nassir F. Marrouche, MD, Chair*
8:30 PM	Adjourn

Faculty slides are available online: medtelligence.net/may9
Scroll to the "Related" section and click on "Syllabus"

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May 9, 2019 | InterContinental San Francisco | San Francisco, CA

Target Audience

This activity is intended for electrophysiologists and allied health professionals in EP.

Accreditation and Credit Designation

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education through the joint providership of The Omnia-Prova Education Collaborative (TOPEC) and Medtelligence. TOPEC is accredited by the ACCME to provide continuing medical education for physicians.

The Omnia-Prova Education Collaborative, Inc. designates this live activity for a maximum of 2.0 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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Faculty

- Nassir F. Marrouche, MD: Consulting Fees: Abbott, Biotronik, Wavelet Health, Cardiac Design, Medtronic, Preventice, Vytronus, Biosense Webster, Marrek Inc, Boston Scientific; Contracted Research: Abbott, Biotronik, Biosense Webster, Boston Scientific, GE Healthcare, Siemens, Vytronus; Ownership Interest: Marrek Inc, Cardiac Design
- Hamid Ghanbari, MD, MPH: Consulting Fees: Preventice; Contracted Research: Toyota, Boston Scientific, Medtronic, Biotronik
- Suneet Mittal, MD: Consulting Fees: Boston Scientific, Cardiva, Medtronic, BioTel, SentreHEART
- Khaldoun G. Tarakji, MD, MPH: Consulting Fees: Medtronic, AliveCor
- Mintu Turakhia, MD, MAS: Consulting Fees: Medtronic, Abbott, Biotronik; Contracted Research: Apple, AHA, Janssen, BMS-Pfizer, Boehringer Ingelheim; Ownership Interest: AliveCor, Forward

Reviewers/Planners

- Sean Barrett has nothing to disclose.
- Ben Caref, PhD has nothing to disclose.
- Pamela Clark has nothing to disclose.

Disclaimer

The views and opinions expressed in this educational activity are those of the faculty and do not necessarily represent the views of TOPEC and Medtelligence. These presentations are not intended to define an exclusive course of patient management; the participant should use his/her clinical judgment, knowledge, experience, and diagnostic skills in applying or adopting for professional use any of the information provided herein. Any procedures, medications, or other courses of diagnosis or treatment discussed or suggested in this activity should not be used by clinicians without evaluation of their patients' conditions and possible contraindications or dangers in use, review of any applicable manufacturer's product information, and comparison with recommendations of other authorities.

This syllabus is not intended to be an exact representation of the faculty presentations.

It is being provided as a useful reference that we encourage you to use during and after the activity.

Impact of Study Duration on Ability to Detect Duration and Burden of AF Using Ambulatory ECG Monitoring Tools

Suneet Mittal, MD
Director, Electrophysiology
Director, The Snyder Center for Comprehensive Atrial Fibrillation
Director, Cardiac Research

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May 9, 2019

Disclosures: Consultant to Abbott, Boston Scientific, and Medtronic

MEDICAL AND CONSUMER WEARABLES FOR ARRHYTHMIA DETECTION, DIAGNOSIS, AND MANAGEMENT

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ECG Monitoring Tools

Spot Single-Lead ECG Check

Event Recorder

Smartphone (eg, AliveCor)

Smartwatch (eg, Kardiaband)

Holter Monitoring (1-2 days)

Holter

Holter Monitoring (1-2 weeks)

Patch Based

(eg, Zio) (eg, ePatch)

Lead Based (eg, CardioKey)

Mobile Telemetry Monitoring (Up to 30 days)

Lead Based (eg, multiple; TeleSense)

Patch Based (eg, SEEQ, Body Guardian)

Garment Based (eg, nECG)

Implantable Loop Recorder (Up to 3 years)

Lead Based (1-Piece)

- ScottCare– TeleSense, TeleSentry
- Spectocor – Pocket ECG
- Telerhythmics – Heartrak TCAT

Lead Based (2-Piece)

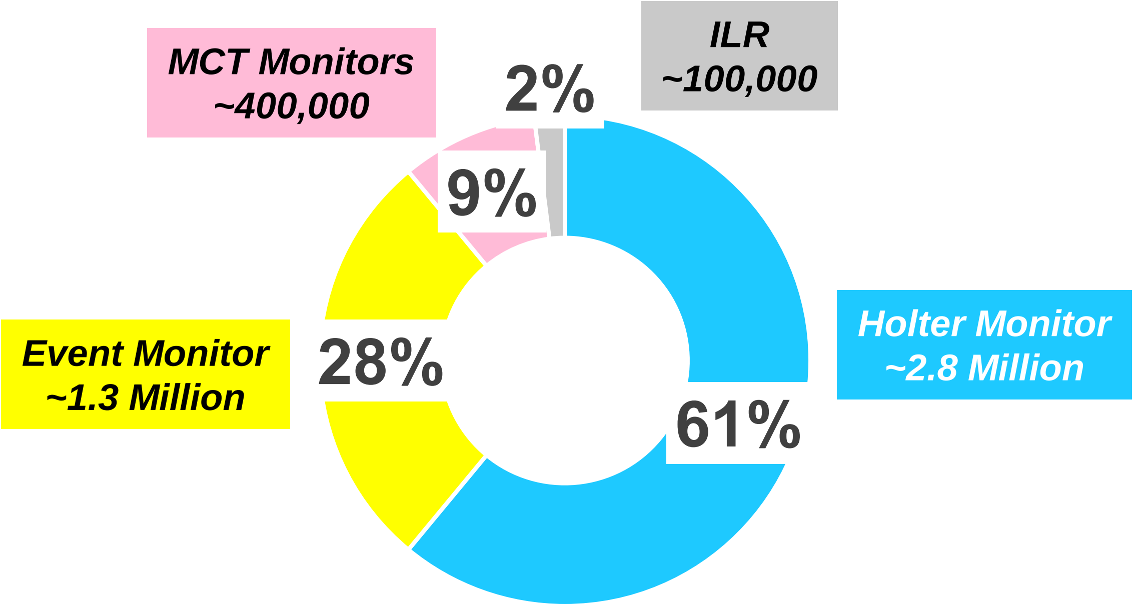
- Applied Cardiac Systems – CORE
- Biomedical Systems – TruVue
- InfoBionic – MoMe Kardia
- LifeWatch – ACT Elite
- Medicomp – Duet

Patch Based

- BioTelemetry – MCOT Patch
- LifeWatch – ECG mini
- Medicomp – TelePatch
- Medtronic – SEEQ
- Nuubo – nECG
- Preventice – BodyGuardian

Mittal S et al. *J Am Coll Cardiol*. 2011;58:1741-9; Mittal S. *Cardiol Rev*. 2017;25:12-16.; Lee RJ, Mittal S. *Heart Rhythm.* 2018.

ECG Monitoring Tools



4.6 Million Tests Annually
1.4 Billion USD

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Use Case Scenarios

- Palpitations

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Case Presentation

- 50-year-old female with hypertension and Sjogren's syndrome reports a several year complaint of palpitations associated with light headedness.
- Episodes occur every few weeks and last 5-10 minutes.
- There has been no ECG documentation obtained during her typical episode.
- Her baseline ECG and echocardiogram are entirely normal.
- She presents for further evaluation
  - CHA_2DS_2-VASc = 2 (if she had atrial fibrillation).

Smartphone-based Diagnosis

- Cheap
- Owned by the patient
- Real time
- Long term
- High fidelity recordings
- No intermediary between patient and doctor

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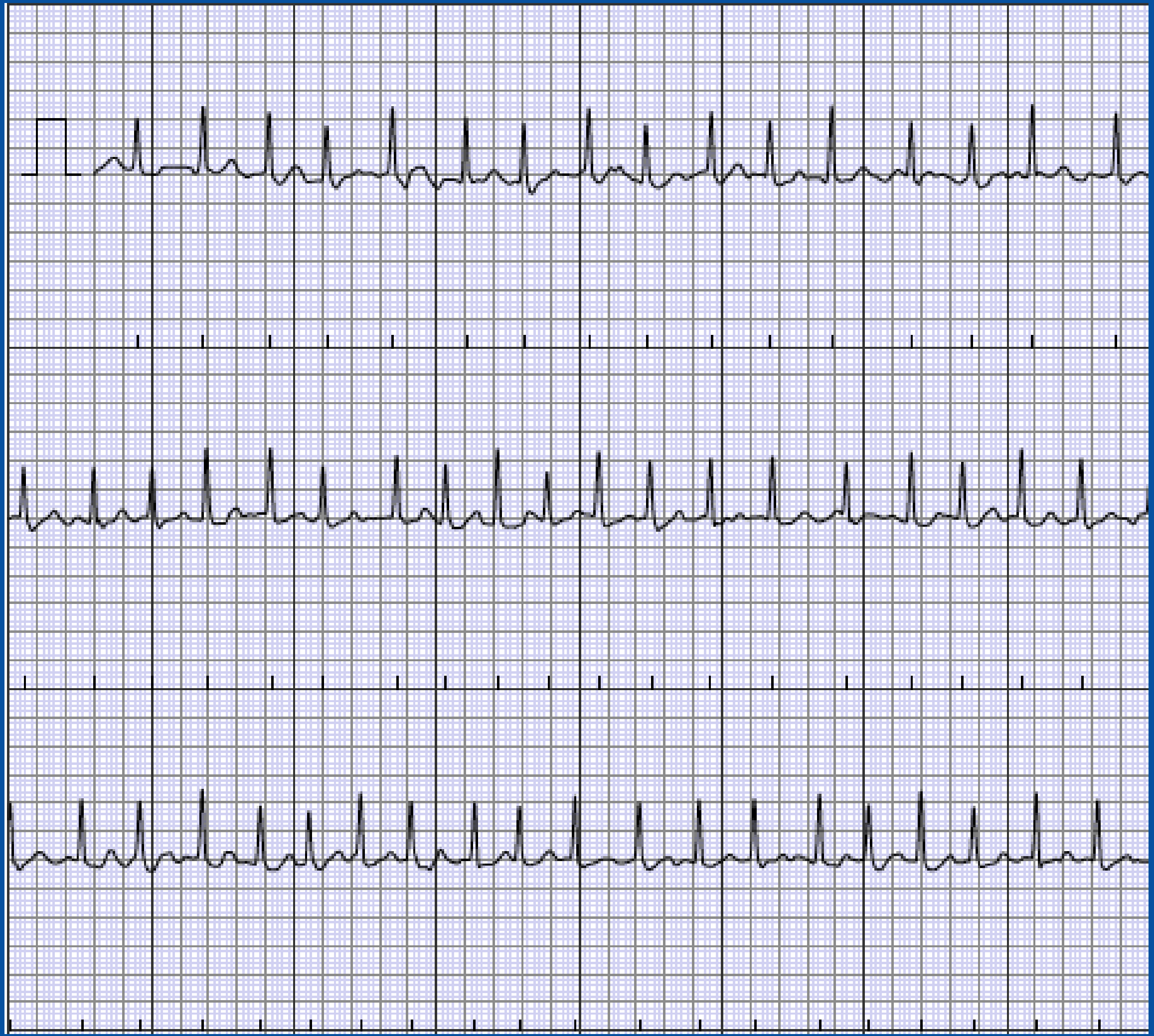


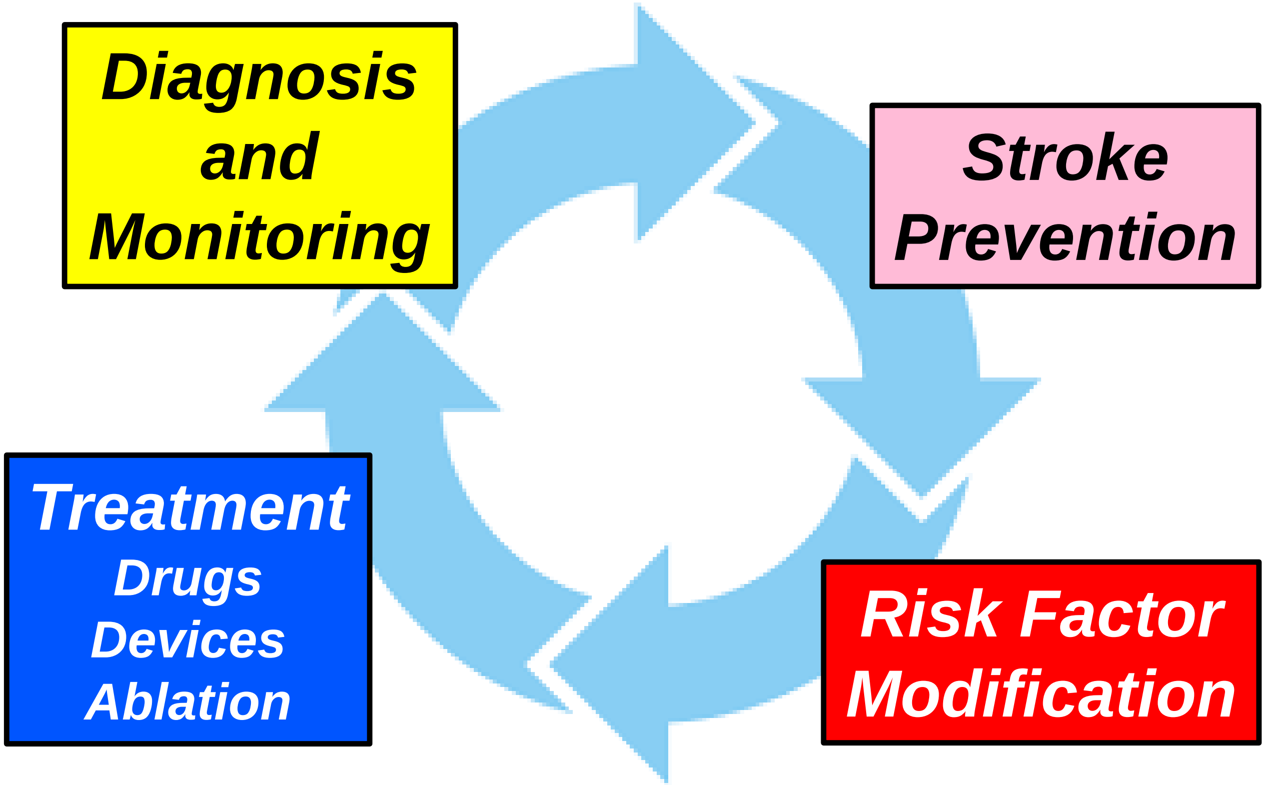
Use Case Scenarios

- Palpitations
- Syncope

Use Case Scenarios

- Palpitations
- Syncope
- Atrial fibrillation

Lifecycle of AF Patients



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Use Case Scenarios

- Palpitations
- Syncope
- Atrial fibrillation
  - Suspected
    - High-risk patients

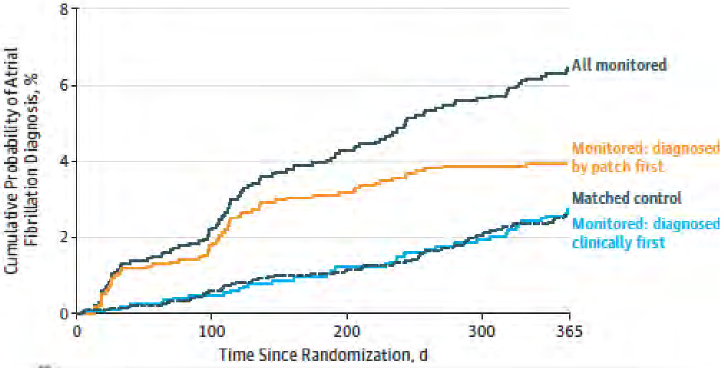
Screening for AF

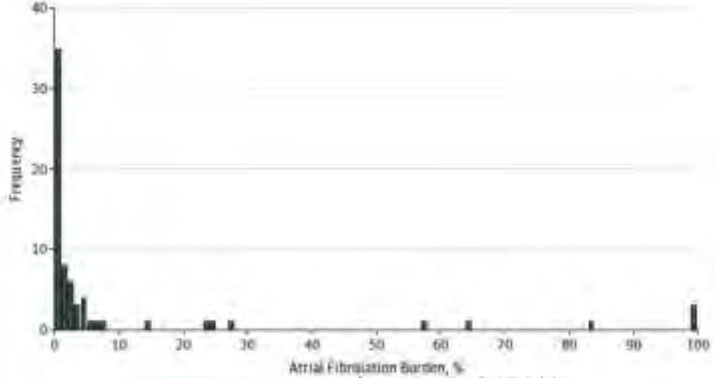
Recommendations	Class	Level
Opportunistic screening for AF is recommended by pulse taking or ECG rhythm strip in patients >65 years of age	I	B
In stroke patients, additional ECG monitoring by long-term non-invasive ECG monitors or implanted loop recorders should be considered to document silent AF	IIa	B
Systematic ECG screening may be considered to detect AF in patients aged >75 years, or those at high stroke risk	IIb	B

ESC 2016 AF Guidelines. Kirchhof P et al. *Eur Heart J*. 2016;37:2893-962.

mSToPS Trial

Characteristic	No. (%) Immediate Monitoring Group (n = 1366)	Delayed Monitoring Group (n = 1293)
Age, mean (SD), y	73.5 (7.4)	73.1 (7.2)
Female	521 (38.1)	505 (39.1)
CHA_2DS_2-VASc score, median (Q1-Q3)[a]	3 (2-4)	3 (2-4)
Qualified by age ≥75 y only	680 (49.8)	606 (46.9)
Qualified as female with age >65 y plus comorbidity	212 (15.5)	237 (18.3)
Qualified as male with age >55 y plus comorbidity	474 (34.7)	450 (34.8)
Comorbidities		
Stroke	187 (13.7)	182 (14.1)
Heart failure	69 (5.1)	59 (4.6)
Hypertension	1053 (77.1)	993 (76.8)
Diabetes	529 (38.7)	472 (36.5)
Sleep apnea	341 (25.0)	374 (28.9)
Prior myocardial infarction	75 (5.5)	72 (5.6)
Chronic obstructive pulmonary disease	129 (9.4)	112 (8.7)
Obesity[b]	236 (17.3)	238 (18.4)
Chronic renal failure	148 (10.8)	124 (9.6)





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Steinhubl SR et al.
JAMA. 2018;320:146-55.

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Use Case Scenarios

- Palpitations
- Syncope
- Atrial fibrillation
  - Suspected
    - High-risk patients
    - Cryptogenic stroke

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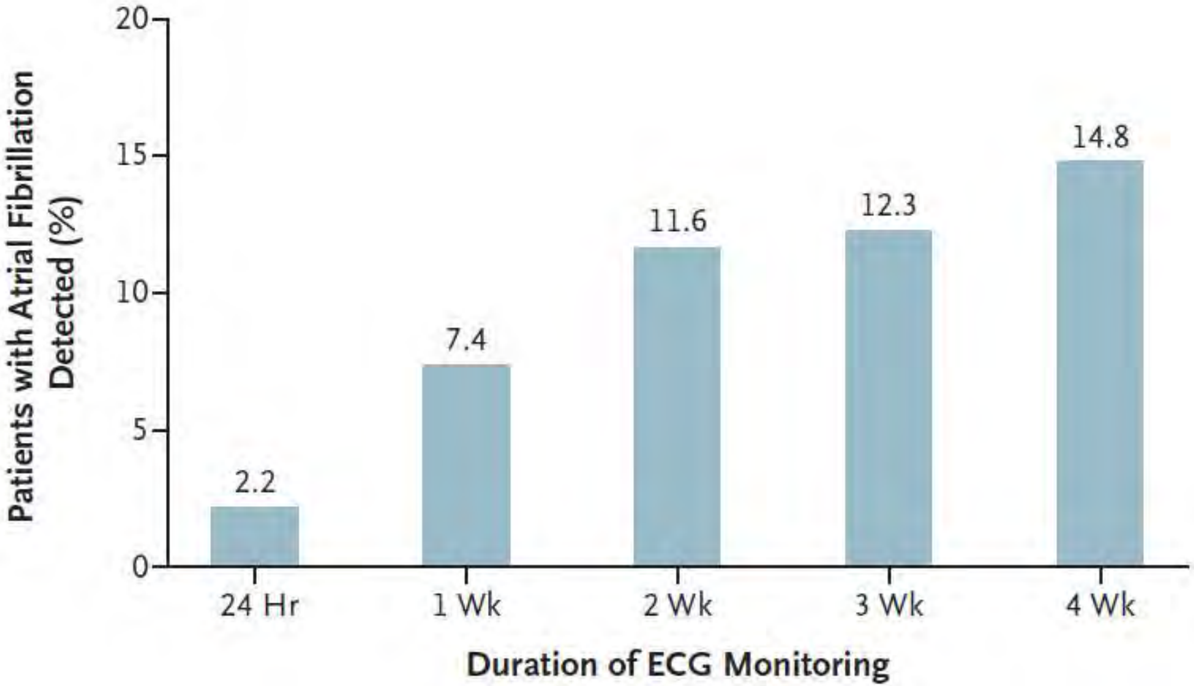
NOAC Trials in Cryptogenic Stroke Patients

- **RE-SPECT ESUS** (NCT02239120)
  - ~6000 patients with ESUS (non-lacunar infarct)
    - ≥60 years of age with at least one additional risk factor for stroke
  - Randomized to aspirin 100 mg daily or dabigatran (110 or 150 mg twice daily)
  - Primary outcome: time to first recurrent stroke
- **NAVIGATE ESUS** (NCT02313909)
  - ~7000 patients with ESUS (non-lacunar infarct)
    - ≥50 years of age
  - Randomized to aspirin 100 mg or rivaroxaban 15 mg daily
  - Primary outcome: time to first recurrent stroke or systemic embolism

Screening for AF in Cryptogenic Stroke Patients: AECG Monitoring



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Gladstone DJ et al. *N Engl J Med*. 2014;370:2467-77.

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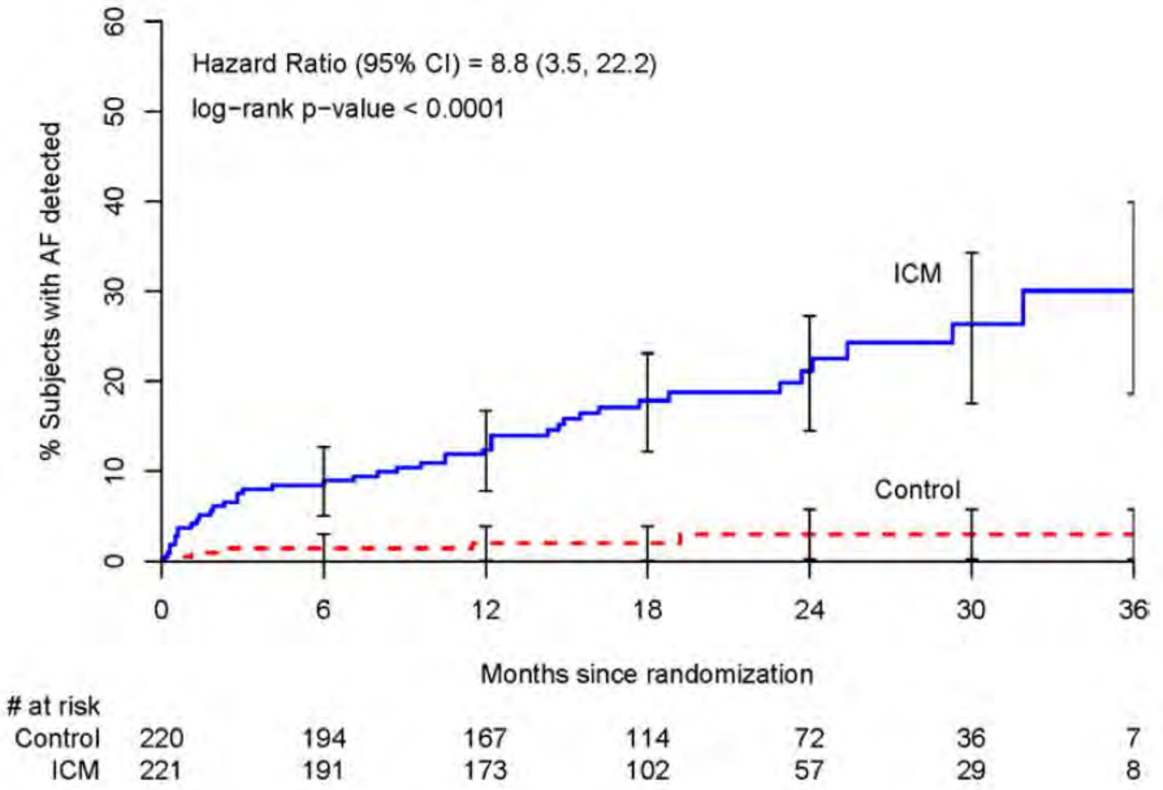
Screening for AF in Cryptogenic Stroke Patients: CRYSTAL AF



Sanna T et al. *N Engl J Med.* 2014;370:2478-86.

Use Case Scenarios

- Palpitations
- Syncope
- Atrial fibrillation
  - Suspected
    - High risk patients
    - Cryptogenic stroke
    - Post-cavotricuspid isthmus ablation

Use Case Scenarios

- Palpitations
- Syncope
- Atrial fibrillation
  - Suspected
  - Known

Case Presentation

- 74-year-old male with hypertension and remote history of SVT ablation.
- A year and a half ago, he had a stress echocardiogram. He exercised for 6 ½ minutes on a Bruce protocol. The exam was normal.
- He recently noticed that his heart rate was elevated while at the gym. He had no symptoms referable to a rate.
- An ECG demonstrated atrial fibrillation with rapid ventricular response. An echocardiogram demonstrated a left atrial diameter of 3.7 cm, left atrial volume index of 31.2 mL/m², a 4.4 cm aortic root, and an ejection fraction of 30%.
- He was referred for evaluation; an ECG showed sinus rhythm. (CHA_2DS_2-VASc = 2)

Case Presentation

Atrial Fibrillation/Flutter

▼ Fastest AF/AFL (HR Range 85-195 bpm, Avg 136 bpm)

AF/AFL Burden
42%

Longest Duration
1 d 8 h

HR Range
64-195 bpm

Avg
113 bpm

Heart Rate

Overall	Max	**195 bpm**	11:35am, 01/26
	Min	**57 bpm**	01:47am, 01/22
	Avg	**93 bpm**	
Sinus	Max	**117 bpm**	01:18pm, 01/26
	Min	**57 bpm**	01:47am, 01/22
	Avg	**79 bpm**	

Preliminary Findings

Patient had a min HR of 57 bpm, max HR of 195 bpm, and avg HR of 93 bpm. Predominant underlying rhythm was Sinus Rhythm. Atrial Fibrillation/Flutter occurred (42% burden), ranging from 64-195 bpm (avg of 113 bpm), the longest lasting 1 day 8 hours with an avg rate of 119 bpm. Isolated SVEs were rare (<1.0%), SVE Couplets were rare (<1.0%), and SVE Triplets were rare (<1.0%). Isolated VEs were rare (<1.0%), VE Couplets were rare (<1.0%), and no VE Triplets were present. Ventricular Bigeminy and Trigeminy were present. MD notification criteria for Rapid Atrial Fibrillation/Atrial Flutter met - notified Juan on 06 Feb 2018 at 3:20 pm CT (TW).

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Duration vs Burden

JAMA Cardiology | Original Investigation

Association of Burden of Atrial Fibrillation With Risk of Ischemic Stroke in Adults With Paroxysmal Atrial Fibrillation
The KP-RHYTHM Study

Alan S. Go, MD; Kristi Reynolds, PhD, MPH; Jingrong Yang, MA; Nigel Gupta, MD; Judith Lenane, RN, MHA;
Sue Hee Sung, MPH; Teresa N. Harrison, SM; Taylor I. Liu, MD, PhD; Matthew D. Solomon, MD, PhD

	No. (%)				
		Burden of Atrial Fibrillation			
Characteristic	Overall (N = 1965)	Tertile 1 (n = 679 [0.01%-2.03%])	Tertile 2 (n = 652 [2.05%-11.28%])	Tertile 3 (n = 634 [11.30%-99.99%])	P Value
Atrial fibrillation burden, median (IQR), %	4.42 (1.11-17.16)	0.56 (0.13-1.18)	4.70 (3.21-6.95)	27.06 (17.74-46.90)	<.001
Total duration of atrial fibrillation, median (IQR), min	710 (175-2540)	89 (19-208)	775 (515-1140)	4456 (26655-7617)	<.001
Longest episode of atrial fibrillation, median (IQR), min	171 (49-590)	31 (6-90)	250 (95-538)	700 (202-1824)	<.001

Go AS, et al. *JAMA Cardiol*. 2018;3(7):601-608.

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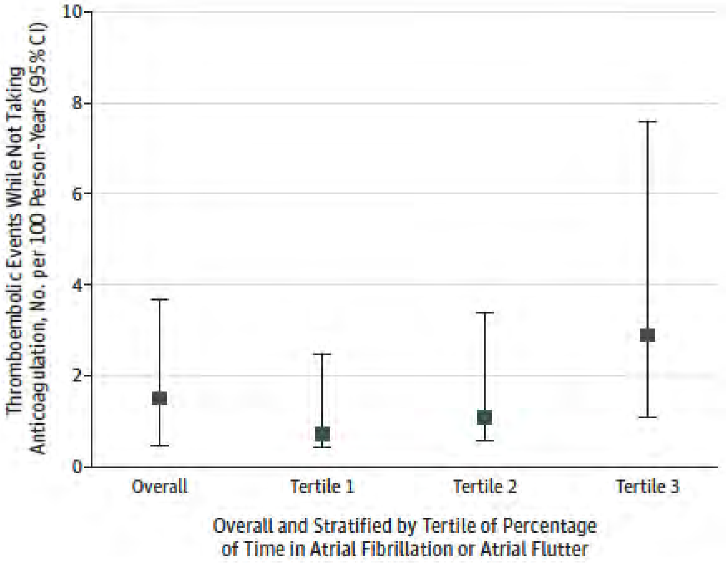
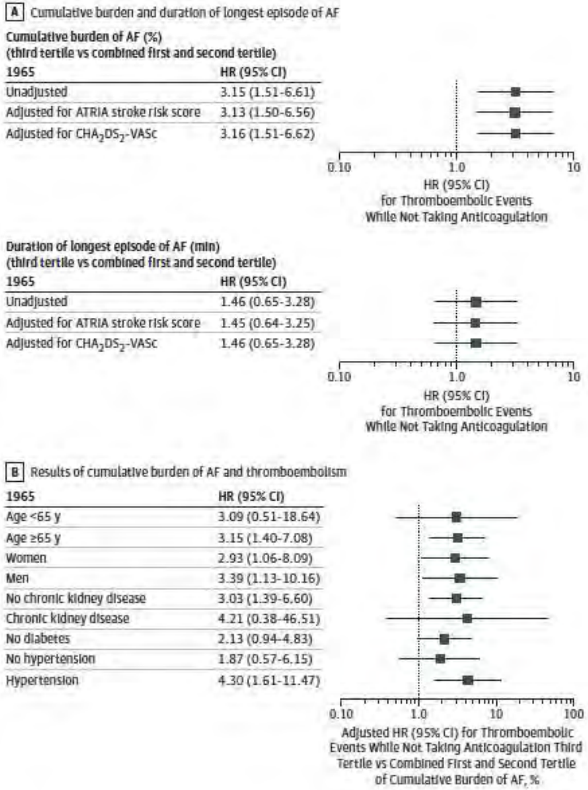
Duration vs Burden



Overall, there were 29 thromboembolic events for 1915 person-years. In tertile 1, there were 5 events over 690 person-years in which patients spent 0.01%-2.03% of time in AF or atrial flutter. In tertile 2, there were 7 events over 639 person-years in which patients spent 2.05%-11.28% of time in AF or atrial flutter. In tertile 3, there were 17 events over 586 person-years in which patients spent 11.36%-99.99% of time in AF or atrial flutter.



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JAMA Cardiology 2018

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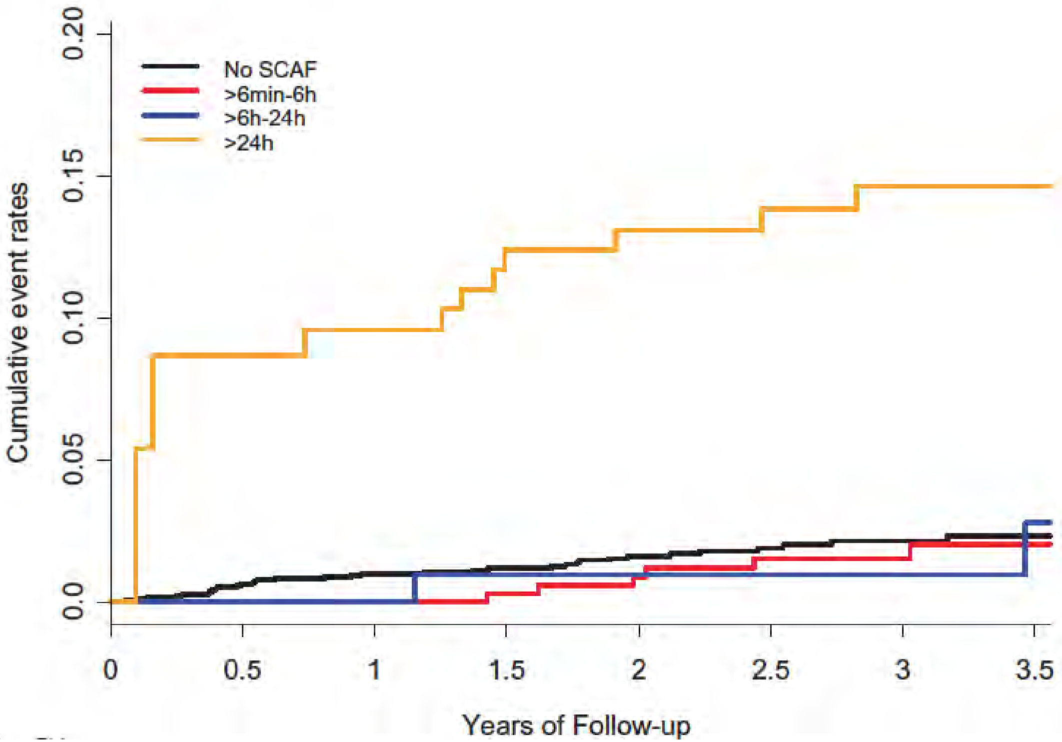
ASSERT Sub-study



Van Gelder IC et al. *Eur Heart J.* 2017;38:1339-44.

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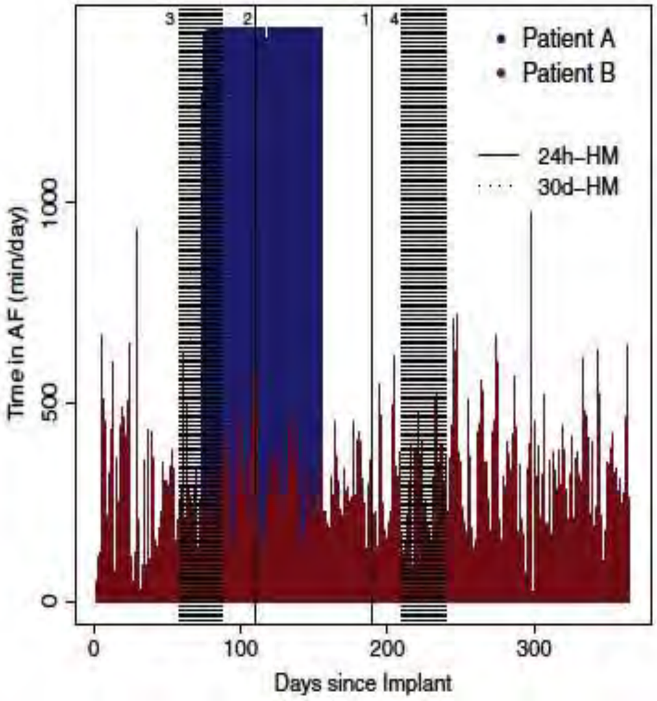
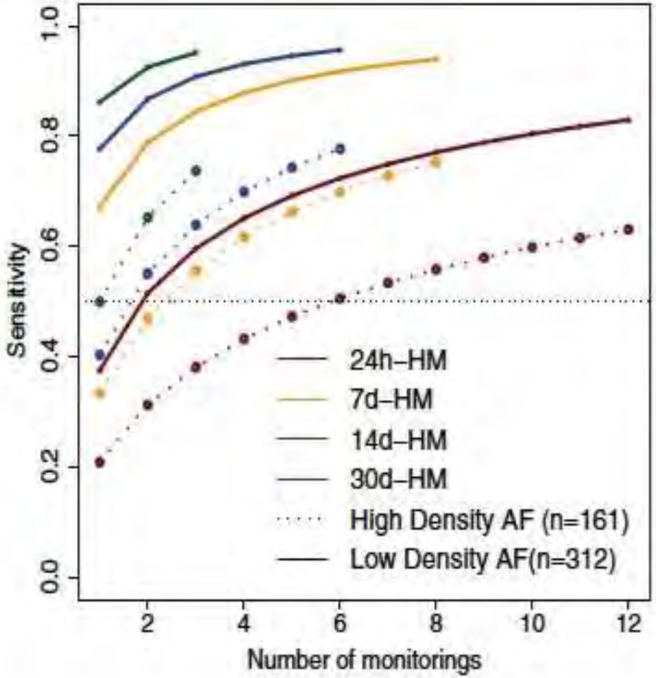
ECG Monitoring Tools for Diagnosis and Evaluation





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Charitos EI et al. *Circulation.* 2012;126:806-14.

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Case Presentation

- 49-year-old male with hypertension, diabetes mellitus, obstructive sleep apnea, and paroxysmal atrial fibrillation
  - CHA_2DS_2-VASc score = 2
- He underwent cryoballoon based pulmonary vein isolation on May 15, 2013
  - Last known recurrence of AF occurred on May 30, 2013
  - He is maintained on rivaroxaban 20 mg daily, which he wishes to discontinue

How do you tell a patient like this that he will need oral anticoagulation for the rest of his life?

Pulse Check

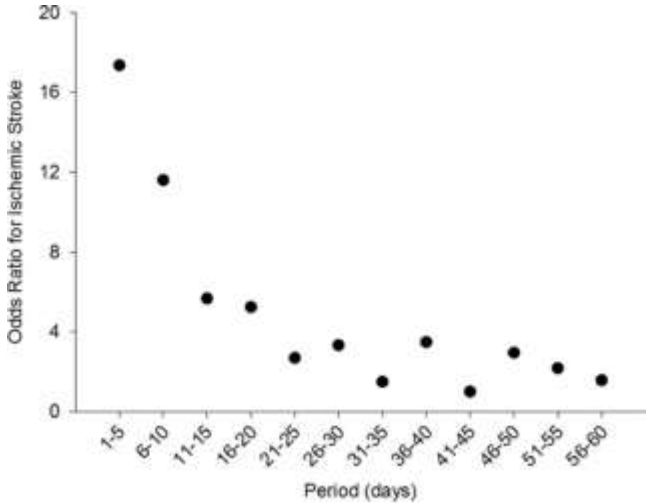
Risk of Stroke or Transient Ischemic Attack After Atrial Fibrillation Ablation with Oral Anticoagulant Use Guided by ECG Monitoring and Pulse Assessment

MICHAEL P. RILEY, M.D., PH.D., ERICA ZADO, PA-C, MATHEW D. HUTCHINSON, M.D., DAVID LIN, M.D., RUPA BALA, M.D., FERMIN C. GARCIA, M.D., DAVID J. CALLANS, M.D., JOSHUA M. COOPER, M.D., RALPH J. VERDINO, M.D., SANJAY DIXIT, M.D., and FRANCIS E. MARCHLINSKI, M.D.

- 1990 patients
- CHADS2
  - 0 (n=840, 42%)
  - 1 (n=796, 40%)
  - ≥2 (n=354, 18%)
- Warfarin stopped in half
- 16 TIAs/stroke (0.2%/patient-year)
  - **12 (75%) of the 16 patients had known recurrent AF**

J Cardiovasc Electrophysiol. 2014;25:591-6.

AF and Short-term Stroke Risk



Period, days prior to stroke	Odds Ratio	95% Confidence Interval	P Value
1-5	17.4	5.39 - 73.1	<.0001
6-10	11.6	3.30 - 51.4	<.0001
11-15	5.66	1.65 - 20.5	0.0046
16-20	5.24	1.60 - 17.5	0.0053
21-25	2.68	0.689 - 9.63	0.1683
26-30	3.33	0.934 - 11.3	0.0647
31-35	1.49	0.296 - 6.06	0.7632
36-40	3.49	0.946 - 12.6	0.0615
41-45	1.00	0.160 - 4.68	1.0000
46-50	2.95	0.709 - 11.3	0.1476
51-55	2.18	0.470 - 8.52	0.3630
56-60	1.56	0.275 - 6.84	0.7445

Turakhia MP et al. *Circ Arrhythm Electrophysiol.* 2015;8:1050-7.

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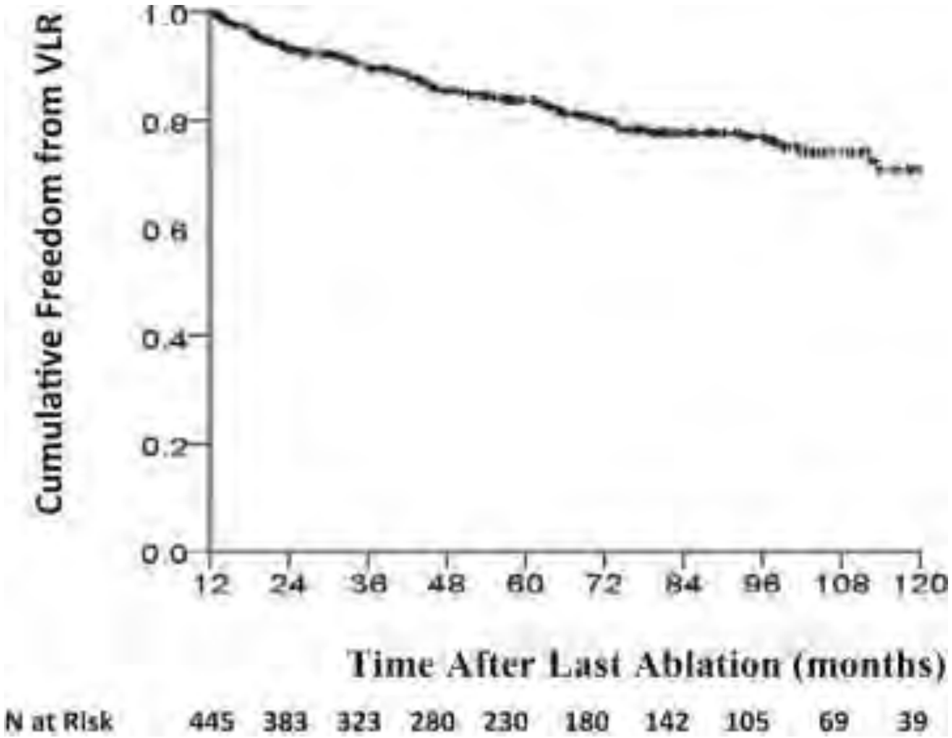
Duration of Follow-up: Very Late Recurrences of AF



Steinberg JS, Mittal S, et al.
Heart Rhythm. 2014;11:771-6.

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The Choices That Must Be Made

Consumer Wearables: Ready for Prime Time?

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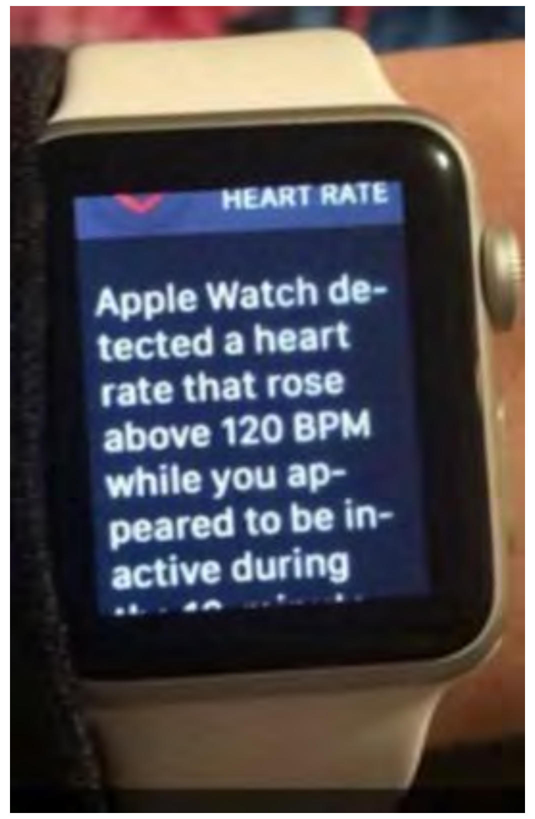
Disclosures

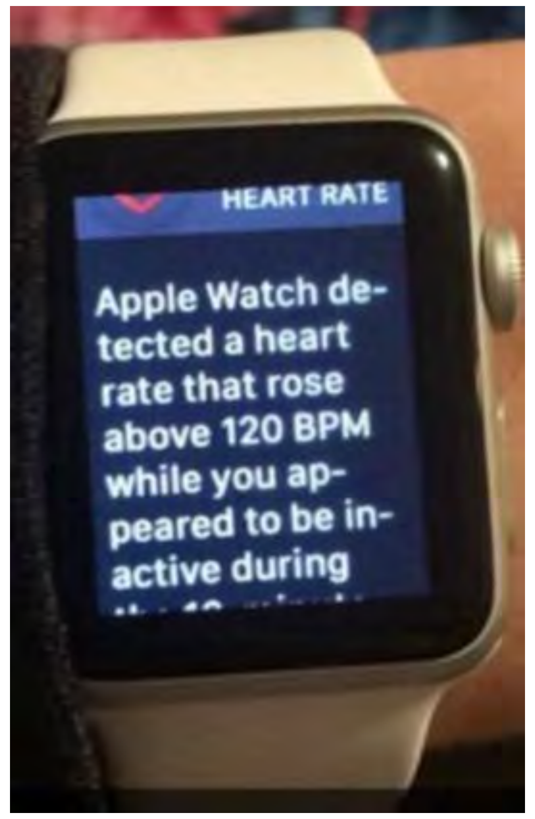
- Research support
  - VA, NIH, AHA, Janssen, Medtronic, iRhythm, Cardiva, AstraZeneca, Boehringer Ingelheim, Apple, SentreHeart, Bristol Myers Squibbs
- Consultant/Honoraria
  - Abbott, Medtronic, Precision Health, Myokardia, Medscape
- Advisor/Board Member
  - iBeat, AliveCor, Forward, Metrica Health, Zipline, CyberHeart

Case 1



- 51 yo man comes in with this message on his smartwatch
- PMH: hypertension, diabetes
- ECG: NSR
- Echo: normal
- 2-week ambulatory ECG: normal

Case 1



- 51 yo man comes in with this message on his smartwatch
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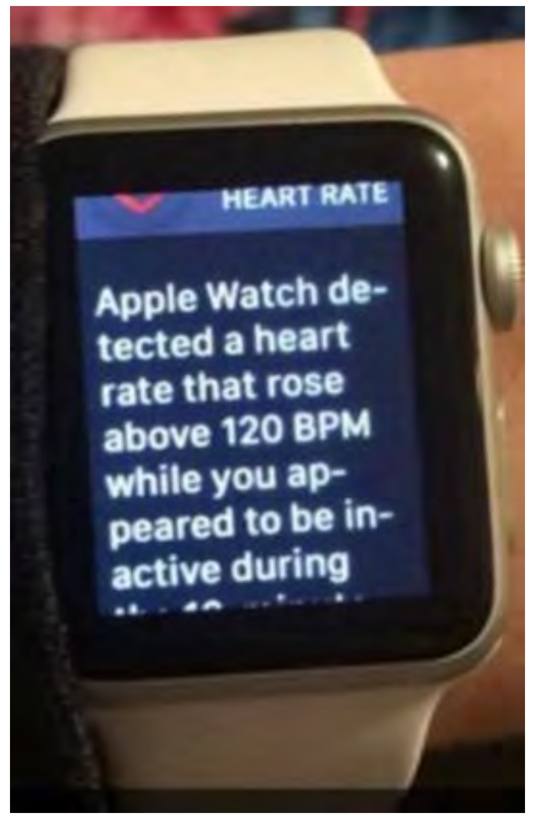
- 2-week ambulatory ECG: normal

Case 2

- 67M daily runner with syncope
- Runs every day in the early morning. Does not remember losing consciousness but woke up on the side of the running trail with scuffs on arms and face

Stock photos. Not for reproduction.

Case 1



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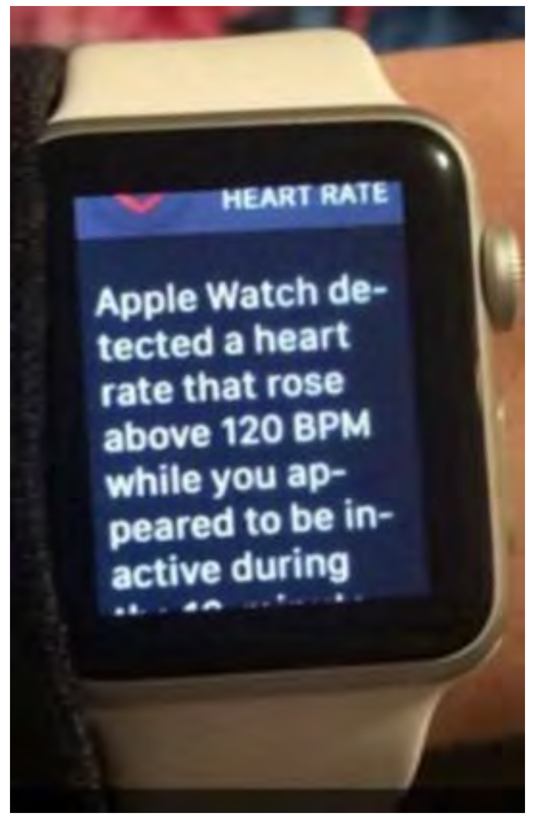
Case 1



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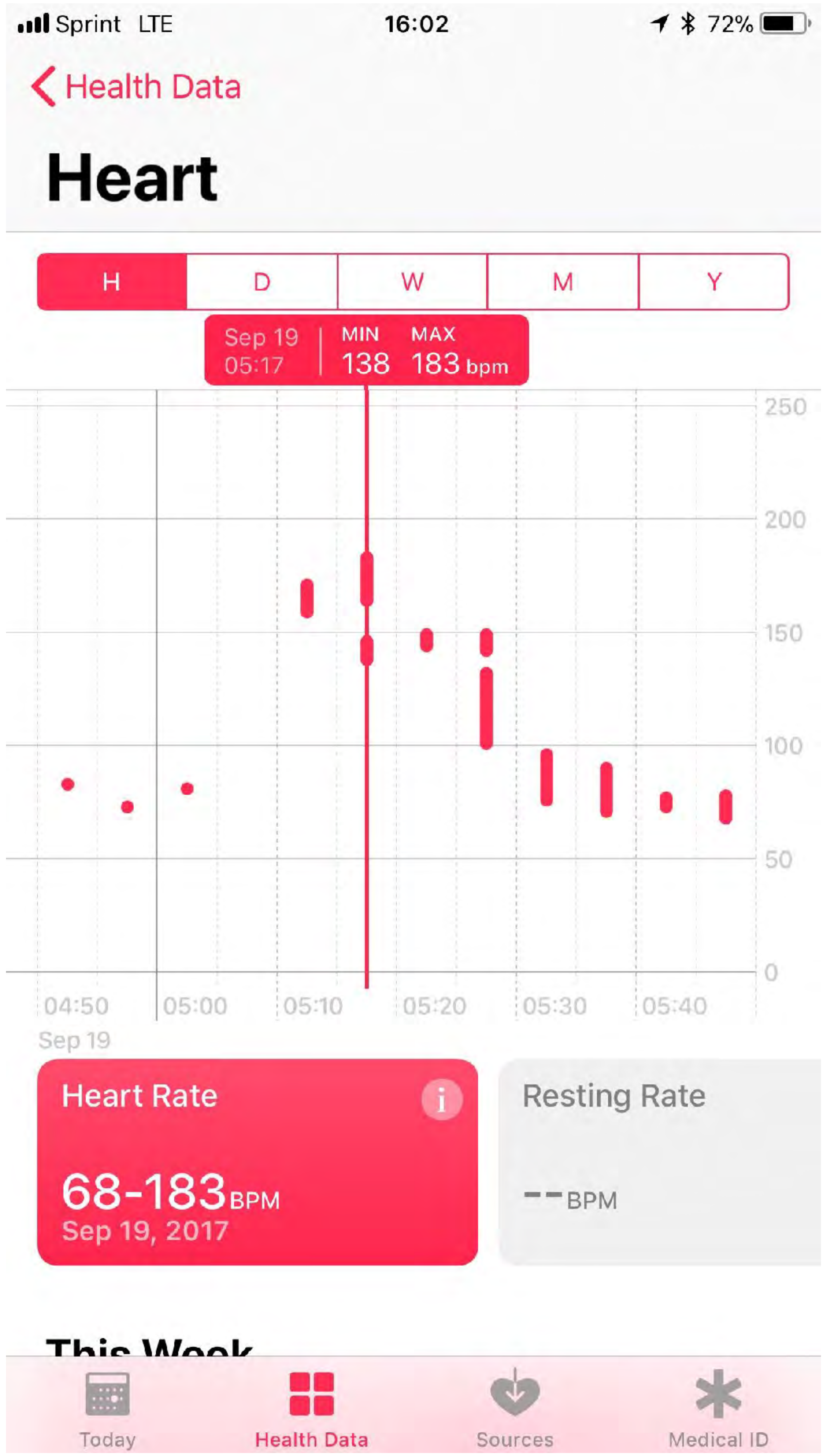

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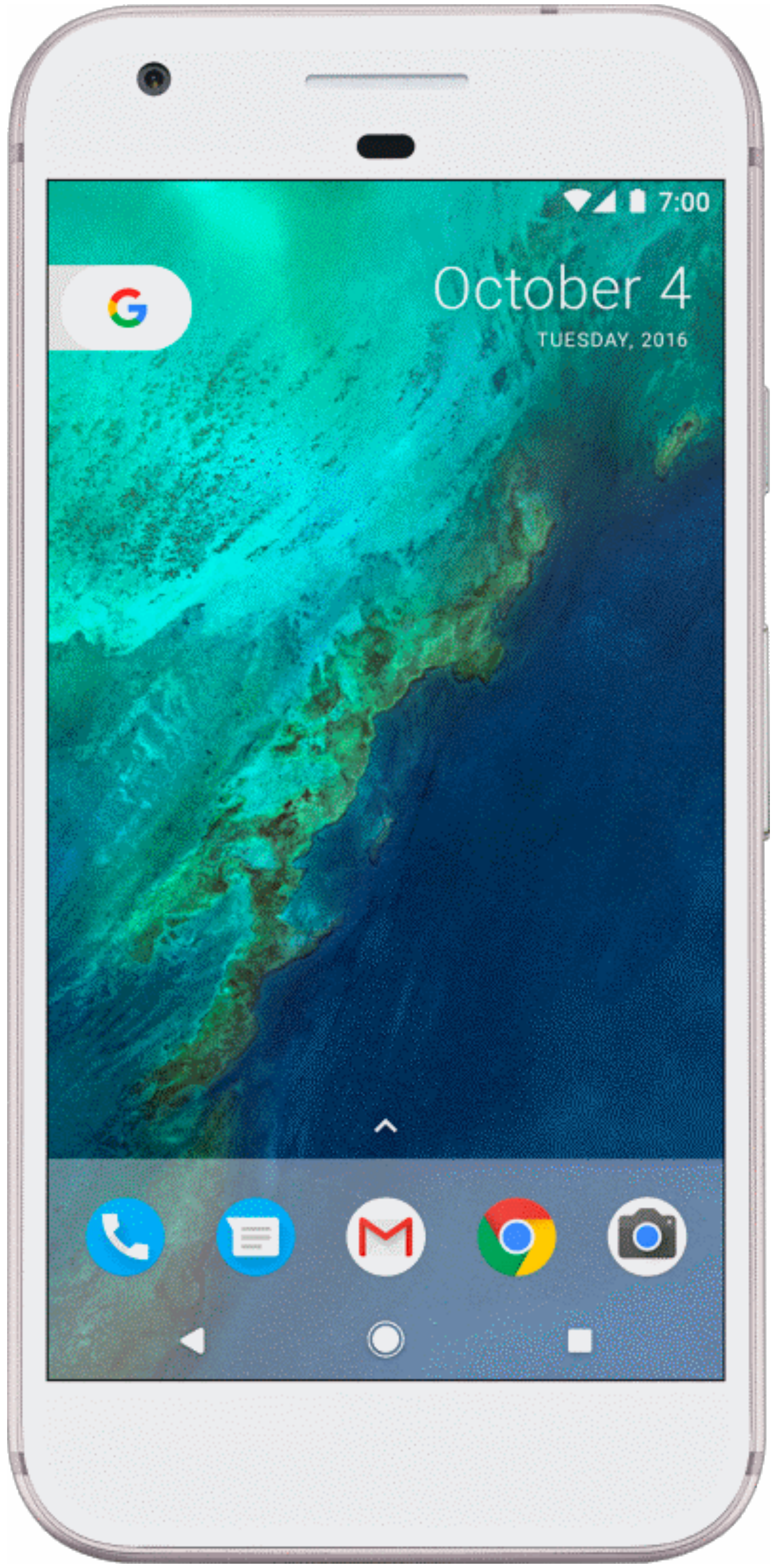
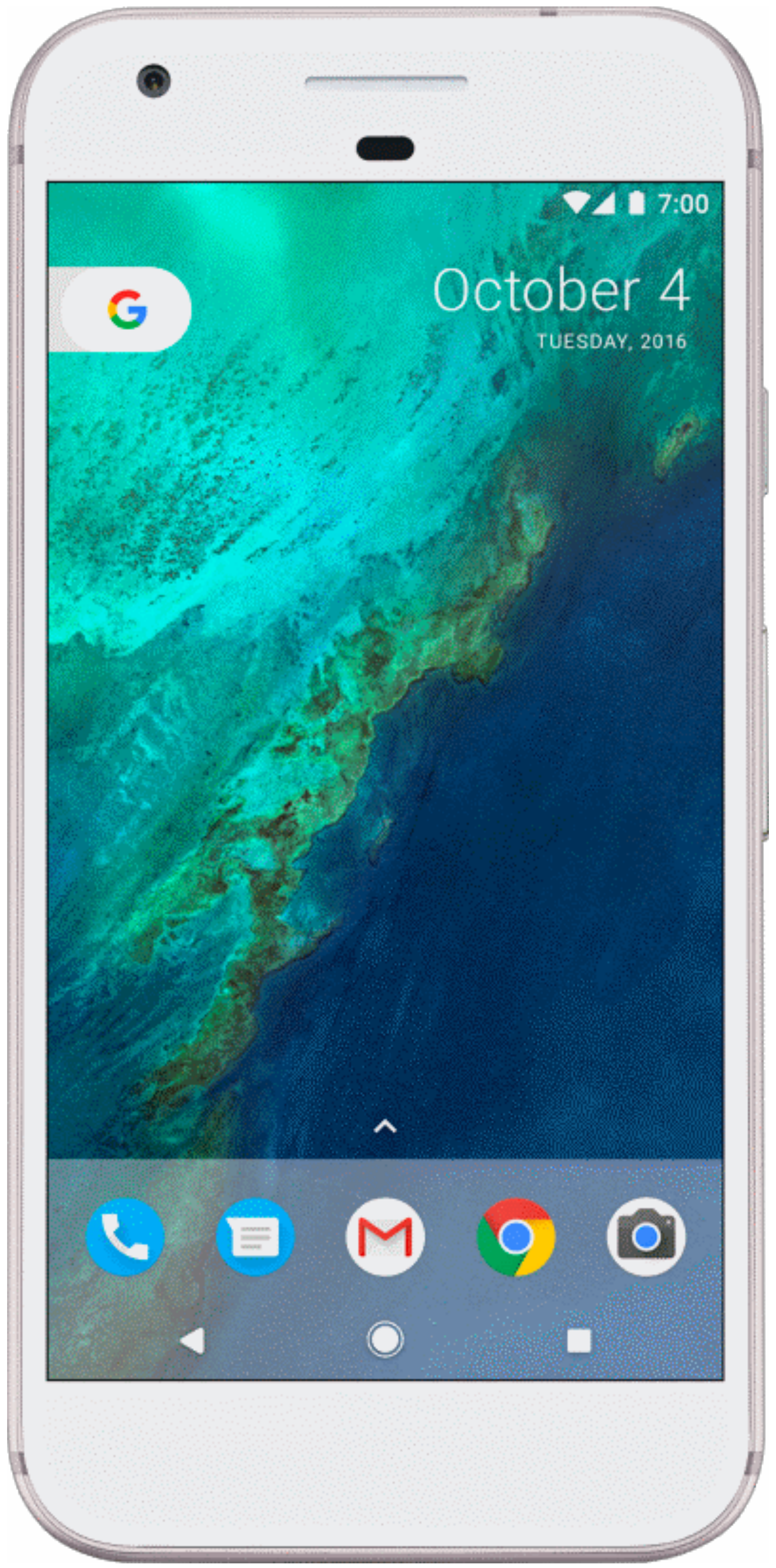
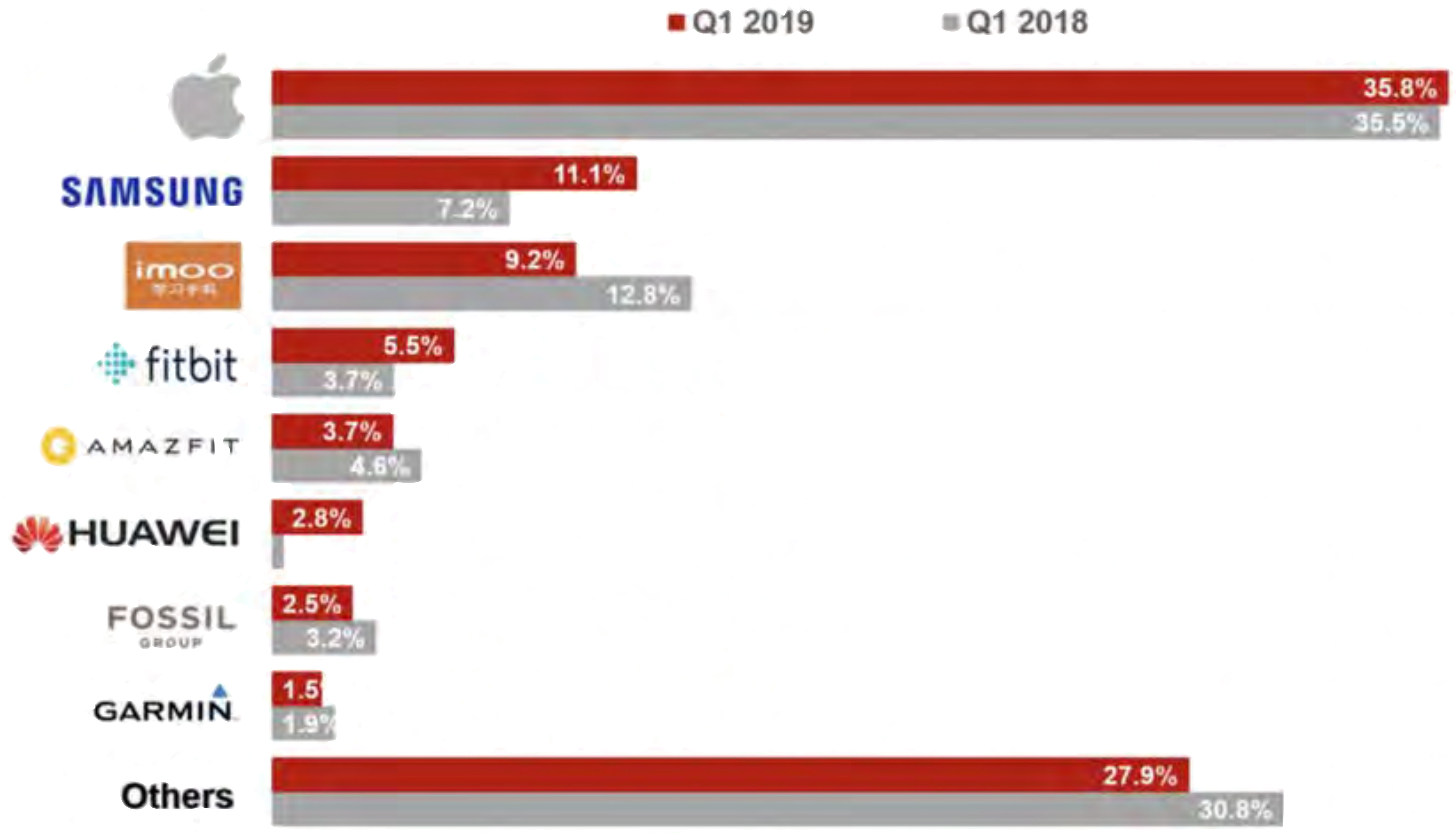


77% of US

Pew Research, 2016; Forbes, 2018



77% of US



- 13%, mostly millenials
- **48% YOY in US**

Pew Research, 2016; Forbes, 2018

Wearable Fitness Trackers and Heart Disease

What Are Fitness Trackers?

Fitness or activity trackers are devices with special sensors that can monitor your movement. Often referred to as "wearables," these devices are typically worn around the wrist as a bracelet or embedded in a mobile phone or wristwatch. They can measure footsteps taken, distance traveled, type of movement (walk, run, or jog), and quality and duration of sleep. Some wearables have additional sensors to monitor heart rate, blood pressure, blood oxygen levels, and perspiration. Data from wearables can be transferred to a smartphone, computer, database, or website. Connected smartphones and wearables can alarm or vibrate to encourage behaviors, such as exercise or sleep. As wearable technology matures, these devices will likely cost less, and it may become easier to share data from them with your health care professional, clinic, or hospital.

Can Fitness Trackers Prevent or Treat Heart Disease?

Professional cardiology society guidelines recommend that most patients participate in regular exercise. However, these societies have not yet given recommendations on how fitness trackers should be used because no long-term studies have been completed that have tested whether the use of fitness trackers can help prevent heart disease. Also, the accuracy of most wearables has not been verified in clinical studies. In fact, some devices may provide inaccurate measurements, particularly during intensive exercise.

What Are the Benefits of Using a Fitness Tracker?

Despite these limitations, fitness trackers still may have benefits for you. Physical inactivity is an important risk factor for heart disease.

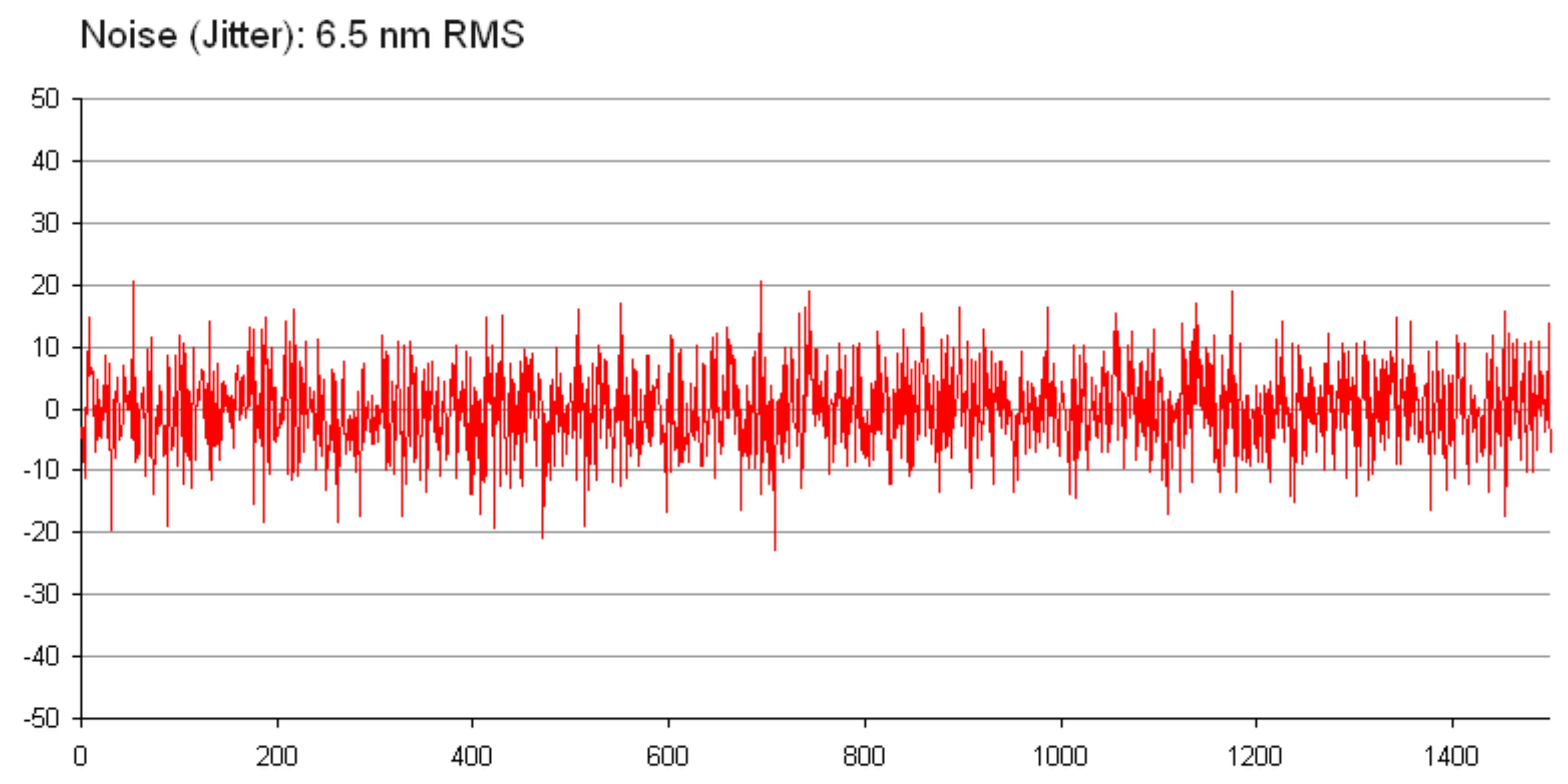
Kaiser DK / Turakhia M, JAMA Cardiol 2016

Google trends search popularity of "atrial fibrillation" (relative values 0-100)

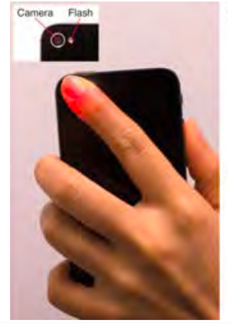
Source: Google Trends

Design challenges of a wearable

- Continuous electrode recording is difficult to impossible
- Real-time versus offline processing
- Battery drain
- Exercise
- Compliance
- Memory, hardware is cheap



Measurement	Notification Threshold	Use case

Measurement		Notification Threshold	Use case
Active HR measurement (smartphone camera)		Low or high	Third-party solutions no uptake

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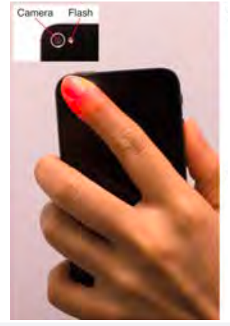
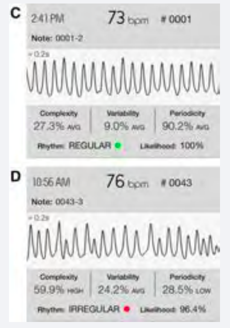
Active HR measurement (smartphone camera)		Low or high	Third-party solutions no uptake
Active irreg rhythm (phone camera,accelerometer)		Normal or afib	Third-party solutions no uptake

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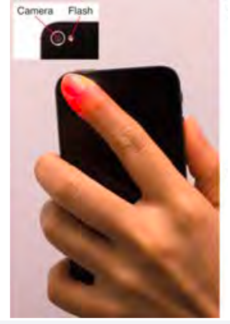
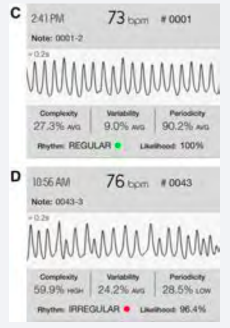
Active HR measurement (smartphone camera)		Low or high	Third-party solutions no uptake
Active irreg rhythm (phone camera,accelerometer)		Normal or afib	Third-party solutions no uptake
Passive HR sampling (every few seconds to minutes)	 	Low or high	Consumer experience No FDA approval

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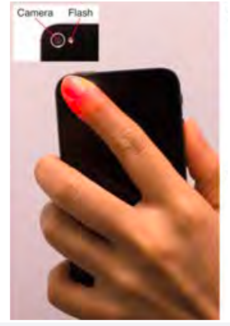
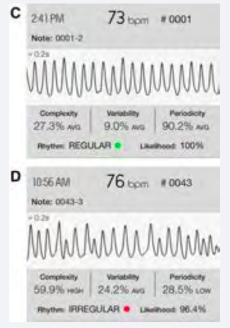
Active HR measurement (smartphone camera)		Low or high	Third-party solutions no uptake
Active irreg rhythm (phone camera,accelerometer)		Normal or afib	Third-party solutions no uptake
Passive HR sampling **(every few seconds to minutes)**		Low or high	Consumer experience No FDA approval
Passive irregular rhythm notification		Single versus repeated confirmation	Consumer-facing **"prediagnostic"** **(not traditional "screening")**

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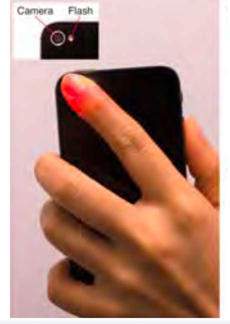
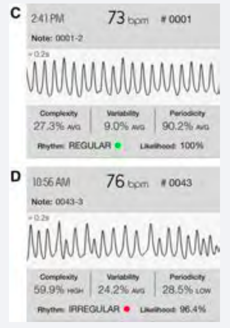
Active HR measurement (smartphone camera)		Low or high	Third-party solutions no uptake
Active irreg rhythm (phone camera,accelerometer)		Normal or afib	Third-party solutions no uptake
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Ad hoc ECG		Varies (FDA) Normal sinus vs Afib	Strong FDA guard rails **Disease management**

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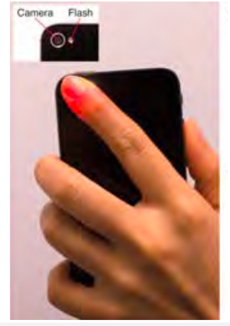
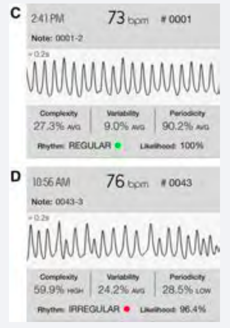
Active HR measurement (smartphone camera)		Low or high	Third-party solutions no uptake
Active irreg rhythm (phone camera,accelerometer)		Normal or afib	Third-party solutions no uptake
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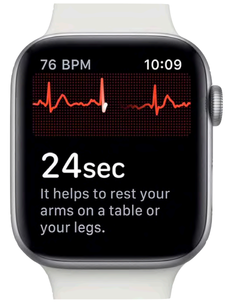
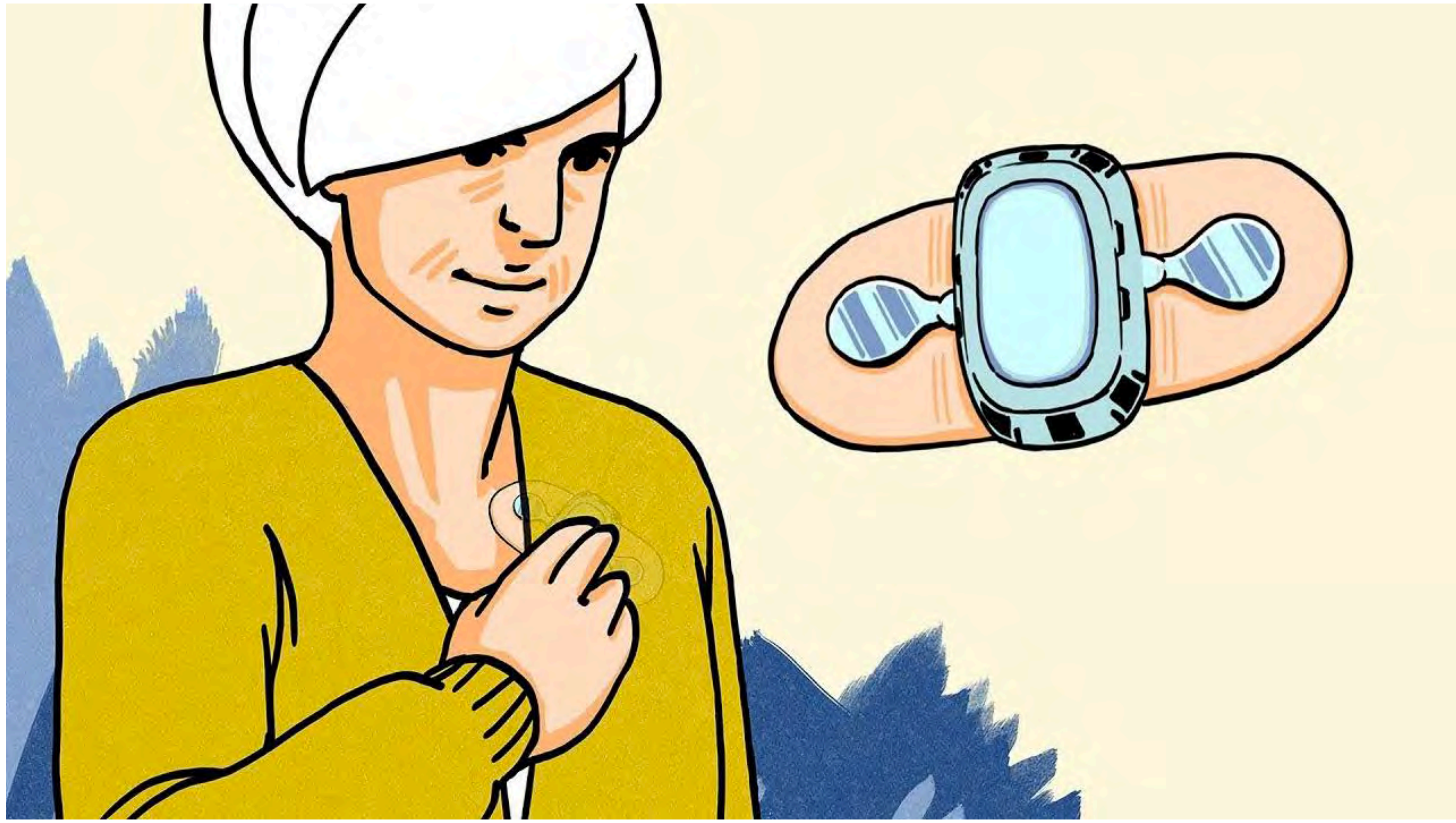
Ad hoc ECG	  	Varies (FDA) Normal sinus vs Afib	Strong FDA guard rails **Disease management**
Blended HR-ECG model **(trained HR sensor)**		To prompt ECG	**Disease management**

JAMA | Original Investigation

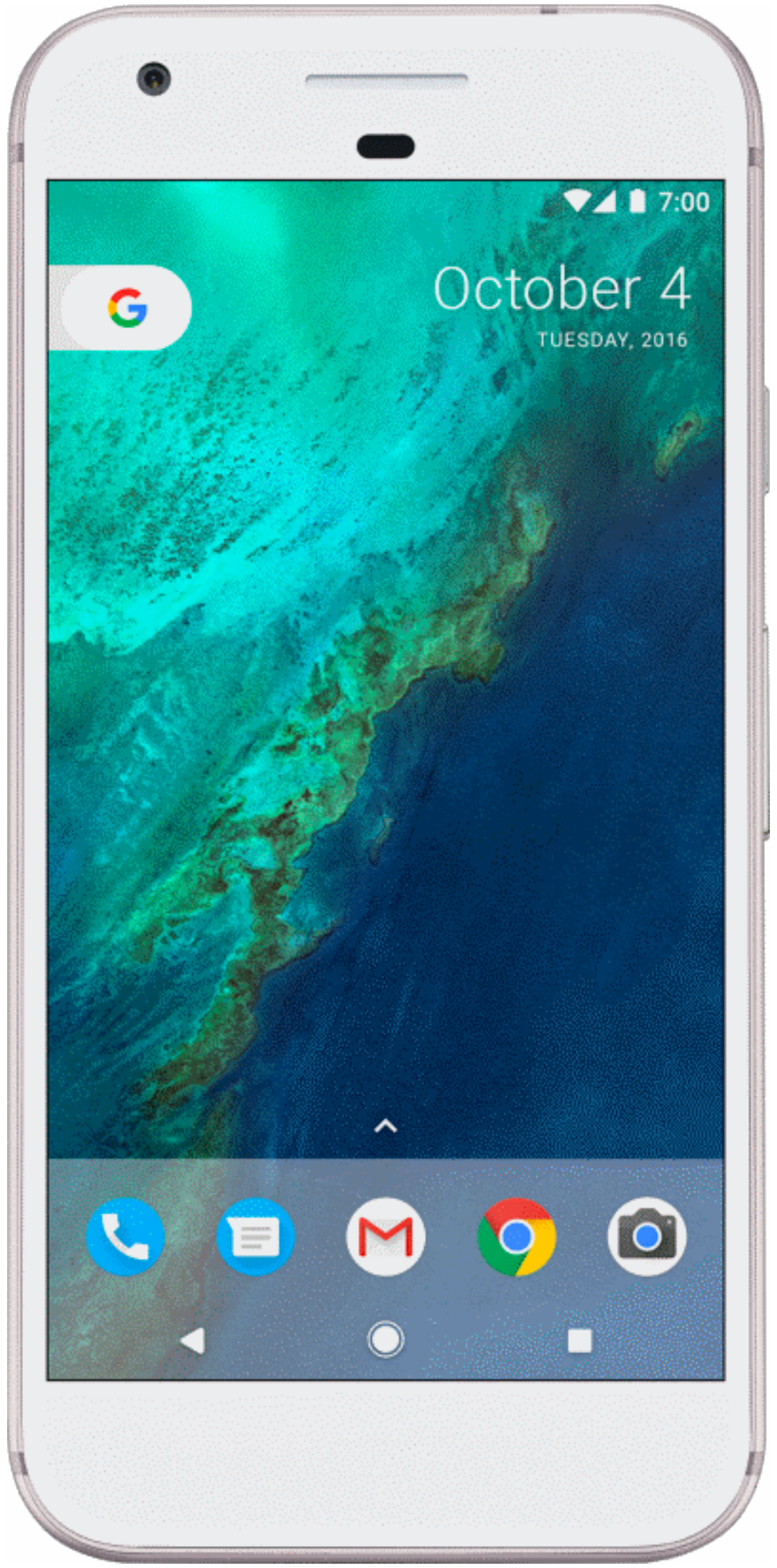
Effect of a Home-Based Wearable Continuous ECG Monitoring Patch on Detection of Undiagnosed Atrial Fibrillation

The mSToPS Randomized Clinical Trial

Steven R. Steinhubl, MD; Jill Waalen, MD, MPH; Alison M. Edwards, MStat; Lauren M. Ariniello, BS; Rajesh R. Mehta, RPh, MS; Gail S. Ebner, BS; Chureen Carter, PharmD, MS; Katie Baca-Motes, MBA; Elise Felicione, MPH, MBA; Troy Sarich, PhD; Eric J. Topol, MD

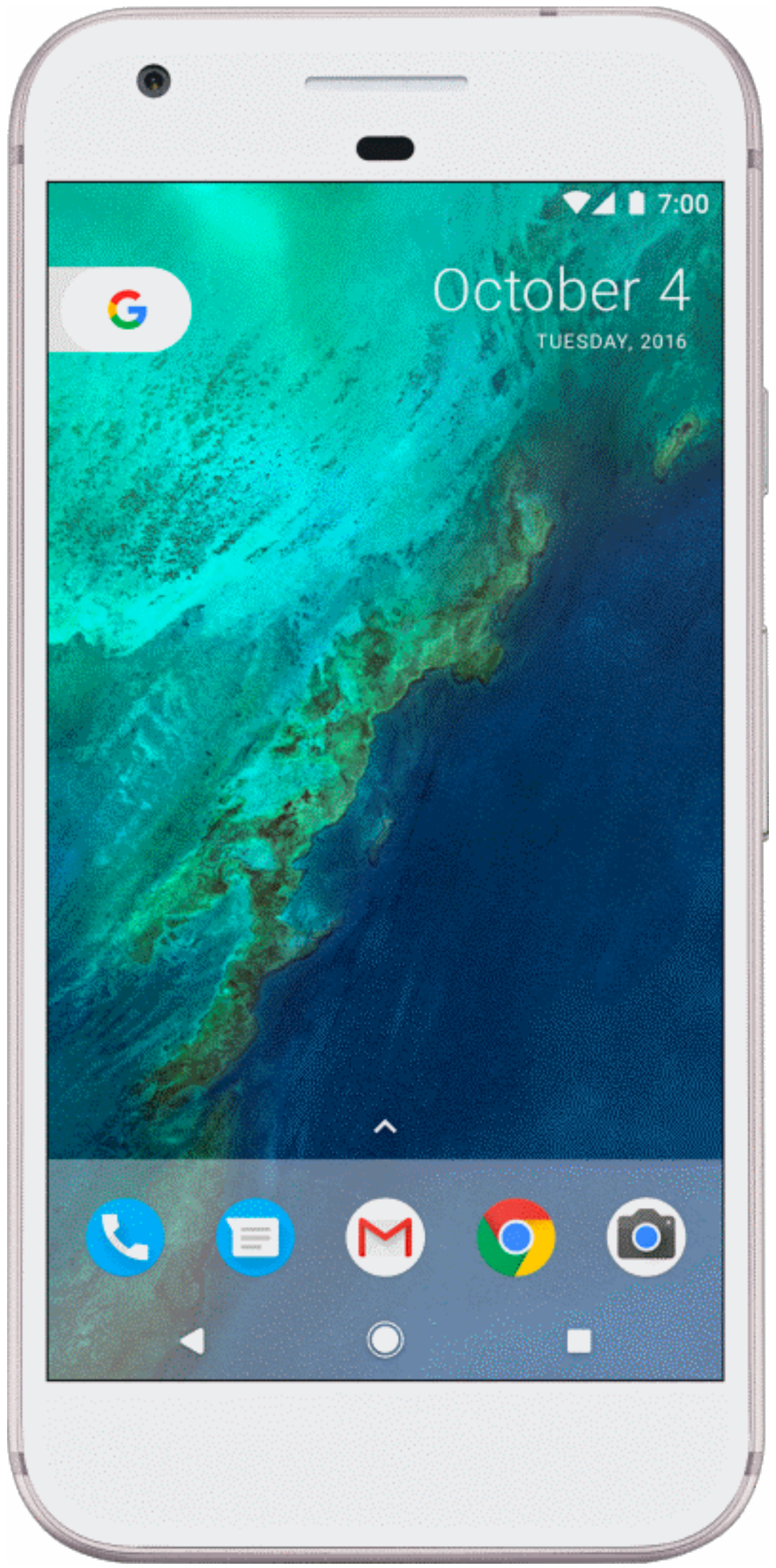


Steinhubl SR, *JAMA*, 2018



◀77% of US

Pew Research, 2016; AliveCor



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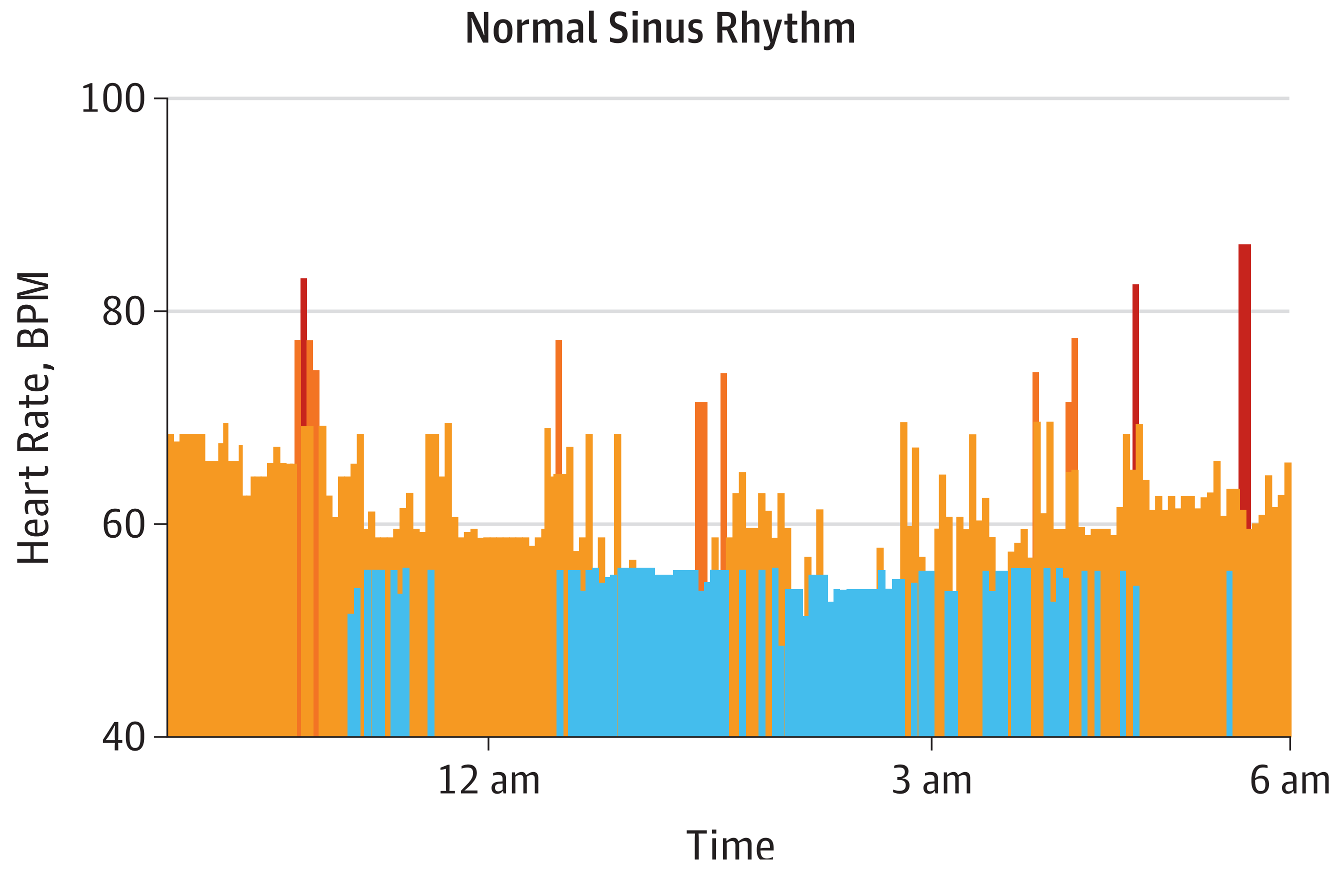
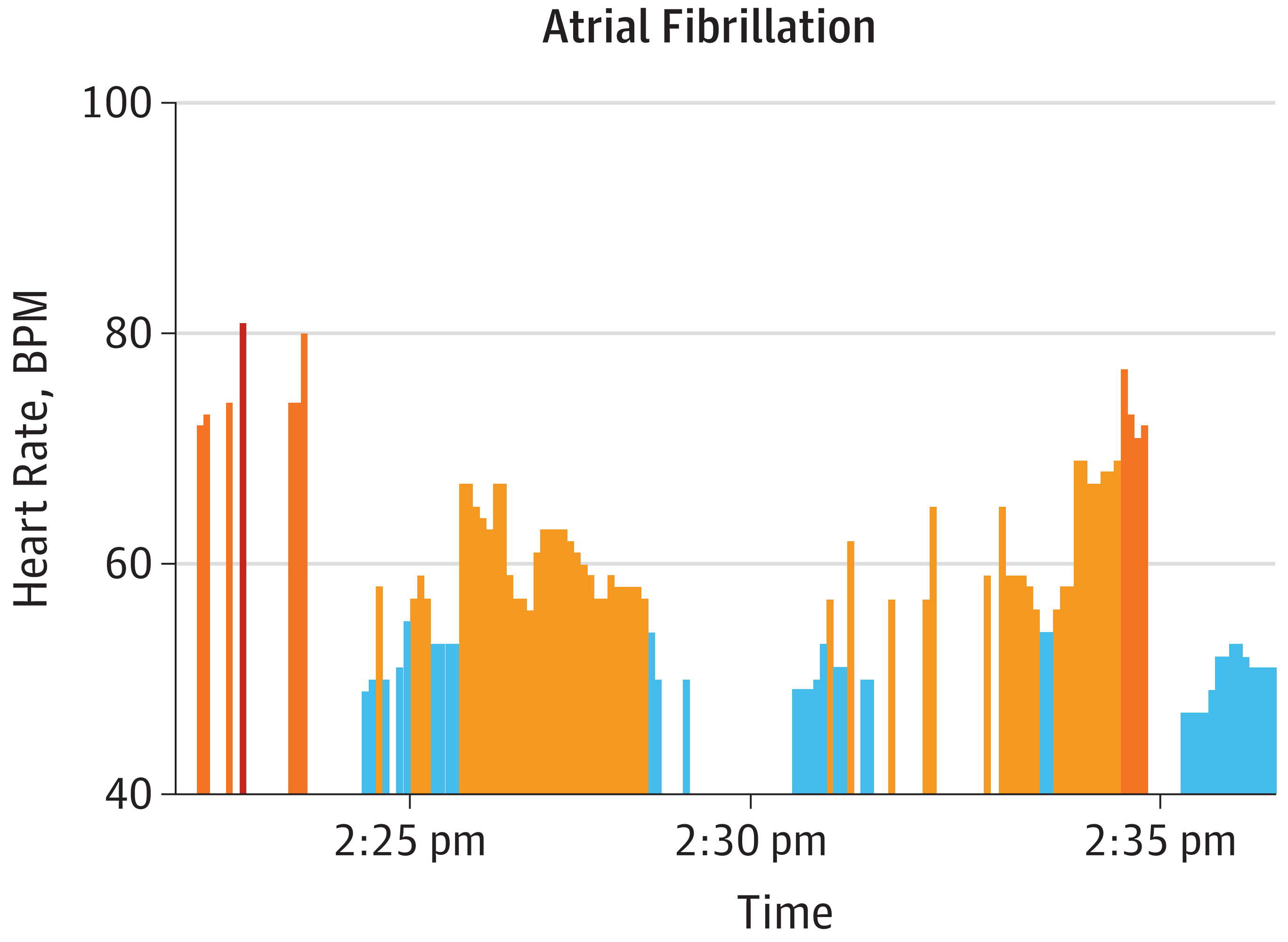
JAMA Cardiology | Original Investigation

Passive Detection of Atrial Fibrillation Using a Commercially Available Smartwatch

Geoffrey H. Tison, MD, MPH; José M. Sanchez, MD; Brandon Ballinger, BS; Avesh Singh, MS; Jeffrey E. Olgin, MD; Mark J. Pletcher, MD, MPH; Eric Vittinghoff, PhD; Emily S. Lee, BA; Shannon M. Fan, BA; Rachel A. Gladstone, BA; Carlos Mikell, BS; Nimit Sohoni, BS; Johnson Hsieh, MS; Gregory M. Marcus, MD, MAS





Tison G, *et al.* JAMA Cardiology 2018.

JAMA Cardiology | Original Investigation

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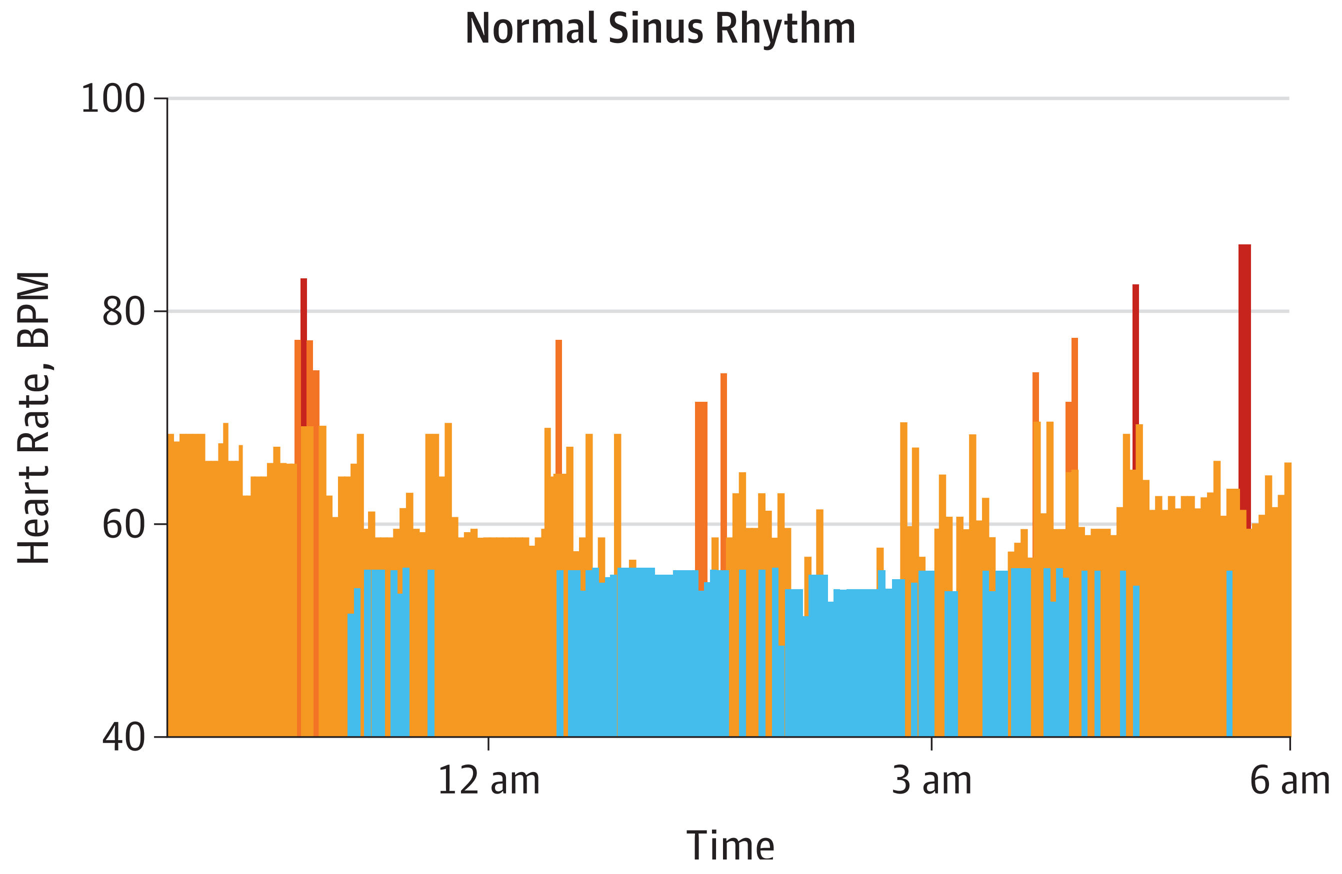


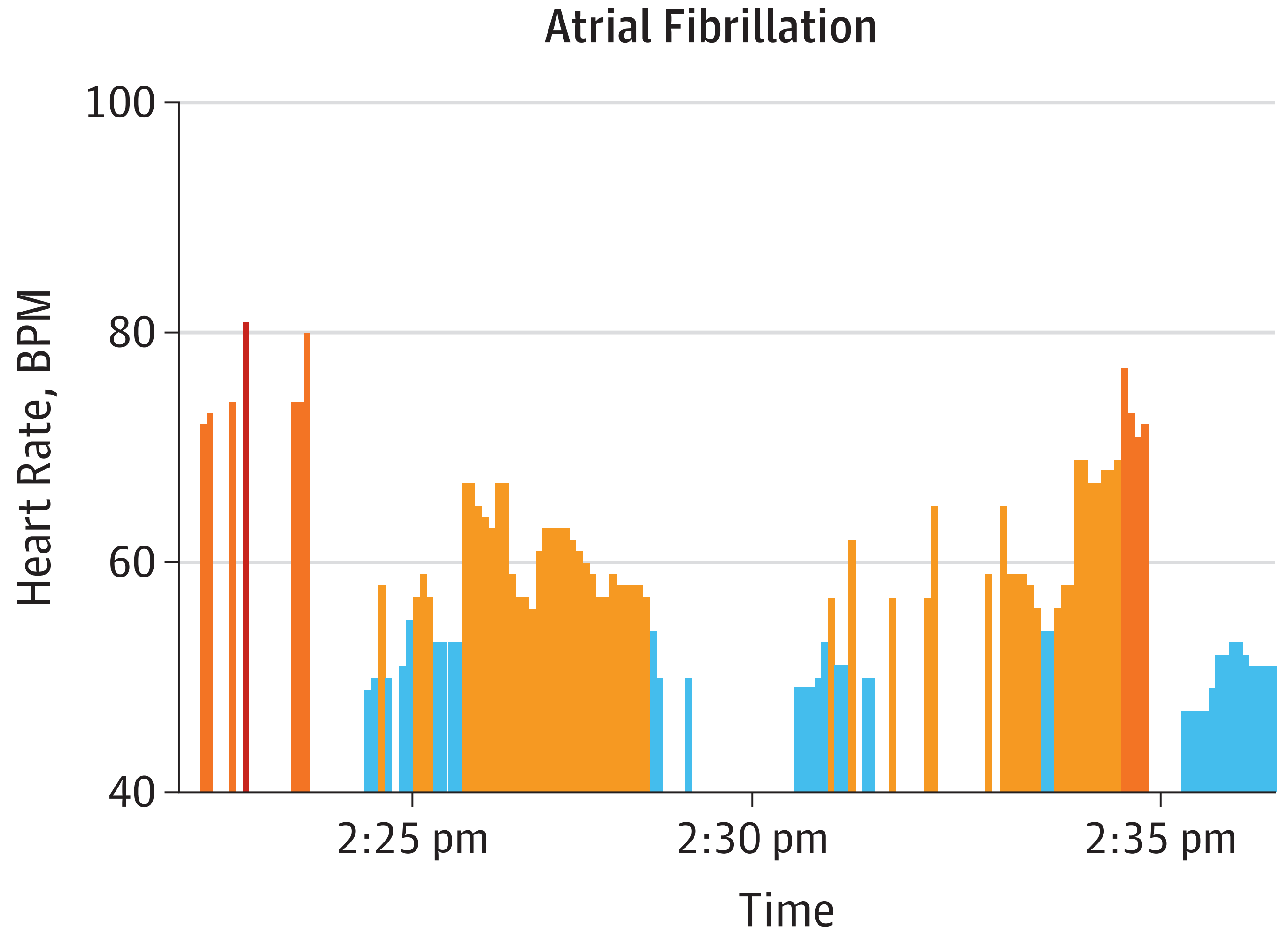
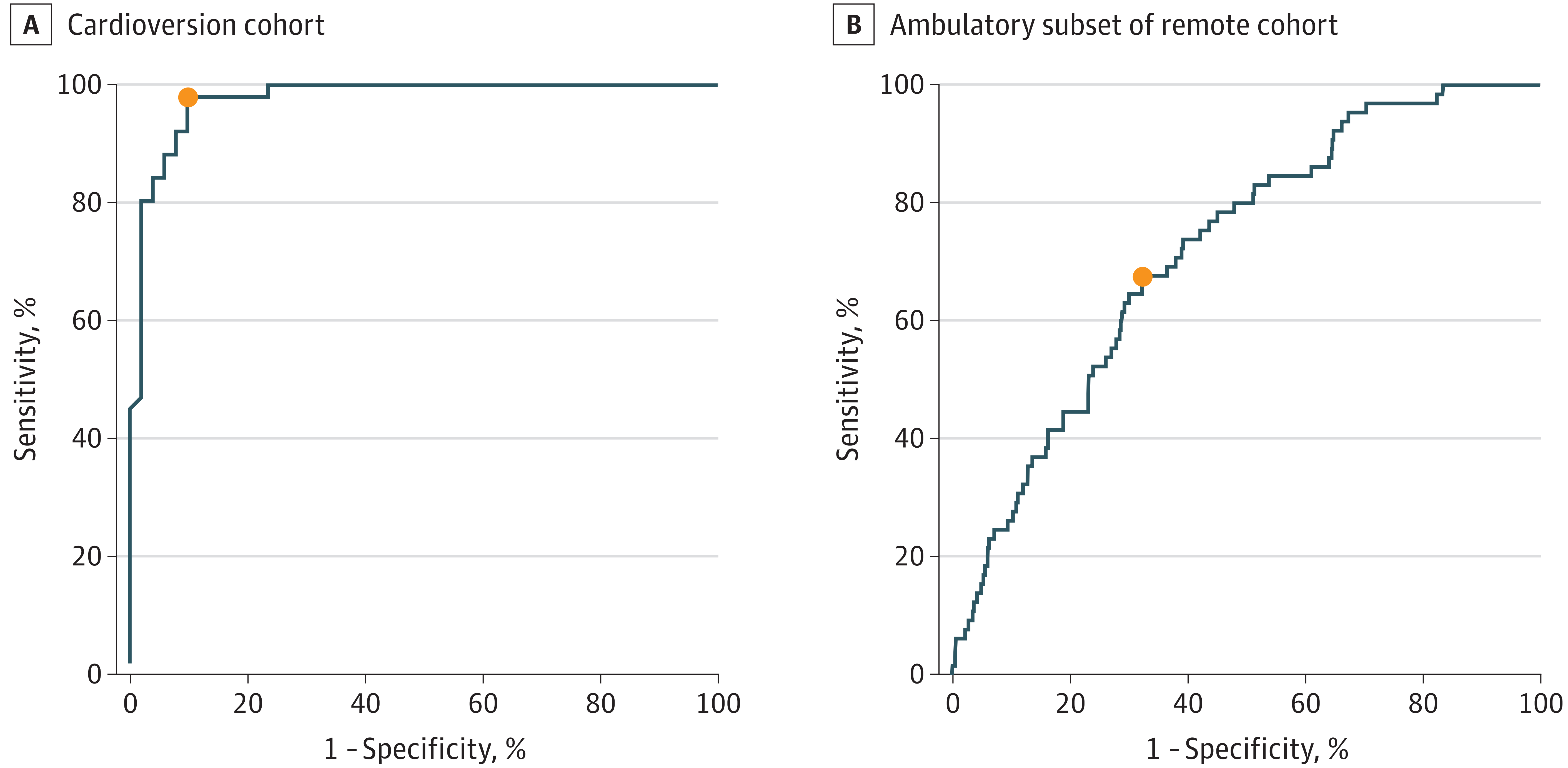


Figure 2. Accuracy of Detecting Atrial Fibrillation in the Cardioversion Cohort



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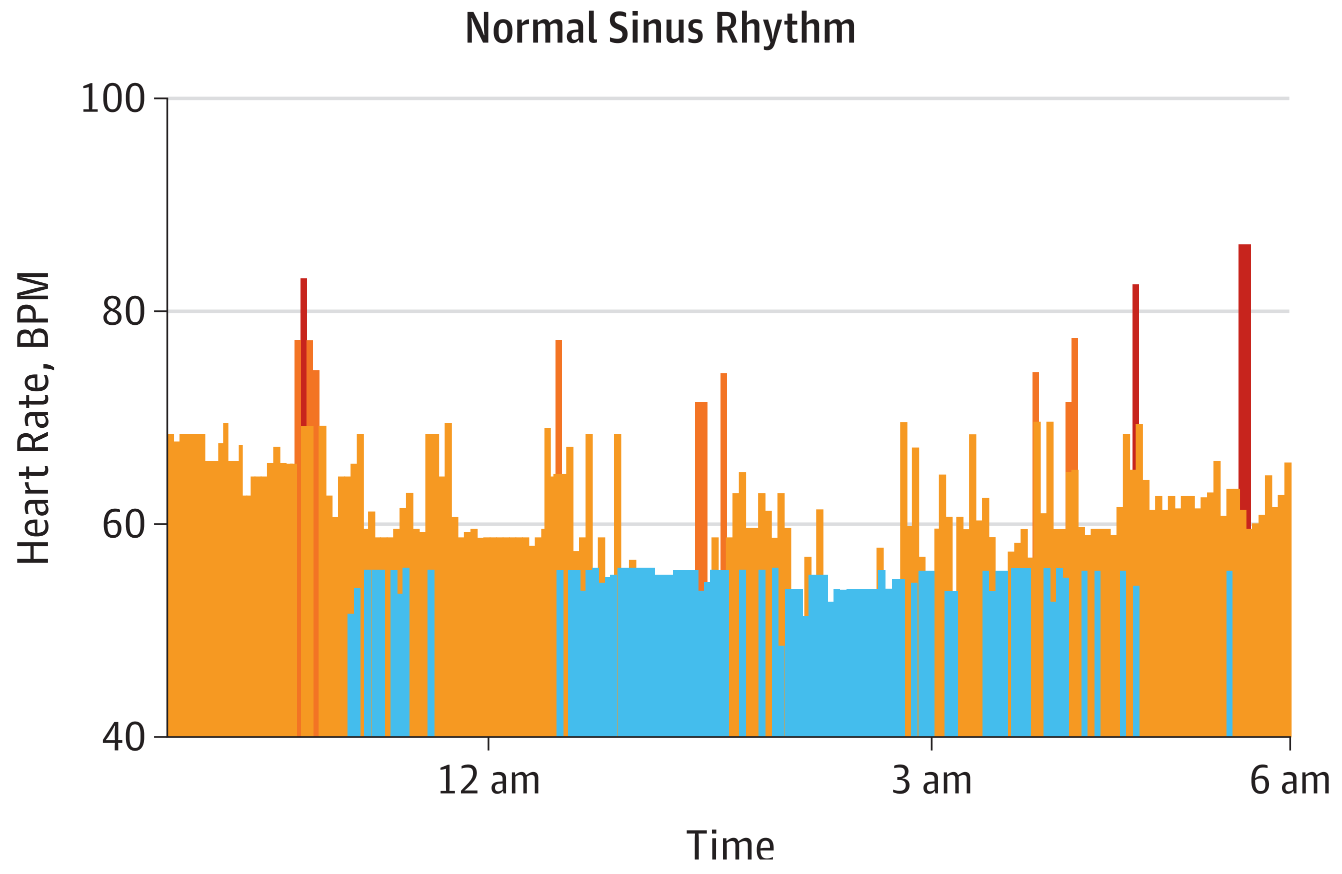
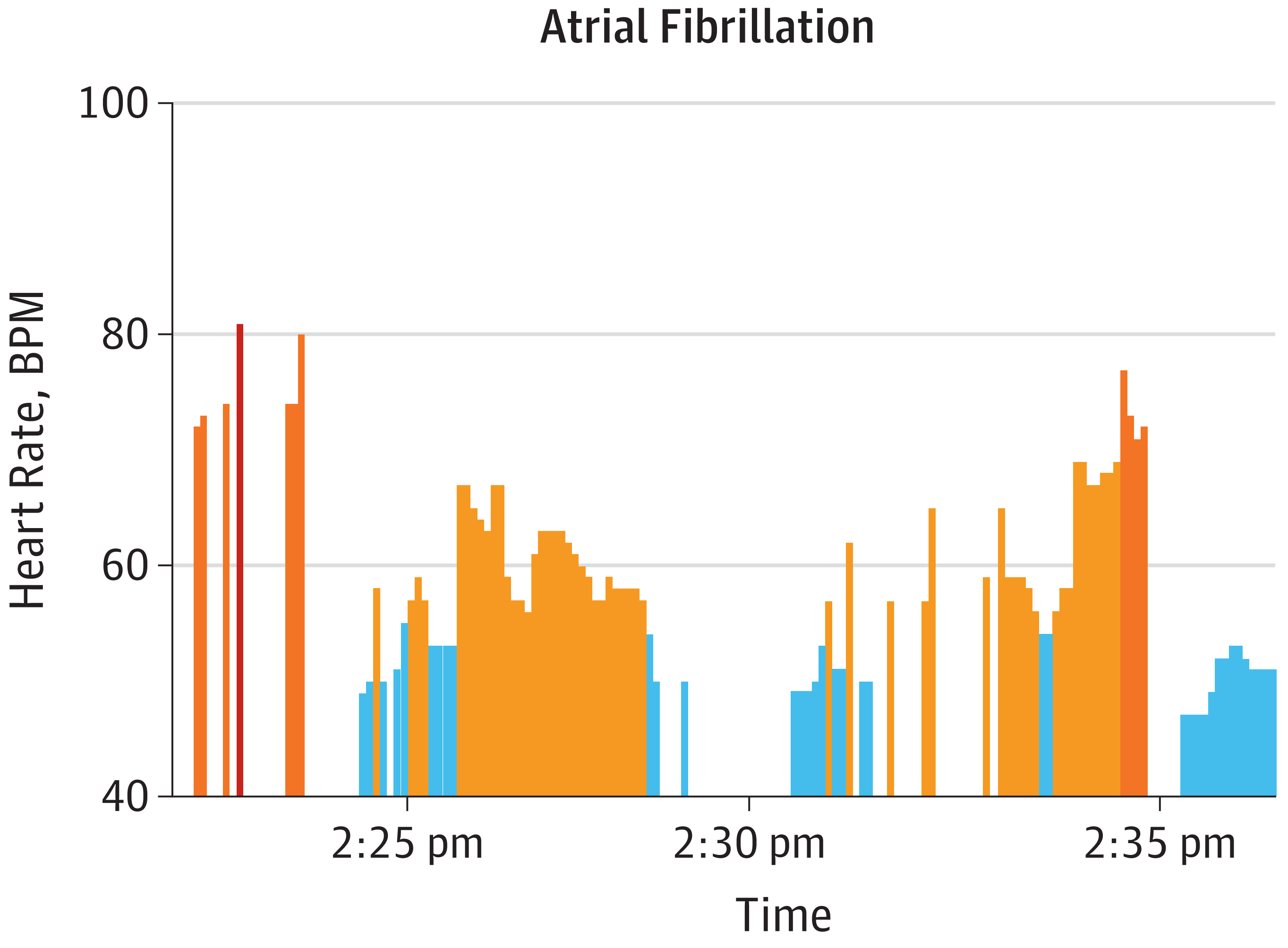
Positive predictive value (PPV): 8%





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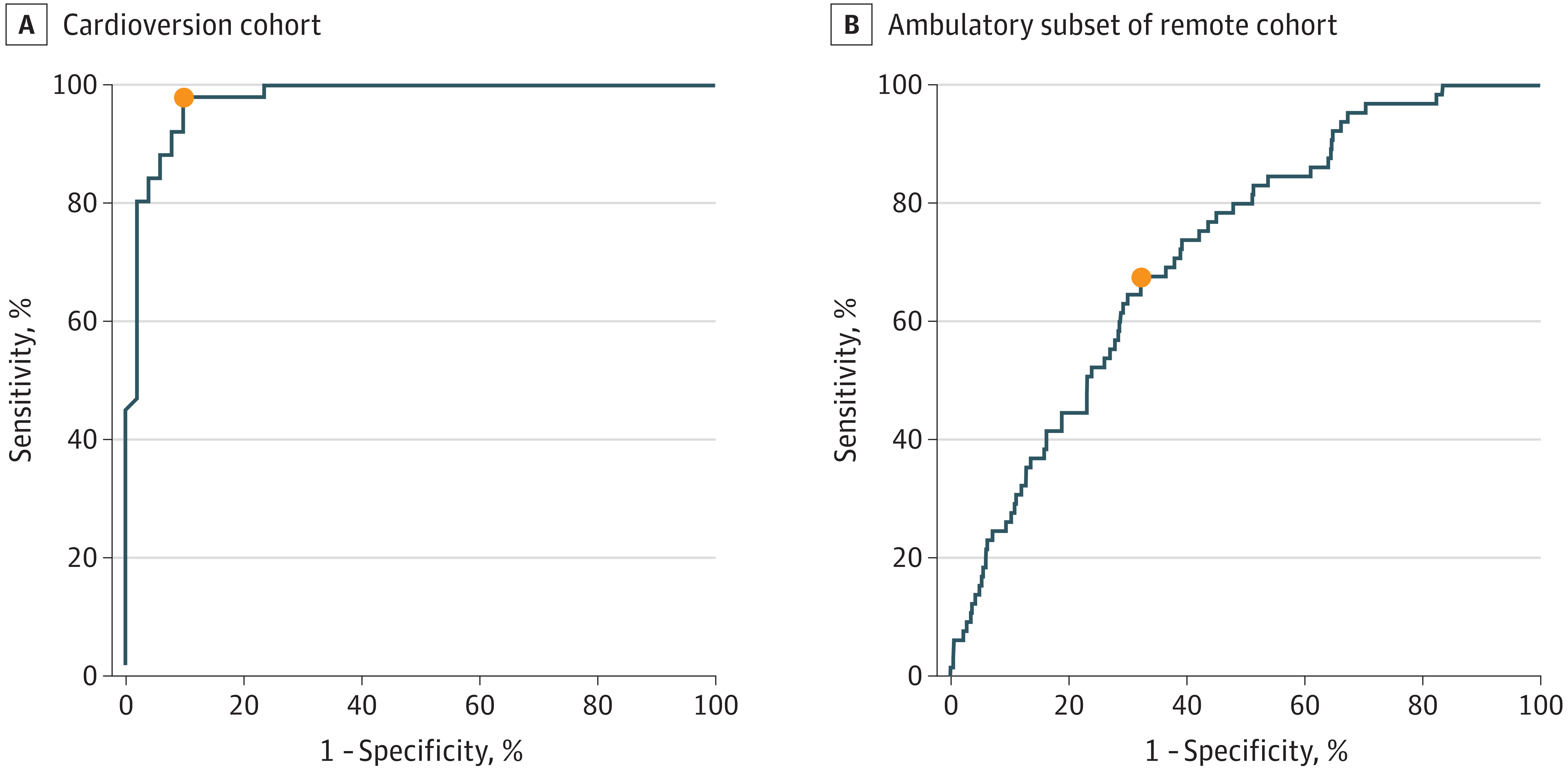


Tison G, *et al.* JAMA Cardiology 2018.

Results of a Large-scale, App-based Study to Identify Atrial Fibrillation Using a Smartwatch:

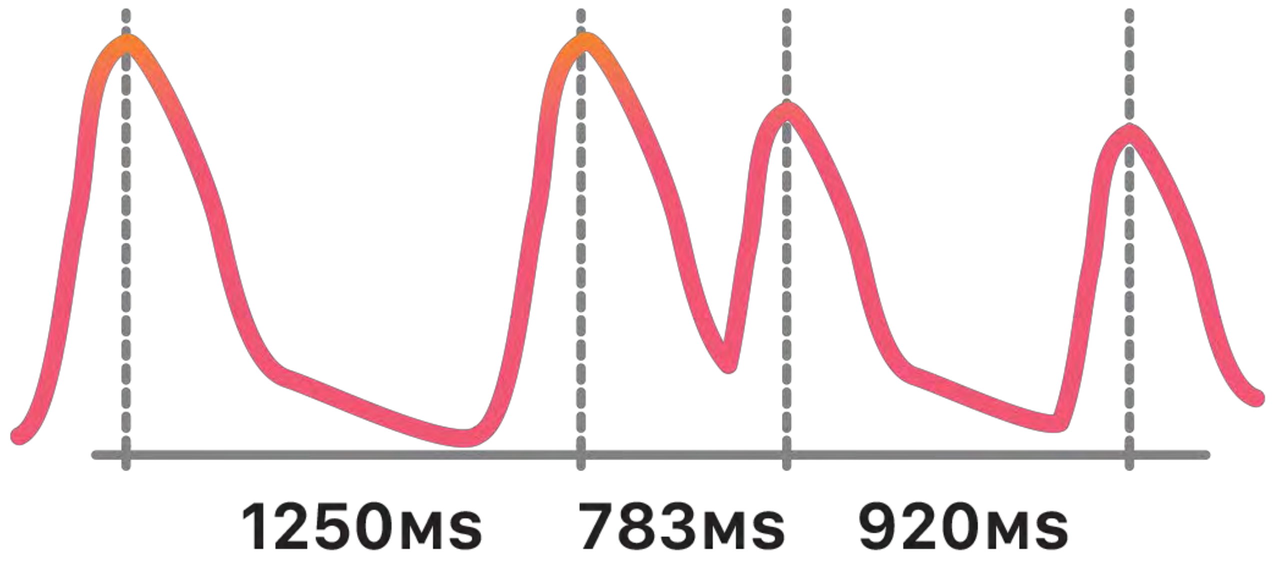
The Apple Heart Study

Mintu Turakhia MD MAS and Marco Perez MD
on behalf of the Apple Heart Study Investigators

NCT # 03335800

Stanford MEDICINE

Irregular Pulse Notification Algorithm



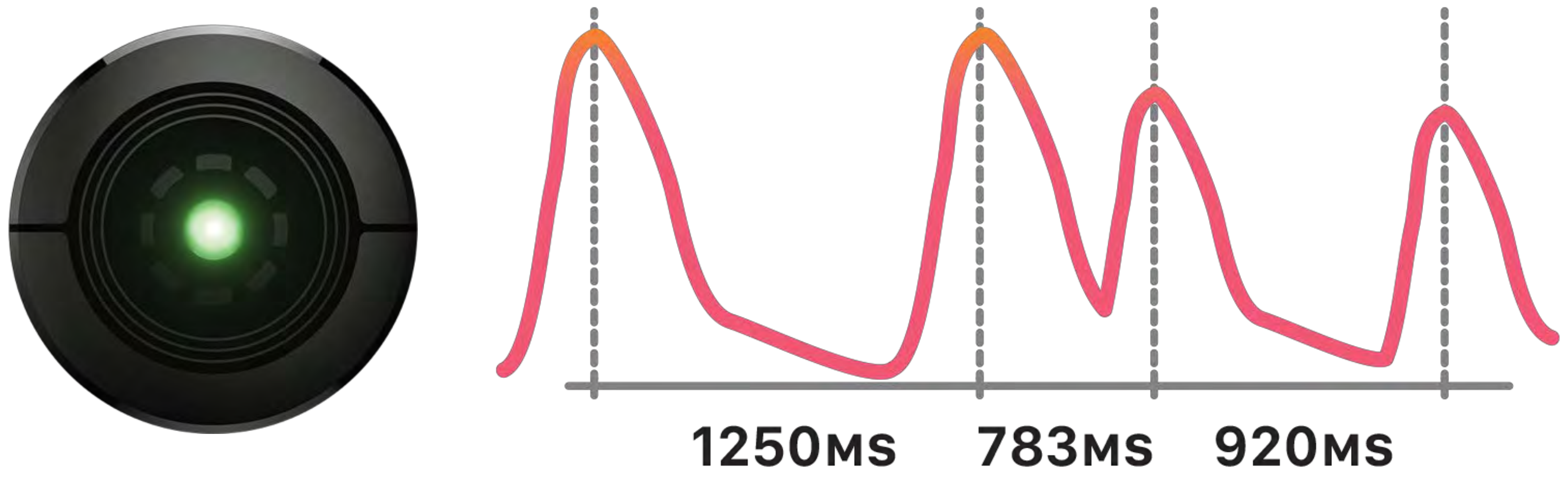
Algorithm results

- Regular pulse
- Suggestive of Afib

Tachogram = Periodic spot measurements

The algorithm does not use the watch ECG feature

Irregular Pulse Notification Algorithm



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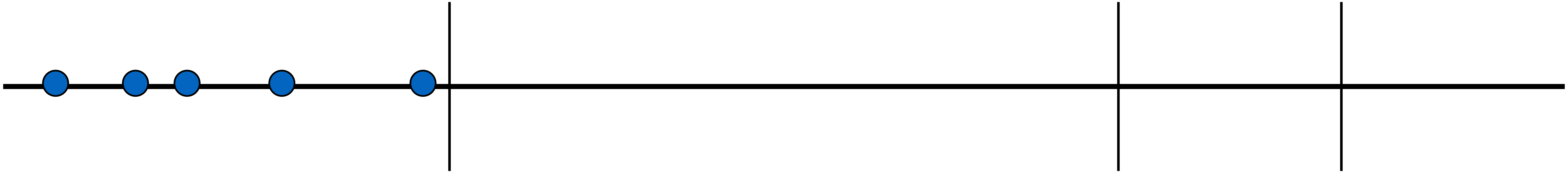

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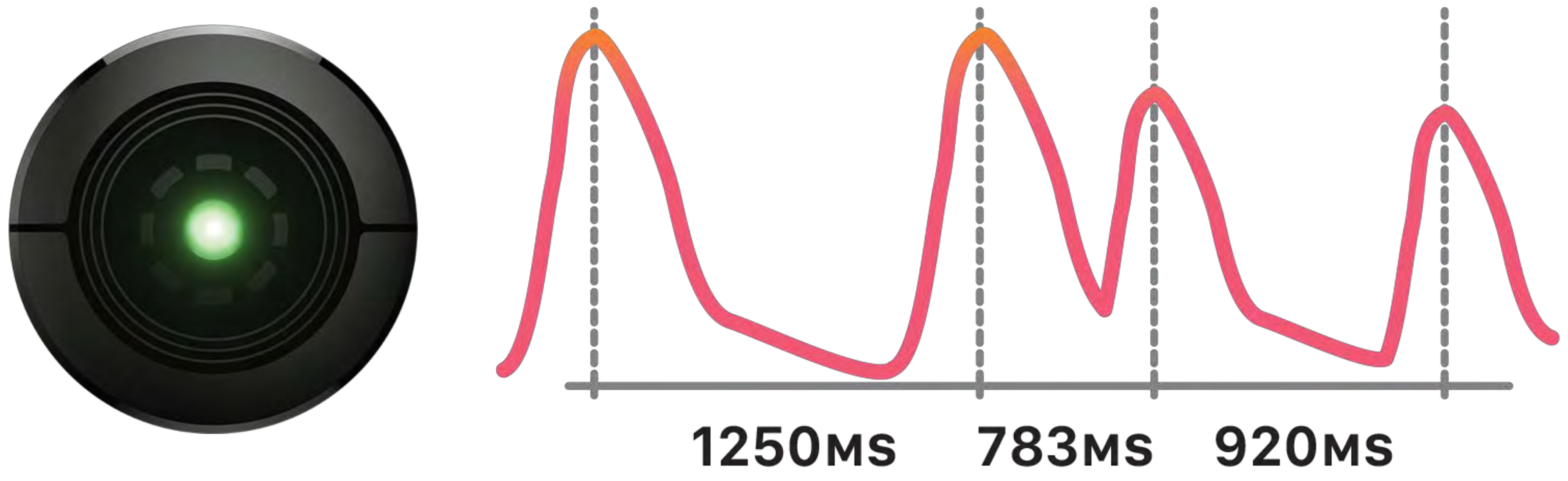

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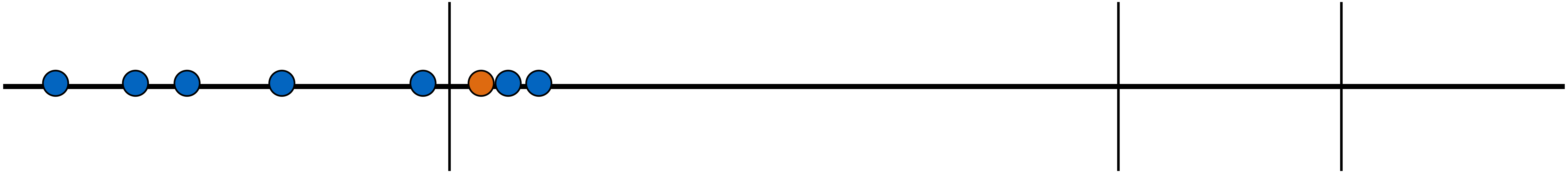


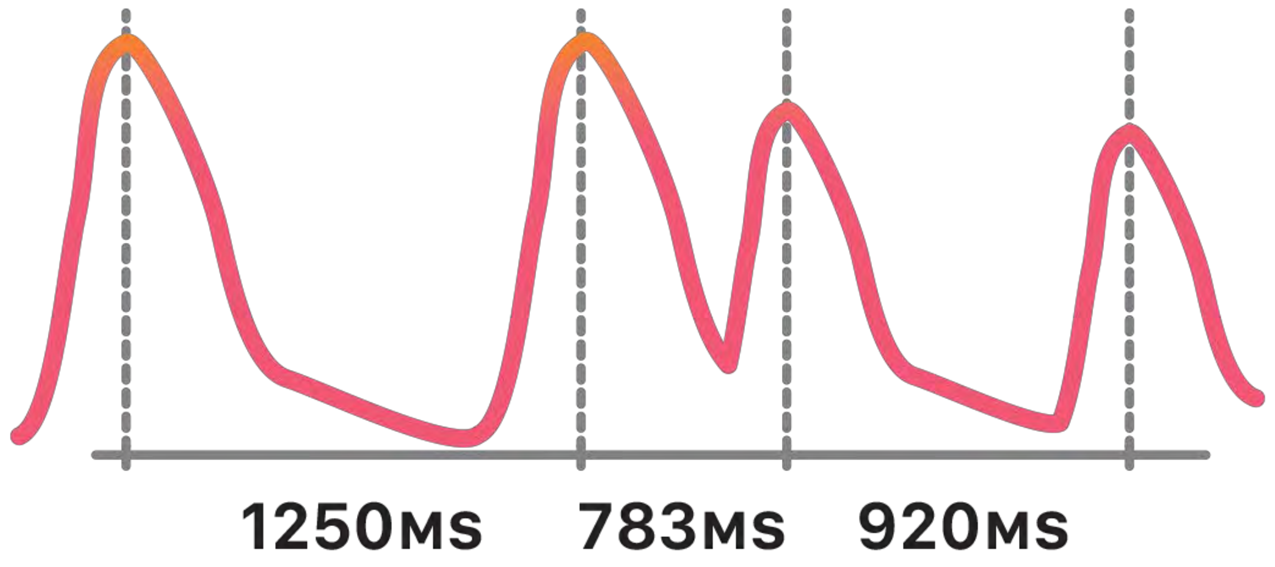
Tachogram = Periodic spot measurements

Positive triggers frequent measurements

Not confirmed ⇒ return to usual sampling

The algorithm does not use the watch ECG feature

Irregular Pulse Notification Algorithm



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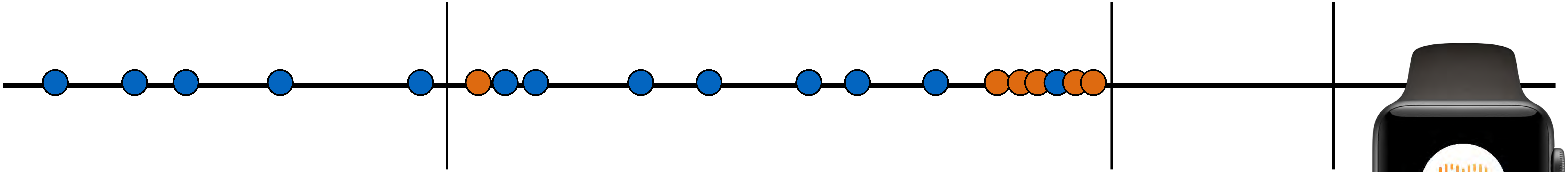


Tachogram = Periodic spot measurements

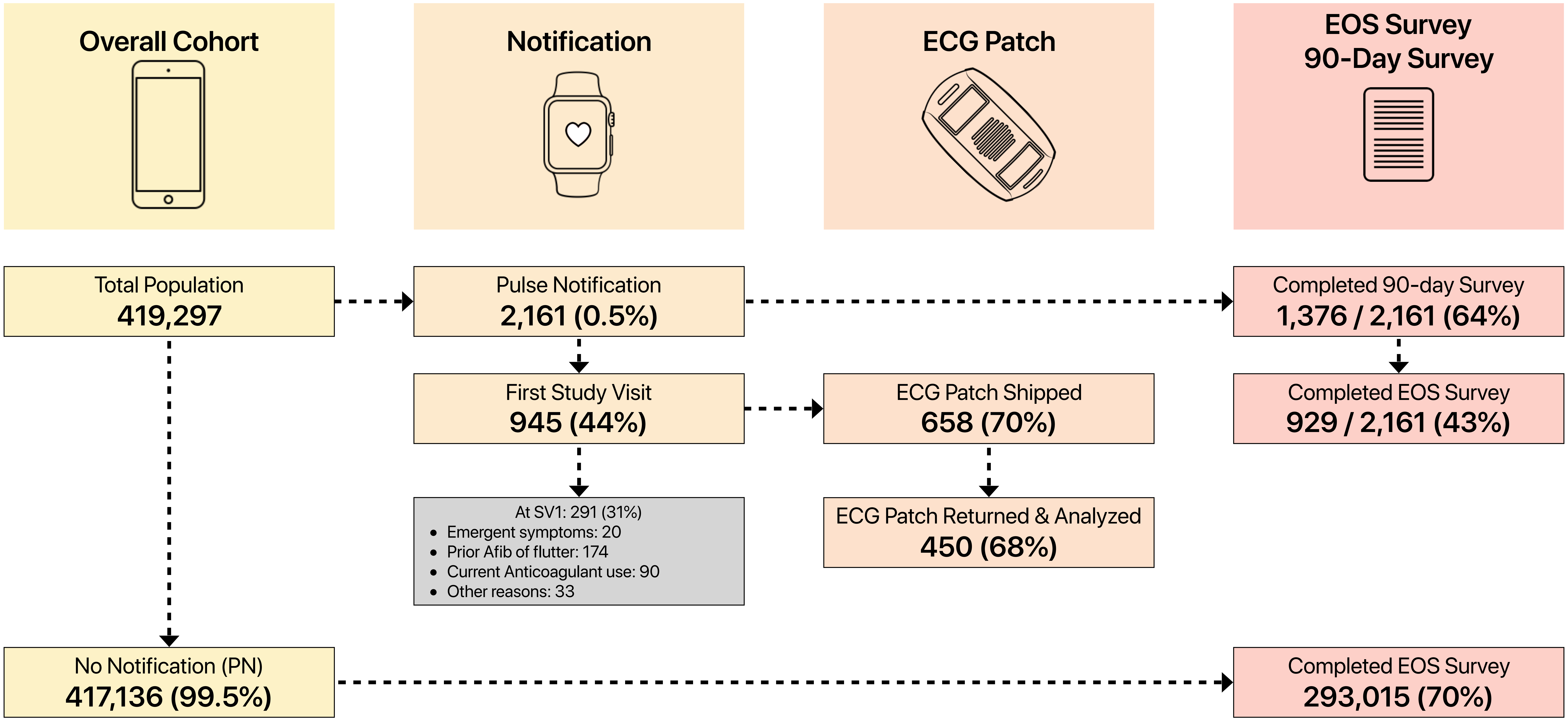
5 confirmations ⇒ notify user

Positive triggers frequent measurements

Not confirmed ⇒ return to usual sampling

The algorithm does not use the watch ECG feature

Consort Diagram

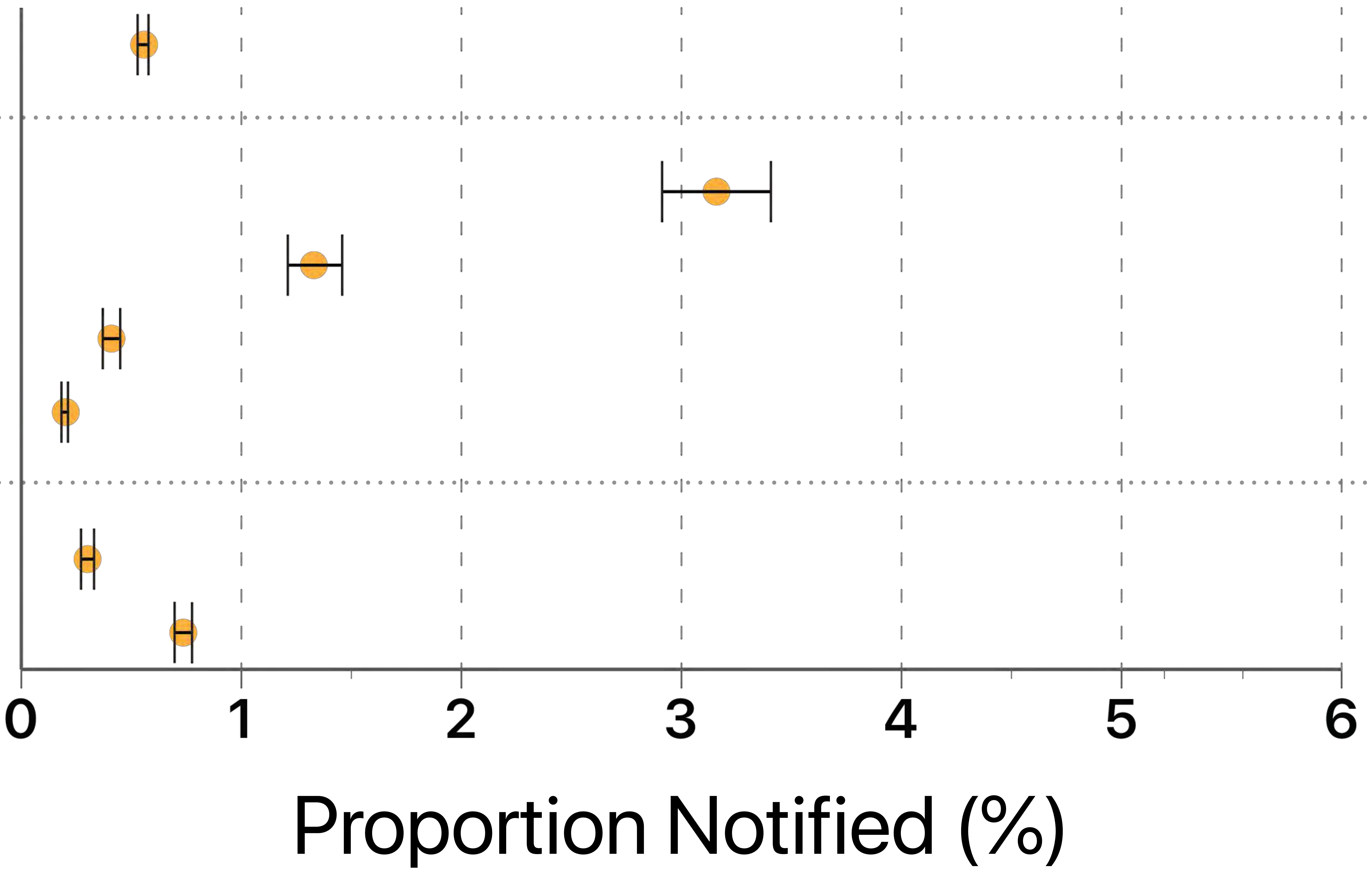


Initial Irregular Pulse Notifications

Overall Cohort

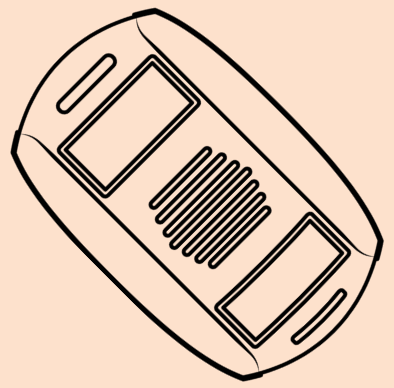
~ 8 Months Monitoring

Grouping		Notified / Total	%
	Overall	2,161 / 419,297	0.52
Age	≥ 65	775 / 24,626	3.2
	55–64	556 / 42,633	1.3
	40–54	488 / 132,696	0.37
	22–39	341 / 219,179	0.16
Sex	Female	461 / 177,087	0.26
	Male	1,672 / 238,700	0.70



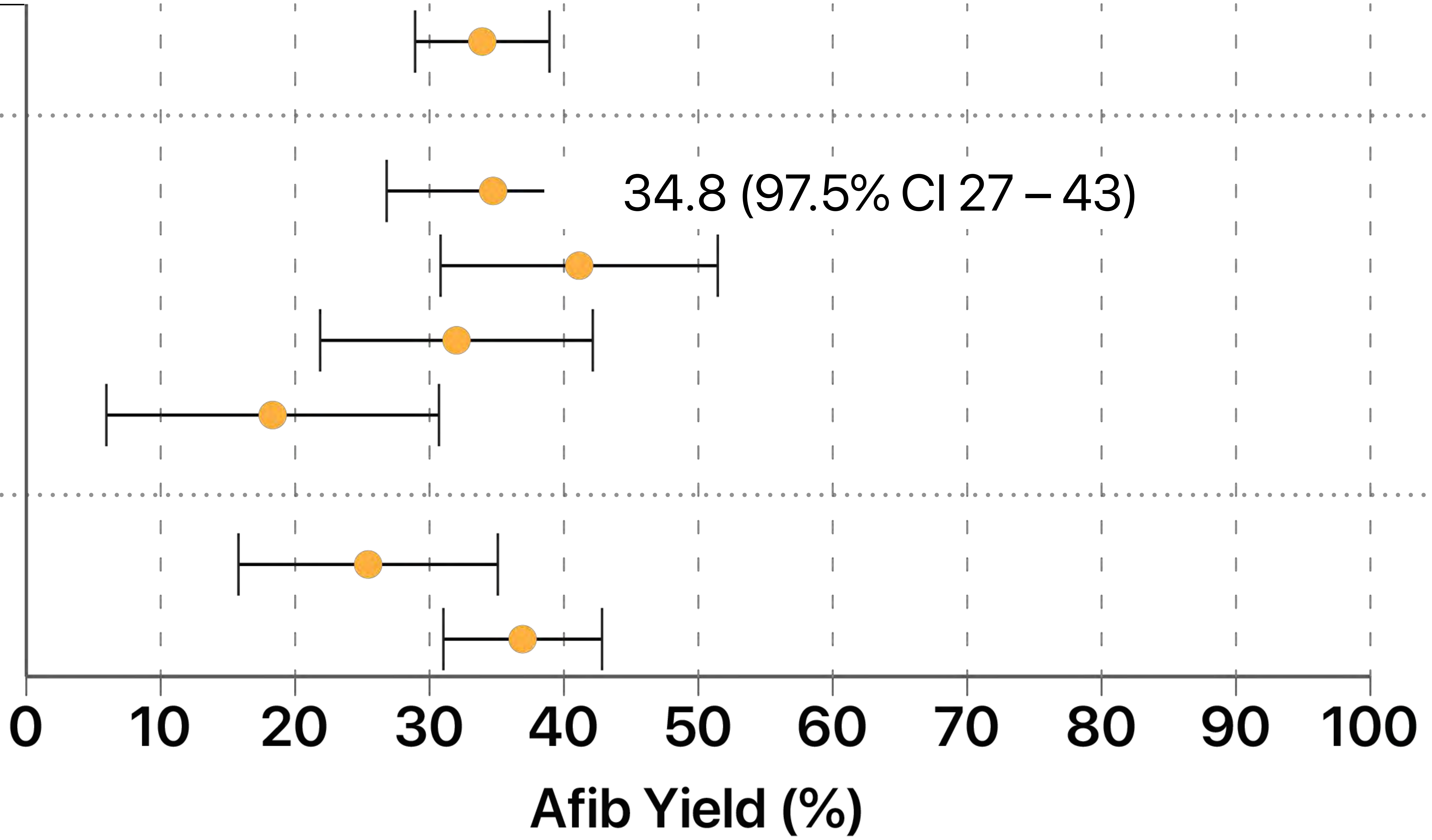
Afib Yield on ECG Patch

ECG Patch (450/2,161)



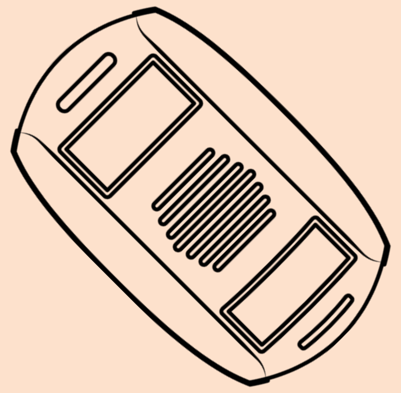
Mean time to hookup: 13 days
Mean wear time: 6.3 days

Grouping		Observed AF / Total	%
	Overall	153 / 450	34.0
Age	≥ 65	63 / 181	34.8
	55–64	47 / 114	41.2
	40–54	34 / 106	32.1
	22–39	9 / 49	18.4
Sex	Female	26 / 102	25.5
	Male	124 / 335	37.0

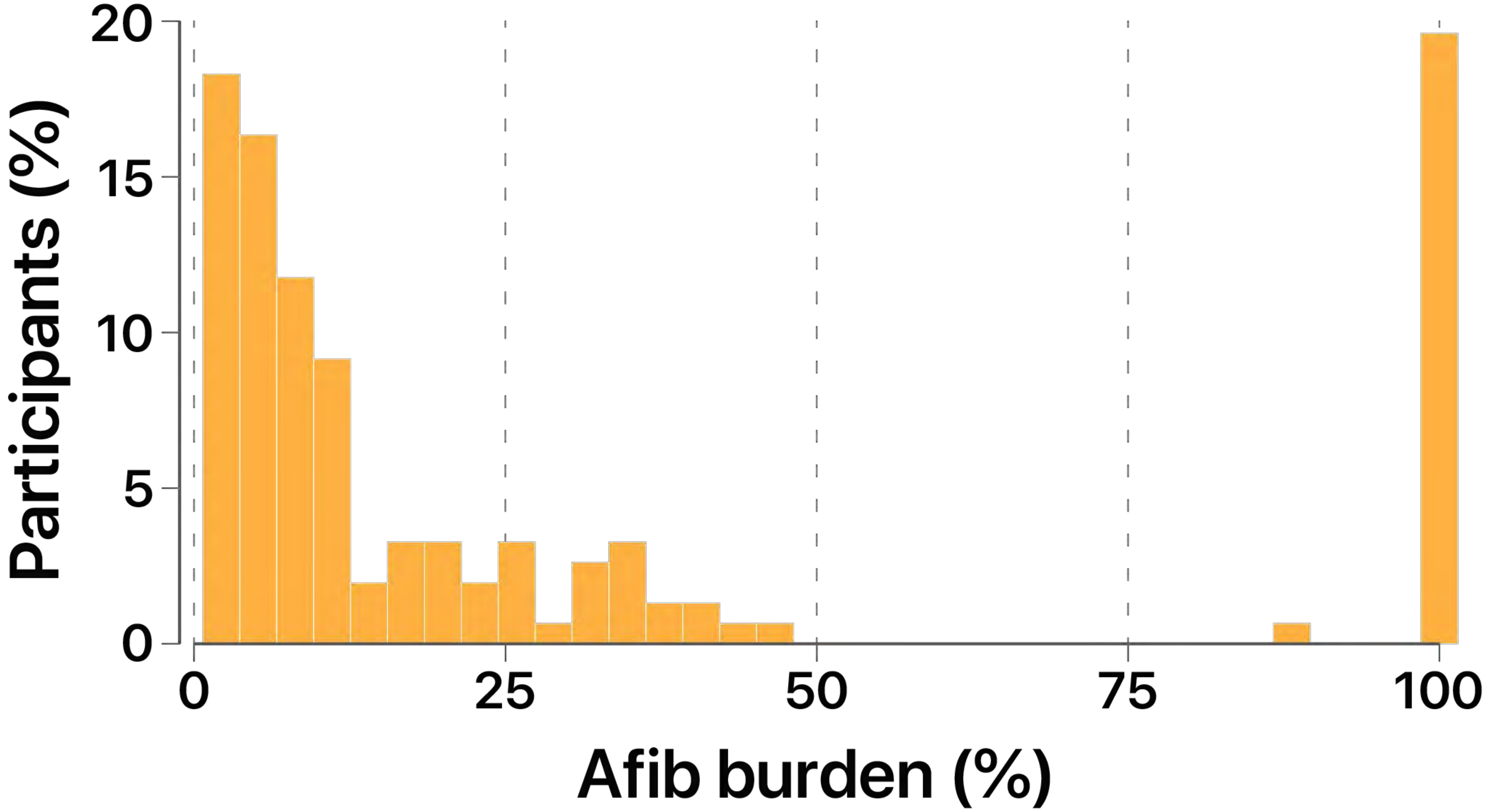


Afib Burden and Duration

ECG Patch
153/450 With AF



Burden



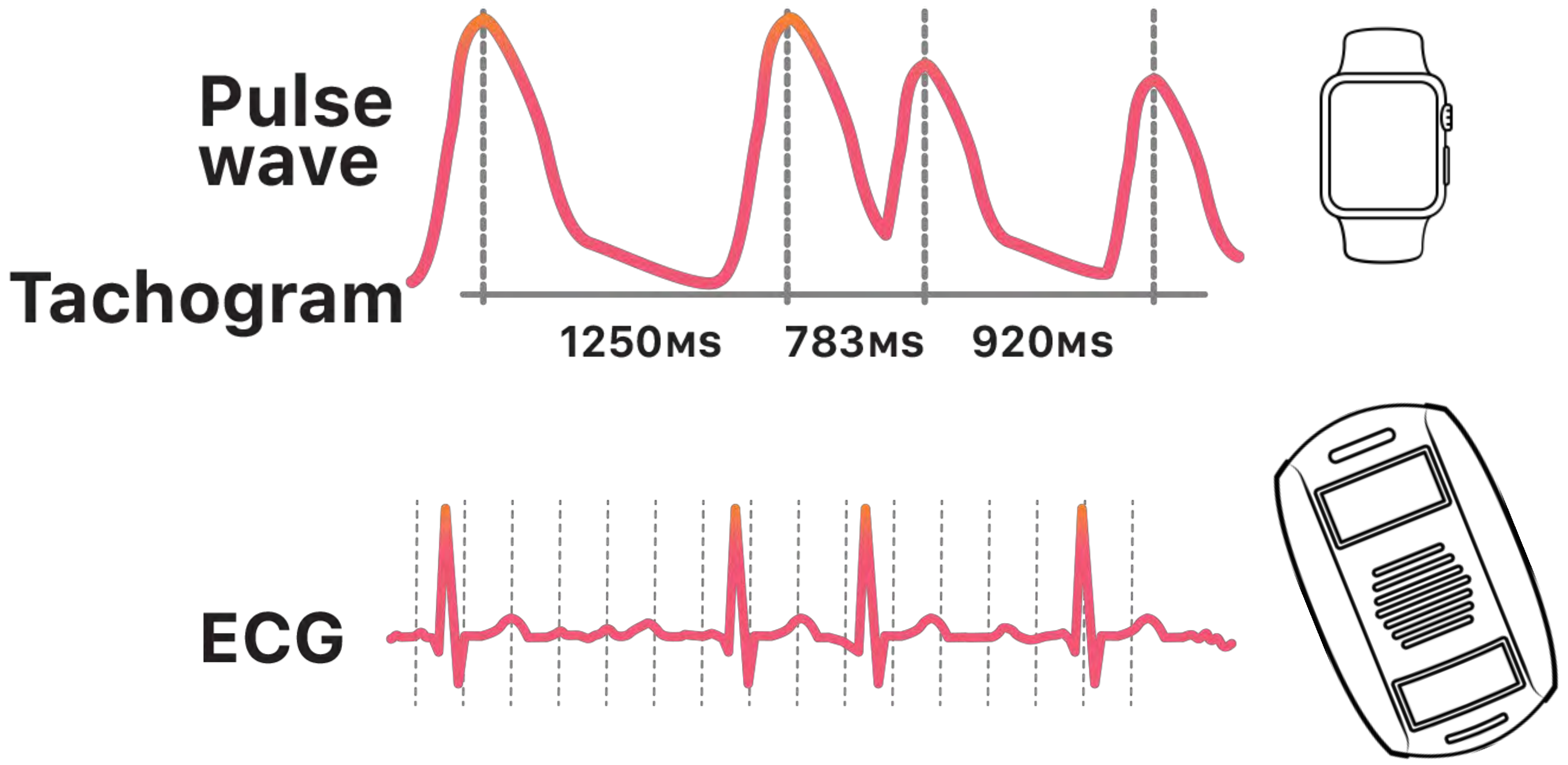
Duration of Longest Episode

24 hr	25.5%
6 hr	34.0%
1 hr	29.4%
6 min	5.9%
30 sec	5.2%

89%

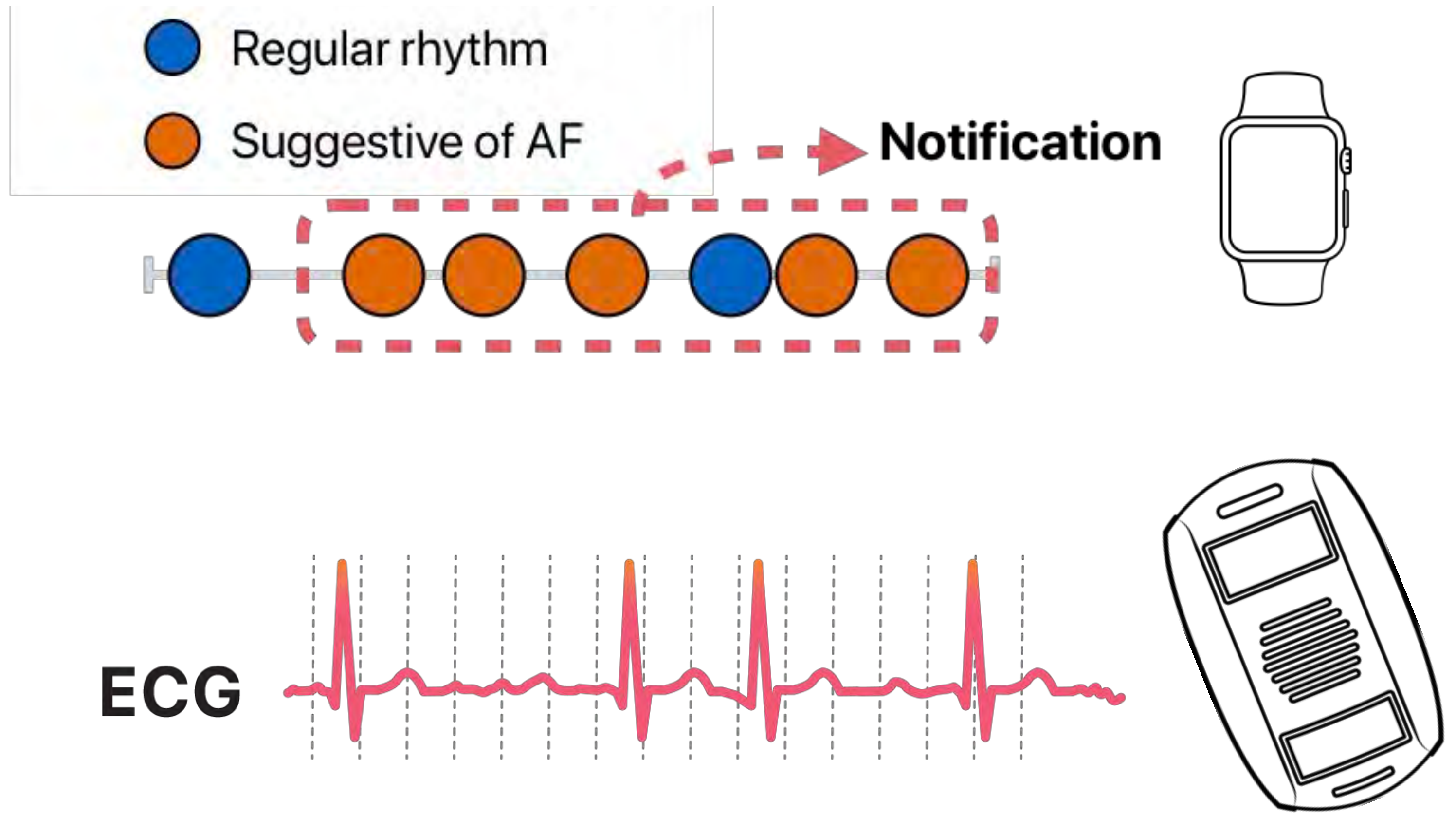
Positive Predictive Values

Irregular Tachograms

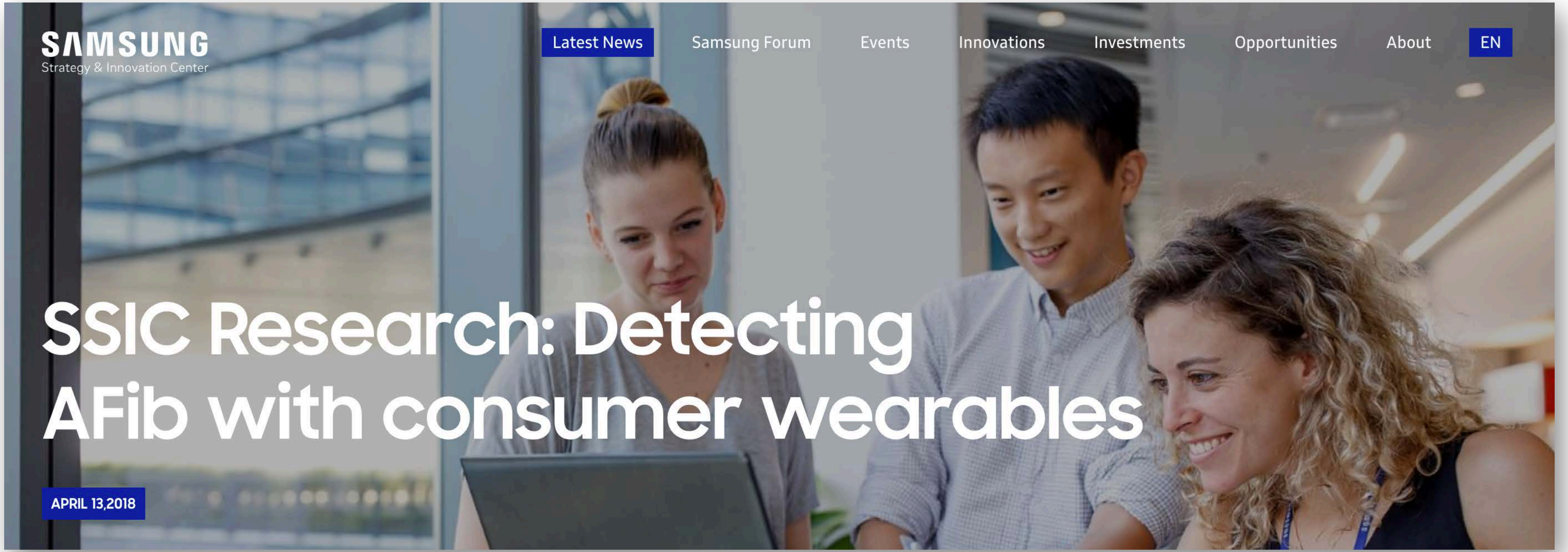


Afib on ECG Patch	Total Positive Tachograms	PPV* (97.5% CI)
1,489	2,089	0.71 (0.69–0.74)

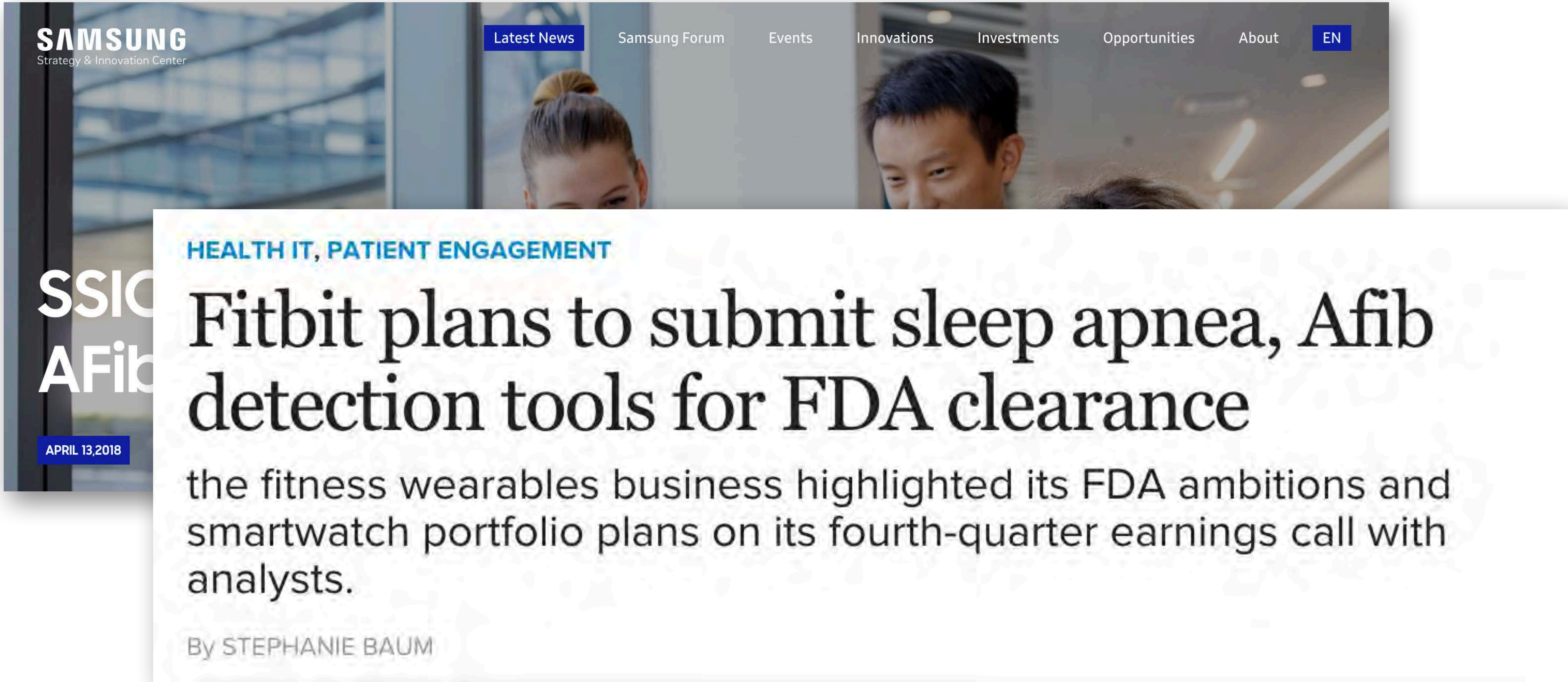
Irregular Pulse Notifications



Afib on ECG Patch	Total Positive Notifications	PPV (95% CI)
72	86	0.84 (0.76–0.92)



All public data (samsung.com, medcitynews.com, clinicaltrials.gov, fastcompany.com)



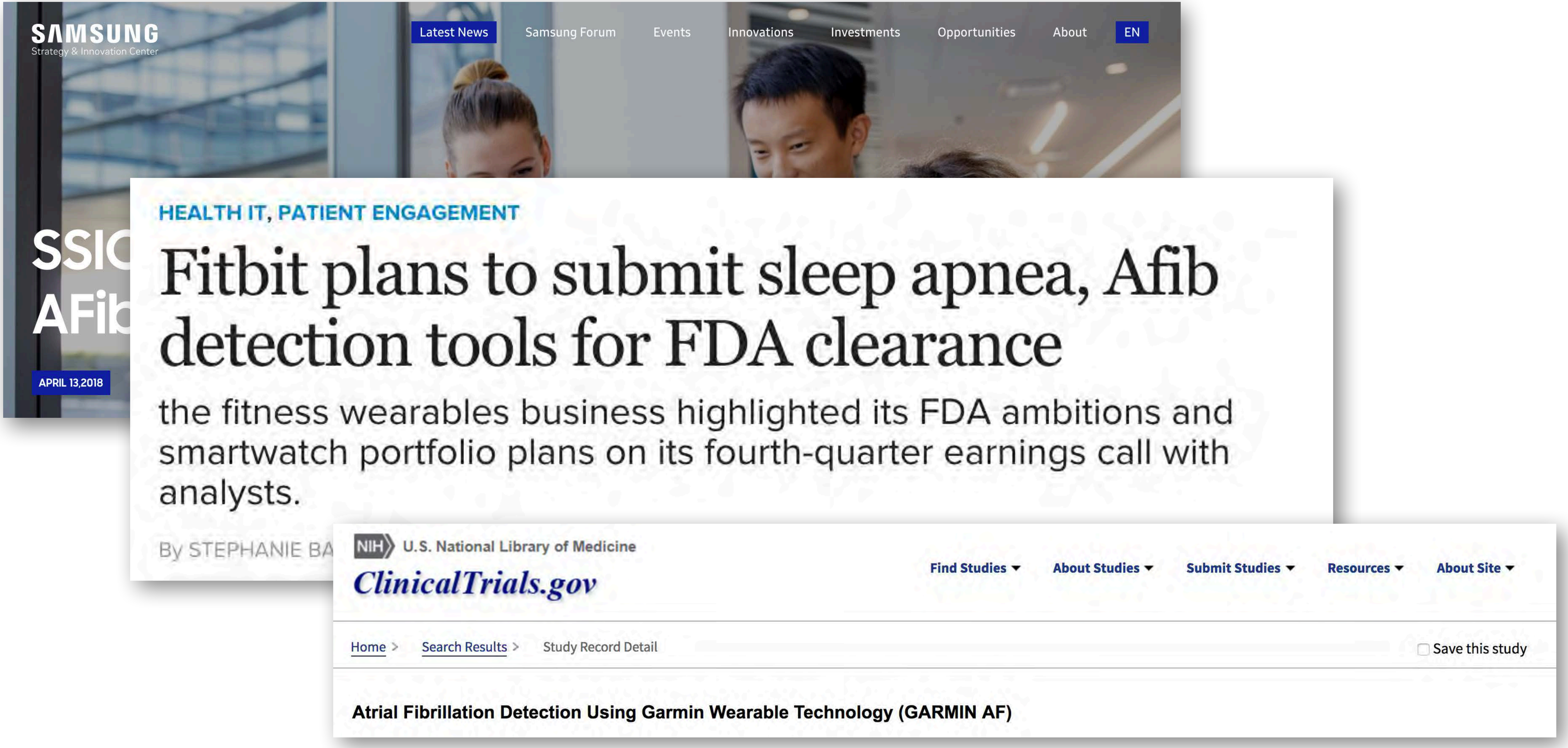
HEALTH IT, PATIENT ENGAGEMENT

Fitbit plans to submit sleep apnea, Afib detection tools for FDA clearance

the fitness wearables business highlighted its FDA ambitions and smartwatch portfolio plans on its fourth-quarter earnings call with analysts.

By STEPHANIE BAUM

All public data (samsung.com, medcitynews.com, clinicaltrials.gov, fastcompany.com)



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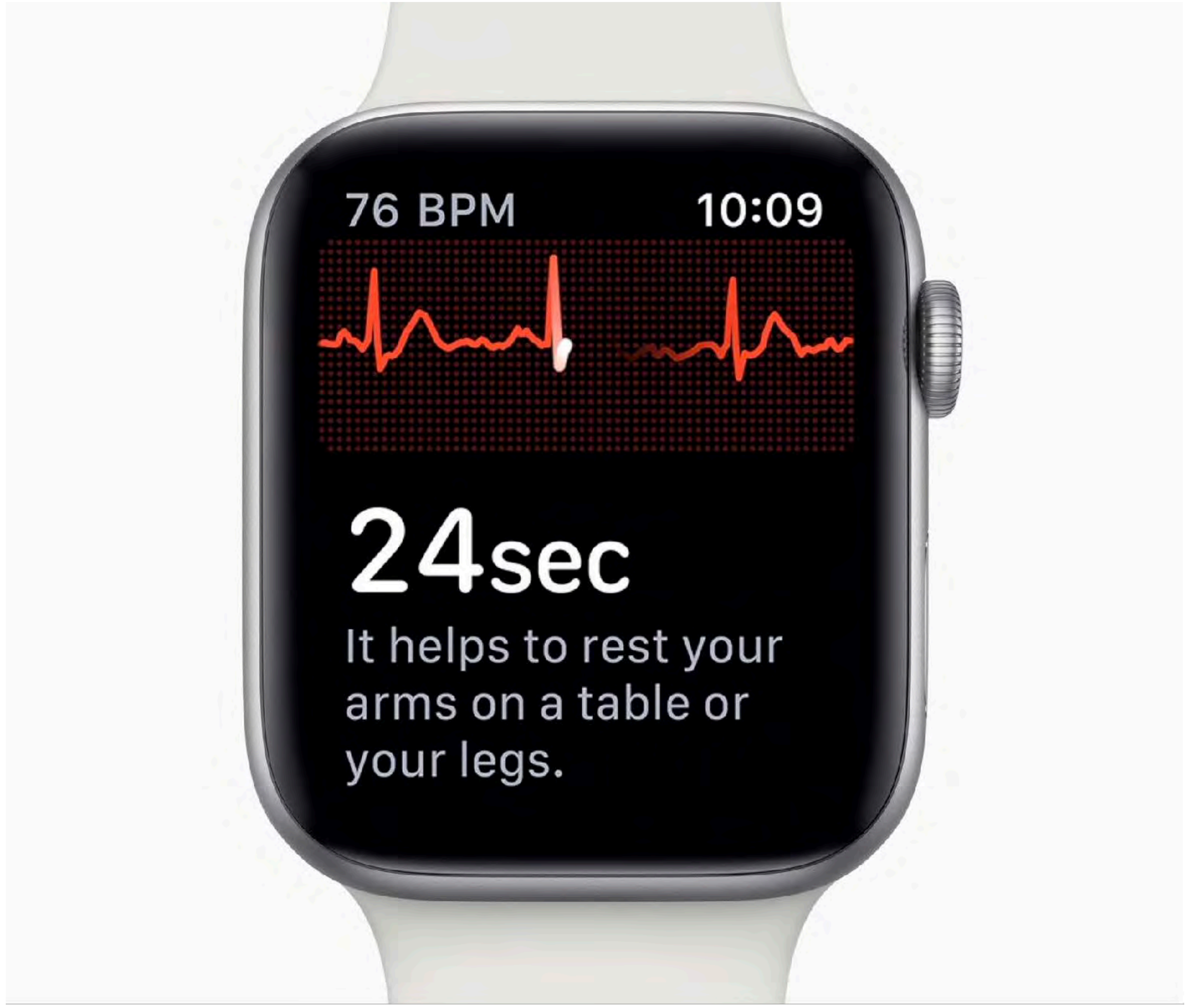

www.apple.com

Courtesy of JK Han MD

US005351695A

United States Patent [19]

Mills et al.

[11] **Patent Number: 5,351,695**

[45] **Date of Patent: Oct. 4, 1994**

[54] **WRIST WORN ECG MONITOR**

[75] Inventors: **Gary N. Mills,** Gladstone; **Habib Homayoun,** Aloha, both of Oreg.

[73] Assignee: **Instromedix, Inc.,** Hillsboro, Oreg.

[21] Appl. No.: **1,748**

[22] Filed: **Jan. 7, 1993**

Related U.S. Application Data

[62] Division of Ser. No. 816,389, Dec. 26, 1991, Pat. No. 5,289,824.

[51] **Int. Cl.**[5] **A61B 5/0428**

[52] **U.S. Cl.** **128/696;** 128/702; 128/901

[58] **Field of Search** 128/696, 901, 702, 710

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Primary Examiner—Lee S. Cohen
Assistant Examiner—Jeffrey R. Jastrzab
Attorney, Agent, or Firm—Kolisch Hartwell Dickinson McCormack & Heuser

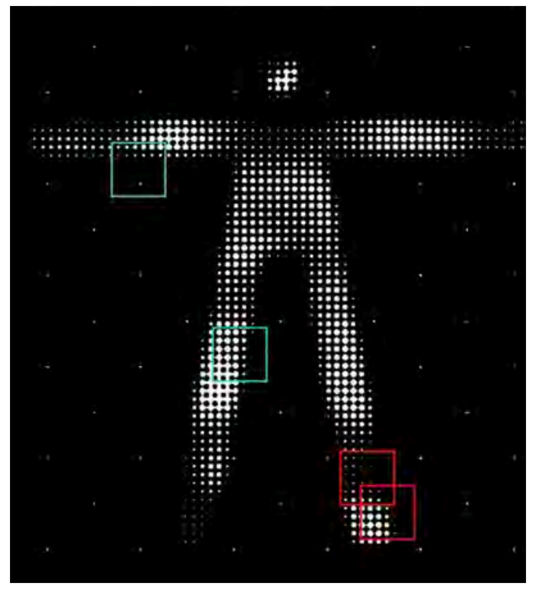
[57] **ABSTRACT**

A compact, lightweight wrist-worn cardiac data and event monitor having dry skin electrodes integral with the monitor's housing is disclosed. Preferably, the skin electrodes are made of titanium nitride-plated stainless steel and form inner, wrist-contacting, and outer, other hand's palm-contactable regions of the housing. Chronometric and other multiple functions are provided to increase the functional density of the monitor by partitioning and very-large-scale-integrating the circuitry, which includes signal detection; data conversion, storage, display and telecommunication; and external push-button controls operable by the patient's other hand. In accordance with the preferred embodiment, a telephonic transmitter is integrally included within the housing for remote diagnostic purposes without the need for external connections. By a preferred method of the invention, a simplified digital filter implemented in firmware ensures that only ECG and event data are recorded at the exclusion of noise and motion artifacts. By another preferred method of the invention, a battery life prediction method is used to extend the useful life of the battery and to indicate to the patient when the battery should be replaced. Event data that may be recorded and tele-transmitted along with the ECG data include time-of-day or elapsed time markers, as well as markers or indications of the detection of any pulses produced, for example, by an implanted pacemaker or an implanted cardio-verter/defibrillator monitor (ICDM).

16 Claims, 6 Drawing Sheets

Courtesy of JK Han MD

Courtesy of JK Han MD



nature medicine
FOCUS | LETTERS
https://doi.org/10.1038/s41591-018-0268-3
Corrected: Publisher Correction

Cardiologist-level arrhythmia detection and classification in ambulatory electrocardiograms using a deep neural network

Awni Y. Hannun[1,6*], Pranav Rajpurkar[1,6], Masoumeh Haghpanahi[2,6], Geoffrey H. Tison[3,6], Codie Bourn[2], Mintu P. Turakhia[4,5] and Andrew Y. Ng[1]

Researchers used portable ECG devices to collect 30,000 30-second clips from patients with varying forms of arrhythmia.

n=64K rhythm strips

Hannun AY, *et al.* Nature Medicine, 2019

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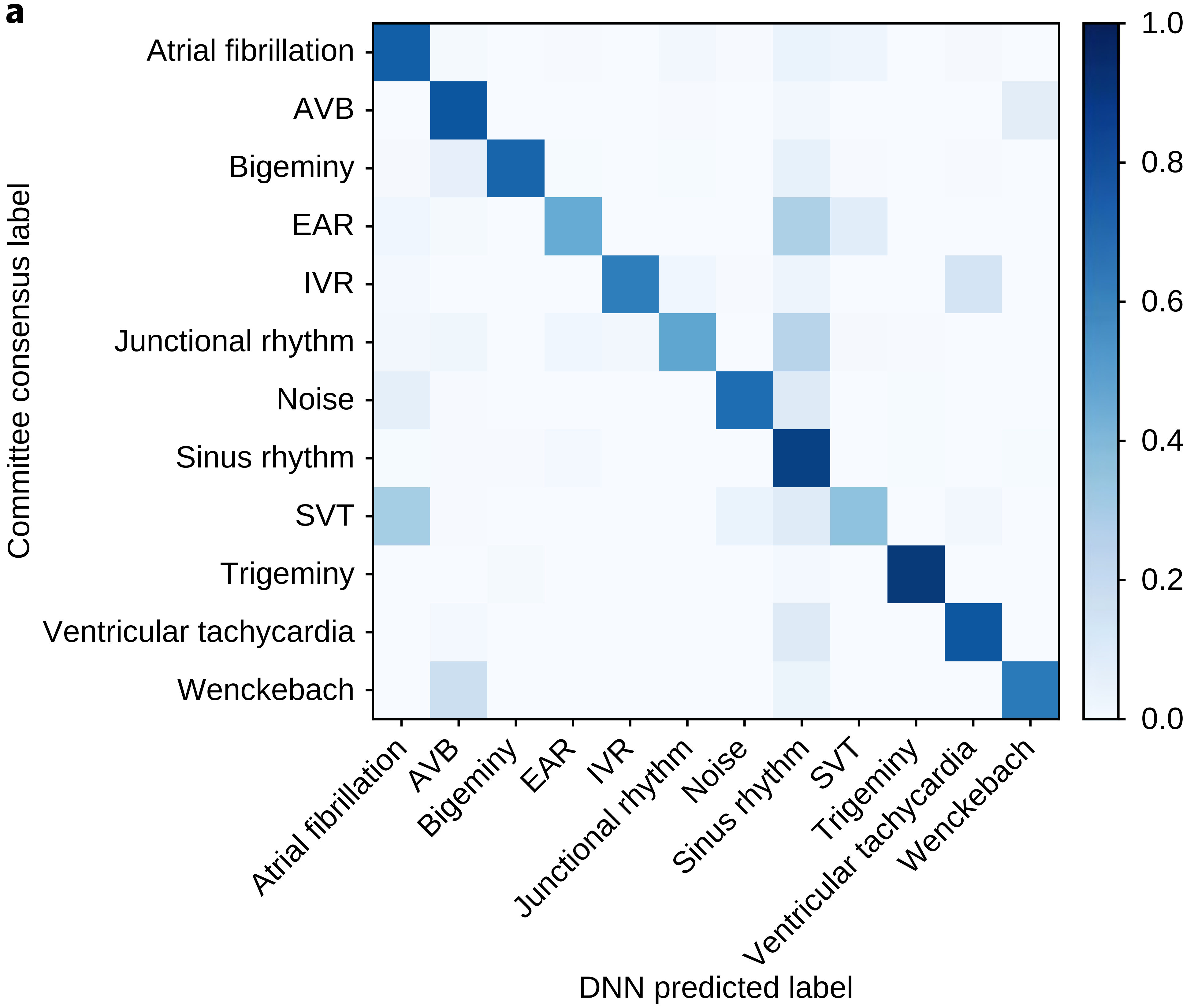

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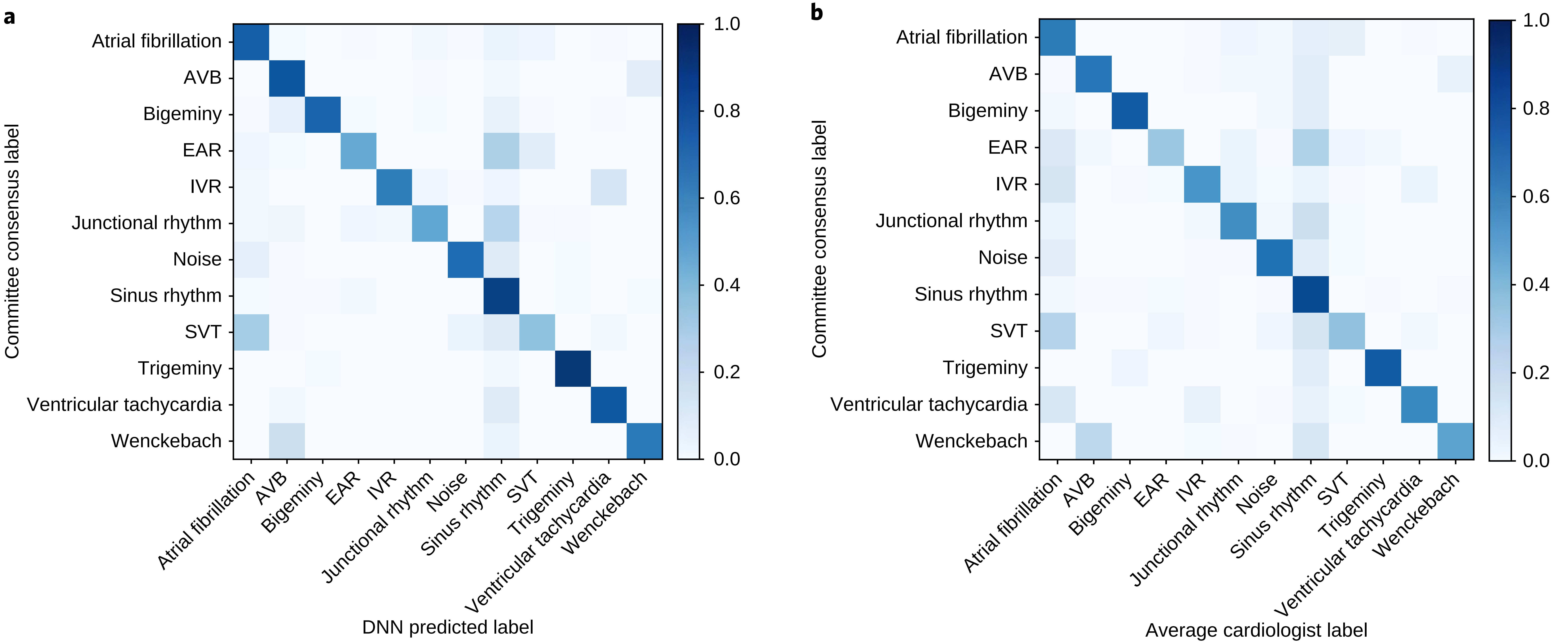
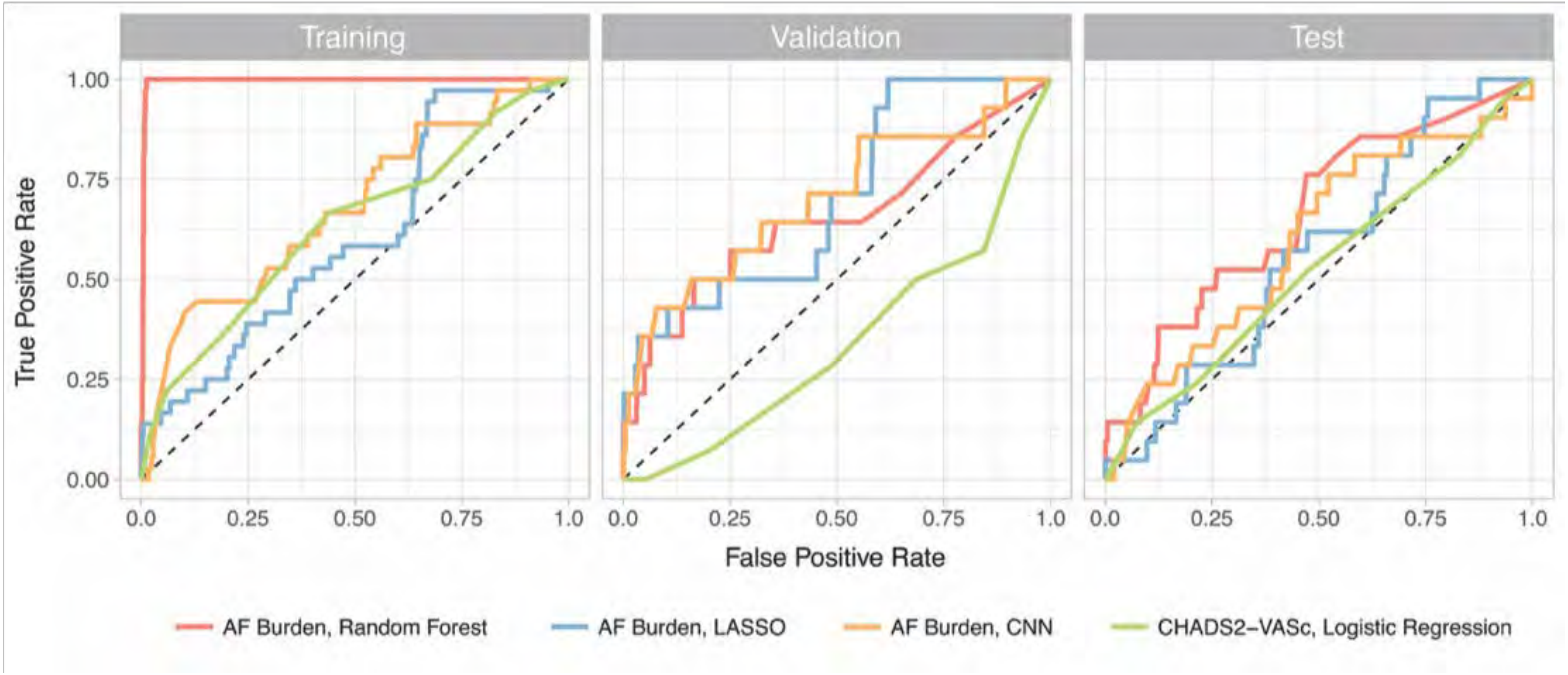


Hannun AY, *et al.* Nature Medicine, 2019

AF burden-based prediction of stroke

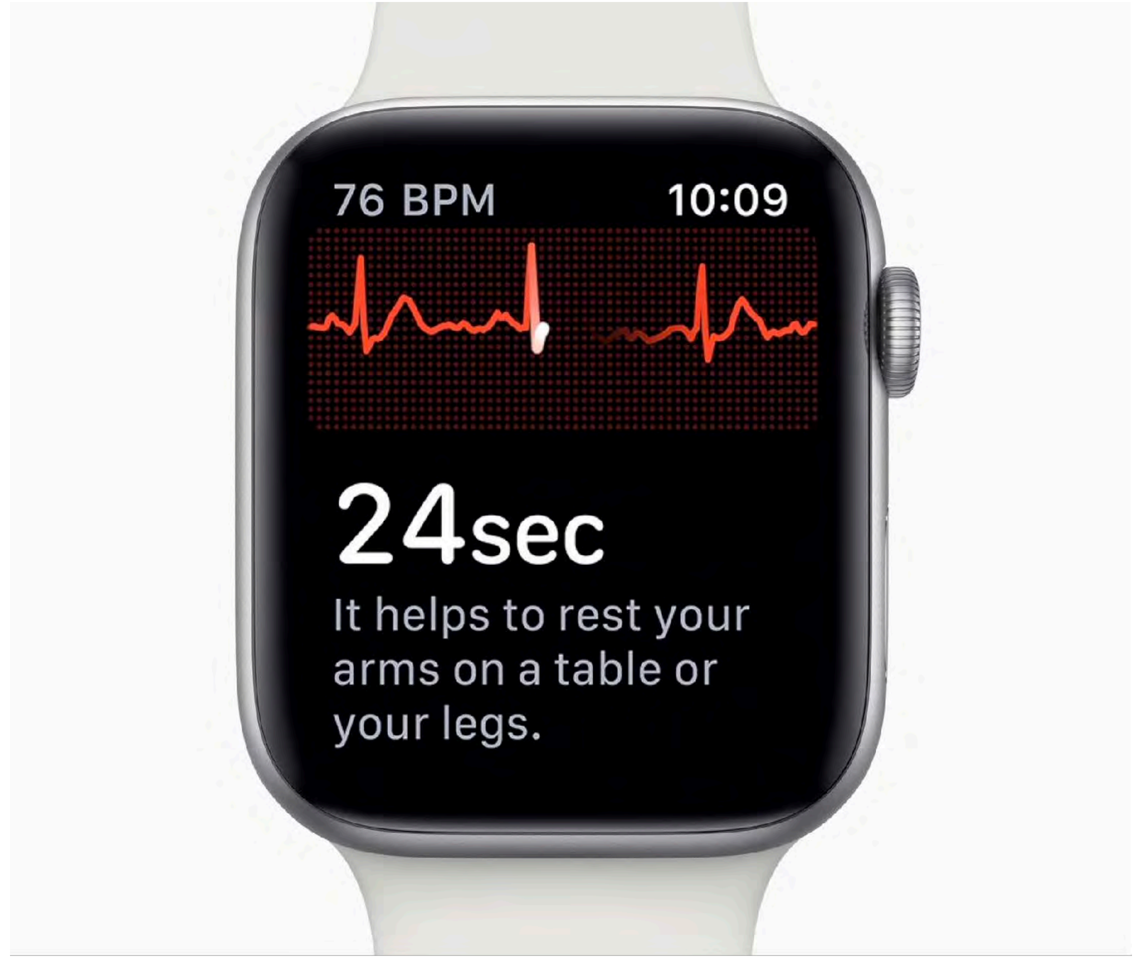


Han LY, et al. Presented.

REACT II trial

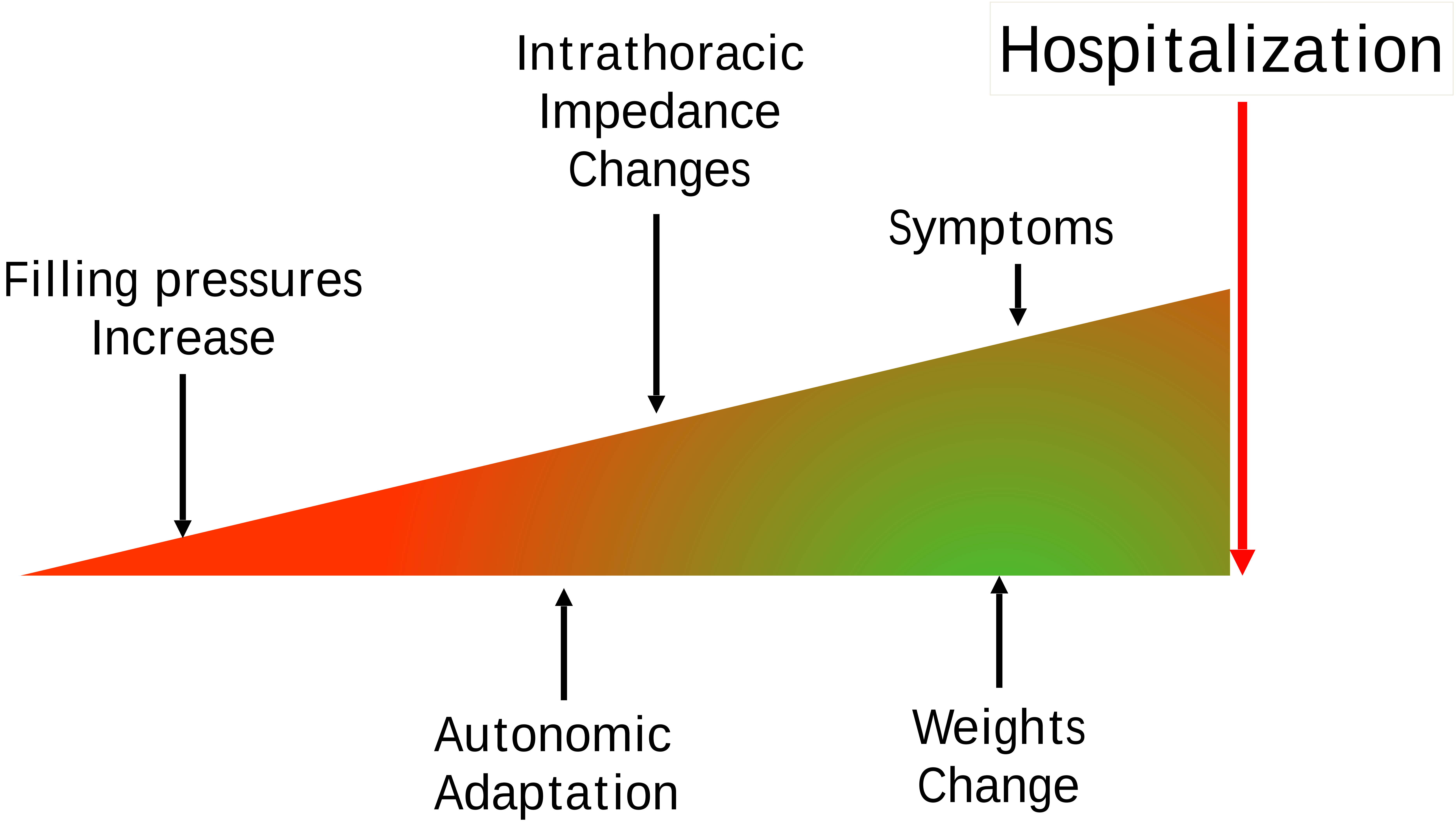
- Paroxysmal AF with CHA2DS2VASC of 2-4 randomized to daily NOAC (usual care) vs rhythm-guided OAC using **wearables**

- 5000 patients, up to 4 years of follow-up



NIH trial proposal; PIs Passman, Hanley, Turakhia

Sensor-based model of congestion



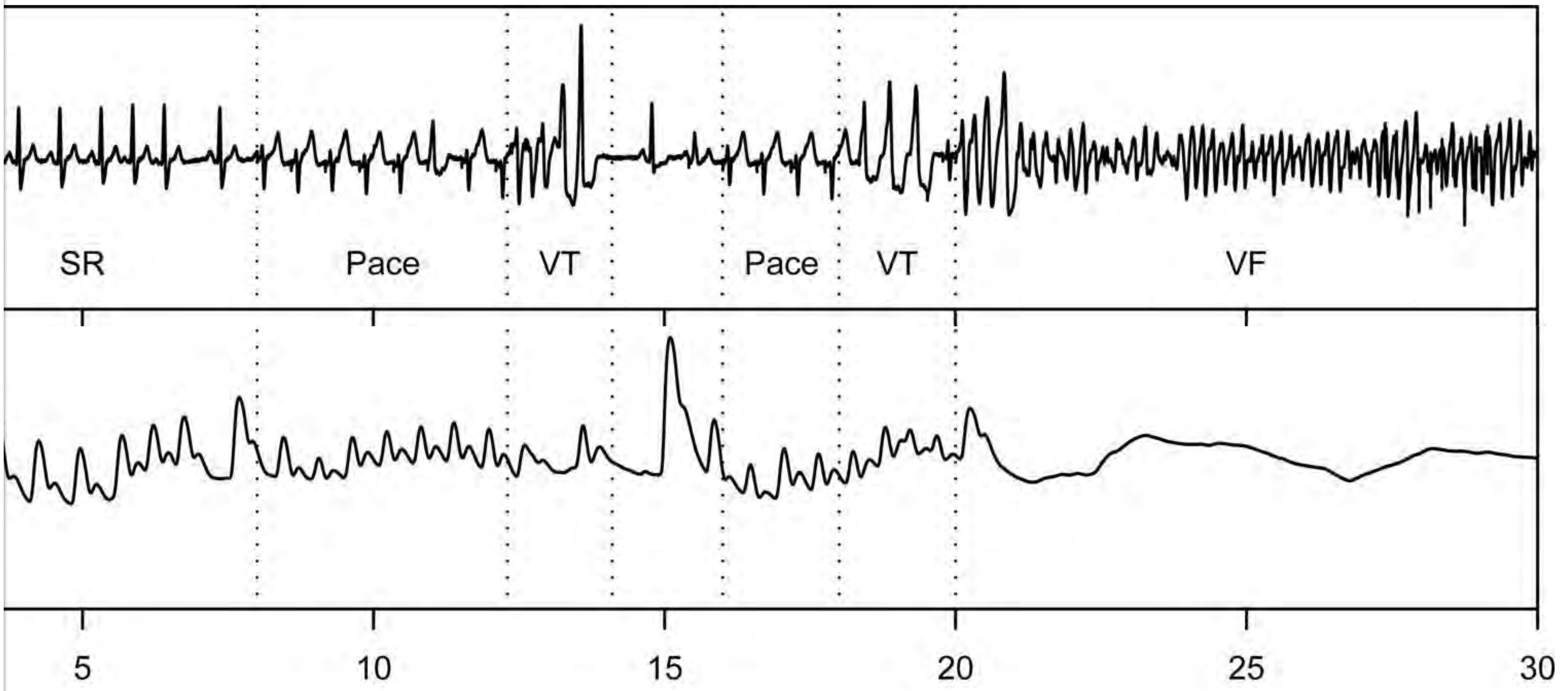
Adamson PB *Current HF Reports* 2009


ECG
PPG
VT
SR
Pace
VT
Pace
VT
VF
0
5
10
15
20
25
30

Monitor & Detect

Dispatch

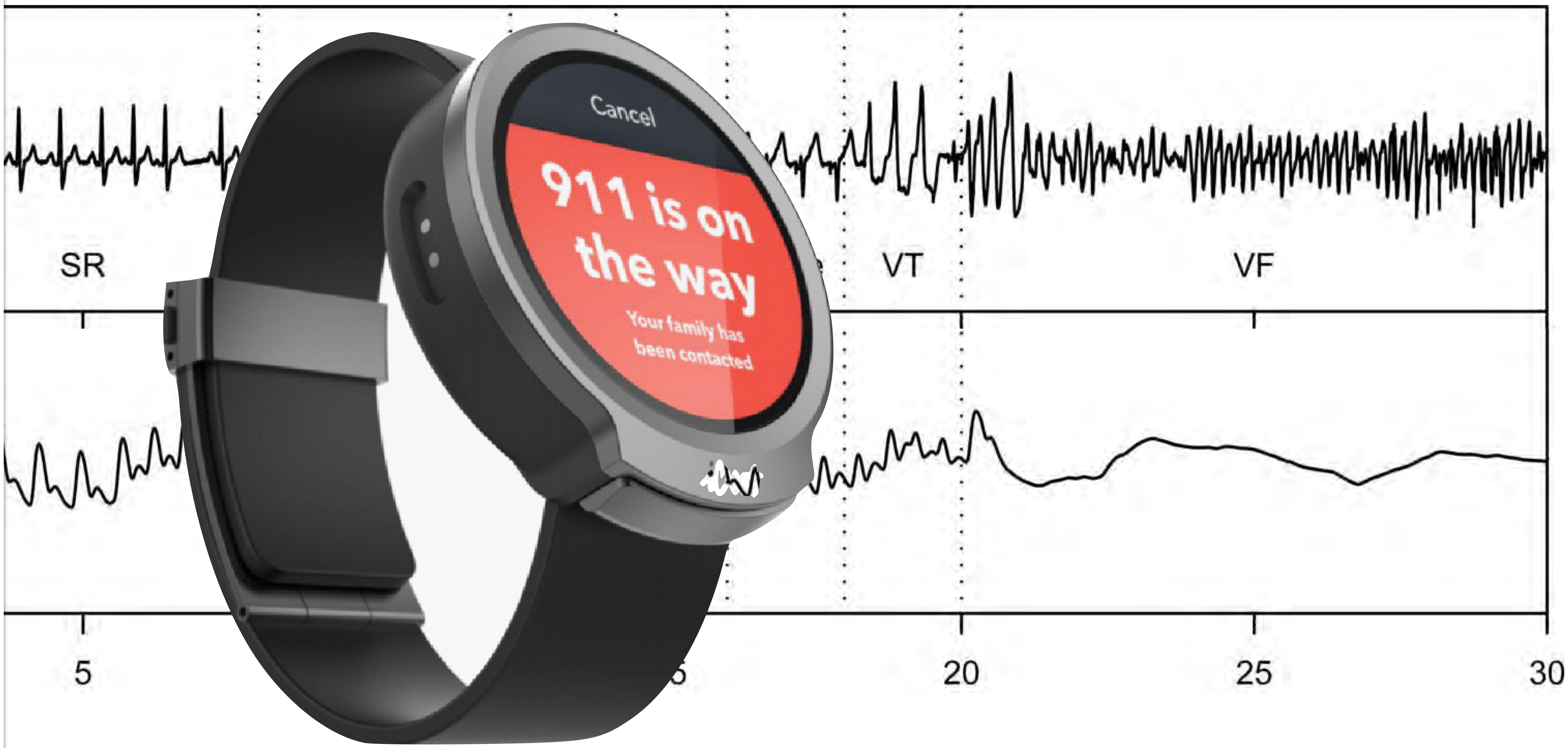
Notify



Monitor & Detect

Dispatch

Notify



Monitor & Detect

Dispatch

Notify

Monitor & Detect

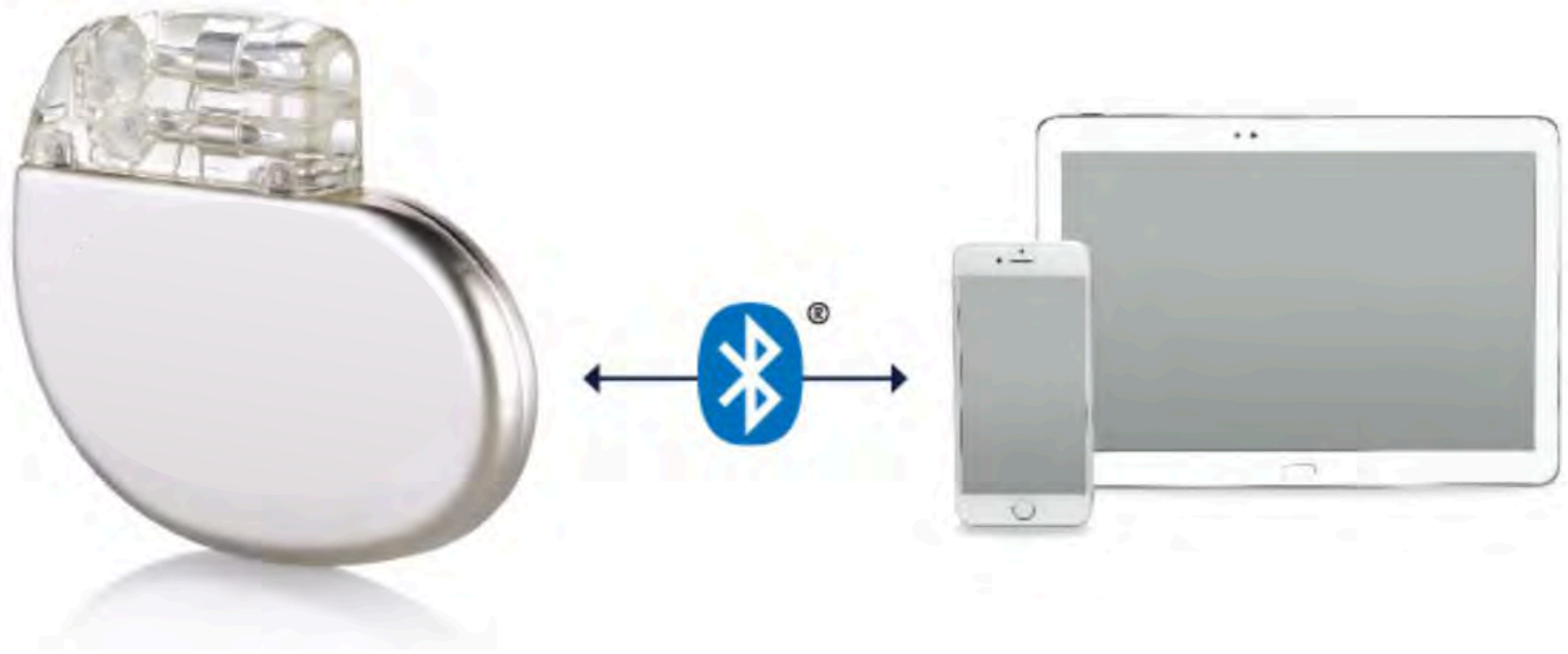
Dispatch

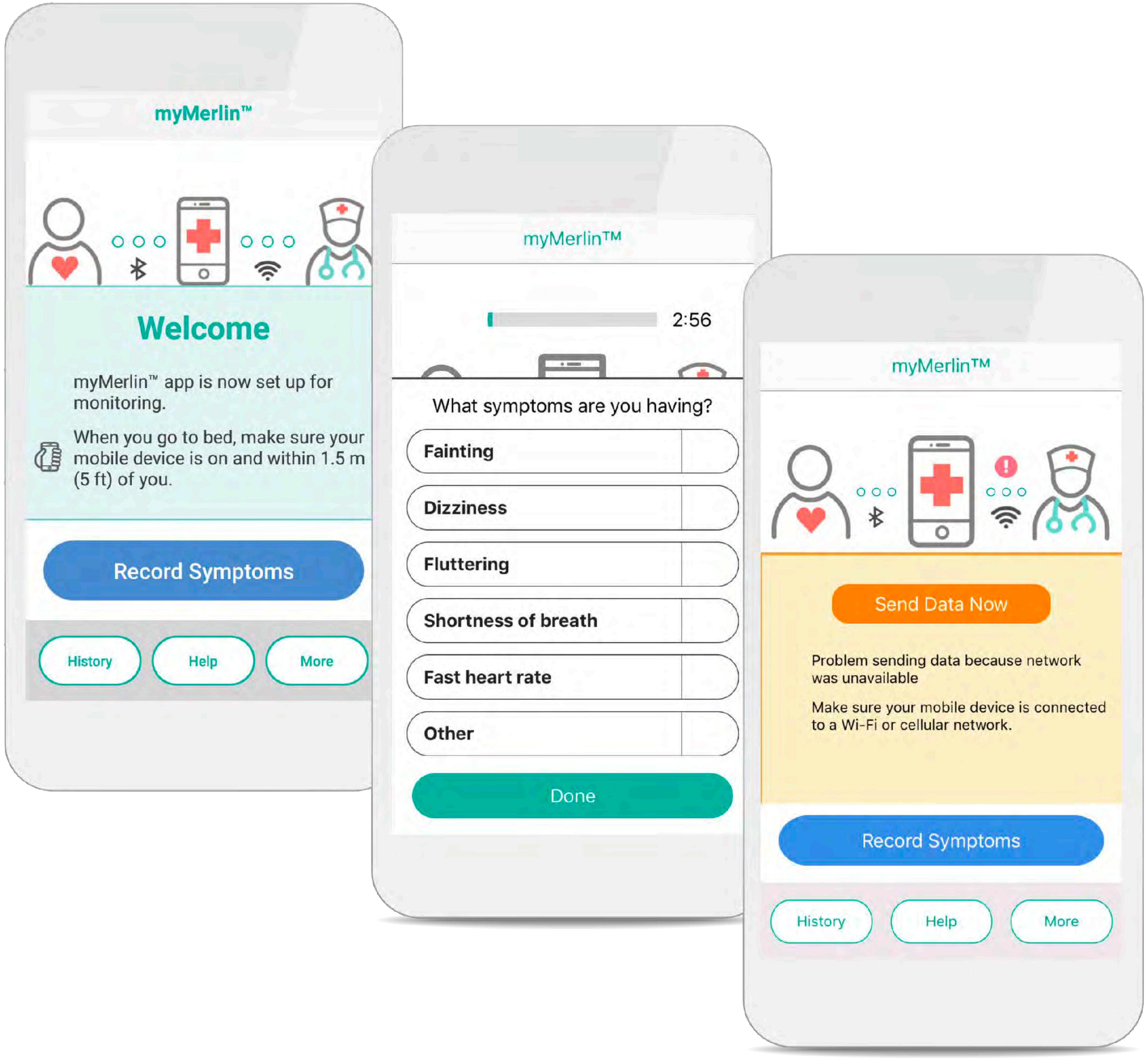
Notify

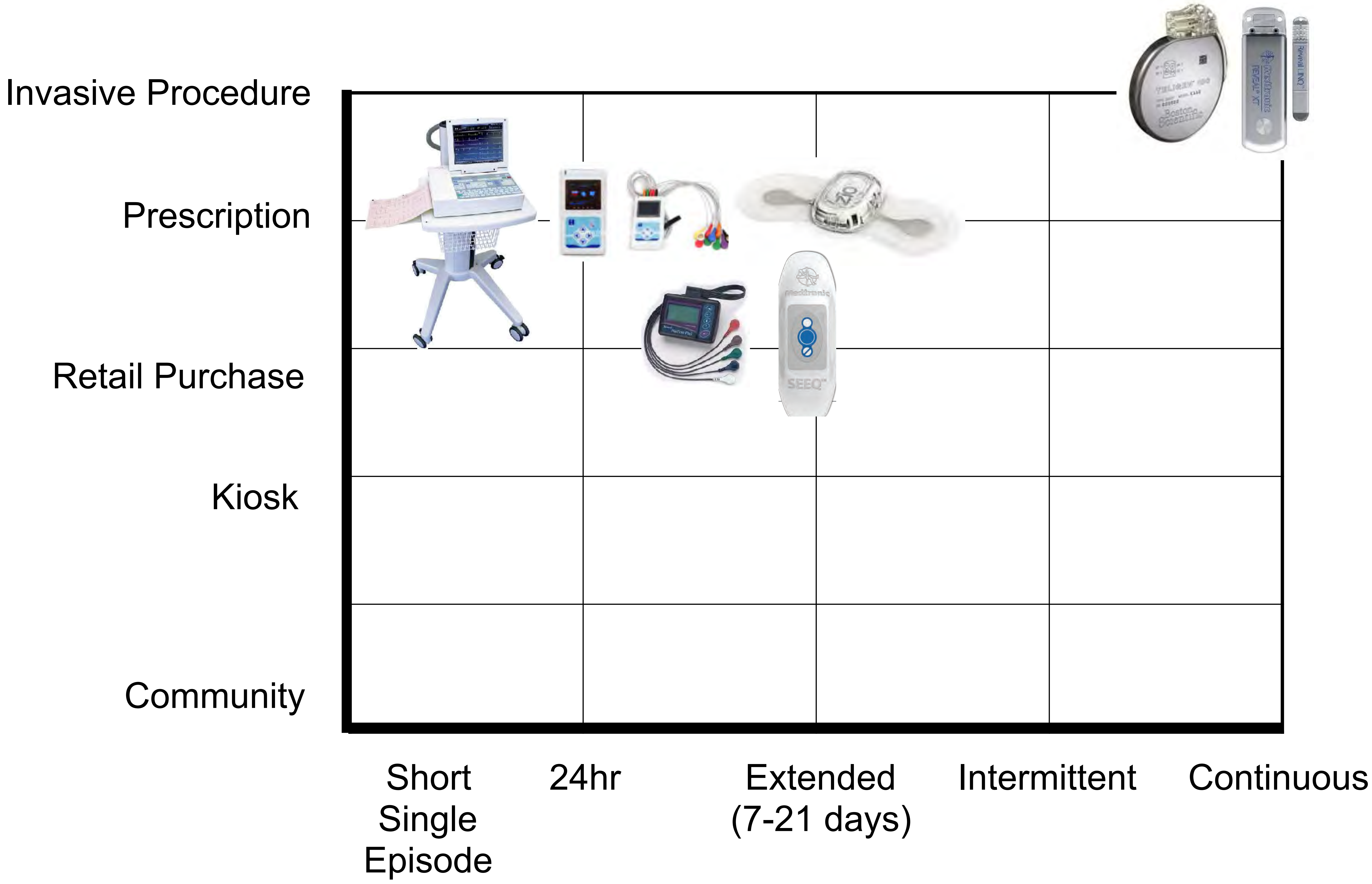
Bluetooth™

4.0

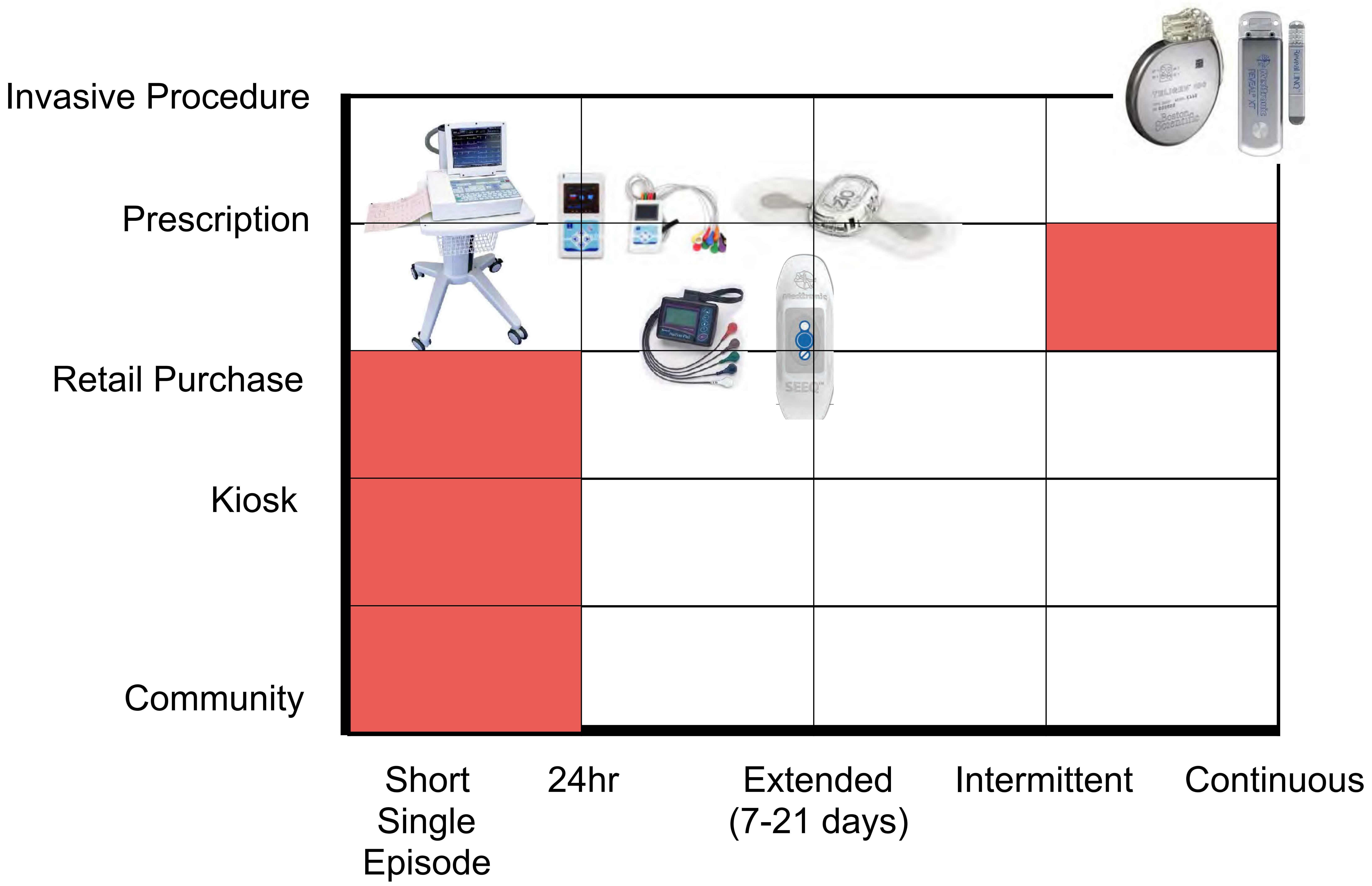
Low Energy



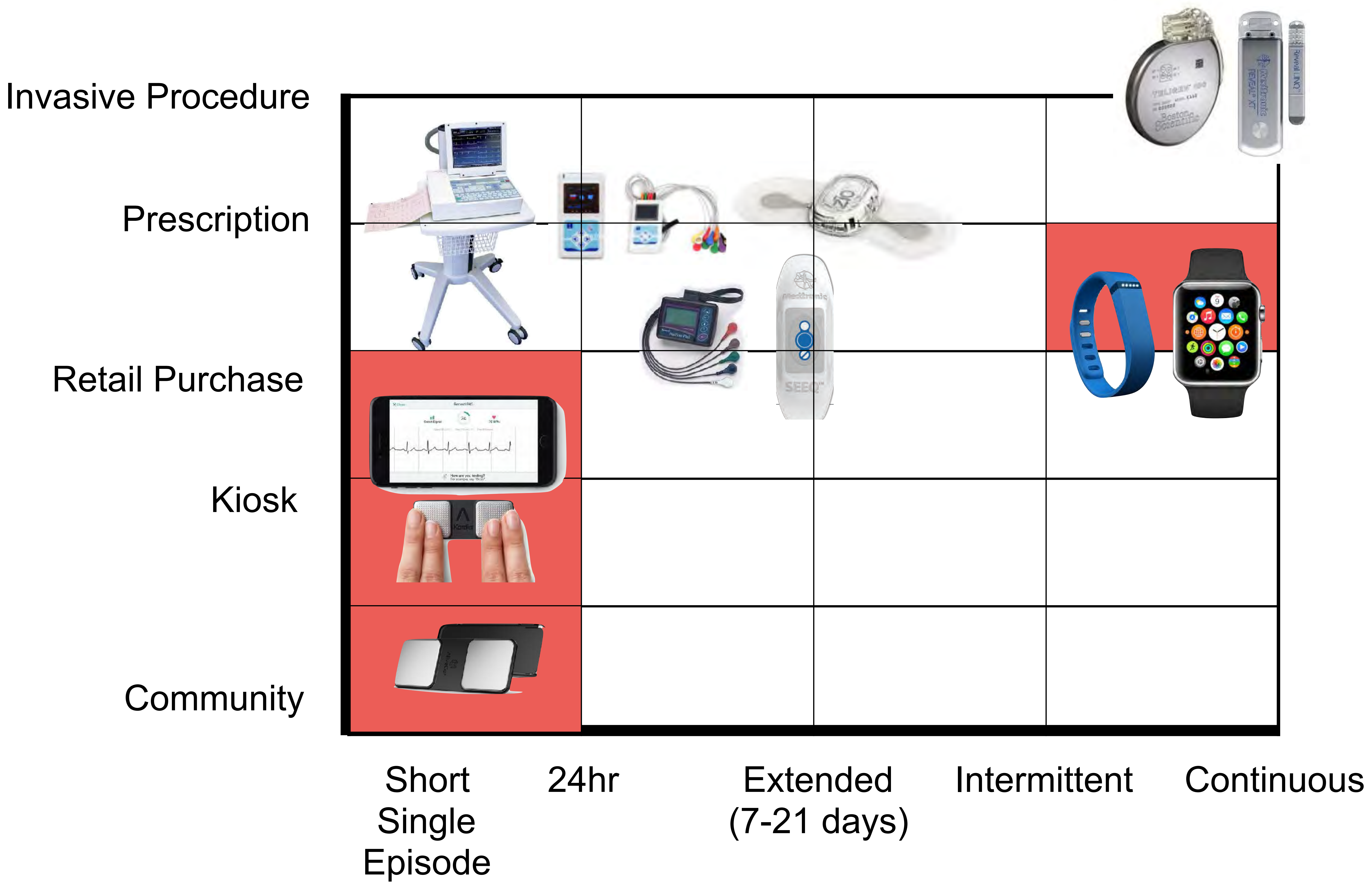

myMerlin™
Welcome
myMerlin™ app is now set up for monitoring.
When you go to bed, make sure your mobile device is on and within 1.5 m (5 ft) of you.
Record Symptoms
History
Help
More
myMerlin™
2:56
What symptoms are you having?
Fainting
Dizziness
Fluttering
Shortness of breath
Fast heart rate
Other
Done
myMerlin™
Send Data Now
Problem sending data because network was unavailable
Make sure your mobile device is connected to a Wi-Fi or cellular network.
Record Symptoms
History
Help
More



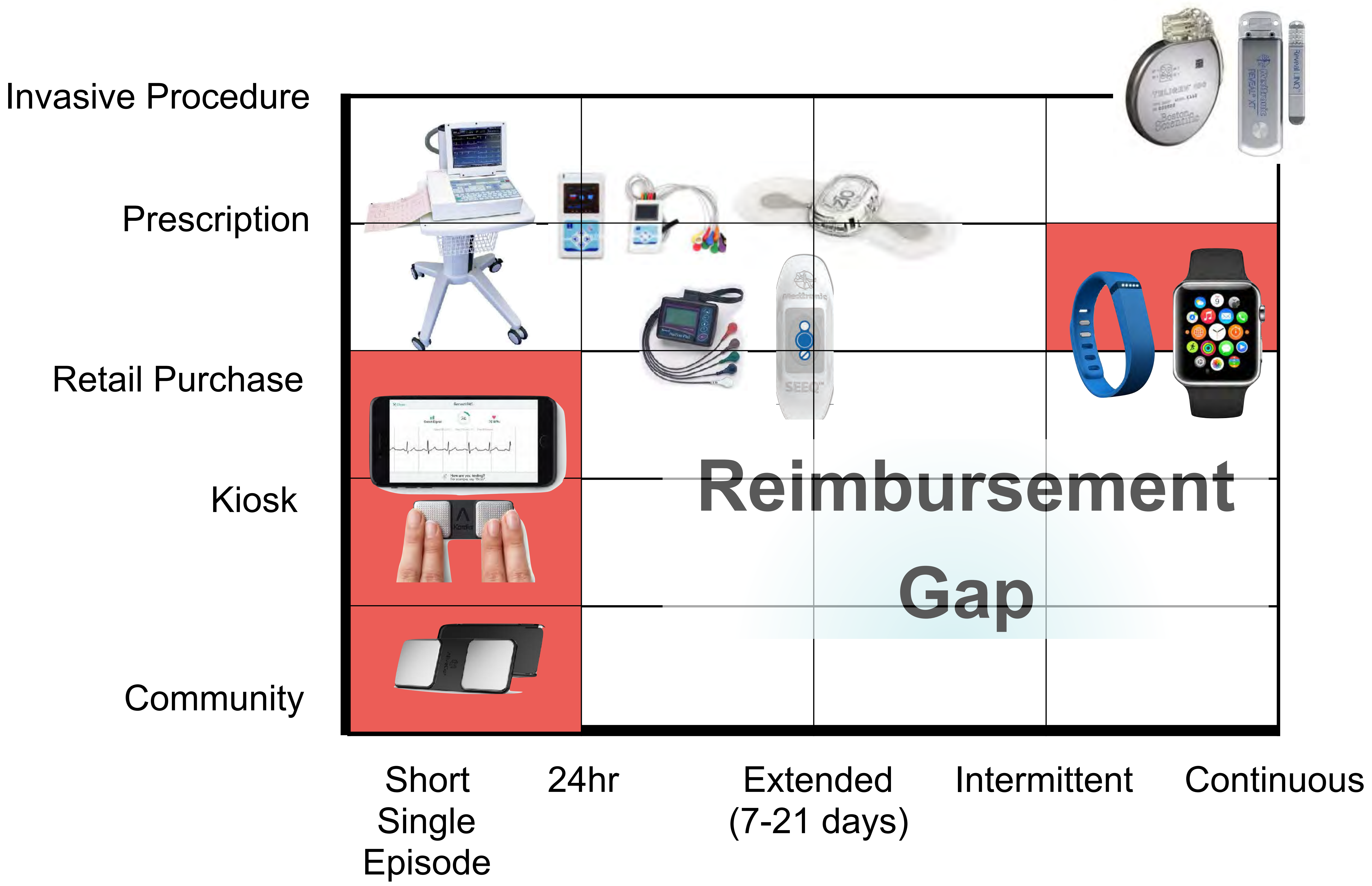
Kaiser DK / Turakhia M, *JICE* 2016



Kaiser DK / Turakhia M, *JICE* 2016



Kaiser DK / Turakhia M, *JICE* 2016



Kaiser DK / Turakhia M, *JICE* 2016

Some things just don't work

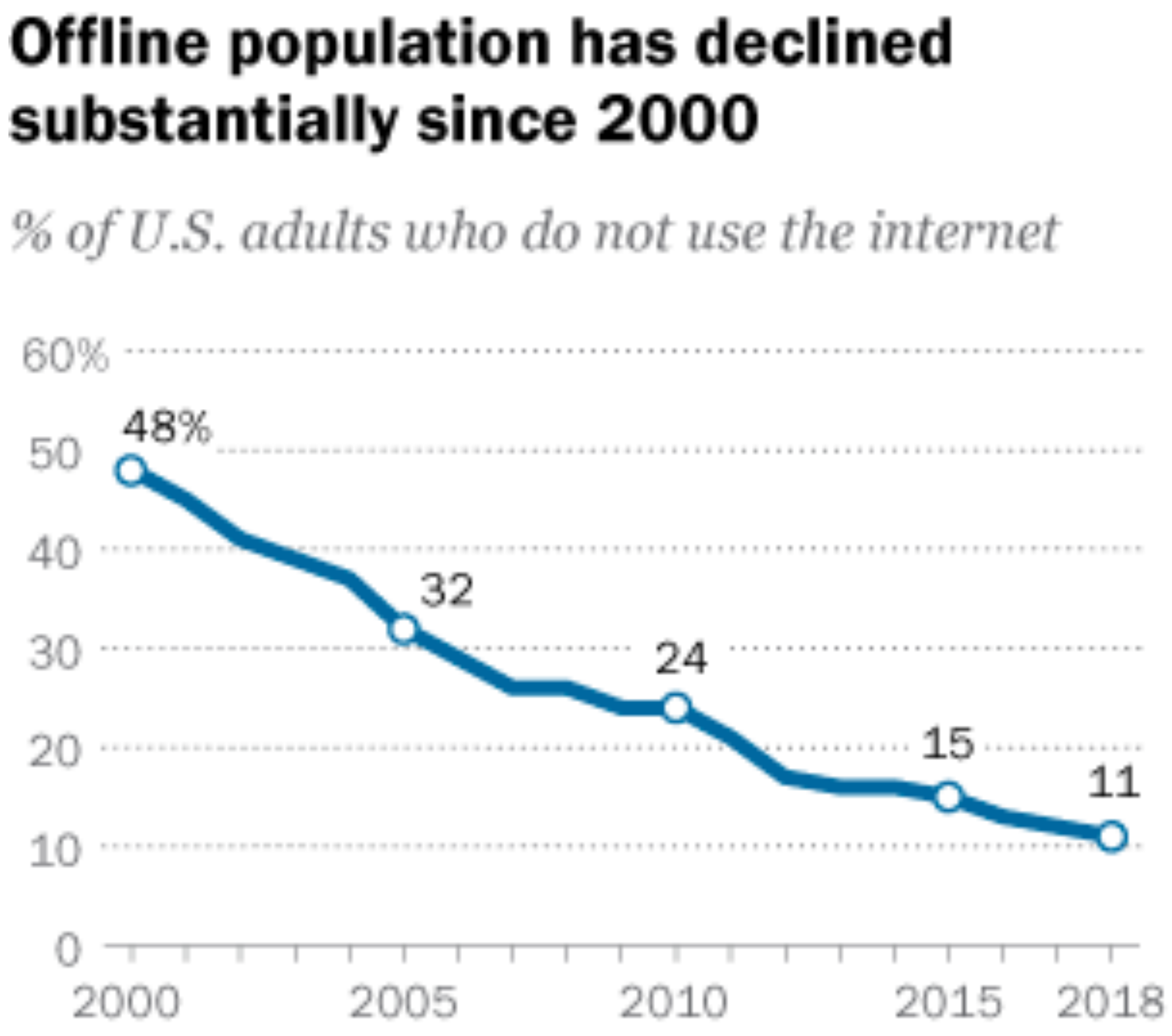
Connectivity

Health-Tracking Startup Fails to Deliver on Its Ambitions

Quanttus spent several years trying to track blood pressure at the wrist, but doing so appears to be even more difficult than the company thought.

by Rachel Metz March 15, 2016

Quanttus, Scanadu



Pew Research, January 2018


752254


752254


752254


amazon
BEST BUY

The telehealth market (distilled)

MDLIVE

American Well

TELADOC

LEMONAID

PlushCare

heal

dr. on demand

FORWARD

In closing

- Wearables have moved beyond "wellness" into rhythm assessment as a prediagnostic or diagnostic
- Integration into clinical care is an unknown
- ECG remains the gold standard
- New challenges and opportunities with brand new uses cases and strategic integration into consumer tech

JAMA Insights | Clinical Update

March 19, 2019

Evaluation of Cardiac Rhythm Abnormalities From Wearable Devices

James E. Ip, MD[1]

» Author Affiliations | Article Information

JAMA. 2019;321(11):1098-1099. doi:10.1001/jama.2019.1681

ATRIAL FIBRILLATION (AF)

An AF alert could be a false positive from irregular rhythm detection by the photoplethysmographic (PPG) sensor

- ☐ **Confirm rhythm with electrocardiogram (ECG) to rule out ectopic rhythms or variable atrioventricular nodal conduction**

  This may involve ambulatory ECG monitoring

If not AF

- ☐ Evaluate for any relevant symptoms (ie, palpitations, exertional dyspnea, presyncope, and syncope)
- ☐ Consider 24-hour Holter monitor if frequent premature ventricular contractions are detected

If AF is confirmed

- ☐ Consider ambulatory ECG monitoring to assess AF burden, heart rates during AF, and correlation with symptoms
- ☐ Consider risk factors for thromboembolism and risks vs benefits of anticoagulation
- ☐ Evaluate for structural heart disease
- ☐ Determine optimal strategy of rate vs rhythm control depending on patient's symptoms
- ☐ Consider referral for further management if indicated

TACHYCARDIA

Beware of inaccurate measurements due to limitations of the PPG-based sensor

- ☐ **Assess if heart rate is appropriate (ie, related to stress, anxiety, pain, infection, dehydration, pregnancy, or medication) or inappropriate and if proportional to baseline physical conditioning**
- ☐ **Evaluate for any underlying comorbidities (ie, cardiac, pulmonary, hematologic, infectious, hormonal, or oncologic conditions)**

If tachycardia is paroxysmal

- ☐ Obtain baseline ECG to evaluate for ventricular preexcitation, obtain ECG during tachycardia, and consider long-term ambulatory ECG monitoring
- ☐ Assess symptoms and evaluate for structural heart disease
- ☐ Consider referral for further management if indicated

BRADYCARDIA

Chronotropic incompetence does not trigger a notification

- ☐ **Determine if bradycardia is primary or secondary (ie, related to medication, hypothyroidism, or infection)**

If bradycardia is detected at rest

- ☐ Confirm with ECG
- ☐ Evaluate heart rate acceleration with exercise (heart rate trends, exercise treadmill testing, or ambulatory ECG monitoring)
  - ☐ **If adequate** ▸ Assess physical fitness to consider enhanced vagal tone; consider evaluation for sleep apnea, especially if bradycardia occurs only during rest
  - ☐ **If inadequate** ▸ Consider intrinsic cardiac electrical disease or secondary cause; consider referral for pacemaker

If primary electrical disease

- ☐ Evaluate for structural heart disease
- ☐ Assess for symptoms that correlate with bradycardia (ie, syncope, presyncope, or exertional tolerance)
  - ☐ **If symptoms** ▸ Consider referral for pacemaker
  - ☐ **If no symptoms** ▸ Consider ambulatory ECG monitoring; consider exercise treadmill test to unmask chronotropic incompetence

Ip, J. *JAMA*. 2019

STANFORD CENTER FOR DIGITAL HEALTH

mintu@stanford.edu
@leftbundle

Thank you!

Wearables and the Transformation of Care of the Arrhythmia Patient

Khaldoun G. Tarakji, MD MPH

@khaldountarakji

Associate Section Head, Section of Cardiac Electrophysiology

Director, Center for Digital Health, Heart and Vascular Institute

Director, Center for International Medical Education, Education Institute

Cleveland Clinic, Cleveland Ohio

Cleveland Clinic

Medical and Consumer Wearables for Arrhythmia Detection

May 9th, 2019

San Francisco, CA

Disclosures:
Consulting / Medical Advisory Board: Medtronic, AliveCor


Online Banking
Transactions
Service
Checking Account
5 304.02
Account Number
Direct Deposit
Debit Withdrawal
Debit Withdrawal
Direct Deposit
Saving Account
Savings Book
Transfer Money
Standing Order
Savings Plan
Messages
Settings
Log Out

Technology

OPINION | COMMENTARY

The New York Times

Siri, Am I About to Have a Heart Attack?

Big data could provide early warning of disease—if medical records can learn to talk to one other.

By Andy Kessler

Jan. 9, 2017 7:16 p.m. ET

ObamaCare was always about paying for health care—costs have outpaced inflation for decades—but seldom about keeping people healthy. As Republicans repeal and replace, they need a vision for the path to better care. Technology now exists to provide cheaper and higher-quality health care, but giant roadblocks stand in the way.

SCIENCE

The New York Times

Redefining Medicine With Apps and iPads

By KATIE HAFNER OCT. 8, 2012

SAN FRANCISCO — Dr. Alvin Rajkomar was doing rounds with his team at the University of California, San Francisco Medical Center when he came upon a puzzling case: a frail, elderly patient with a dangerously low sodium level.

The Prediction

?

TIME

Why the Death of Malls Is About More Than Shopping

THE NEW YORKER

News Culture Books Business & Tech Humor Cartoons Magazine Video Podcasts Archive Goings On Subscribe

PERSONAL HISTORY

THE DEATH OF A MOVIE THEATRE

By Thomas Beller September 6, 2018

The New York Times

UDACITY Nanodegree

Want to Earn a Nanodegree in Tech?

The Opinion Pages

Skip Your Annual Physical

The New York Times

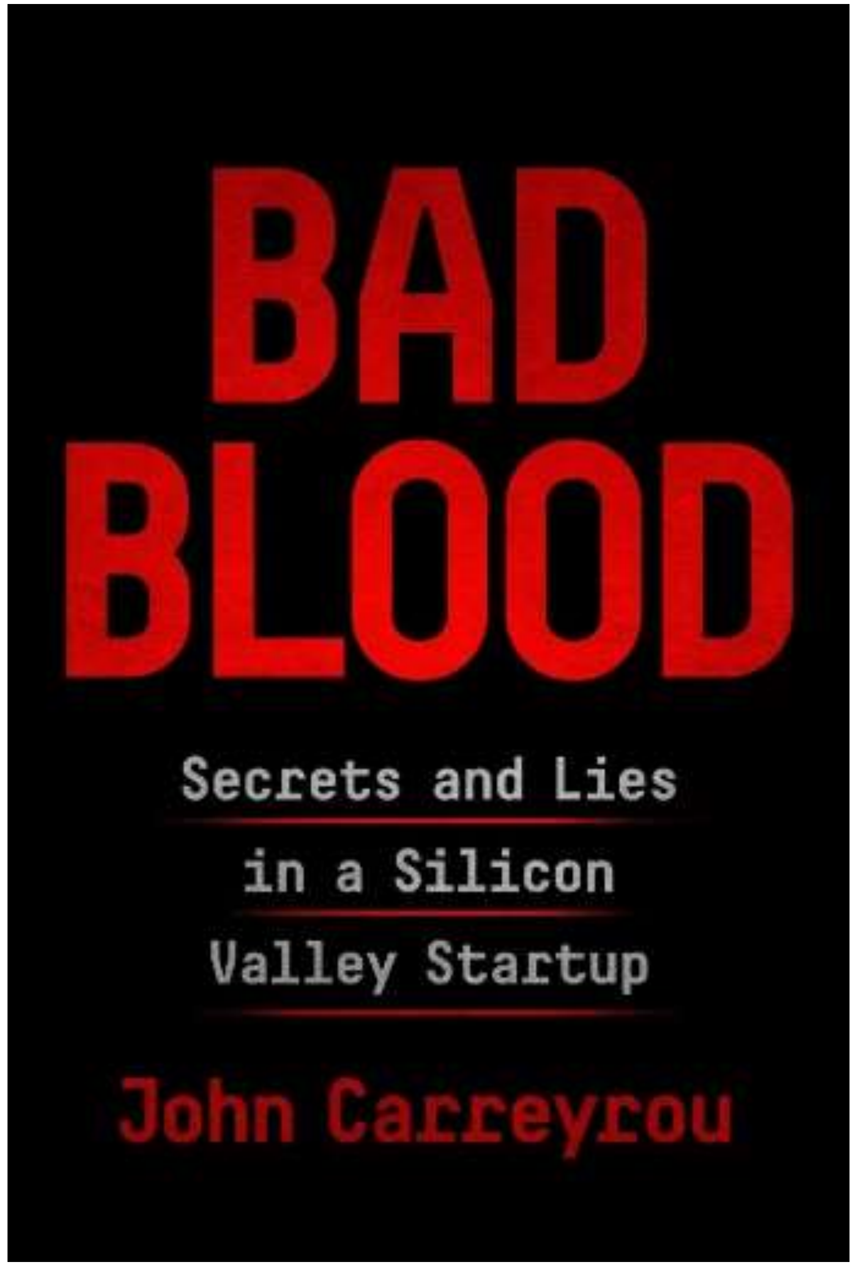
ASK WELL

Ask Well: Do I Need an Annual Physical?

By Karen Weintraub April 17, 2015 5:36 am

Physicians: The Concerns

Bad Precedents



Burnout


The NEW ENGLAND JOURNAL of MEDICINE

Perspective

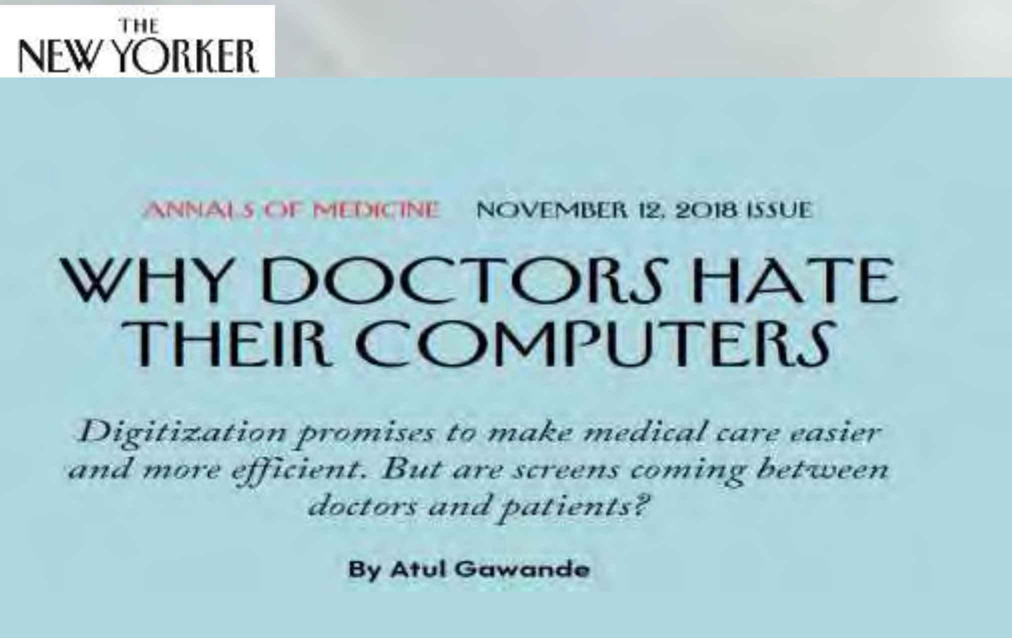
JANUARY 25, 2018

Beyond Burnout — Redesigning Care to Restore Meaning and Sanity for Physicians

Alexi A. Wright, M.D., M.P.H., and Ingrid T. Katz, M.D., M.H.S.

Burnout rates in Medicine are twice as high as in other fields

54% of US physicians reported at least 1 symptom of burnout


THE NEW YORKER

ANNALS OF MEDICINE NOVEMBER 12, 2018 ISSUE

WHY DOCTORS HATE THEIR COMPUTERS

Digitization promises to make medical care easier and more efficient. But are screens coming between doctors and patients?

By Atul Gawande

Scaring the healthy

Demanding 100% accuracy!

Main Stream and Social Media

New Apple watch saved my husbands life this week! Only two days old and it diagnosed A-Fib and 150bpm. He went to ER which he never did with same symptoms. Found major blockage in arteries as a result. Two stents later, he is as good as new! Telling the world. Thank U!

7:12 PM · 1/10/19 · Twitter for iPad

91 Retweets **834** Likes

Are Patients / Consumers Ready?

"You can't list your iPhone as your primary-care physician."

- > One-half of individuals who purchase a wearable device stop using it (one third of these before 6 months)

- The gap between recording information and changing behavior is substantial

The New York Times

DISRUPTIONS

Where Wearable Technology Ends Up (Hint: Not Your Wrist)

Pete Ryan

By Nick Bilton

JAMA | Original Investigation

Effect of Wearable Technology Combined With a Lifestyle Intervention on Long-term Weight Loss
The IDEA Randomized Clinical Trial

John M. Jakicic, PhD; Kelliann K. Davis, PhD; Renee J. Rogers, PhD; Wendy C. King, PhD; Marsha D. Marcus, PhD; Diane Helsel, PhD, RD; Amy D. Rickman, PhD, RD, LDN; Abdus S. Wahed, PhD; Steven H. Belle, PhD

IMPORTANCE Effective long-term treatments are needed to address the obesity epidemic. Numerous wearable technologies specific to physical activity and diet are available, but it is unclear if these are effective at improving weight loss.

OBJECTIVE To test the hypothesis that, compared with a standard behavioral weight loss intervention (standard intervention), a technology-enhanced weight loss intervention (enhanced intervention) would result in greater weight loss.

DESIGN, SETTING, PARTICIPANTS Randomized clinical trial conducted at the University of Pittsburgh and enrolling 471 adult participants between October 2010 and October 2012, with data collection completed by December 2014.

INTERVENTIONS Participants were placed on a low-calorie diet, prescribed increases in physical activity, and had group counseling sessions. At 6 months, the interventions added telephone counseling sessions, text message prompts, and access to study materials on a website. At 6 months, participants randomized to the standard intervention group initiated self-monitoring of diet and physical activity using a website, and those randomized to the enhanced intervention group were provided with a wearable device and accompanying web interface to monitor diet and physical activity.

MAIN OUTCOMES AND MEASURES The primary outcome of weight was measured over 24 months at 6-month intervals, and the primary hypothesis tested the change in weight between 2 groups at 24 months. Secondary outcomes included body composition, fitness, physical activity, and dietary intake.

RESULTS Among the 471 participants randomized (body mass index [BMI], 25 to <40; age range, 18-35 years; 28.9% nonwhite; 77.2% women), 470 (233 in the standard intervention group, 237 in the enhanced intervention group) initiated the interventions as randomized, and 74.5% completed the study. Weight change at 24 months differed significantly by intervention group (difference, 2.4 kg [95% CI, 1.0-3.7]; *P* = .002). Both groups had significant improvements in body composition, fitness, physical activity, and diet, with no significant difference between groups.

	Standard Intervention	Enhanced Intervention
Weight, mean (95% CI), kg		
Baseline	95.2 (93.0-97.3)	96.3 (94.2-98.5)
24 mo	92.8 (90.6-95.0)	89.3 (87.1-91.5)
Estimated weight loss, mean (95% CI), kg	5.9 (5.0-6.8)	3.5 (2.6-4.5)

CONCLUSIONS AND RELEVANCE Among young adults with a BMI between 25 and less than 40, the addition of a wearable technology device to a standard behavioral intervention resulted in less weight loss over 24 months. Devices that monitor and provide feedback on physical activity may not offer an advantage over standard behavioral weight loss approaches.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT01131871

Author Video Interview and JAMA Report Video

Supplemental content

Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: John M. Jakicic, PhD, University of Pittsburgh, Department of Health and Physical Activity, Physical Activity and Weight Management Research Center, 32 Oak Hill Ct, Pittsburgh, PA 15261 (jjakicic@pitt.edu).

JAMA. 2016;316(11):1161-1171. doi:10.1001/jama.2016.12858

Physicians: The Opportunities

Opportunities

Patient care

Research

Cost / Value

Global and Future Opportunities

Opportunities

Patient care

Research

Cost / Value

Global and Future Opportunities

Atrial Fibrillation

- Most common arrhythmia affecting > 5 million people – Chronic condition
- Projected 12 million by 2050
- AF accounts for 15 – 20 % of strokes in US
- Strokes secondary to AF are more detrimental
- 18% of AF triggered strokes present with AF that is newly detected

Benjamin EJ et. al. *Circulation.* 2018
Miyasaka Y et. al. *Circulation.* 2006
Marini C. et. Al. *Stroke.* 2005
Lin HJ et. al. *Stroke.* 1995

Fig 1| Zio Patch

Fig 2| MyDiagnostick

Fig 3| Zenicor-ECG

Body Guardian
Preventice

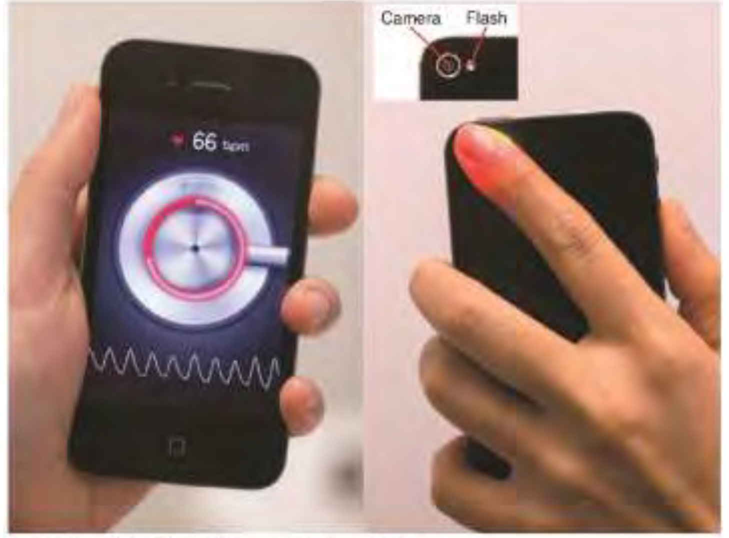
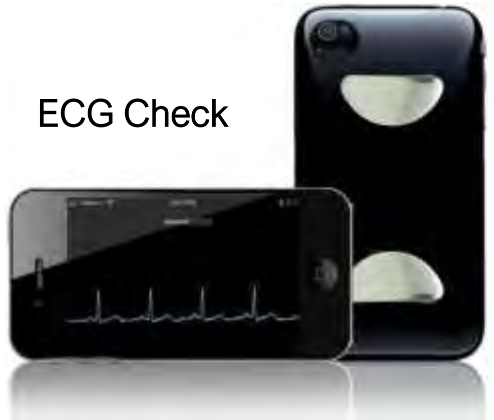


Fig 6| Cardiio Rhythm smartphone application on iPhone

Fig 4| AliveCor KardiaMobile

Fig 5| Kardia Band on Apple Watch

ECG Check



Zungsontiporn N. *BMJ* 2018

Smartphone ECG Example

Using a novel wireless system in monitoring patients after the atrial fibrillation ablation procedure: The iTransmit study

Khaldoun G. Tarakji, MD, MPH, FHRS, Oussama M. Wazni, MD, FHRS, Thomas Callahan, MD, FHRS, Mohamed Kanj, MD, Ali H. Hakim, Kathy Wolski, MPH, Bruce L. Wilkoff, MD, FHRS, Walid Saliba, MD, FHRS, Bruce D. Lindsay, MD, FHRS

From the Section of Cardiac Pacing and Electrophysiology, Robert and Suzanne Tomsich Department of Cardiovascular Medicine, Heart and Vascular Institute, Cleveland Clinic, Cleveland, Ohio.

Tarakji el al. *Heart Rhythm.* 2015

Assessing the accuracy of an automated atrial fibrillation detection algorithm using smartphone technology: The iREAD Study

Amila D. William, MD,[*] Majd Kanbour, MD,[†] Thomas Callahan, MD, FHRS,[*] Mandeep Bhargava, MD, FHRS,[*] Niraj Varma, MD, PhD, FHRS,[*] John Rickard, MD, FHRS,[*] Walid Saliba, MD, FHRS,[*] Kathy Wolski, MPH,[‡] Ayman Hussein, MD, FHRS,[*] Bruce D. Lindsay, MD, FHRS,[*] Oussama M. Wazni, MD, FHRS,[*] Khaldoun G. Tarakji, MD, MPH, FHRS[*]

From the [*]Department of Cardiovascular Medicine, Cleveland Clinic, Cleveland, Ohio, [†]Department of Cardiovascular Medicine, Marshall University, Huntington, West Virginia, and [‡]Cleveland Clinic Coordinating Center for Clinical Research, Cleveland Clinic, Cleveland, Ohio.

William AD et. al. *Heart Rhythm.* 2018 Oct;15(10):1561-1565

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
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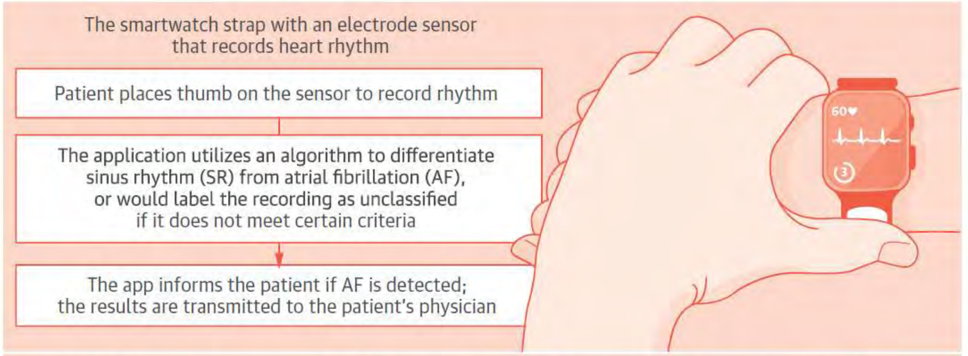
ORIGINAL INVESTIGATIONS

Smartwatch Algorithm for Automated Detection of Atrial Fibrillation

Joseph M. Bumgarner, MD,[a] Cameron T. Lambert, MD,[a] Ayman A. Hussein, MD,[a] Daniel J. Cantillon, MD,[a] Bryan Baranowski, MD,[a] Kathy Wolski, MPH,[b] Bruce D. Lindsay, MD,[a] Oussama M. Wazni, MD, MBA,[a] Khaldoun G. Tarakji, MD, MPH[a]

CENTRAL ILLUSTRATION Automated Atrial Fibrillation Detection Algorithm Using Novel Smartwatch Technology



Method for interpreting the recording:	% of patients with interpretable results	Accuracy of AF diagnosis compared to 12 lead electrocardiogram
App algorithm only	66%	93% sensitivity; 84% specificity
Physician only	87%	99% sensitivity; 83% specificity
Recordings labeled as "unclassified" by the app algorithm when reviewed by physician	100%	100% sensitivity; 80% specificity

Bumgarner, J.M. et al. J Am Coll Cardiol. 2018;71(21):2381-8.

Smartphone ECG Example

Using a novel wireless system in monitoring patients after the atrial fibrillation ablation procedure: The iTransmit study

Khaldoun G. Tarakji, MD, MPH, FHRS, Oussama M. Wazni, M
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From the Section of Cardiac Pacing and Electrophysiology, Robert
Cardiovascular Medicine, Heart and Vascular Institute, Cleveland C

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Amila D. William, MD,* Majd Kanbour, MD,† Thomas Callahan, MD, FHRS,*

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21, 2018

AL INVESTIGATIONS

watch Algorithm for
ated Detection of Atrial Fibrillation

arner, MD,[a] Cameron T. Lambert, MD,[a] Ayman A. Hussein, MD,[a] Daniel J. Cantillon, MD,[a]
i, MD,[a] Kathy Wolski, MPH,[b] Bruce D. Lindsay, MD,[a] Oussama M. Wazni, MD, MBA,[a]
akji, MD, MPH[a]

They work

Patients will adopt them

Automated algorithms are good but not perfect

For clinical decisions, still need physician over-read

LLUSTRATION Automated Atrial Fibrillation Detection Algorithm Using Novel Smartwatch Technology

smartwatch strap with an electrode sensor that records heart rhythm

places thumb on the sensor to record rhythm

pplication utilizes an algorithm to differentiate nus rhythm (SR) from atrial fibrillation (AF), or would label the recording as unclassified if it does not meet certain criteria

The app informs the patient if AF is detected; the results are transmitted to the patient's physician

Method for interpreting the recording:	% of patients with interpretable results	Accuracy of AF diagnosis compared to 12 lead electrocardiogram
App algorithm only	66%	93% sensitivity; 84% specificity
Physician only	87%	99% sensitivity; 83% specificity
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Tarakji el al. *Heart Rhythm.* 2015

William AD et. al. *Heart Rhythm.* 2018 Oct;15(10):1561-1565

Recorded: Tuesday, June 26, 2018 at 11:19:48 AM
Heart Rate: 85 bpm **Duration:** 30s

Finding by Alivecor: Possib… …ibrillation

Kardia

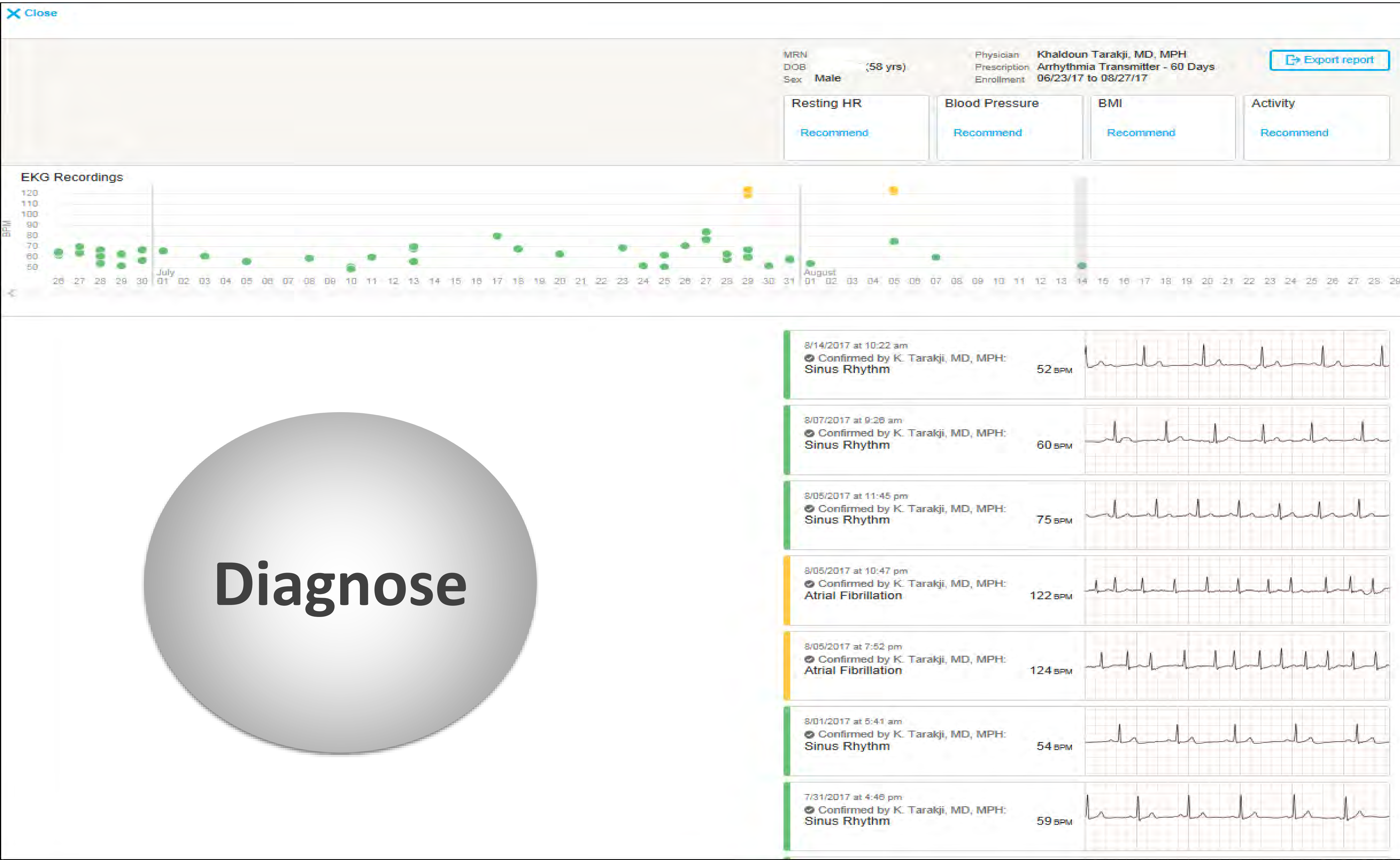
Enhanced Filter, Mains filter: 60Hz Scale: 25mm/s, 10mm/mV

Sin… …hm — ♥ 67 BPM Average

T… ECG d… s not show signs of atrial fibrillation.

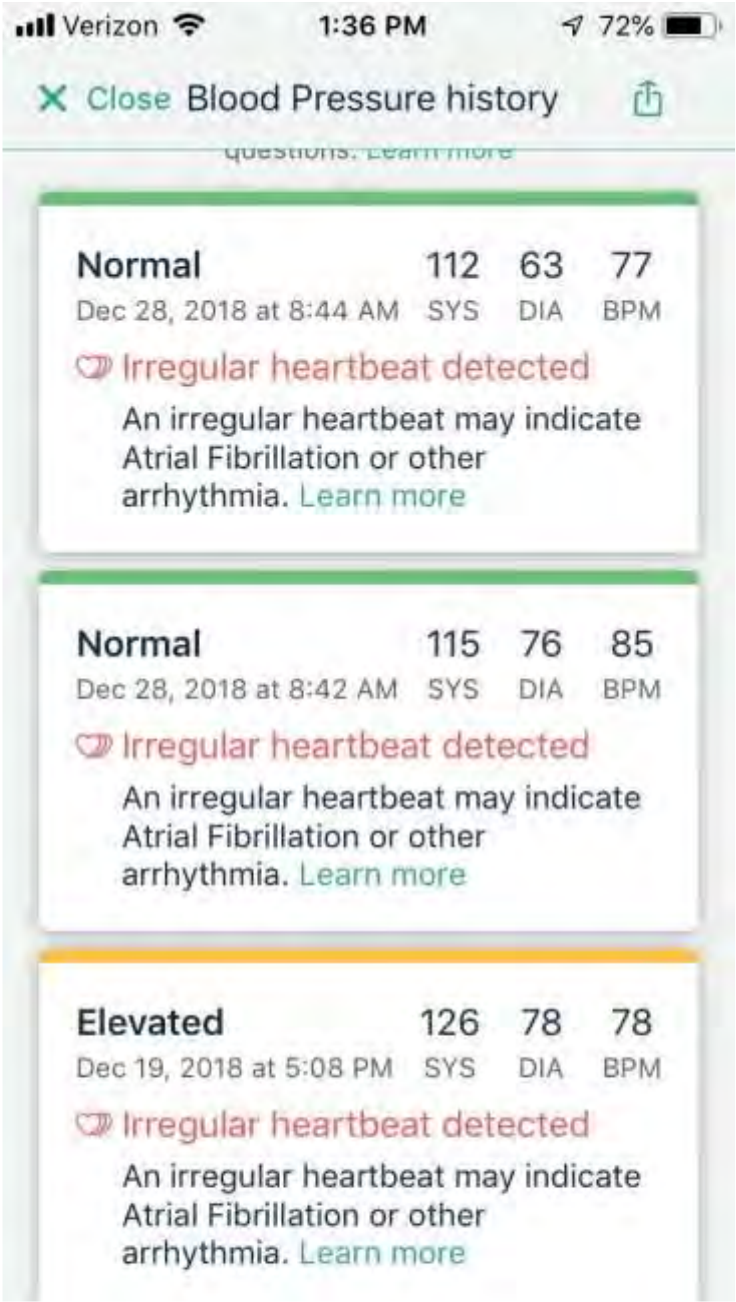
25 mm/s, 10 mm/mV, Lead I, 514Hz, iOS 12.2, watchOS 5.2, Watch4,2 — The waveform is similar to a Lead I ECG. For more information, see Instructions for Use.

58-year-old man with palpitation diagnosed as anxiety attacks



Diagnose

76-year-old man with hypertension and diabetes



62-year-old man overseas

Sinus Rhythm — 57 BPM Average

This ECG does not show signs of atrial fibrillation.

25 mm/s, 10 mm/mV, Lead I, 514Hz, iOS 12.2, watchOS 5.1.3, Watch4,2 — The waveform is similar to a Lead I ECG. For more information, see Instructions for Use.

Atrial Fibrillation — 73 BPM Average

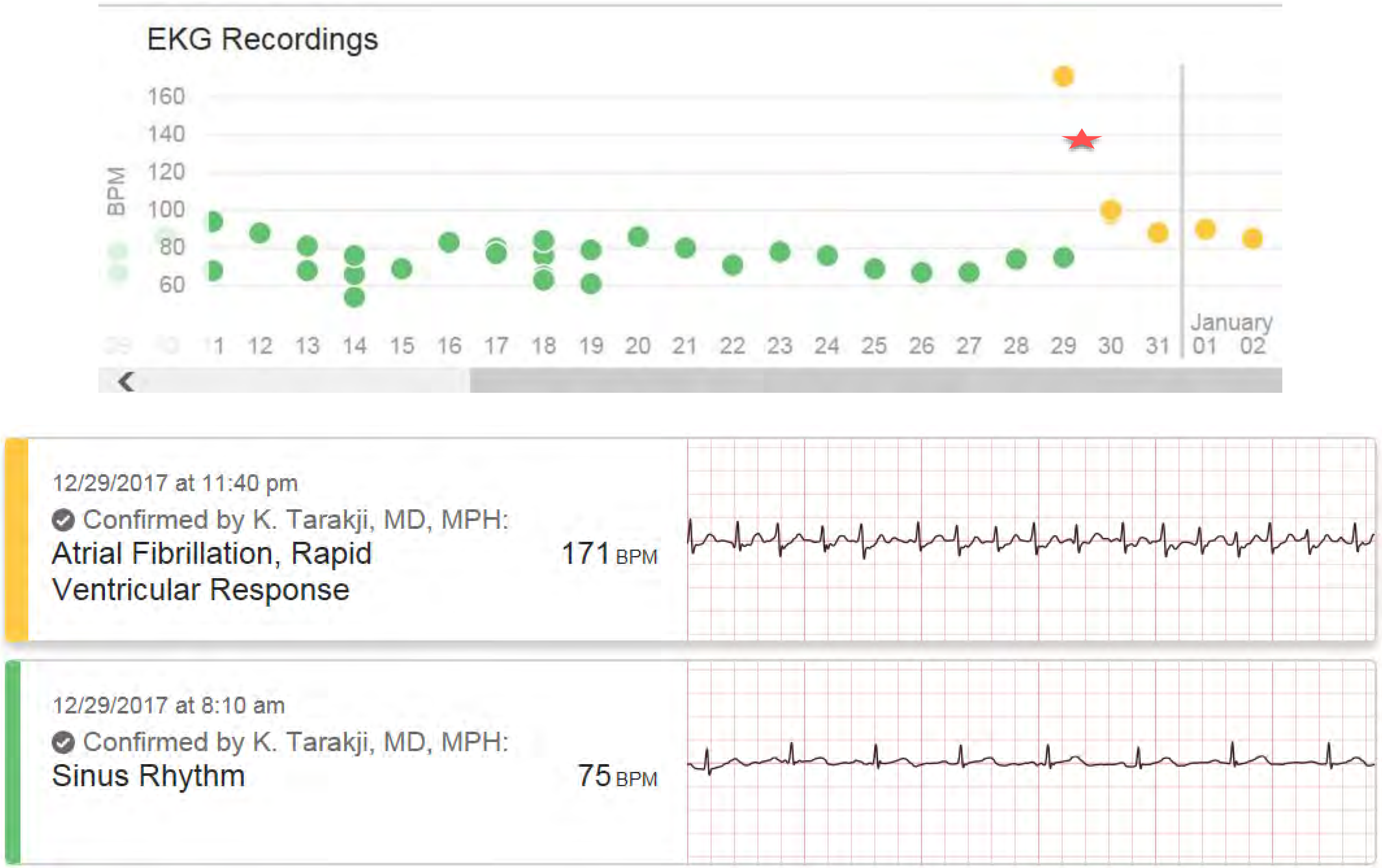
This ECG shows signs of AFib.

If this is an unexpected result, you should talk to your doctor.

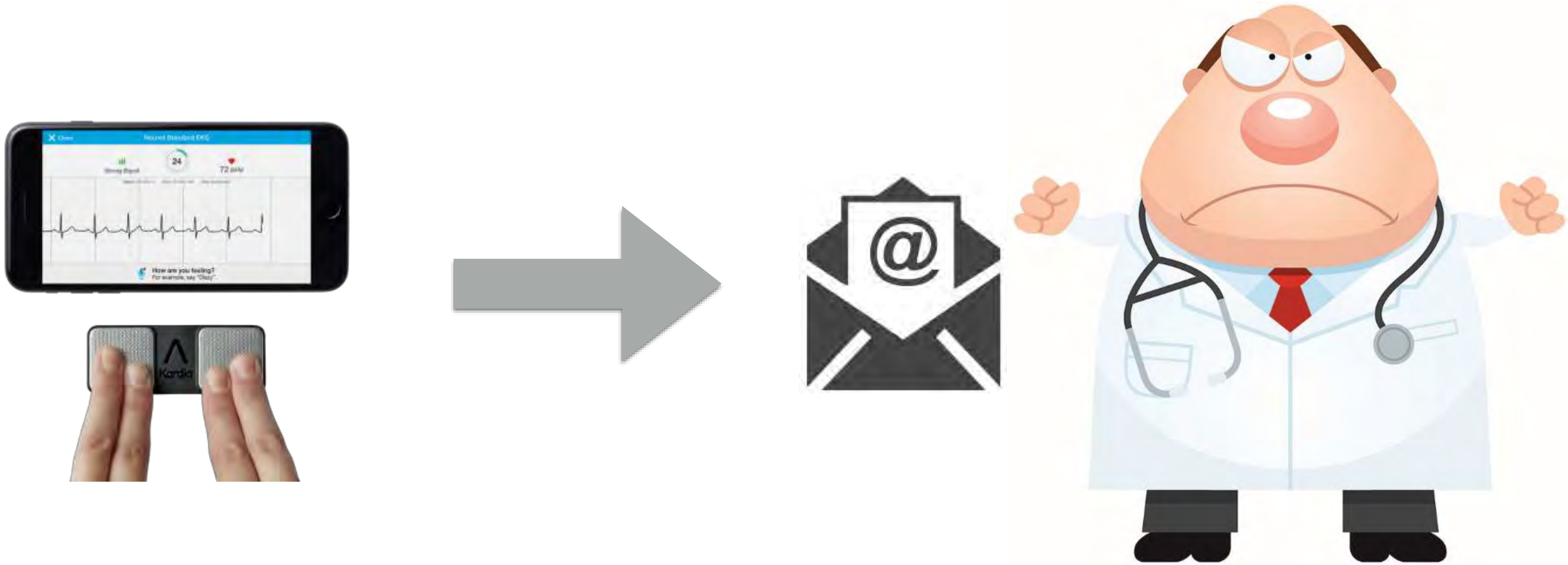
25 mm/s, 10 mm/mV, Lead I, 514Hz, iOS 12.2, watchOS 5.2, Watch4,2 — The waveform is similar to a Lead I ECG. For more information, see Instructions for Use.

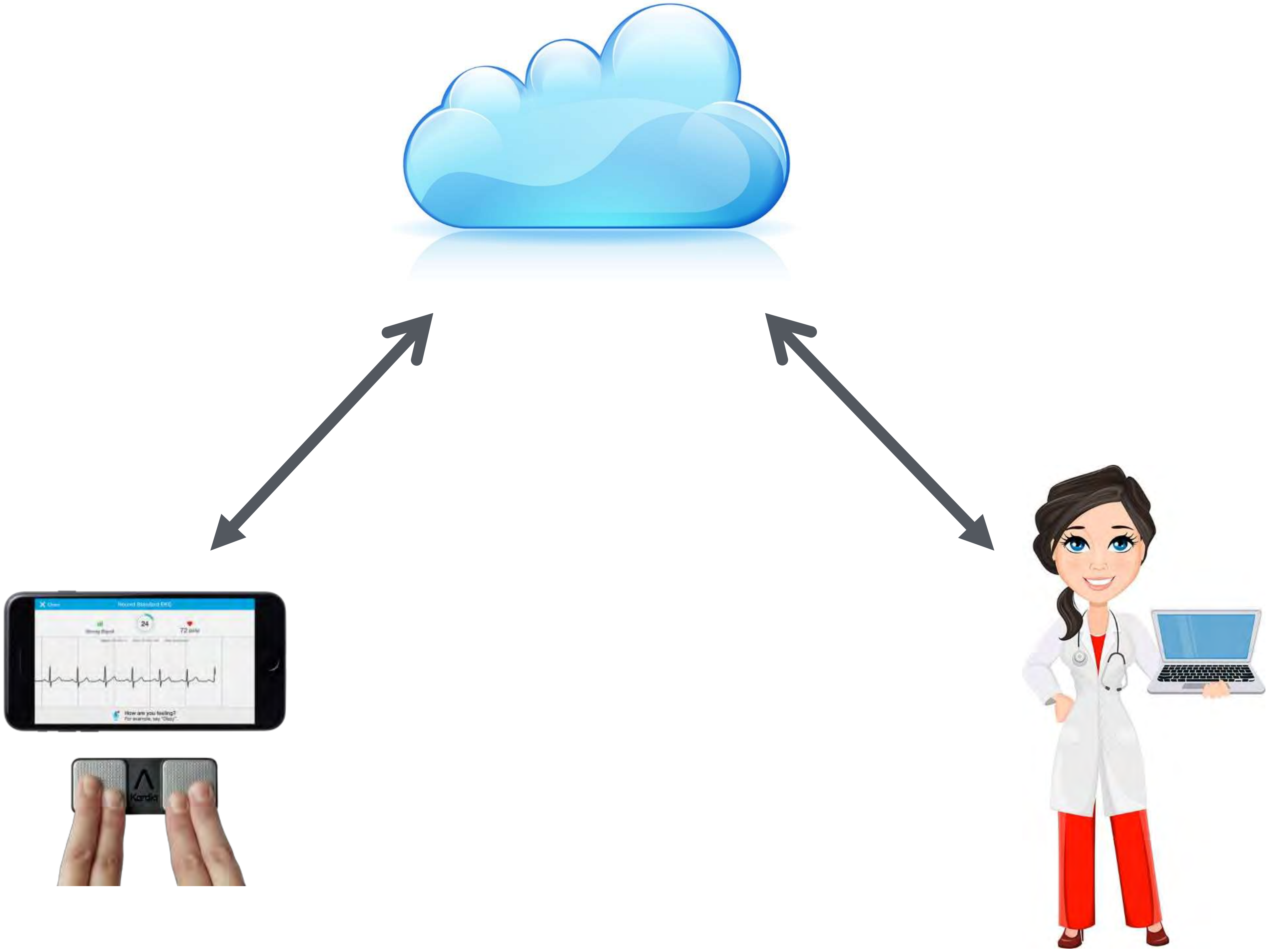
44-year-old man with atrial fibrillation

Manage

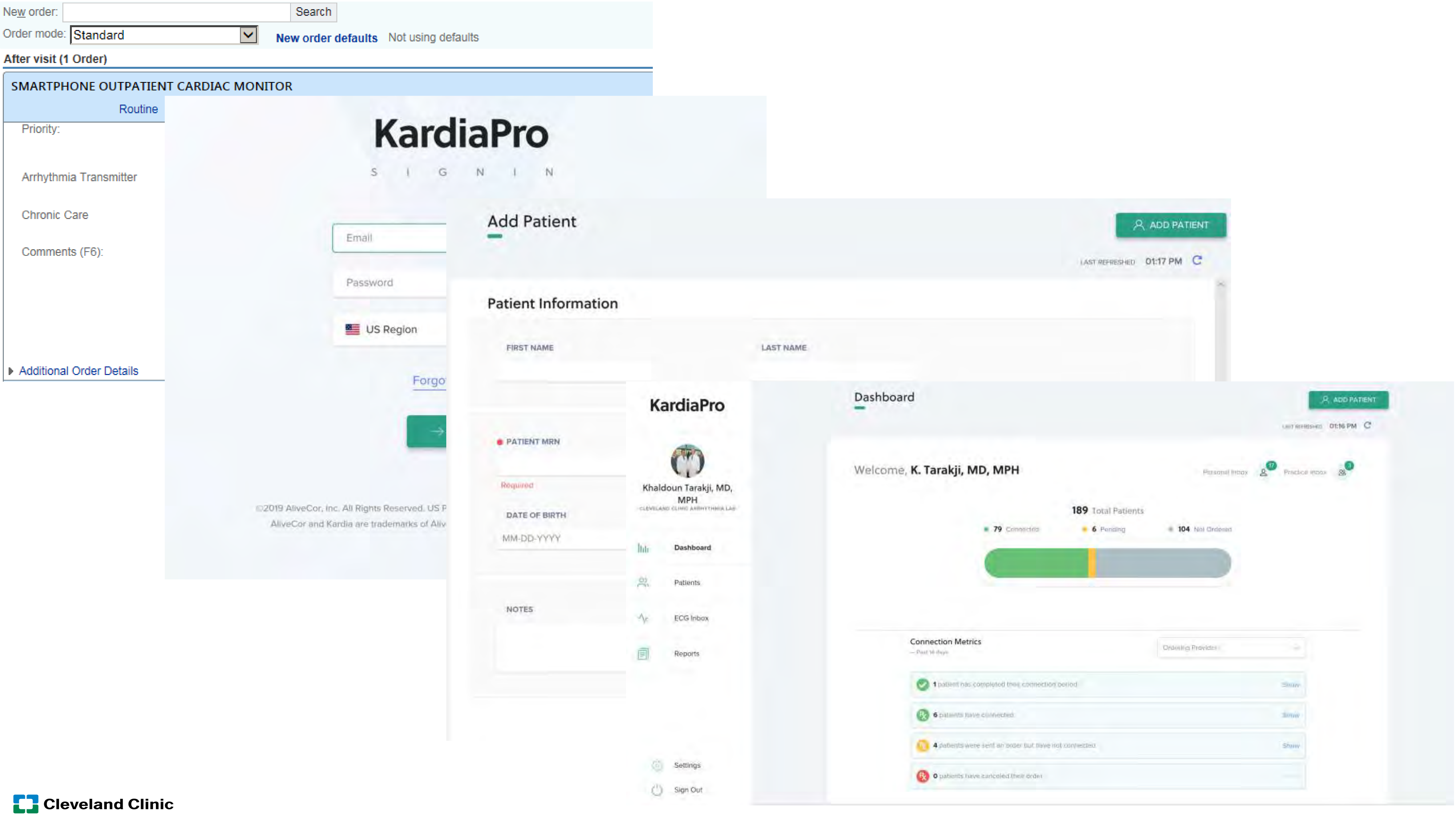


★ Started DOAC


How are you feeling?
Kardia



Cleveland Clinic



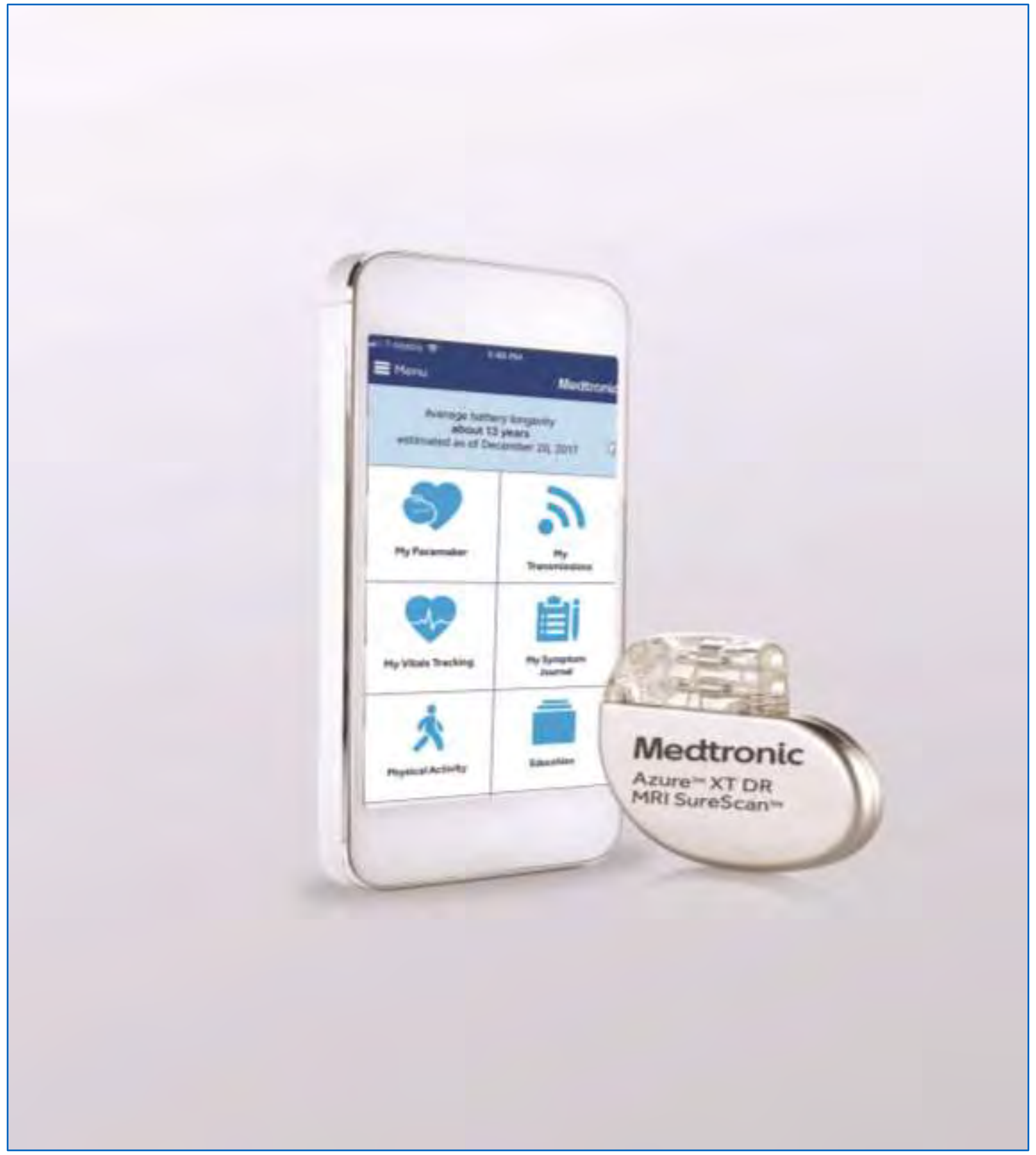
Cleveland Clinic

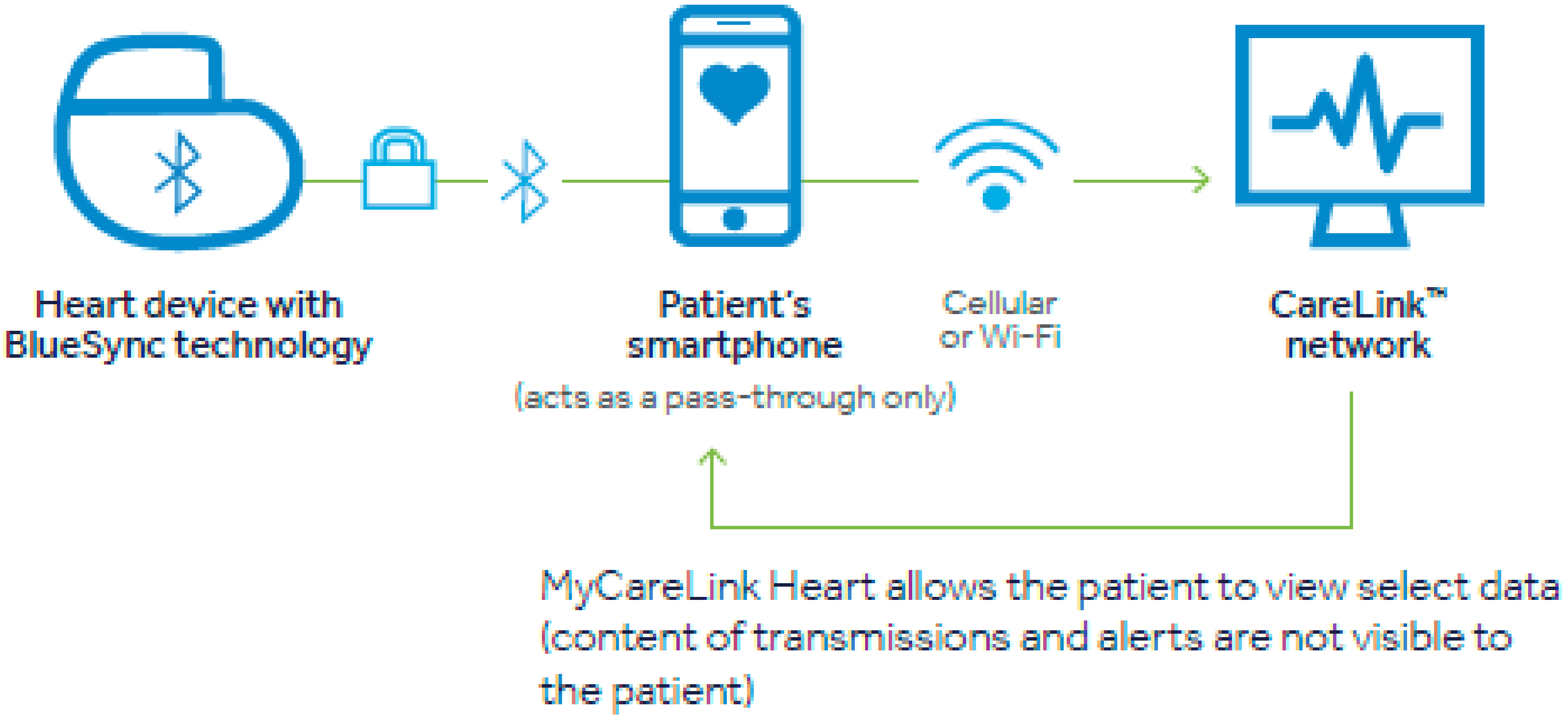
Overview | Profile | Reports | ECG | Blood Pressure | Weight

LAST REFRESHED 01:25 PM

	DATE	ANALYSIS	ANALYSIS BY	BPM + ECG PREVIEW
	FILTER	FILTER	FILTER	FILTER
	02-16-2019 10:47 AM	Normal	Kardia Instant Analysis	72 bpm
	02-13-2019 09:27 PM	Normal	Kardia Instant Analysis	69 bpm
	02-12-2019 11:54 AM	Normal	Kardia Instant Analysis	77 bpm
	02-10-2019 10:16 PM	Normal	Kardia Instant Analysis	69 bpm

First pacemaker to use smartphone directly for remote monitoring of the device





My Care Link Heart App

Opportunities

Patient care

Research

Cost / Value

Global and Future Opportunities

JAMA | Original Investigation

Effect of a Home-Based Wearable Continuous ECG Monitoring Patch on Detection of Undiagnosed Atrial Fibrillation

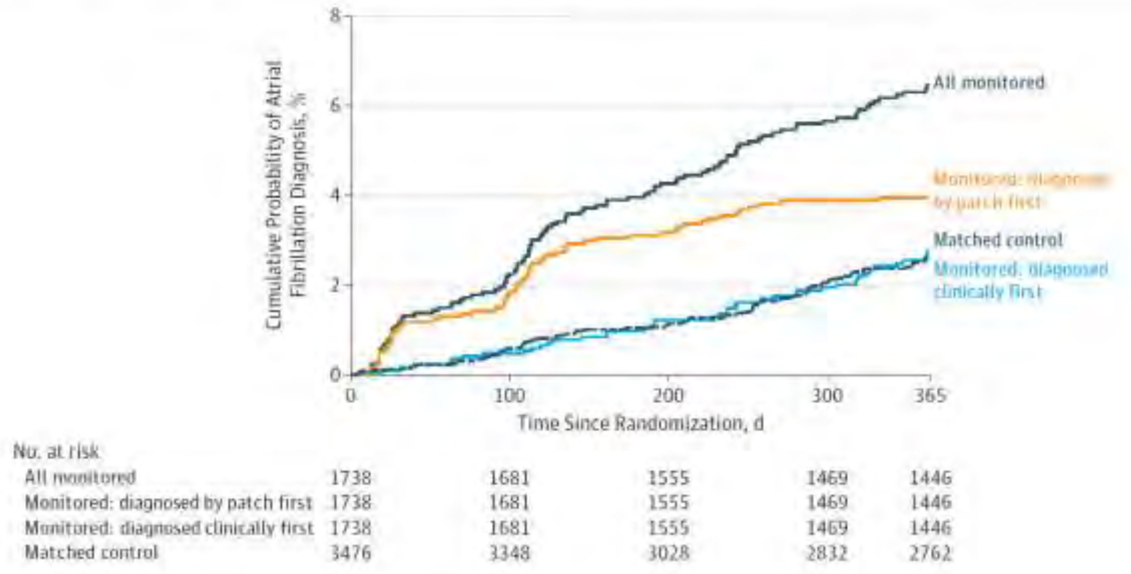
The mSToPS Randomized Clinical Trial

Steven R. Steinhubl, MD; Jill Waalen, MD, MPH; Alison M. Edwards, MStat; Lauren M. Ariniello, BS; Rajesh R. Mehta, RPh, MS; Gail S. Ebner, BS; Chureen Carter, PharmD, MS; Katie Baca-Motes, MBA; Elise Felicione, MPH, MBA; Troy Sarich, PhD; Eric J. Topol, MD

- Direct to participant randomized clinical trial among members of a healthcare plan

- 3 groups
    - Immediate monitoring (patch x 2)
    - Delayed monitoring (after 4 months)
    - Observation group

Figure 2. Cumulative Rate of First Diagnosis of Atrial Fibrillation in the Actively Monitored and Observational Cohorts



Incidence of AF diagnosis was 3.9% in the immediate monitoring group vs 0.9% in the delayed group

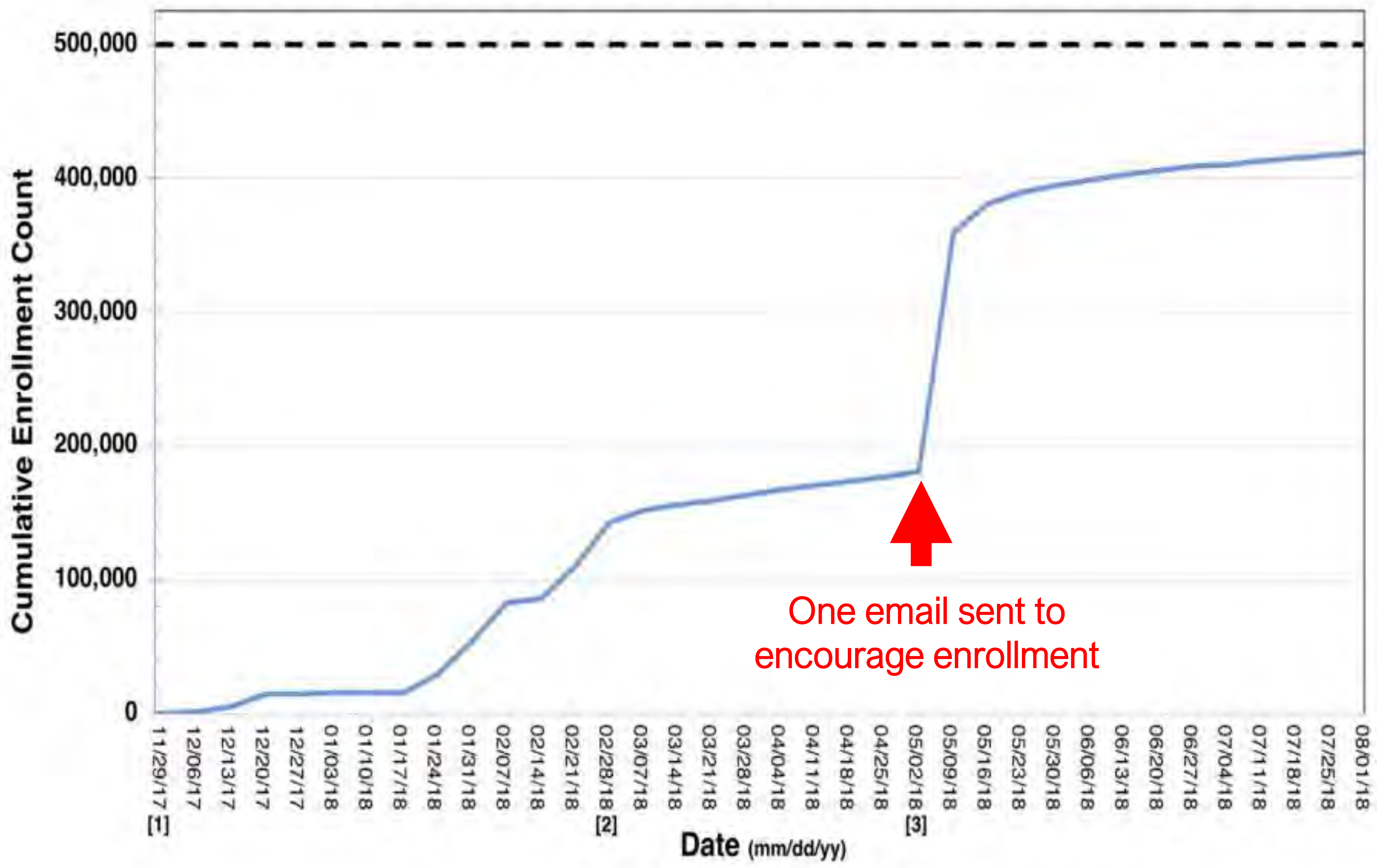
Monitored group led to more use of healthcare resources

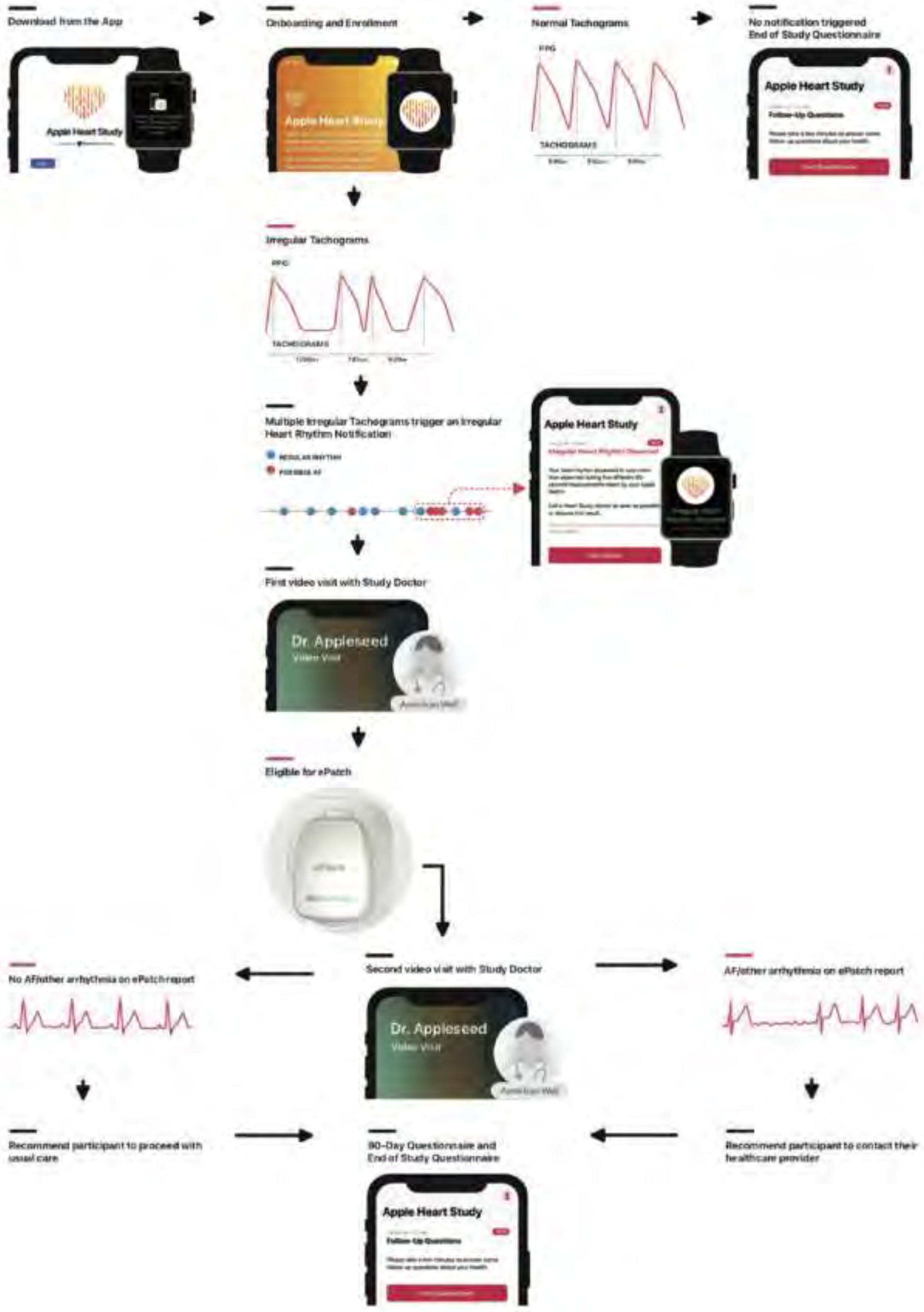
Cleveland Clinic

Steinhubl et. al. *JAMA*. 2018

Rationale and design of a large-scale, app-based study to identify cardiac arrhythmias using a smartwatch: The Apple Heart Study

Mintu P. Turakhia, MD, MAS,[a,b] Manisha Desai, PhD,[c] Haley Hedlin, PhD,[c] Amol Rajmane, MD, MBA,[d] Nisha Talati, MBA,[d] Todd Ferris, MD, MS,[e] Sumbul Desai, MD,[f] Divya Nag[f] Mithun Patel, MD,[f] Peter Kowey, MD,[g] John S. Rumsfeld, MD, PhD,[h] Andrea M. Russo, MD,[i] Mellanie True Hills, BS,[j] Christopher B. Granger, MD,[k] Kenneth W. Mahaffey, MD,[d] and Marco V. Perez, MD[l] *Stanford, Palo Alto, Cupertino, CA; Philadelphia PA; Denver Colorado; Camden NJ; Decatur TX; Durham NC*



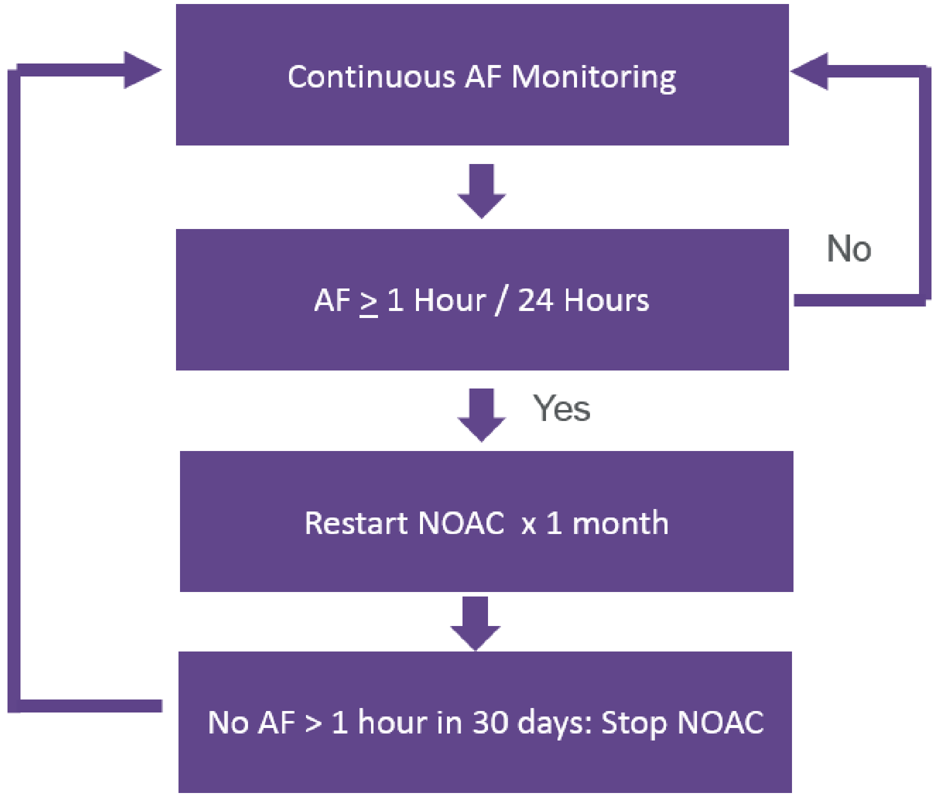


Turakhia MP et. al. *Am Heart J.* 2019

Targeted Anticoagulation for Atrial Fibrillation Guided by Continuous Rhythm Assessment With an Insertable Cardiac Monitor: The Rhythm Evaluation for Anticoagulation With Continuous Monitoring (REACT.COM) Pilot Study

ROD PASSMAN, M.D., M.S.C.E.,* PETER LEONG-SIT, M.D.,† ADIN-CRISTIAN ANDREI, PH.D.,‡ ANNA HUSKIN, R.N., B.S.N.,‡ TODD T. TOMSON, M.D.,‡ RICHARD BERNSTEIN, M.D., PH.D.,* ETHAN ELLIS, M.D.,§ JONATHAN W. WAKS, M.D.,§ and PETER ZIMETBAUM, M.D.§

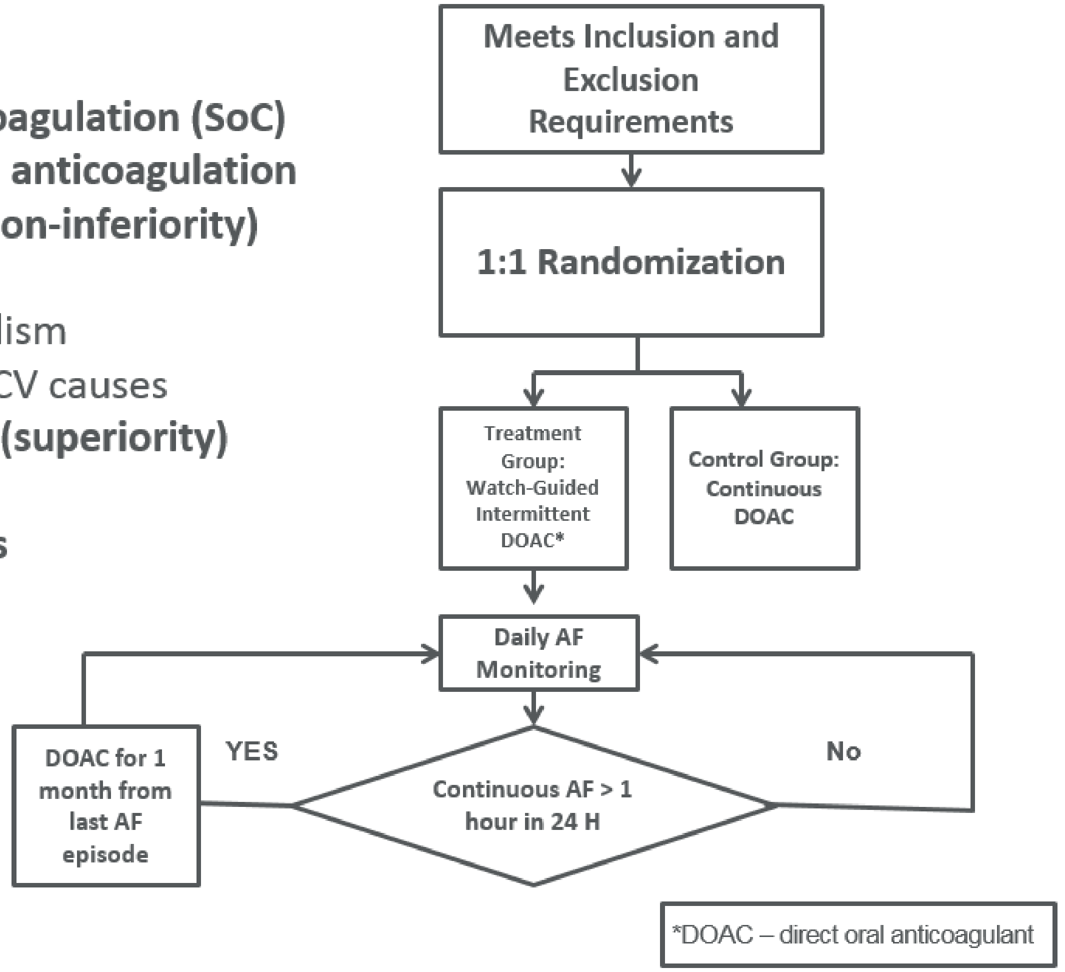
J Cardiovasc Electrophysiol. 2016 March ; 27(3): 264–270.



94% reduction in the time on NOAC

*R*hythm *E*valuation for *A*nti*c*oagulation *T*herapy for *A*trial *F*ibrillation (REACT-AF)

- **1:1 randomized trial**
  - **Chronic anticoagulation (SoC)**
  - **Watch-guided anticoagulation**
- **Primary endpoint (non-inferiority)**
  - Stroke (all)
  - Arterial embolism
  - Death due to CV causes
- **Secondary endpoint (superiority)**
  - Major bleeds
- **Follow-up 30 months**



*Courtesy Dr. Rod Passman, Northwestern Medical Center

Opportunities

Patient care

Research

Cost / Value

Global and Future Opportunities

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 71, NO. 21, 2018

PUBLISHED BY ELSEVIER

ORIGINAL INVESTIGATIONS

Smartwatch Algorithm for Automated Detection of Atrial Fibrillation

Joseph M. Bumgarner, MD,[a] Cameron T. Lambert, MD,[a] Ayman A. Hussein, MD,[a] Daniel J. Cantillon, MD,[a] Bryan Baranowski, MD,[a] Kathy Wolski, MPH,[b] Bruce D. Lindsay, MD,[a] Oussama M. Wazni, MD, MBA,[a] Khaldoun G. Tarakji, MD, MPH[a]

- 100 patients presenting for elective cardioversion for AF
- ECG pre and post Cardioversion
- Simultaneous Kardia Band Smart Watch recording

8% of patients were in sinus rhythm and did not need cardioversion

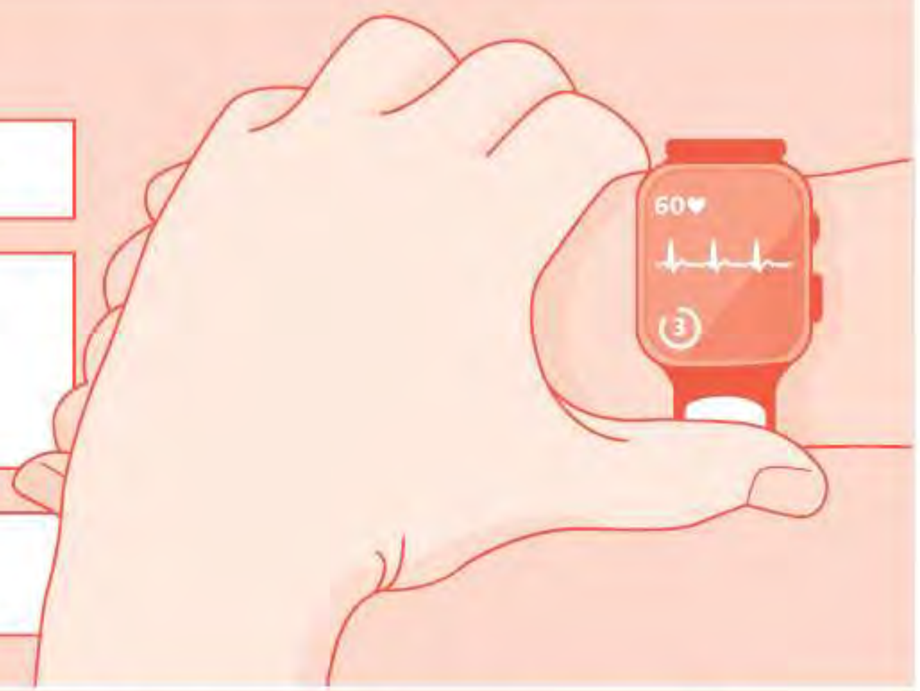
CENTRAL ILLUSTRATION Automated Atrial Fibrillation Detection Algorithm Using Novel Smartwatch Technology

The smartwatch strap with an electrode sensor that records heart rhythm

Patient places thumb on the sensor to record rhythm

The application utilizes an algorithm to differentiate sinus rhythm (SR) from atrial fibrillation (AF), or would label the recording as unclassified if it does not meet certain criteria

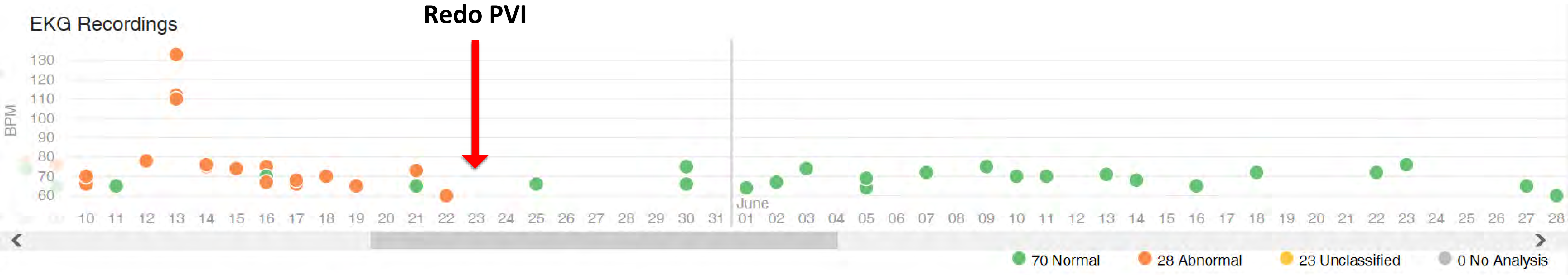
The app informs the patient if AF is detected; the results are transmitted to the patient's physician



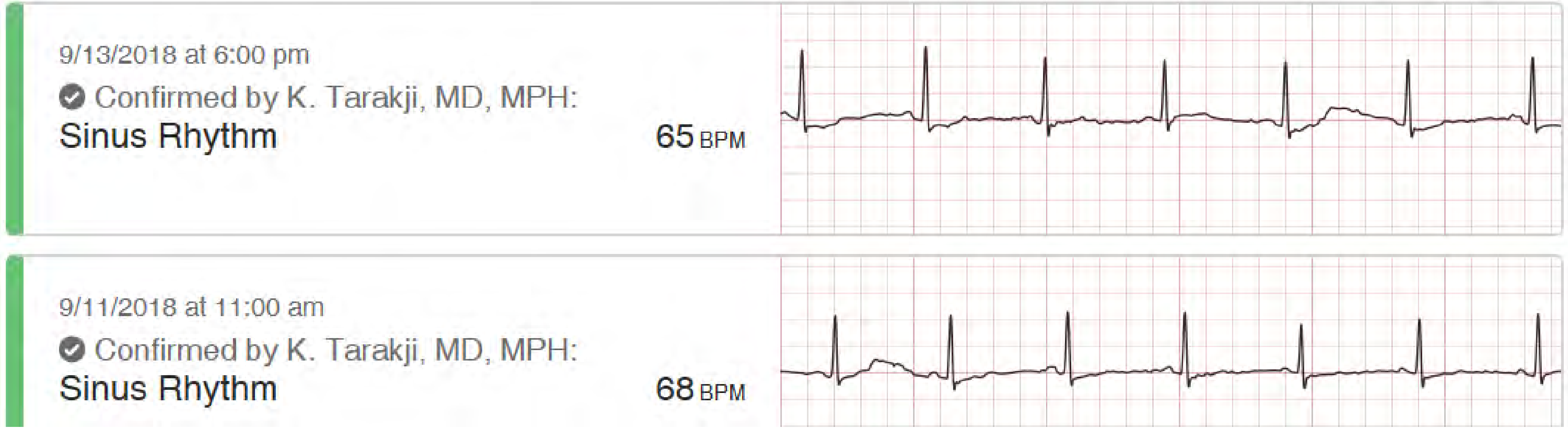
Method for interpreting the recording:	% of patients with interpretable results	Accuracy of AF diagnosis compared to 12 lead electrocardiogram
App algorithm only	66%	93% sensitivity; 84% specificity
Physician only	87%	99% sensitivity; 83% specificity
Recordings labeled as "unclassified" by the app algorithm when reviewed by physician	100%	100% sensitivity; 80% specificity

Bumgarner, J.M. et al. J Am Coll Cardiol. 2018;71(21):2381-8.

68-year-old woman s/p redo AF ablation



Follow up



Viewpoint

February 6, 2018

Is It Time for a New Medical Specialty?

The Medical Virtualist

Michael Nochomovitz, MD[1]; Rahul Sharma, MD, MBA[2]

» Author Affiliations | Article Information

JAMA. 2018;319(5):437-438. doi:10.1001/jama.2017.17094

The Washington Post

Health & Science • Perspective

Telemedicine is getting trendy, but doctors may not be keeping up

- Telehealth market is expected to rapidly rise to 12.13B by 2022
- The Medical Virtualist
- Change in medical school curriculum
- Bedside manner vs Webside manner?
- **Telemedicine ≠ Video Chat** but could be of great value when supported by additional tools (All monitors could be order remotely)

Opportunities

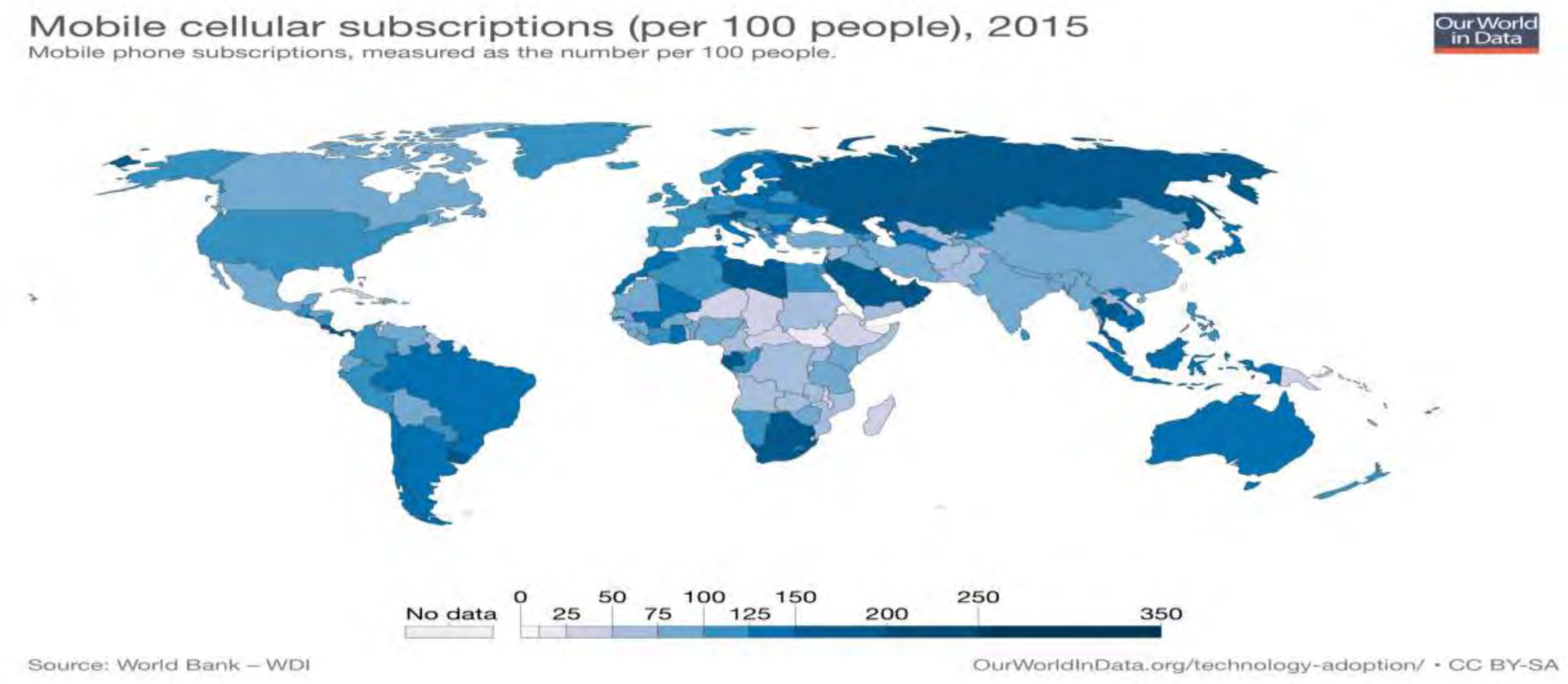
Patient care

Research

Cost / Value

Global and Future Opportunities

Smart Devices: Not limited to the rich



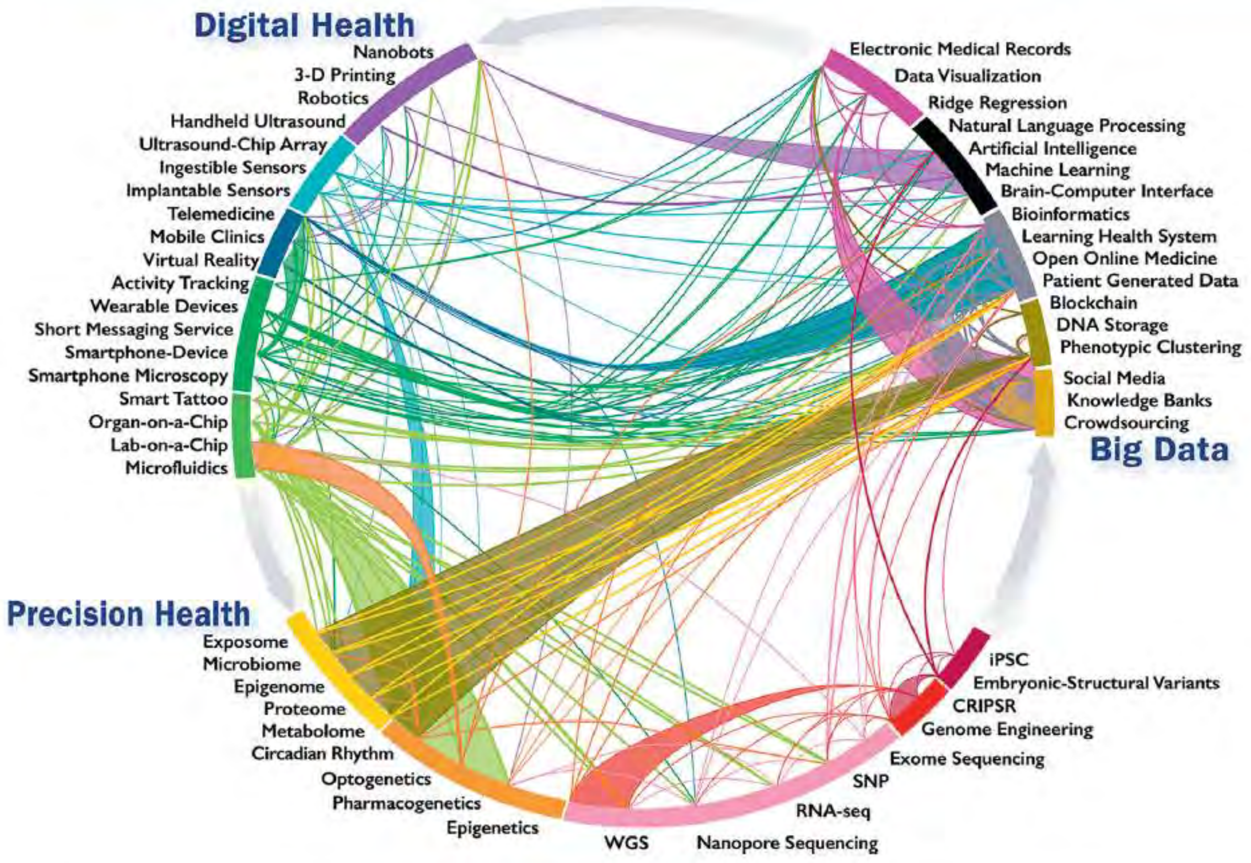
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
VOL. 70, NO. 21, 2017
ISSN 0735-1097/$36.00
https://doi.org/10.1016/j.jacc.2017.10.018
PUBLISHED BY ELSEVIER

HEALTH POLICY STATEMENT

2017 Roadmap for Innovation—ACC Health Policy Statement on Healthcare Transformation in the Era of Digital Health, Big Data, and Precision Health

A Report of the American College of Cardiology Task Force on Health Policy Statements and Systems of Care

FIGURE 1 New Innovations in Healthcare



Infographic of emerging innovations and developments in digital health (14-32), big data (33-51), and precision health (52-78) and their intraconnections and interconnections. 3d indicates 3-dimensional; CRISPR, clustered regularly interspaced short palindromic repeats; DNA, deoxyribonucleic acid; iPSC, induced pluripotent stem cells; RNA, ribonucleic acid; SNP, single nucleotide polymorphism; WGS, whole genome sequencing.

Heart Rhythm Society℠

DIGITAL HEALTH WORKING GROUP CHARGE

Purpose

There is a growing awareness and increasing expectation by patients and the public for access to transparent and secure health care data. This Working Group will provide guidance, recommendations and resources to HRS members about safely sharing and exchanging data with patients obtained from personal health records, cardiovascular implantable and remote monitoring devices and continuous, personal biometric monitoring. Opportunities for guidance include patient access to data, education on current challenges in healthcare, promoting open communication with patients about data sharing and suggestions to manufacturers.

DIGITAL HEALTH SUMMIT:
EP HITS CENTER STAGE – READY OR NOT!

>>>> 8 Sessions on Wednesday, May 8th <<<<

1. Digital Health In EP
2. Digital Health Tools For Arrhythmia Identification
3. The Wearables & Apps: Show Me the Data
4. Venture Capitalist & Entrepreneur Roundtable
5. AI in EP: Computational Approaches; AI in Hospitals
6. The Role of Tech Giants in Healthcare
7. Success Stories: Driving Digital Health Pathways
8. Digital Health Live Virtual Visit

Register today! HRSsessions.org

*In partnership w/ European Heart Rhythm Association (EHRA)
*Not eligible for CME credit or MOC points

Heart Rhythm Society

2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation

Nonloop external event recorders can be used for intermittent transtelephonic recordings that can be initiated by patients with symptoms or on a schedule. These recorders are applied to the chest or held by hand. Older conventional transtelephonic monitors required the recording of rhythm strips while connected in real time over the phone, but more recent monitors allow the storage of rhythm strips with transmission at a later time. Event recording occurs after an event is detected by the patient; the diagnostic yield is dependent on the recognition of symptoms, the duration of symptomatic episodes, or on scheduled or more frequent use to detect asymptomatic arrhythmias.

More recently, smartphone-based ECG monitors have been developed that can be helpful for long-term intermittent surveillance.[950,951] Recordings from electrodes embedded in a smartphone case or a card are connected via low-energy Bluetooth technology to smartphone applications. These monitors are nonlooping; patients can record during symptoms that persist long enough to activate the application. Recordings are stored and can be transmitted via wireless or

cellular networks. In a study conducted after AF ablation, a smartphone-based single-lead system was compared to transtelephonic monitor ECGs with 100% sensitivity and 97% specificity in detecting AF or flutter.[951] Multi-lead and reconstructed 12-lead recording devices are being developed, but have not been studied in the setting of AF ablation. Continuous ECG monitoring technology using such applications are also in development.

2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry

11. Section 9: Emerging Technologies

11.1. Use of smartphone technology for AECG recording

Smartphone-based AECG is a potentially disruptive technology, blurring the traditional models of prescribed device and physician interpretation, and also definitions of patient versus consumer. Already, over 50 million Americans wear a connected device to track activity and that number is expected to grow to over 160 million with the recent introduction of the "smart" watches. Almost all activity sensors include heart rate and some chest-worn body sensors

Fact sheet

Final Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2019

Nov 01, 2018 | Initiatives, Legislation, Physicians

Share

Related Releases

CMS Launches Podcast to Reach Stakeholders via Modern Platform
Feb 19, 2019

New App Displays What Original Medicare Covers
Feb 06, 2019

New Online Tool Displays Cost Differences for Certain Surgical

Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

CMS is finalizing our proposals to pay separately for two newly defined physicians' services furnished using communication technology:

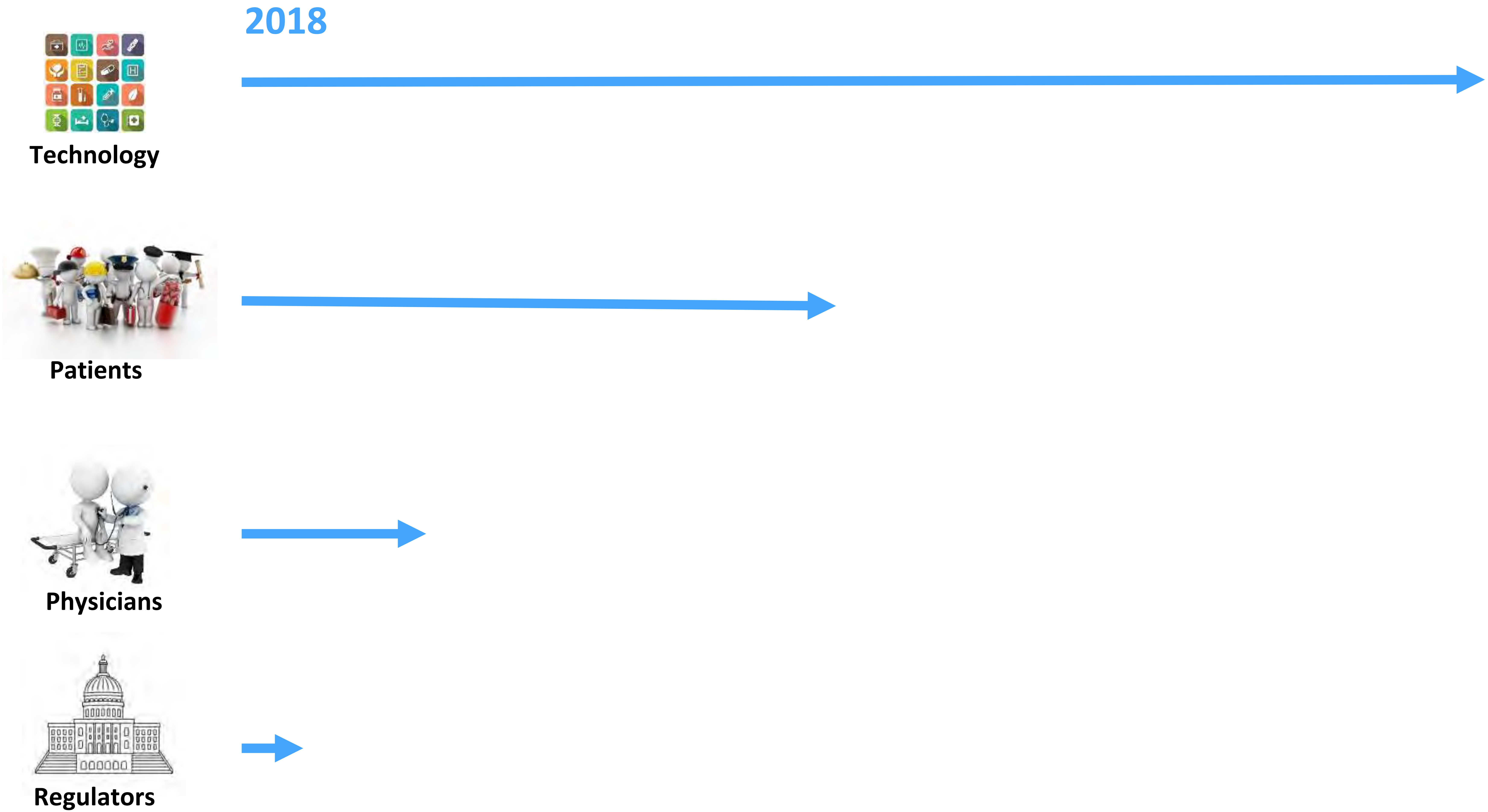
- Brief communication technology-based service, e.g. virtual check-in (HCPCS code G2012) and
- Remote evaluation of recorded video and/or images submitted by an established patient (HCPCS code G2010)

Practitioners could be separately paid for the brief communication technology-based service when the patient checks in with the practitioner via telephone or other telecommunications device to decide whether an office visit or other service is needed. This would increase efficiency for practitioners and convenience for beneficiaries. Similarly, the service of remote evaluation of recorded video and/or images submitted by an established patient would allow practitioners to be separately paid for reviewing patient-transmitted photo or video information conducted via pre-recorded "store and forward" video or image technology to assess whether a visit is needed.

CMS is also finalizing policies to pay separately for new coding describing chronic care remote physiologic monitoring (CPT codes 99453, 99454, and 99457) and interprofessional internet consultation (CPT codes 99451, 99452, 99446, 99447, 99448, and 99449)

Evolution of Digital Health

Need Assessment Testing Validation	Usability: Patients Healthcare teams	Easy Workflow Portals	Outcome data	Rules and Regulations


2018
Technology
Patients
Physicians
Regulators

An APPLE  a day keeps the electrophysiologist away?

An APP  a day keeps the electrophysiologist away?

Best consumer products to keep the electrophysiologist away!

- New age of patient physician relationship
- Patients as partners
- Challenges and Opportunities

“The measure of intelligence is the ability to change”

Albert Einstein


Thank You
@KhaldounTarakji

Practical Applications of Machine Learning and Artificial Intelligence (AI) in Wearable Cardiac Monitoring Technology

Hamid Ghanbari, MD, MPH
Assistant Professor
Vice Chair of Innovation
University of Michigan Cardiovascular Center

Case

- 82-year-old Female with history of long-standing persistent AF and managed with a rate control strategy (metoprolol) is seen in clinic. She continues to have mild symptoms (fatigue/exercise intolerance). How do you manage her heart rate?

1. 10-second EKG in the office and titrate Beta Blockers to achieve heart rate <110
2. AF ablation
3. Amiodarone
4. Use AI to personalize rate control


LET'S SOLVE THIS PROBLEM BY USING THE BIG DATA NONE OF US HAVE THE SLIGHTEST IDEA WHAT TO DO WITH
TOM FISH BURNE

What Is Artificial Intelligence?

- Artificial Intelligence → Prediction

- Prediction

  Input → ⬬ → Output

- ex. Autonomous Vehicles

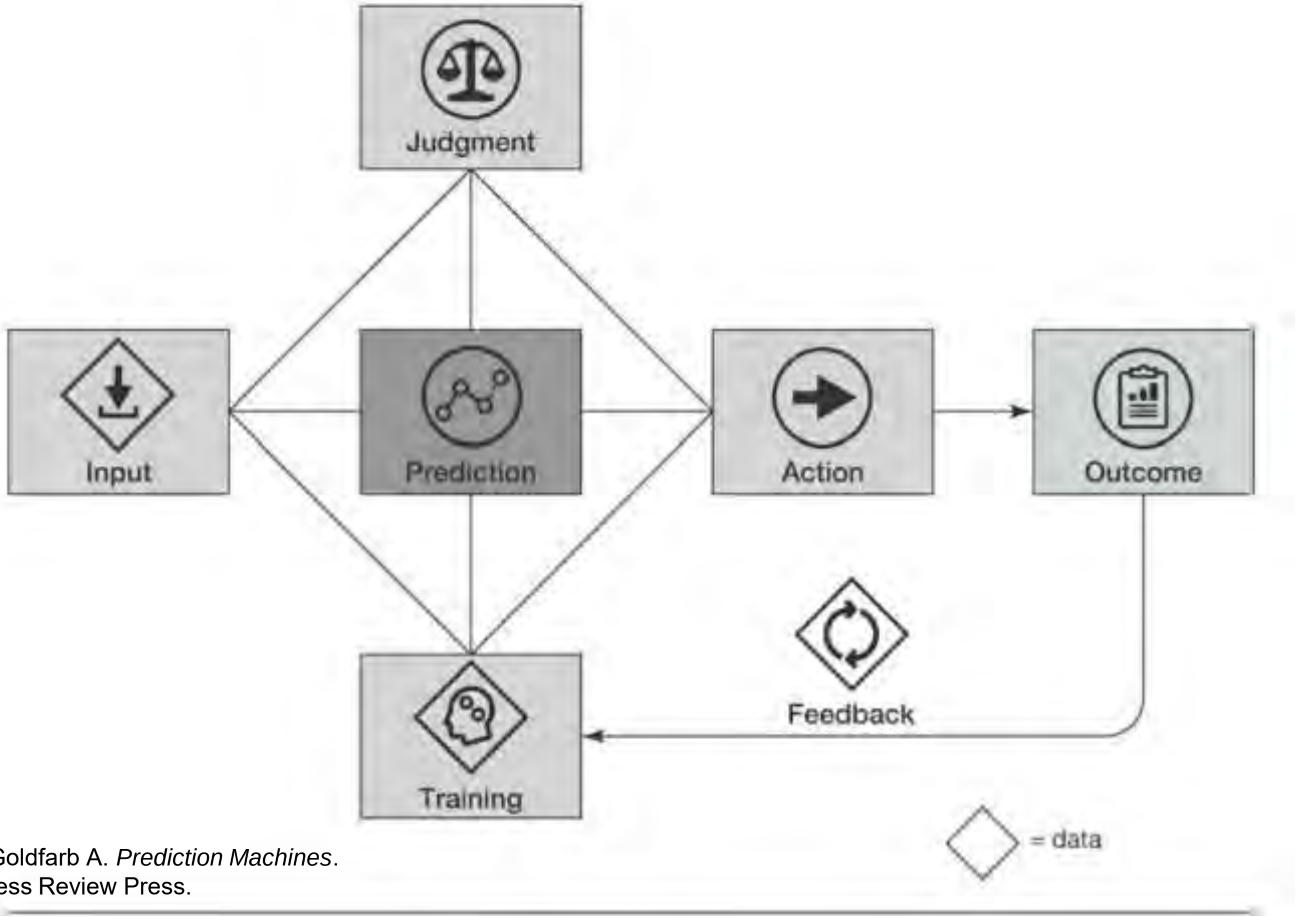
AI = Better + Cheaper Prediction

- Artificial Intelligence makes prediction
  – Cheaper
  – Better

- ⬇ cost of prediction
  - ⬆ the value of complements (data, judgment, and action)
  - ⬇ the value of substitutes (human prediction)

- Small changes in prediction are meaningful if mistakes are costly

Prediction Is the Hidden Input in Decision Making



Agrawal A, Gans J, Goldfarb A. *Prediction Machines*. 2018. Harvard Business Review Press.

Artificial Intelligence: Machine Learning vs Deep Learning

Artificial intelligence (AI)

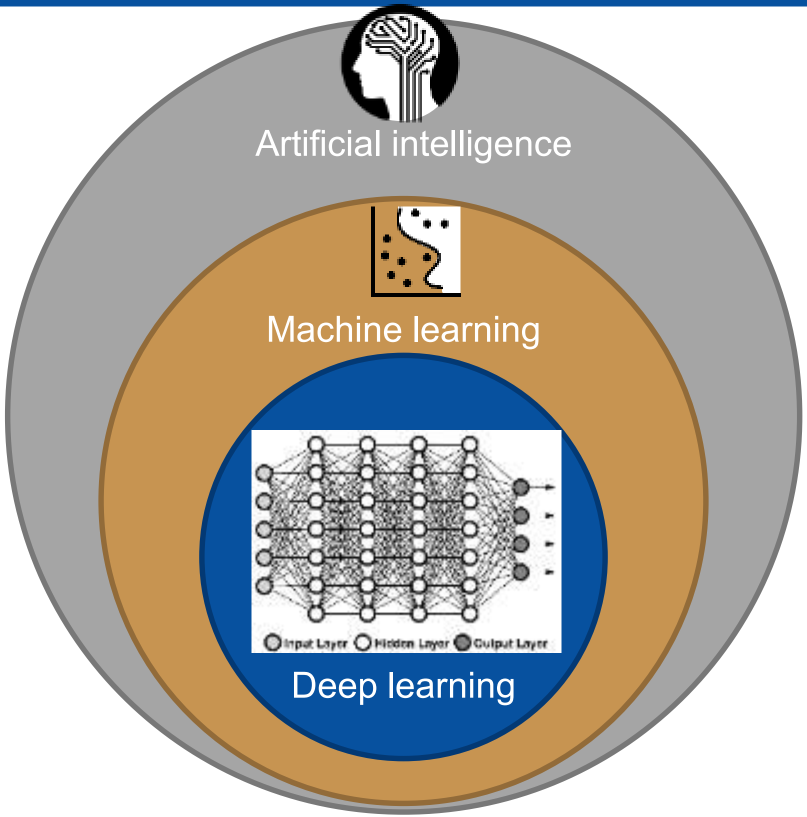
Any technique which enable computers to mimic human behavior

Machine learning (ML)

A subset of AI techniques which use statistical methods to improve machine performance with experience

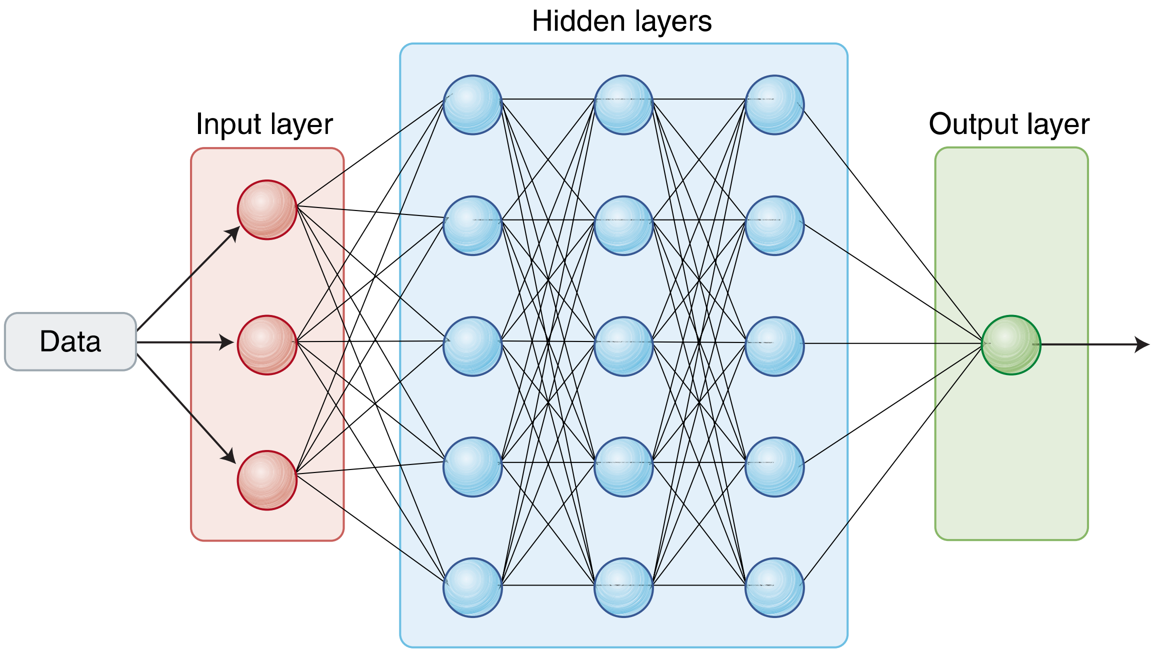
Deep learning (DL)

A subset of machine learning techniques which use deep neural networks (DNNs) to build fundamental and rigorous representations of data with experience



Deep Learning Neural Network

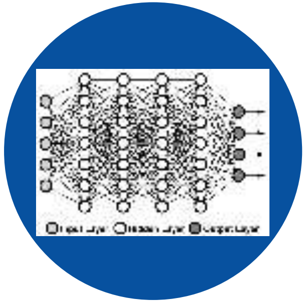
- GPUs
- Cloud Computing
- Lots of Diverse Data
- Open Source Software



Topol EJ. *Nat Med*. 2019;25:44-56.

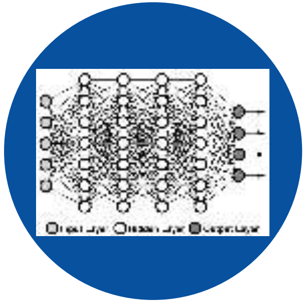
Deep Learning and ECG

Input

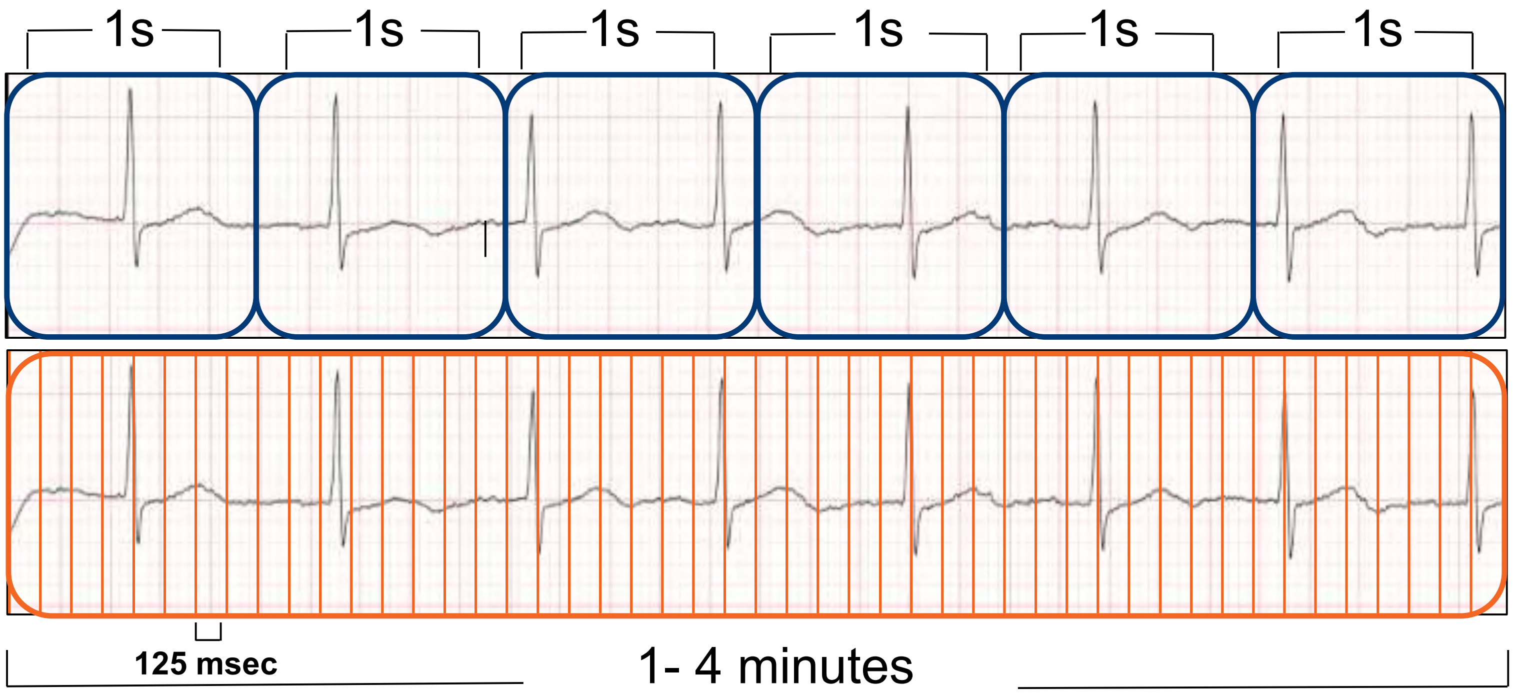


Output

Deep Learning and ECG

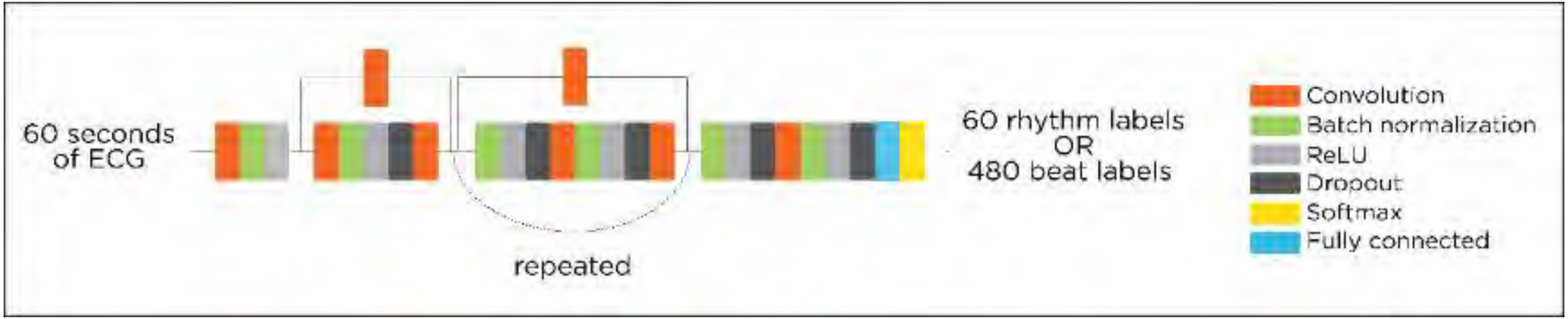
ECG →  → Rhythm

ECG Classification



Inside the Black Box: *Detection of arrhythmia using deep neural nets*

It's Just Math!

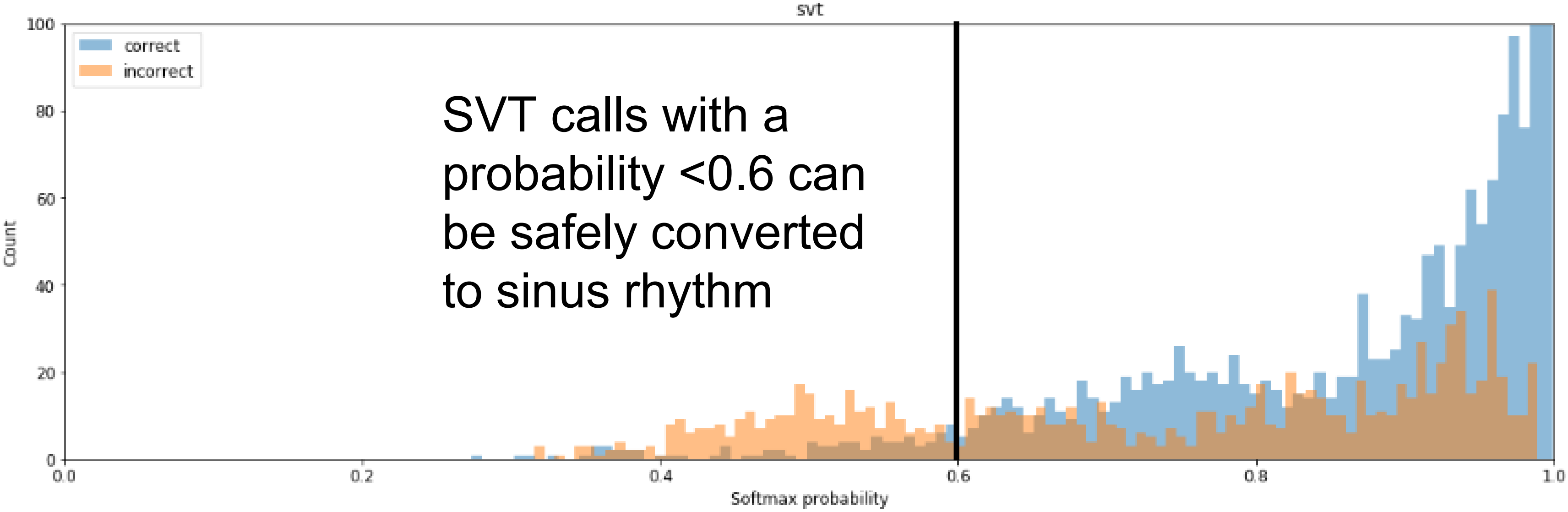


33 convolutional layers and 1 fully connected layer

Rhythm classes: Afib, Atrial, Sinus, SVT, BI, BII1, BII2, BIII, SVT, Junctional

Tiplitzky, Roberts, Mehta, Ghanbari. HRJ 2019

Output = Probability for Each Rhythm Label



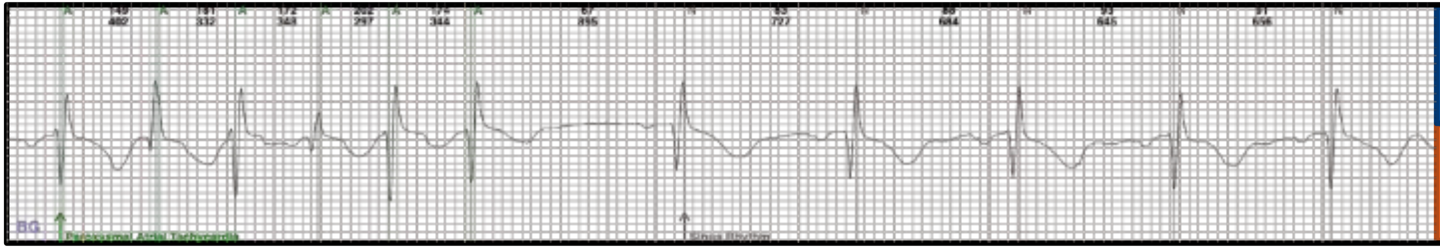
Performance tuning is used to balance precision and sensitivity by setting a probability threshold.

Data: Diversity and Number of Individuals Are Critical

- Real patient data mined from the platform
- Detailed annotations made and adjudicated by skilled technicians
- Gold-standard validation data adjudicated by 3 board-certified electrophysiologists

Database summary

28,000 ECG STRIPS	17,000 PATIENTS	2,000 HOURS OF ECG



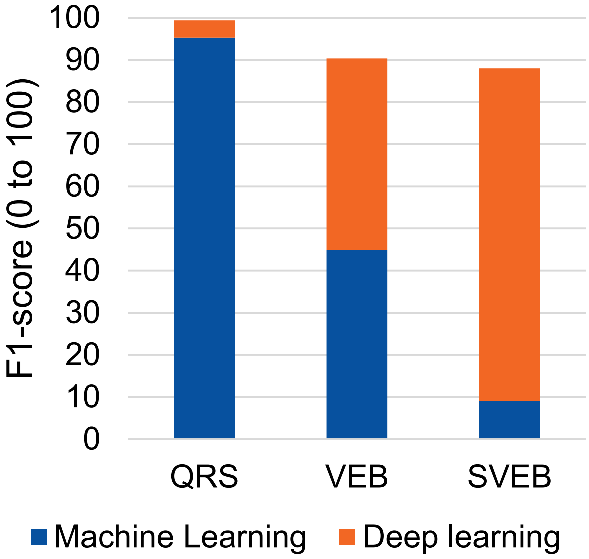
84 RHYTHM TYPES

22 BEAT TYPES

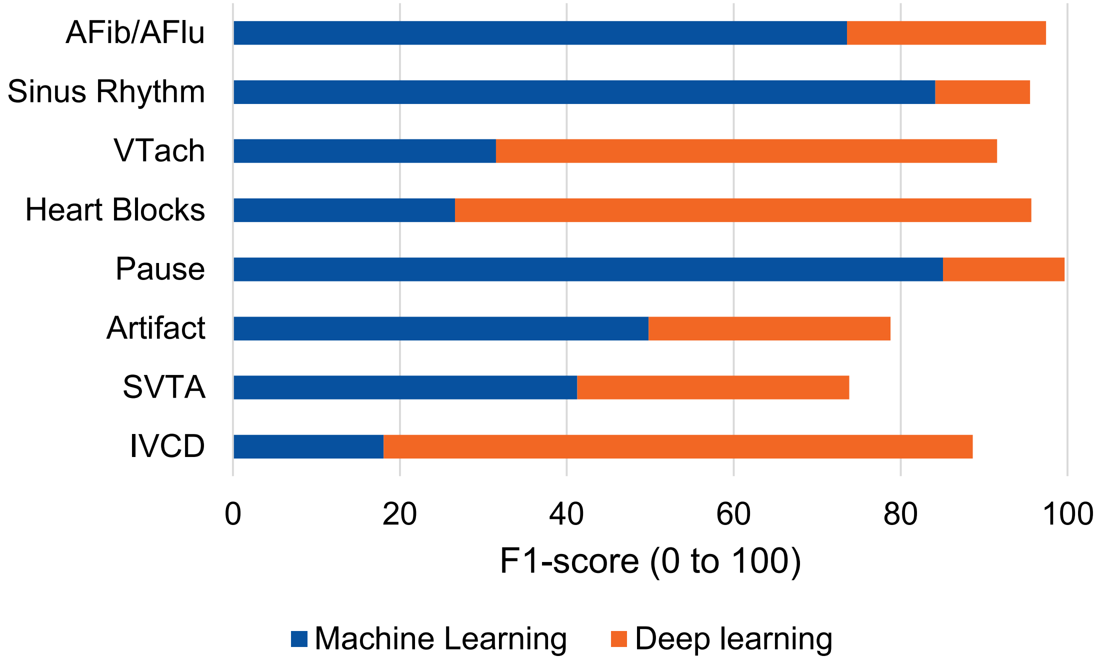
Real-world Validation

$$\text{F1-score} = 2 \times \frac{\text{sensitivity} \times \text{precision}}{\text{sensitivity} + \text{precision}}$$

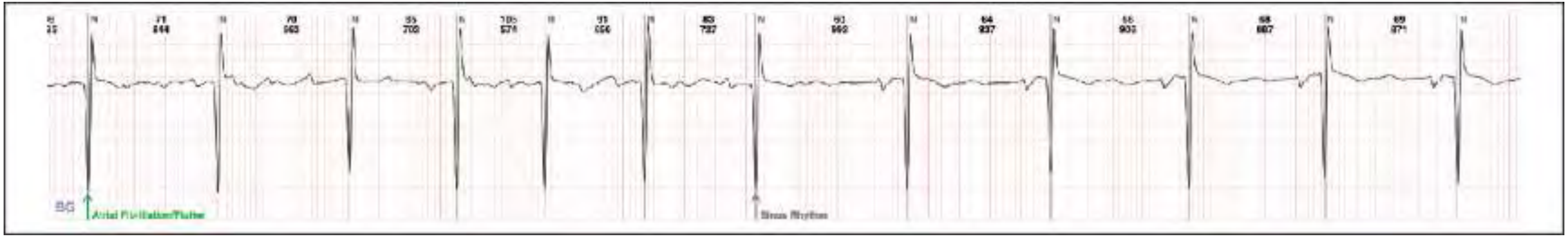
Beat detection/classification performance



Rhythm classification performance



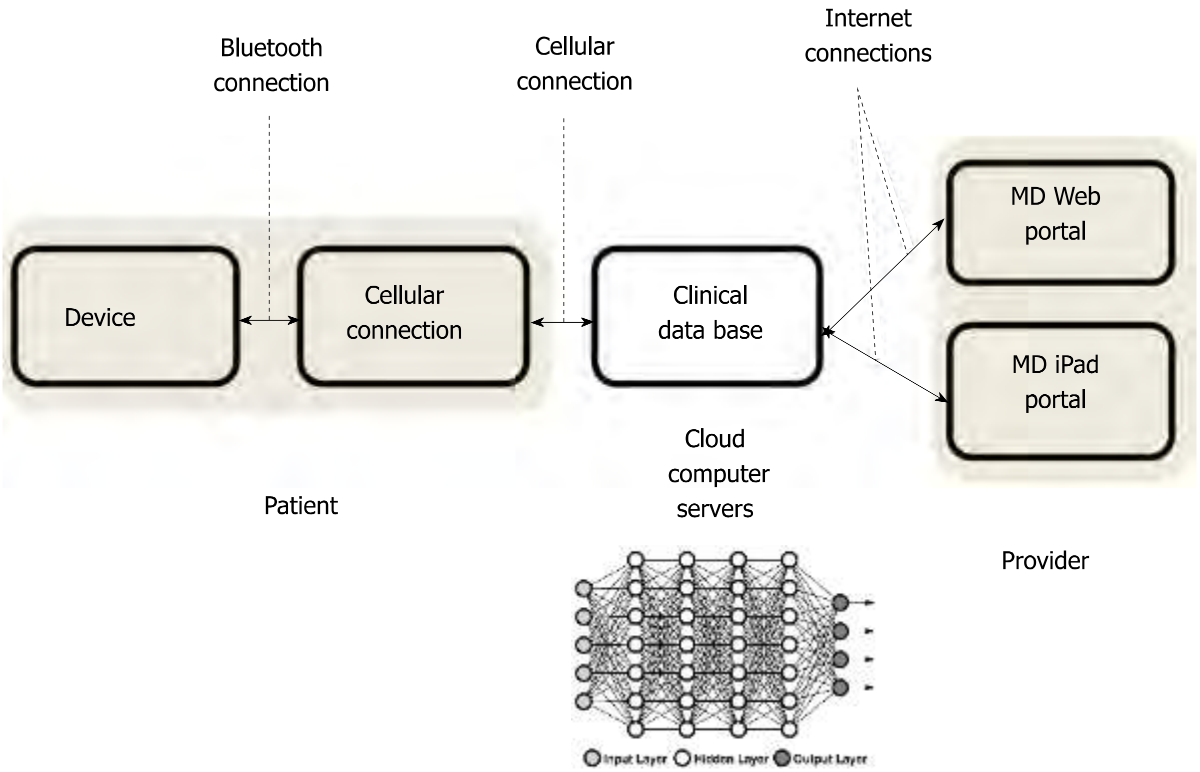
Validation of Deep Learning for AF Duration



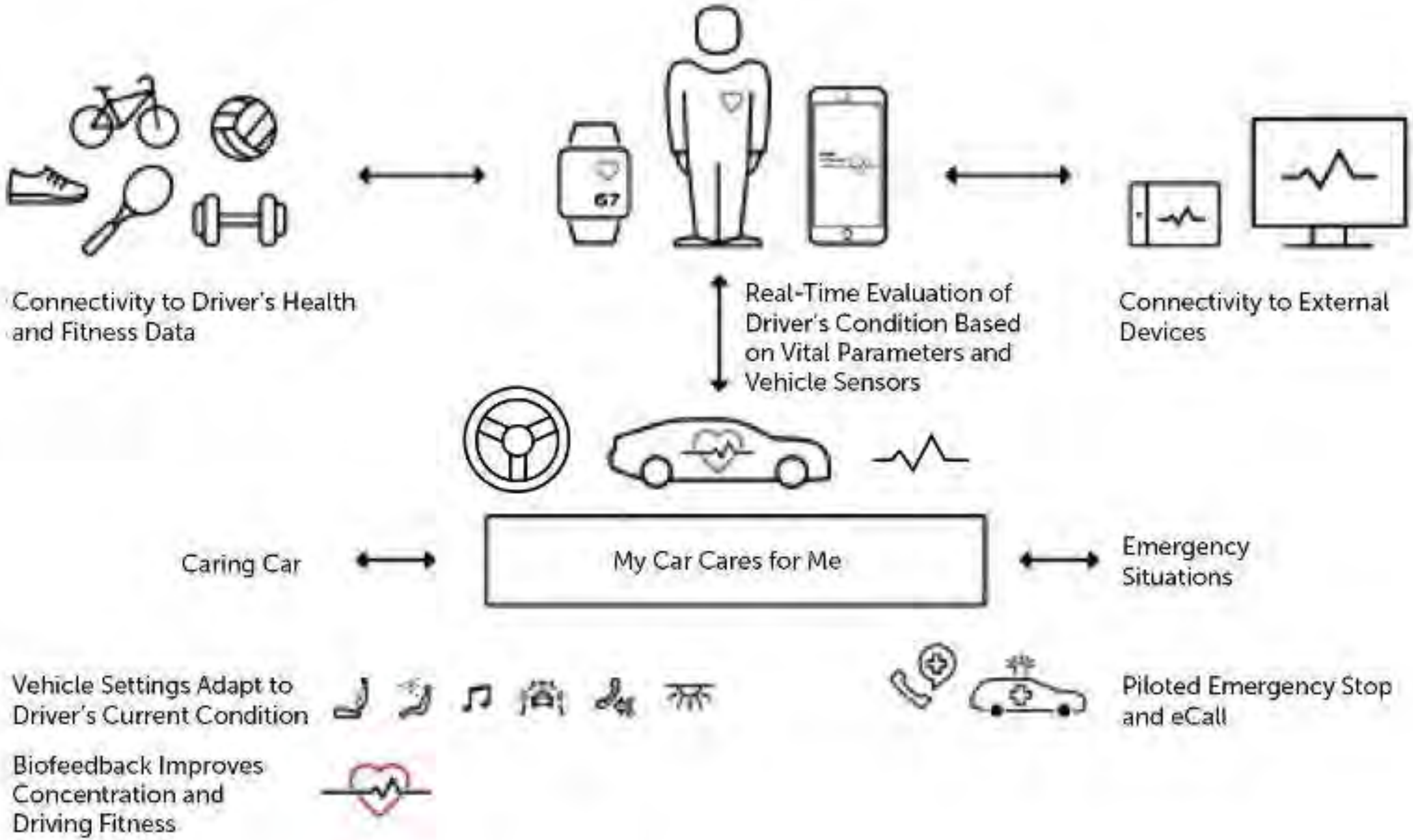
	AFib	Sinus Rhythm
Duration Sensitivity (%)	95.9	99.0
Duration Precision (%)	99.2	94.9

Tiplitzky, Roberts, Mehta, Ghanbari. HRJ 2019

Clinical Use of ECG Detection using DNN



Bruce CJ et al. *World J Cardiol*. 2016;8:559-65.


67
Connectivity to Driver's Health and Fitness Data
Real-Time Evaluation of Driver's Condition Based on Vital Parameters and Vehicle Sensors
Connectivity to External Devices
Caring Car
My Car Cares for Me
Emergency Situations
Vehicle Settings Adapt to Driver's Current Condition
Piloted Emergency Stop and eCall
Biofeedback Improves Concentration and Driving Fitness

Data Are the New Oil

- Data are the key complements to prediction.

- In order to make a good prediction, the machine must have enough individuals (or units of analysis) and diversity in the training data.

- The particular prediction problem will tell you what you need.

Day 1	Day 2	Day 3	Day 4
Symptoms	Symptoms	Symptoms	Symptoms
Affect	Affect	Affect	Affect
Sleep	Sleep	Sleep	Sleep
ECG	ECG	ECG	ECG
Accelerometer	Accelerometer	Accelerometer	Accelerometer
GPS	GPS	GPS	GPS
Bio-impedance	Bio-impedance	Bio-impedance	Bio-impedance

21 Days

Demographics	Risk Factors	Imaging	Baseline Questionnaires
Age Gender Race	Weight Height Hypertension CAD CHF History of CVA Diabetes PVD	Election Fraction Left Atrial Size Valvular abnormalities (Mitral, Aortic, Tricuspid) Functional Capacity	AFEQT SF-36 CCS-AF PROMIS anxiety PROMIS depression PANAS-SF SSAS

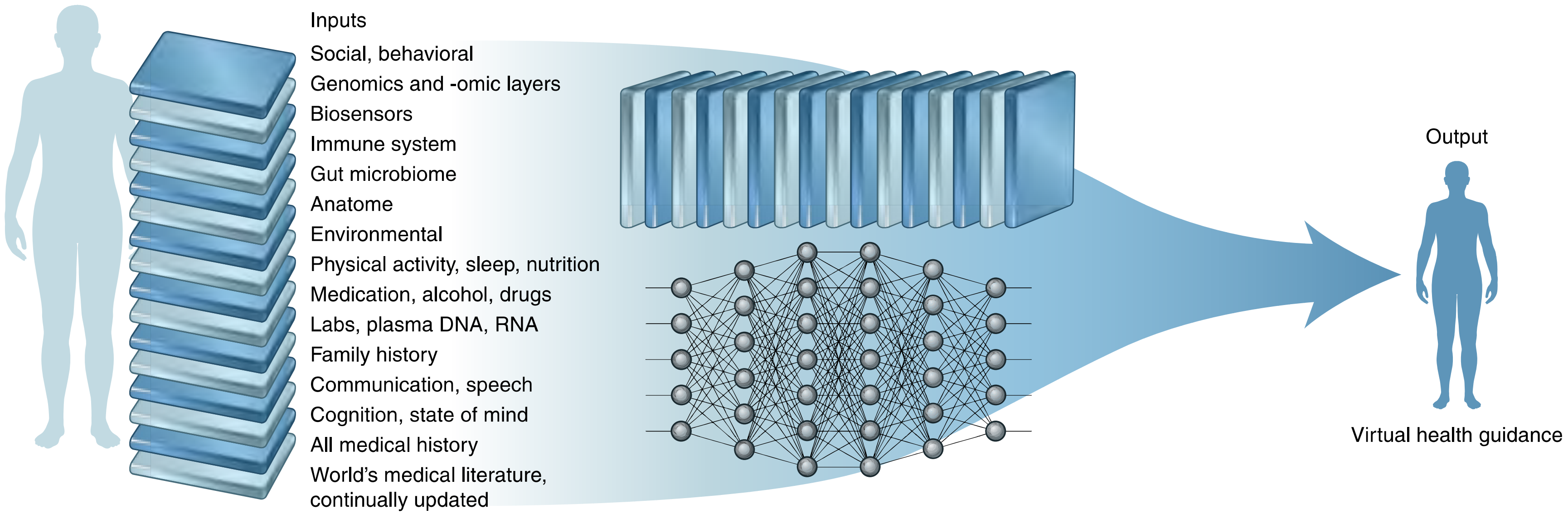
CAD: coronary artery disease; CVA: cerebrovascular accidents; PVD: peripheral vascular disease; CHF: congestive heart failure

MiAfib Project

- Prediction Problem: AF that is likely to be symptomatic
- Results:
  - Identified 66/89 (74.12%) AUC=0.92, F1=0.88

Methods	Sensitivity	Specificity	AUC	F1
Markov Chain Automatically Generated States (MCGENS)	0.90	0.74	0.92	**0.88**
F-wave suppression	0.18	0.93	0.65	0.23
HRV Based Method	0.06	0.995	0.91	0.11

Li Z, Gryak J, Ghanbari H, et al. *Conf Proc IEEE Eng Med Biol Soc*. 2018;Jul:4034-7.



Topol EJ. *Nat Med*. 2019;25:44-56.

I've never been good at giving bad news. Perhaps you'd like to spend a few minutes with our hospital's new empathy robot.