

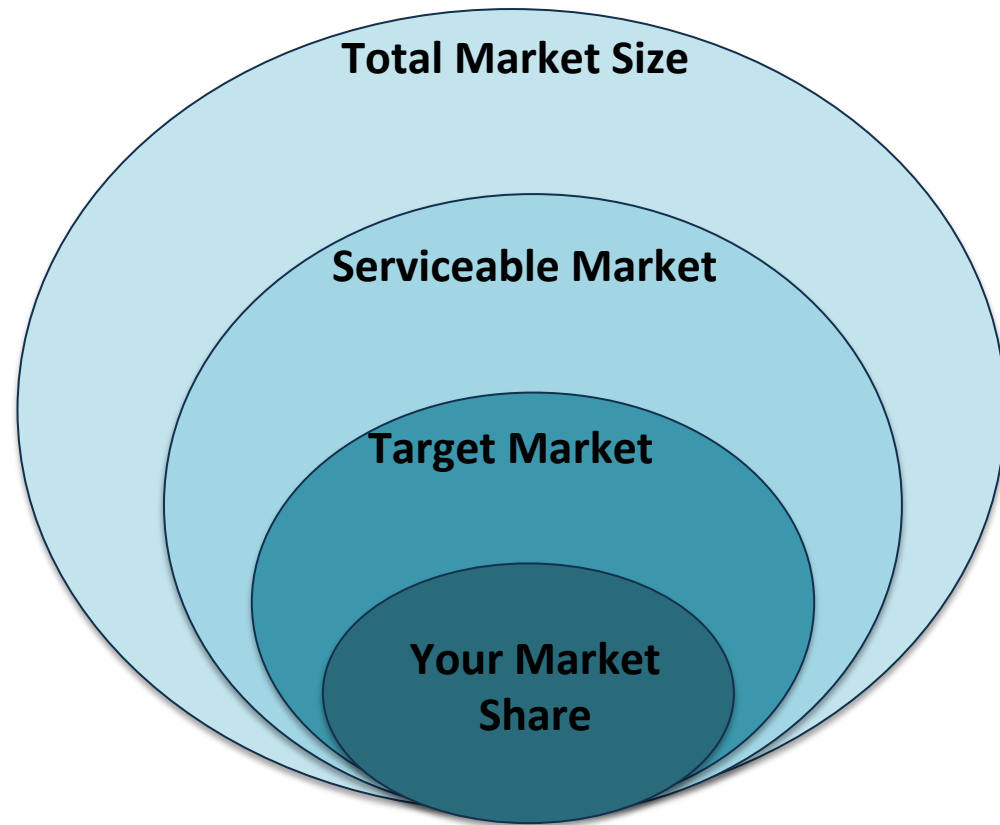


Market Assessment

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Market Analysis

- Who are your clients?
- Who are the end-users?
- Consumer segments
- Market size
- Market share
- Market characteristics
- Growth potential
- Existing competitors
- Barrier to entry
- Territories



Atrial Fibrillation (AF)

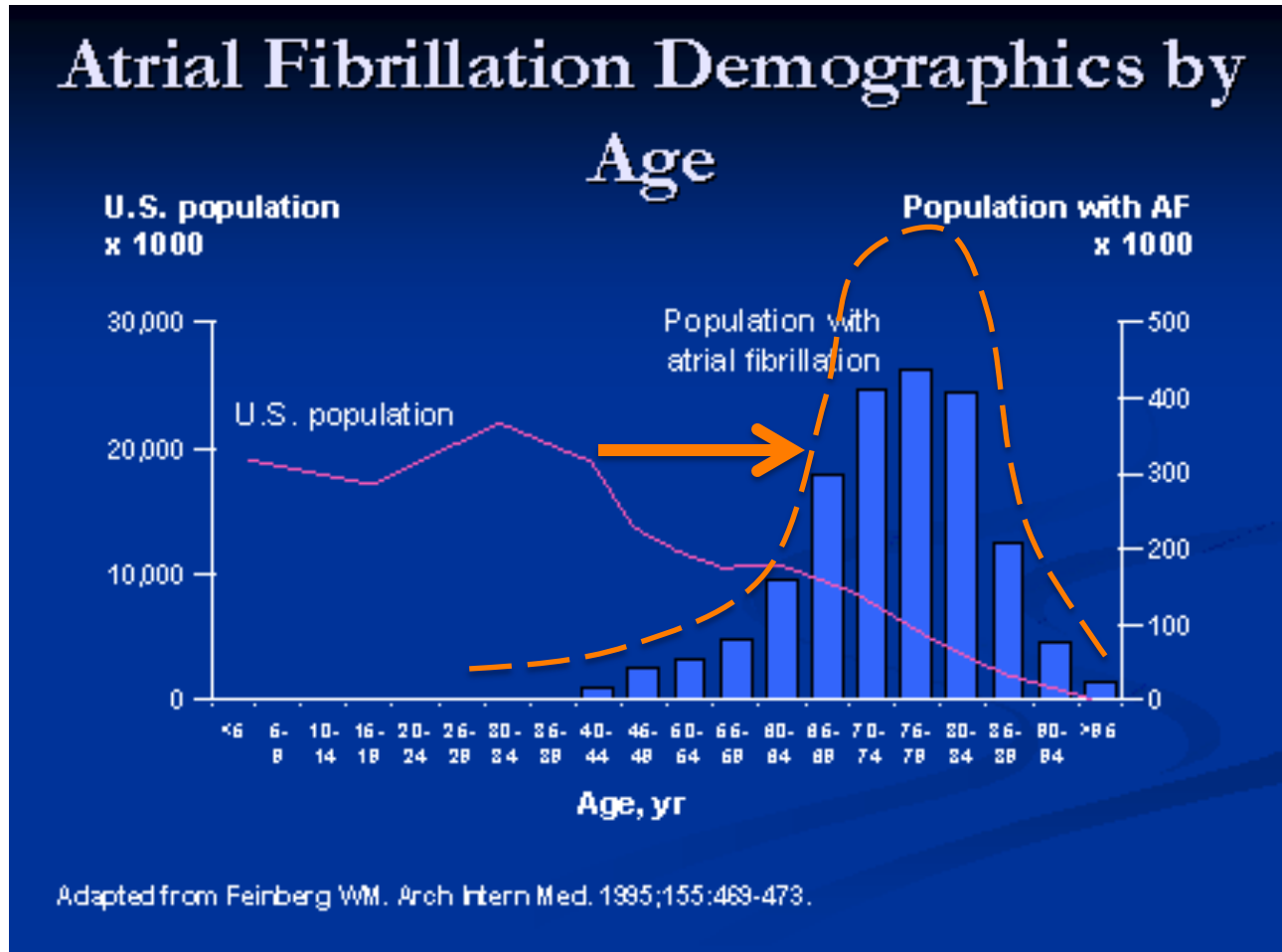
- One of the most common [heart arrhythmias](#) (heart irregular rhythm) today
- Affecting an estimated 1% of the population.
- US 2% of <65 yrs and 9% >65 yrs have AF
- Can even lead to heart failure
- The leading cause of stroke
- Early detection and diagnosis is paramount in order to be able to prevent stroke



Atrial fibrillation can increase stroke risks five-fold. Learn more about what you can do to lower risks and live a healthy life.

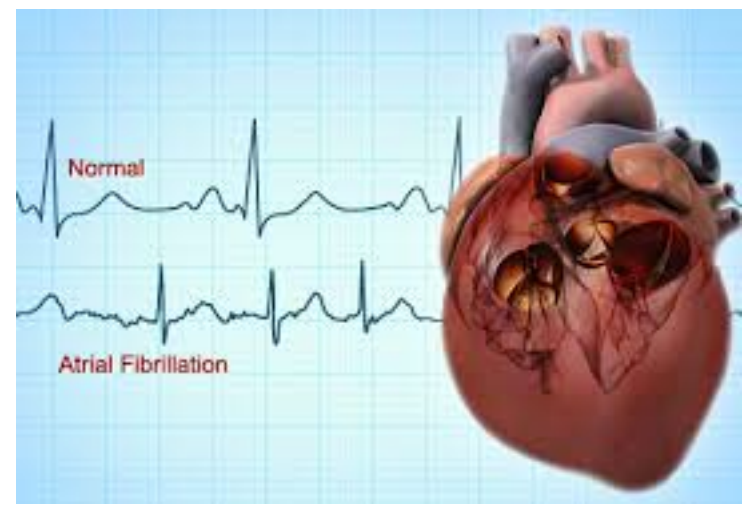
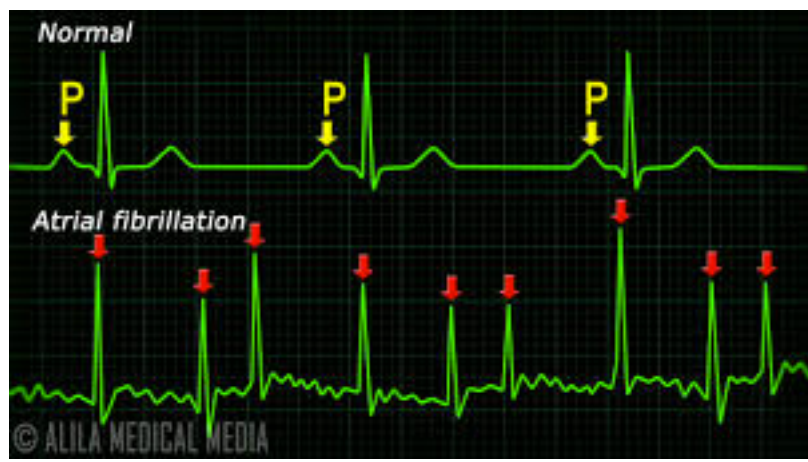
VISIT OUR INTERACTIVE GUIDE NOW >

AF Occurrence by Age



http://www.vtachmd.com/myweb2/who_ge1.gif

Detection of Atrial Fibrillation (AF)



Detection of Atrial Fibrillation (AF)

Atrial fibrillation is detected and diagnosed as the result of a test called an [electrocardiogram \(ECG or EKG\)](#) that records the heart's electrical activity.

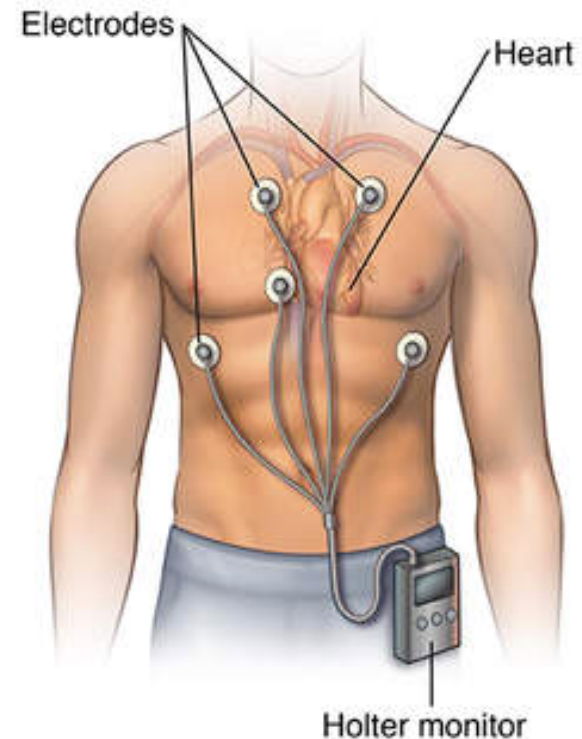
Because Atrial fibrillation occurs irregularly, the short ECG a doctor would typically perform in-office is unlikely to detect it.

For this reason many healthcare providers use Holter monitors* to observe their patients' hearts over a longer period of time, usually over the course of several days or a couple of weeks.

Detection of Atrial Fibrillation (AF)

Holter monitors:

a portable device that records the rhythm of the heart continuously, typically for 24–48 hours, by means of electrodes attached to the chest.



Heart Monitor

A heart monitor for use as a non-invasive screening tool for identifying potential atrial fibrillation in patients comprises a sensor for producing an output waveform of the patient's actual sinus rhythm, a processing unit arranged to store the normalized waveform of an ideal sinus rhythm and to compare the actual and ideal sinus rhythm waveforms and to produce an output dependent on the difference on a display. The value of the output is indicative of whether the patient is atrial fibrillation or other cardiac arrhythmia.

Inventor: Prof. Dawood Parker

Product Development: Dr. Surya Raghu



Machine translation

1. (WO2007135464) HEART MONITOR

[PCT Biblio. Data](#)
[Description](#)
[Claims](#)
[National Phase](#)
[Notices](#)
[Drawings](#)
[Documents](#)

Latest bibliographic data on file with the International Bureau

PermaLink

Pub. No.: WO/2007/135464 International Application No.: PCT/GB2007/050280
 Publication Date: 29.11.2007 International Filing Date: 22.05.2007
 IPC: A61B 5/0452 (2006.01)

Applicants: MELYS AFS LTD [GB/GB]; Whitland Abbey, Whitland, Carmarthenshire SA34 0LG (GB) (For All Designated States Except US).
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Inventors: PARKER, Dawood; (GB).
 BOWES, Mark; (GB)

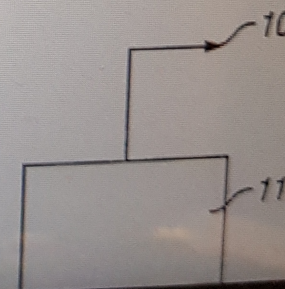
Agent: EVANS, Huw David Duncan; Chapman Molony, Cardiff, South Glamorgan CF24 4AY (GB)

Priority Data: 0610292.5 24.05.2006 GB

Title (EN) HEART MONITOR
 (FR) DISPOSITIF DE SURVEILLANCE CARDIAQUE

Abstract: (EN) A heart monitor for use as a non-invasive screening tool for identifying potential atrial fibrillation in patients comprises a sensor (10) for producing an output waveform of the patient's actual sinus rhythm, a processing unit (11) arranged to store the normalised waveform of an ideal sinus rhythm and to compare the actual and ideal sinus rhythm waveforms and to produce an output dependant on the difference on a display (12). The value of the output is indicative of whether the patient is atrial fibrillation or other cardiac arrhythmia.

(FR) L'invention décrit un dispositif de surveillance cardiaque destiné à être utilisé comme outil de contrôle non invasif permettant d'identifier une fibrillation auriculaire potentielle chez un patient. Le dispositif comporte un détecteur 10 pour produire une forme d'onde de sortie du rythme sinusal réel du patient; une unité de traitement 11 arrangée pour stocker la forme d'onde normalisée d'un rythme sinusal idéal, pour comparer la forme d'onde réelle des rythmes sinusaux à la forme d'onde idéale, et pour, en fonction de la différence





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(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2010/0022897 A1**

Parker et al. (43) **Pub. Date: Jan. 28, 2010**

(54) **HEART MONITOR**

(30) **Foreign Application Priority Data**

(76) Inventors: **Dawood Parker**, Carmarthenshire (GB); **Mark Bowes**, Caermarthen (GB)

May 24, 2006 (GB) 0610292.5

Publication Classification

(51) **Int. Cl.**
A61B 5/0402 (2006.01)
A61B 5/024 (2006.01)

(52) **U.S. Cl.** 600/500; 600/508; 600/509

(57) **ABSTRACT**

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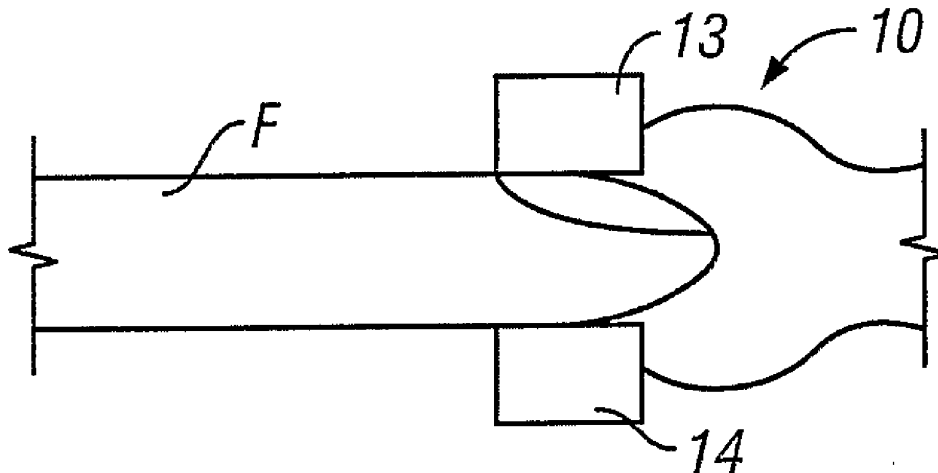
A heart monitor for use as a non-invasive screening tool for identifying potential atrial fibrillation in patients comprises a sensor for producing an output waveform of the patient's actual sinus rhythm, a processing unit arranged to store the normalised waveform of an ideal sinus rhythm and to compare the actual and ideal sinus rhythm waveforms and to produce an output dependant on the difference on a display. The value of the output is indicative of whether the patient is atrial fibrillation or other cardiac arrhythmia.

(21) Appl. No.: **12/302,042**

(22) PCT Filed: **May 22, 2007**

(86) PCT No.: **PCT/GB2007/050280**

§ 371 (c)(1),
(2), (4) Date: **Sep. 22, 2009**



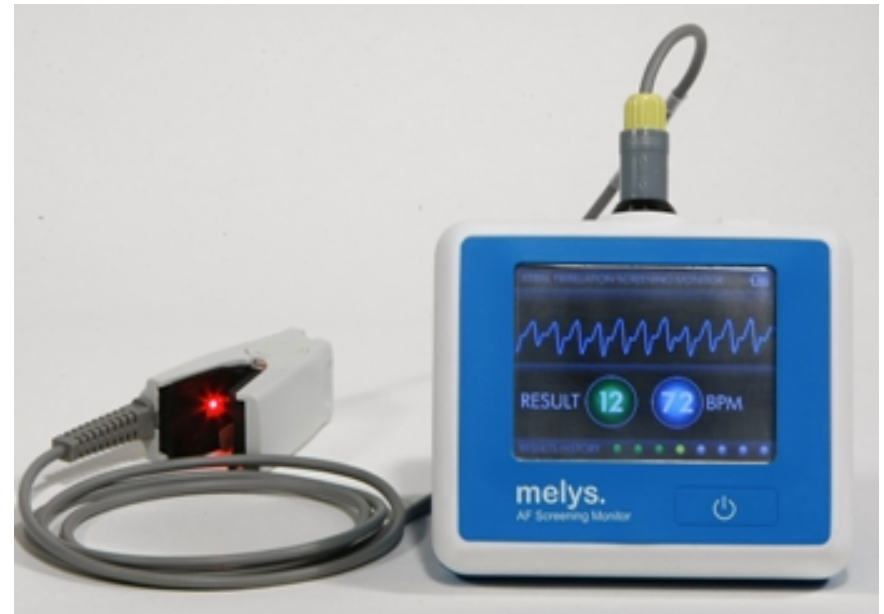
Product Status

- FDA Approved Feb. 2014
- US Patent Allowed 2015
- 30 prototypes fabricated
- Ready to be manufactured

Detection of Atrial Fibrillation (AF)

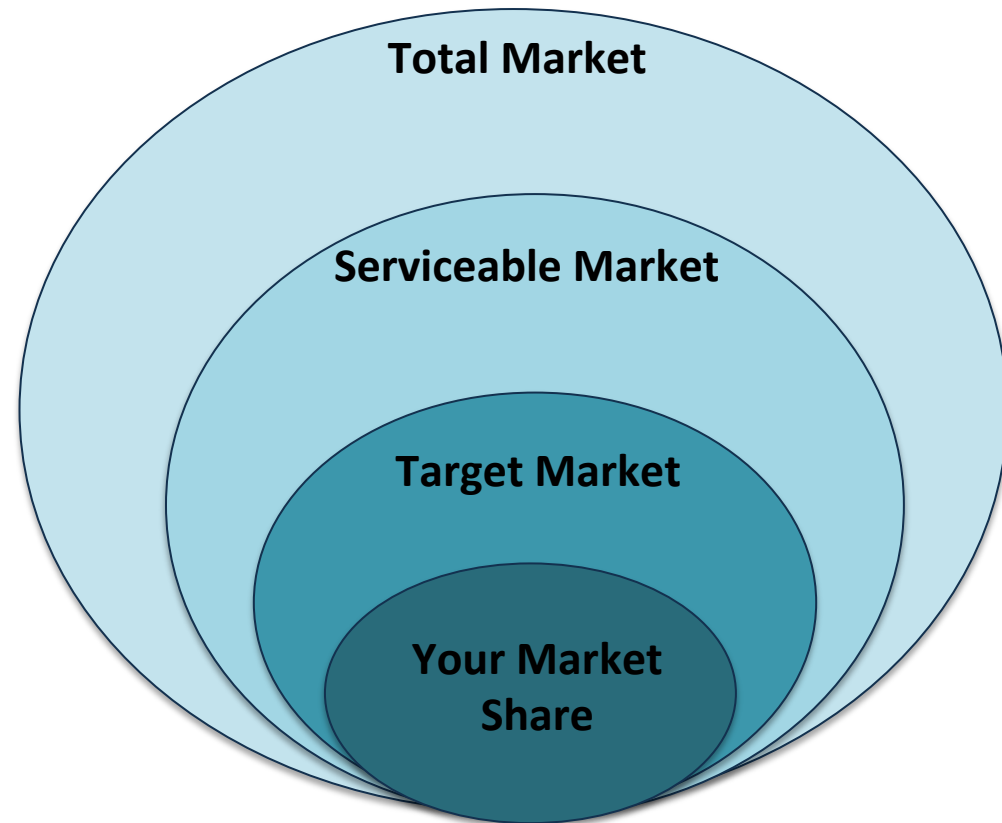
Atrial Fibrillation Monitor (AFM)

The Melys Atrial Fibrillation Monitor is a non-invasive tool that can be used by medical professionals, non-medical staff, and patients to quickly monitor specifically for AF, on site or at home, using a simple finger clip sensor.



Market Analysis Exercise

- Who are your clients?
- Who are the end-users?
- Consumer segments?
- Market size?
- Market share?
- Market characteristics?
- Growth potential?
- Existing competitors?
- Barrier to entry?
- Territories?





Raghu's market size calculation.....

AFSM Market Size Estimates

Market	Item	Number in US
Home monitoring of AF patients	Total number of people with AF in the US	7,500,000
Professional ambulatory emergency medical equipment	Ambulances	40,000
	Fire-dept. based vehicles	75,000
	Police vehicles	260,000
	First Responder sites	290,000
	Registered Hospitals	5,708
	Lifeboats	
		Total

AFSM Market Size Estimates

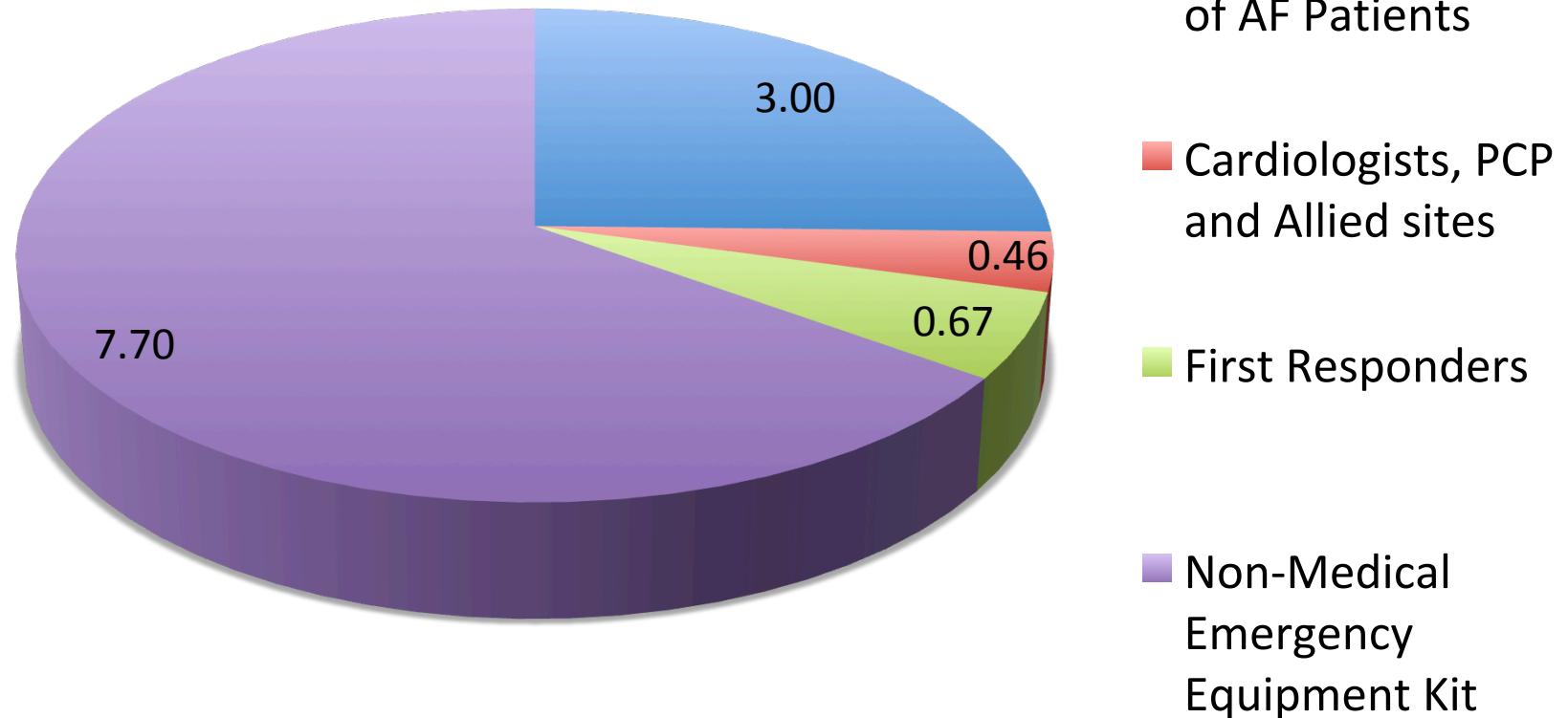
Physician Statistics (All included under PCP)	Cardiologists in US	16,800
	PCPs in US	250,000
	Allied medical sites	190,000
	Total	456,800
Non-professional emergency medical equipment	Private Schools	33,740
	Public Schools	95,000
	Establishments with paid employees	7,387,000
	Establishments in arts, entertainment, and recreation as of Q1, 2015	140,766
	Bus transportation services	
	Airlines	
	Total	7,656,506

AFSM Market Size Estimates

Military / Defense	Troop transport	
	Helicopters	
	Ships	
	Airplanes	
	Bases	
	Military training facilities	
	Military schools & academies	57
	Total	
Government???	All office locations	

The Opportunity

In Millions of Units Needed





Competition analysis.....

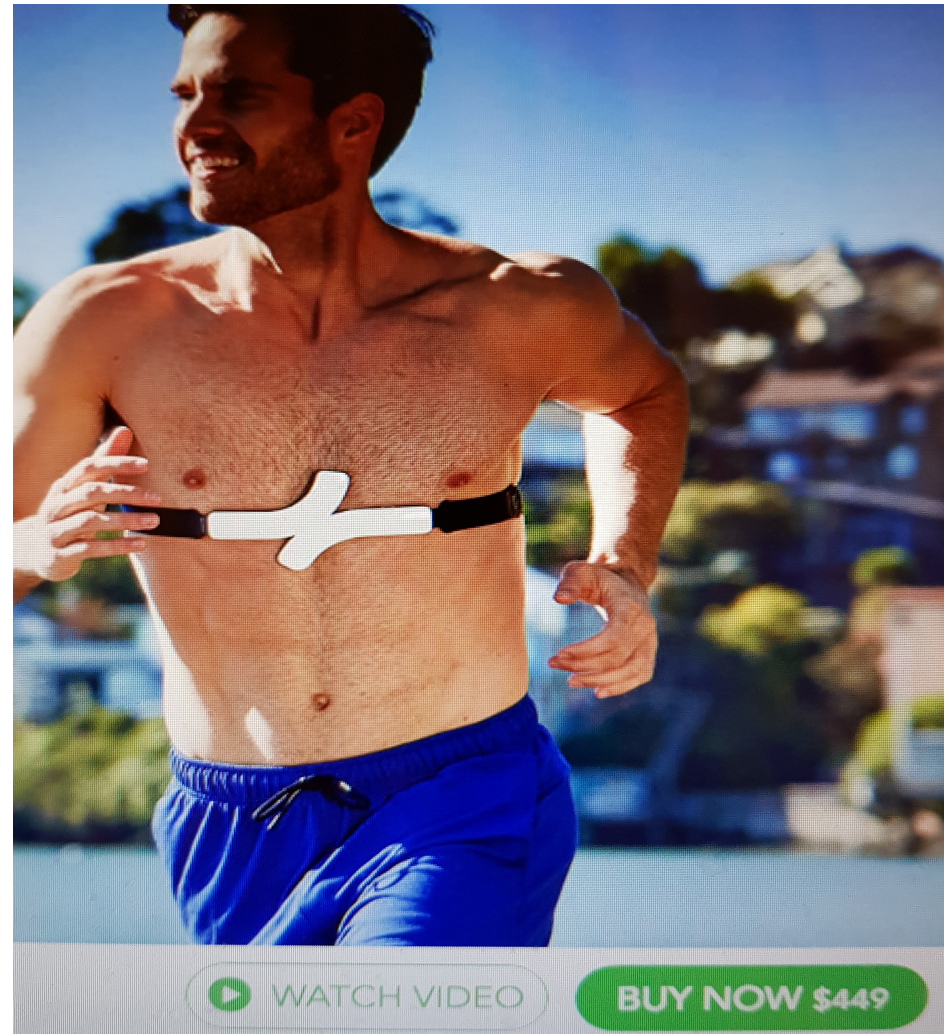
Alternative Products

QardioCore:

“The World first wearable ECG – Free from patches and wires”

\$449

QardioCore is the world’s first ECG monitor to allow for the continuous screening and managing of heart conditions without the need for a prescription and a doctor’s visit.



Competition

- Alivecorea
- Afibalert(cellphoneApp. and internet based, PHI sensitive)



The Competition

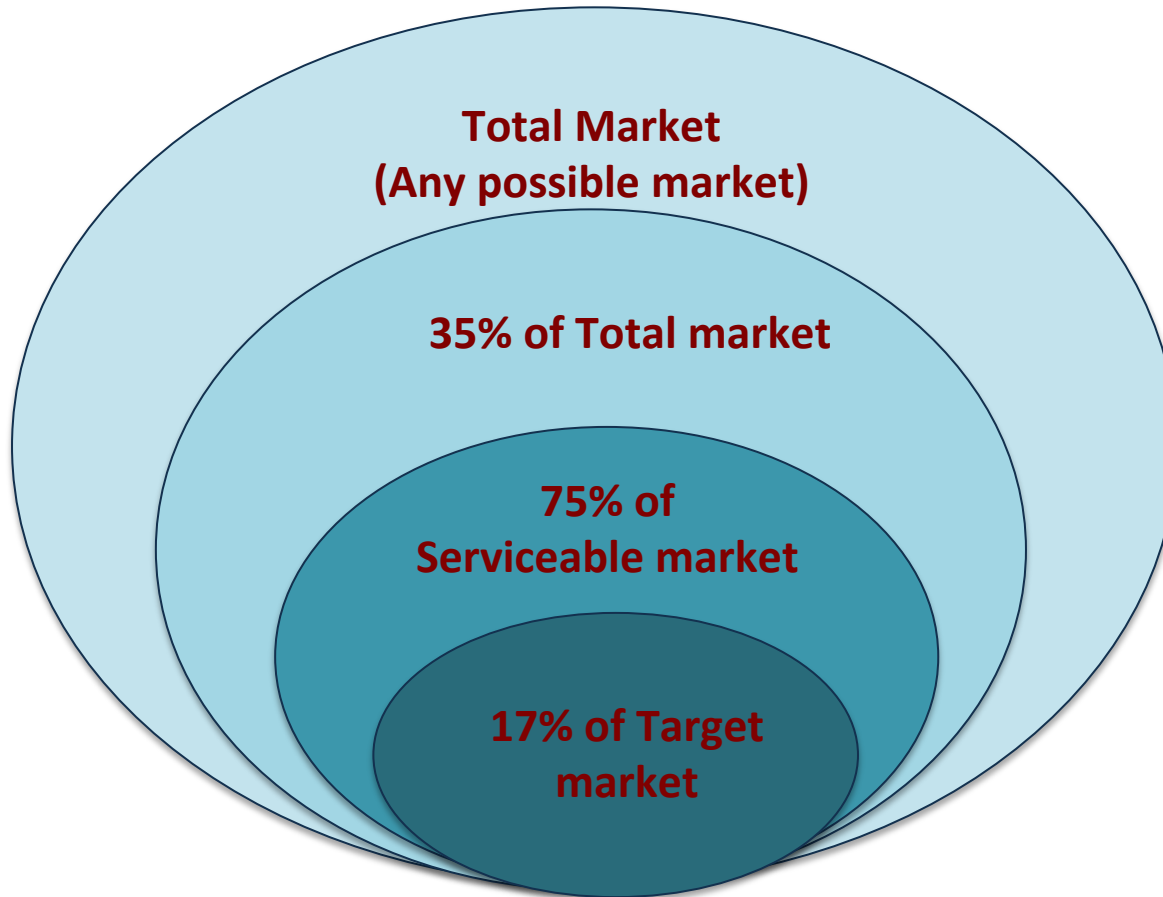
	AfibAlert	Melys AFM
False negatives	Approx. 8%	Zero
Population-based screening	No	Yes
Context	Single patient interface with physician	Population based screening or individual monitoring
Ease of use	45-second test, two electrodes	20-second test, finger clip
Home monitoring	Yes	Yes
Prescription necessary	Yes	Yes

Other products: Omron HCG-801, HeartScan, Heartcheck Pen, Alivecore Mobile ECG

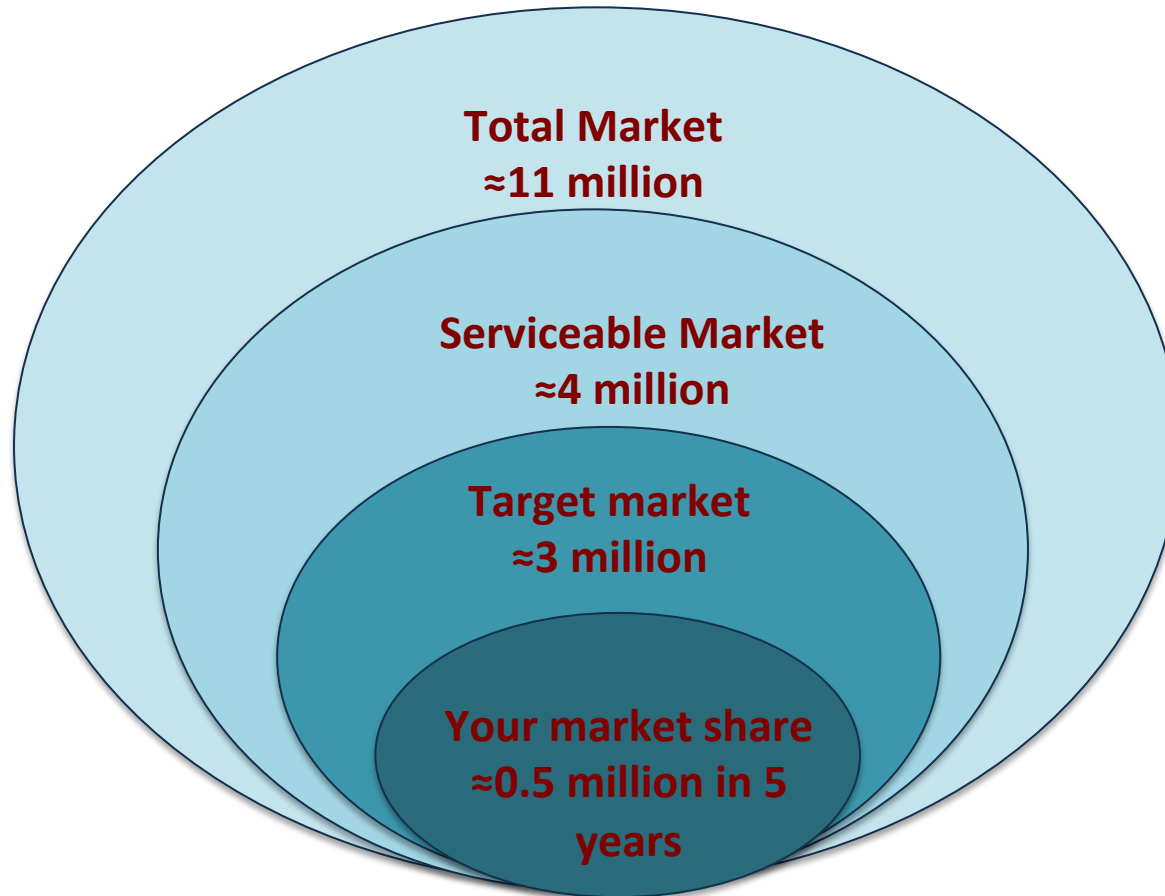
Competitive Advantage

- Easy to use for patients as well as medical professionals
- Green-yellow-red indication in 20 seconds
- 99% accuracy: medical quality
- Small, handheld, lightweight
- Affordable for home or professional use
- Rapid monitoring tool as a precursor to additional diagnostic procedures
- Validated technology (Patented/ FDA approval)
- Provided with detection results data on mobile App.

Your Market Share



Your Market Share



Marketing Strategy

- Market push through cardiologists,
- Insurance and Medicare
- Sales through medical distributors
- Initial market surveys conducted - enthusiastic

Market Penetration Strategy

	Year 1	Year 2	Year 3	Year 4	Year 5
Home monitoring	0.25% of 1/50th of target market of 3M AF patients in US	1% of 1/50th of target market of 3M AF patients in US	10% of 1/50th of target market of 3M AF patients in US	30% of 6/50th of target market of 3M AF patients in US	40% of 12/50th of target market of 3M AF patients in US
PCP	Each Cardiologist office that uses prescribes to 10 patients	Each Cardiologist office that uses prescribes to 20 patients	Each Cardiologist office that uses prescribes to 40 patients	Each Cardiologist office that uses prescribes to 75 patients	Each Cardiologist office that uses prescribes to 100 patients
Professional emergency medical equipment		0.5% of the 190000 Allied medical sites using for routine screening	1% of the 190000 Allied medical sites using for routine screening	10% of the 190000 Allied medical sites using for routine screening	15% of the 190000 Allied medical sites using for routine screening
Non-professional emergency medical				5% of the 40000 ambulances and 75,000 fire dept. vehicles in US	25% of the 40000 ambulances and 75,000 fire dept. vehicles in US
					5% of the 140766 official recreational facilities in US

Thank you for your attention

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