Associazione Culturale Giuseppe Dossetti

FIBRILLAZIONE ATRIALE E ICTUS CARDIOEMBOLICO:

Misure legislative, strategie di prevenzione ed acceso alle cure nei 21 Sistemi Sanitari Regionali

Camera dei Deputati, Roma 13 Giugno 2014

I nuovi dispositivi impiantabili nella gestione del paziente:
Ruolo e Prospettive del Controllo Remoto

Emanuela Teresa Locati, MD PhD
Cardiologia 3 - Elettrofisiologia
Ospedale Niguarda
Milano



Azienda Ospedaliera
Ospedale Niguarda Ca' Granda

Fibrillazione Atriale

La fibrillazione atriale è un'aritmia sopraventricolare caratterizzata da una attivazione atriale caotica e disorganizzata

E' la più comune forma di aritmia sostenuta[1];
Risulta asintomatica nel 70% degli episodi ricorrenti[4];
L'incidenza aumenta con l'età[2];
Aumentati rischi di ictus[1], Scompenso Cardiaco e mortalità[3];

Classificazione:

- PAROSSISTICA (PAF)
  (transitoria, termina spontaneamente, in meno di 48 ore ritorna il SR)
- PERSISTENTE
  (non termina spontaneamente in meno di 48 ore, può essere ancora cardiovertita in ritmo sinusale)
- PERMANENTE
  (Incapacità dei metodi farmacologici e non-farmacologici di ristabilire il ritmo sinusale)

Prevalenza della FA in pazienti con Scompenso cardiaco

Predominant NYHA Class	Prevalence of AF (%)	Study
I	4	SOLVD–Prevention (1992)[14a]
II-III	10 to 26	SOLVD–Treatment (1991)[14b] CHF-STAT (1995)[14c] MERIT-HF (1999)[14d] DIAMOND-CHF (1999)[501]
II-IV	12 to 27	CHARM (2003) Val-HeFT (2003)[848]
III-IV	20 to 29	Middlekauff (1991)[14e] Stevenson (1996) GESICA (1994)[14f]
IV	50	CONSENSUS (1987)[14g]

Fuster V et al. *Circulation. 2006;114:e257-e354.*

Journal of the American College of Cardiology
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ISSN 0735-1097/05/$30.00
doi:10.1016/j.jacc.2005.07.044

Monitored Atrial Fibrillation Duration Predicts Arterial Embolic Events in Patients Suffering From Bradycardia and Atrial Fibrillation Implanted With Antitachycardia Pacemakers

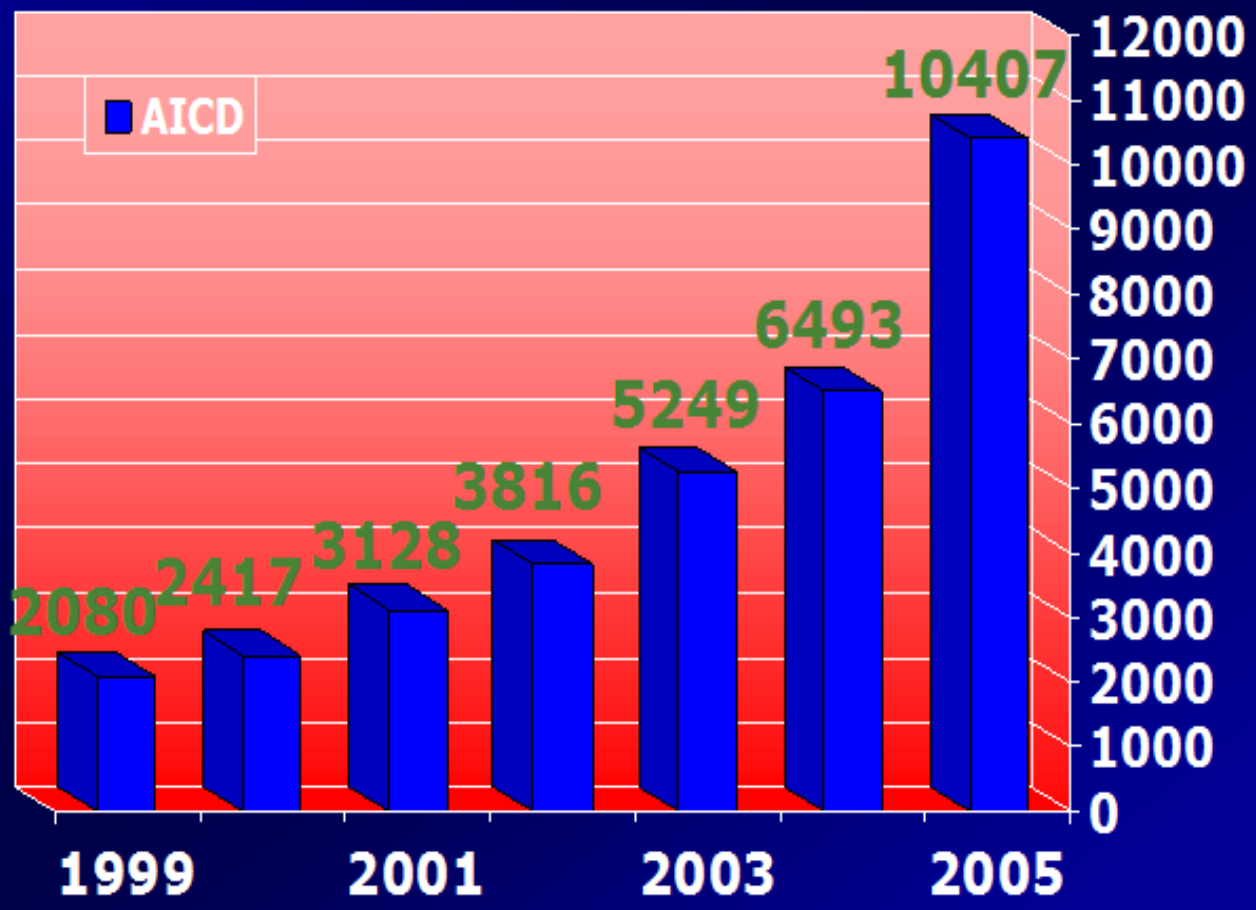
Alessandro Capucci, MD,* Massimo Santini, MD,† Luigi Padeletti, MD,‡ Michele Gulizia, MD,§ GianLuca Botto, MD,‖ Giuseppe Boriani, MD,¶ Renato Ricci, MD,† Stefano Favale, MD,# Francesco Zolezzi, MD,** Natale Di Belardino, MD,†† Giulio Molon, MD,‡‡ Fabrizio Drago, MD,§§ Giovanni Q. Villani, MD,* Elena Mazzini, MS,‖‖ Marco Vimercati, MS,‖‖ Andrea Grammatico, PHD,‖‖ on behalf of the Italian AT500 Registry Investigators

Piacenza, Rome, Florence, Catania, Como, Bologna, Bari, Vigevano, Velletri, Negrar, and Milan, Italy

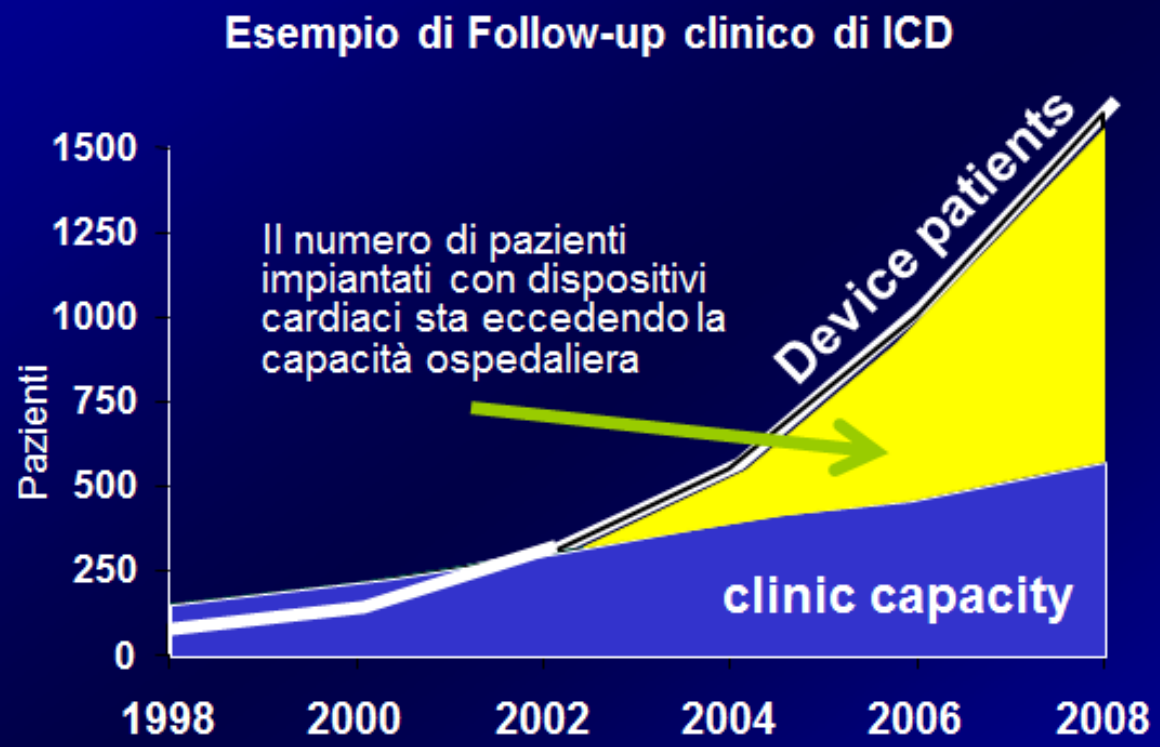
In pazienti con cardiopatia ischemica, ipertensione, diabete mellito e con rischio di stroke, sono frequenti eventi tromboembolici.

Episodi di fibrillazione atriale più lunghi di un giorno, sono indipendentemente associati a eventi tromboembolici (il rischio di eventi aumenta di 3.1 volte)

Numero impianti ICD Italia negli anni



Impatto dell'espansione delle indicazioni sulla domanda di risorse



* ACC/AHA/NASPE 2002 guideline update.

Distribuzione della popolazione Europea per età e sesso nell'anno 2000 e 2050:

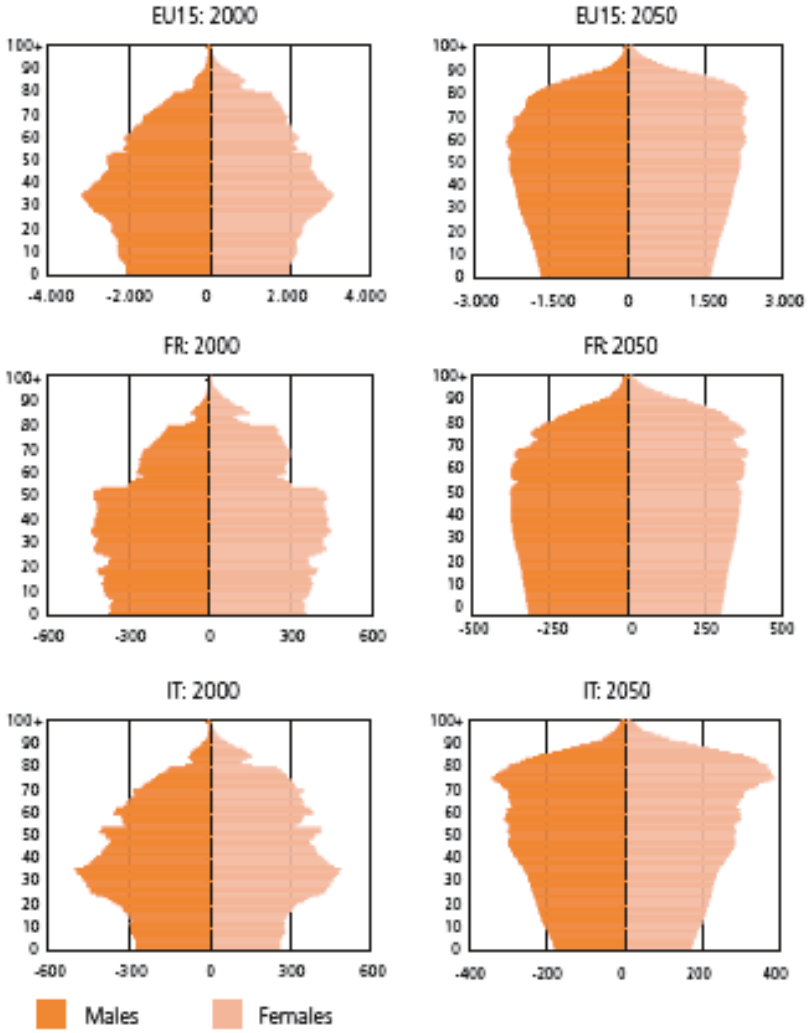


Figura 2 Population Ageing in the EU, France and Italy, 2000-2050

Source: Eurostat: Population by sex and age on 1st January of each year. Population projections – baseline scenario (Eurostat projections 1995, revision 1998)

Media di 15 paesi Europei

Francia

Italia

Rapporto SHARE (Survey of Health, Ageing and Retirement in Europe), 2005

History of Home Monitoring

2000 

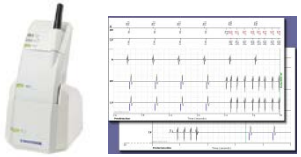
First application of BIOTRONIK Home Monitoring for technical feasibility studies

2002 

Global launch as only FDA & CE approved system for remote monitoring in pacemaker and ICD patients

2003 

First internet-based Home Monitoring system
Internet based service center and world's first wireless and cellular transmitter for early detection

2006 

Bidirectional telemetry and IEGM-Online HD
Significant increase in data volume to enable remote device follow-up and transmit real-time online IEGMs

2009 

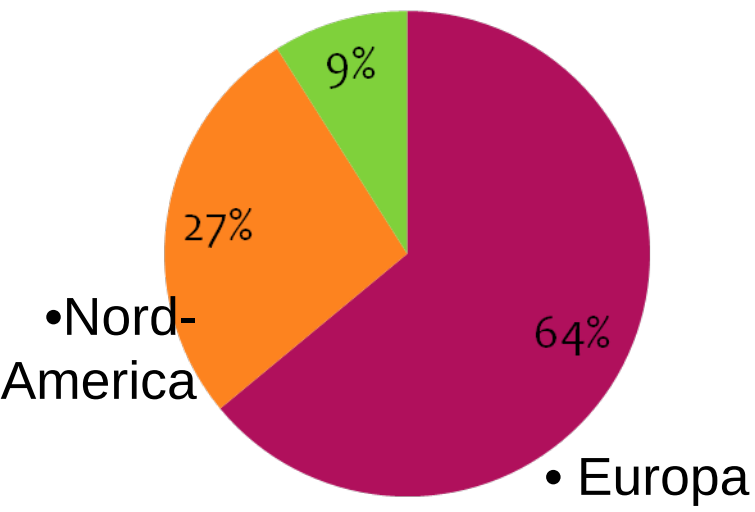
New system interface with **intelligent traffic light system** & **expanded FDA and CE Mark approvals** for replacement of in-clinic follow-ups and early detection

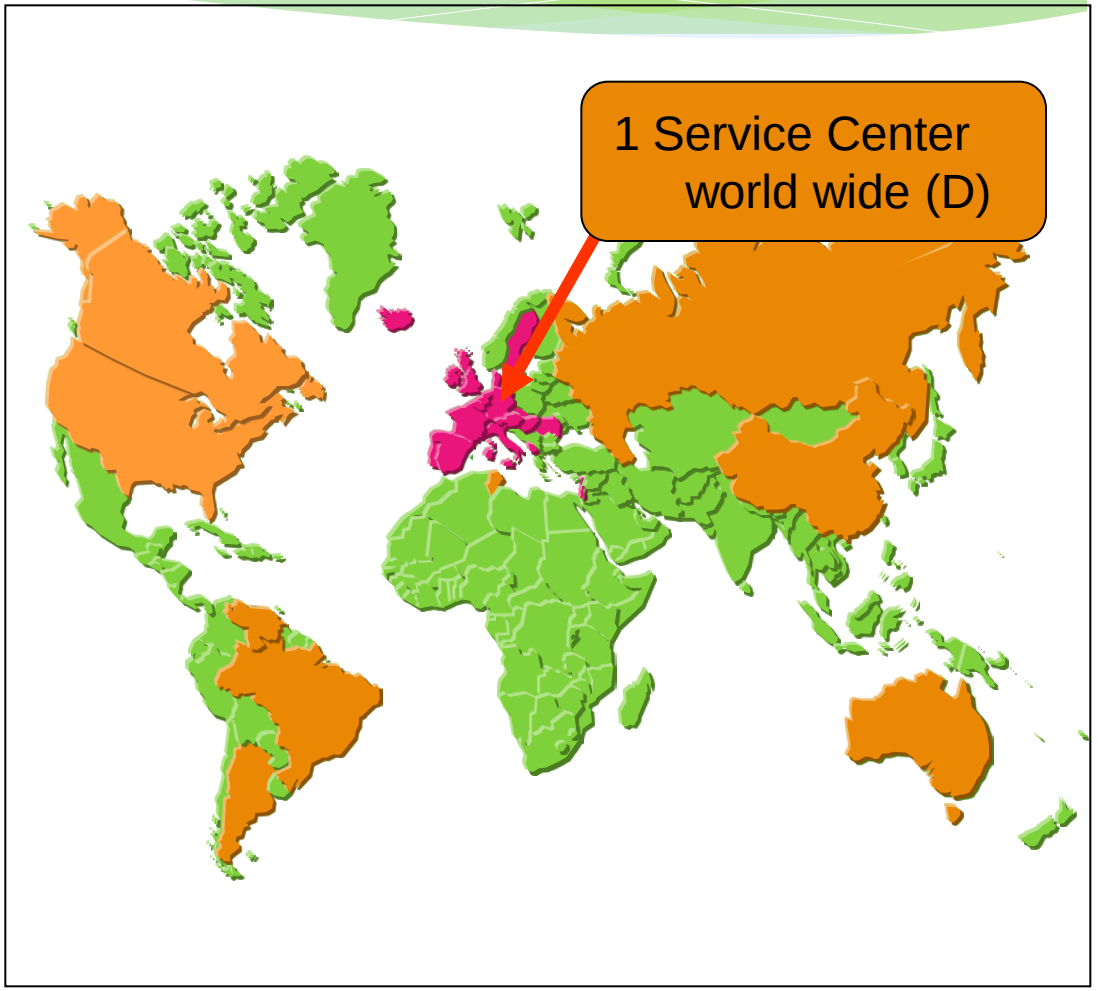
2012 

12+ years of experience in Home Monitoring
New unique diagnostic options for advanced heart failure under clinical investigation

30.000 Home Monitoring ® Systems Implanted Worldwide

- 100% = 30.000 Systems





BIOTRONIK

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Medtronic CareLink Network

> 450.000
Patients WW
> 4000 Hospitals





> 39.000 Patients in Europe > 865 Hospitals



> 8.159 Patients in Italy >152 Hospitals

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Medtronic CARELINK® NETWORK

Boston Scientific LATITUDE Remote Patient Management System

Patient's Home

Boston Scientific Device





LATITUDE Communicator



LATITUDE Weight Scale



LATITUDE BP Monitor



Optional components. Available for an additional fee.

LATITUDE Web Server





Health Following Physician & RN

Objectives

- Collaborative patient management
- HF management



Device Managing Physician & RN

Objectives

- Device management
- Arrhythmia management

Arrhythmia & EP

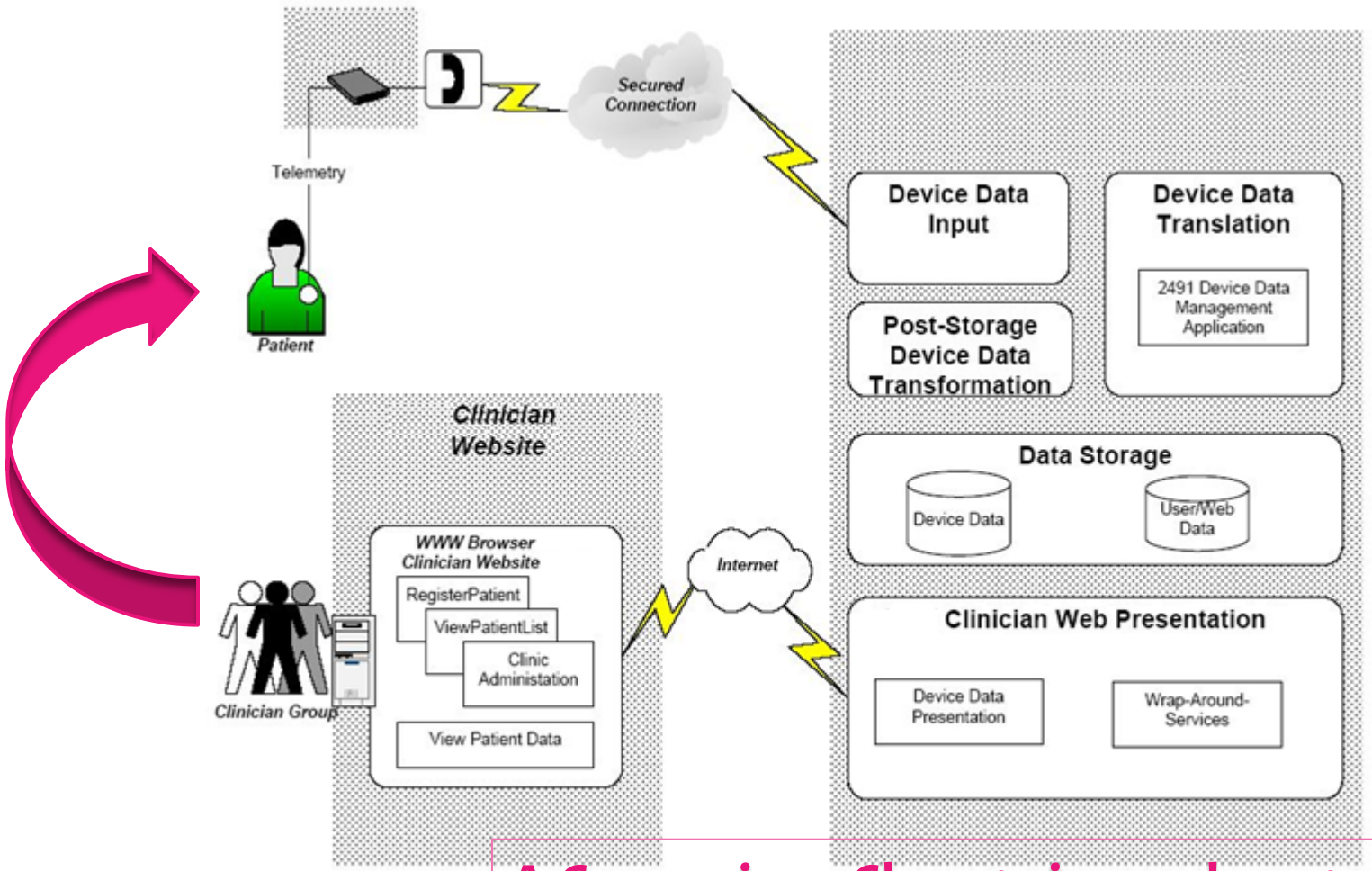
the heart.org from WebMD

Medscape EDUCATION

REMOTE ICD/PM MONITORING SYSTEMS

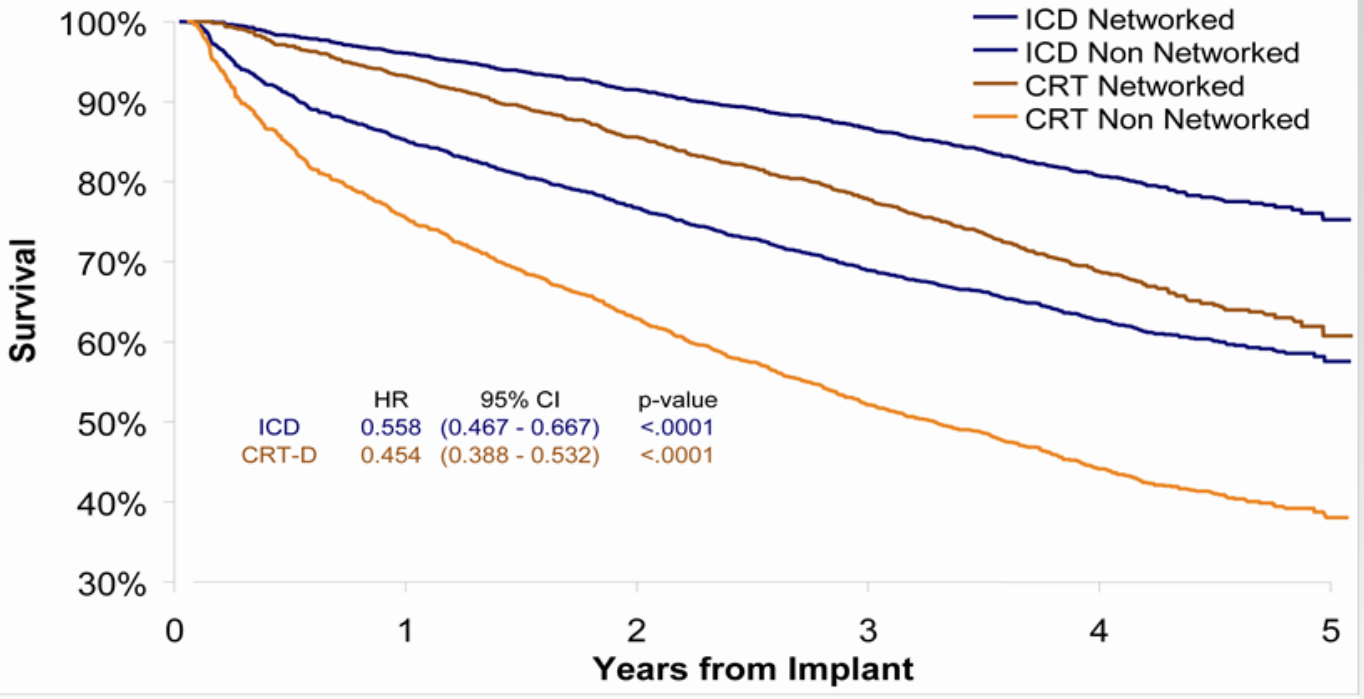
	Biotronic	St Jude	Medtronic	Boston	Sorin
Denomination	Home Monitoring	Merlin.Net	Carelink	Latitude	SmartView
Transmission	Auto/Demand	Auto/Demand	Auto/Demand	Auto/Demand	Auto/Demand
Type of Tansmission	GSM	Analogic/GSM	Analogic	Analogic	Analogic/GSM
Archiving System	Proprietary	Proprietary	Proprietary	Proprietary	Proprietary
Type of Device	ICD/PM	ICD/PM	ICD/PM/LR	ICD/PM	ICD
Internet Web based	Yes	Yes	Yes	Yes	Yes
Heart Failure Monitoring	Yes	Yes	Yes	Yes	Yes
Scheduling transmission	Yes	Yes	Yes	Yes	Yes

Remote Monitoring Work-Flow



A Copernican Change in work organization!

The ALTITUDE Survival Study



Networked	ICD	3,026	2,651	2,034	1,353	554	31
	CRT-D	2,110	1,913	1,479	1,065	470	20
Non-Networked	ICD	3,026	2,592	1,988	1,304	530	34
	CRT-D	2,110	1,813	1,407	1,003	452	26
Networked	ICD		96%	92%	87%	81%	75%
	CRT-D		93%	86%	78%	69%	61%
Non-Networked	ICD		85%	77%	69%	63%	58%
	CRT-D		76%	63%	52%	44%	38%

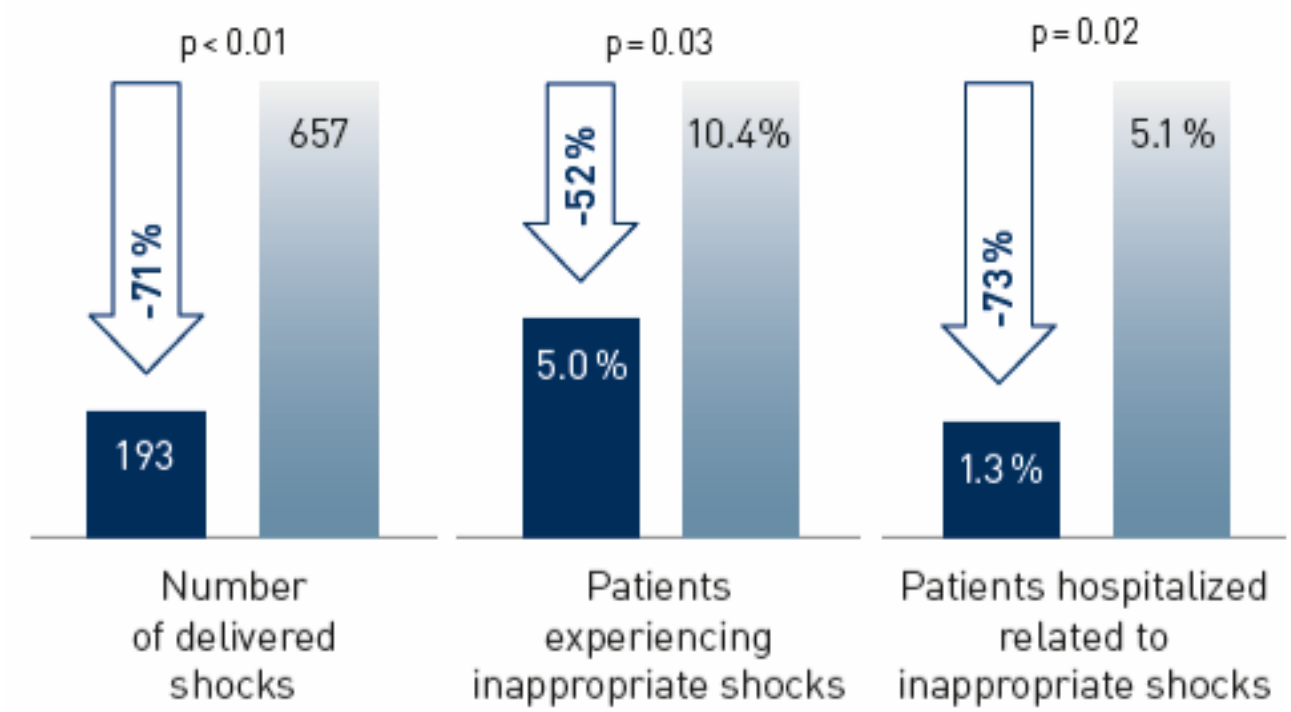
Arrhythmia & EP

Saxon L, et al. *Circulation*. 2010;122:2359-2367.

theheart.org from WebMD

Medscape EDUCATION

ECOST trial:
Reduction of appropriate and inappropriate shock



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Guedón-Moreau L et al., ECOST study, European Heart Journal, 2012.

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association.

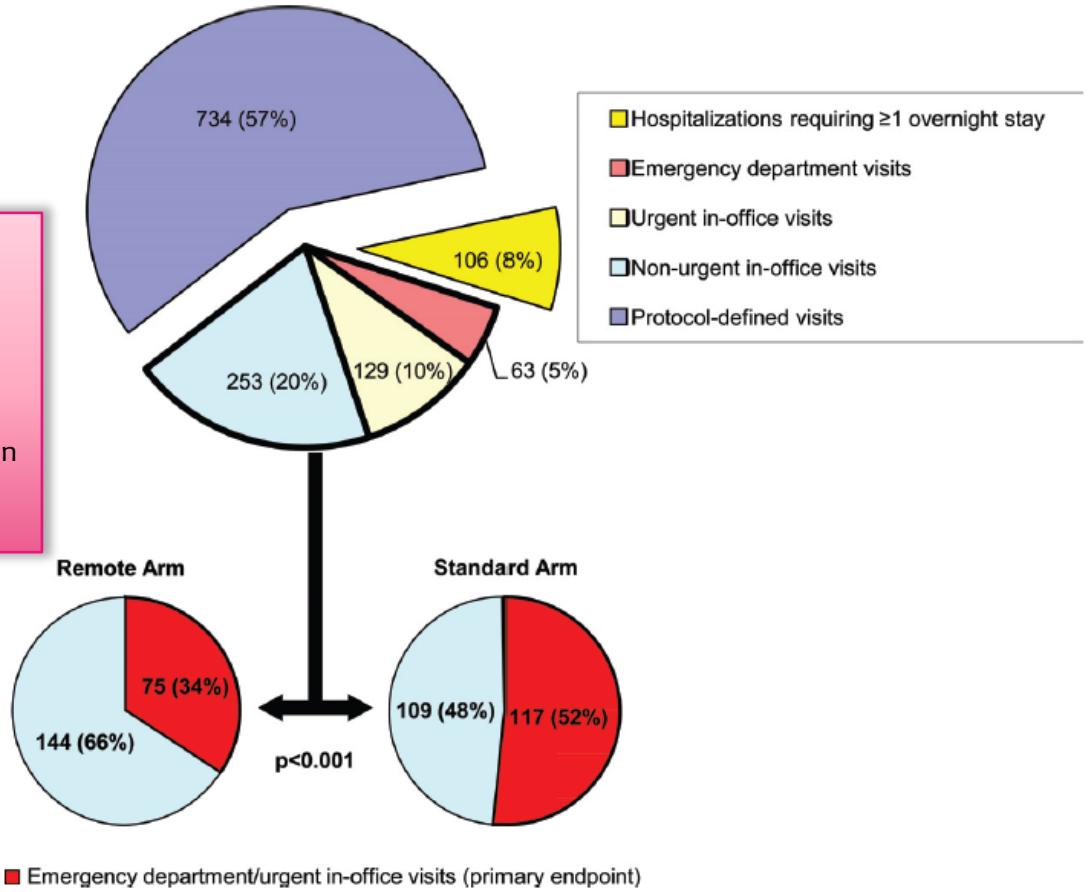
Remote Monitoring Reduces Healthcare Use and Improves Quality of Care in Heart Failure Patients With Implantable Defibrillators : The Evolution of Management Strategies of Heart Failure Patients With Implantable Defibrillators (EVOLVO) Study

Maurizio Landolina, Giovanni B. Perego, Maurizio Lunati, Antonio Curnis, Giuseppe Guenzati, Alessandro Vicentini, Gianfranco Parati, Gabriella Borghi, Paolo Zanaboni, Sergio Valsecchi and Maurizio Marzegalli

Circulation. 2012;125:2985-2992; originally published online May 24, 2012;

Conclusions

The results of the EVOLVO study demonstrate that remote monitoring can reduce emergency department/urgent in-office visits and, in general, total healthcare use in HF patients with modern ICD/CRT-D. Compared with standard follow-up through in-office visits and audible ICD alerts,remote monitoring results in increased efficiency for healthcare providers and improved quality of care for patients.



Home Monitoring Study

Table 3 Classifications of 2411 true-positive MCEs

Event description	All	During HM sessions
Deaths	134	0
Strokes	5	0
Acute myocardial infarctions	6	2
Worsening heart failures	137	74
Syncope events	19	5
Atrial arrhythmias	868	808
Sustained ventricular arrhythmias	434	394
Unsustained ventricular arrhythmias	178	170
Effective/ineffective ventricular device therapies	246	223
Ineffective maximal energy shocks	10	7
Inappropriate device therapies	62	57
Sensing failures	193	174
Capture failures or threshold raises	134	103
Out-of-range impedances	43	41
Suboptimal device programming	59	40
Battery depletion or device error status	4	4
Pocket/device infections	8	0
Others	351	276

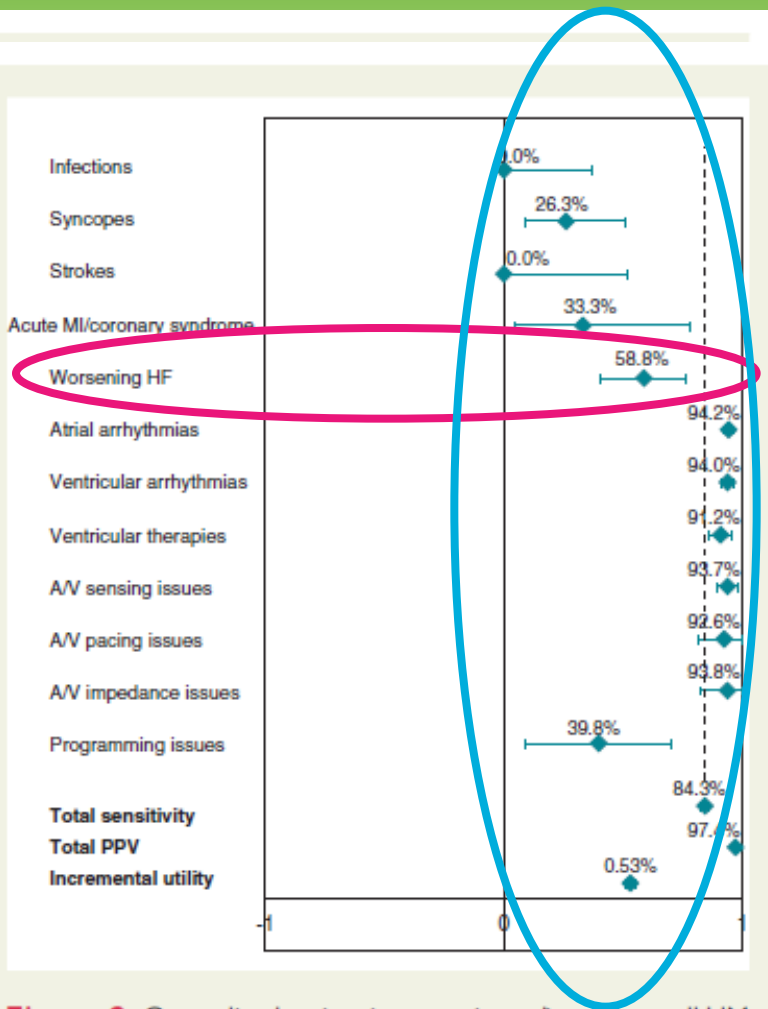


Figure 2 Generalized estimating equation-adjusted overall HM sensitivity, PPV, and IU. Home Monitoring sensitivity estimates for subgroups of MCEs are also displayed.GEE, generalized estimating equation; HM, Home Monitoring.

IN-TIME trial

(Preliminary results)

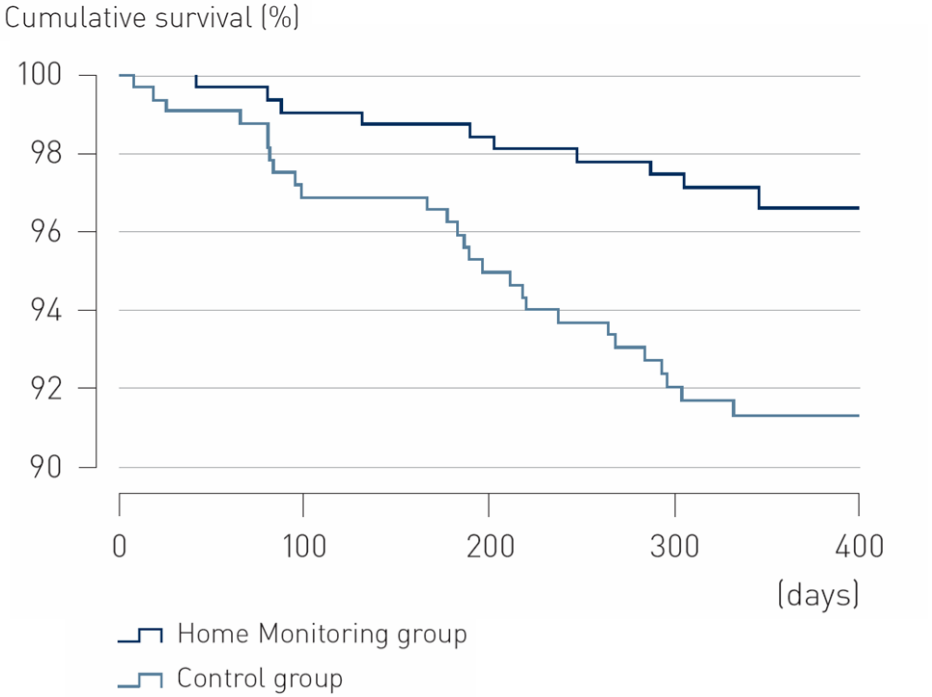
All-cause Mortality

HM lower at one-year follow up



Cumulative survival

HM higher at one year follow-up



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Hindricks G et al., IN-TIME study, Hot Line II, ESC Congress 2013.

People Are Living Longer



Doctor		Patient
Continuous Data	WHY?	Partner Their Care
Review Data Daily		Feel Engaged
Act in Minutes vs Months		Learn Themselves

Benefits of Remote Monitoring

Clinical

- Monitoring of ICD malfunctions
- Monitoring of ICD in recall
- Better management of clinical episodes (AF burden, VT/VF, shock)
- Heart failure monitoring
- Better QoL of patients

Logistics

- Optimization of time spent by and patients
- Optimization of hospital access
- Optimization of ICD sostitution (ERI)
- Cost savings
- Optimization of time spent by physicians

European Heart Journal (2013) **34**, 2281–2329
doi:10.1093/eurheartj/eht150

2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

The Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA).

Authors/Task Force Members: Michele Brignole (Chairperson) (Italy)*, Angelo Auricchio (Switzerland), Gonzalo Baron-Esquivias (Spain), Pierre Bordachar (France), Giuseppe Boriani (Italy), Ole-A Breithardt (Germany), John Cleland (UK), Jean-Claude Deharo (France), Victoria Delgado (Netherlands), Perry M. Elliott (UK), Bulent Gorenek (Turkey), Carsten W. Israel (Germany), Christophe Leclercq (France), Cecilia Linde (Sweden), Lluís Mont (Spain), Luigi Padeletti (Italy), Richard Sutton (UK), Panos E. Vardas (Greece)

Recommendations	Class [a]	Level [b]	Ref. [c]
Device-based remote monitoring should be considered in order to provide earlier detection of clinical problems (e.g. ventricular tachyarrhythmias, atrial fibrillation) and technical issues (e.g. lead fracture, insulation defect).	IIa	A	174–176

6.5 Remote management of arrhythmias and device

The usefulness of remote monitoring has been extensively addressed in the recent joint European and American expert consensus statement on CRT in heart failure to which we refer.[w124] This Task Force endorses that document and believes that there is sufficient evidence to give the recommendation that follows.[174–176]

Diagnosing AF before the first complications occur is a recognized priority for an early starting of anticoagulation therapy and prevention of stroke. Recent data, collected in patients with implanted devices, reinforce the assumption that even short episodes of 'silent' AF convey an increased risk for stroke.[153] For this issue, we refer to a specific guideline and consensus document.[w352,w353]

Guidelines of ICD Remote Monitoring

EUROPEE

1) HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices*:

- **ICD/CRT/PM:**
  - Controlli da fare OBBLIGATORIAMENTE in **ambulatorio**:
    - Dopo l'impianto
    - 1° controllo (entro 12 settimane)
    - **1 volta all'anno**
  - Controlli che si possono fare in **remoto: tutto il resto!!**
    - PM/CRT-P ogni 3-12 mesi
    - ICD/CRTD ogni 3-6 mesi
    - Frequenza maggiore all'avvicinarsi della scarica
- **REVEAL:**
  - Non è necessario il controllo in ambulatorio
  - Frequenza controlli ogni 1-6 mesi

2) ESC Guideline for diagnosis and treatment of HF 2008:**

- Remote monitoring: Class of recommendation **IIb**, level of evidence **C**

*Wilkoff et al. Europace 2008; 10, 707–725
** Dickstein et al. European Heart Journal 2008

ITALIANE*

- **Il controllo remoto PUO' sostituire il controllo standard ambulatoriale.**
- Controlli da fare OBBLIGATORIAMENTE in **ambulatorio**:
  - **dopo l'impianto**
  - **a distanza di 1 mese** per la verifica della stabilizzazione del sistema e per la personalizzazione della programmazione
  - almeno **una volta l'anno** per una valutazione clinica globale del paziente.

RICONOSCIUTO IL VANTAGGIO NELLA GESTIONE DI:

- Recall (esclusi paz a rischio per i quali si suggerisce sostituzione preventiva)
- Aritmie ventricolari e sopraventricolari
- Scompenso:
  - IMPORTANTE: la **valutazione automatica della soglia LV** dovrebbe essere considerata condizione necessaria per sostituire parte dei controlli

*AIAC: Consensus Document sul monitoraggio remoto dei dispositivi impiantabili. GIU 2009

Models of Remote Monitoring

VERY IMPORTANT TO CONSIDER CLEARLY THE DIFFERENCE BETWEEN

REMOTE ICD CONTROL

REMOTE PATIENT MONITORING

MANAGING CLINICAL PROBLEMS IS FAR MORE COMPLEX THAN SIMPLE DEVICE CHECK!!!

Training at Enrollment



Pre-dimission of new patients

At clinic follow-up of previously implanted patients

Better in presence of a relative of elderly patients!



- Instruction on how to use monitor
- Explanation of kind of service offered
- Sign informed consent
- Entering data in the web site

Who does what:
Primary Nursing Model

Personnel:

* Cardiologist (Electrophysiologist)
* Registered Nurse
* *Biomedical Engeneer*

Roles

Nurse



- Training of patient
- Informed consent
- Programming transmissions
- First filtering of urgent cases

Physician



- Referting transmissions
- Evaluation and management of critical cases

Revision of Transmissions

Nurse

Verify if programmed transmissions have been received

No

Recall patients

Yes

Perform first screening highlighting transmissions with priority

Submit transmissions to the physician



Physician



Perform revision

The patient needs further work-up?

No

Refert transmission and archive on PC

Yes

Discuss the case with engineer and collegues

Contact the patient and if necessary recall for clinic visit

PLANNING OF ACTIVITIES

Need to define few and simple points:

1. **What service you want to offer**
   - Device Check ONLY
   - Patient Monitoring
2. **To which patients**
3. **Who does what**
   - Patient Training
   - Revision of transmissions
   - Telephonic conntact with patients
4. **When and how**



From Theory to Practice…

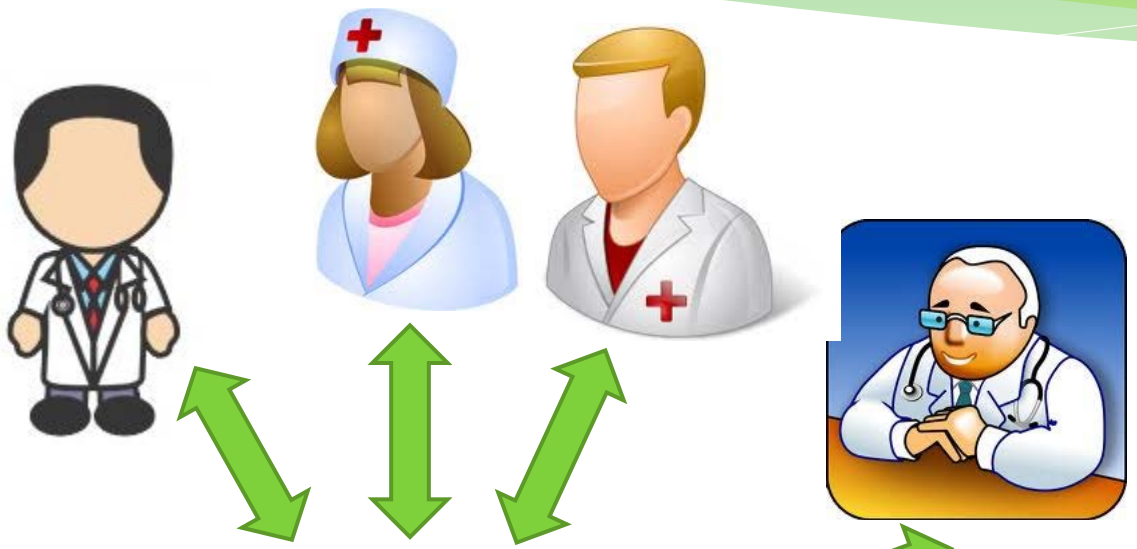
… How to follow a patient by remote monitoring

- Informed Consent
- Patient Training
- Collecting clinical data from Hospital files
- Patient Recall
- Device Programming
- Theraputic Decisions
- Alarm Programming/Revision
- Interaction with Other Care Givers
- Remote FUP Revision
- Inserting data in web site



NEED OF A WELL-DEFINED WORKING MODEL!

Patient management far more complex than device monitoring





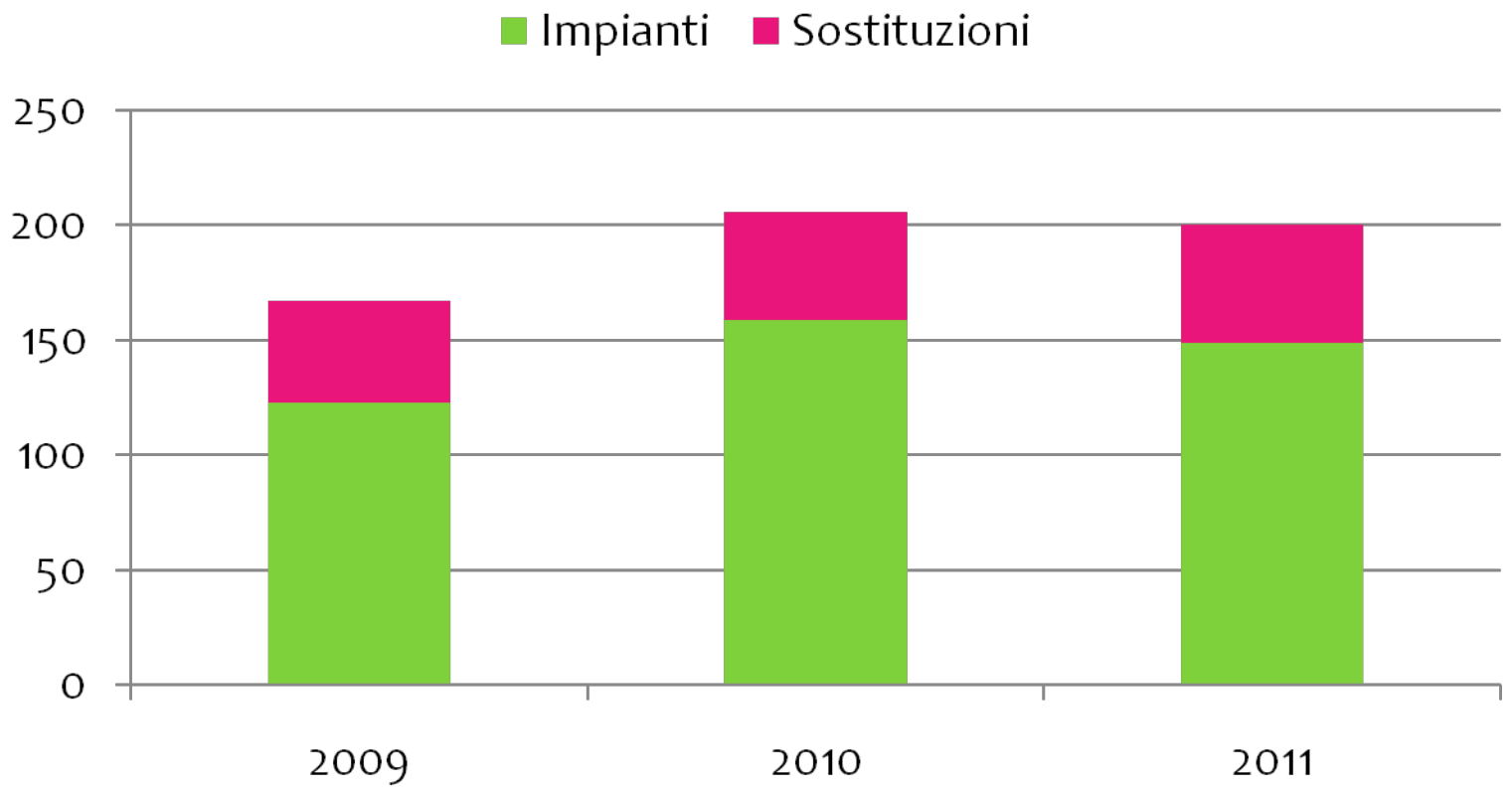
Electrophysiologists
Heart failure Specialists
ER Personnel
General physicians
Diabetologists
Nephrologists
Neurologists
Endocrinologists
Cardiopediatricians
…

…Foresee interactions with other Specialists!

Experience at Niguarda Hospital

* **Started at June 2011**
* System in use: Medtronic CareLink Network
* Personnnel dedicated: one Physisican, one Nurse and one BM Engineer
* Closer cooperation with the Electrophysiologists, Heart Failure Specialists and Cardiopediatricians

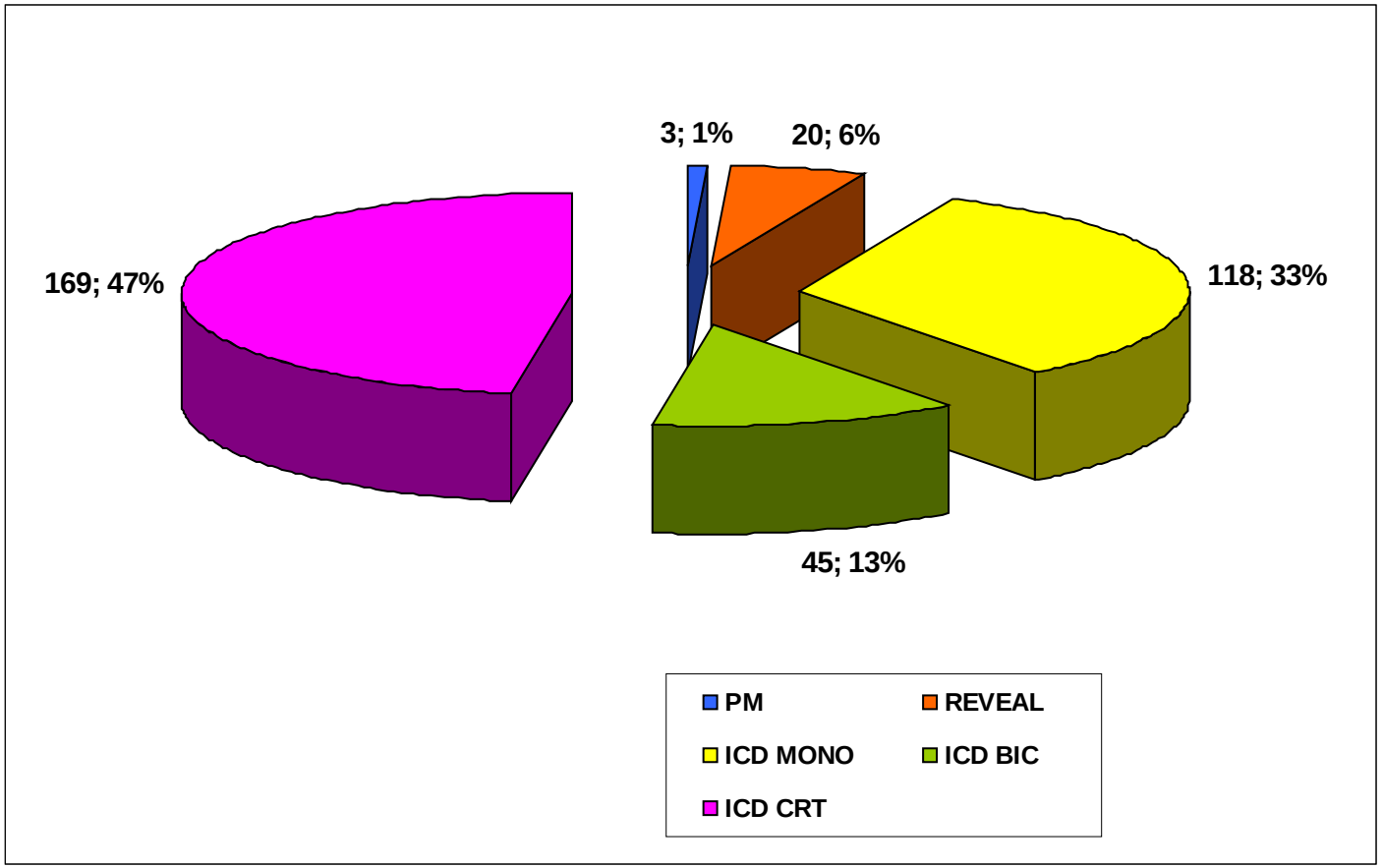
Activity at Niguarda Hospital
ICD Implants



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HM Activity at Niguarda Hospital
Patients Enrolled in CareLink

355 Devices Followed by CareLink at May 28st, 2014



Patients Followed at Niguarda Hospital

At May 28th, 2014

- Total 355 patients followed by Carelink
  - *3 Pacemaker*
  - *20 Reveal*
  - *332 ICD (169 CRT, 118 MONO, 45 BIC)*
- 52 inactive patients
  - *22 Deceased*
  - *12 Explanted (7/20 Reveal, 5/334 ICD x TxC)*
  - *15 Dimissed **(4% non compliant!)***
  - *3 Transfered to other Hospitals*

Clinic Visits and Rehospitalizations Induced by Remote Monitoring

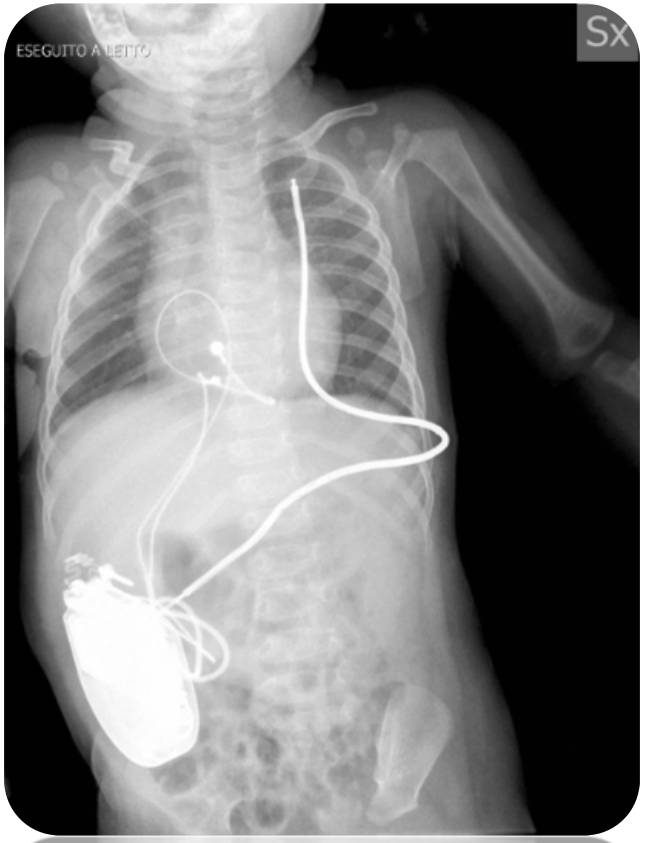
At May 28th, 2014 (approx 1000 transmissions per year)

* Approx 150 clinic visits for reprogramming devices and/or optimizing pharmacologic therapies **(2% of transmissions → clinical visit with change of programmation or therapy)**

* Approx 70 hospitalizations to substitute ICD or electrocatheters or managing major clinical problems (complex arrhytmias/heart failure) **(1% of transmission → hospitalization)**

Clinical Case 1

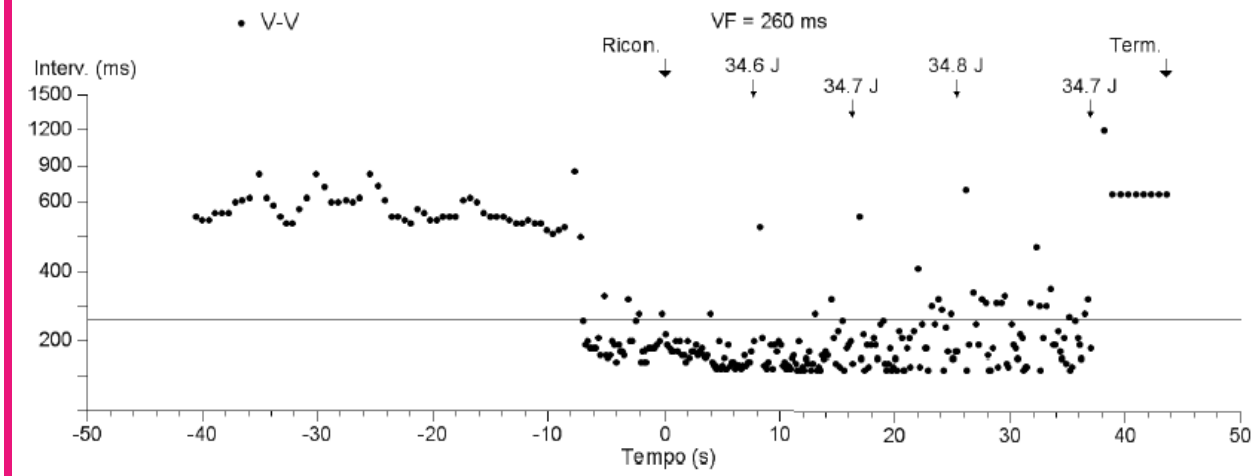
* Patient History
  * Baby 6 mos old
  * Non compacted left ventricle
  * WPW
  * Secondary prevention
  * Implantated by ICD MONO with finger as bridge to cardiac transplant



Clinical Case 1

☐	28-set-2011 13.16 (Trasmissione iniziale)	(4 shock 3 inefficaci), 3 episodi di alta frequenza-NS, 1 VT/VF	Visto	3.14 V	Protecta™ XT VR 19-set-2011		5-dic-2011		2

Tipo	ATP Seq	shock	Succ.	ID#	Data	Ora hh:mm	Durata hh:mm:ss	Media min-¹ V	Max min-¹ V	Attività all' Insorgenza
VF	0	4	Sì	6	27-Sep-2011	13:40	:46	273	353	Riposo



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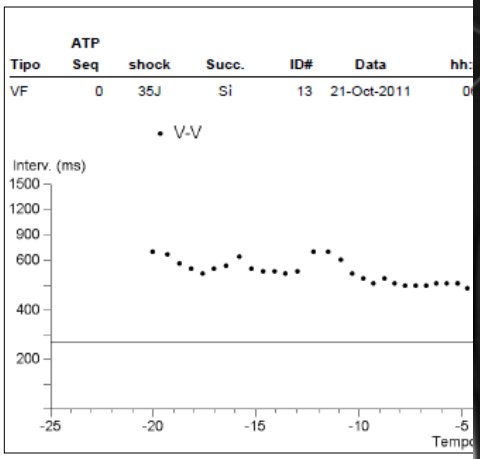
Clinical Case 1

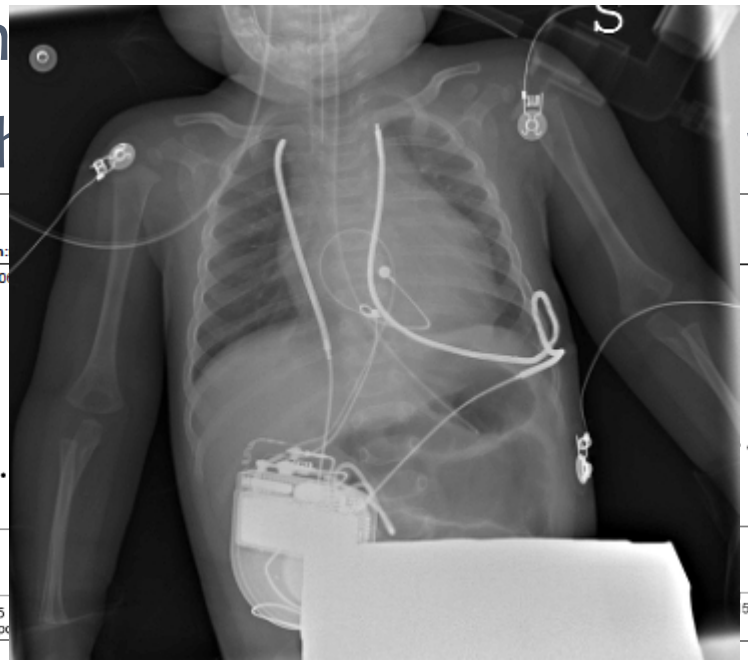


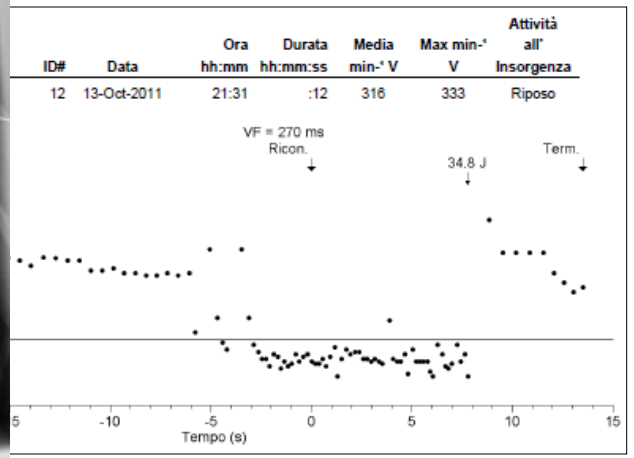


Clinical Case 1

- **Early detection of problem**
- Second finger inserted
- Further epysodies resolved by single shock
- Three ICDs h multiple shocks
- The patient h rdiac transplant







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Clinical Case 2

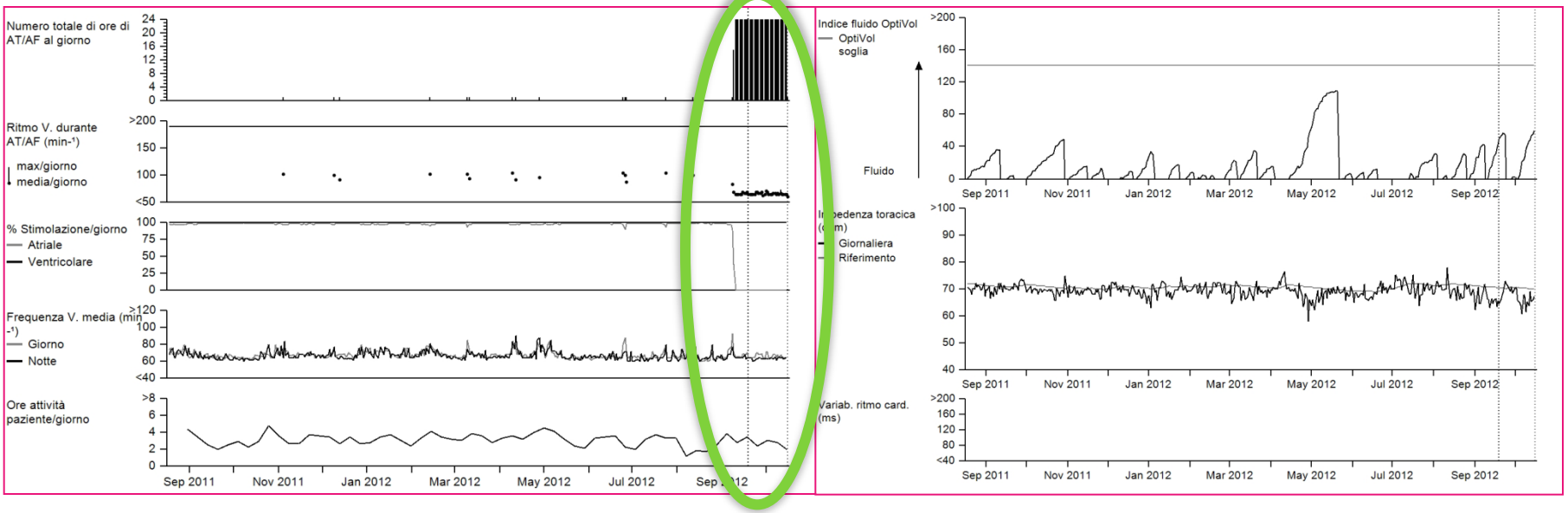
Patient

- Male aged 75 yrs
- CMPD non ischemic
- Secondary prevention
- NYHA class II-III
- 2006 ICD-CRT, 2010 ICD-CRT replaced for battery exhaustion

Tutti	Nome del paziente	Data ricezione	CareAlert	Riepilogo eventi	Stato	Batteria	Dispositivo		Prossima trasmissione	Note Generali	Totale trasmissioni
☐	[redacted]	16-ott-2012 00:16		Burden quotidiano di AT/AF > soglia, 26 giorni in AT/AF dall'ultima sessione	Visto	3.05 V	Consulta™ CRT-D 26-apr-2010		14-nov-2012	M LINK	10

* Programmed transmission
* AT/AF burden since one month

Clinical Case 2



* Persistent AF since one month
* Progressive fluid accumulation and reduced inthratoracic impedence

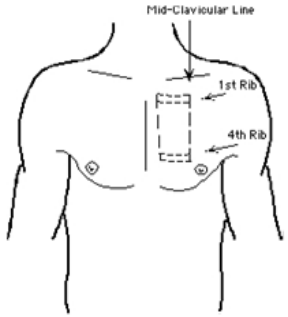
→ Clinic visit is scheduled to perform ECV of PAF

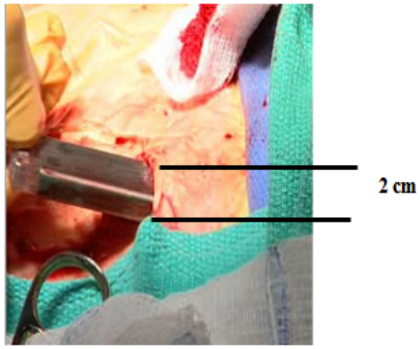
Reveal® XT

Il nuovo sistema per il monitoraggio cardiaco completo (sincope, AF, VT, etc.)



Impianto

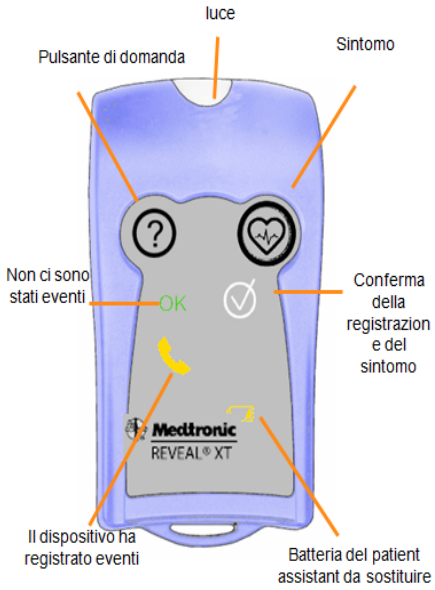




Longevita' di 3 anni

MRI Safe

Reveal XT Patient Assistant



8 condizioni di allarme

- Raggiunto il massimo numero di episodi sintomatici
- Raggiunto il massimo numero di episodi automatici
- Fast VT/VT
- Asistolia
- Bradicardia
- Burden quotidiano di AT/AF
- Frequenza ventricolare durente FA
- Batteria del Reveal bassa

Remote Control of ILRs



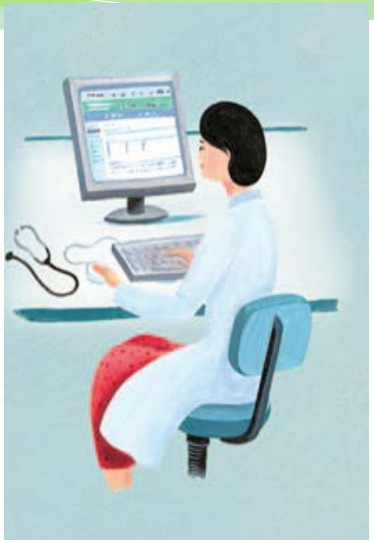
The patient activates the «Patient Assistant» after a symptomatic event



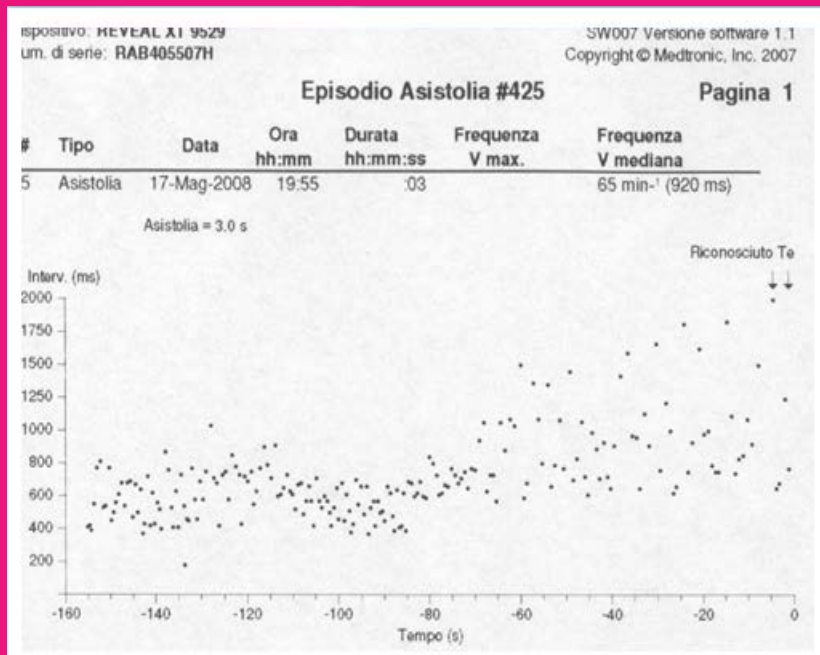
The patient contacts the physician to agree on a transmission



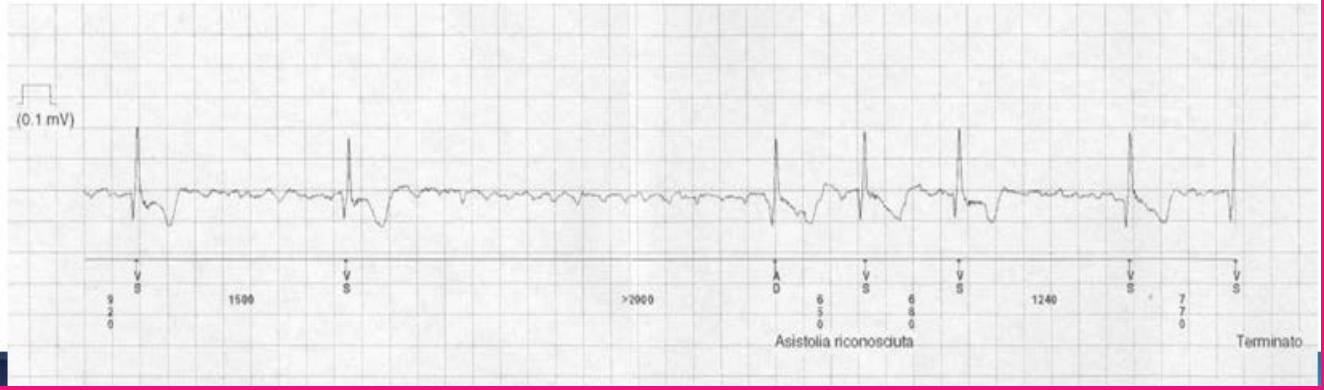
The patient transmits all memorized data directly from home



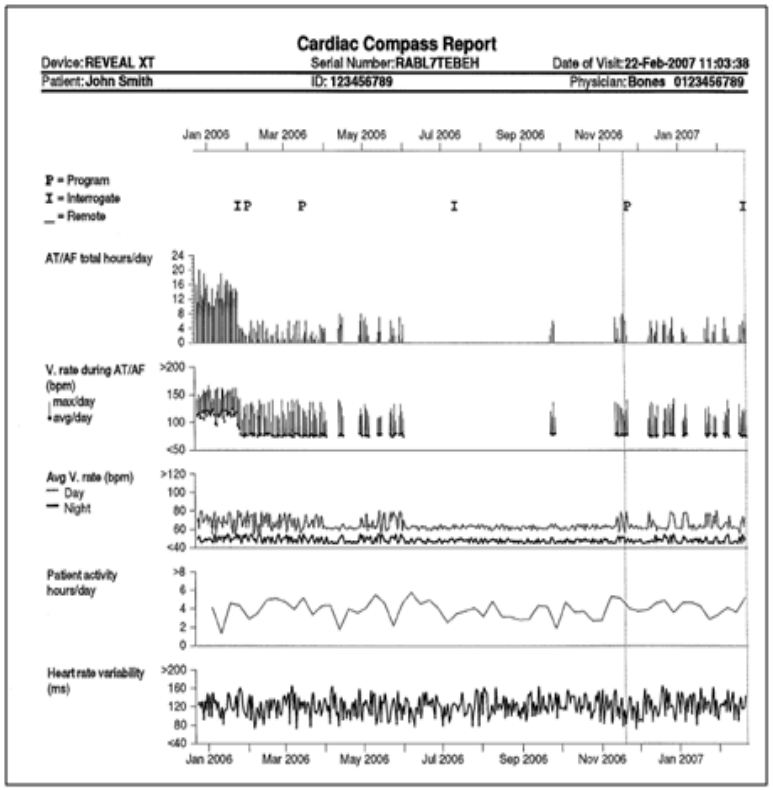
The physician revises the data on Carelink Medtronic Website



Episodio asistolia durante FA



Reveal XT : Cardiac Compass Report



- **AT/AF totale ore/dgiorno:** AF sintomatica o asintomatica? Ricomparsa dell' AF?
- **Frequenza ventricolare durante AT/AF**
- **Frequenza ventricolare media (giorno/notte):** è nella norma?
- **Attività paziente:** accertare lìattività paziente settimanale
- **Heart Rate variability:** una ridotta HRV può indicare un peggioramento nelle condizioni del paziente

Medtronic: Insertable Loop Recorder Reveal LINQ®



European Heart Journal (2010) **31**, 2369–2429
doi:10.1093/eurheartj/ehq278

ESC GUIDELINES

Guidelines for the management of atrial fibrillation

The Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC)

Developed with the special contribution of the European Heart Rhythm Association (EHRA)†

Endorsed by the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: A. John Camm (Chairperson) (UK)*, Paulus Kirchhof (Germany), Gregory Y.H. Lip (UK), Ulrich Schotten (The Netherlands), Irene Savelieva (UK), Sabine Ernst (UK), Isabelle C. Van Gelder (The Netherlands), Nawwar Al-Attar (France), Gerhard Hindricks (Germany), Bernard Prendergast (UK), Hein Heidbuchel (Belgium), Ottavio Alfieri (Italy), Annalisa Angelini (Italy), Dan Atar (Norway), Paolo Colonna (Italy), Raffaele De Caterina (Italy), Johan De Sutter (Belgium), Andreas Goette (Germany), Bulent Gorenek (Turkey), Magnus Heldal (Norway), Stefan H. Hohloser (Germany), Philippe Kolh (Belgium), Jean-Yves Le Heuzey (France), Piotr Ponikowski (Poland), Frans H. Rutten (The Netherlands).

European Heart Journal (2010
doi:10.1093/eurheartj/ehq278

Guidelines for
fibrillation

The Task Force for
European Society of

Developed with the speci
(EHRA)†

Endorsed by the Europea

Authors/Task Force Mem
(Germany), Gregory Y.H
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Nawwar Al-Attar (France
(UK), Hein Heidbuchel (
Dan Atar (Norway), Paol
Johan De Sutter (Belgiun
Magnus Heldal (Norway)
Jean-Yves Le Heuzey (Fra
(The Netherlands).

Tools for non-continuous ECG monitoring

Available non-continuous ECG methods include scheduled or symptom-activated standard ECGs, Holter (24 h to 7 days) monitoring and transtelephonic recordings, patient- and automatically activated devices, and external loop recorders. If AF is present at the time of recording, use of the standard 12-lead ECG is sufficient to confirm the diagnosis. In paroxysmal AF, prolonged non-continuous recording will facilitate AF detection. It has been estimated that 7 day Holter ECG recording or daily and symptom-activated event recordings may document the arrhythmia in ~70% of AF patients, and that their negative predictive value for the absence of AF is between 30 and 50%.[3] In stroke survivors, a step-wise addition of five daily short-term ECGs, one 24 h Holter ECG, and another 7 day Holter ECG will each increase the detection rate of AF by a similar extent.[34]

Incidenza della FA asintomatica

	(%)
Riscontro occasionale/ ECG*	16 - 25
Durante terapia AA / TTEM^	56 - 70
Portatori di PM – ICD / Memorie device°	51 - 74

*Kerr CR et al. Eur Heart J 1996; 17 (suppl C): 48-51; Nieuwlaat R et al. Eur Heart J 2005; 26: 1422-34; Miyasake Y et al. Circulation 2006; 114: 119-25

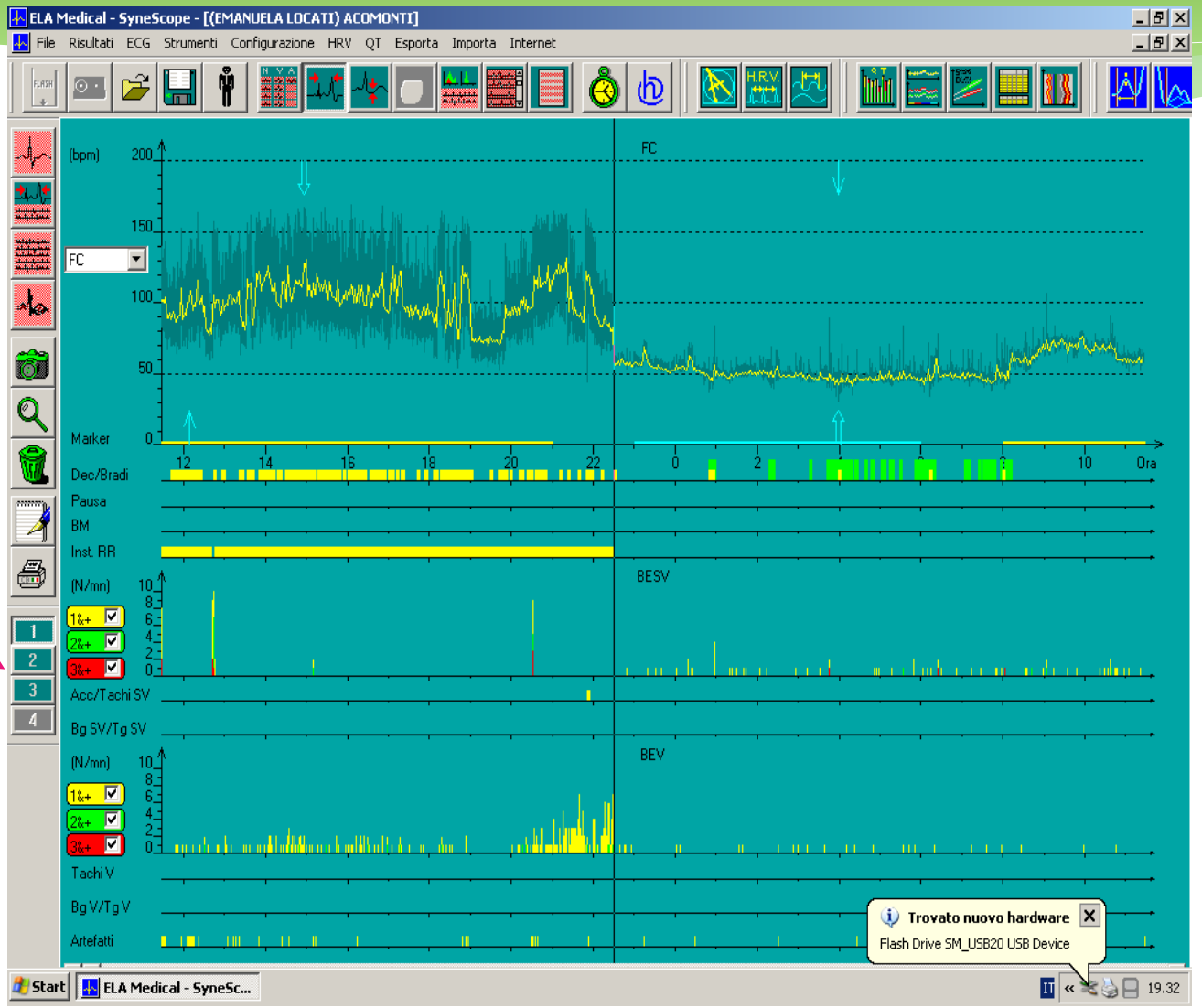
^Fetsch T et al. Eur Heart J 2005; 26: 1422-34; Patten M et al. Eur Heart J 2004; 25: 1395-404

° Israel CW et al J Am Coll Cardiol 2004; 43:47-5; Glotzer TV et al. Circulation 2003; 107: 1614-9 ; Capucci A et al. J Am Coll : Cardiol 2005; 26: 1913-20

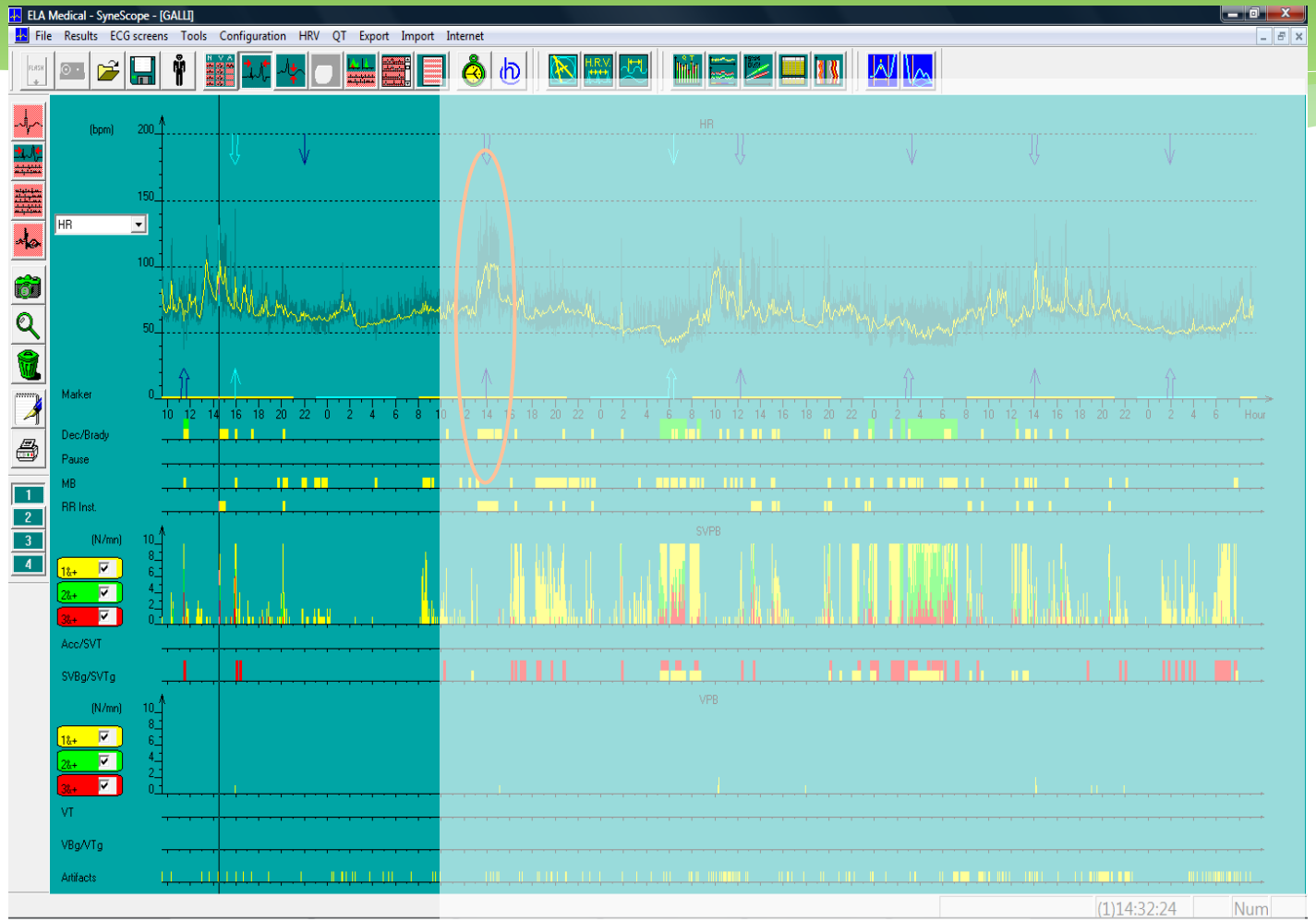
Asyntomatic FAP during Multiday Holter

Holter
72 hours

M.A., Male, 74 yrs totally asyntomatic during recording



Onset of FAP during Multiday Holter



G.A., Female, 76 yrs, Hx of TIA

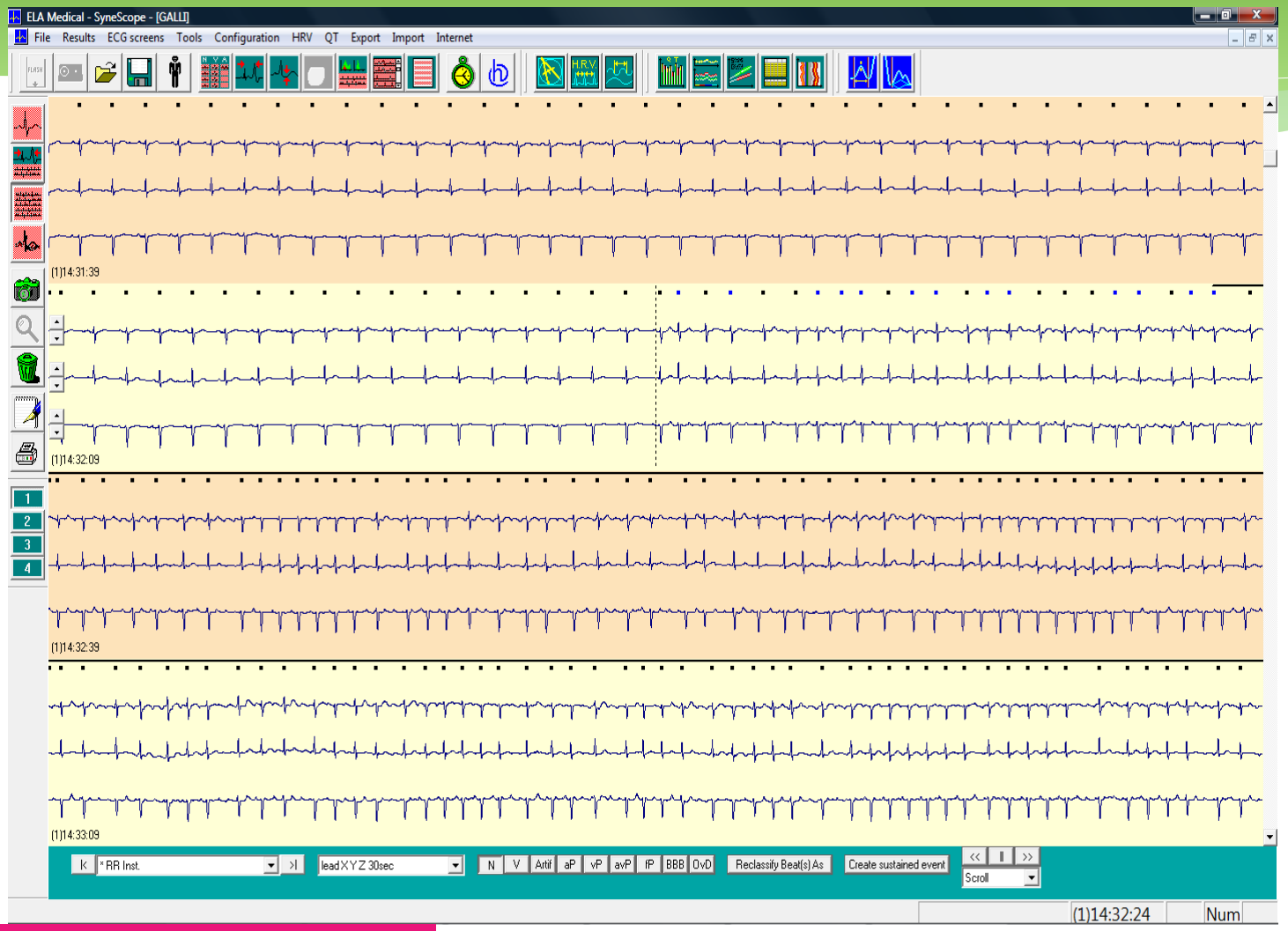
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Onset of FAP during Multiday Holter



G.A., Female, 76 yrs, Hx of TIA

Onset of FAP during Multiday Holter



G.A., Female, 76 yrs, Hx of TIA

Event Recorders con trasmissione transtelefonica di prima generazione



CG-7000™
12-lead Standard ECG



CG-6106™
“Loop Recorder” 90 sec 1-lead ECG



CG-2206™
“Event Recorder” 30 sec 1-lead ECG

SORIN | SPIDERFLASH



SFA®



SFT®

Up to 30 days monitoring

ECG Strips up to 22.5 minutes

Heart Rate Profile

3 Recording Modalities

- Patient activation (SFA®/SFT®)
- Hourly time table (SFA®/SFT®)
- Auto-trigger (SFT®)

From External Loop Recorder to Extended Holter monitoring

Europace, 2013

Role of extended external loop recorders for the diagnosis of unexplained syncope, pre-syncope, and sustained palpitations

Emanuela T. Locati*, Anna Maria Vecchi, Sara Vargiu, Giuseppe Cattafi, and Maurizio Lunati

Department of Cardiovascular, Cardiology Unit 3 – Electrophysiology, Niguarda Hospital, Milan, Italy

Received 24 June 2013; accepted after revision 19 September 2013

Aims To assess the diagnostic yield of new external loop recorders (ELRs) in patients with history of syncope, pre-syncope, and sustained palpitations.

Methods and results Since 2005, we have established a registry including patients who consecutively received ELR monitoring for unexplained syncope or pre-syncope/palpitations. The registry included 307 patients (61% females, age 58 ± 19 years, range 8–94 years) monitored by high-capacity memory ELR of two subsequent generations: SpiderFlash-A® (SFA®, Sorin CRM), storing two-lead electrocardiogram (ECG) patient-activated recordings by loop-recording technique (191 patients, 54 patients with syncope, years 2005–09), and SpiderFlash-T® (SFT®), adding auto-trigger detection for pauses, bradycardia, and supraventricular/ventricular arrhythmias (116 patients, 38 patients with syncope, years 2009–12). All the patients previously underwent routine workup for syncope or palpitation, including one or more 24 h Holter, not conclusive for diagnosis. Mean monitoring duration was 24.1 ± 8.9 days. Among 215 patients with palpitations, a conclusive diagnosis was obtained in 184 patients (86% diagnostic yield for palpitation). Among 92 patients with syncope, a conclusive diagnosis was obtained in 16 patients (17% clinical diagnostic yield for syncope), with recording during syncope of significant arrhythmias in 9 patients, and sinus rhythm in 7 patients. Furthermore, asymptomatic arrhythmias were de novo detected in 12 patients (13%), mainly by auto-trigger detection, suggesting an arrhythmic origin of the syncope.

Conclusions The diagnostic yield of ELR in patients with syncope, pre-syncope, or palpitation of unknown origin after routine workup was similar to implantable loop recorder (ILR) within the same timeframe, therefore, ELR could be considered for patients candidate for long-term ECG monitoring, stepwise before ILR.

Keywords Syncope • Palpitations • Ambulatory ECG monitoring • Cardiac arrhythmias • External loop recorder • Implantable loop recorder

Study population



Role of extended external loop recorders for the diagnosis of unexplained syncope, pre-syncope, and sustained palpitations

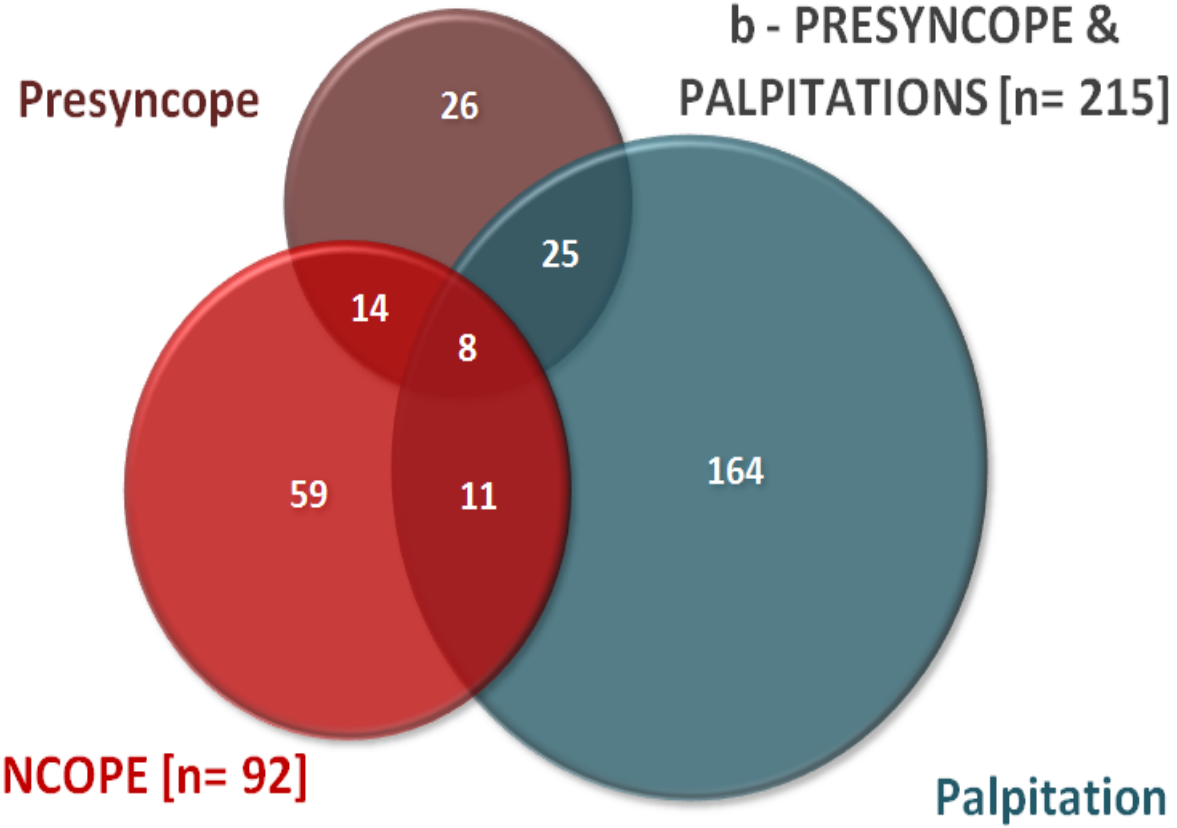
Emanuela T. Locati*, Anna Maria Vecchi, Sara Vargiu, Giuseppe Cattafi, and Maurizio Lunati

Aims

Methods and results

Conclusions

Keywords



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Ospedale Niguarda Ca' Granda

Syncope due to 60 sec asystole during chronic AF



Role of extended external loop recorders for the diagnosis of unexplained syncope, pre-syncope, and sustained palpitations

Emanuela T. Locati*, Anna Maria Vecchi, Sara Vargiu, Giuseppe Cattafi, and Maurizio Lunati

Aims

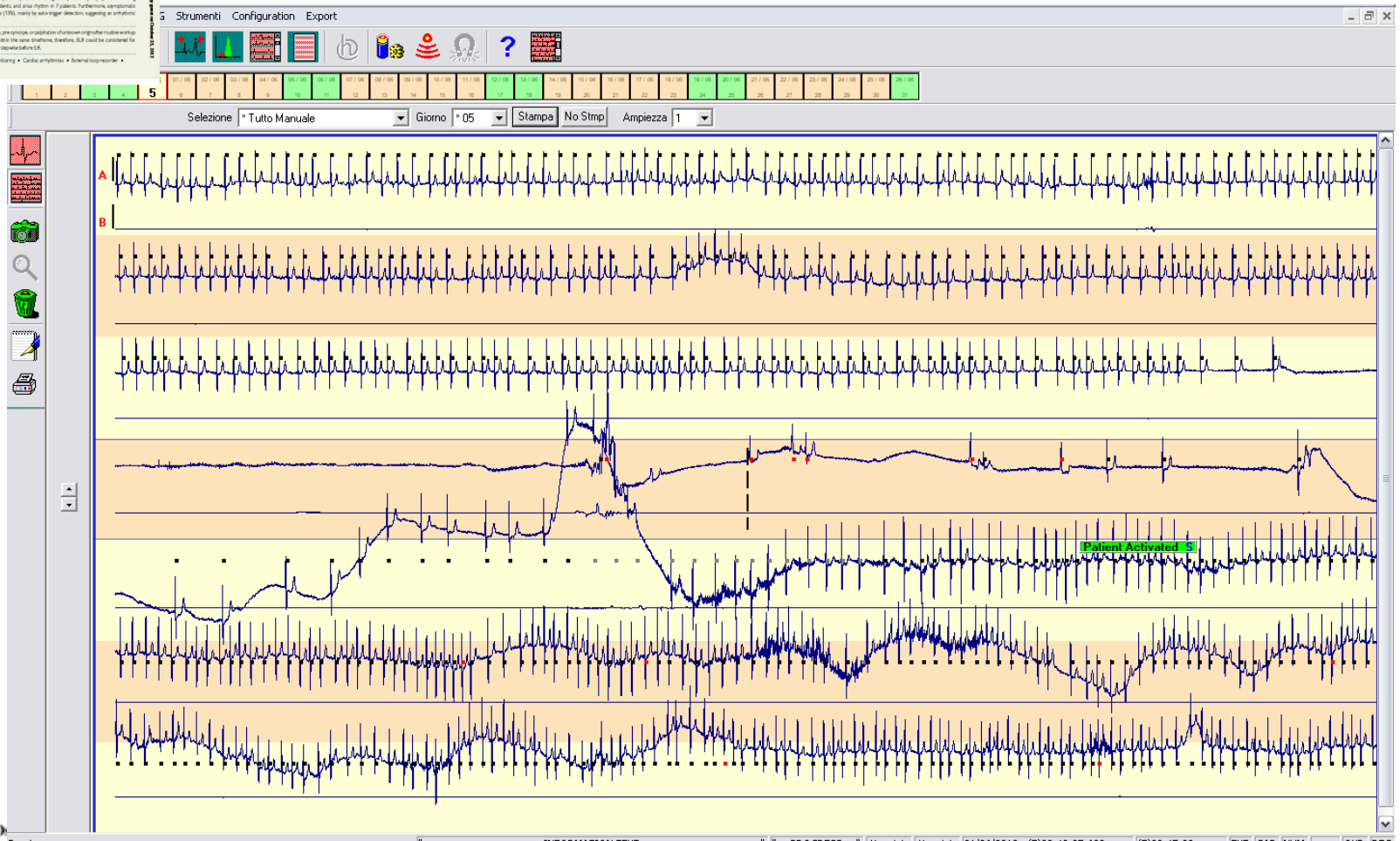
Methods and results

Conclusions

Keywords

SpiderFlash-T
Automatic & patient activation

Female, 70 yrs
Permanent AF, Hx of syncope
24 Holter negative for pauses



Syncope due to 60 sec asystole during chronic AF



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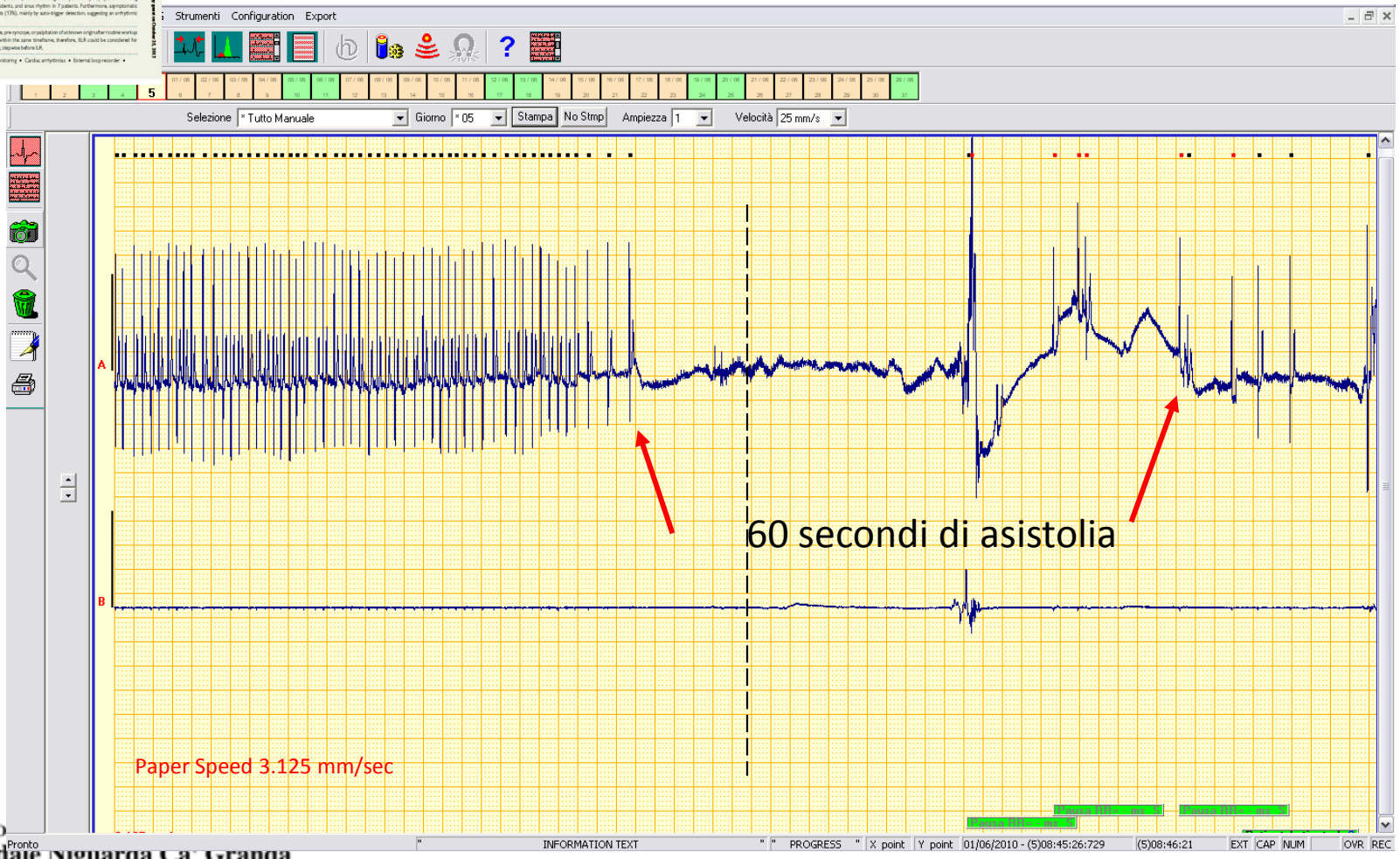
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Keywords

SpiderFlash-T
Automatic & patient activation

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Permanent AF, Hx of syncope
24 Holter negative for pauses



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Zio Patch

MEDICINE

Comparison of 24-hour Holter Monitoring with 14-day Novel Adhesive Patch Electrocardiographic Monitoring☆

Paddy M. Barrett, MB, BCh, BAO,[a] Ravi Komatireddy, MD,[a] Sharon Haaser, RN, BSN, CCRC,[a] Sarah Topol, RN, BSN, BA,[a] Judith Sheard, MPH,[a] Jackie Encinas, MS,[a] Angela J. Fought, MS,[b] Eric J. Topol, MD[a,c]

[a]Scripps Translational Science Institute, La Jolla, Calif; [b]Fought Statistical Consulting, Chicago, Ill; [c]Scripps Health, La Jolla, Calif.

ABSTRACT

BACKGROUND: Cardiac arrhythmias are remarkably common and routinely go undiagnosed because they are often transient and asymptomatic. Effective diagnosis and treatment can substantially reduce the morbidity and mortality associated with cardiac arrhythmias. The Zio Patch (iRhythm Technologies, Inc, San Francisco, Calif) is a novel, single-lead electrocardiographic (ECG), lightweight, Food and Drug Administration–cleared, continuously recording ambulatory adhesive patch monitor suitable for detecting cardiac arrhythmias in patients referred for ambulatory ECG monitoring.

METHODS: A total of 146 patients referred for evaluation of cardiac arrhythmia underwent simultaneous ambulatory ECG recording with a conventional 24-hour Holter monitor and a 14-day adhesive patch monitor. The primary outcome of the study was to compare the detection arrhythmia events over total wear time for both devices. Arrhythmia events were defined as detection of any 1 of 6 arrhythmias, including supraventricular tachycardia, atrial fibrillation/flutter, pause greater than 3 seconds, atrioventricular block, ventricular tachycardia, or polymorphic ventricular tachycardia/ventricular fibrillation. McNemar's tests were used to compare the matched pairs of data from the Holter and the adhesive patch monitor.

RESULTS: Over the total wear time of both devices, the adhesive patch monitor detected 96 arrhythmia events compared with 61 arrhythmia events by the Holter monitor ($P < .001$).

CONCLUSIONS: Over the total wear time of both devices, the adhesive patch monitor detected more events than the Holter monitor. Prolonged duration monitoring for detection of arrhythmia events using single-lead, less-obtrusive, adhesive-patch monitoring platforms could replace conventional Holter monitoring in patients referred for ambulatory ECG monitoring.

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KEYWORDS: Atrial fibrillation; Cardiac arrhythmias; Electrocardiographic; Holter monitor; iRhythm; Zio Patch



Figure 1 The Zio Patch (iRhythm Technologies, Inc, San Francisco, Calif) is an FDA-cleared, single-use, noninvasive, water-resistant, 14-day, ambulatory ECG monitoring adhesive patch.

Zio Patch

CLINICAL RESEARCH STUDY

Comparison of 24 Novel Adhesive P

Paddy M. Barrett, MB, BCh, BAO,[a] I
Judith Sheard, MPH,[a] Jackie Encina
[a]Scripps Translational Science Institute,

ABSTRACT

BACKGROUND: Cardiac
are often transient and
morbidity and mortality
San Francisco, Calif) is
Administration–cleared,
cardiac arrhythmias in p
METHODS: A total of 14
ambulatory ECG record
monitor. The primary ou
time for both devices. A
supraventricular tachyca
ventricular tachycardia,
were used to compare th
RESULTS: Over the total
events compared with 6
CONCLUSIONS: Over the
than the Holter monitor.
lead, less-obtrusive, adh
in patients referred for a
© 2014 The Authors. Pu
(2014) 127, 95.e11-95.e.

KEYWORDS: Atrial fibril

ZIO®XT

Zio® Patch Report for
Report #1, Training

iRhythm Technologies, Inc.
Tel: (888) 693-2401
www.zioreports.com

Date of Birth	Patient ID	Gender	Primary Indication
			Arrhythmia (unspecified)

Prescribing Clinician	Managing Location
Dr. E. Physician	iNCC Lincolnshire

This report is a compilation of multiple patients' arrhythmias.

Enrollment Period	Analysis Time
13 days 16 hours 02/22/13, 01:22pm to 03/08/13, 05:03am	13 days 11 hours (after artifact removed)

Ventricular Tachycardia (4 beats or more)
▼ Fastest VT (HR Range 99-182 bpm, Avg 135 bpm) No. of Episodes: 4
Patient Triggered Event? (± 45s) YES ☐ NO ☒

Supraventricular Tachycardia (4 beats or more)
▼ Fastest SVT (HR Range 156-187 bpm, Avg 164 bpm) No. of Episodes: 5871
YES ☐ NO ☒

Pauses (3 secs or longer)
▼ Longest Pause (5.4 s, 11 bpm) No. of Episodes: 3
YES ☐ NO ☒

Atrial Fibrillation
▼ Fastest AF (HR Range 126-212 bpm, Avg 158 bpm) AF Burden: 12%
YES ☐ NO ☒

AV Block (2nd° Mobitz II)
▼ Slowest AV Block - 2nd° Mobitz II (29 bpm) No. of Episodes: 192
YES ☐ NO ☒

Heart Rate

Maximum HR	212 bpm	(at 07:52pm on 03/04)
Minimum HR	29 bpm	(at 03:46pm on 02/25)
Average HR	72 bpm	

Patient Events

Number of Triggered Events: 3
Findings within ± 45 sec of Triggers:
AV Block, Supraventricular Tachycardia, Sinus Rhythm, Ventricular Ectopic beat(s), Supraventricular Ectopic beat(s)

Number of Diary Entries: 3
Findings within ± 45 sec of Entries:
Atrial Fibrillation, AV Block, Pause(s), Sinus Rhythm, Supraventricular Ectopic beat(s)

Ectopics

Rare: 0 to <1.0%
Occasional: 1.0% to <5.0%
Frequent: 5.0%+

Supraventricular Ectopy (SVE/PACs)

Isolated	Frequent	5.4%	76752
Couplet	Occasional	3.7%	26323
Triplet	Occasional	1.7%	7781

Ventricular Ectopy (VE/PVCs)

Isolated	Rare	<1.0%	5154
Couplet	Rare	<1.0%	19
Triplet	Rare	<1.0%	1

Longest Ventricular Bigeminy Episode 4.8 s
Longest Ventricular Trigeminy Episode 7.7 s



Technologies, Inc, San
single-use, noninvasive,
CG monitoring adhesive

NUUBO: Wireless Long-Term Holter



Nuubo nECG Platform 2014

nuubo

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NUUBO: Wireless Long-Term Holter

BlendFix® *Sensor Electrode Technology*

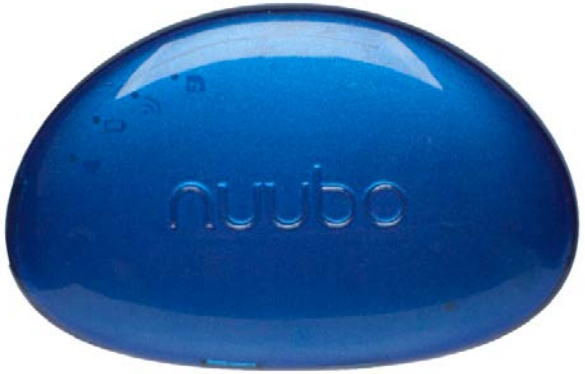
- Proprietary **biomedical e-textile technology** *(wearable sensor)*
- Cost-effective, continuous and **non-invasive**
- Excellent **ECG signal quality** and dynamic control
- Extremely **easy-to-use,** minimal impact on patient lifestyle
- Available in **different sizes .**



NUUBO: Wireless Long-Term Holter

Wireless Sensor Device

- Wireless dynamic ECG can be used in **real-time** and **holter**
- **Long-duration:** 8 GB capacity (removable micro-SD card, stores up to 2 months in continuous ECG recording mode)
- ECG in environments with **high levels of physical activity**, such as sports



Technical specifications

ECG
Channels: *single-lead // Three-leads*
Sampling rate: *250 sps*
Bandwidth: *0.05-100 Hz*
Class: *IIa*
Type: *CF*

Bluetooth® *v2.0+EDR Class I (50 m)*
Accelerometer *3-axis*
HR transmitter (5.5 khz)

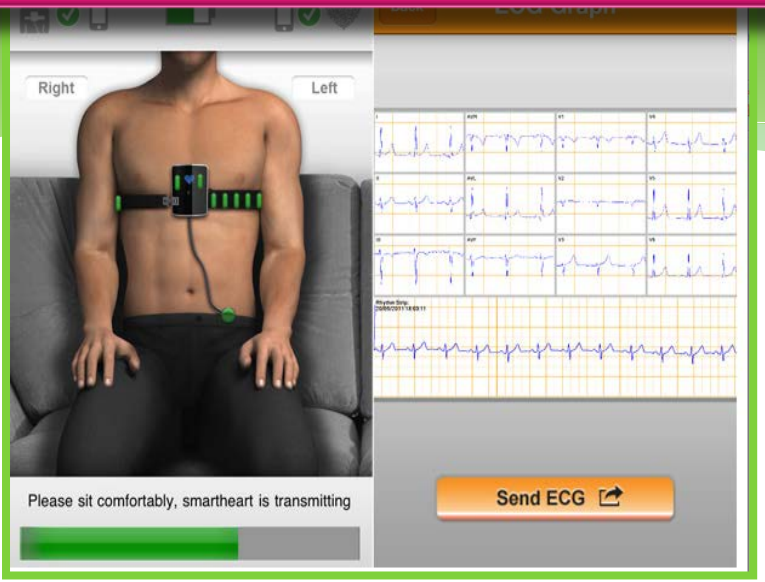


NUUBO: Wireless Long-Term Holter

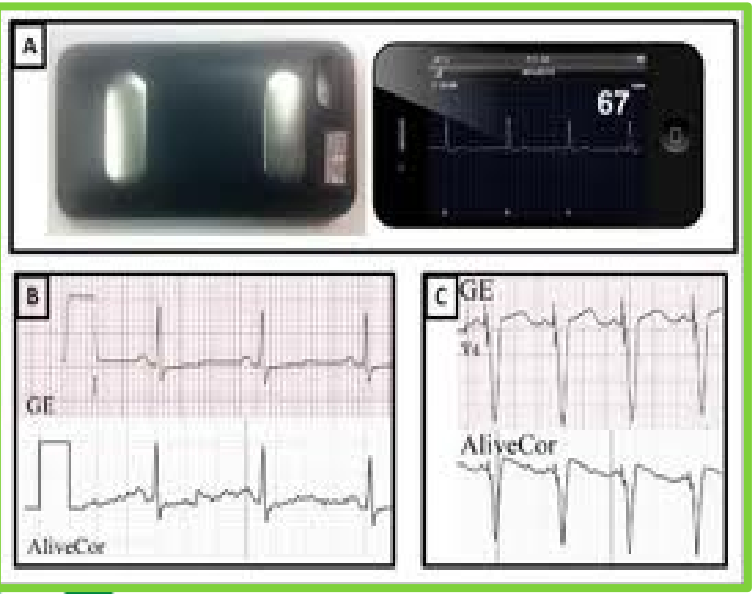
AMG,
Female
24 yrs
Hx of
Palpitation
at effort,
Sister
with SD



CardioDefender: SmartPhone Event Recorder



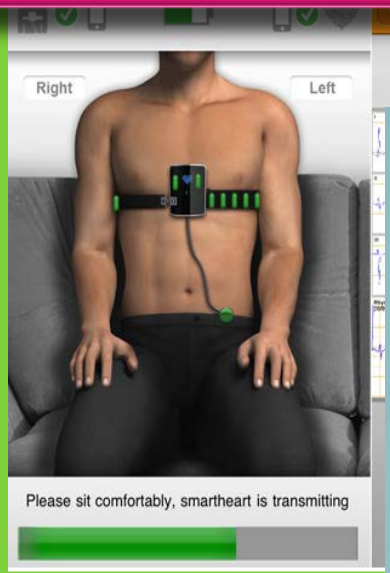


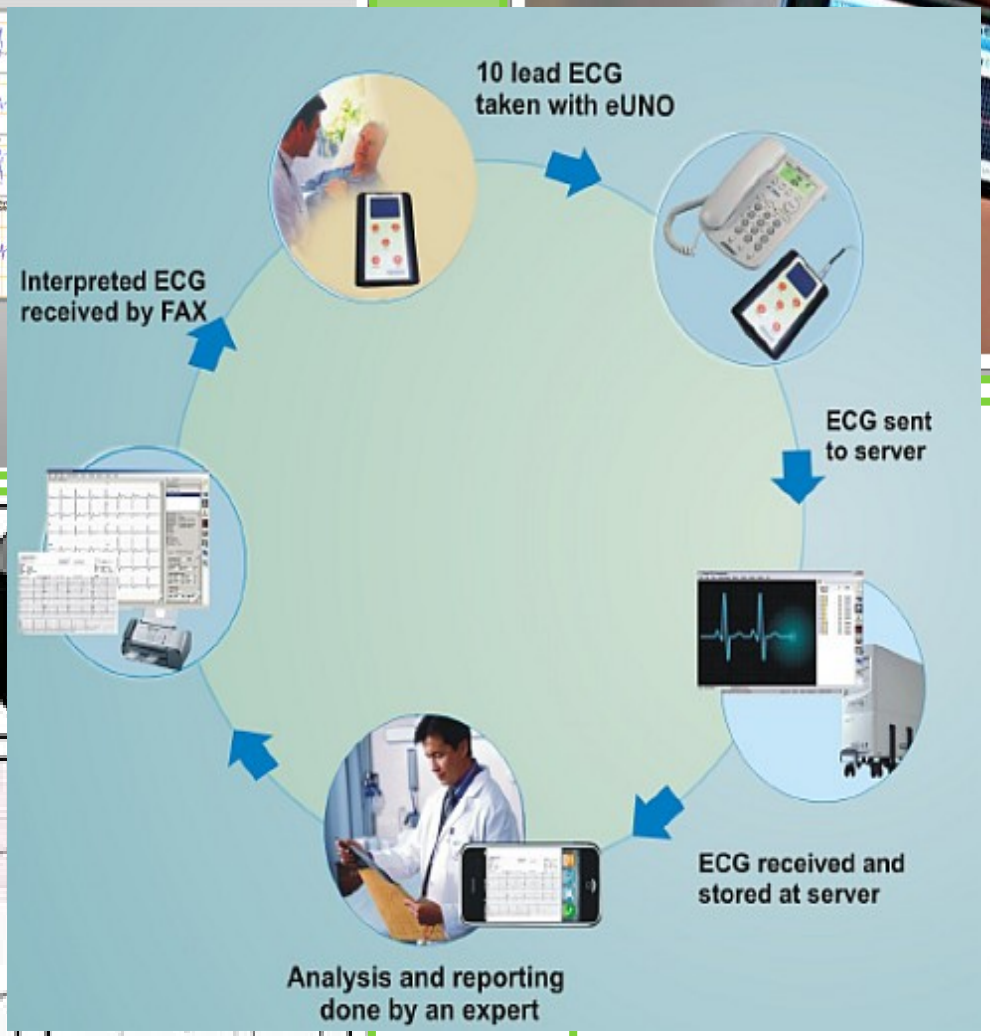




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CardioDefender: SmartPhone Event Recorder













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Necessità di una tariffa di rimborso per Holter Prolungato: Prospettiva di risparmio rispetto alla spesa attuale

Scenario 1 - Uso esclusivo di ILR (*secondo linee guida attuali*)

Registratore	Pazienti	Rimborso/paziente	Costo/anno	Costo totale/anno
ILR (impianto)	**100**	**3.239 €**	**323.940 €**	**345.420 €**
ILR (controllo)	**100**	**214,8 €[1]**	**21.480 €**	

[1]: 17,90€ ogni controllo – si ipotizzano circa 4 controlli all'anno per 3 anni.

Scenario 2 - Uso di Holter 24 ore standard prima di ILR (*scenario attuale*)

Registratore	Pazienti	Rimborso/paziente	Costo/anno	Costo totale/anno	Risparmio vs scenario 1
Holter	**100**	**63,33 €**	**6.333 €**		
ILR (impianto + controlli)	**95[2]**	**3.454,20 €**	**328.149 €**	**334.482 €**	**10.938 € (-3%[3])**

[2]: si assume un potere diagnostico del 5% per l'Holter 24 standard nei pazienti studiati per sincope.
[3]: rispetto a scenario 1

Scenario 3 - Uso di ELR prima di ILR (*proposta*)

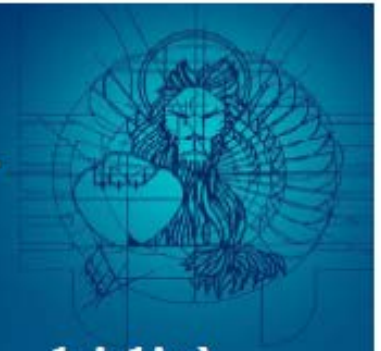
Registratore	Pazienti	Rimborso/paziente	Costo/anno	Costo totale/anno	Risparmio vs scenario 1	Risparmio vs scenario 2
ELR	**100**	**250 €**	**25.000 €**			
ILR (impianto + controlli)	**65[4]**	**3.454,20 €**	**224.523 €**	**249.523 €**	**95.897 € (-28%[3])**	84.595 € (-25%[5])

[3]: rispetto a scenario 1
*[4]: si considera il potere diagnostico del 35% nei pazienti studiati per sincope come pubblicato nel seguente articolo **Role of extended external loop recorders for the diagnosis of unexplained syncope, pre-syncope, and sustained palpitations.** [Locati T., Vecchi A.M., Vargiu S., Cattafi G., Lunati M. – Europace 2013]*
[5]: rispetto a scenario 2

HM: Reimbursement Issues

COUNTRY	In-clinic device check	Remote device check	Remote disease management
Germany	✓	✓	✓ X
Portugal	✓	✓	X
Spain	n/a	n/a	n/a
UK	✓	✓	X
Netherlands	✓	✓∞	X
Nordics	✓	✓∞	X
France	✓	X	X
Italy	✓	X	X
Switzerland	✓	X	X
Belgium	✓	X	X

Fibrillazione atriale



Considerata la sua epidemiologia, morbidità e mortalità, la FA ha un significativo impatto socio-sanitario che richiede più attenzione e risorse rispetto a quelle destinate finora.

Enorme carico di FA:
Necessità di un'adeguata organizzazione per gestirla!

