2014: nowadays the “one shot” technologies and the injectable monitor allow a wide and complete AF patient management. Why shouldn’t we use them?

Gaetano Senatore

DIVISION OF CARDIOLOGY
HOSPITAL OF CIRIE’ & IVREA
ITALY

A.S.L. 6 Ospedale di Ciriè

Table 1. Different Methods of Cardiac Monitoring

	Advantages	Disadvantages
Noninvasive		
Continuous hospital telemetry	• Accurate diagnosis • Detects asymptomatic events	• Requires inpatient monitoring • Expensive • Restricts patient movement
Ambulatory ECG (Holter)	• Easy to use • Continuous recording • Detects asymptomatic events	• Short monitoring period • Need for patient to keep symptom diary
Patient-triggered event recorder	• Longer monitoring periods • Correlation of symptoms and rhythm	• Does not detect asymptomatic events • Requires patient participation
Prolonged ambulatory ECG (mobile cardiovascular telemetry)	• Continuous monitoring • Detects asymptomatic events	• Costly • Patient compliance, skin irritation
Invasive		
Implantable loop recorder	• Longer periods of follow-up • Internet-based data transmission	• Costly and invasive • False-positive and false-negative detections
Pacemakers and defibrillators	• Detects asymptomatic events • Offers therapy	• Costly and invasive • Great risk of complications

Review article

FIC Federazione Italiana di Cardiologia
Italian Federation of Cardiology

Efficacy and safety of catheter ablation versus antiarrhythmic drugs for atrial fibrillation: a meta-analysis of randomized trials

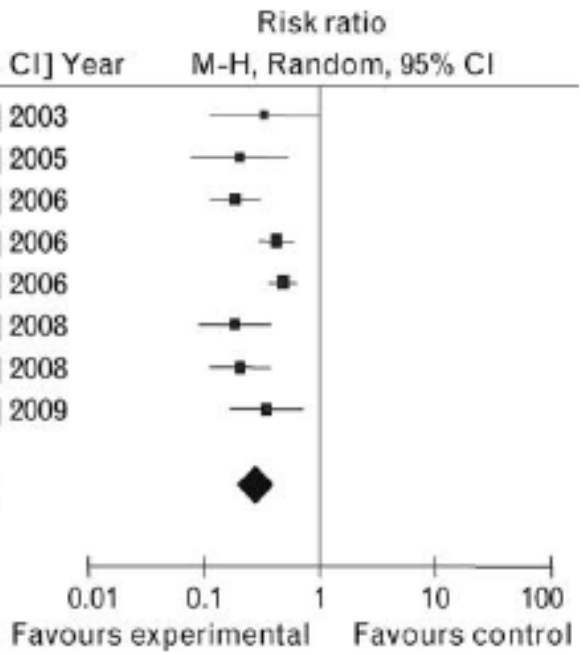
Carlo Bonanno, Mariemma Paccanaro, Luigi La Vecchia, Renato Ometto and Alessandro Fontanelli

Fig. 1

Study	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk ratio M-H, Random [95% CI]	Year
Krittayaphong *et al.* [8]	3	15	9	15	6.9%	0.33 [0.11, 0.99]	2003
RAAFT [9]	4	33	22	37	8.1%	0.20 [0.08, 0.53]	2005
APAF [12]	14	99	75	99	14.6%	0.19 [0.11, 0.31]	2006
Oralet *et al.* [11]	25	77	53	69	17.2%	0.42 [0.30, 0.60]	2006
CACAF [10]	30	68	63	69	18.3%	0.48 [0.37, 0.64]	2006
A4 [14]	7	53	42	59	11.2%	0.19 [0.09, 0.38]	2008
PABA-CHF [13]	8	41	40	40	12.8%	0.20 [0.11, 0.37]	2008
Forleo *et al.* [15]	7	35	20	35	11.0%	0.35 [0.17, 0.72]	2009
Total (95% CI)		421		423	100.0%	0.29 [0.20, 0.41]	
Total events	98		324				

Heterogeneity: $Tau^2 = 0.16$; $Chi^2 = 22.47$, df = 7 ($P = 0.002$); $I^2 = 69\%$

Test for overall effect: $Z = 6.91$ ($P < 0.00001$)

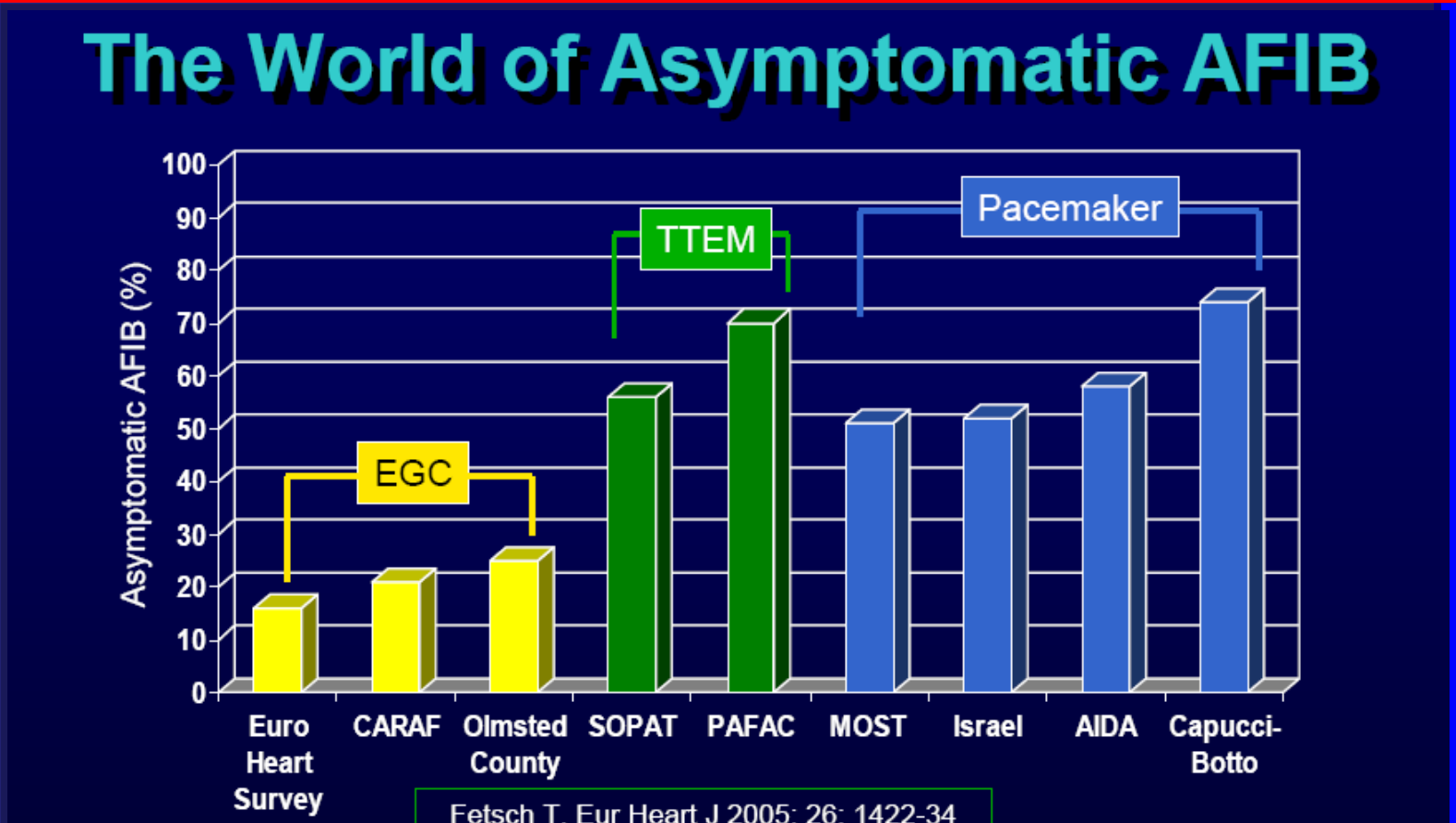


Effects of radiofrequency catheter ablation on proportion of patients with recurrence of atrial tachycardia. A4, Catheter Ablation Versus Antiarrhythmic Drugs for Atrial Fibrillation; APAF, A Randomized Trial of Circumferential Pulmonary Vein Ablation Versus Antiarrhythmic Drug Therapy in Paroxysmal Atrial Fibrillation; CACAF, Catheter Ablation For The Cure Of Atrial Fibrillation Study; CI, confidence interval; df, degrees of freedom; PABA-CHF, Pulmonary-Vein Isolation for Atrial Fibrillation in Patients with Heart Failure; RAAFT, Radiofrequency Ablation vs. Antiarrhythmic Drugs as First-line Treatment of Symptomatic Atrial Fibrillation.

AF MONITORING

	Pts n.	Abl.	AAD	Follow-up
CACAF	137	59.4 %	6 %	Daily TTECG
RAAFT	70	87 %	37%	Event record for 1 month, symptoms
Oral 2006	146	74 %	58%	Daily TTECG
Pappone	198	86 %	22 %	Daily event monitor
Forleo	70	80 %	43 %	ECG and symptoms
A4 study	112	89 %	23 %	ECG and 3 24h-Holter
PABA-CHF	81	71% (88%)	0 % (AVN)	Loop event monitor 2-6 m

AF MONITORING



Fetsch T. Eur Heart J 2005; 26: 1422-34

Patten M. Eur Heart J 2004; 25: 1395-404

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

Glotzer TV. Circulation 2003; 107: 1614-9
Israel CW. J Am Coll Cardiol 2004; 43:47-52
Capucci A. J Am Coll Cardiol 2005; 26: 1913-20
Defaye P. PACE 1998; 21: 250-255

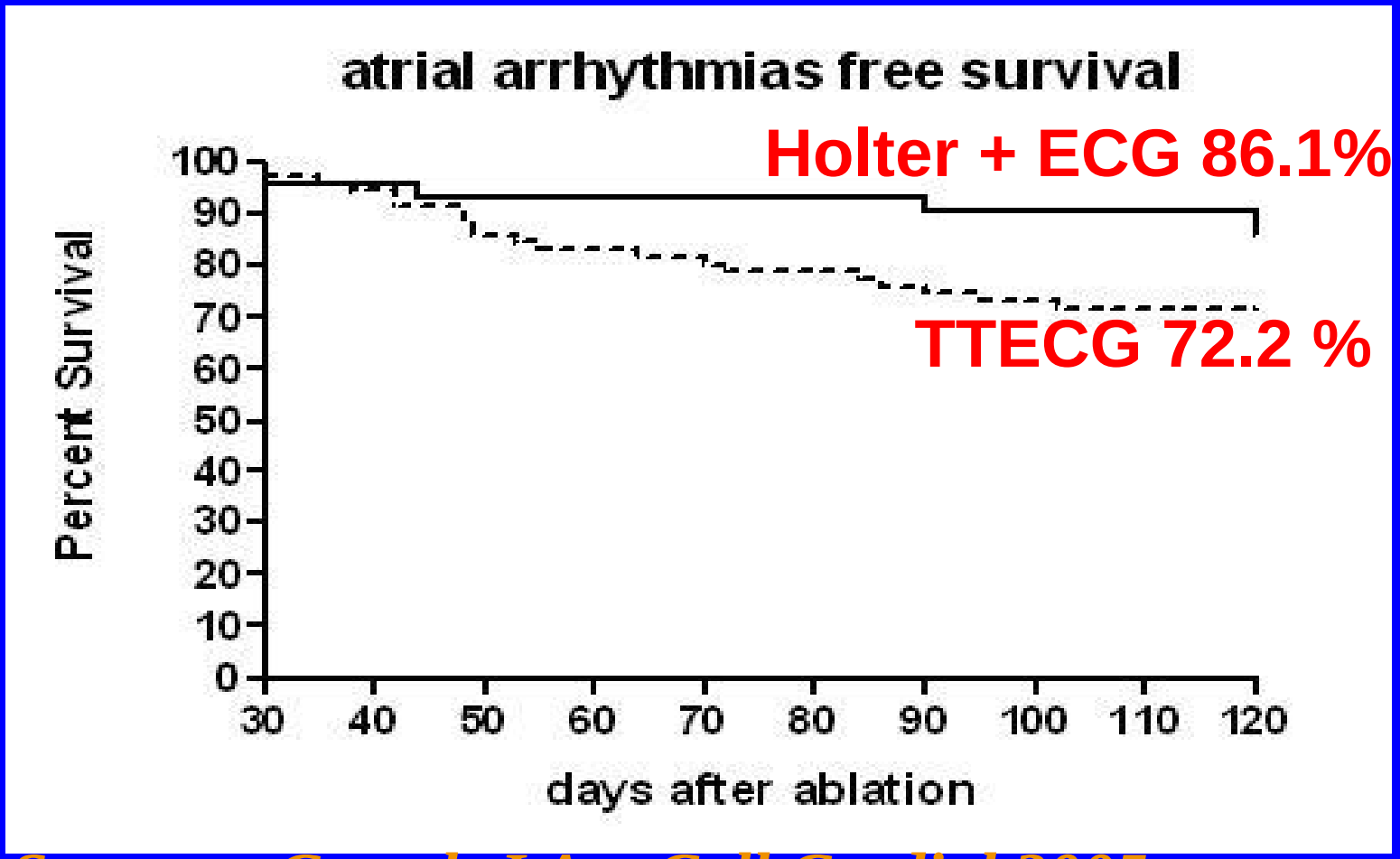
DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

RESULTS



Senatore G et al, J Am Coll Cardiol 2005

DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

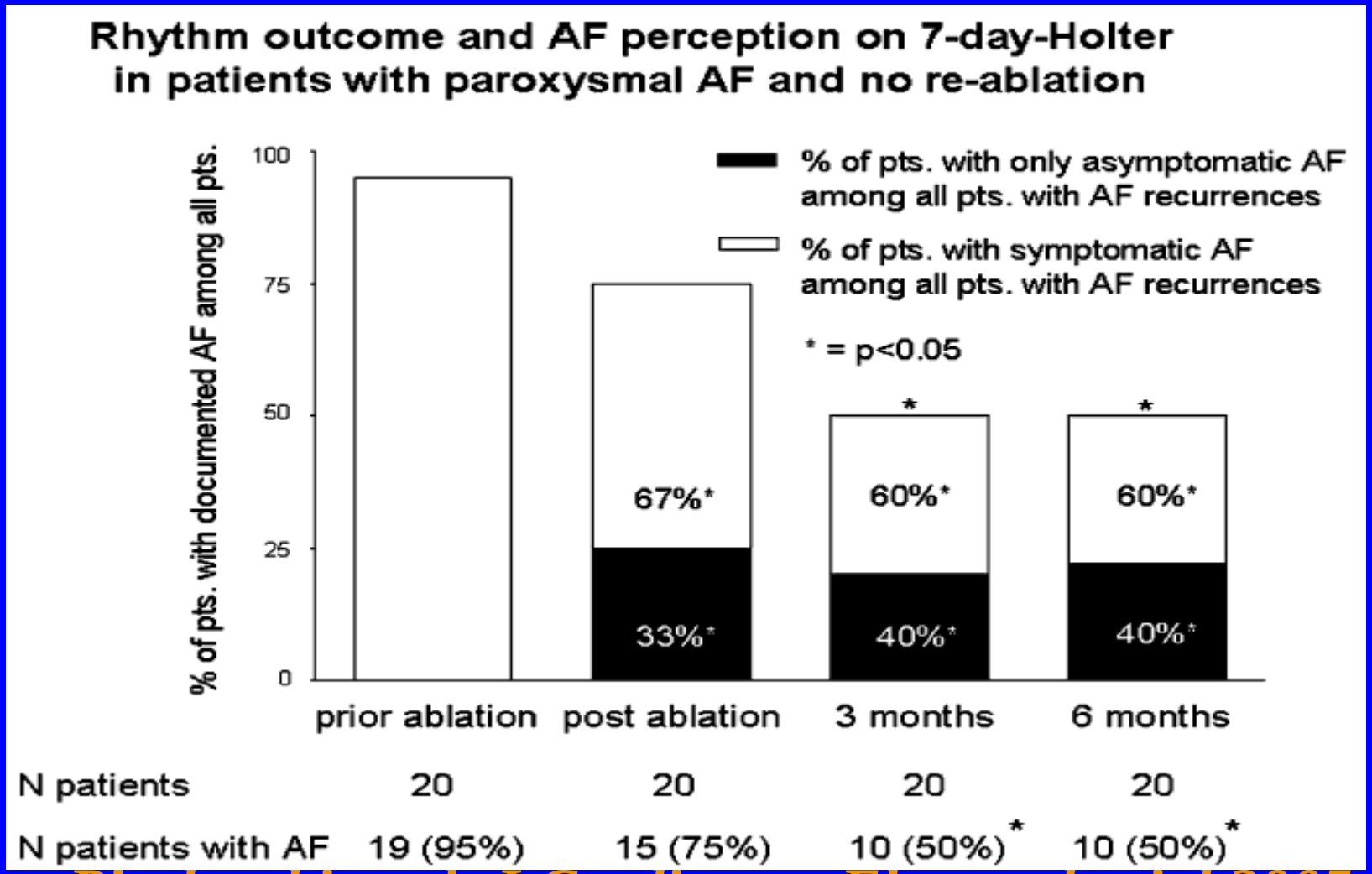
AF MONITORING

TABLE 1. Rhythm Outcome and Perception of AF Before and After RF Ablation

			Patients With AF			
	n	Patients With SR, n	n	Asymptomatic Patients Only	Symptomatic Patients Only	Symptomatic + Asymptomatic Patients
Before ablation	114	22 (19%)	92	5 (5%)	35 (38%)	52 (57%)
After ablation						
Immediately	114	36 (32%) P=0.12	78	17 (22%) P=0.027	16 (21%) P=0.002	45 (57%) P=0.48
3 Months	114	65 (57%) P=0.001	49	18 (38%) P=0.021	8 (16%) P=0.001	23 (46%) P=0.001
6 Months	108	54 (50%) P=0.001	54	20 (37%) P=0.021	14 (26%) P=0.078	20 (37%) P=0.001
12 Months	70	45 (64%) P=0.021	25	9 (36%) P=0.05	5 (20%) P=0.07	11 (44%) P=0.001

Hindricks G et al, Circulation 2005

AF MONITORING



Piorkowki et al, J Cardiovasc Electrophysiol 2005

DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

CONCLUSIONS

- **Intensive follow-up rather than symptom related follow-up is helpful in evaluating efficacy rate and incidence of asymptomatic AF recurrences**

- **1987 pts (1083M, 904F), mean age 53.2yrs (29-81)**
  - **-69.8%pts persistent AF**
  - **-30% pts paroxysmal AF**
    - **5% with Cryoballon**
  - **-0.2% pts permanent AF**

AF MONITORING

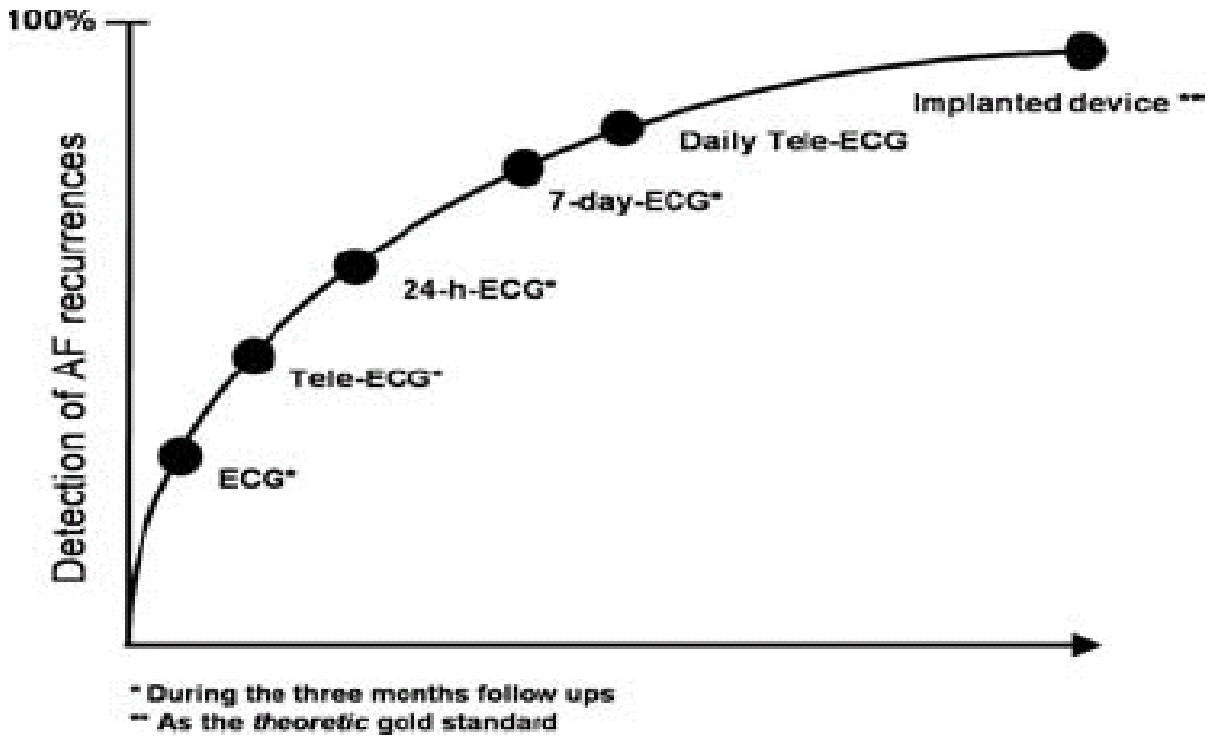


Figure 2. *Estimated correlation between follow-up strategy and the rate of atrial fibrillation detection after RF ablation.*

Arya A et al, PACE 2007

AF MONITORING

Continuous vs Intermittent Monitoring

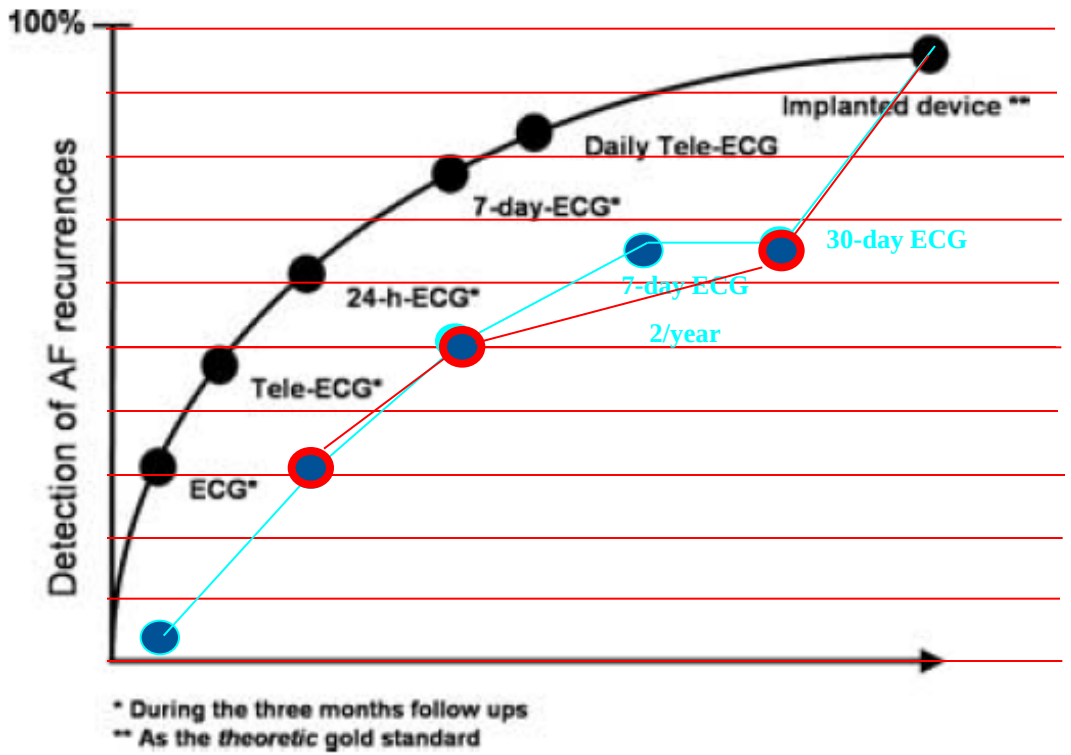
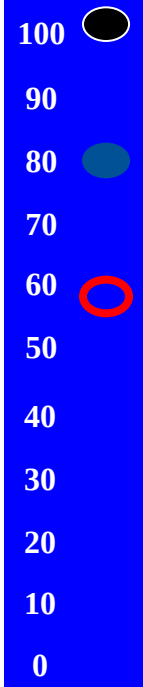


Figure 2. *Estimated correlation between follow-up strategy and the rate of atrial fibrillation detection after RF ablation.*



Arya (PACE 2007)

Botto (JCE 2009)

Ziegler (HR 2006)

The NPV of 24-hour Holter (2/year), 1-week Holter, and 1-month Holter monitoring was very low and ranged from 53% to 64.6%.

NPV = chance that a negative test result (= no AF detected) will be correct.

AF MONITORING

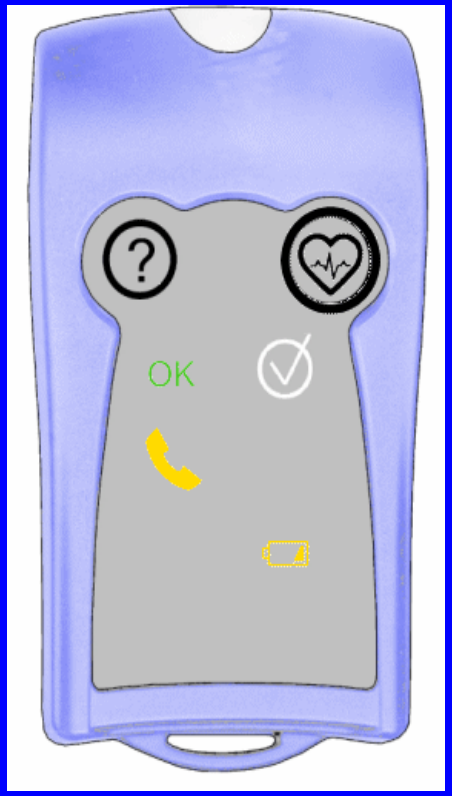
DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di
ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

ACTIVATOR FOR SYMPTOMS



DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

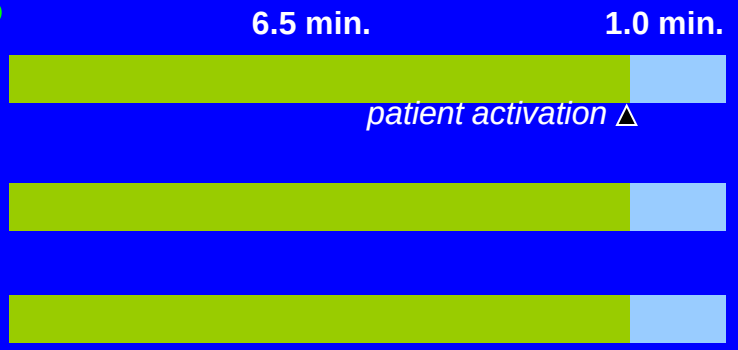
A.S.L. 6 Ospedale di Ciriè

AF MONITORING

Event Storage: 49.5 Minutes

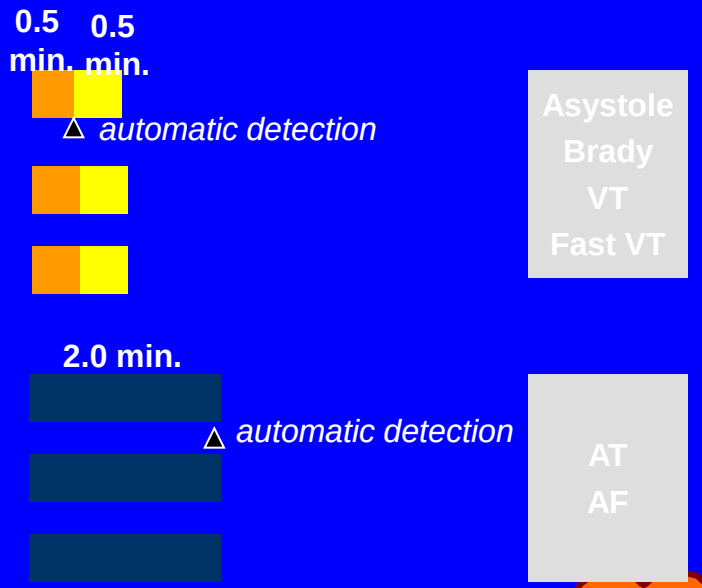
Patient Activated Episodes: 22.5 minutes

- 3 most recent manual events: 7.5 minutes each
- Post patient activation, no further activations are recognized for 5 minutes



Automatic Activated Episodes: 27 minutes

- Oldest episodes are always overwritten
- If storage memory is full, the oldest strip for an episode type (asystole, brady etc.) that has >3 strips already stored will be overwritten



DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

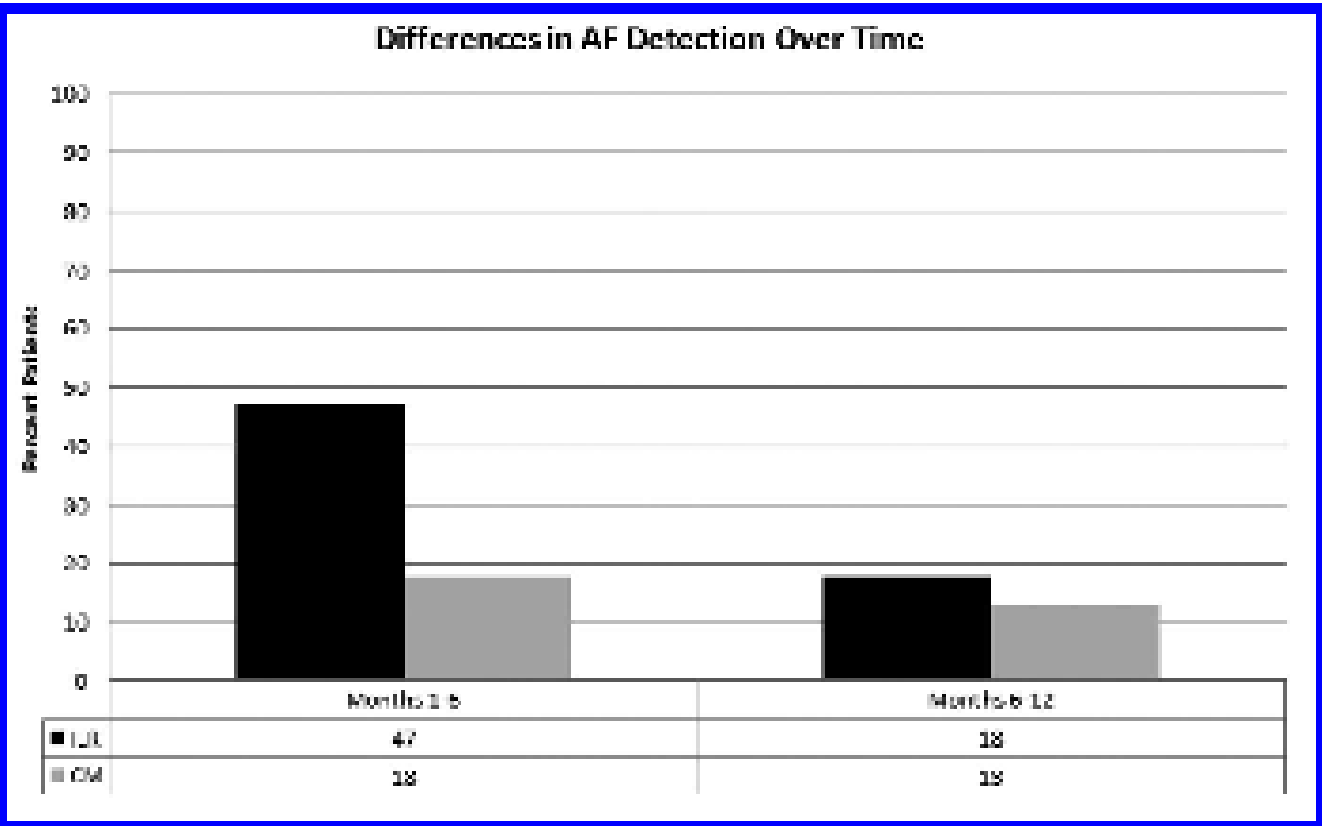
Assessing Arrhythmia Burden After Catheter Ablation of Atrial Fibrillation Using an Implantable Loop Recorder:
The ABACUS Study

	ILR Arm (N = 20)	Conventional Monitoring Arm (N = 18)	P-Value
Age	61 ± 9	57 ± 12	0.204
Gender (male)	17 (85%)	16 (89%)	1.000
Paroxysmal atrial fibrillation	9 (45%)	8 (44%)	1.000
First time ablation	13 (65%)	13 (72%)	0.734
Diabetes	4 (20%)	1 (6%)	0.344
Hypertension	11 (55%)	9 (50%)	1.000
Prior stroke/transient ischemic attack	4 (20%)	3 (17%)	1.000
Body mass index (BMI)	30 ± 4	30 ± 4	1.000
Sleep apnea	3 (15%)	2 (11%)	1.000
Prior myocardial infarction	0 (0%)	0 (0%)	1.000
CHADS2 score	2.1 ± 0.5	2.2 ± 0.8	0.999

Kapa S et al, JCE 2013

AF MONITORING

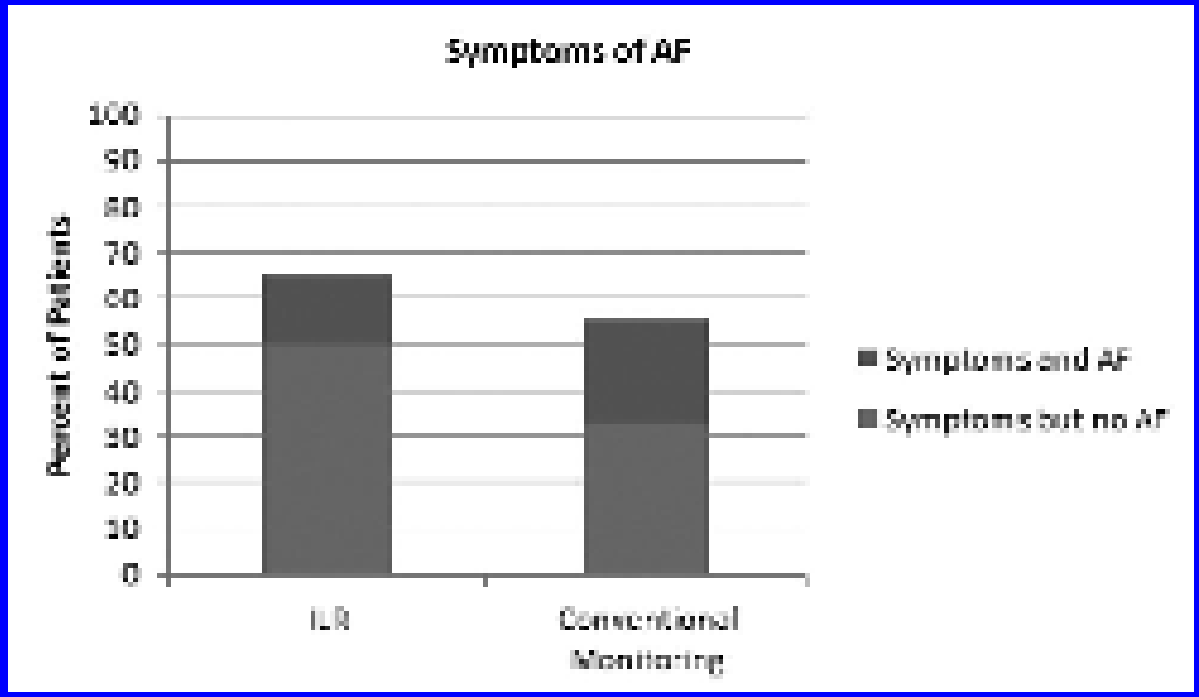
Assessing Arrhythmia Burden After Catheter Ablation of Atrial Fibrillation Using an Implantable Loop Recorder:
The ABACUS Study



Kapa S et al, JCE 2013

AF MONITORING

Assessing Arrhythmia Burden After Catheter Ablation of Atrial Fibrillation Using an Implantable Loop Recorder:
The ABACUS Study



Kapa S et al, JCE 2013

DIVISION OF CARDIOLOGY CIRIE' & IVREA ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

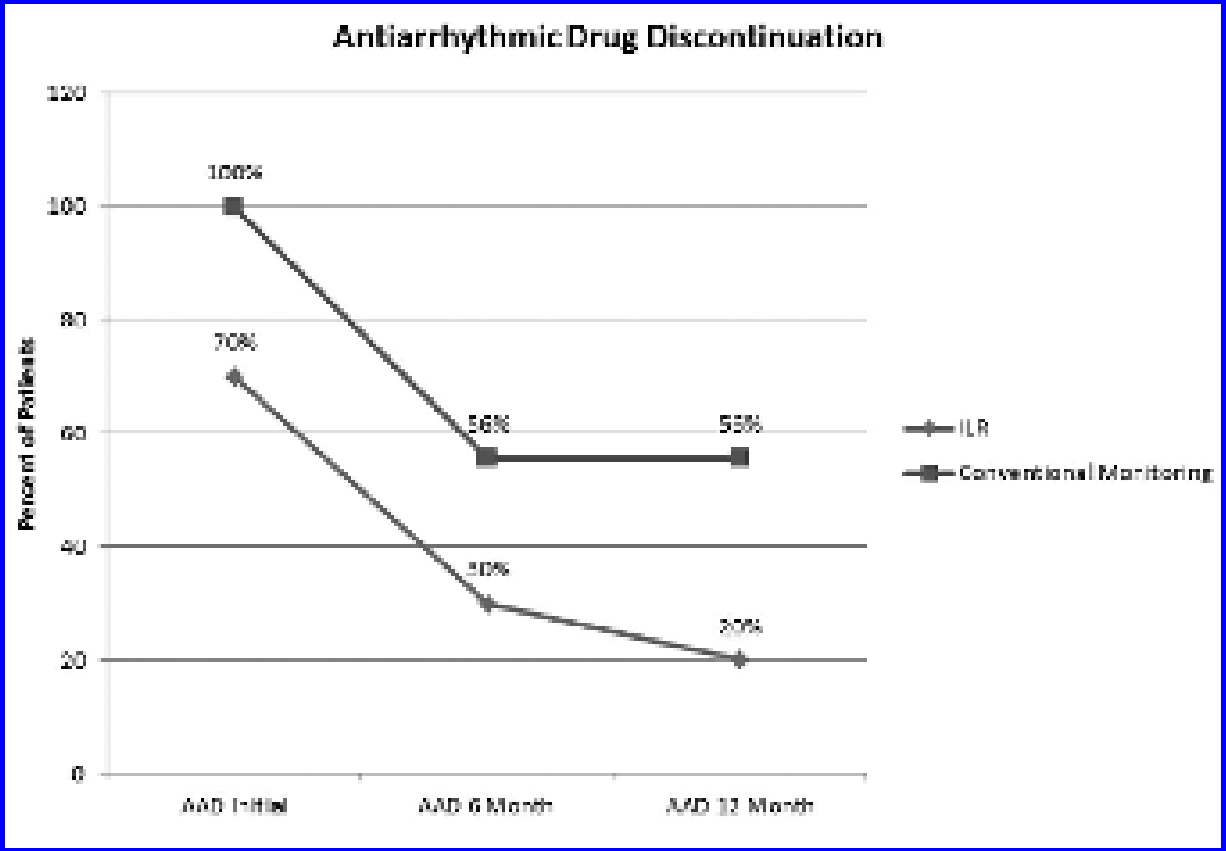
Assessing Arrhythmia Burden After Catheter Ablation of Atrial Fibrillation Using an Implantable Loop Recorder:
The ABACUS Study

	AF	VT	Asystole	Bradycardia Events	Total
ILR episodes (number)	915	60	227	32	1234
EP agreement with ILR interpretation (number)	420	3	8	4	435
ILR accuracy	46.0%	5.0%	3.5%	12.5%	35.2%
Causes of ILR misinterpretation	PVC/APCs (36%)	T-wave oversensing (6%)	Loss of electrode contact (80%)	Undersensing (72%)	
	Over/undersensing (34%)	Noise (67%)	Poor electrode contact (13%)	Poor electrode contact (25%)	

Kapa S et al, JCE 2013

AF MONITORING

Assessing Arrhythmia Burden After Catheter Ablation of Atrial Fibrillation Using an Implantable Loop Recorder:
The ABACUS Study



Kapa S et al, JCE 2013

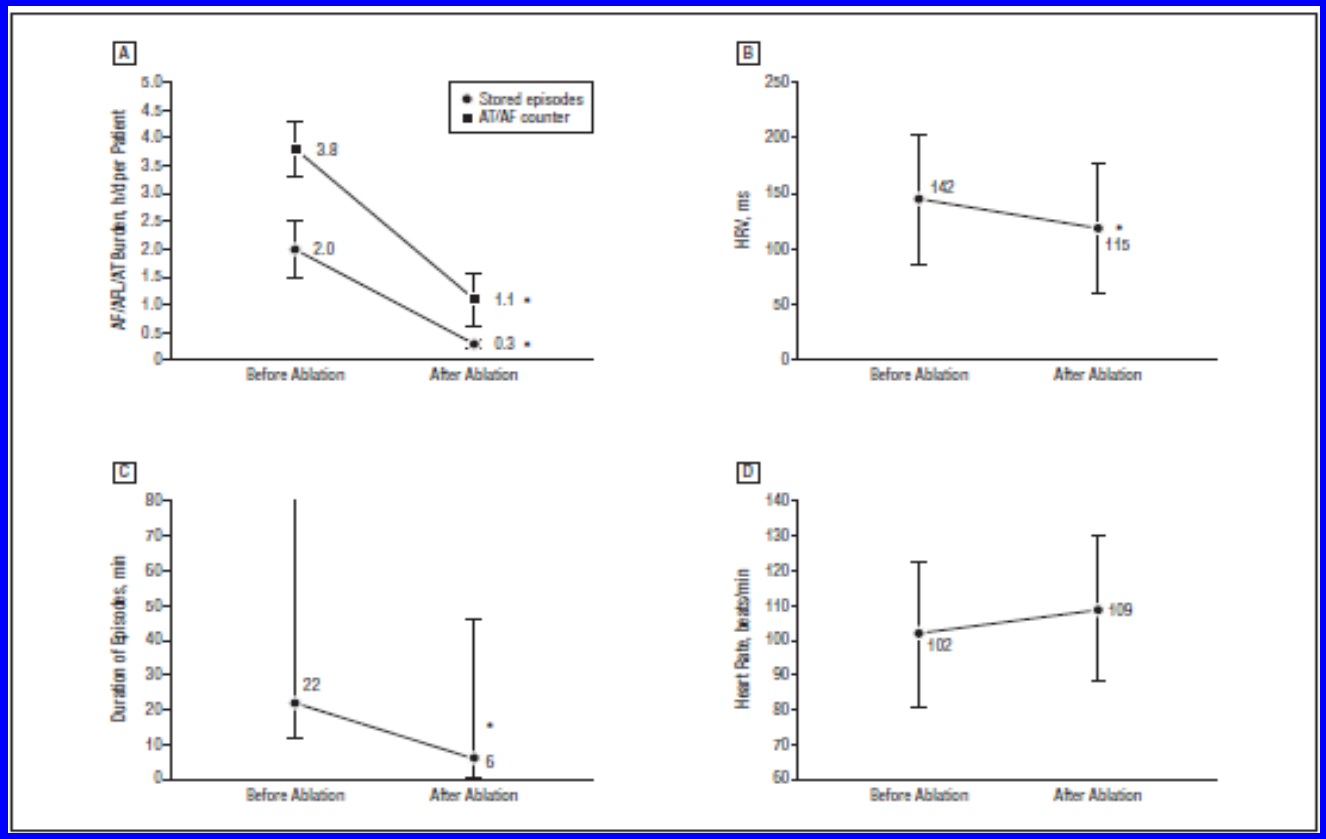


Table 5. Characteristics of Asymptomatic vs Symptomatic Episodes of AF/AFL/AT

Characteristic	Asymptomatic Episode	Symptomatic Episode	OR (95% CI)	*P* Value
Ratio of postablation to preablation state	3.0	0.9	3.19 (2.53-4.01)	<.001
Ratio of AF to AFL/AT	3.2	6.6	2.03 (1.49-2.76)	<.001
Ratio of no drug to AAD	0.4	0.2	1.69 (1.28-2.23)	<.001
HRV, mean (SD), ms	116 (57)	142 (62)	1.07 (1.05-1.09)[a]	<.001
Heart rate, mean (SD), beats/min	105 (22)	110 (22)	1.08 (1.03-1.14)[a]	.003
Episode duration, median (IQR), min	4 (2-26)	16 (4-138)	1.00 (1.00-1.00)[a]	.05
Interepisode time, median (IQR), h	96 (18-2234)	62 (10-2744)	1.00 (1.00-1.00)	.3

Discerning the Incidence of Symptomatic and Asymptomatic Episodes of Atrial Fibrillation Before and After Catheter Ablation (DISCERN AF)

A Prospective, Multicenter Study

Atul Verma, MD, FRCPC; Jean Champagne, MD; John Sapp, MD; Vidal Essebag, MD, PhD; Paul Novak, MD; Allan Skanes, MD; Carlos A. Morillo, MD; Yaariv Khaykin, MD; David Birnie, MD

DIVISION OF CARDIOLOGY CIRIE' & IVREA ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

	Overall Follow-Up Period			Excluding the First 3 Months of Follow-Up			
	Total	Symptomatic Patients	Asymptomatic Patients	Total	Always Symptomatic Patients	Always Asymptomatic Patients	Symptomatic-Asymptomatic Patients
Global							
Patients with any AF recurrence ≥ 6 minutes	98 (69%)	53 (54%)	45 (46%)	46 (32%)	15 (33%)	21 (46%)	10 (22%)
Patients without AF recurrence	45 (31%)	13 (29%)	32 (71%)	97 (68%)	39 (40%)	45 (46%)	2 (2%)
Based on duration of AF recurrence							
Patients with AF >6 minutes <1 hour	24 (17%)	9 (38%)	15 (62%)	17 (12%)	6 (35%)	9 (53%)	2 (12%)
Patients with AF >1 hour < 12 hours	31 (22%)	16 (52%)	15 (48%)	17 (12%)	5 (29%)	7 (41%)	5 (29%)
Patients with AF >12 hours < 24 hours	19 (13%)	13 (68%)	6 (32%)	4 (3%)	1 (25%)	0 (0%)	3 (75%)
Patients with AF >= 24 hours	24 (17%)	15 (63%)	9 (37%)	8 (6%)	3 (38%)	5 (63%)	0 (0%)

Tondo C et al, J Cardiovasc Electrophysiology 2013

CARE LINK

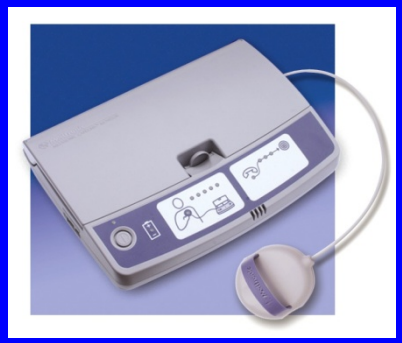
Implantable devices

ILR

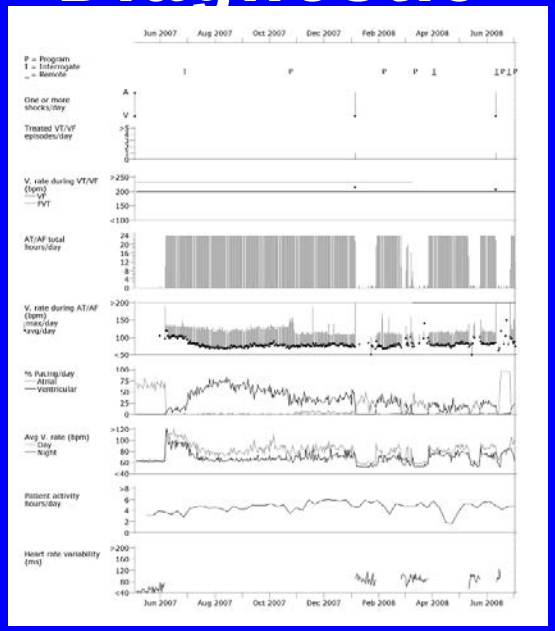
Pacemaker

ICD

Remote Monitoring



Diagnostic



Medtronic CARELINK Patient Management Network

DIVISION OF CARDIOLOGY CIRIE' & IVREA ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

CARE LINK

- **Routine Follow-up**
- **Symptomatic event**

Medtronic
CARELINK
Patient Management Network

AF MONITORING & CARE LINK

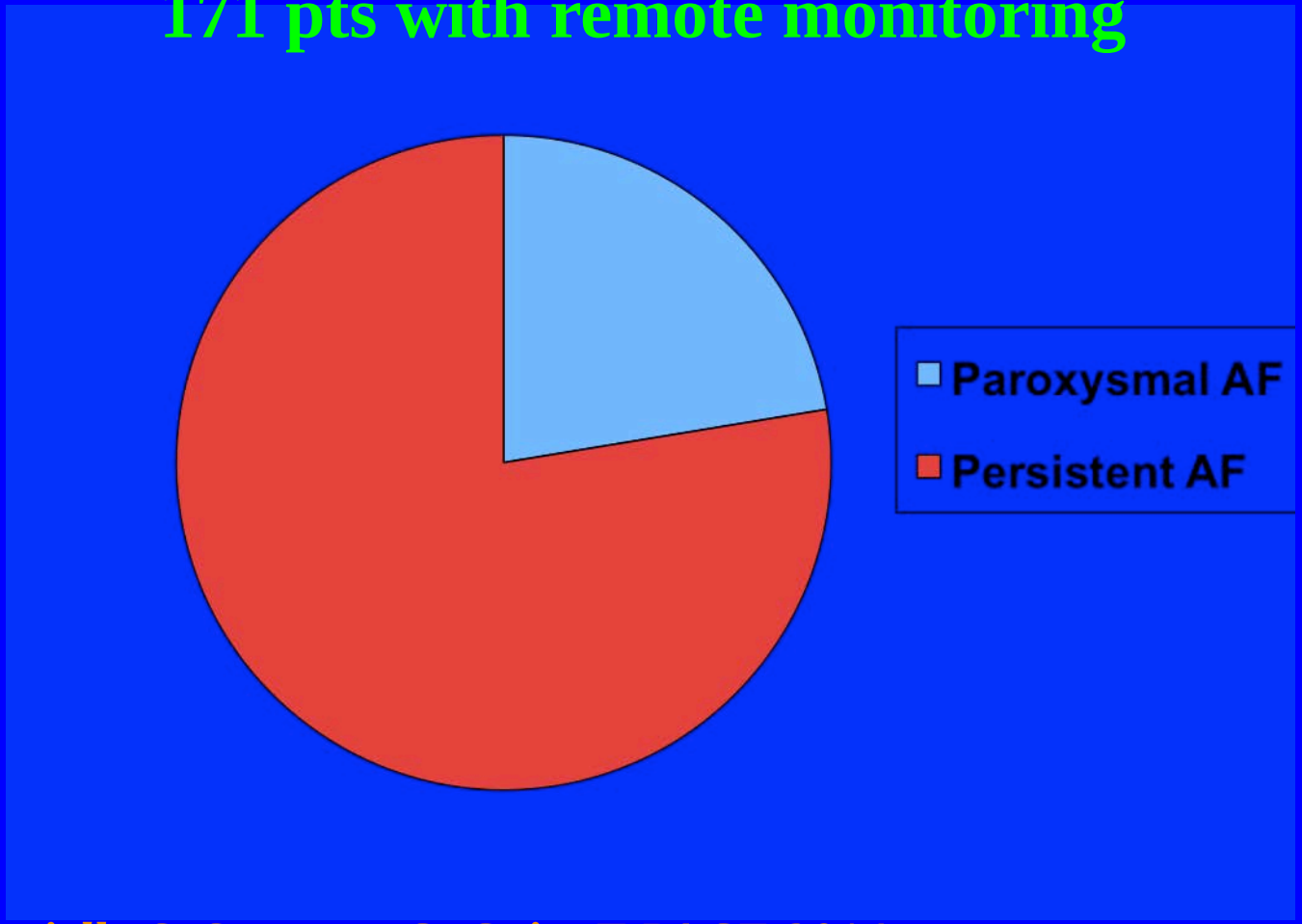
- **Monthly follow-up**
- **Mean time for analysis 2.8 minutes**

AF MONITORING

- 233 pts (105M, 80F), mean age 57.1 yrs (39-81)
  - post-ablation persistent AF
  - 171 pts with remote monitoring

AF MONITORING

171 pts with remote monitoring



Manganiello S, Senatore G, Gaita F PACE 2014

AF MONITORING

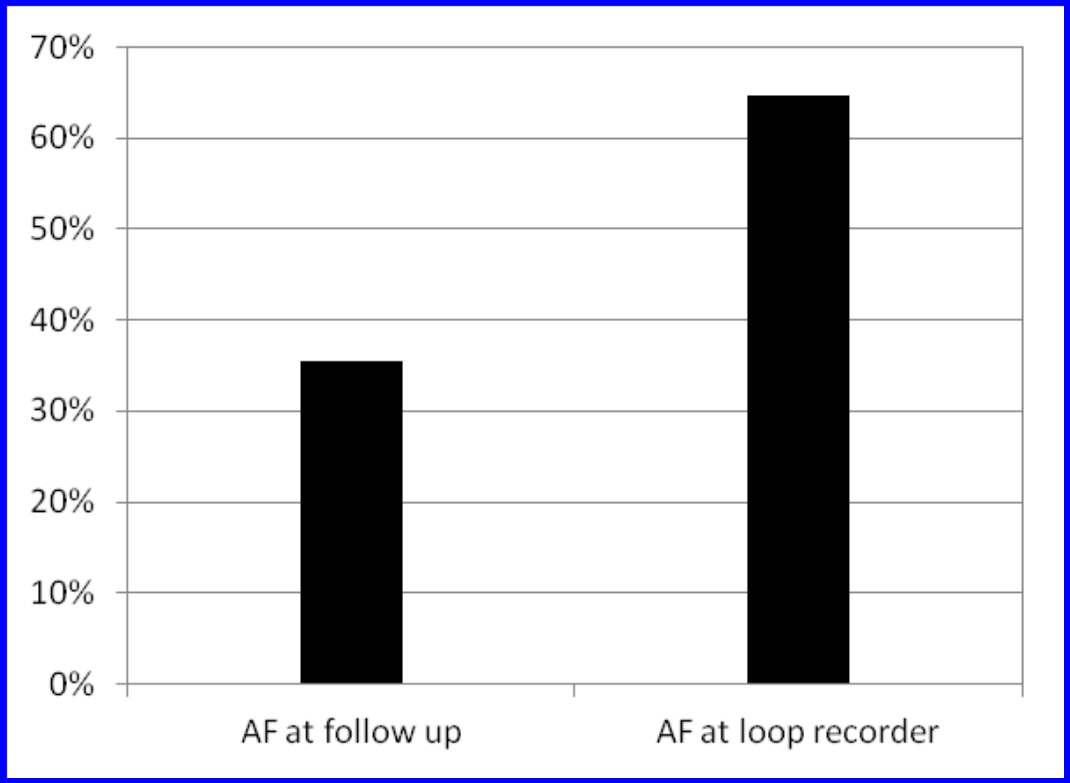
171 pts with remote monitoring: patient characteristics

Variables	All N=171
Age, years (SD)	64.5±9.6
Male, n (%)	122 (71.3)
Type of atrial fibrillation, n (%)	
Paroxysmal	28 (16.4)
Persistent	143 (83.6)
Risk factors for thromboembolism, n (%)	
Cardiac failure	3 (1.7)
Hypertension	124 (75.5)
Diabetes mellitus	21 (12.2)
Prior stroke/TIA	9 (5.2)
Vascular disease*	10 (5.8)
LVEF, % (SD)	56.6±11.1
Follow up	
Mean duration of follow up, years	2,7

Manganiello S, Senatore G, Gaita F PACE 2014

AF MONITORING

Long term follow up

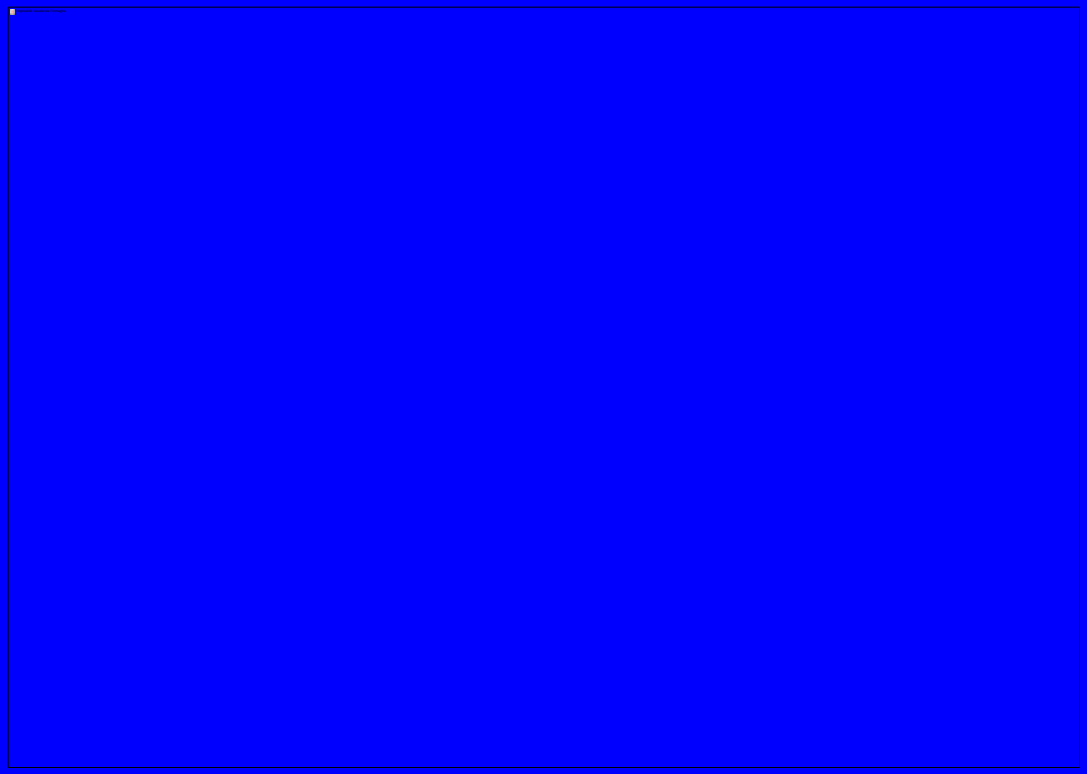


Manganiello S, Senatore G, Gaita F PACE 2014

DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

AF MONITORING

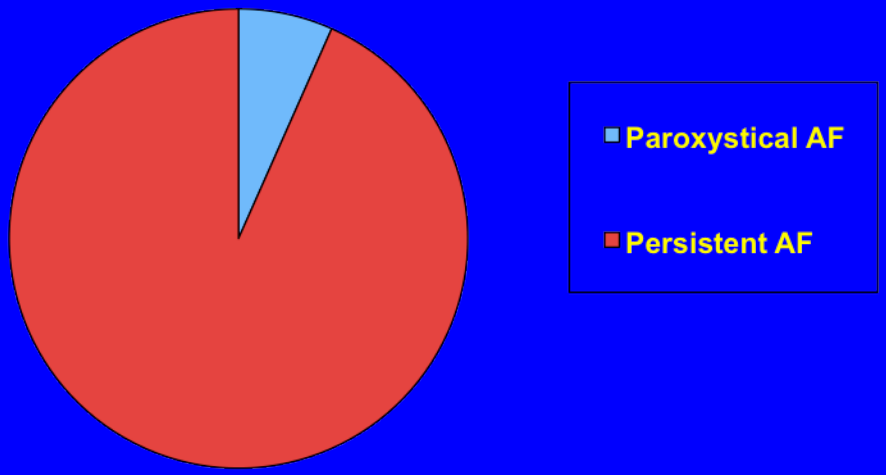
50 patients had AF recurrences at traditional follow up



Manganiello S, Senatore G, Gaita F PACE 2014

AF MONITORING

95 patients had AF recurrences at loop recorder



Manganiello S, Senatore G, Gaita F PACE 2014

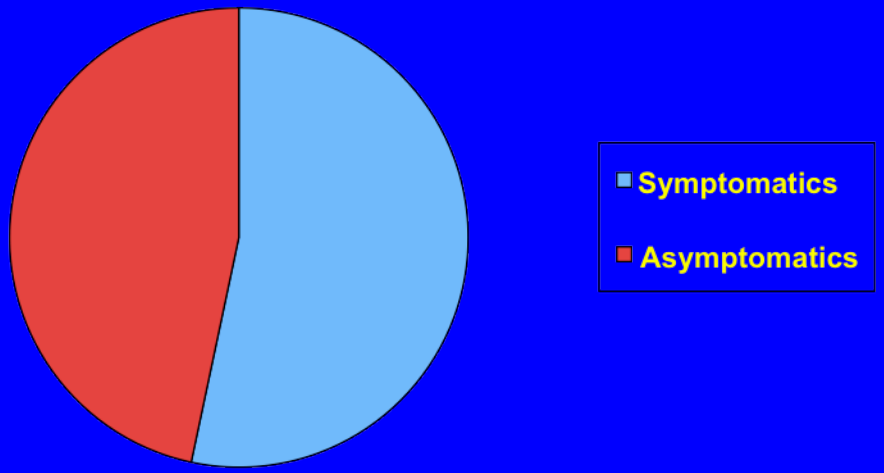
DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

45 of 95 patients who suffered AF recurrences at loop recorder **were asymptomatics**



Manganiello S, Senatore G, Gaita F PACE 2014

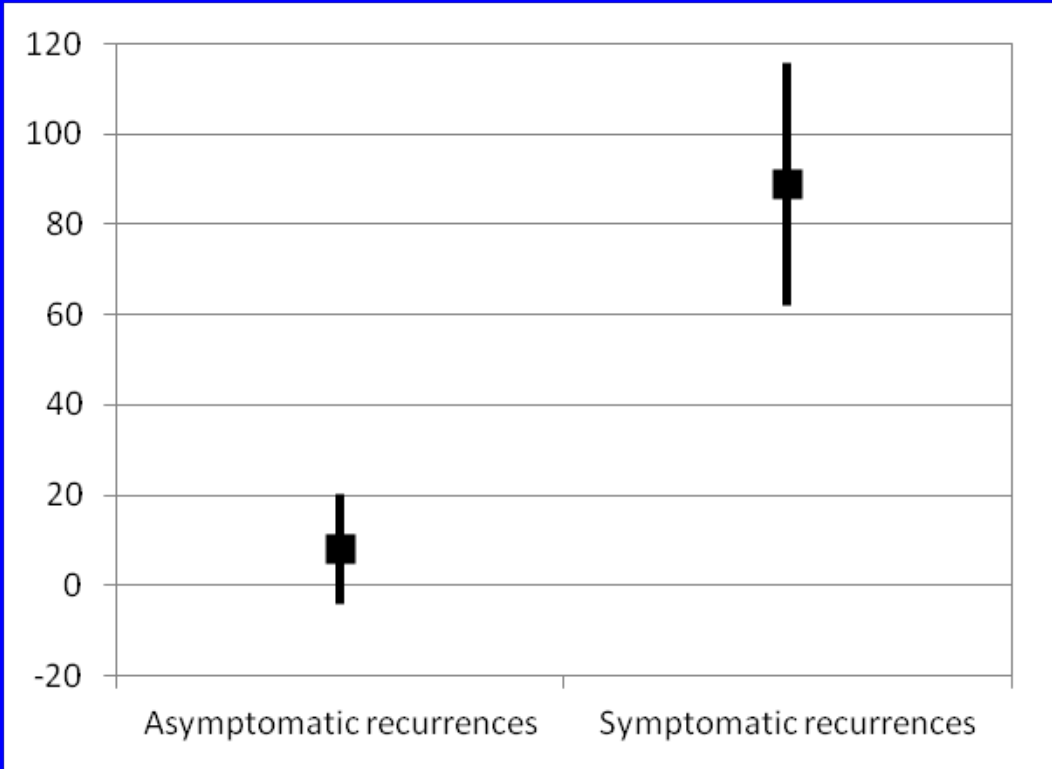
DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

AF burden % at loop recorder



Manganiello S, Senatore G, Gaita F PACE 2014

DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

Characteristics of patient population with AF recurrences (1)

Variables	Asymptomatic patients N=45	Symptomatic patients N=50	P value
Age, years (SD)	61.6±10.7	66.6±8.4	**0.029**
Type of atrial fibrillation, n (%)			
Paroxysmal	4 (11.4)	1 (2.5)	0.088
Persistent	31 (88.6)	39 (97.5)	0.088
Risk factors for thromboembolism, n (%)			
Cardiac failure	0 (0)	1 (2.5)	0.347
Hypertension	24 (68.6)	34 (85)	0.133
Diabetes mellitus	3 (8.6)	5 (12.5)	0.612
Prior stroke/TIA	1 (2.8)	3 (7.5)	0.374
Vascular disease*	1 (2.8)	5 (12.5)	0.125
LVEF, % (SD)	58.4±4.2	58.5±5.1	0.918

Manganiello S, Senatore G, Gaita F PACE 2014

AF MONITORING

Characteristics of patient population with AF recurrences (2)

Beta blockades	19 (54.3)	24 (60)	0.249
Digitalis	1 (2.8)	4 (10)	0.185
Calcium channel blockers	1 (2.8)	2 (5)	0.223
Antiarrhythmic drugs	12 (34.3)	15 (37.5)	0.084
Anticoagulants	-	-	
Antiplatelet agents	3 (8.6)	3 (7.5)	0.029
Type of ablation			
PVI plus linear lesion	35 (100)	40 (100)	-
Follow up			
Duration of follow up, months	669.6±288.9	788.2±282.2	0.137
AF burden	8.0±12.3	88.8±26.9	**<0.001**
Max AF duration	18.9±23.4	26.2±21.7	0.402

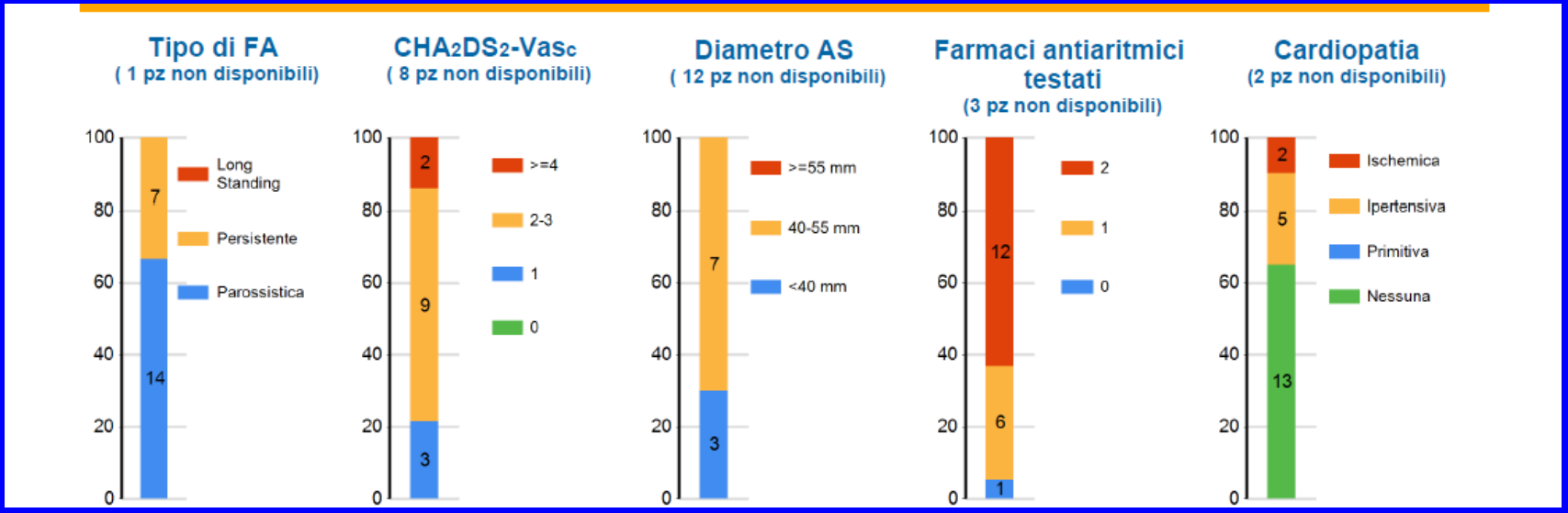
Manganiello S, Senatore G, Gaita F PACE 2014

DIVISION OF CARDIOLOGY CIRIE' & IVREA ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

41 pz (31 M, 10 F) mean age 66 ±12 yrs



DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

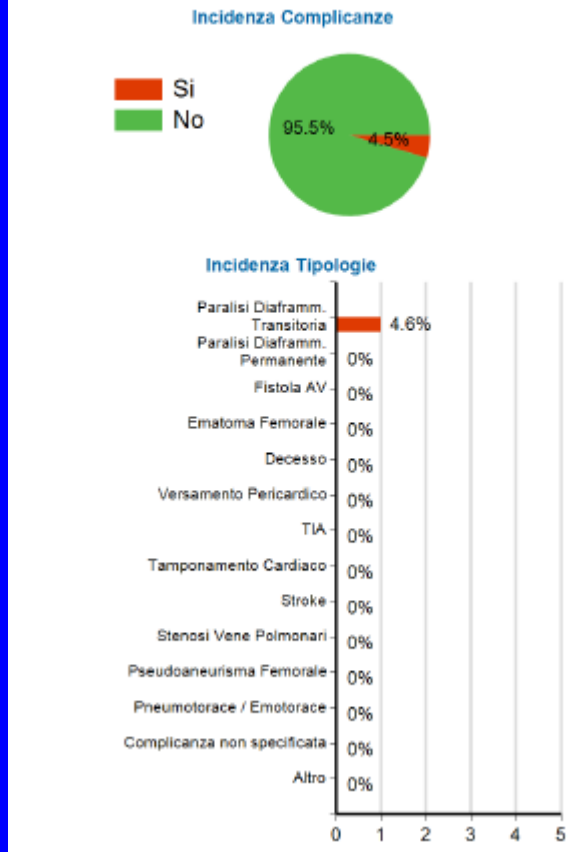
LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

Dati Procedurali

Tempi medi (min):	Procedura: **114**	Fluoroscopia: **28**	Catetere LA: **61**
Mix palloni 23mm/28mm: **1 / 19**		Mix Achieve 15mm/20mm/No: **1 / 20 / 0**	
Numero medio applicazioni (overall):	**1.7**		

Complicanze periprocedurali

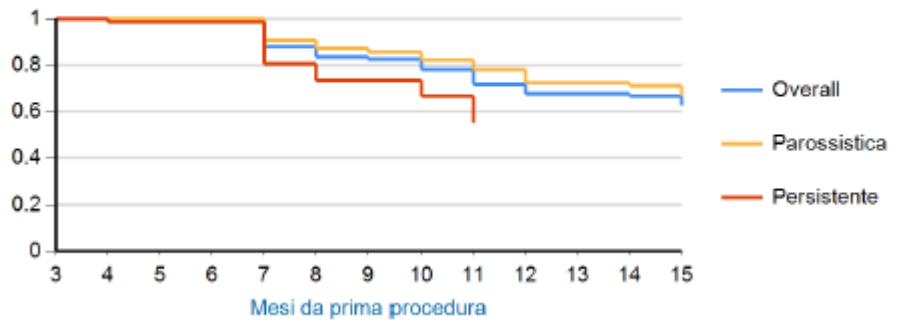


DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

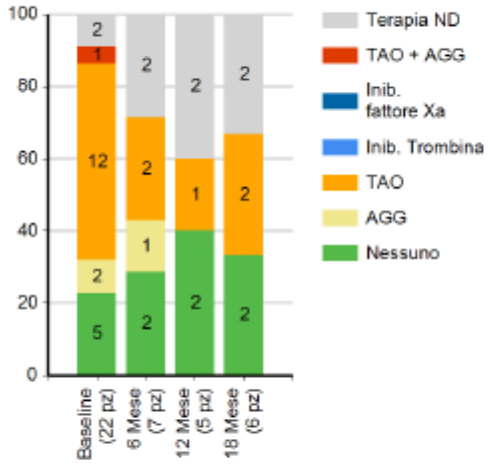
LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

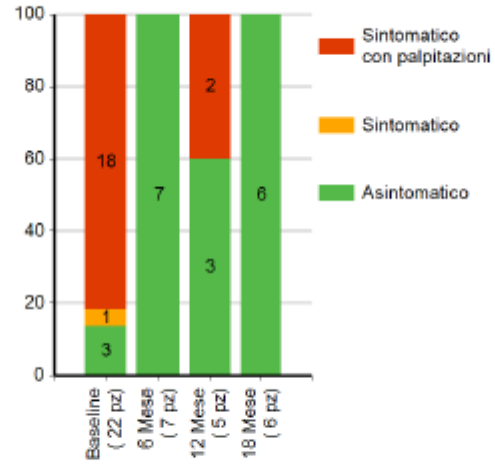
Libertà da Recidiva AF secondo Kaplan - Meier



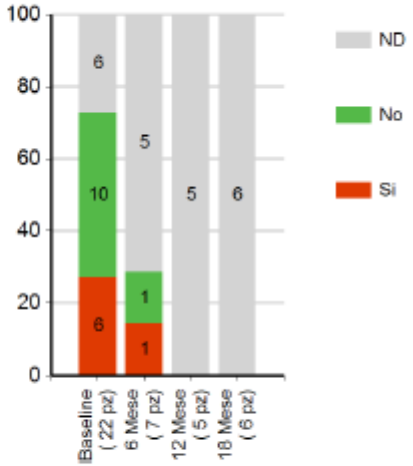
Terapia antitrombotica



Sintomaticità



Terapia antiaritmica



I valori inferiori al 4% della popolazione non sono mostrati nei grafici

DIVISION OF CARDIOLOGY CIRIE' & IVREA ITALY

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

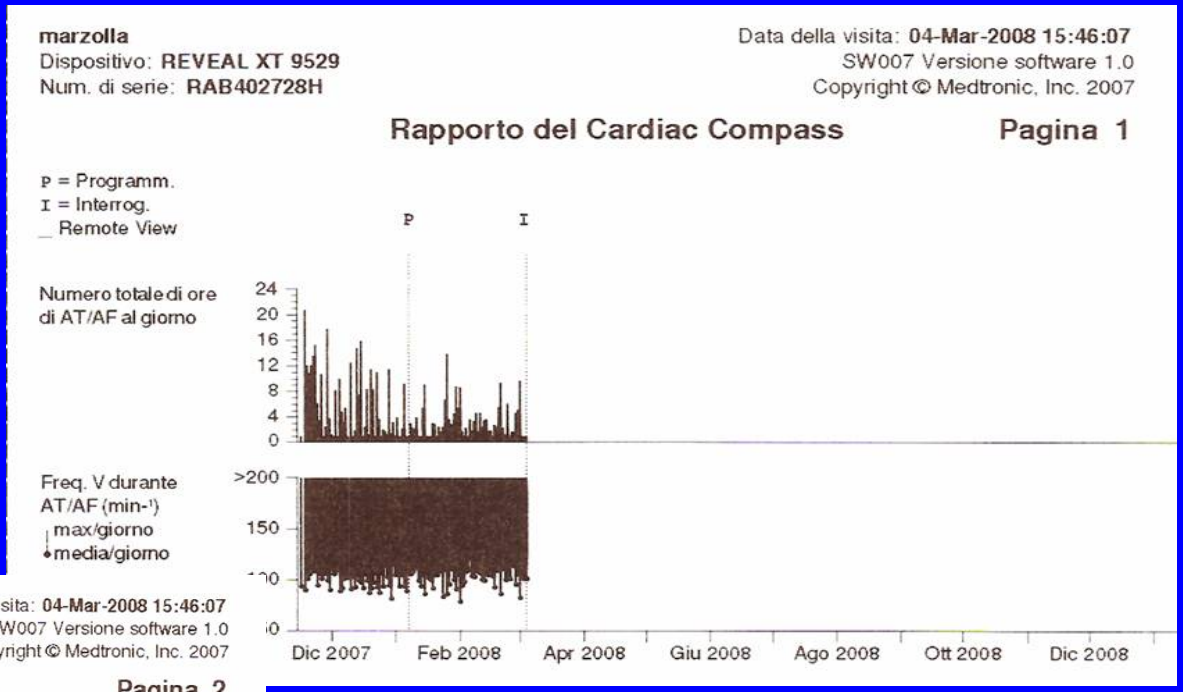
- **Indication to PM**
- **Management ventricular rate**
- **Management AAD**
- **Scheduling cardioversion**
- **Management of symptoms**
- **New AF ablation procedure**
- **Stop anticoagulation**

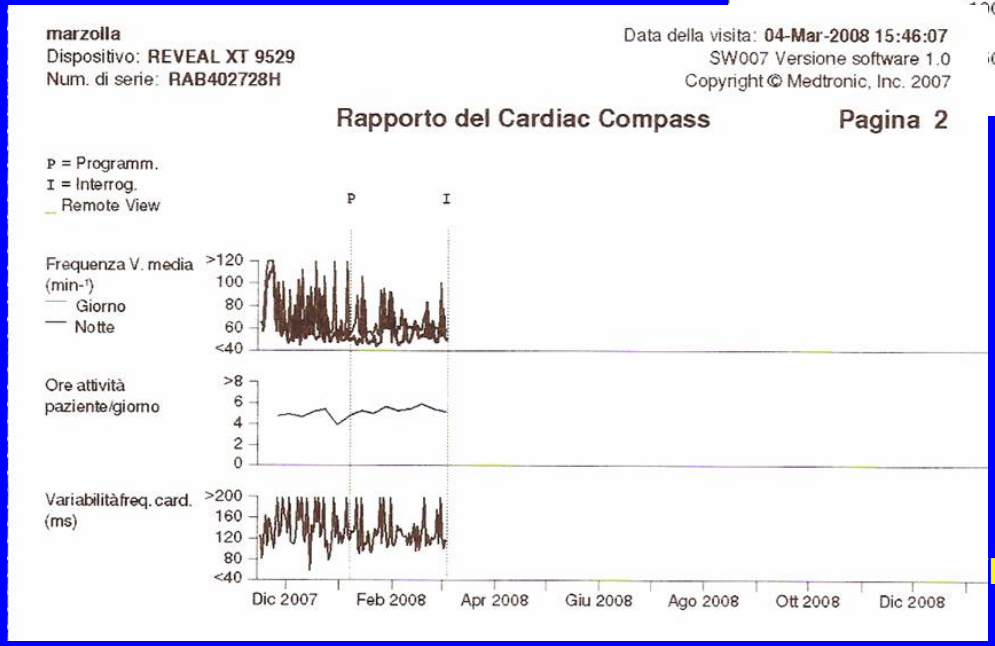
AF MONITORING

CASE REPORT

- Male 60 yrs
- AF refractory to AAD
- Patient underwent AF ablation
- β-blockers at discharge

AF MONITORING





ISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

marzolla
Dispositivo: **REVEAL XT 9529**
Num. di serie: **RAB402728H**

Data della visita: **04-Mar-2008 15:46:07**
SW007 Versione software 1.0

Riepilogo AT/AF

	Sessione precedente 16-Nov-2007 al 07-Gen-2008 52 giorni	Ultima sessione 07-Gen-2008 al 04-Mar-2008 57 giorni
Riepilogo AT/AF		
% di tempo AT/AF	24.1 %	13.8 % ↓
AT/AF media ore/giorno	5.8 ore/giorno	3.3 ore/giorno ↓

marzolla
Dispositivo: **REVEAL XT 9529**
Num. di serie: **RAB402728H**

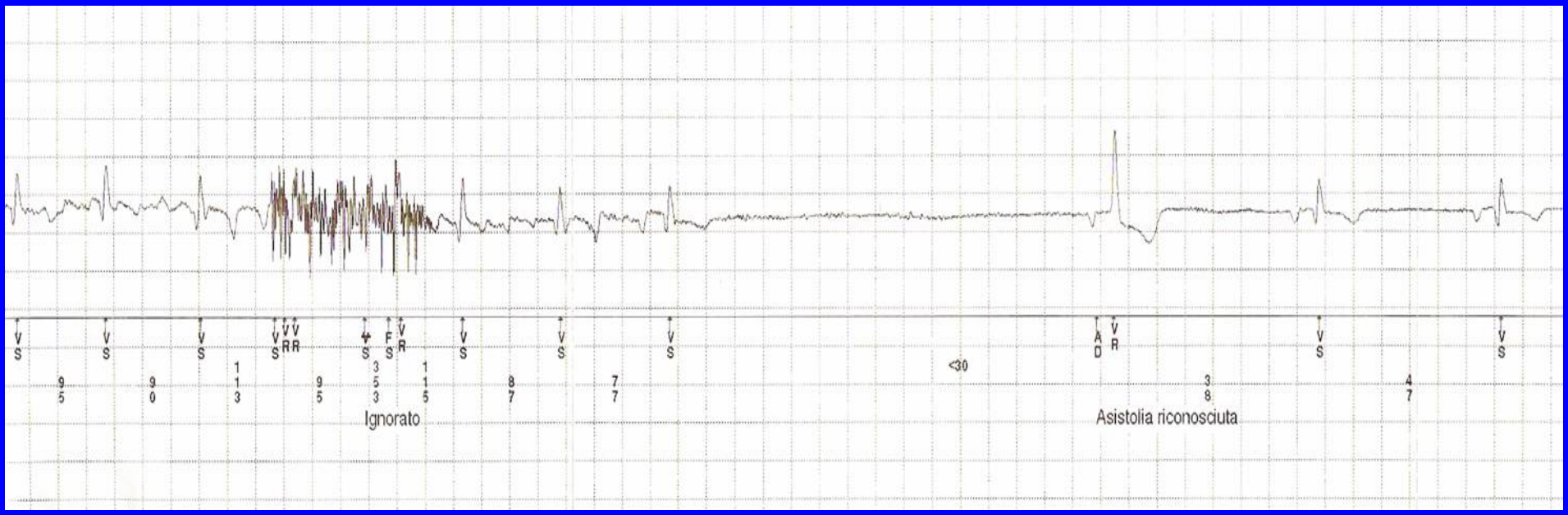
Data della visita: **04-Mar-2008 15:46:07**
SW007 Versione software 1.0
Copyright © Medtronic, Inc. 2007

Riepilogo AT/AF

Da ult. sess. dal 07-Gen-2008 al 04-Mar-2008

Durate AT/AF	Episodi	Ore di inizio AT/AF	Episodi
>72 h	0	09:00 - 12:00	264
da 48 a 72 ore	0	12:00 - 15:00	121
da 24 a 48 ore	0	15:00 - 18:00	193
da 12 a 24 ore	0	18:00 - 21:00	98
da 4 a 12 ore	7	21:00 - 00:00	71
da 1 a 4 ore	30	00:00 - 03:00	38
da 10 min a 1 ora	109	03:00 - 06:00	26
da 2 min a 10 min	783	06:00 - 09:00	118

AF MONITORING

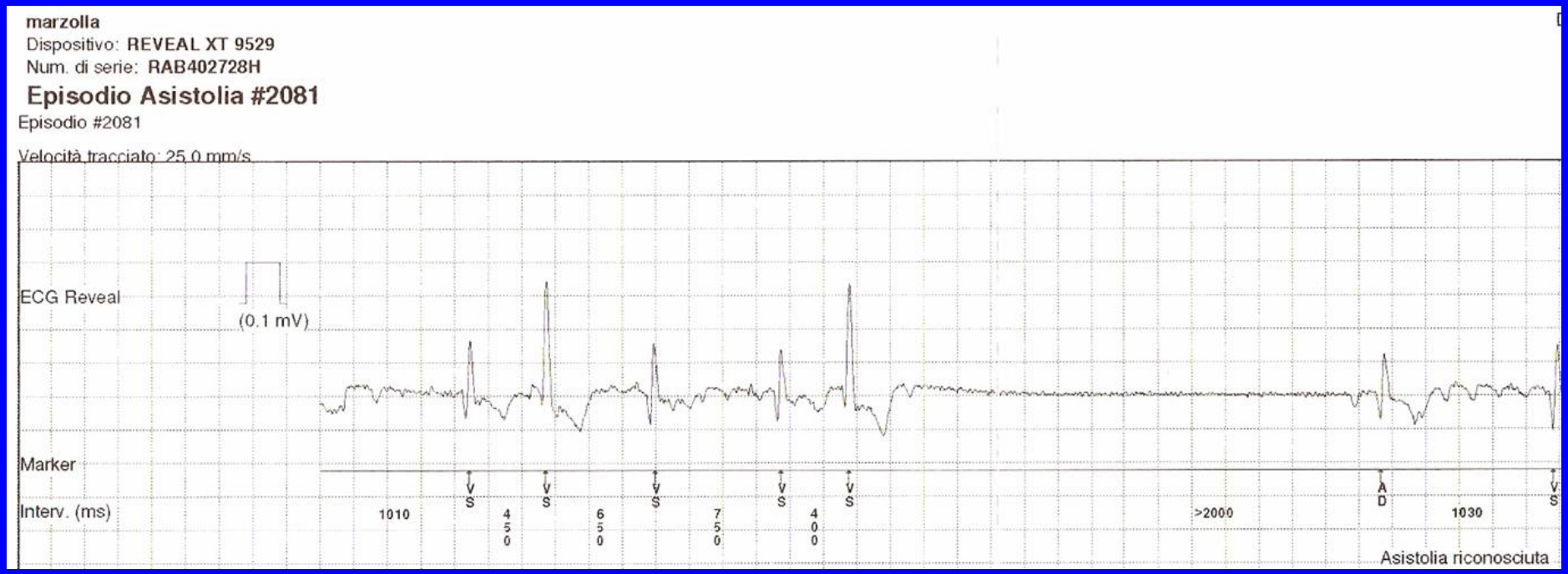


DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING



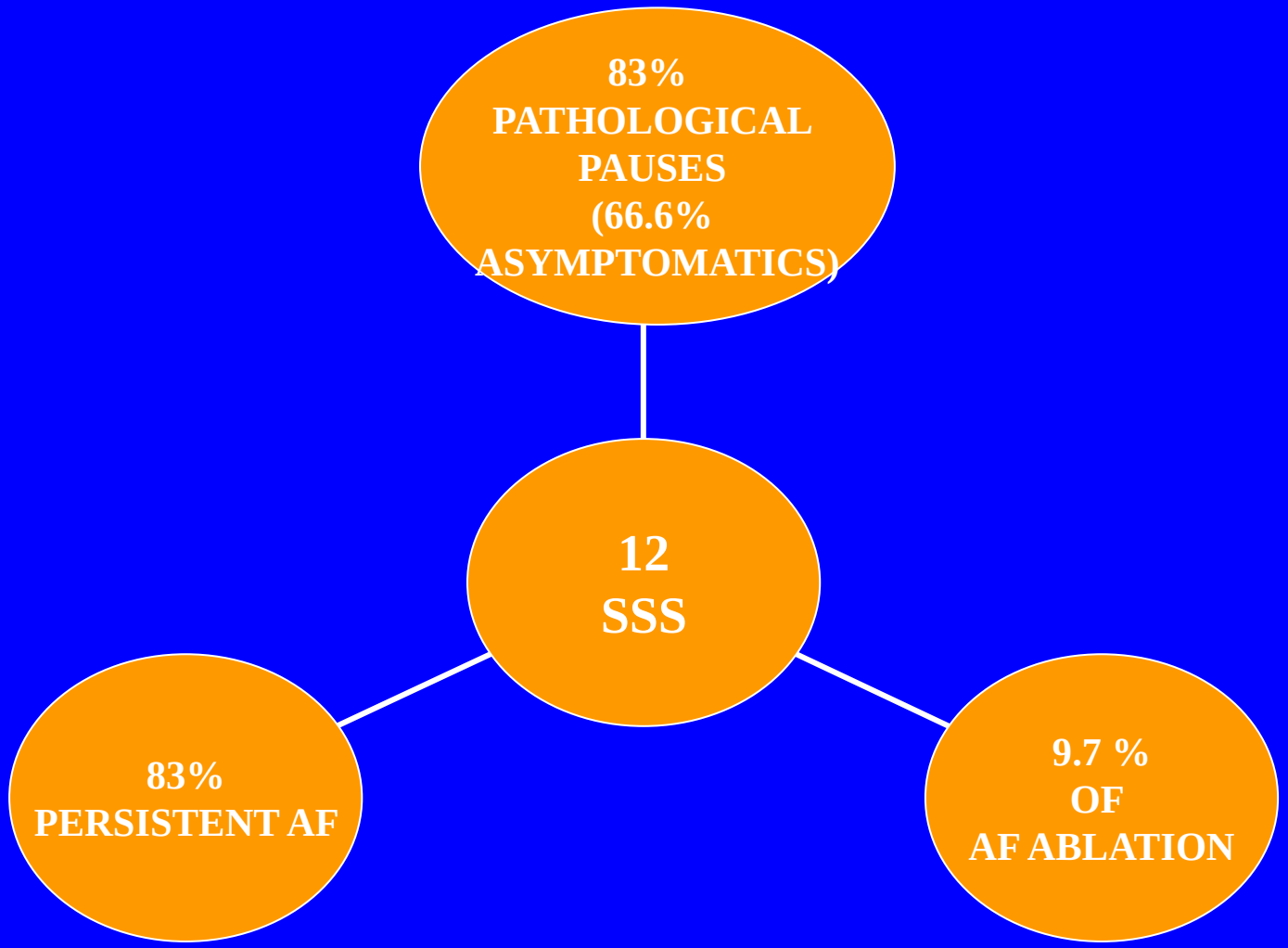
DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

12 SSS undergoing implantation PM post AF ablation

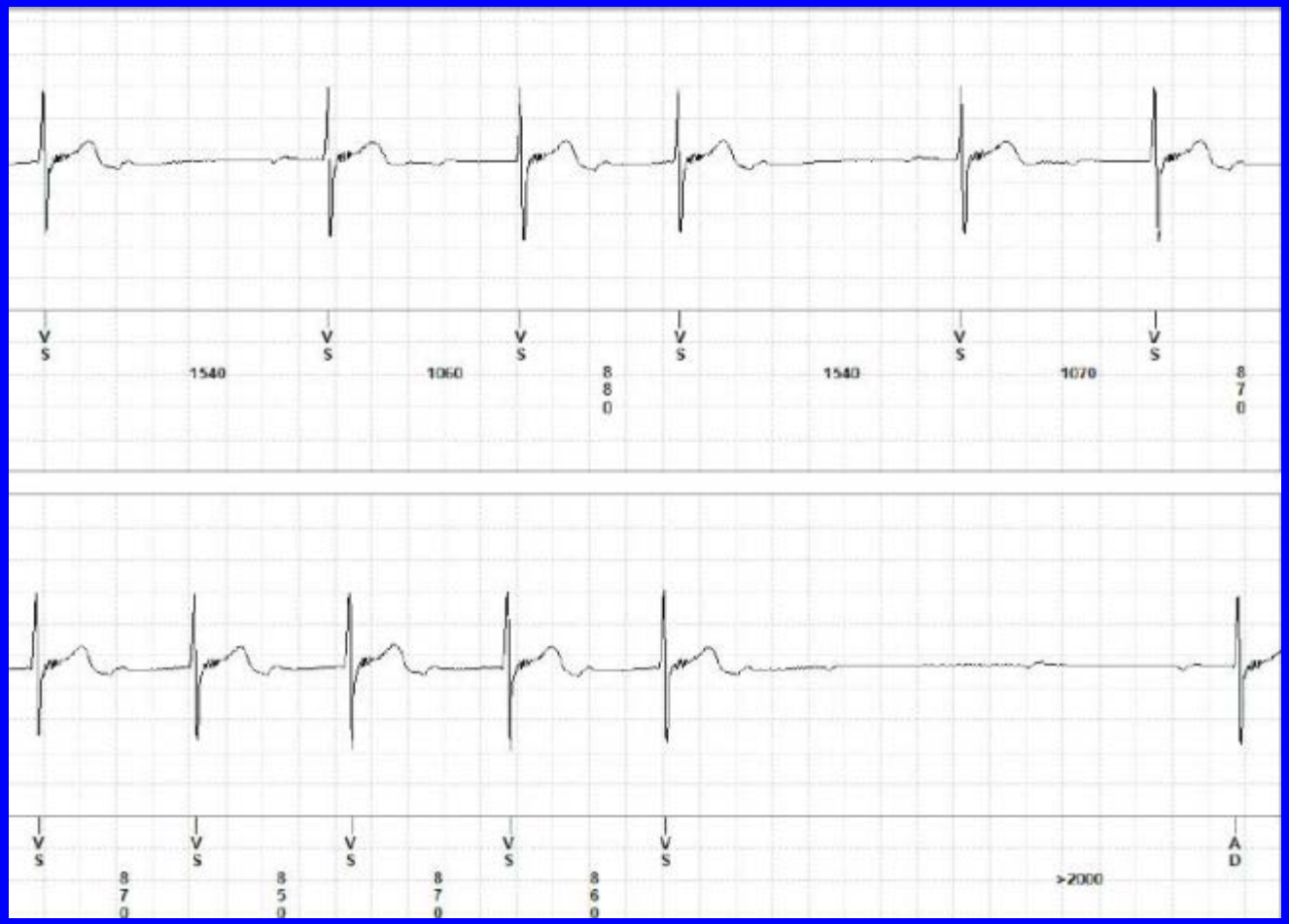


DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di
ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING



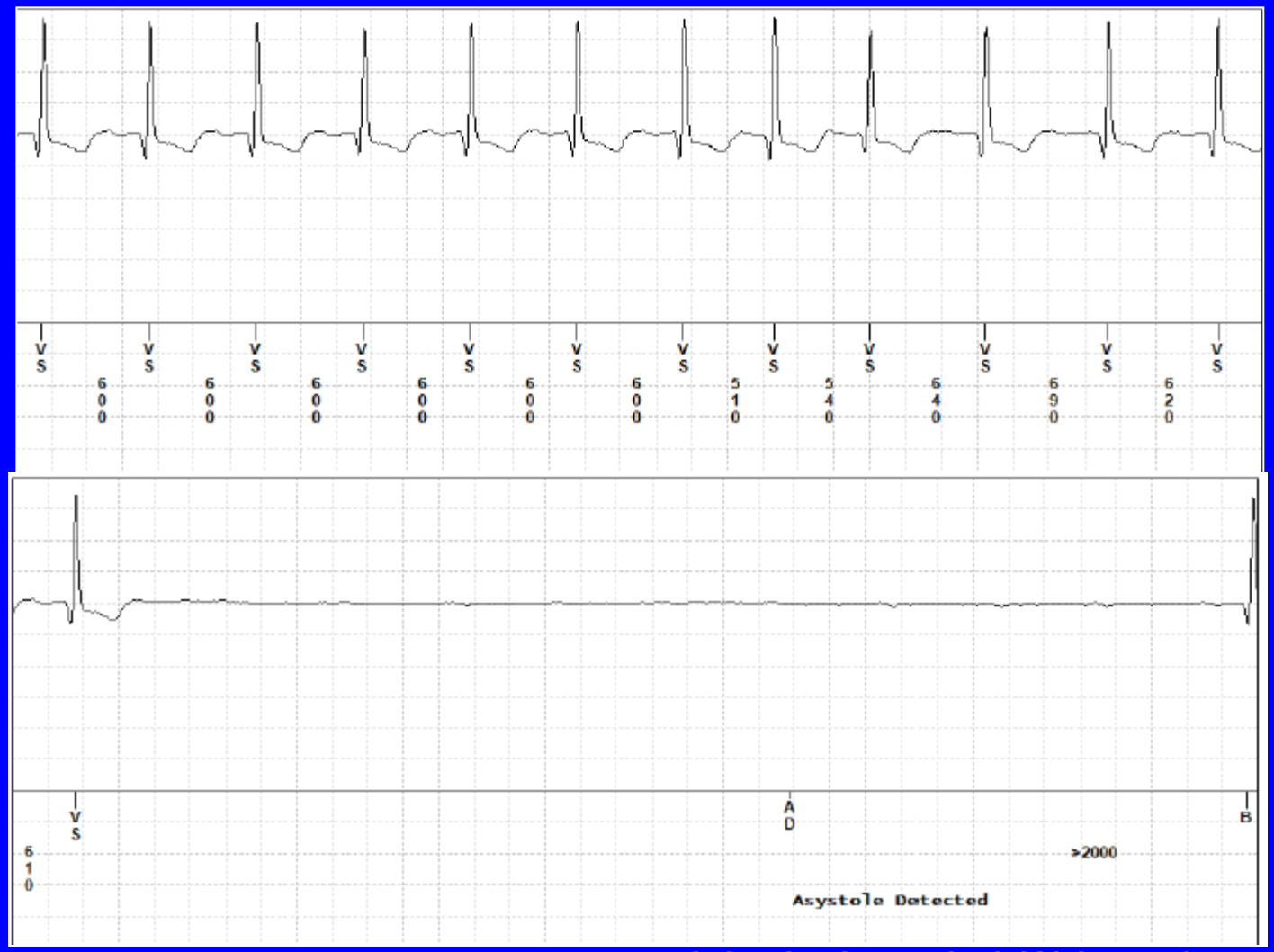
DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

Asyptomatic registration



DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

- **Indication to PM**
- **Management ventricular rate**
- **Management AAD**
- **Scheduling cardioversion**
- **Management of symptoms**
- **New AF ablation procedure**
- **Stop anticoagulation**

AF MONITORING

CASE REPORT

- Female 61 yrs
- AF refractory to AAD
- Patient underwent AF ablation
- AF at discharge; cardioversion scheduled after 2 months
- β-blockers at discharge

DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA
A.S.L. 6 Ospedale di Ciriè

AF MONITORING

Symptom

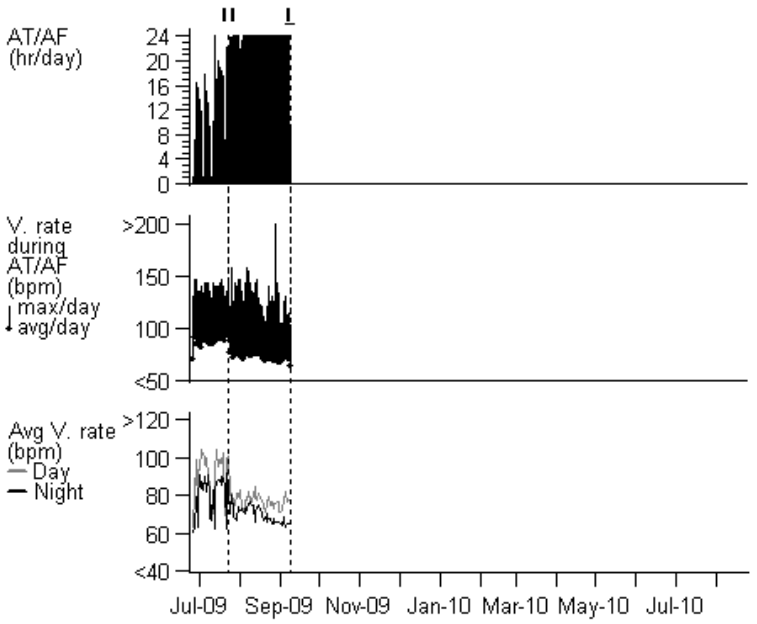
Device: Reveal® XT 9529 | Serial Number: RAB613237S | Date of Interrogation: 08-Sep-2009 09:34:25

Device Status

Battery Status	Good

Episodes (29)	Since: 23-Jul-2009
Symptom	1
FVT	0
VT	0
Asystole	3
Brady	0
AT/AF	
AT	0
AF	25
% of Time AT/AF	99.7%

Cardiac Compass Trends (Jun-2009 to Sep-2009)



F.P.

DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

Device: Reveal® XT 9529 Serial Number: RAB613237S Date of Interrogation: 08-Sep-2009 09:34:25

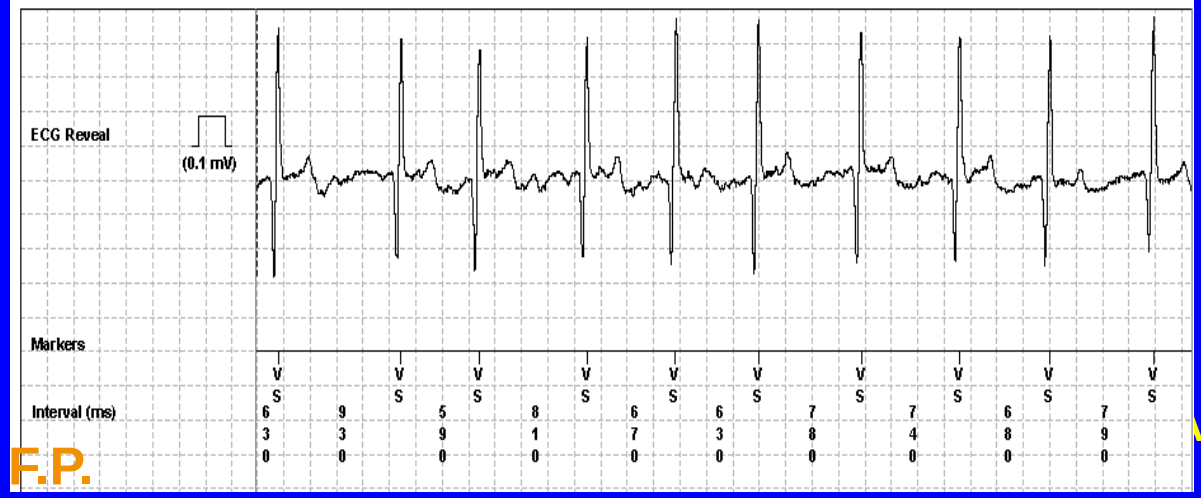
SYMPTOM FVT VT Asystole Brady AT AF Sorted by Date/Time

View/Print

(all)	ID#	Type	Date	Time hh:mm	Duration hh:mm:ss	Max V. Rate	Median V. Rate	Detail
	389	Asystole	08-Sep-2009	06:16	:03		67 bpm (900 ms)	ECG
	388	Asystole	08-Sep-2009	06:05	:03		54 bpm (1110 ms)	ECG
	387	AF	03-Sep-2009	21:00		(Episode in progress)		
	386	Asystole	04-Aug-2009	15:03	:03		61 bpm (980 ms)	ECG
	385	SYMPTOM	04-Aug-2009	11:18				ECG
	384	AF	02-Aug-2009	10:10	>99:59:59	261 bpm (230 ms)	61 bpm (980 ms)	ECG
	383	AF	02-Aug-2009	04:00	06:06:00	111 bpm (540 ms)	58 bpm (1040 ms)	ECG
	382	AF	02-Aug-2009	02:40	01:14:00	94 bpm (640 ms)	74 bpm (810 ms)	ECG
	381	AF	02-Aug-2009	02:24	:14:00	97 bpm (620 ms)	82 bpm (730 ms)	ECG
	380	AF	02-Aug-2009	02:08	:10:00	95 bpm (630 ms)	85 bpm (710 ms)	ECG
	379	AF	02-Aug-2009	02:00	:06:00	85 bpm (710 ms)	72 bpm (830 ms)	ECG
	378	AF	01-Aug-2009	21:42	04:02:00	111 bpm (540 ms)	85 bpm (710 ms)	ECG

Quick Look | ECG corrente | Episodi | Istogrammi della frequenza | Altri report | Note | Cronologia azioni

Device: Reveal® XT 9529 Serial Number: RAB613237S Date of Interrogation: 08-Sep-2009 09:34:25



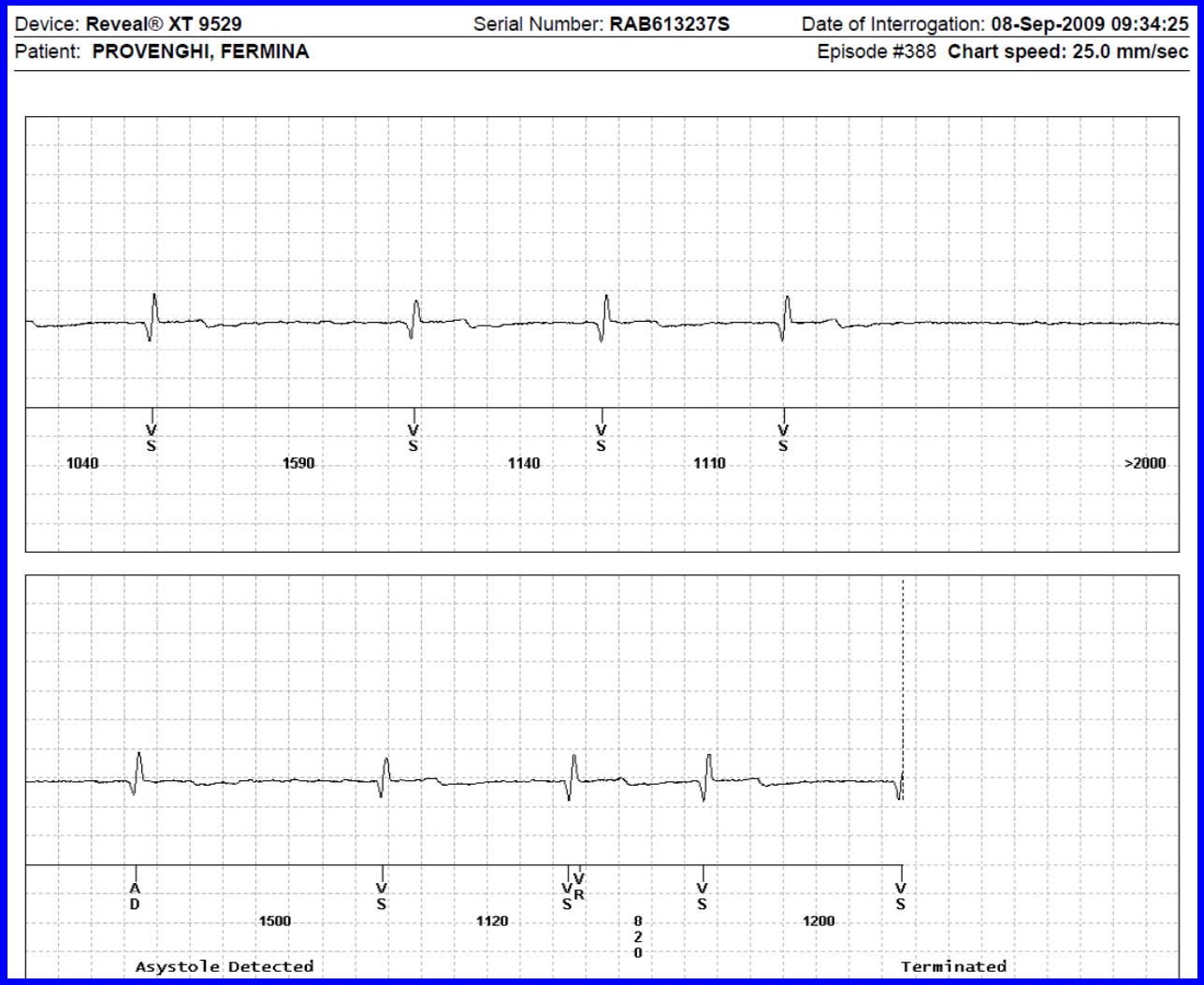
F.P.

CARDIOLOGY CIRIE' & IVREA ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING



F.P.

DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

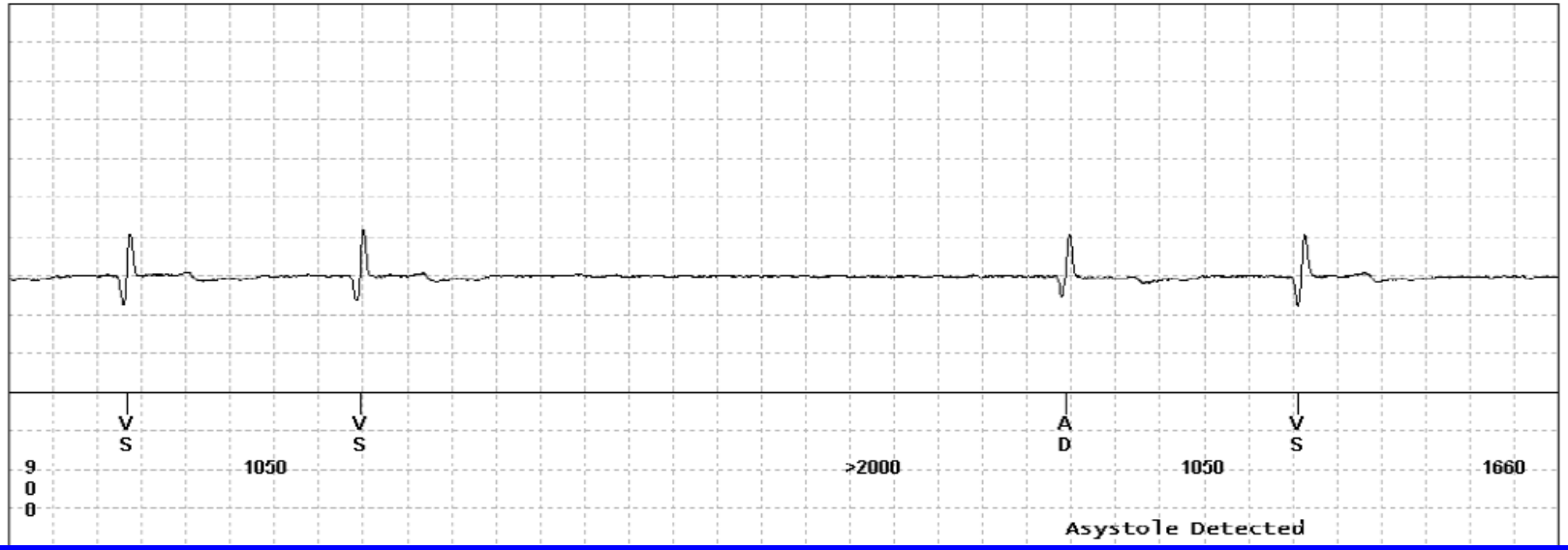
LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

Device: **Reveal® XT 9529** Serial Number: **RAB613237S** Date of Interrogation: **08-Sep-2009 09:34:25**

Patient: **PROVENGHI, FERMINA** Episode #389 **Chart speed: 25.0 mm/sec**



F.P.

DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

- **Indication to PM**
- **Management ventricular rate**
- **Management AAD**
- **Scheduling cardioversion**
- **Management of symptoms**
- **New AF ablation procedure**
- **Stop anticoagulation**

AF MONITORING

CASE REPORT

- Female 75 yrs
- AF refractory to AAD
- Patient underwent AF ablation
- Palpitations during follow-up

D.R.

DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA
A.S.L. 6 Ospedale di Ciriè

AF MONITORING

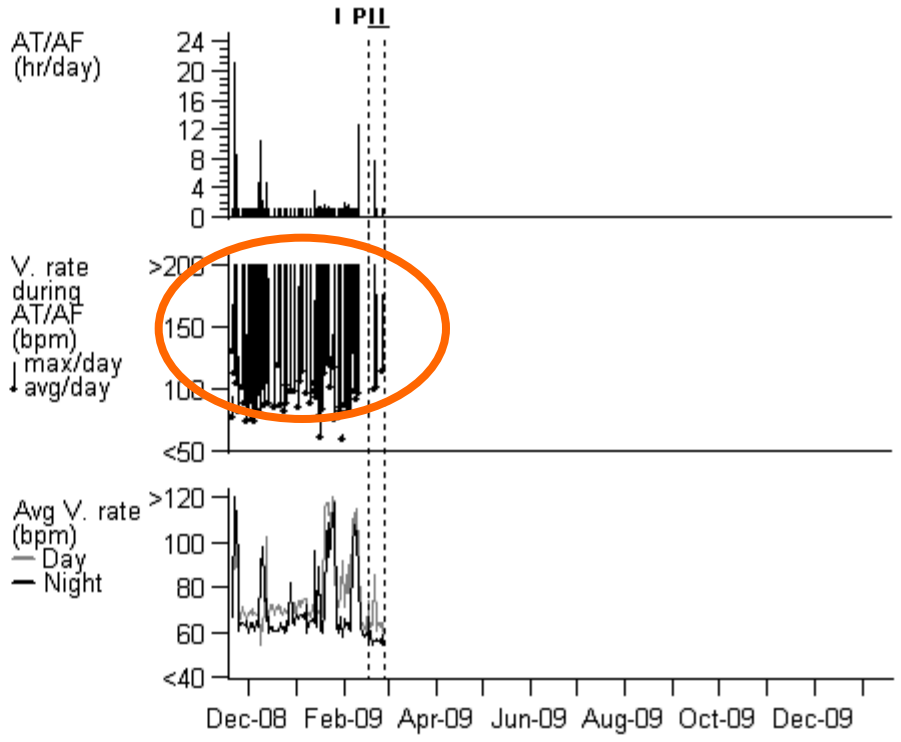
Device: Reveal® XT 9529 | Serial Number: RAB601168S | Date of Interrogation: 27-Feb-2009 15:09:11

Device Status

Battery Status	Good

Episodes (7)	Since: 16-Feb-2009
Symptom	2
FVT	0
VT	0
Asystole	0
Brady	0
AT/AF	
AT	0
AF	5
% of Time AT/AF	2.9%

Cardiac Compass Trends (Nov-2008 to Feb-2009)



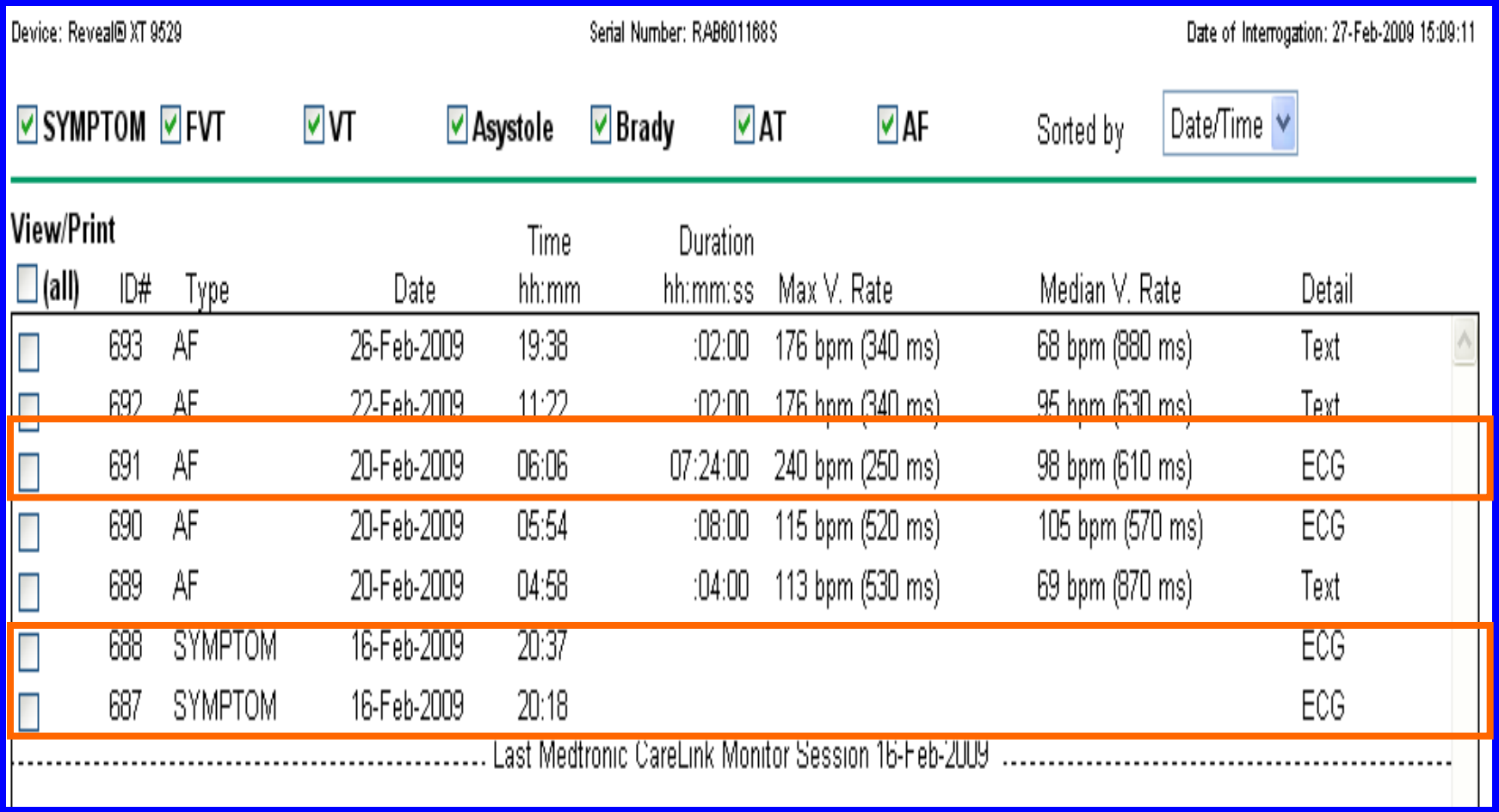
D.R.

DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING



Device: Reveal® XT 9529 Serial Number: RAB601168S Date of Interrogation: 27-Feb-2009 15:09:11

☑ SYMPTOM ☑ FVT ☑ VT ☑ Asystole ☑ Brady ☑ AT ☑ AF Sorted by Date/Time

View/Print

(all)	ID#	Type	Date	Time hh:mm	Duration hh:mm:ss	Max V. Rate	Median V. Rate	Detail
☐	693	AF	26-Feb-2009	19:38	:02:00	176 bpm (340 ms)	68 bpm (880 ms)	Text
☐	692	AF	22-Feb-2009	11:22	:02:00	176 bpm (340 ms)	95 bpm (630 ms)	Text
☐	691	AF	20-Feb-2009	06:06	07:24:00	240 bpm (250 ms)	98 bpm (610 ms)	ECG
☐	690	AF	20-Feb-2009	05:54	:08:00	115 bpm (520 ms)	105 bpm (570 ms)	ECG
☐	689	AF	20-Feb-2009	04:58	:04:00	113 bpm (530 ms)	69 bpm (870 ms)	Text
☐	688	SYMPTOM	16-Feb-2009	20:37				ECG
☐	687	SYMPTOM	16-Feb-2009	20:18				ECG

Last Medtronic CareLink Monitor Session 16-Feb-2009

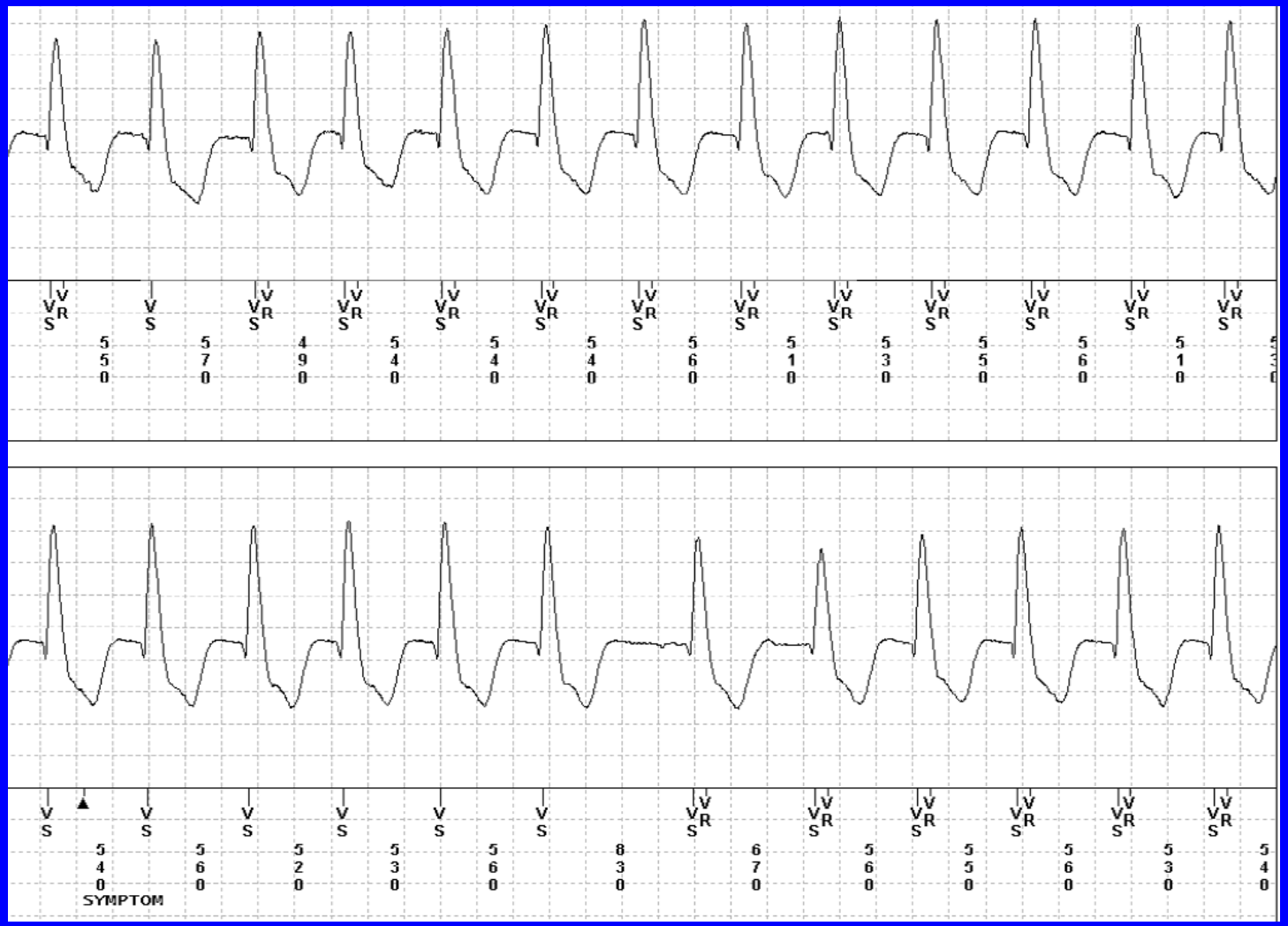
D.R.

DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING



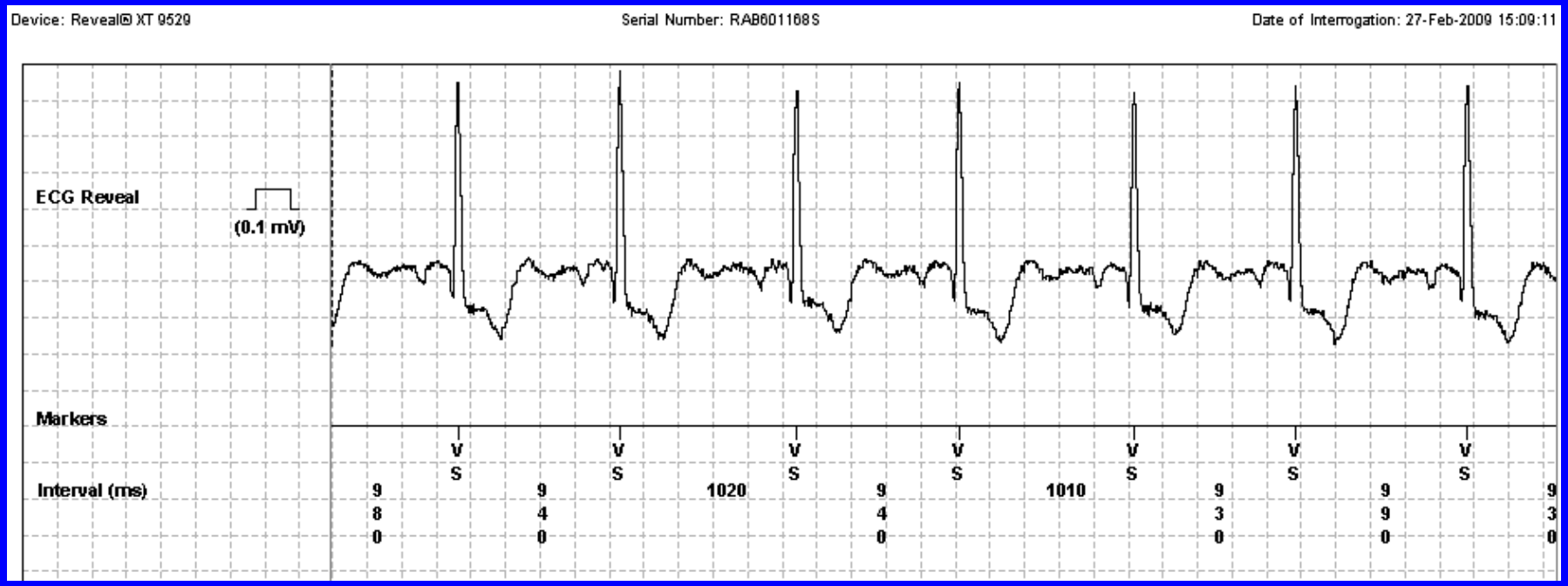
D.R.

DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING



D.R.

DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING & CARE LINK

CONCLUSIONS

- **CareLink e Reveal XT**
  - **Continuous monitoring**
  - **Management of symptomatic events**
  - **Quick follow-up (less than 3 minutes)**
  - **Time & money save**

Table 1. Different Methods of Cardiac Monitoring

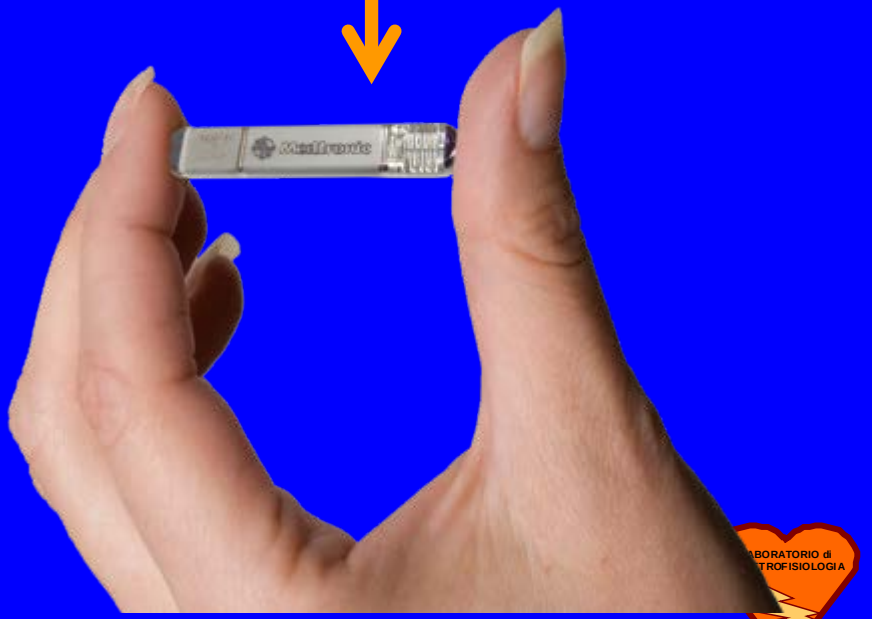
	Advantages	Disadvantages
Noninvasive		
Continuous hospital telemetry	• Accurate diagnosis • Detects asymptomatic events	• Requires inpatient monitoring • Expensive • Restricts patient movement
Ambulatory ECG (Holter)	• Easy to use • Continuous recording • Detects asymptomatic events	• Short monitoring period • Need for patient to keep symptom diary
Patient-triggered event recorder	• Longer monitoring periods • Correlation of symptoms and rhythm	• Does not detect asymptomatic events • Requires patient participation
Prolonged ambulatory ECG (mobile cardiovascular telemetry)	• Continuous monitoring • Detects asymptomatic events	• Costly • Patient compliance, skin irritation
Invasive		
Implantable loop recorder	• Longer periods of follow-up • Internet-based data transmission	• Costly and invasive • False-positive and false-negative detections
Pacemakers and defibrillators	• Detects asymptomatic events • Offers therapy	• Costly and invasive • Great risk of complications

Miniaturized Reveal LINQ ICM Device

Breakthrough Technology

3-year monitoring
remote management*

87% smaller and
wireless transmissions

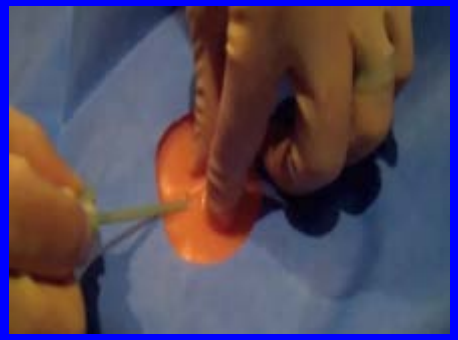


DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

A.S.L. 6 Ospedale di Ciriè

Reveal LINQ™

Device	Procedure	Venue	Data



As simple as a holter,
with the benefits of continuous monitoring and wireless connectivity!

DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

Reveal LINQ ICM caratteristiche

Parameter	Reveal XT ICM	Reveal LINQ ICM
Longevity	3 years	*3 years
Electrode Spacing (inside-to-inside)	41 mm	38 mm
Volume	9 cc	1.2 cc
Mass	15 g	2.5 g
Episode Storage	49 min	59 min
Patient Symptom Mark	Patient Assistant	Patient Assistant
Cardiac Compass®	Same	Same
MRI Compatibility	MR Conditional	MR Conditional
Clinician Notification	No	Nightly Transmission / CareAlert Notifications
Bi-Directional Telemetry	B	B
Detection Algorithms	Full View	Full View + P-SENSE detection
CareLink® Network	Yes	Yes
Wireless Telemetry	No	1-Way, Transmit Only

* Under the following usage scenarios: • Average of 1 auto-detected episode per day • Average of 1 patient-activated episode per month • Less than or equal to 6 months shelf life (between device manufacture and insertion). Note: Under maximum shelf storage time (12 months), longevity is reduced by approximately 3 months.

Event Report

Event

Reveal LINQ™

Event Report Medtronic

Received: 23-Jan-2012

John Lee

Date of Birth:	ID:	Physician:	Battery:
01-Jan-1945	123-45-6789	Dr. Robert	OK

Phone:	Reason for Monitoring:	Date of Implant:
(555)-555-5555 (555)-555-0000	Palpitations	06-Dec-2011

History

Infrequent, severe palpitations. Holter showed asymptomatic AF.

Event Summary: *Tachy episode detected (ID #38)*

Interval (ms)

Detected

Term

Tachy episode
- Detected: 22-Jan-2012
- Duration: 00:03:32
- Max V. Rate: 200 bpm
- Median V. Rate: 194 bpm

Time (sec)

09:02:52

ECG suspended for 00:08:00

09:06:29

Counters

	Since 09-Jan-2012	Lifetime
Symptom	0	0
Tachy	2	2
Pause	0	0
Brady	0	0
AT	0	0
AF	1	36
% of Time in AT/AF	100%	22%

Observations 09-Jan-2012 to 23-Jan-2012

- CareAlert: AT/AF Daily Burden > Threshold
- CareAlert: Average V. Rate during AT/AF > Threshold
- CareAlert: Symptom + Detected Episode
- CareAlert: Symptom (Patient Activated)

Signature

Patient: John Lee
Serial Number: RAC000123

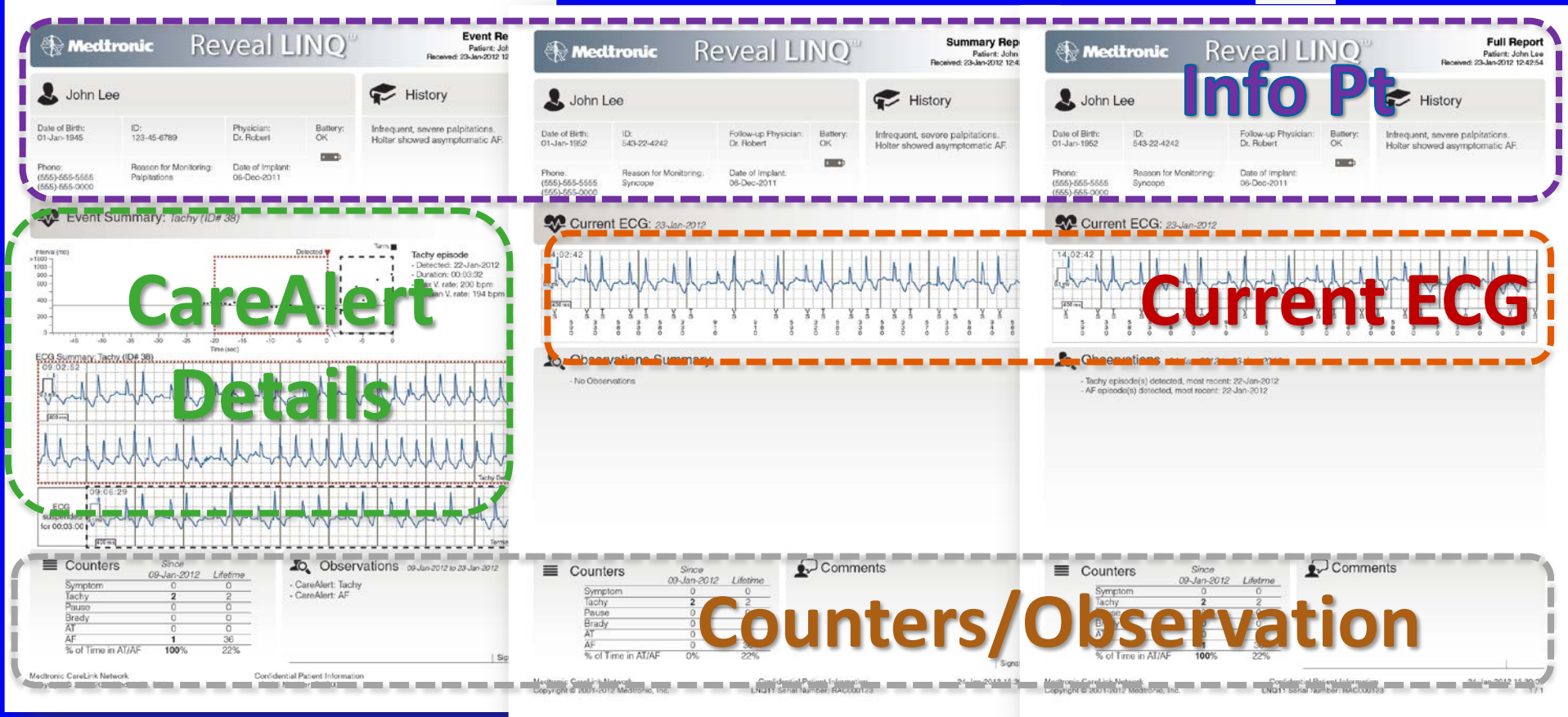
Confidential Patient Information

1 / 1

Event

Summary

Full



DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

Monitor MyCareLink™

- **LCD Display**

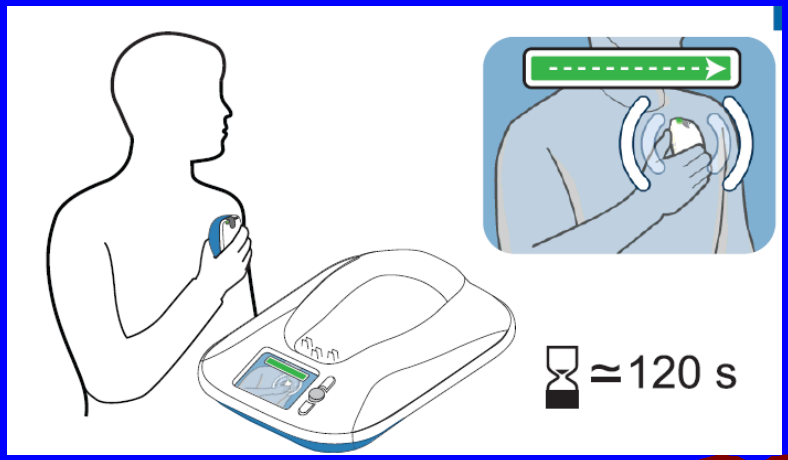
- **multiprovider connection GSM Roaming**

Tipi di Trasmissione

From LINQ to MyCareLink

•Wireless Automatic

•Manual



AF MONITORING

- **Indication to PM**
- **Management ventricular rate**
- **Management AAD**
- **Scheduling cardioversion**
- **Management of symptoms**
- **New AF ablation procedure**
- **Stop anticoagulation**

AF MONITORING

CASE REPORT

- Male 62 yrs
- AF refractory to AAD
- Patient underwent AF ablation
- Asymptomatic

AF MONITORING

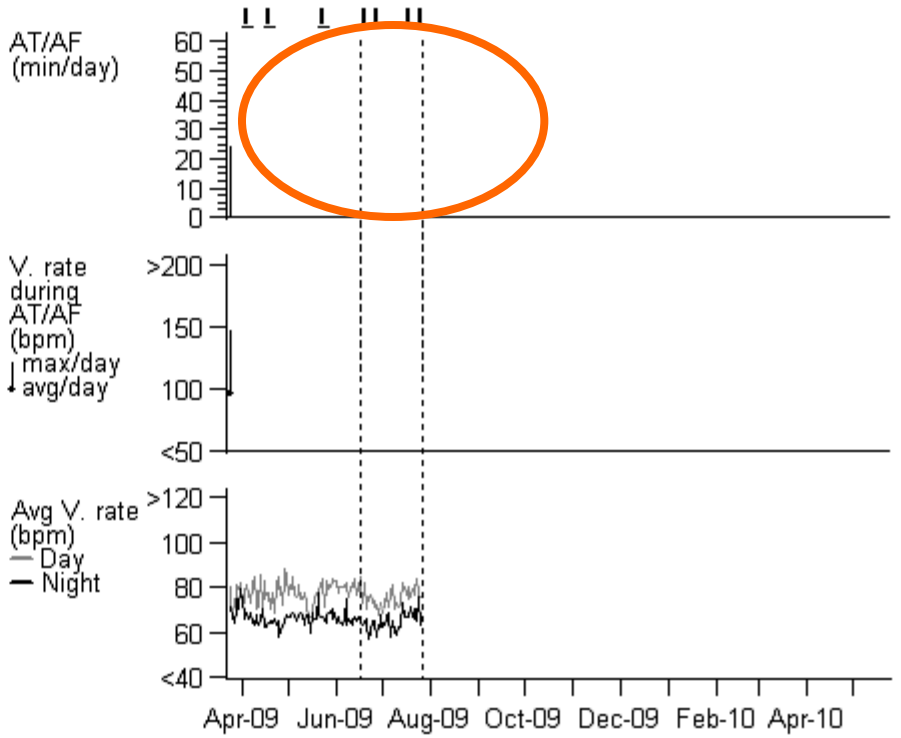
Device: Reveal® XT 9529 | Serial Number: RAB607801S | Date of Interrogation: 26-Jul-2009 09:19:58

Device Status (Implanted: 24-Mar-2009)

Battery Status	Good

Episodes (0)	Since: 16-Jun-2009
Symptom	0
FVT	0
VT	0
Asystole	0
Brady	0
AT/AF	
AT	0
AF	0
% of Time AT/AF	0.0%

Cardiac Compass Trends (Mar-2009 to Jul-2009)



P.C.

DIVISION OF CARDIOLOGY CIRIE' & IVREA
ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

No recurrences post AF ablation

Medtronic

Quick Look

Device: Reveal® XT 9529 | Serial Number: RAB664433S | Date of Interrogation: 16-Oct-2013 07:22:04

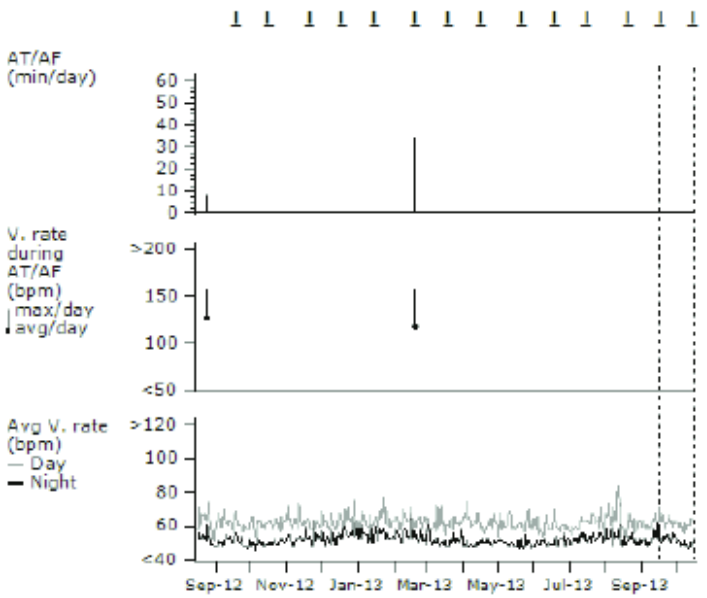
Patient: GIAMMELLO, CLAUDIO | Physician:

Device Status (Implanted: 13-Oct-2011)

Battery Status	Good

Episodes (0)	Since: 16-Sep-2013
Symptom	0
FVT	0
VT	0
Asystole	0
Brady	0
AT/AF	
AT	0
AF	0
% of Time AT/AF	0.0%

Cardiac Compass Trends (Aug-2012 to Oct-2013)



DIVISION OF CARDIOLOGY CIRIE' & IVREA ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

$CHADS_2$

Stroke Risk Factor	Score
Congestive Heart Failure	1
Hypertension	1
Age (> 75 years)	1
Diabetes	1
Prior **S**troke / TIA	2
Max Score	***6***

CHA_2DS_2-VASc

Stroke Risk Factor	Score
Congestive Heart Failure / LV Dysfunction	1
Hypertension	1
Age (≥ 75 years)	2
Diabetes	1
Prior **S**troke / TIA / thrombo-embolism	2
Vascular Disease[1]	1
Age 65-74	1
Sex **C**ategory (female)	1
Max Score	***9***

DIVISION OF CARDIOLOGY CIRIE' & IVREA ITALY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Ciriè

AF MONITORING

CONCLUSIONS

- **Does every patient need an implantable device in the follow-up?**

SOCIETA' SPORTIVA
CALCIO NAPOLI S.p.A.