ASSOCIAZIONE ITALIANA
PAZIENTI SCOMPENSATI CARDIACI
INCONTRO NAZIONALE ANNUALE

SALERNO, 5 OTTOBRE 2018
h 10:00 – 16:30
Hotel Polo Nautico

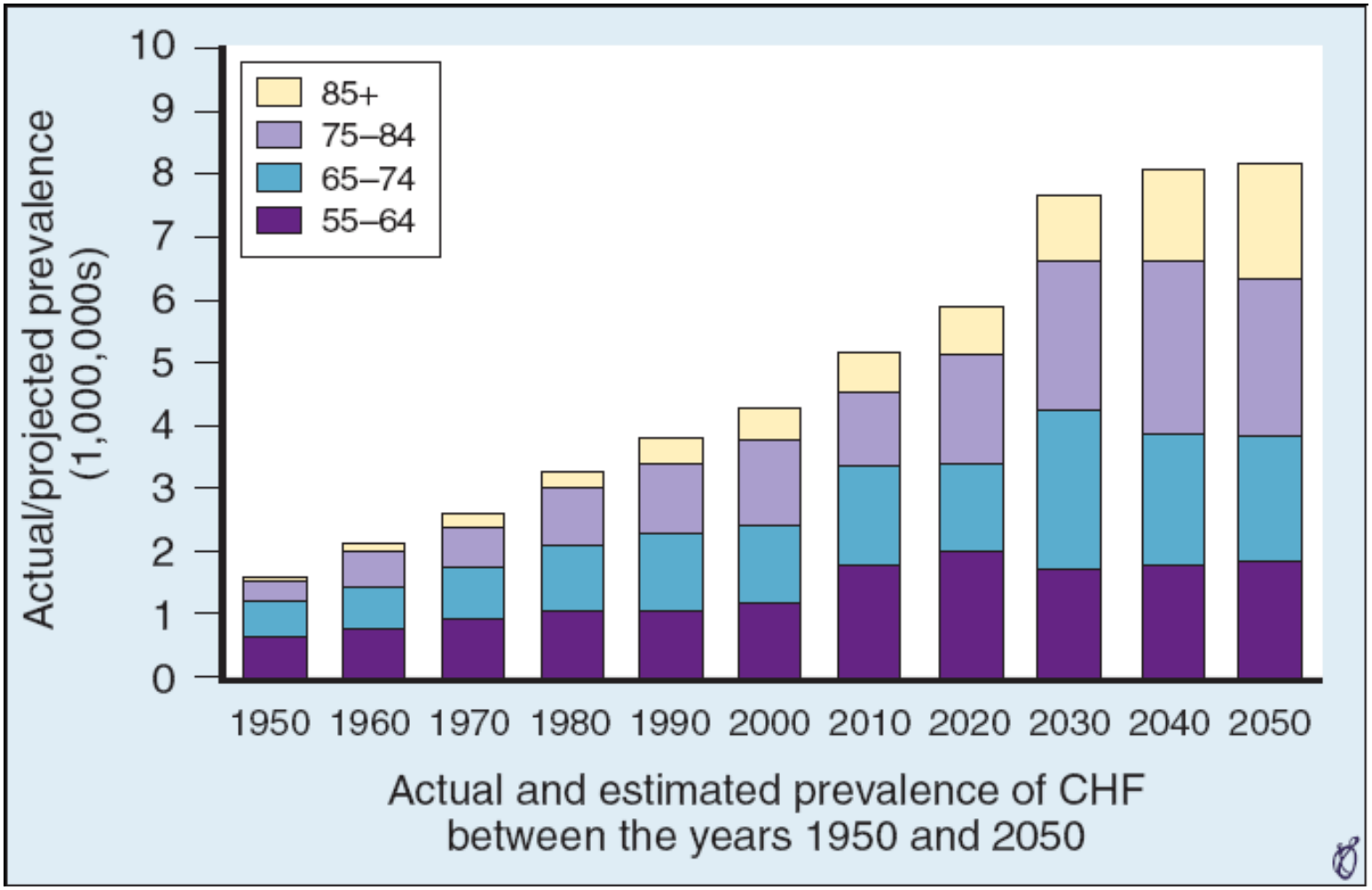
II monitoraggio remoto e la telemedicina come strumento di continuità di cura Ospedale Territorio

Giuseppe Stabile

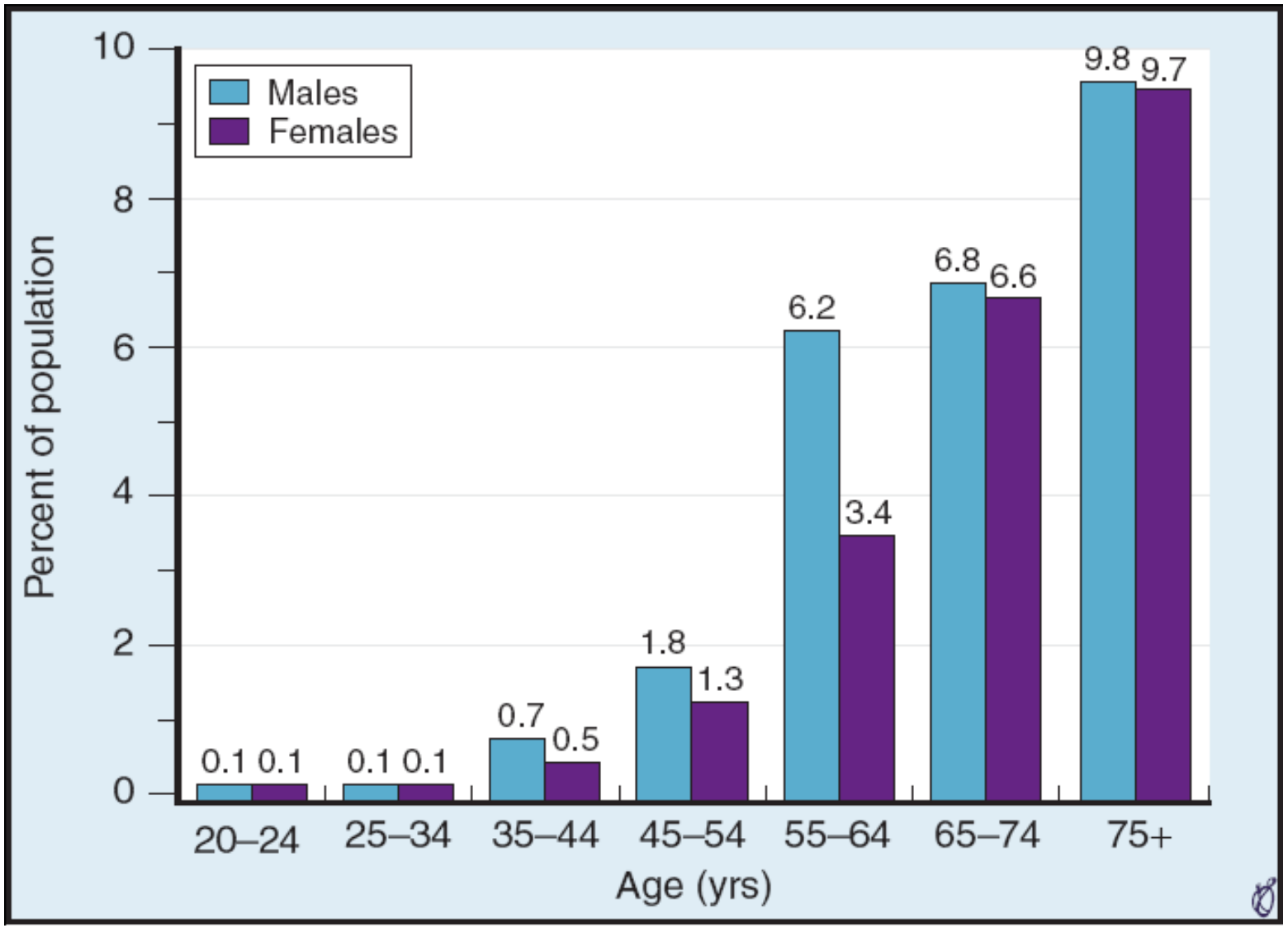
AIAC
Associazione Italiana Aritmologia e Cardiostimolazione

aritmologiaincampania

Clinica Mediterranea, Napoli

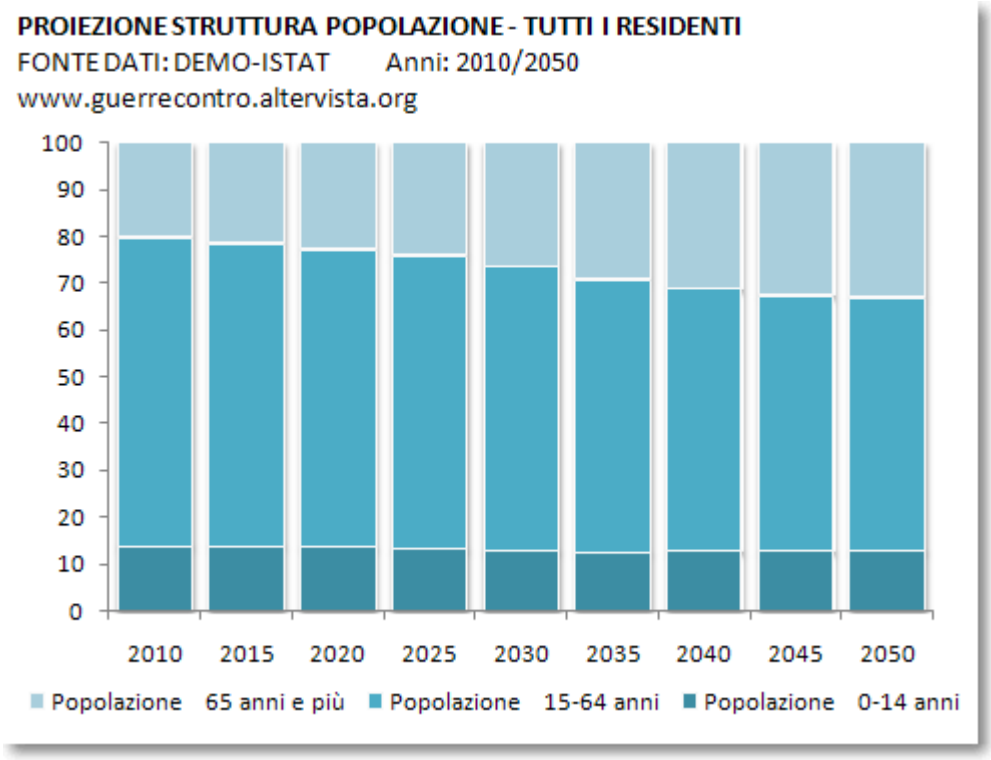


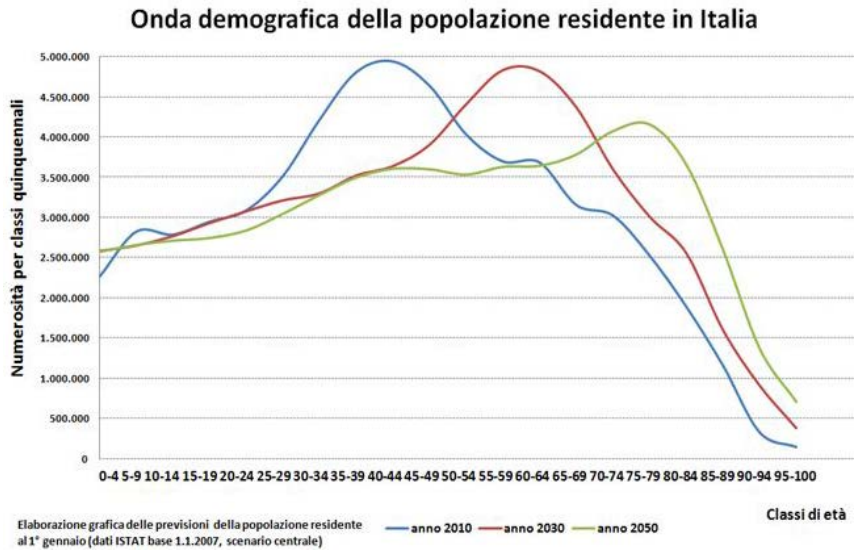
www.nhlbi.nih.gov/health/public/heart/other/CHF



www.nhlbi.nih.gov/health/public/heart/other/CHF

Italian Population





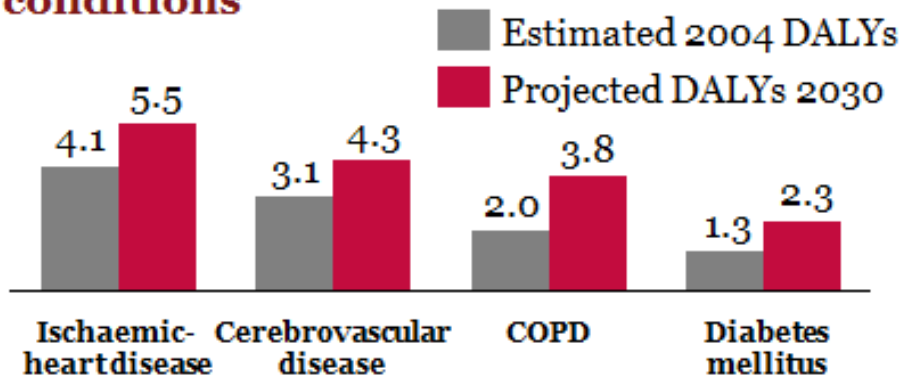
- Increased Longevity
- Increase in the population over 65 years old

Older population is at high risk to suffer of:

- **Heart Failure (HF)**
- **Atrial Fibrillation (AF)**

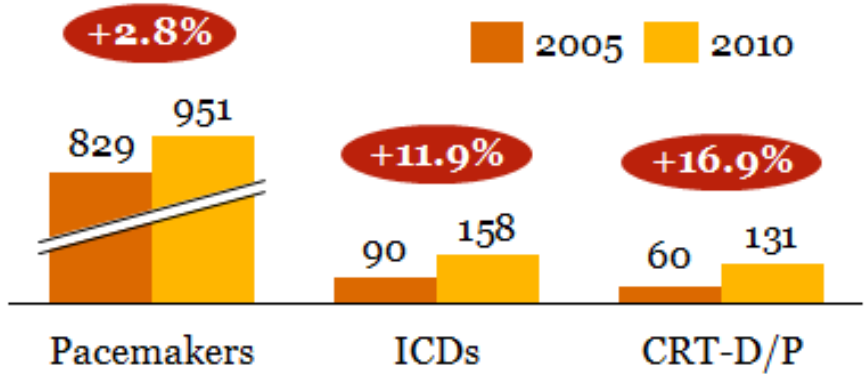
The chronic disease burden is increasing – with physician capacity rather shrinking than growing

Global DALYs for selected chronic conditions



Source: World Health Organisation, Global health risks: Mortality and burden of disease attributabel to selected major risks, 2009

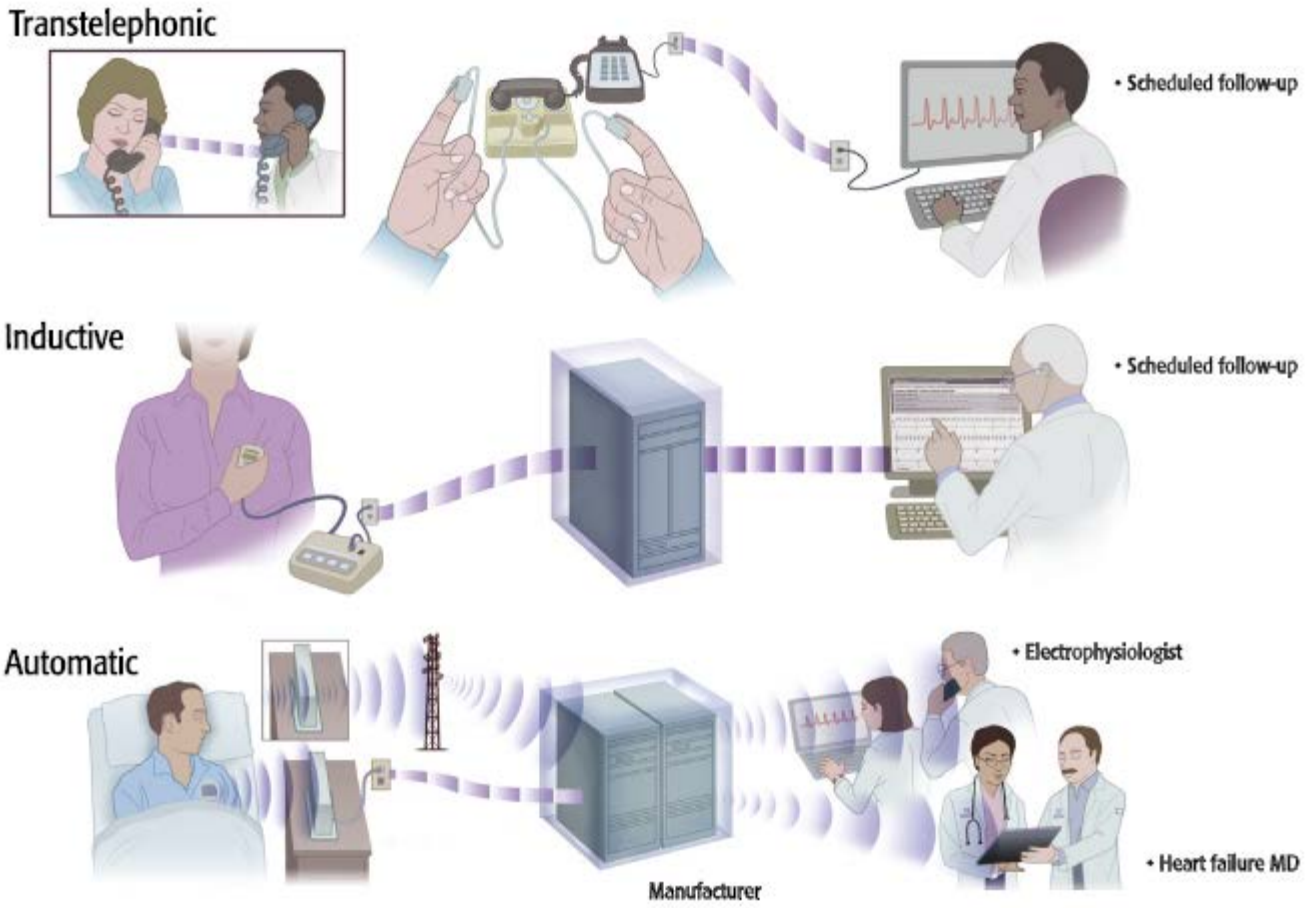
CIED-Implants per 1 million inhabitants



Source: www.eucomed.org/uploads/_medical_technology/facts_figures/110518_statistics_for_cardiac_rhythm_management_products_20052010.pdf (update available for 2012)

- Increasing chronic conditions are the greatest challenge for health economies in Europe
- Chronic conditions drive the demand for medical capacity
- Yet, physician capacity will rather decrease in the future
- Required: improved disease management – and increased efficiency in the provision of care

Need for innovative solutions



1971

1990

2001

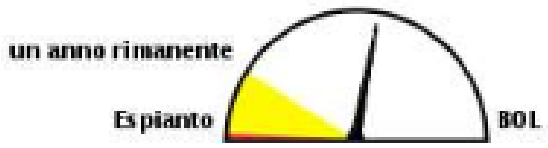
Informazioni sulle apparecchiature/paziente

Stato del paziente	Monitorato
Medico (dispositivo)	Stabile, Giuseppe
Data imp.	21 Ott 2008

Elettrocateteri

Batteria

OK Tempo approssimato per espianto: 3 anni Da 12 Mar 2010



Interrogazione iniziata dal paziente	On
Da ultimo follow-up a distanza	0
Dall'impianto	1

Riepilogo clinico

Parametri	Misurazione più recente	
Frequenza cardiaca media	58 min^{-1}	11 Mar 2010

EGM più recente: 12 Mar 2010

(Fare clic per dettagli)

Eventi

	Da ultimo follow-up 15 Feb 2010	Percentuale Stimol.
Terapia FV	0	A 5%
Terapia TV	0	VD 100%
Terapia TV-1	0	VS 100%
ATR > 48 h	0	

Riepilogo impostazioni

FV	200 min^{-1}	ATP	41 J, 41 J, 41 J x 6
TV	160 min^{-1}	ATP	41 J, 41 J, 41 J x 4
LRL - MTR	50 - 130 min^{-1}		
Modalità	DDD-BiV		

Boston Scientific

LATITUDE® Patient Management | Report creato 16 Mar 2010

Report gestione HF

[redacted]

Data di nascita
Dispositivo COGNIS 100-D P107/002845
Modo Tachy Monitor + Terapia

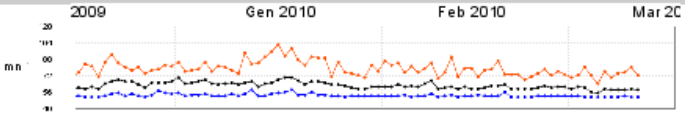
Ultimo invio
12 Mar 2010
Ultima interrogazione ambulatoriale
28 Set 2009
Data Imp.
21 Ott 2008

Allarmi personalizzati

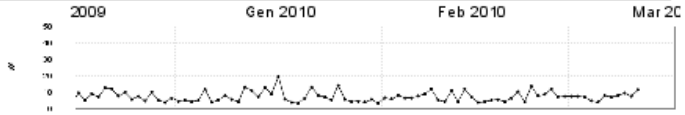
Non ci sono allarmi da visualizzare.

Trend

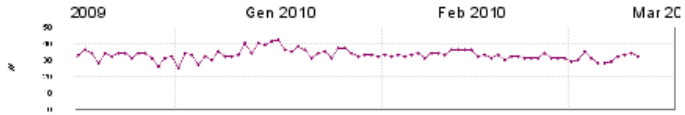
Frequenza cardiaca
Max
Media
Min



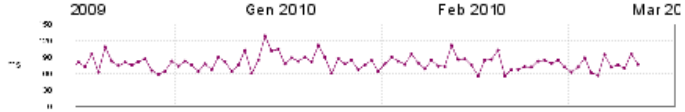
Livello di attività
% di attività della giornata



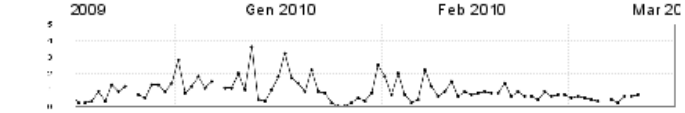
HRV Footprint



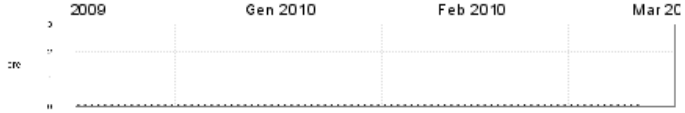
SDANN



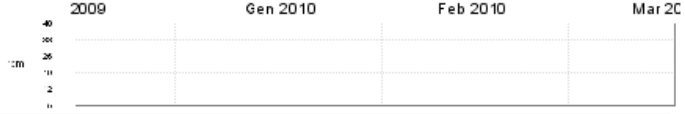
Autonomic Balance Monitor



Burden atriale



Frequenza respiratoria
Max
Media
Min



Firma del medico

Eventi dall'ultimo follow-up (15 Feb 2010)

Non ci sono eventi da visualizzare.

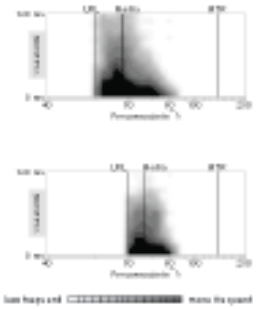
Heart Rate Variability

Ult misura nella 24 ore, terminata il 11 Mar 2010 22:53

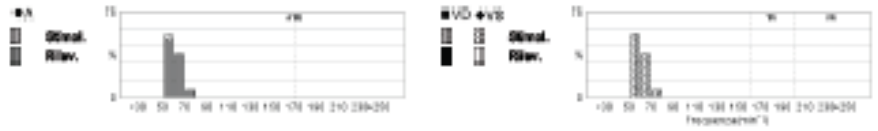
% di tempo impiegato	97
Footprint	32 %
SDANN	76 ms
Modalità	DDD
Ritardo AV rilevato	100 - 130 ms
Camera di pacing	BiV
LV Offset	-40 ms

Referenza: termine del periodo di 24[redacted]ott 2008 22:37

% di tempo impiegato	68
Footprint	18 %
SDANN	48 ms
Modalità	DDD
Ritardo AV rilevato	100 - 130 ms
Camera di pacing	BiV
LV Offset	0 ms



Istogrammi da ultimo follow-up (15 Feb 2010)



Contatori Brady e CRT dall'ultimo follow-up: (15 Feb 2010)

% di pacing

Atriale	5 %
Ventricol. destra	100 %
Ventricol. sinistra	100 %

ConLri Burden Atriale da ultimo follow-up (15 Feb 2010)

Episodi per durata

< 1 Minute	0
1 min - < 1 h	0
1 h - < 24 h	0
24 h - < 48 h	0
> 48 h	0

Batteria OK

Tempo approssimato per esianto: 3 anni Da 12 Mar 2010

Impostazioni

Impostazioni di defibrillazione

Zona FV	200 min⁻¹	ATP, 8 Shock
Zona TV	160 min⁻¹	ATP, 6 Shock

Impostazioni Brady e CRT

Modo Brady	DDD
Limite freq. inf.	50 min⁻¹
Max freq. trascinam.	130 min⁻¹
Frequenza massima sensore	130 min⁻¹
Ritardo AV stimolato	120 - 160 ms
Ritardo AV rilevato	100 - 130 ms
Camera di pacing V	BiV
LV Offset	-40 ms

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LATITUDE® Patient Management

Dettagli sull'episodio

[redacted]

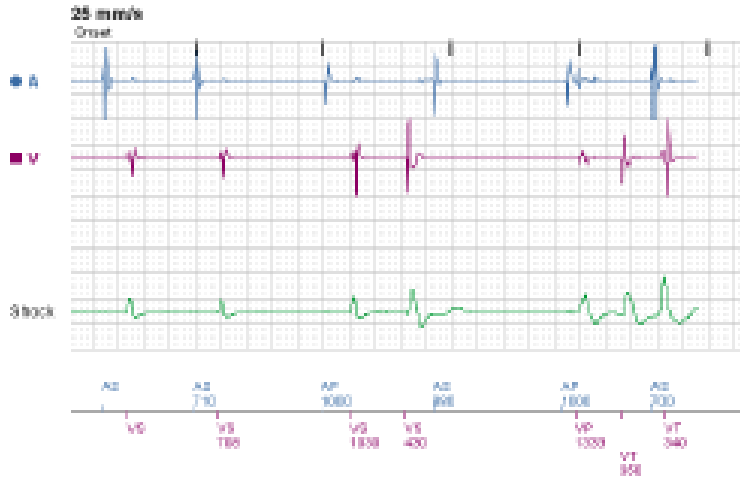
ID 19
Data di nascita
Dispositivo TBLIGBN 100 P110/000273
Modo Tachy Monitor + Terapia

Event V-3 09 Feb 2010 18:58

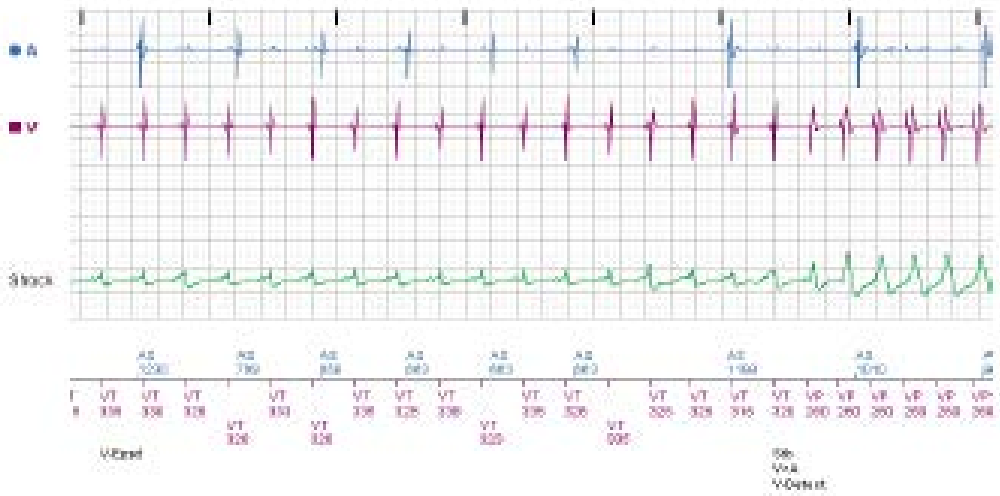
Onset Evento TV

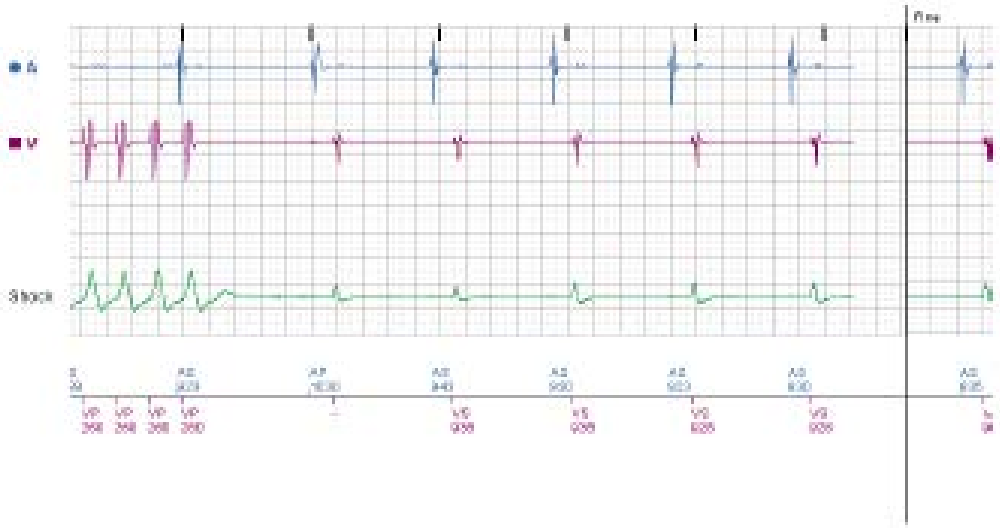
Frequenza A media	73 min⁻¹	
Frequenza V media	183 min⁻¹	
Rilevazione	Rhythm ID	
Rilevazione		Tentat. 1, Raffica V ATP
Frequenza A media	76 min⁻¹	Tempo trascorso
Frequenza V media	187 min⁻¹	Informazioni ATP
zona di frequenza:	TV	Numero raffiche
Stabilità	8 ms	
Frequenza V>A	Vero	
AFib	Falso	
RhythmID correlato	Falso	
SRD soddisfatto	Falso	
Timeout ATP	Falso	

Event term.: 00:00:21



25 mm/s





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DETTAGLIO SULL'EVENTO

Evento precedente

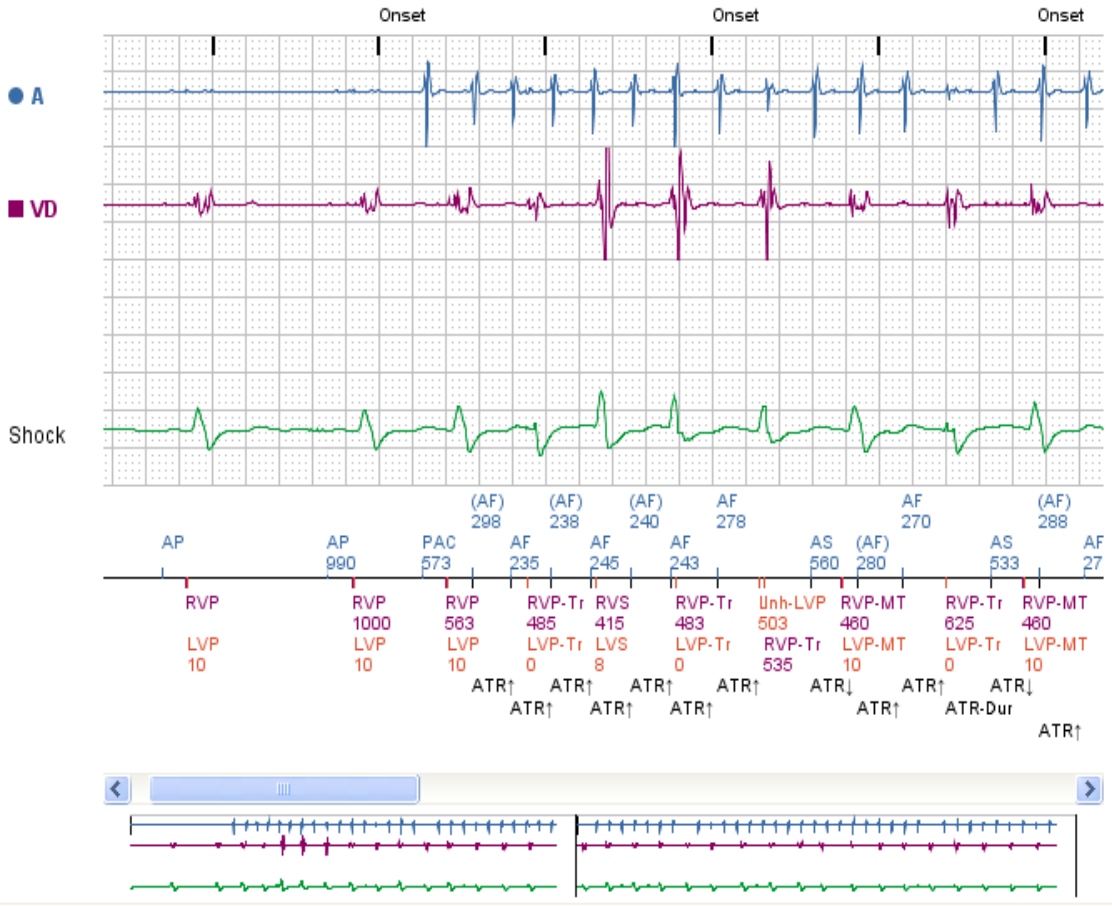
Evento successivo

Stampare il report dettagliato dell'episodio

Evento ATR-38: 27 Dic 2009 16:02, ATR, frequenza A: 174 min^{-1}

Onset | Fine

EGM visualizzato a 25 mm al secondo

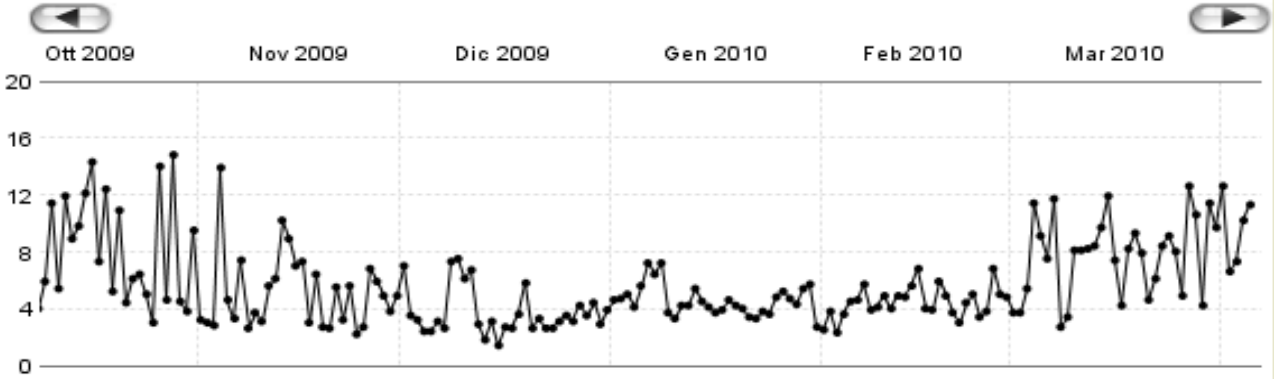


TREND: PERSONALIZZATO Selezione Trend

Vedi: 6 mesi

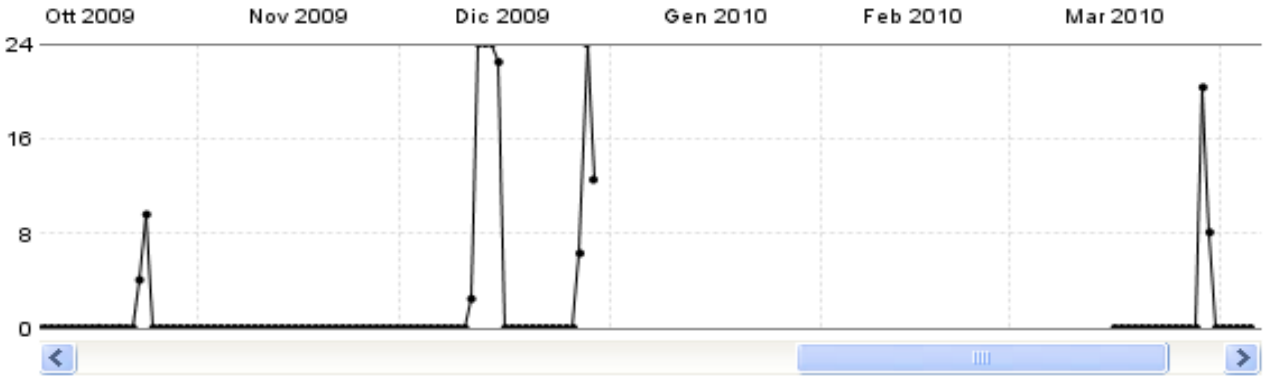
Livello di attività

% di attività della giornata



Vedere valori

Burden atriale



Vedere valori

	30 Mar 2010	31 Mar 2010	01 Apr 2010	02 Apr 2010	03 Apr 2010	04 Apr 2010	05 Apr 2010
Livello di attività (% di attività della giornata)	11,4	9,7	12,6	6,6	7,3	10,2	11,3
Burden atriale							
Tempo totale (ore)	8,1	0,0	0,0	0,0	0,0	0,0	0,0
N. di eventi	1	0	0	0	0	0	0

Sensori

Sensors:	**What Clinicians ask / do during a physical exam:**
Sleep Incline	*"How many pillows do you sleep on at night?"*
Thoracic Impedance	Listen to lung sounds for signs of pulmonary edema
Respiratory Rate	*"Are you out of breath? Have difficulty breathing?"*
Activity Level	*"Have you been feeling tired?"*
Weight	*"Have you gained weight?"*
Blood Pressure	*Measure blood pressure*
Night Heart Rate	*Is resting heart rate elevated?*
Daily Heart Rate	
Heart Rate Variability (SDANN)	
% LV Paced	

AT/AF Burden	
RV Rating during AT/AF	
V-Therapy	

Indici multiparametrici

Multiple Sensor Measurements

Heart Sounds
S1 & S3

Impedance
Thoracic

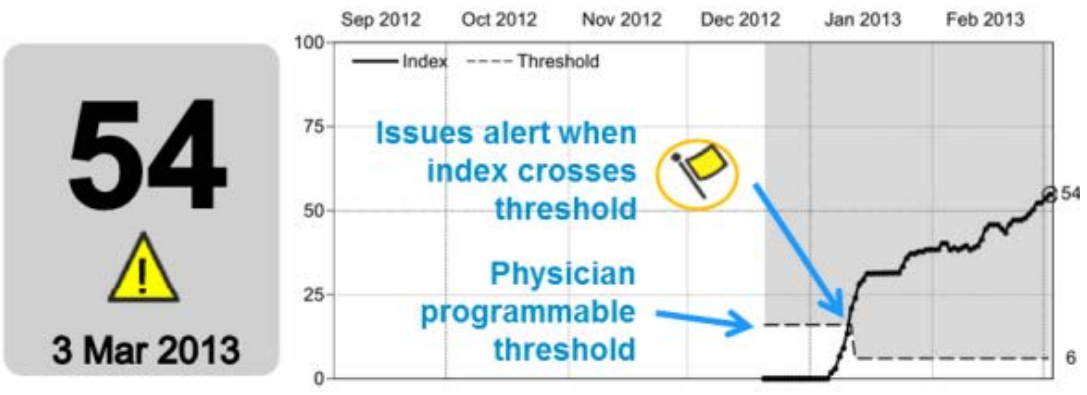
Respiration
Rate & Volume

Activity
Time Spent Active

Heart Rate
Night

Combined into a single, simple index with alert

HeartLogic™ Heart Failure Index



High sensitivity: 70 % in detecting heart failure events

Low burden of less than 2 alerts per patient per year

Weeks of advanced notice to clinicians of a potential event

Journal of the American College of Cardiology
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Published by Elsevier Inc.

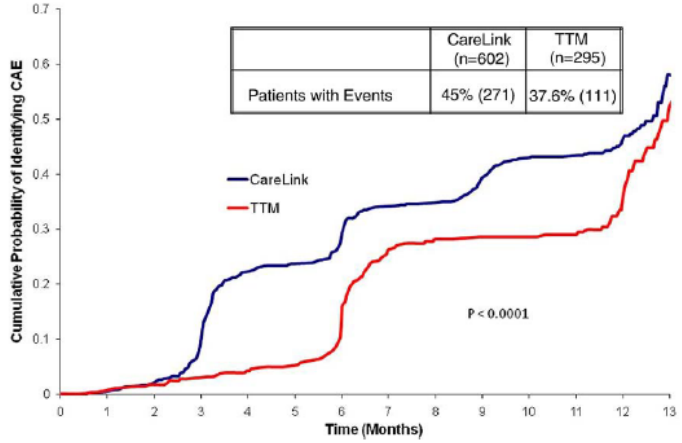
Vol. 54, No. 22, 2009
ISSN 0735-1097/09/$36.00
doi:10.1016/j.jacc.2009.10.001

QUARTERLY FOCUS ISSUE: HEART RHYTHM DISORDERS

Clinical Benefits of Remote Versus Transtelephonic Monitoring of Implanted Pacemakers

George H. Crossley, MD,* Jane Chen, MD,† Wassim Choucair, MD,‡ Todd J. Cohen, MD,§ Douglas C. Gohn, MD,‖ W. Ben Johnson, MD,¶ Eleanor E. Kennedy, MD,# Luc R. Mongeon, PHD,** Gerald A. Serwer, MD,†† Hongyan Qiao,** Bruce L. Wilkoff, MD,‡‡ for the PREFER Study Investigators

Nashville, Tennessee; St. Louis, Missouri; Corpus Christi, Texas; Mineola, New York; Lancaster, Pennsylvania; Des Moines, Iowa; Little Rock, Arkansas; Minneapolis, Minnesota; Ann Arbor, Michigan; and Cleveland, Ohio



	CareLink (n=602)	TTM (n=295)
Patients with Events	45% (271)	37.6% (111)

Figure 3 Composite CAE

Survival curves represent the difference in probability of clinically actionable event (CAE) identification between the Remote and Control arms. TTM = transtelephonic monitoring.

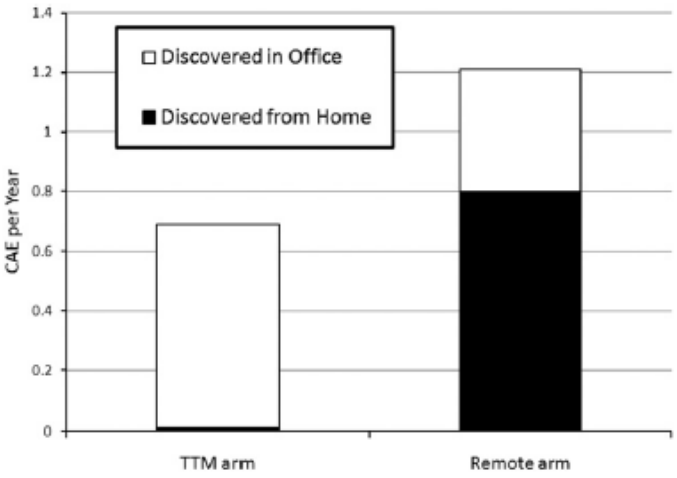


Figure 4 CAE Rate by Source

The number of clinically actionable events (CAEs) by their source. The number of CAEs discovered by transtelephonic monitoring (TTM) per year in the TTM arm was very small (0.01).

European Heart Journal (2010) 31, 2246–2252
doi:10.1093/eurheartj/ehq203

CLINICAL RESEARCH
Arrhythmia/electrophysiology

Contributions of remote monitoring to the follow-up of implantable cardioverter–defibrillator leads under advisory

Laurence Guédon-Moreau[1]*, Philippe Chevalier[2], Christelle Marquié[1], Claude Kouakam[1], Didier Klug[1], Dominique Lacroix[1], Francois Brigadeau[1], and Salem Kacet[1] on behalf of the ECOST trial Investigators

Efficacy and Safety of Automatic Remote Monitoring for Implantable Cardioverter-Defibrillator Follow-Up

The Lumos-T Safely Reduces Routine Office Device Follow-Up (TRUST) Trial

Niraj Varma, MA, DM, FRCP; Andrew E. Epstein, MD; Anand Irimpen, MD; Robert Schweikert, MD; Charles Love, MD; for the TRUST Investigators

European Heart Journal
doi:10.1093/eurheartj/ehs425

CLINICAL RESEARCH

A randomized study of remote follow-up of implantable cardioverter defibrillators: safety and efficacy report of the ECOST trial

Laurence Guédon-Moreau[1]*, Dominique Lacroix[1], Nicolas Sadoul[2], Jacques Clémenty[3], Claude Kouakam[1], Jean-Sylvain Hermida[4], Etienne Aliot[2], Michel Boursier[5], Olivier Bizeau[6], and Salem Kacet[1], for the ECOST trial Investigators

Journal of the American College of Cardiology
© 2011 by the American College of Cardiology Foundation
Published by Elsevier Inc.
Vol. 57, No. 10, 2011
ISSN 0735-1097/$36.00
doi:10.1016/j.jacc.2010.12.012

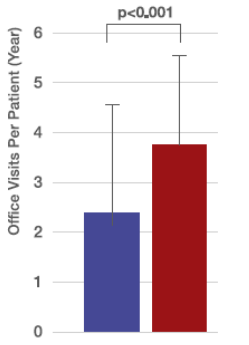
CLINICAL RESEARCH — Clinical Trial

The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) Trial

The Value of Wireless Remote Monitoring With Automatic Clinician Alerts

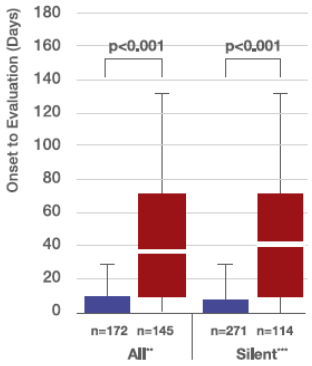
George H. Crossley, MD,* Andrew Boyle, MD,† Holly Vitense, PhD,‡ Yanping Chang, MS,§ R. Hardwin Mead, MD,‖ for the CONNECT Investigators

Reduction in In-Clinic Evaluations*



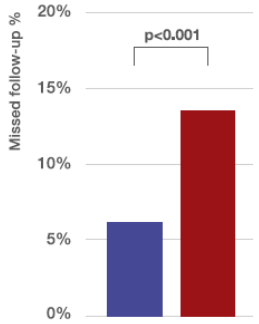
*Data from TRUST are presented and show that remote monitoring reduced in-clinic evaluations by 45% per year. A similar effect was seen in the CONNECT trial in which remote management was associated with a reduction of office visits from 6.3 in conventional care to 3.9 per person year.

Early Detection*



*Data from TRUST are presented. The CONNECT Trial shows similar results for early detection
**In CONNECT, median time from event to clinical decision was 4.6 days in the Remote arm vs. 22 days in conventional care.
***Time to detect clinically asymptomatic (silent) conditions was not reported in CONNECT™.

Rates of failed scheduled evaluations in remote only vs. conventional care over 1 year*



*Data from TRUST are presented. Rates of failed calendar-based evaluations in remote only vs. conventional care over 1 year data information was not available from the CONNECT Trial

— REMOTE MONITORING — CONVENTIONAL

Il monitoraggio remoto dei PMK/ICD permette:

- Ridurre le visite ambulatoriali
- Diagnosi precoce di eventi correggibili
- Non compromette la sicurezza

Il monitoraggio remoto dei PMK/ICD ha un impatto positivo sulla soddisfazione dei pazienti e la qualità di vita:

- Riduzione costi
- Riduzione perdita ore di lavoro
- Alta compliance al follow-up
- Consolidamento rapporto paziente-medico

Un quarto dei pazienti non effettua il primo follow-up un anno dopo l'impianto di un PMK/ICD

Al-Khatib CAE 2013

DISEASE MANAGMENT

- **Fibrillazione atriale**

- **Scompenso cardiaco**

Europace Advance Access published April 4, 2015

Europace
doi:10.1093/europace/euu318

CLINICAL RESEARCH

Remote monitoring improves outcome after ICD implantation: the clinical efficacy in the management of heart failure (EFFECT) study

Antonio De Simone[1]*, Loira Leoni[2], Mario Luzi[3], Claudia Amellone[4], Giuseppe Stabile[5], Vincenzo La Rocca[1], Alessandro Capucci[3], Antonio D'onofrio[6], Ernesto Ammendola[7], Francesco Accardi[8], Sergio Valsecchi[8], and Gianfranco Buja[2]

[1]Laboratorio di Elettrofisiologia, Clinica San Michele, Via Montella, 16, Maddaloni (CE) 81024, Italy; [2]Policlinico Universitario, Padua, Italy; [3]Università Politecnica delle Marche, Ancona, Italy; [4]Ospedale di Cirié – ASL TO 4, Cirié (TO), Italy; [5]Clinica Mediterranea, Naples, Italy; [6]Ospedale Monaldi, Naples, Italy; [7]Ospedale Monaldi SUN, Naples, Italy; and [8]Boston Scientific Italia, Milan, Italy

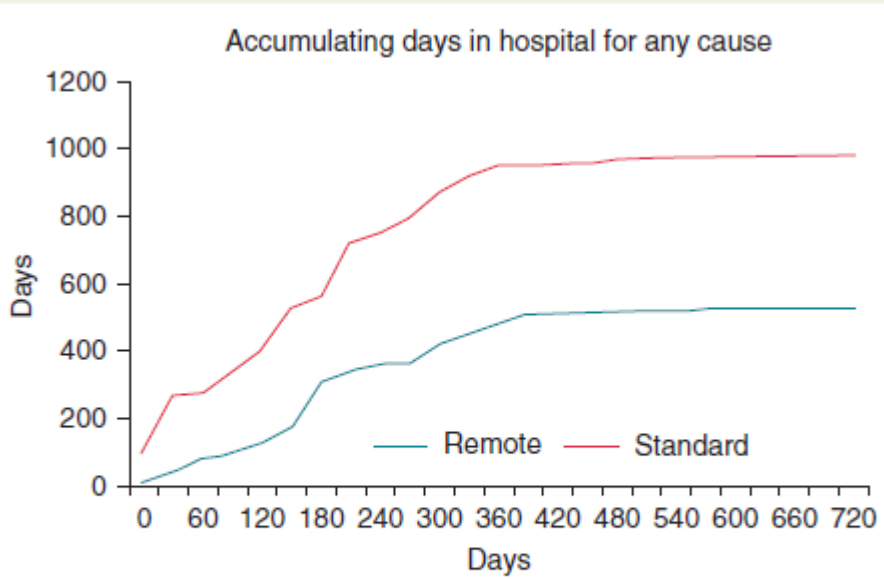


Figure 3 Graph of accumulating days in hospital over time for the two study arms.

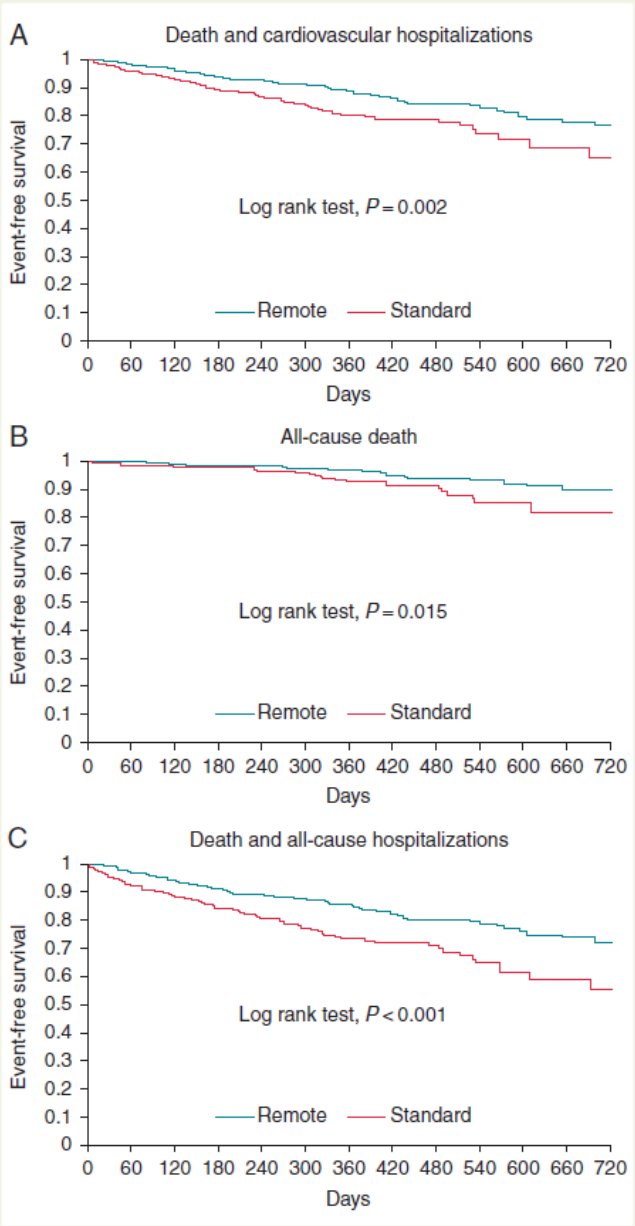


Figure 2 Kaplan–Meier estimates of the time to the primary endpoint of death or cardiovascular hospitalization (*A*), the time to all-cause death (*B*), the time to death or all-cause hospitalization (*C*).

HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices

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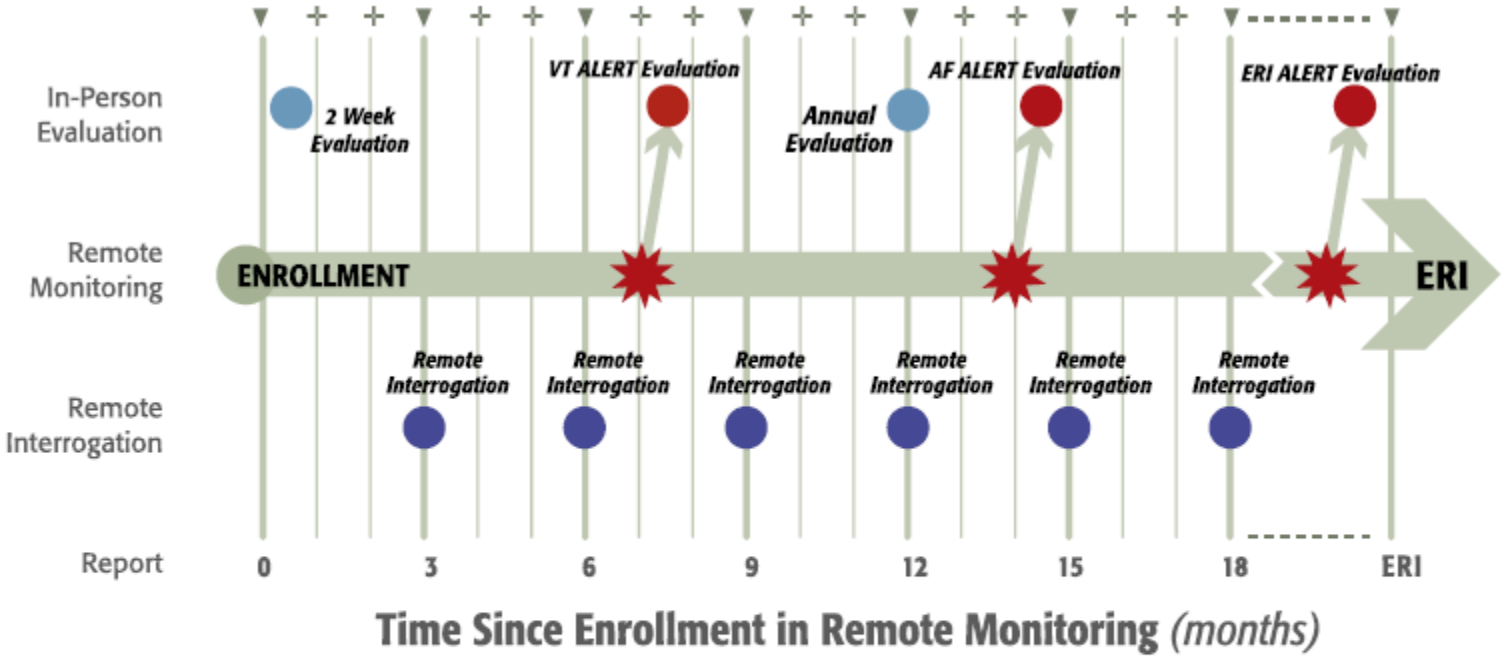

* Any wireless PM, ICD, CRT device with auto thresholds and auto-sensing algorithms
▼ Interim report generation & communication with other health care providers, including heart failure data
✛ Interim (monthly) remote monitoring heart failure report

ABBREVIATIONS: AF = atrial fibrillation; CHF = congestive heart failure; ERI = elective replacement indicator.

Figure 3 Event-based model of cardiac implantable electronic device follow-up.

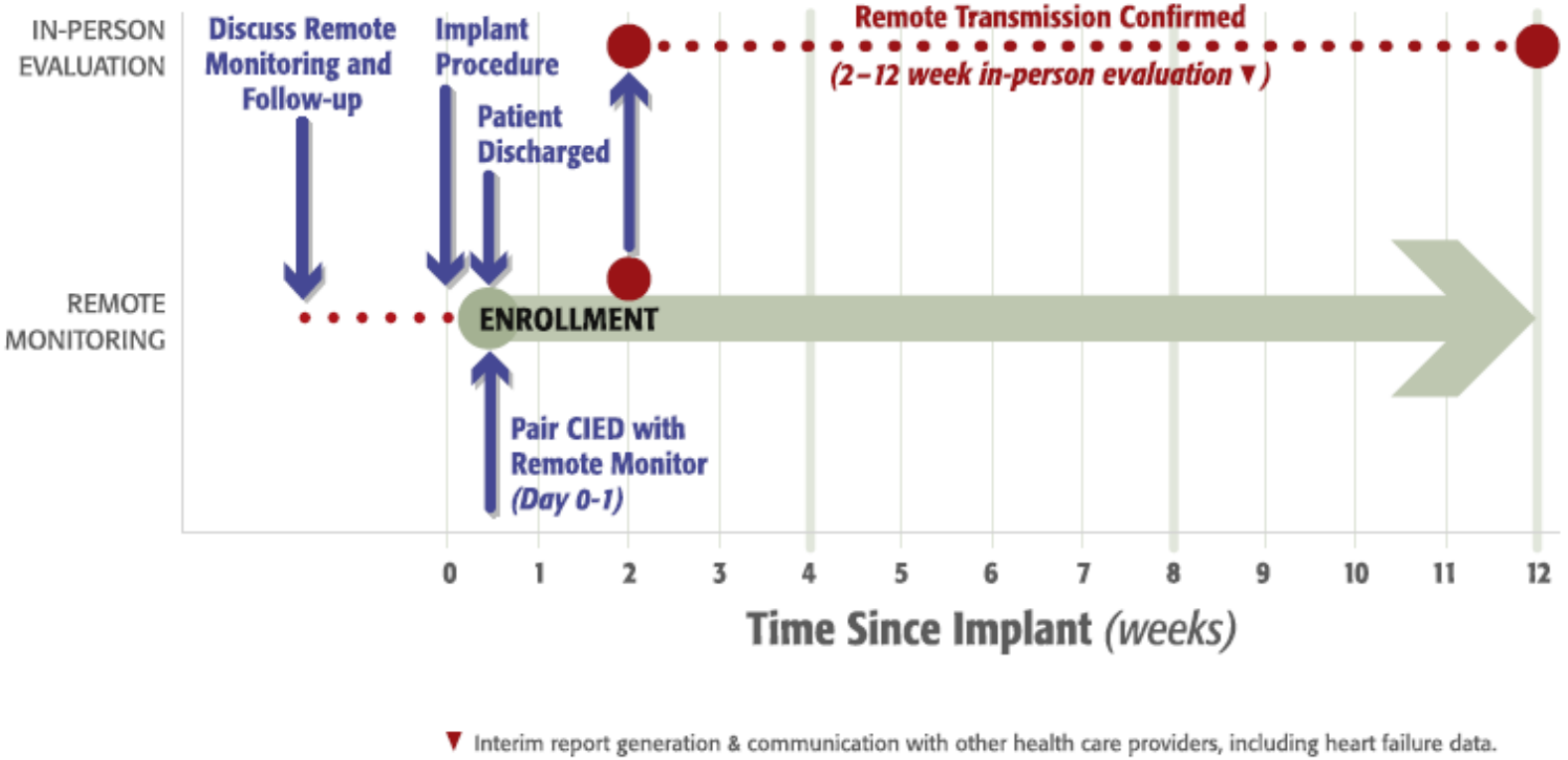

Figure 4 Initiation of remote monitoring. CIED = cardiac implantable electronic device.

Table 2 Goals of the Initial Education Process Before CIED Implantation

- Explain the clinical utility of CIED follow-up.
- Differentiate between in-office and remote follow-up.
- Outline the desired frequency of CIED follow-up.
- Discuss the differences between RM and RI.
- Understand the health care providers involved in patient's care and determine who will be responsible for CIED follow-up.
- Assess the suitability of the patient as a candidate for RM (eg, are analog phone lines present, does the patient have an adapter to connect using cable or Voice over Internet protocols, and is the patient willing to pay for cellular-based monitoring).
- Determine the patient's desire to access their RM data (when available).

CIED = cardiac implantable electronic device; RM = remote monitoring.

Il monitoraggio remoto di un PMK/ICD non gestisce l'emergenza

HRS Remote Monitoring Consensus Statement Recommendations

Device Follow-Up Paradigm	Class of Recommendation	Level of Evidence
A strategy of remote CIED monitoring and interrogation, combined with at least annual IPE, is recommended over a calendar-based schedule of in-person CIED evaluation alone (when technically feasible).	I	A
All patients with CIEDs should be offered RM as part of the standard follow-up management strategy.	I	A
Before implementing RM, it is recommended that each patient be educated about the nature of RM, their responsibilities and expectations, potential benefits, and limitations. The occurrence of this discussion should be documented in the medical record.	I	E
It is recommended that all CIEDs be checked through direct patient contact 2–12 weeks postimplantation.	I	E
It may be beneficial to initiate RM within the 2 weeks of CIED implantation.	IIa	C
All patients with an implantable loop recorder with wireless data transfer capability should be enrolled in an RM program, given the daily availability of diagnostic data.	I	E
It is recommended that allied health care professionals responsible for interpreting RM transmissions and who are involved in subsequent patient management decisions have the same qualifications as those performing in-clinic assessments and should ideally possess IBHRE certification for device follow-up or equivalent experience.	I	E
It is recommended that RM programs develop and document appropriate policies and procedures to govern program operations, the roles and responsibilities of those involved in the program, and the expected timelines for providing service.	I	E

CIED = cardiac implantable electronic device; HRS = Heart Rhythm Society; IBHRE = International Board of Heart Rhythm Examiners; IPE = in-person evaluation; RM = remote monitoring.

Device and Disease Management	Class of Recommendation	Level of Evidence
RM should be performed for surveillance of lead function and battery conservation.	I	A
Patients with a CIED component that has been recalled or is on advisory should be enrolled in RM to enable early detection of actionable events.	I	E
RM is useful to reduce the incidence of inappropriate ICD shocks.	I	B-R
RM is useful for the early detection and quantification of atrial fibrillation.	I	A
The effectiveness of RM for thoracic impedance alone or combined with other diagnostics to manage congestive heart failure is currently uncertain.	IIb	C

B-R = level of evidence B indicates a moderate level from randomized trials; CIED = cardiac implantable electronic device; ICD = implantable cardioverter-defibrillator; RM = remote monitoring.

I benefici del monitoraggio remoto

Per l'OSPEDALE / SSN

- Riduzione del numero di **visite ambulatoriali** *(50%)*
- Riduzione del **tempo medico e risorse infermieristiche** *(60%)*
- Riduzione dei **costi ospedalieri** *(60%)*
- Riduzione del numero e durata **ospedalizzazioni**
- **Durata del singolo FUP** *(4-8 minuti rispetto ai 26 min per quello tradizionale)*

Per il PAZIENTE

- Miglior **compliance** e **soddisfazione** del paziente

Clinici:

- **Individuazione precoce di eventi** clinici e malfunzionamenti del device
- Riduzione del numero di **shock inappropriati**
- Migliore **qualità di vita**
- Aumentata sopravvivenza

Economici:

- Riduzione dei costi di trasporto per i pazienti *(60%)*

Per la SOCIETA'

- Riduzione delle **giornate di lavoro retribuite perse**, sia per il paziente (se in età lavorativa) che per l'eventuale accompagnatore

Ricci et al. Remote monitoring of implantable cardiac devices: health technology assessment. Giornale Italiano di Cardiologia. 2015

Situazione italiana

- I sistemi di Remote Monitoring sono utilizzati in circa l' **88%** dei centri che impiantano PMK/ICD
- Sono utilizzati in circa **30.000** pazienti (< 10%) nonostante i benefici clinici ed economici

FOLLOW-UP DEI PAZIENTI IMPIANTATI CON PMK/ICD:

- Visita ambulatoriale (controllo e riprogrammazione) (codice 89.48.1) – in 4 Regioni il rimborso è differenziato in base altipo di dispositivo (PM: 89.48.01 e ICD: 89.48.02)
- Controllo remoto del dispositivo: **attualmente nessun imborso**

Un eccezione: Trento

PROVINCIA AUTONOMA DI TRENTO
Deliberazione di Giunta Provinciale 13.06.2016, n. 1010
Integrazione del Nomenclatore delle prestazioni di assistenza specialistica ambulatoriale, di diagnostica per immagini e di laboratorio erogabili nell'ambito del Servizio sanitario Provinciale e altre direttive.

NOTA	CODICE	DESCRIZIONE	TARIFFA (in euro)	BRANCA
I	99.99.2	MONITORAGGIO DINAMICO DELLA GLICEMIA (HOLTER GLICEMICO). Incluso addestramento del paziente all'uso dell'apparecchio (1)	166,50	ALTRO ENDOCRINOLOGIA
IAR	99.99.3	PAC DIABETOLOGIA PEDIATRICA CONTROLLO ANNUALE < 9 ANNI (1)	117,50	ALTRO ENDOCRINOLOGIA
IAR	99.99.4	PAC DIABETOLOGIA PEDIATRICA CONTROLLO ANNUALE > 9 ANNI (1)	125,25	ALTRO ENDOCRINOLOGIA
I	89.48.2	CONTROLLO IN REMOTO DI PAZIENTI PORTATORI DI PACEMAKER, DEFIBRILLATORE E LOOP RECORDER. Massimo 4 controlli/anno (2)	25,55	CARDIOLOGIA

(1) prestazioni esentate dalla compartecipazione (codice di esenzione 013)
(2) la prescrizione è riservata allo specialista pubblico

Situazione Europea

Reimbursed

Not reimbursed:

Situazione Europea

PAESE	SITUAZIONE	Descrizione
Germania	Rimborsato	a controllo progetto pilota (Agosto – Ottobre 2014)
Italia	Non Rimborsato	
Spagna	Non Applicabile	Global budget
Francia	Rimborsato	Price premium 800 – 1.000€
UK	Rimborsato	Accordi per singolo ospedale (50% visita)
Olanda	Rimborsato	Accordi per singolo ospedale
Austria	Non Rimborsato	
Belgio	Non Rimborsato	
Finlandia	Rimborsato	119€ a paziente (compenso annuale)
Danimarca	Rimborsato	110€ a paziente (compenso annuale)
Svezia	Rimborsato	200€ per diagnosi via web, -50% se non vi è diagnosi
Portogallo	Rimborsato	25€ ogni controllo del dispositivo in remoto

* Dati Assobiomedica: Controllo Remoto

grazie per l'attenzione