Atrial Fibrillation

Why It's Important

Updated on 2007 / 11 / 23

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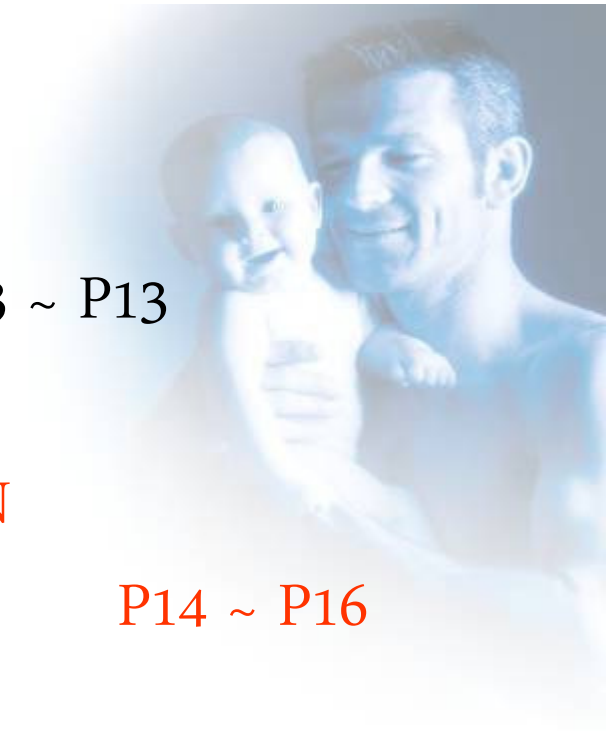
CONTENT



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Stroke Statistics

- Stroke is the leading cause of disability world wide
- Approximately 750,000 strokes occur in the US annually
- Among the elderly a disabling stroke is feared even more than death

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What is Atrial Fibrillation

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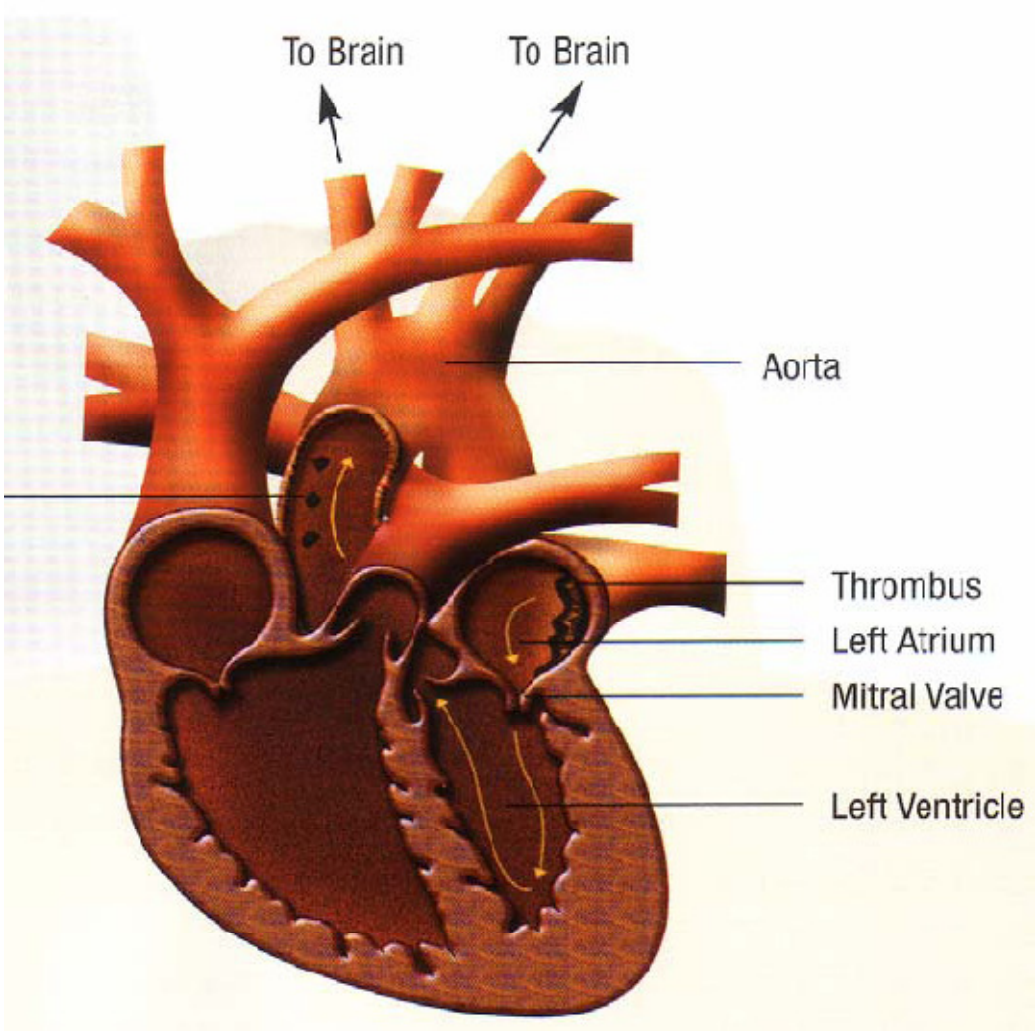


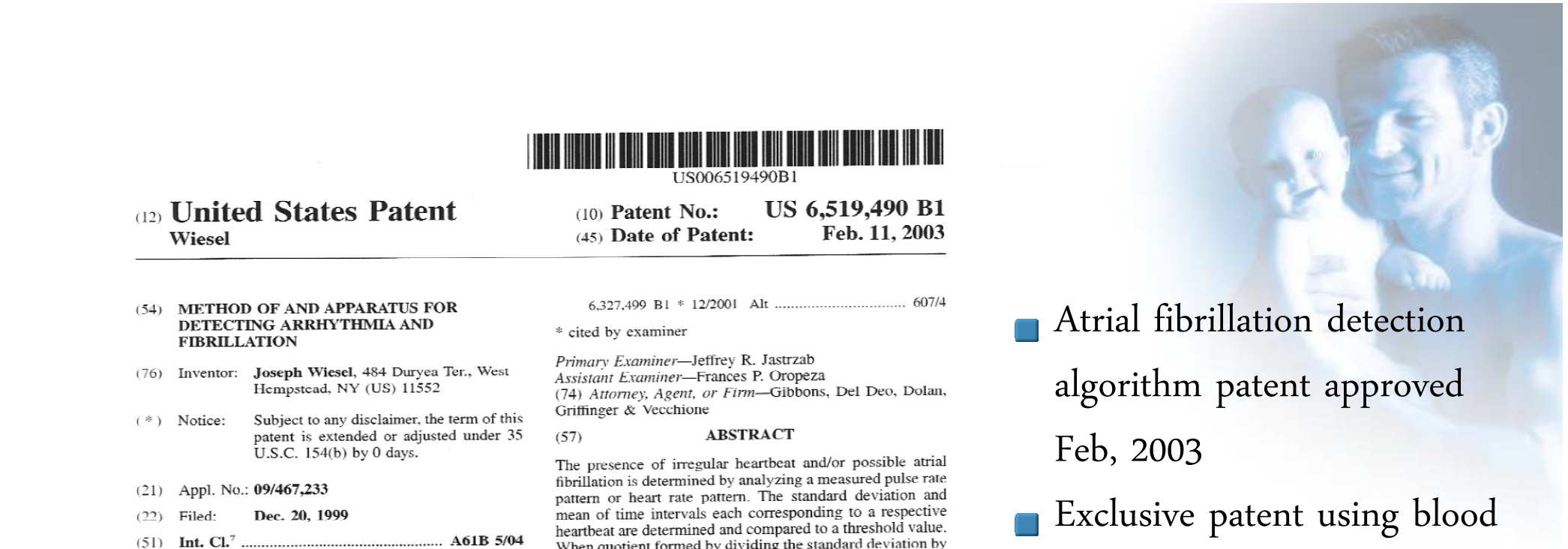
- Upper chambers (atria) beat in a rapid irregular pattern
- Blood is pooled in the atria resulting in clots that can break off and go to the brain
- Treatment with anticoagulants (warfarin) has been proven to markedly reduce the risk of stroke in atrial fibrillation

Stroke Risk Factors

- Many strokes can be prevented by attention to risk factors
- Controllable risk factors include, hypertension, atrial fibrillation, high cholesterol, diabetes and smoking
- Up to 80% of people will develop high blood pressure as they grow older
- Two types of strokes hemorrhagic (blood vessels break in the brain. Ischemic (blood clot blocks blood vessels in the brain.

Atrial Fibrillation

- Most common sustained rhythm abnormality
- Present in approximately 2 million americans
- 15% of people with strokes have atrial fibrillation
  - AF increases risk of stroke 6 times.
- Prevalence increases with age
  - Ages 50-59 6.7% of strokes
  - Ages 80-89 36.2% of strokes
  - Symptoms may include palpitations, shortness of breath or dizziness
  - Many have no symptoms



US006519490B1

(12) **United States Patent**
Wiesel

(10) **Patent No.: US 6,519,490 B1**
(45) **Date of Patent: Feb. 11, 2003**

(54) **METHOD OF AND APPARATUS FOR DETECTING ARRHYTHMIA AND FIBRILLATION**

(76) Inventor: **Joseph Wiesel**, 484 Duryea Ter., West Hempstead, NY (US) 11552

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/467,233**

(22) Filed: **Dec. 20, 1999**

(51) **Int. Cl.**[7] **A61B 5/04**
(52) **U.S. Cl.** **600/518**
(58) **Field of Search** 600/382, 384, 600/485, 500, 502, 504, 509, 513, 515, 516, 517, 518, 519, 521, 526; 607/4, 5, 6, 14, 18, 25

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(57) **ABSTRACT**

The presence of irregular heartbeat and/or possible atrial fibrillation is determined by analyzing a measured pulse rate pattern or heart rate pattern. The standard deviation and mean of time intervals each corresponding to a respective heartbeat are determined and compared to a threshold value. When quotient formed by dividing the standard deviation by the mean has a value greater than or equal to the threshold value, the shortest one of the time intervals and its succeeding time intervals are determined, and the succeeding time interval is compared to the mean. If the succeeding time interval is less than the mean, then the heartbeat is irregular. Alternatively, if the succeeding time interval is greater than the mean, the shortest time interval and its succeeding time interval are eliminated from the sample values, a new mean and standard deviation are determined, and the quotient of the new standard deviation divided by the new mean are compared to the threshold value. When the quotient is greater than the threshold value, the next shortest interval is determined, and the absolute value of the difference between the next shortest interval and the shortest interval is compared to an empirically determined value. If the difference is greater than the empirically determined value, the heartbeat is irregular. Alternatively, if the difference is greater than the empirically determined value, then the next shortest interval and its succeeding interval are redefined as the new shortest interval and is succeeding interval. The steps are repeated until it is determined that the heartbeat is regular or irregular.

40 Claims, 4 Drawing Sheets

- Atrial fibrillation detection algorithm patent approved Feb, 2003
- Exclusive patent using blood pressure monitor for detecting atrial fibrillation granted Dec, 2005

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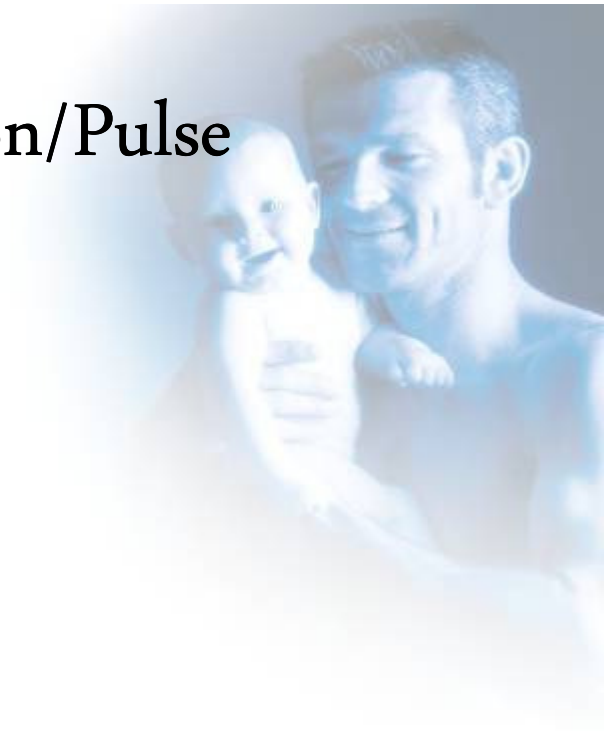
Microlife Irregular Heartbeat Detection/Pulse

Arrhythmia Detection clinical study

Dr. KW Forstner May 2003



- 52 patients
- Detected 66.6 % atrial fibrillation
- Detected 85.7% premature contractions
- Detected 66.6% sinus bradycardia
- Detected all tachycardia

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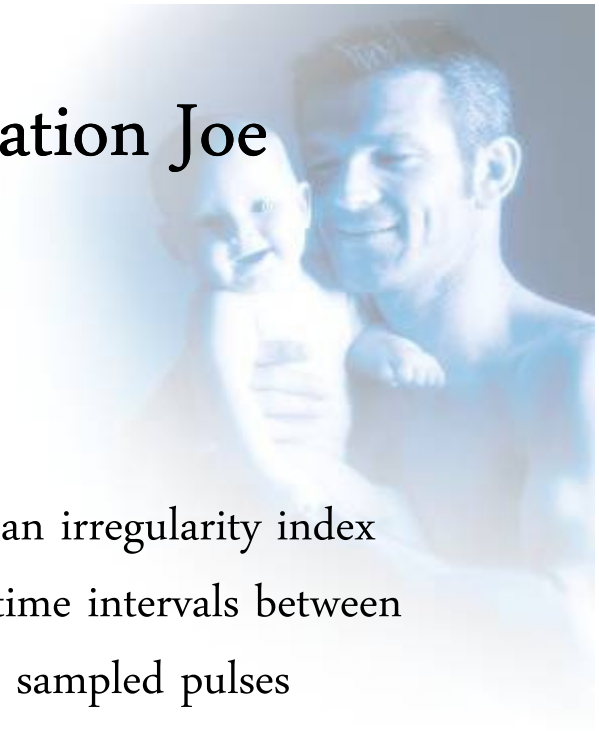
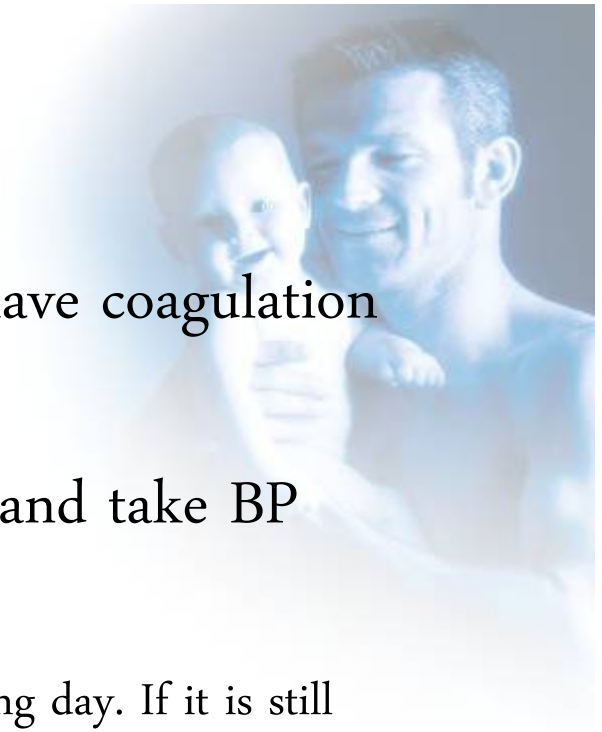
Study to detect recurrent Atrial Fibrillation Joe Wiesel MD July 2006



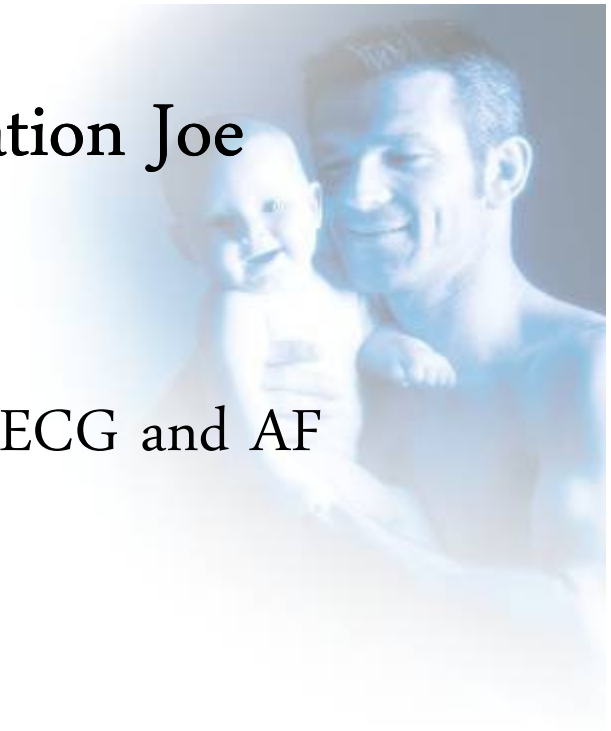
- How the detection works
  - Last 10 heartbeats during deflation of cuff and calculates an irregularity index
    - The index is defined as the standard deviation of the time intervals between the beats divided by the mean time interval for the 10 sampled pulses
    - If the threshold is greater than 0.06 the rhythm is AFib
  - Averages the time between

Sustained Atrial Fibrillation



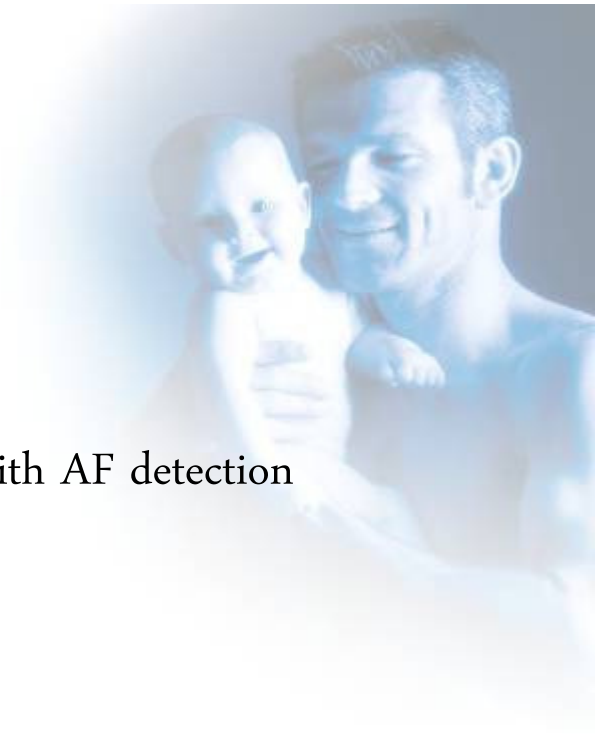
- It takes at least 48 hours of AF to begin to have coagulation of blood in the atria of the heart
- Patients who detect AF should wait an hour and take BP again.
  - If AF still is present be sure to take BP again the following day. If it is still present get to the emergency room or doctors office to be confirmed by ECG and placed on blood thinners to break blood clots that may be forming
  - AF lasting less than 48 hours is considered low risk according to the ACCP

Study to detect recurrent atrial fibrillation Joe Wiesel MD July 2006



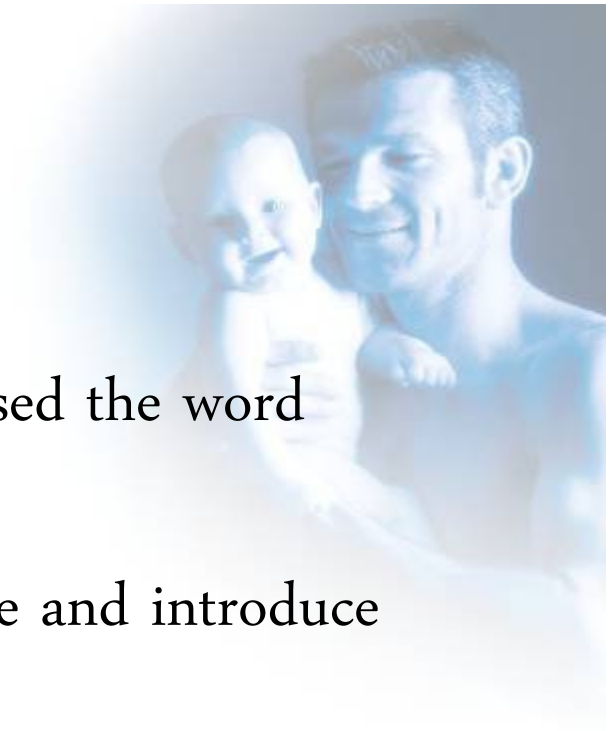
- ~ 400 patients in office paired readings with ECG and AF algorithm in BPM
  - ECG is the gold standard for detecting Atrial Fibrillation
  - 53 with AF
  - 56 paired readings (3 false positives)
  - Sensitivity 100%
    - Detected all AF!
  - Specificity 91%
    - Detected 53 of the 56 cases with AF
      - 3 arrhythmia's not associated with AF detected

Dr. Fitzig Trial Update



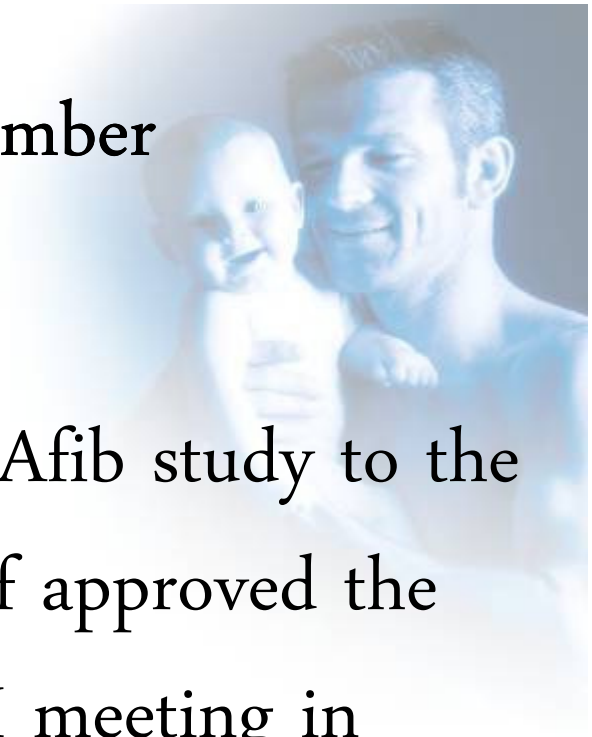
- New York Hospital
  - 76 patients tested
  - Paired readings with ECG and Microlife BPM equiped with AF detection
    - 3 BP readings taken with one minute intervals
- Single readings
  - 97.2% Sensitivity 86.67% Specificity
- Three readings
  - 100% Sensitivity 91.67% Specificity
- 100 Patients by October 15
  - Begin FDA approval process!

FDA Approval Strategy



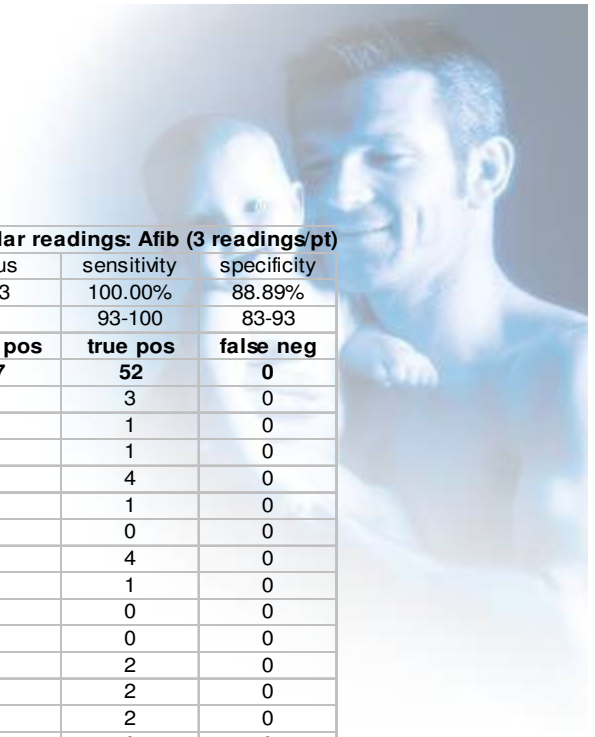
- Submit data on 100 patients by Dec 1
- Omron has approval for an ECG that has used the word arrhythmia in its IFU
- ML may reference this product as a predicate and introduce IFU
- Detects heart arrhythmia's*
  - "*Arrhythmia's of this type correlate with Atrial Fibrillation a major cause of strokes "Journal of Stroke and Cerebrovascular Disease, Vol 16, No. 1 (January-February), 2008

UPDATED INFORMATION in November



- Dr. Wiesel submitted his 205 patient Afib study to the ASH abstract committee on Nov. 19. If approved the abstract would be presented at the ASH meeting in May/New Orleans.

Clinical Data



	Single irregular reading: AFib (individual readings)						Two or more irregular readings: Afib (3 readings/pt)			
	afib	sinus	sensitivity	specificity			afib	sinus	sensitivity	specificity
readings	156	460	98.08%	87.83%		**pts**	52	153	100.00%	88.89%
95% confidence intervals			94-99	85-91					93-100	83-93
Date	**True neg**	**false pos**	**true pos**	**false neg**			**True neg**	**false pos**	**true pos**	**false neg**
	404	**56**	**153**	**3**			**136**	**17**	**52**	**0**
4/25/07	15	6	9	0			5	2	3	0
4/26/07	18	3	3	0			6	1	1	0
4/30/07	32	1	3	0			10	1	1	0
5/1/07	30	3	11	1			11	0	4	0
5/2/07	47	4	3	0			16	1	1	0
5/3/07	27	0	0	0			9	0	0	0
5/7/07	15	0	12	0			5	0	4	0
5/8/07	26	7	3	0			9	2	1	0
5/9/07	24	3	0	0			8	1	0	0
5/10/07	8	8	0	0			2	3	0	0
5/14/07	36	3	5	1			12	1	2	0
5/15/07	21	6	6	0			7	2	2	0
5/16/07	39	0	6	0			13	0	2	0
5/17/07	29	10	0	0			10	3	0	0
5/21/07	37	2	0	0			13	0	0	0
5/22/07	0	0	9	0			0	0	3	0
5/31/07	0	0	12	0			0	0	4	0
6/4/07	0	0	5	1			0	0	2	0
6/5/07	0	0	3	0			0	0	1	0
6/12/07	0	0	3	0			0	0	1	0
6/13/07	0	0	3	0			0	0	1	0
6/20/07	0	0	3	0			0	0	1	0
6/21/07	0	0	3	0			0	0	1	0
6/25/07	0	0	3	0			0	0	1	0
6/26/07	0	0	3	0			0	0	1	0
6/27/07	0	0	3	0			0	0	1	0
7/1/07	0	0	6	0	one patient re-do new a fib		0	0	2	0
7/2/07	0	0	6	0			0	0	2	0
7/12/07	0	0	3	0			0	0	1	0
7/17/07	0	0	3	0			0	0	1	0
7/24/07	0	0	3	0			0	0	1	0
7/30/07	0	0	3	0	one patient re-do new a fib		0	0	1	0
8/1/07	0	0	6	0			0	0	2	0
8/2/07	0	0	3	0	one patient re-do new a fib		0	0	1	0
8/22/07	0	0	3	0			0	0	1	0
8/28/07	0	0	3	0			0	0	1	0
8/30/07	0	0	3	0			0	0	1	0

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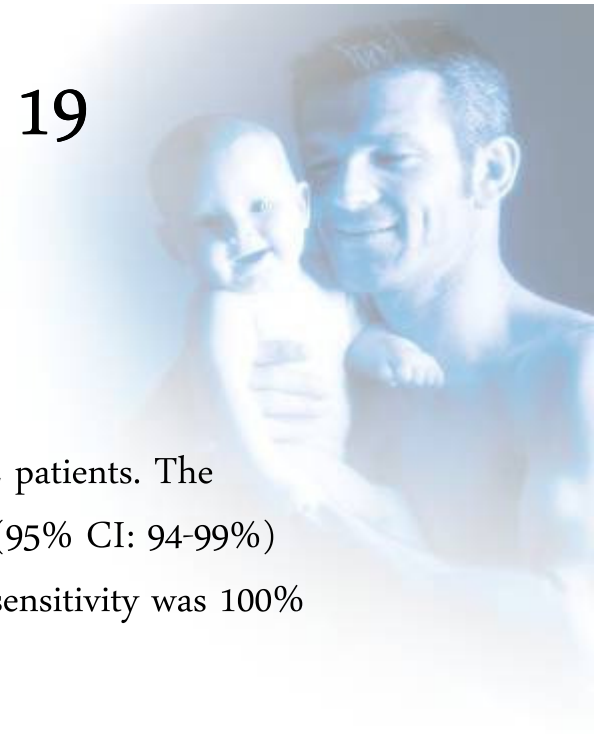
ASH Abstract Submitted in November 19



A total of 205 patients were enrolled. EKG evidence of AF was present in 52 patients. The sensitivity and specificity to identifying AF for individual readings was 98% (95% CI: 94-99%) and 88% (85-91%). For the three sequential readings grouped together, the sensitivity was 100% (93-100%) and specificity 89%(83-93%).

The Microlife blood pressure monitor designed to detect AF has a very high sensitivity for detecting AF with a low false postive rate (specificity near 90%). The use of this device may reduce the risk of stroke due to AF by detecting asymptomatic AF and allowing for appropriate treatment with anticoagulation.

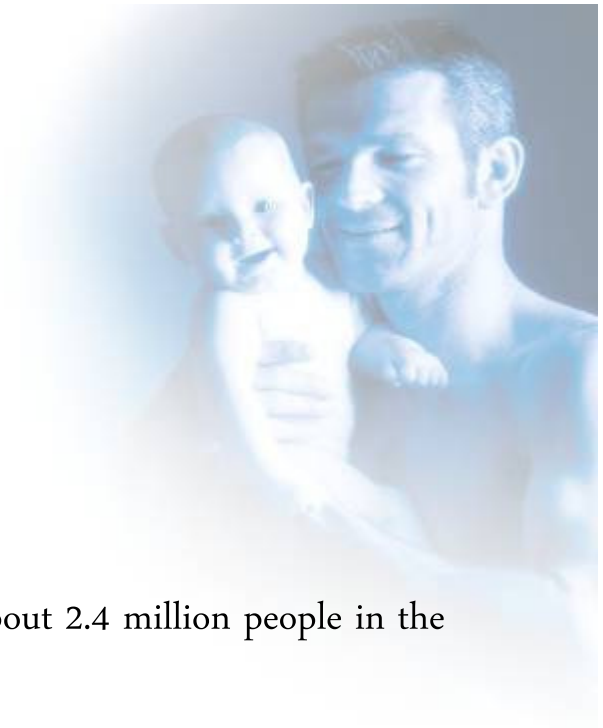
Interesting links:

Web links related to the topic of AF and Stroke:

1. http://en.wikipedia.org/wiki/Atrial_fibrillation#Routine_primary_care_visit
2. http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&dopt=AbstractPlus&list_uids=16908781
3. http://en.wikipedia.org/wiki/Stroke
4. http://www.strokecenter.org/prof/guidelines.htm

Associations:

1. http://www.strokeassociation.org/presenter.jhtml?identifier=1200037
2. http://www.eusi-stroke.com
3. http://www.stroke.org.uk/
4. http://www.strokefoundation.com.au



Who gets Afib? Afib is the most common type of heart arrhythmia. About 2.4 million people in the United States are affected.

People of all ages can get Afib Young people with otherwise healthy normal hearts can develop Afib.

It is most often found in older people with some other heart disease.

It affects about 15% of people over age 85.

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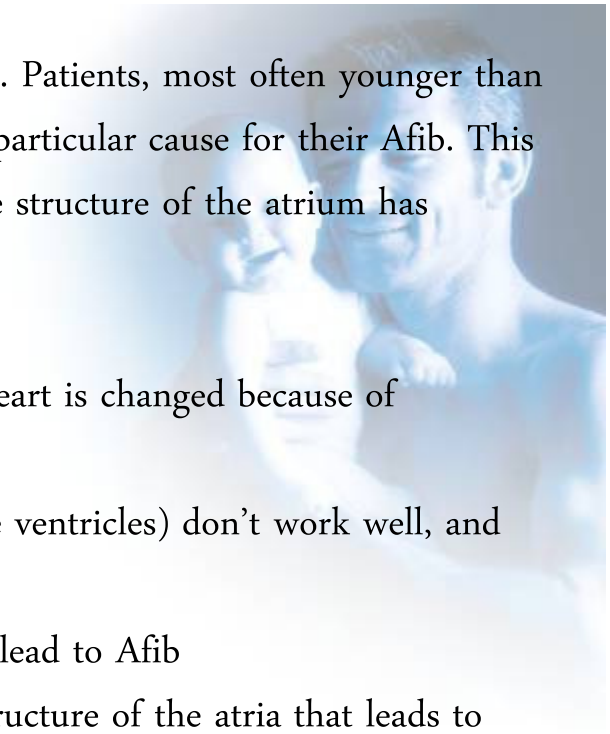
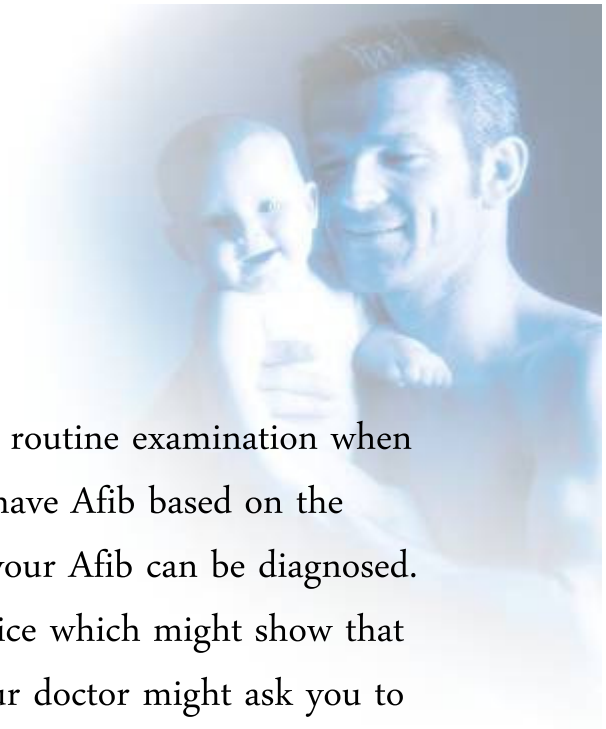


- **What causes Afib?** Sometimes there is no obvious reason or cause for the AF. Patients, most often younger than 65, who develop Afib may have no changes in their heart structure or other particular cause for their Afib. This has been called "Lone Afib ." In other patients, AF occurs because the tissue structure of the atrium has changed and enlarged, called remodeling. This can be due to:
- High blood pressure
- Coronary artery disease-a condition in which the normal blood flow to the heart is changed because of blockages in arteries
- Heart failure—a condition in which the heart's main pumping chambers (the ventricles) don't work well, and this can lead to problems with the atria
- Valvular heart disease—damage to a valve can cause the atria to enlarge and lead to Afib
- Lung diseases-some people with chronic lung diseases have changes in the structure of the atria that leads to Afib
- Thyroid problems—an overactive thyroid gland can lead to Afib
- Excessive alcohol intake—People who drink alcohol often, in large quantities, or who have drinking binges may get Afib.
- Sometimes people who have had heart bypass or other heart surgery may develop atrial fibrillation soon after the surgery. This may be related to scarring or irritation. This may convert on its own, or require other treatment.



- **How is Afib diagnosed?** Your doctor may suspect you have Afib during a routine examination when he noticed an irregular heart beat. Or your doctor may suspect that you have Afib based on the symptoms that you tell him you are having. There are several ways that your Afib can be diagnosed. First, the doctor may do an EKG (a tracing of your heart beat) in the office which might show that you are in Afib. Or if you are having short episodes or spells of Afib, your doctor might ask you to wear a special monitor for 24 hours (Holter monitor) or even as long as a month (Event monitor). These monitors can "catch" the episode of irregular heartbeat and help your doctor to see whether or not it is Afib.