PRO E CONTRO:
SOLUZIONI "AVANZATE" O TRADIZIONE?
Prevenzione primaria della morte improvvisa post-infarto: S-ICD

Novara, 13 settembre 2019

Antonio Mazzuero

Elettrostimolazione ASL VCO

Ospedale S. Biagio, Domodossola (VB)

ICH GCP | Clinical Trials Registry

Arrhythmias Detection in a Real World Population: the RHYTHM DETECT Registry

Arrhythmias Detection in a Real World Population

Added	1568100980
Sponsors	**Lead Sponsor** Maurizio Eugenio Landolina
Source	IRCCS Policlinico S. Matteo
Oversight Info	**Has Dmc** No
Brief Summary	The study is a prospective multicenter registry. Consecutive patients with indications of implant / replacement or upgrade of implantable cardioverter defibrillator (ICD) will be enrolled. The primary objective of the study is to determine the predictors of appropriate anti-tachycardia therapy (with shock) in a non-selected population of patients implanted with an ICD. Secondary objectives of the study are: - the incidence of anti-tachycardia therapies; - the predictors of inappropriate therapy and onset of arrhythmia burden; - the adherence to the current guidelines in the Italian clinical practice; - the predictors of heart failure (HF) onset and response to cardiac resynchronization therapy (CRT)

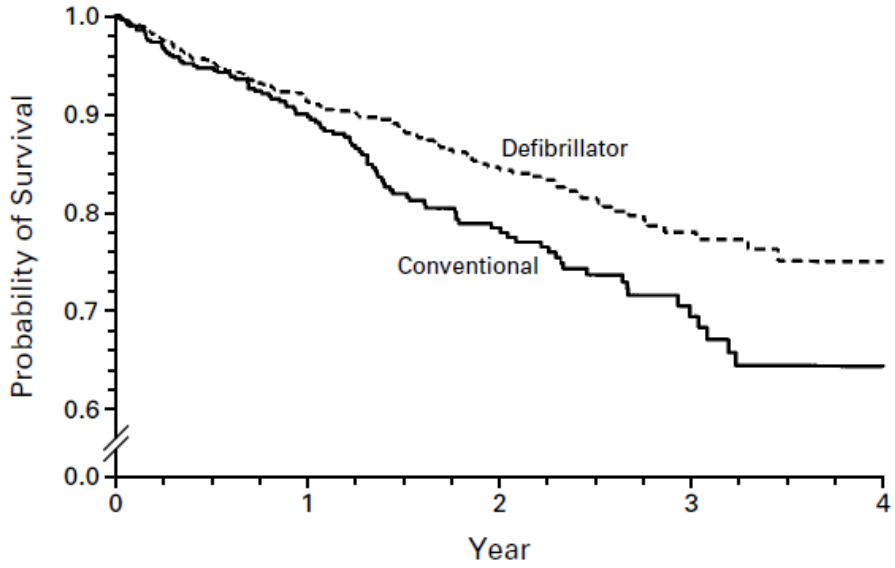
The New England
Journal of Medicine

VOLUME 346 MARCH 21, 2002 NUMBER 12

PROPHYLACTIC IMPLANTATION OF A DEFIBRILLATOR IN PATIENTS WITH MYOCARDIAL INFARCTION AND REDUCED EJECTION FRACTION

ARTHUR J. MOSS, M.D., WOJCIECH ZAREBA, M.D., PH.D., W. JACKSON HALL, PH.D., HELMUT KLEIN, M.D., DAVID J. WILBER, M.D., DAVID S. CANNOM, M.D., JAMES P. DAUBERT, M.D., STEVEN L. HIGGINS, M.D., MARY W. BROWN, M.S., AND MARK L. ANDREWS, B.B.S., FOR THE MULTICENTER AUTOMATIC DEFIBRILLATOR IMPLANTATION TRIAL II INVESTIGATORS*

13 "lead problems" (1,8%)
5 infezioni non fatali (0,7%)



No. at Risk					
Defibrillator	742	503 (0.91)	274 (0.84)	110 (0.78)	9
Conventional	490	329 (0.90)	170 (0.78)	65 (0.69)	3

Figure 2. Kaplan–Meier Estimates of the Probability of Survival in the Group Assigned to Receive an Implantable Defibrillator and the Group Assigned to Receive Conventional Medical Therapy.

The difference in survival between the two groups was significant (nominal P=0.007, by the log-rank test).

Long-Term Benefit of Primary Prevention With an Implantable Cardioverter-Defibrillator

An Extended 8-Year Follow-Up Study of the Multicenter Automatic Defibrillator Implantation Trial II

Ilan Goldenberg, MD; John Gillespie, MD; Arthur J. Moss, MD; W. Jackson Hall, PhD; Helmut Klein, MD; Scott McNitt, MS; Mary W. Brown, MA; Iwona Cygankiewicz, MD; Wojciech Zareba, MD, PhD; and the Executive Committee of the Multicenter Automatic Defibrillator Implantation Trial II

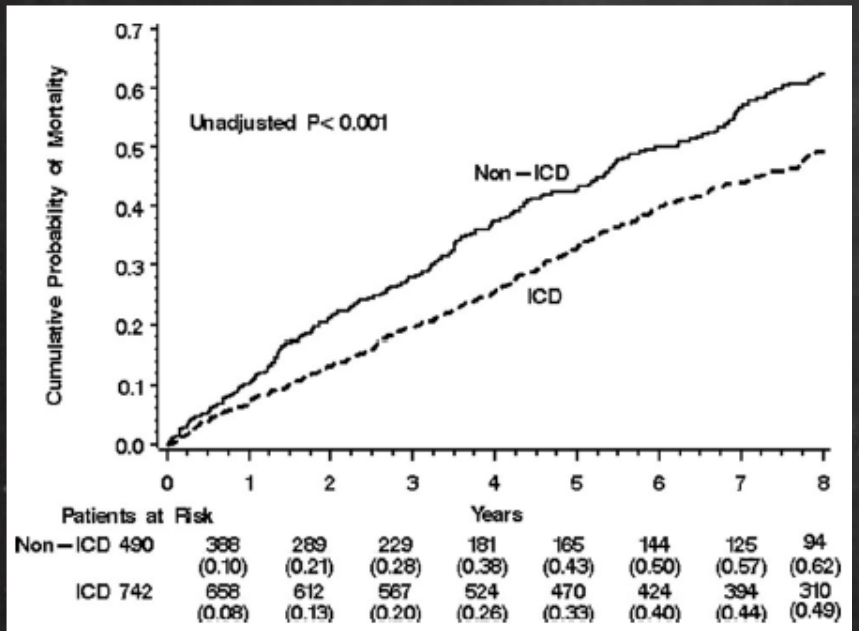


Figure 1. Kaplan-Meier estimates of the cumulative probability of all-cause mortality in ICD and non-ICD patients. All enrolled patients are included at time 0 by treatment allocation, and follow-up is censored on change in treatment arm after enrollment.

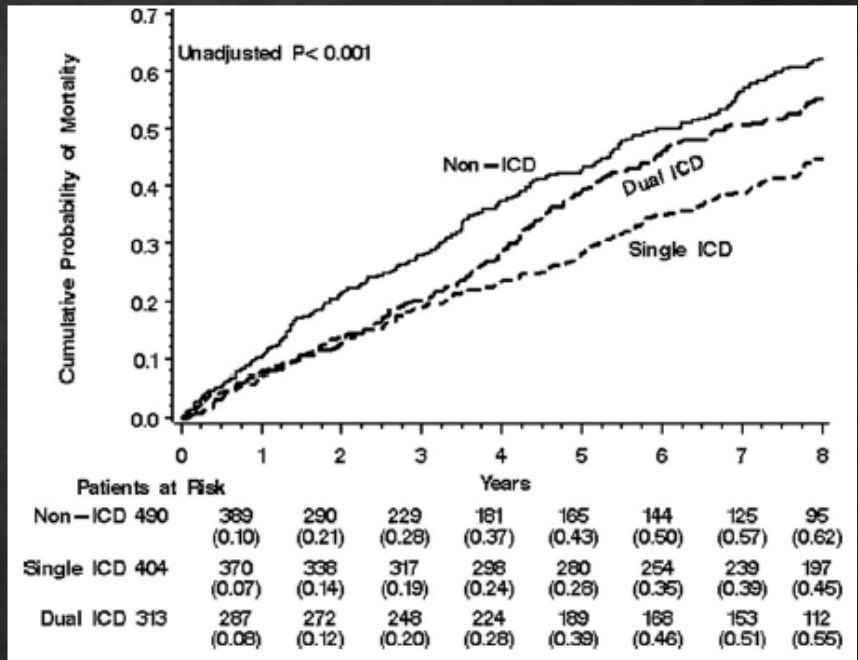


Figure 2. Kaplan-Meier estimates of the cumulative probability of all-cause mortality by in-trial device pacing type and in non-ICD patients. Follow-up is censored on change in treatment arm.

Number needed to treat: 8

(*Circulation*. 2010;122:1265-1271.)

Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark

Rikke Esberg Kirkfeldt[1,2]*, Jens Brock Johansen[2,3], Ellen Aagaard Nohr[4], Ole Dan Jørgensen[2,5], and Jens Cosedis Nielsen[1]

[1]Department of Cardiology, Aarhus University Hospital, Skejby, Denmark; [2]The Danish Pacemaker and ICD Register, Odense University Hospital, Odense, Denmark; [3]Department of Cardiology, Odense University Hospital, Odense, Denmark; [4]Department of Public Health, Section for Epidemiology, Aarhus University, Aarhus, Denmark; and [5]Department of Heart, Lung, and Vascular Surgery, Odense University Hospital, Odense, Denmark

Received 23 May 2013; revised 11 November 2013; accepted 21 November 2013; online publish-ahead-of-print 17 December 2013

Table 1 Patient and procedure characteristics

	Total ($n = 5918$)	No complication ($n = 5356$)	Complication ($n = 562$)
CIED type			
Single-chamber PM	1160 (20)	1080 (20)	80 (14)
Dual-chamber PM	3029 (51)	2758 (52)	271 (48)
CRT-P	209 (4)	189 (4)	20 (4)
Single-chamber ICD	684 (12)	627 (12)	57 (10)
Dual-chamber ICD	391 (7)	336 (6)	55 (10)
CRT-D	445 (8)	366 (7)	79 (14)

Table 2 Cumulative incidence of complications at six months[a]

	All ($n = 5918$)	New implant ($n = 4355$)	Generator replacement ($n = 1136$)	Upgrade/ lead revision ($n = 427$)
Major complications				
Lead related re-intervention	143 (2.4; 2.0–2.8)	120 (2.8; 2.3–3.2)	10 (0.9; 0.3–1.4)	13 (3.0; 1.4–4.7)
Infection	49 (0.8; 0.6–1.1)	24 (0.6; 0.3–0.8)	17 (1.5; 0.8–2.2)	8 (1.9; 0.6–3.2)
Pneumothorax requiring drainage	51 (0.9; 0.6–1.1)	45 (1.0; 0.7–1.3)	0	6 (1.4; 0.3–2.5)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

An Entirely Subcutaneous Implantable Cardioverter–Defibrillator

Gust H. Bardy, M.D., Warren M. Smith, M.B., Margaret A. Hood, M.B., Ian G. Crozier, M.B., Iain C. Melton, M.B., Luc Jordaens, M.D., Ph.D., Dominic Theuns, Ph.D., Robert E. Park, M.B., David J. Wright, M.D., Derek T. Connelly, M.D., Simon P. Fynn, M.D., Francis D. Murgatroyd, M.D., Johannes Sperzel, M.D., Jörg Neuzner, M.D., Stefan G. Spitzer, M.D., Andrey V. Ardashev, M.D., Ph.D., Amo Oduro, M.B., B.S., Lucas Boersma, M.D., Ph.D., Alexander H. Maass, M.D., Isabelle C. Van Gelder, M.D., Ph.D., Arthur A. Wilde, M.D., Ph.D., Pascal F. van Dessel, M.D., Reinoud E. Knops, M.D., Craig S. Barr, M.B., Pierpaolo Lupo, M.D., Riccardo Cappato, M.D., and Andrew A. Grace, M.B., Ph.D.

N Engl J Med 2010;363:36-44.

Cause of cardiac disease — no. (%)	
Coronary artery disease	37 (67)
Nonischemic cardiomyopathy	10 (18)
Congenital heart disease	2 (4)
Other condition	6 (11)
Indication for ICD — no. (%)	
Primary prevention	43 (78)
Secondary prevention	12 (22)

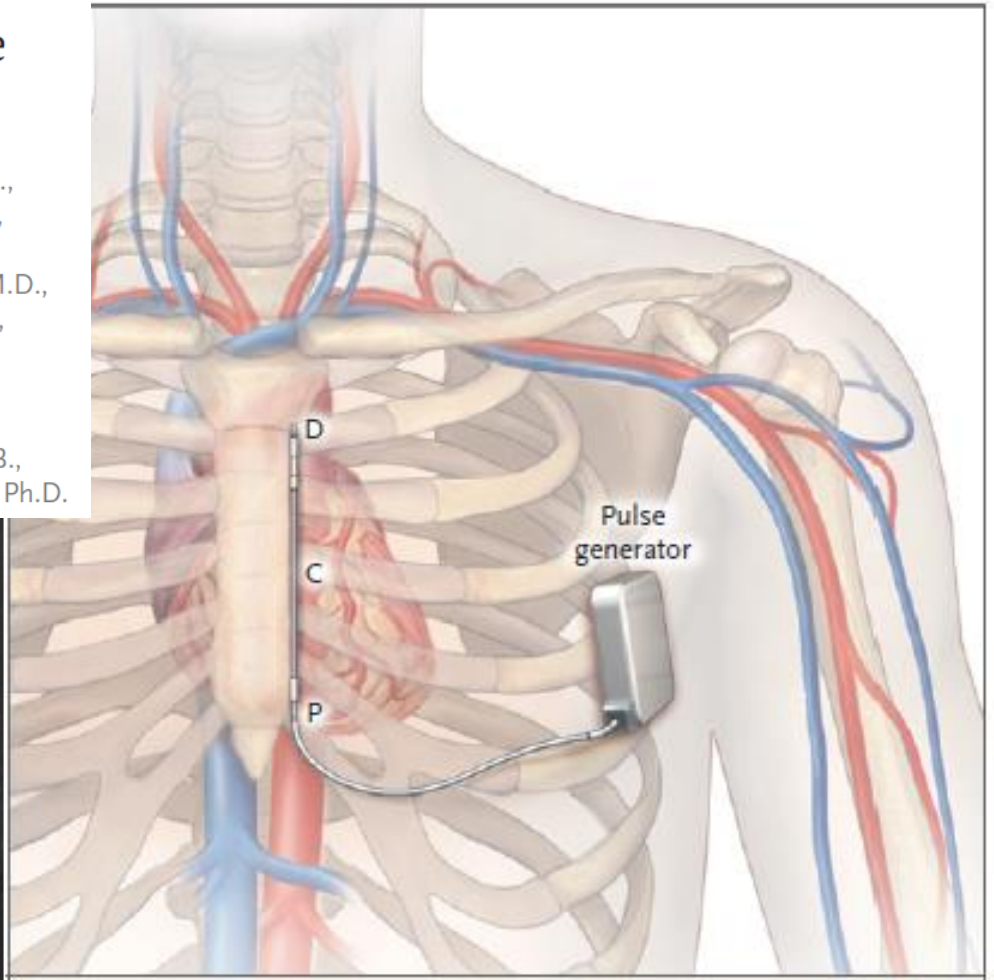


Figure 2. Locations of the Components of a Subcutaneous Implantable Cardioverter–Defibrillator In Situ.

The distal and proximal sensing electrodes (D and P, respectively) of the LGen-S8 device are shown, with the left lateral pulse generator and an 8-cm parasternal coil electrode (C).

Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry

The EFFORTLESS Study

Lucas Boersma, MD, PhD,[a,b] Craig Barr, MD,[c] Reinoud Knops, MD,[b] Dominic Theuns, PhD,[d] Lars Eckardt, MD,[e] Petr Neuzil, MD, PhD,[f] Marcoen Scholten, MD, PhD,[g] Margaret Hood, MBCHB,[h] Juergen Kuschyk, MD,[i,j] Paul Jones, MS,[k] Elizabeth Duffy, MS,[k] Michael Husby, MS, MPH,[k] Kenneth Stein, MD,[k] Pier D. Lambiase, MD, PhD,[l] on behalf of the EFFORTLESS Investigator Group

(J Am Coll Cardiol 2017;70:830–41)

Primary cardiac disease	
Previous MI/ischemia/CAD	282 (28.6)
Channelopathy*	199 (20.2)
Hypertrophic cardiomyopathy	106 (10.8)
Nonischemic cardiomyopathy	91 (9.2)
Dilated cardiomyopathy	84 (8.5)
Arrhythmogenic right ventricular dysplasia	32 (3.2)
Genetic	31 (3.1)
Valvular disease	21 (2.1)
Structural defect	19 (1.9)
Other†	44 (4.5)
Unknown	76 (7.7)

Follow up medio 3,1 anni

TABLE 2 Complications

Description	Events	Patients	% of Patients
Infection requiring device removal	27	24	2.4
Erosion	17	17	1.7
Inappropriate shock: oversensing	12	11	1.1
Other procedural complications	13	10	1.0
Hematoma	9	9	0.9
Discomfort	8	8	0.8
Suboptimal electrode position	7	7	0.7
Electrode movement	7	7	0.7
Premature battery depletion	5	5	0.5
PG movement	6	5	0.5
Unable to convert during procedure	6	5	0.5
Incision/superficial infection	5	5	0.5
Other technical complications	4	4	0.4
Suboptimal PG and electrode position	3	3	0.3
Inability to communicate with the device	3	3	0.3
Inappropriate shock: SVT above discrimination zone (normal device function)	2	2	0.2
Suboptimal pulse generator position	1	1	0.1
Total	135	115	11.7

PG = pulse generator; SVT = supraventricular tachycardia.

Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry

The EFFORTLESS Study

Lucas Boersma, MD, PhD,[a,b] Craig Barr, MD,[c] Reinoud Knops, MD,[b] Dominic Theuns, PhD,[d] Lars Eckardt, MD,[e] Petr Neuzil, MD, PhD,[f] Marcoen Scholten, MD, PhD,[g] Margaret Hood, MBCHB,[h] Juergen Kuschyk, MD,[i,j] Paul Jones, MS,[k] Elizabeth Duffy, MS,[k] Michael Husby, MS, MPH,[k] Kenneth Stein, MD,[k] Pier D. Lambiase, MD, PhD,[l] on behalf of the EFFORTLESS Investigator Group

(J Am Coll Cardiol 2017;70:830–41)

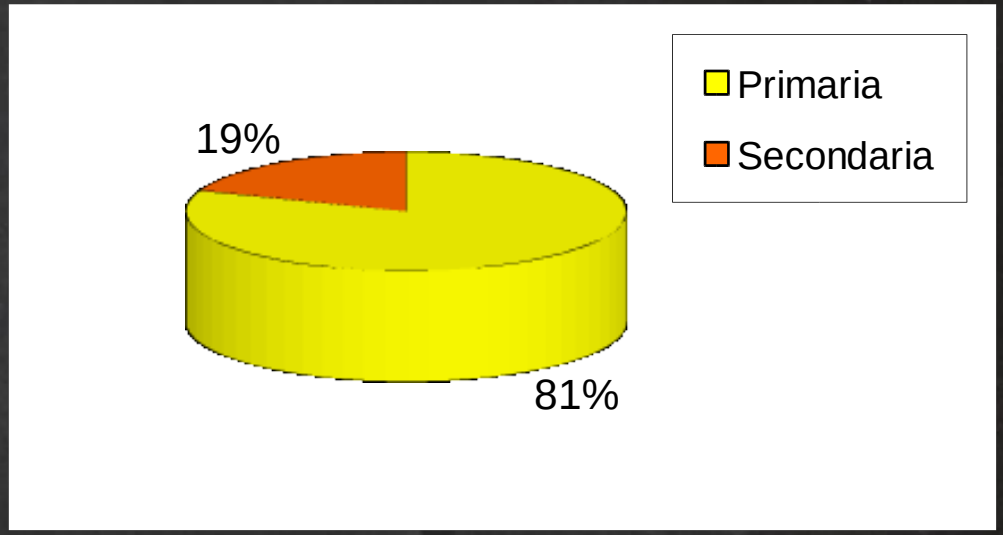
Efficacia: 97,4%

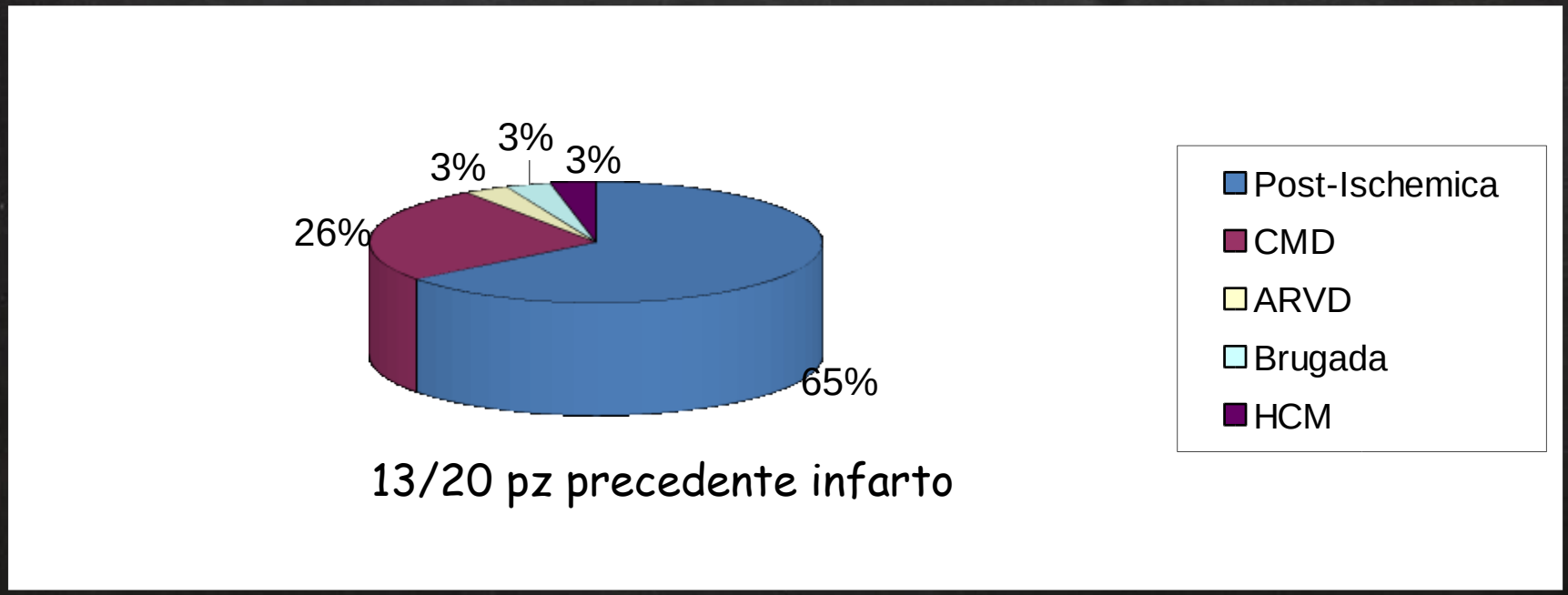
Shock appropriati
- 1anno: 5,8%
- 5 anni: 13,5%

Shock inappropriati:
1 anno: 8,1%
5 anni: 11,7%

La nostra popolazione

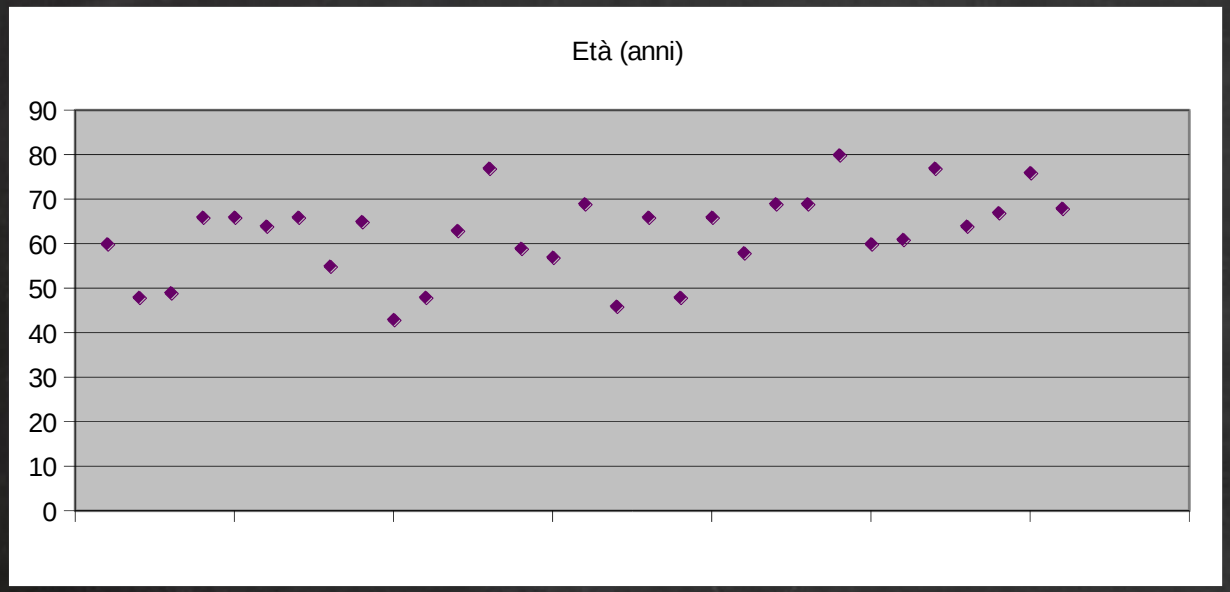
31 pazienti
(5 donne)

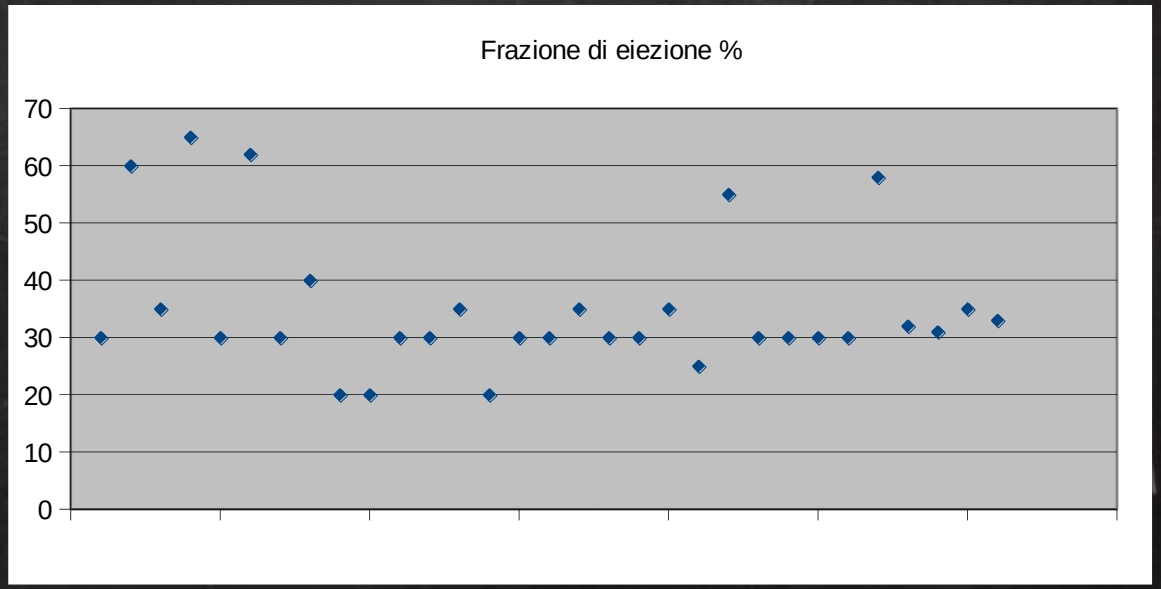




13/20 pz precedente infarto

Caratteristiche



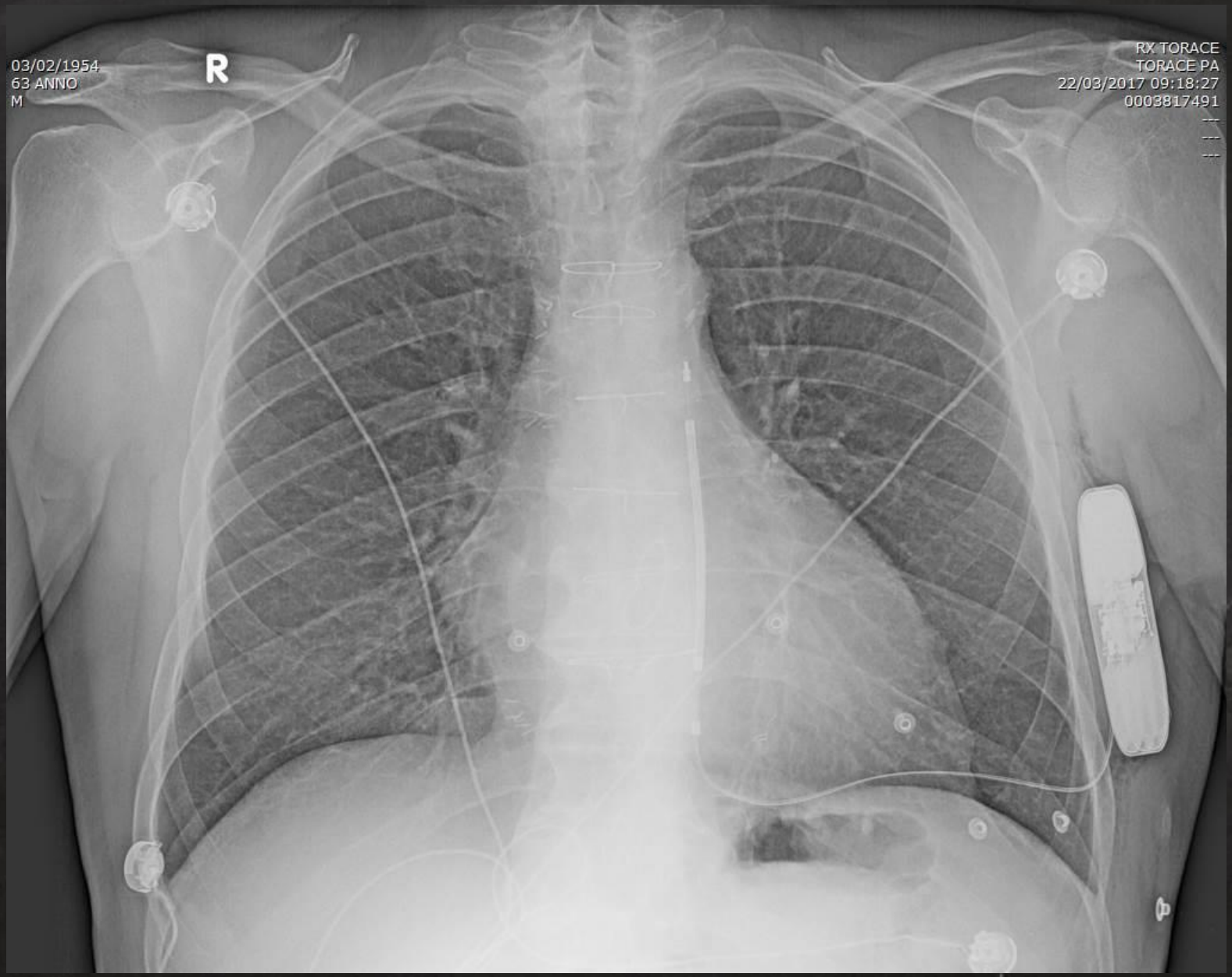


Dal 2014 al 2019

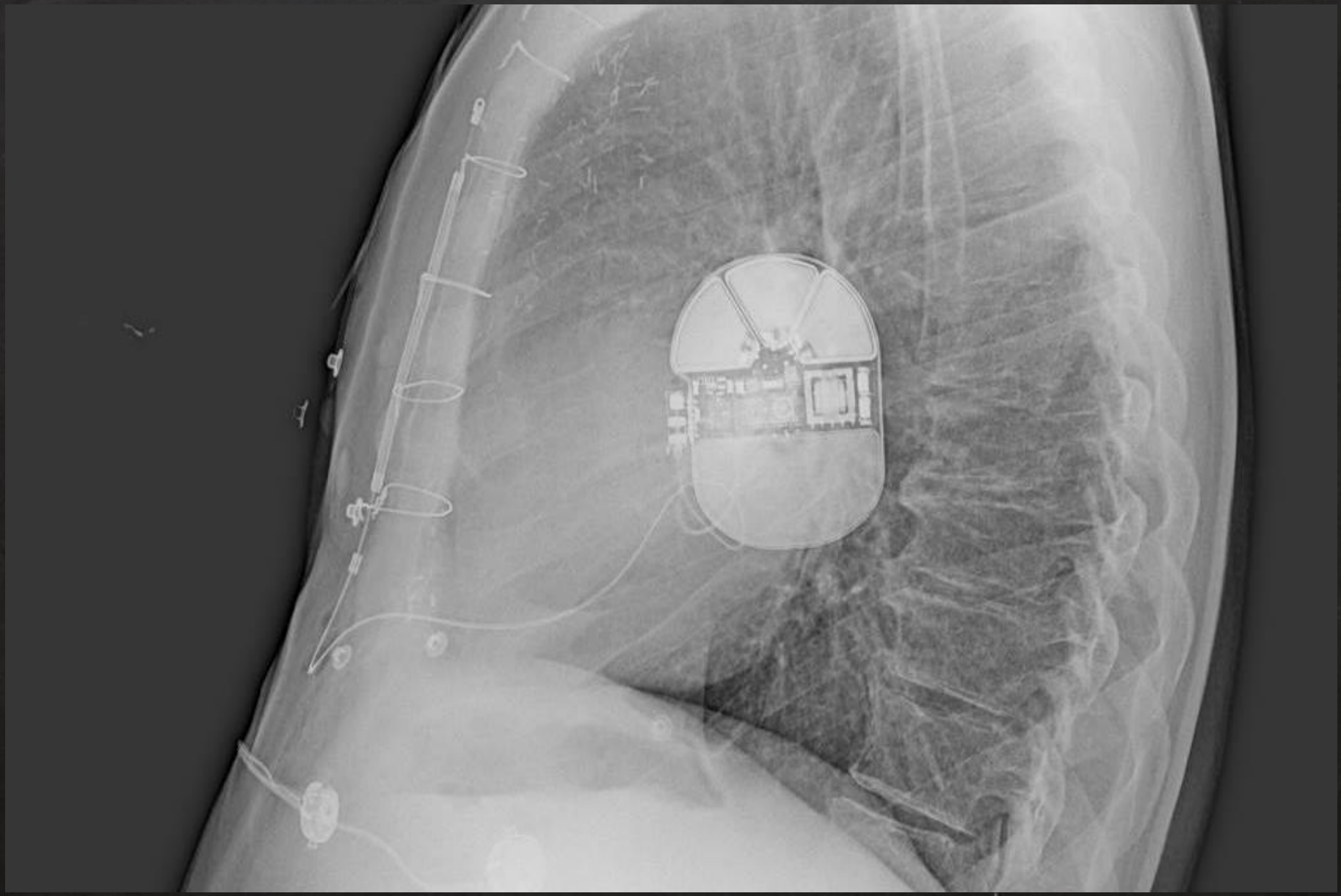
- Da tre incisioni a due incisioni
- Da screening manuale ad automatico
- Da tasca sottocutanea ad intermuscolare
- Da anestesia generale/sedazione profonda a blocco del piano del serrato (paziente sveglio)

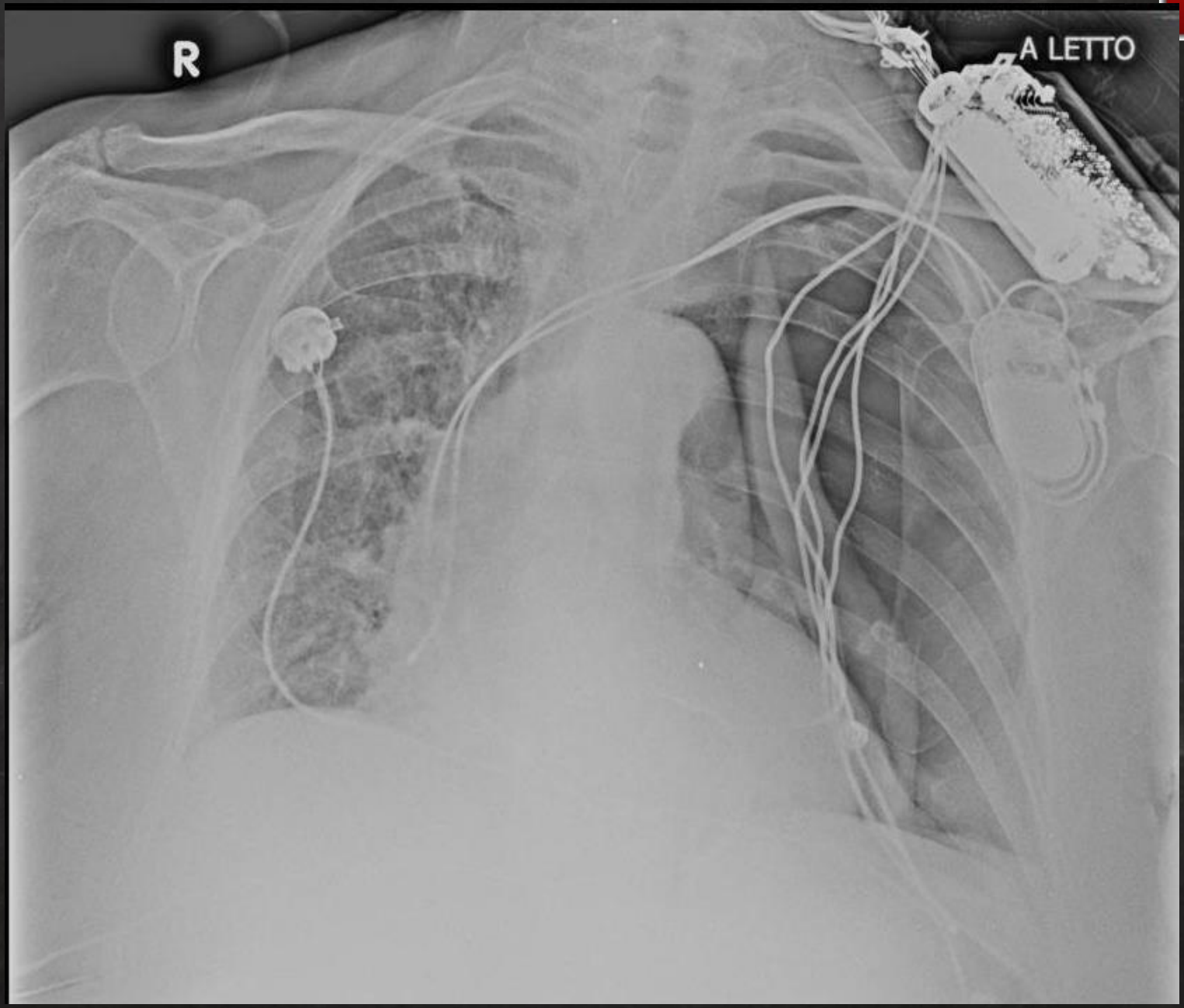
- Compatibilità MRI
- Monitoraggio remoto

RX torace

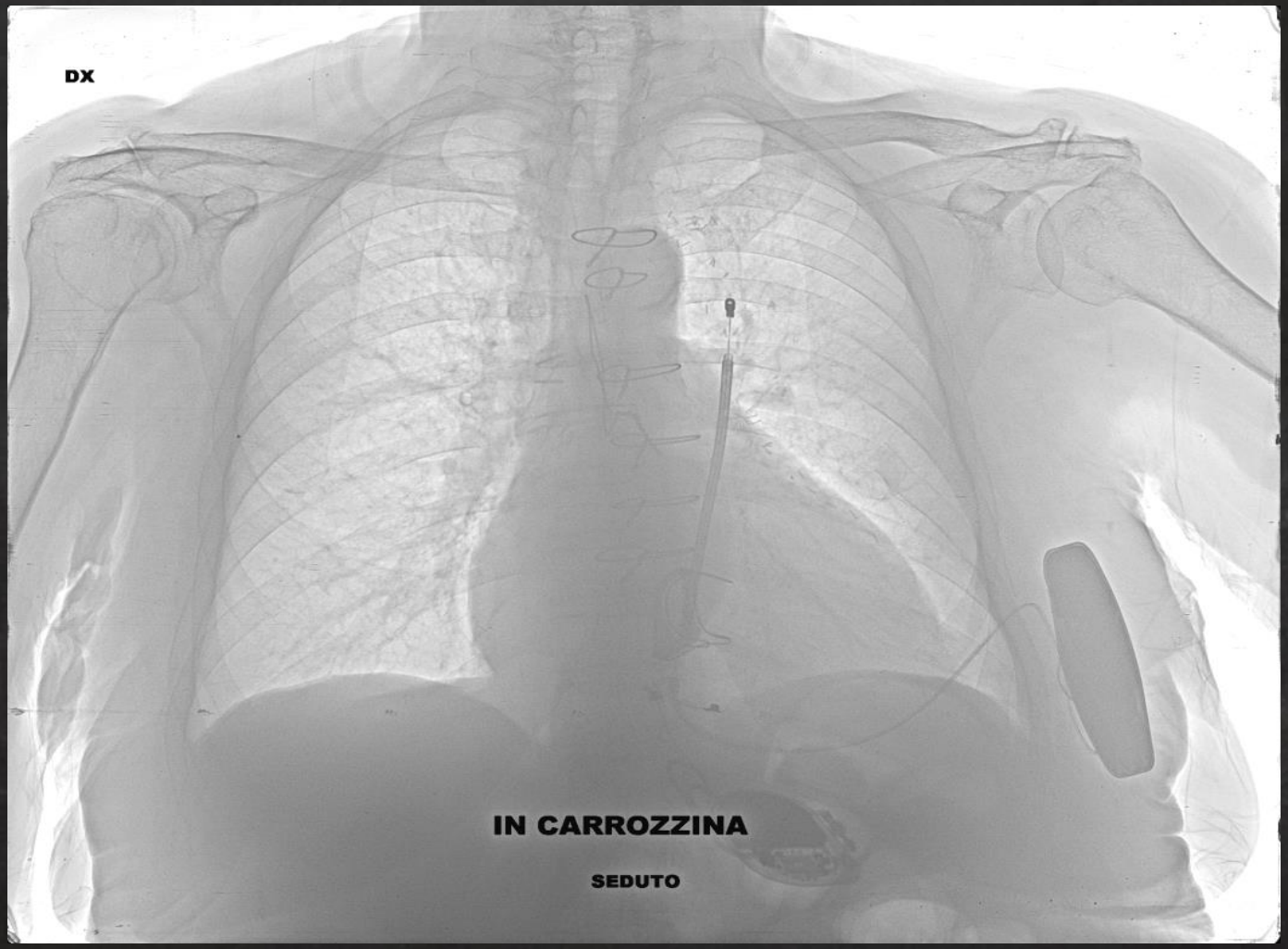

03/02/1954
63 ANNO
M
R
RX TORACE
TORACE PA
22/03/2017 09:18:27
0003817491

RX torace

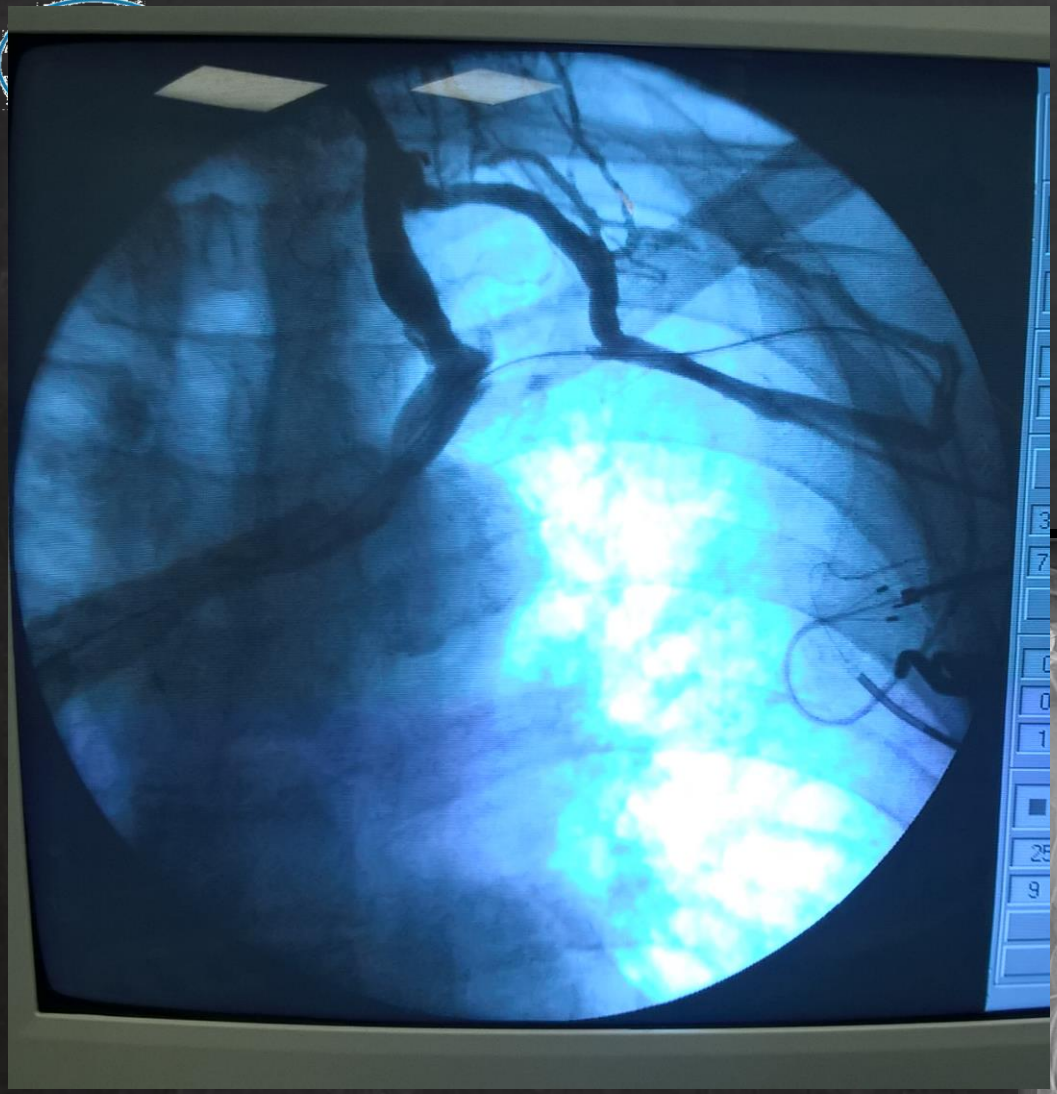


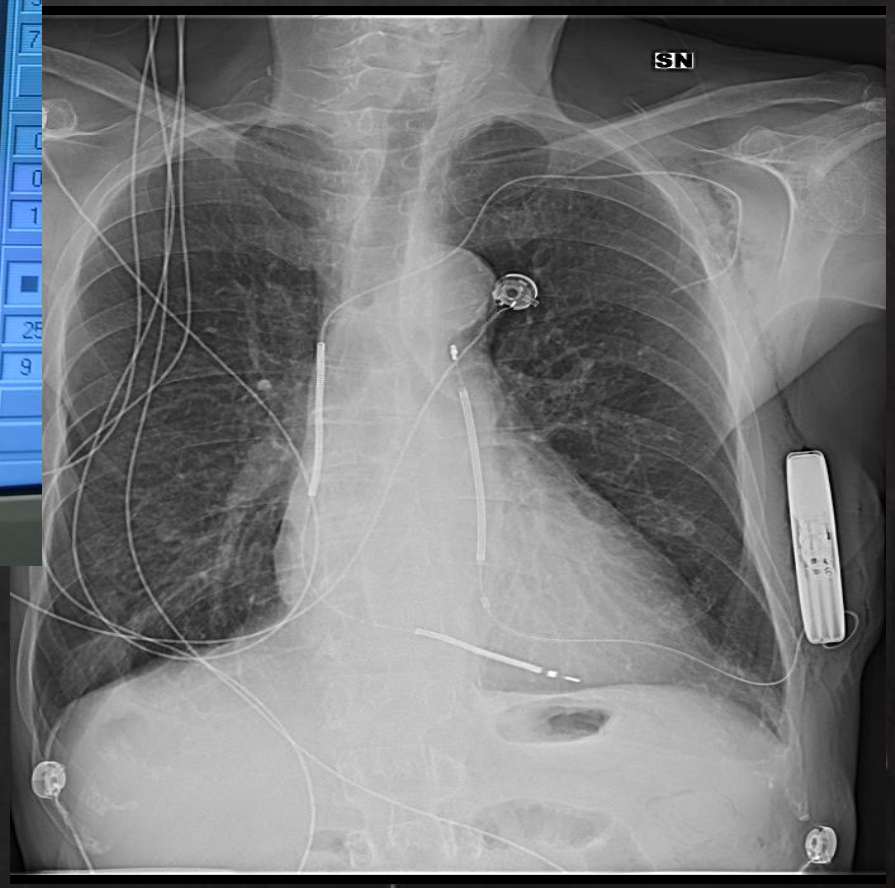

R
A LETTO

Donna 77 anni, cardiopatia ischemica (normale FE), dializzata



Arresto da TV polimorfa (non evidenti cause reversibili)... protesi valvolare tricuspidalica, portatrice di pace maker monocamerale epicardico





Uomo 76 anni, già ICD VR per CMD primitiva (FE 25-35%).

34 shock inappropriati per frattura catetere in tasca

Outcome

Tutti pazienti viventi

Nessuna complicanza

Nessuna revisione

1 intervento inappropriato

1 intervento appropriato

REFERTO COMPLETO S-ECG
TRATTATI

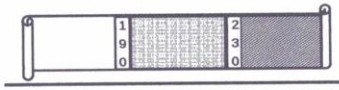
Boston Scientific

Referto stampato il: 26/08/2017 16:00
Versione software del programmatore: 4.03
Versione software del dispositivo: 3.1.529

Nominativo paziente [redacted]
Data Ultimo follow up: 30/03/2017
Data follow up: 17/07/2017
Data di Impianto: 26/07/2016

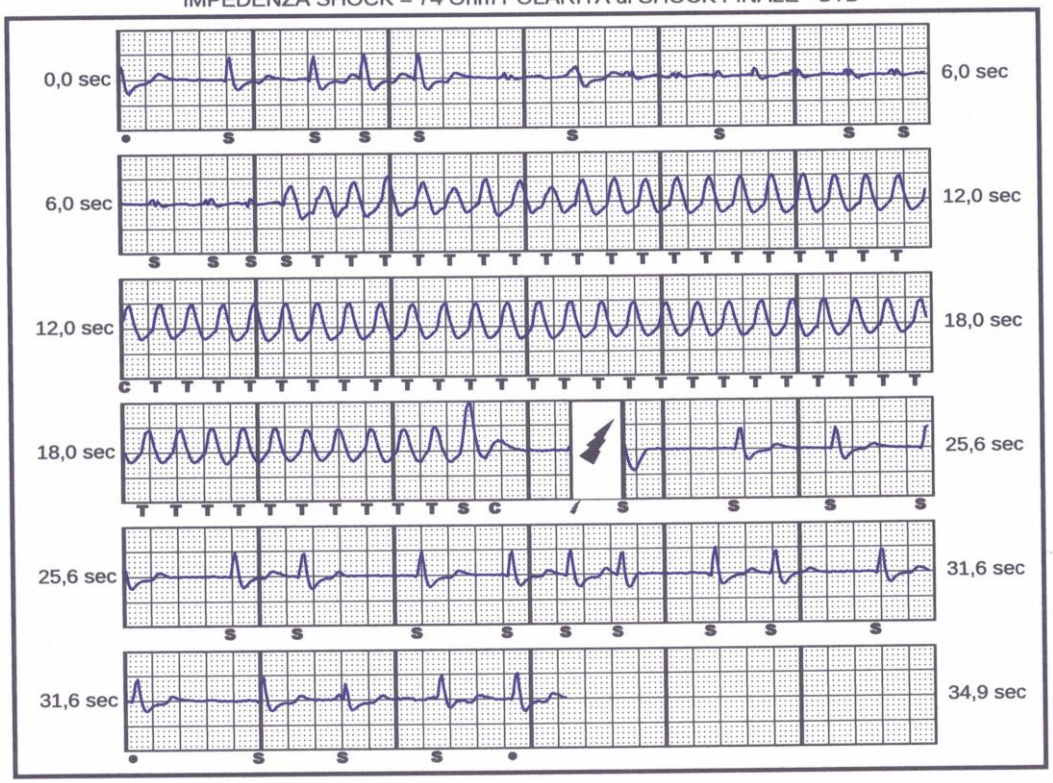
N. modello dispositivo: A219 EMBLEM™ MRI S-ICD
N. di Serie Dispositivo: 100738
N. Modello Elettrodo: 3401
N. di Serie Elettrodo: A128277

Impostazioni dispositivo
Terapia: ON
Intervallo di erogazione shock: 230 bpm
Intervallo di erogazione condizionata shock: 190 bpm
Post shock pacing: ON
SMART Pass: ON

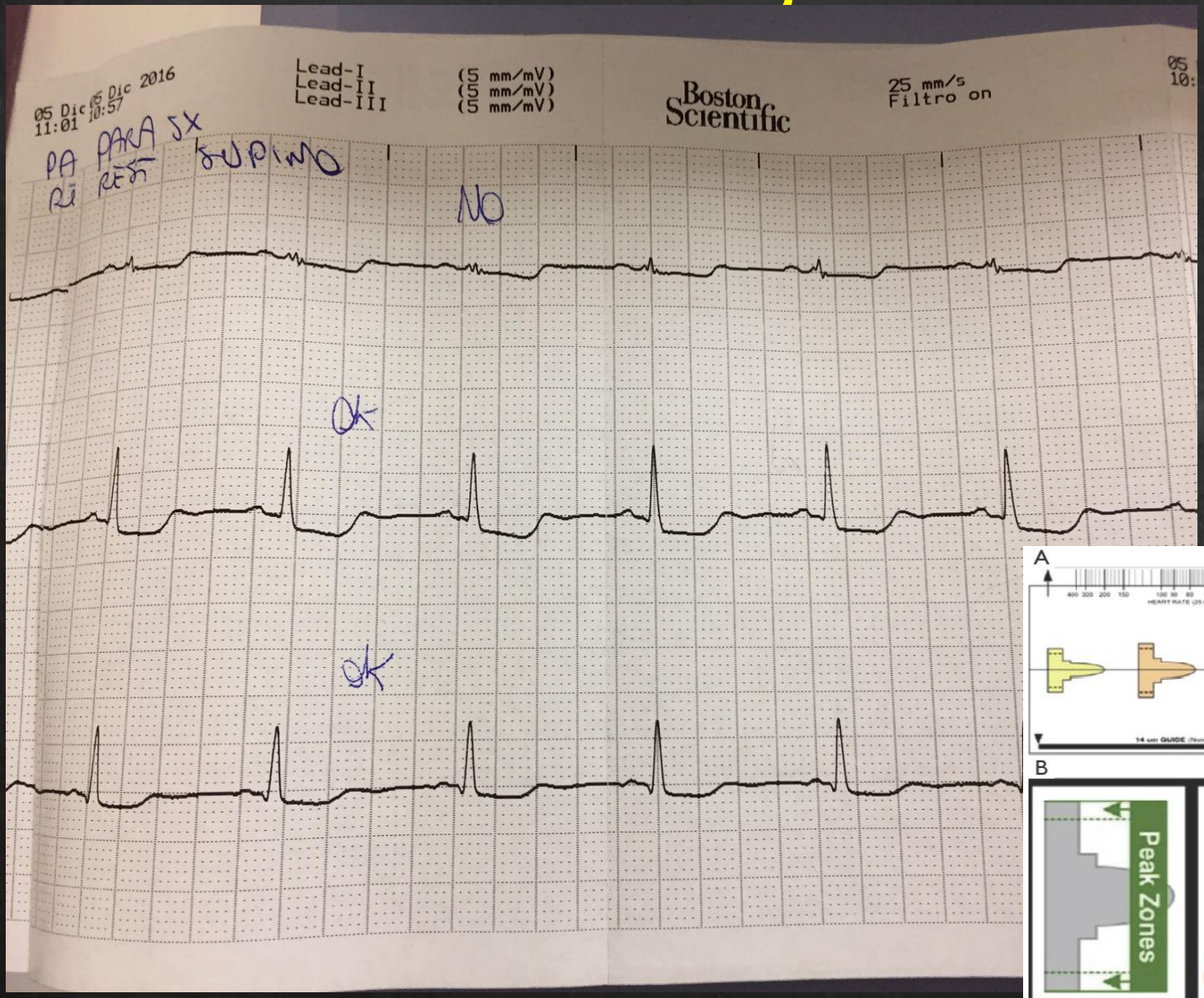


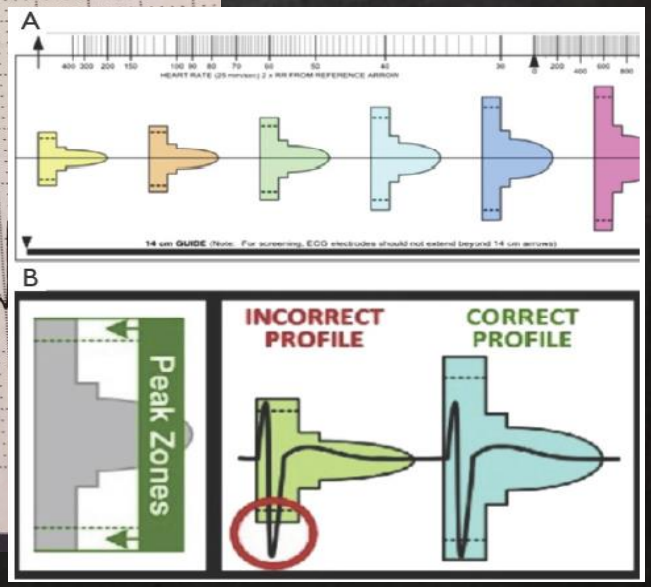
Impostazione guadagno: 1X
Configurazione di sensing: Vettore secondario
S = Battito percepito
P = Battito stimolato
N = Disturbi
T = Rilevamento tachicardia
C = Inizio carica
. = Scartato
= Shock
= Fine episodio

EPISODIO TRATTATO 002: 15/07/2017 10:57:30 25 mm/sec 2.5 mm/mV
IMPEDENZA SHOCK = 74 Ohm POLARITÀ di SHOCK FINALE= STD



Screening manuale





Screening automatico

ZOOM ® View™
Referto di screening automatico EMBLEM™ S-ICD
17 Lug 2017 12:04

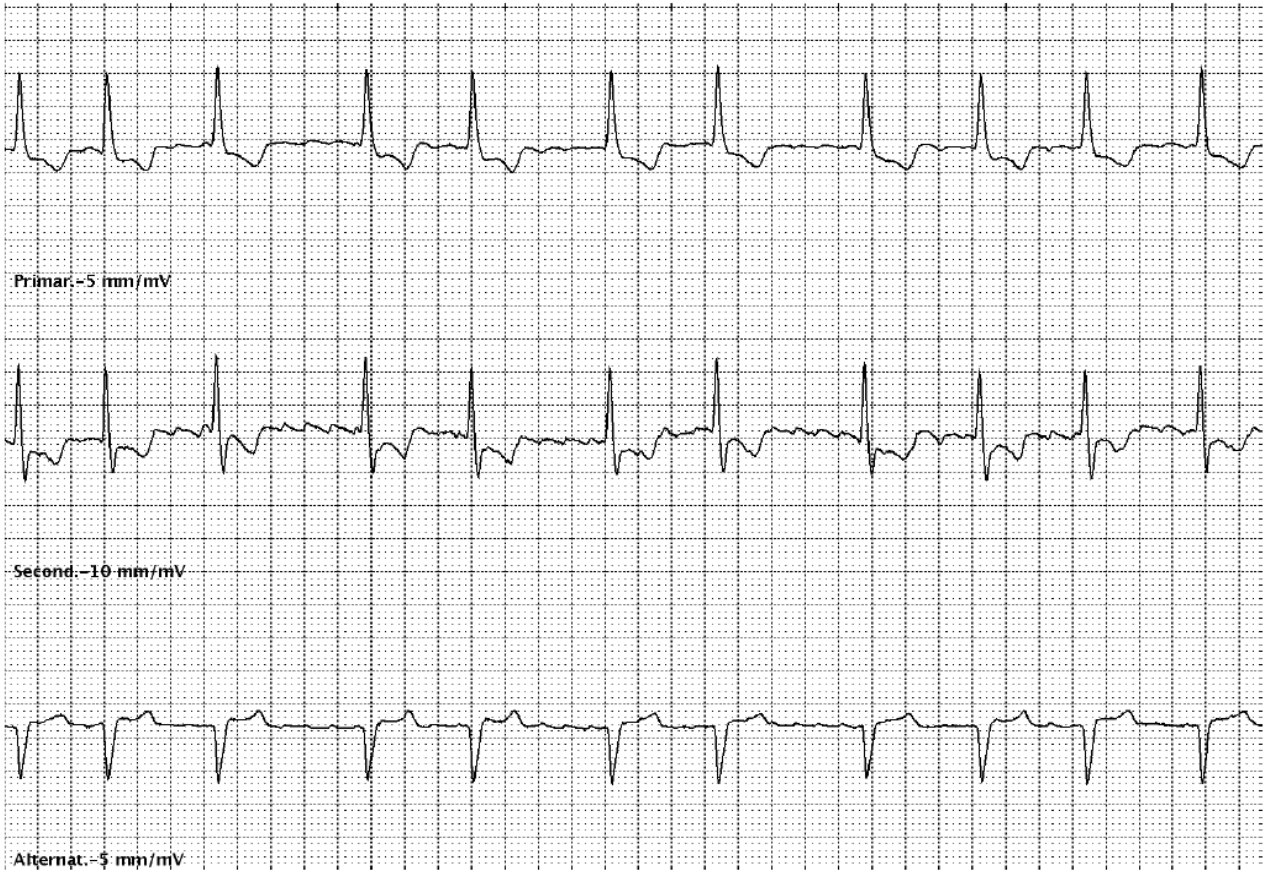
Supino

17 Lug 2017 12:01

Risultati

Primar.	OK
Second.	OK
Alternat.	OK

Note



Screening automatico

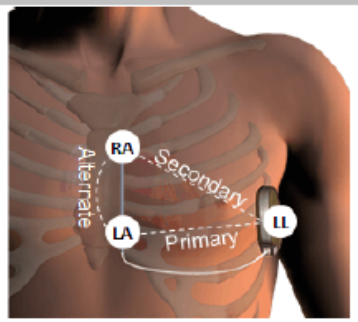
Boston Scientific

ZOOM ® View™	Report creato 17 Lug 2017 12:04
Referto di screening automatico EMBLEM™ S-ICD	
Nome paziente o ID	
Data di nascita	9 Nov 1948
Nome medico	dott. mazzuero
Nome della clinica	
Cartella medica n.	

Generali

Diagnosi:

Note screening:



Riepilogo risultati

Pos. elettr. Margine sternale sx.

Derivazione	Supino	In piedi/ Seduto	para dx-seduto	para dx-supino	Altro	Altro	La morfologia è costante fra le posture?	Indicare tutte le derivazioni accettabili*
Primar. (Lead-III)	OK	OK	OK	OK			Si ☐ No ☐	☐
Second. (Lead-II)	OK	FALLITO	OK	OK			Si ☐ No ☐	☐
Alternat. (Lead-I)	OK	OK	FALLITO	OK			Si ☐ No ☐	☐

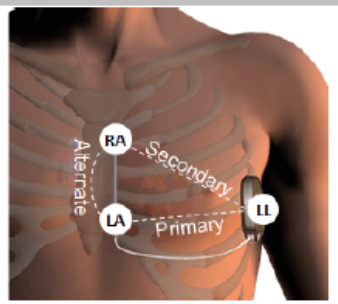
Screening fallito

Boston Scientific	ZOOM ® View™	Report creato 17 Lug 2017 15:39
	Referto di screening automatico EMBLEM™ S-ICD	
	Nome paziente o ID	
	Data di nascita	23 Feb 1970
	Nome medico	mazzuero
	Nome della clinica	
	Cartella medica n.	

Generali

Diagnosi:

Note screening:



Riepilogo risultati

Pos. elettr. Margine sternale sx.

Derivazione	Supino	In piedi/ Seduto	para dx-supino	Altro	Altro	Altro	La morfologia è costante fra le posture?	Indicare tutte le derivazioni accettabili*
Primar. (Lead-III)	FALLITO	FALLITO	FALLITO				Si ☐ No ☐	☐
Second. (Lead-II)	FALLITO	FALLITO	FALLITO				Si ☐ No ☐	☐
Alternat. (Lead-I)	FALLITO	FALLITO	FALLITO				Si ☐ No ☐	☐

Screening fallito

para dx supino

17 Lug 2017 15:37

Risultati

Primar.	FALLITO
Second.	FALLITO
Alternat.	FALLITO

Note