Azienda Ospedaliera
"Città della Salute e della Scienza di Torino"

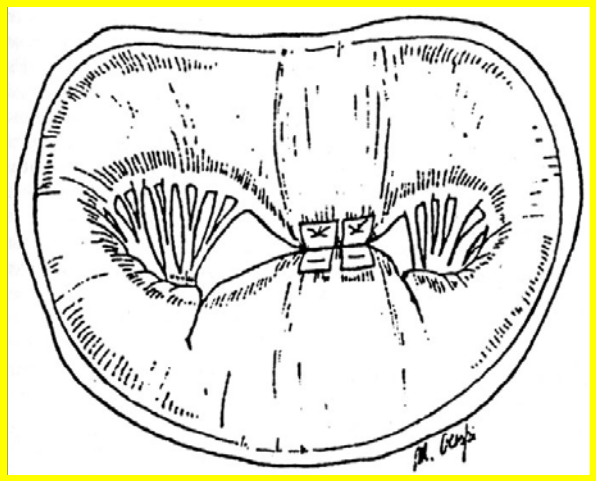
XXIV Giornate Cardiologiche Torinesi

"ADVANCES IN CARDIAC ARRHYTHMIAS AND GREAT INNOVATIONS IN CARDIOLOGY"

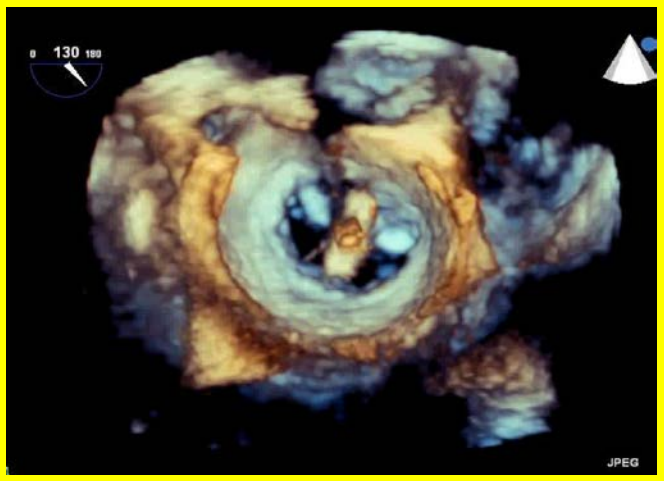
Turin, October 25-27, 2012
Centro Congressi Unione Industriale

The S.Giovanni Battista "Molinette" Hospital experience with…

Transcatheter mitral valve repair



C. Moretti

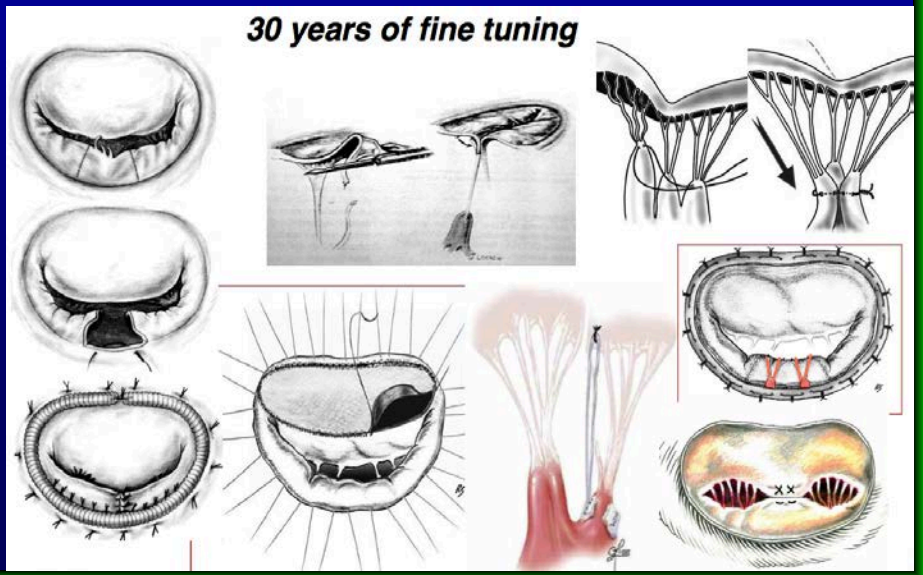


Division of Cardiology – University of Turin
Città della Salute e delle Scienza Hospital

Interventionalist meets Valve Surgeon… (Who's Who ??)

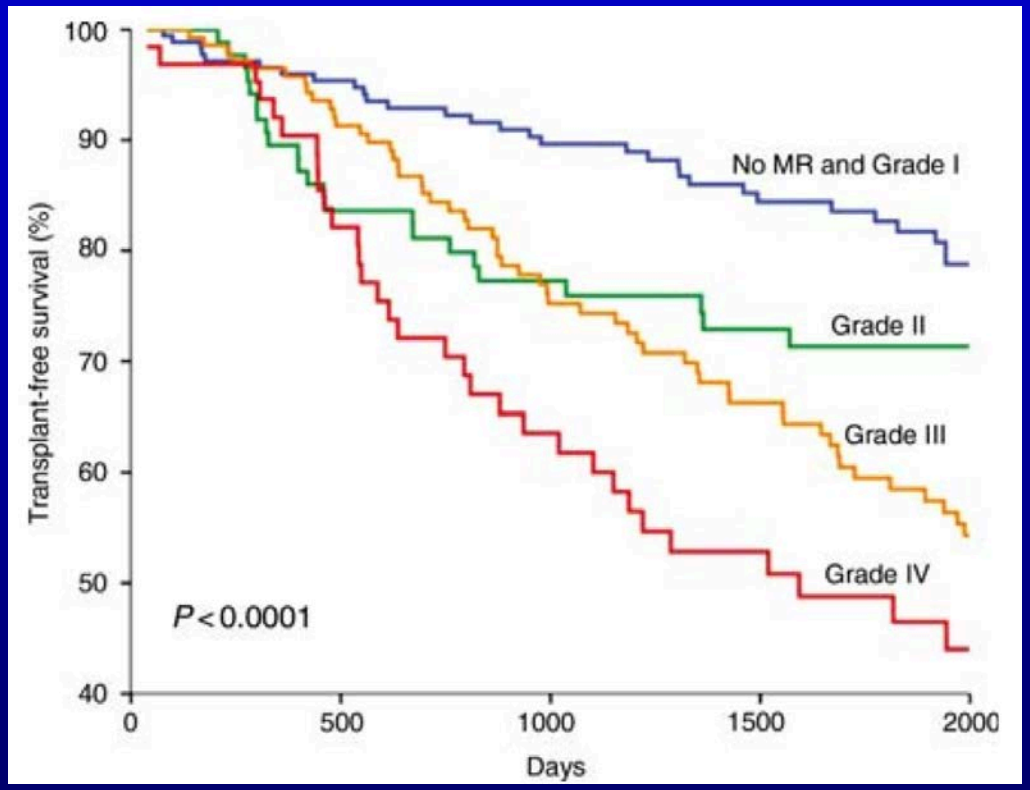
The EVEREST II Trial: Design and rationale for a randomized study of the evalve mitraclip system compared with mitral valve surgery for mitral regurgitation

Laura Mauri, MD, MSc,[a,b,c] Gaurav Garg, MBBS, MSc,[a] Joseph M. Massaro, PhD,[b] Elyse Foster, MD,[d] Donald Glower, MD,[e] Paul Mehoudar, MS,[f] Ferolyn Powell, MS,[f] Jan Komtebedde, DVM,[f] Elizabeth Abbottmott, MS,[f] and Ted Feldman, MD[g] *Boston, MA; San Francisco and Menlo Park, CA; Durham, NC; and Evanston, IL*



Functional Mitral Regurgitation

PROGNOSTIC IMPLICATION



Prognostic implications of functional mitral regurgitation according to the severity of the underlying chronic heart failure: a long-term outcome study. Bursi et al. European Journal of Heart Failure (2010) 12, 382–388

469 CHF PTS, 5-YR F.UP

- One in six pts with severe FMR
- The degree of FMR correlated with LV remodelling , systolic disfunction and symptoms.
- FMR significantly associated with a progressively increased risk of death or heart TX.

Unmet Needs

Euro Heart Survey:

Surgery for Functional Mitral Regurgitation Not an Option


Clinical research

What are the characteristics of patients with severe, symptomatic, mitral regurgitation who are denied surgery?

Isolated MR (n=877)

No Severe MR (n=331)

Severe MR (n=546)

No Symptoms (n=144)

Symptoms (n=396)

No Intervention (n=193) 49%

Intervention (n=203) 51%

Mirabel et al, European Heart J 2007;28:1358-1365

Impact of Mitral Valve Annuloplasty on Mortality Risk in Patients With Mitral Regurgitation and Left Ventricular Systolic Dysfunction

Audrey H. Wu, MD, MPH,* Keith D. Aaronson, MD, MS,* Steven F. Bolling, MD, FACC,†
Francis D. Pagani, MD, PHD, FACC,† Kathy Welch, MS, MPH,‡ Todd M. Koelling, MD, FACC*
Ann Arbor, Michigan

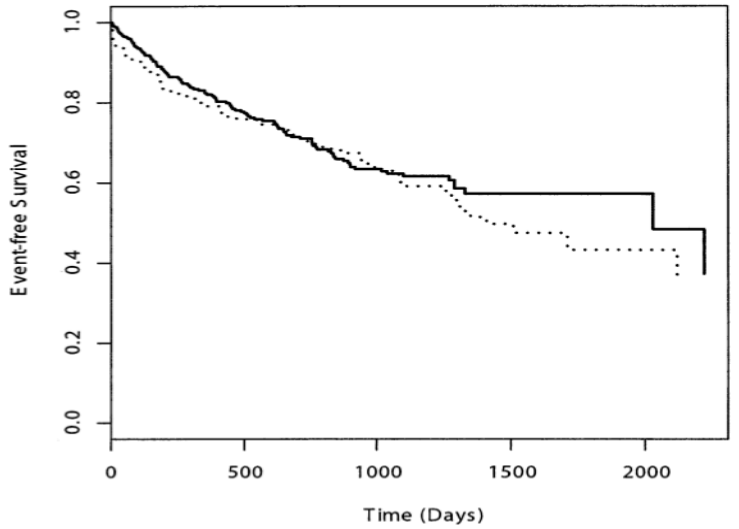


Figure 1. Event-free survival for non-mitral-valve annuloplasty (MVA) group **(solid line)** and MVA group **(dotted line)**.

"…retrospective analysis of this large cohort of patients with LV disfunction and significant MR demonstrates no mortality benefit conferred by undergoing MVA. (…)MVA was not associated with the combined endpoint of death, LV assist device implantation, or UNOS status 1 heart transplantation".

Background in the Management (Moderate-Severe) Secondary MR

1. Operative mortality is higher than in primary MR
2. Long-term prognosis is worse (comorbidities)
3. No evidence that surgery prolongs life (5-yrs death 50%)
    1. CABG alone does not correct MR in most patients
    2. Untreated MR is associated with recurrent HF and death
    3. Functional improvement uniformly reported after MVS
4. Persistence and high recurrence rate of MR after MV repair

Non randomized observational trials for most

Retrospective trials

One randomized study not powered to evaluate the outcome has compared CABG with CABG/MVRepair in moderate ischemic MR

→ Improvement in class/LV function

Fattouch JTCVS 2009

Indications for mitral valve surgery in secondary mitral regurgitation

	Class	Level
Surgery is indicated in patients with severe MR undergoing CABG, and LVEF > 30%.	I	C
Surgery should be considered in patients with moderate MR undergoing CABG (Exercise echo is recommended to identify dyspnea, increase in severity of MR and in SPAP).	IIa	C
Surgery should be considered in symptomatic patients with severe MR, LVEF < 30%, option for revascularization, and evidence of viability.	IIa	C
Surgery may be considered in patients with severe MR, LVEF > 30%, who remain symptomatic despite optimal medical management (including CRT if indicated) and have low comorbidity, when revascularization is not indicated.	IIb	C

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doi:10.1093/ejcts/ezs294

ORIGINAL ARTICLE

Mitraclip therapy and surgical mitral repair in patients with moderate to severe left ventricular failure causing functional mitral regurgitation: a single-centre experience†

Maurizio Taramasso[a], Paolo Denti[a], Nicola Buzzatti[a], Michele De Bonis[a], Giovanni La Canna[a], Antonio Colombo[b], Ottavio Alfieri[a] and Francesco Maisano[a,*]

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Table 1: Preoperative clinical features

	Surgery (*n* = 91)	MitraClip (*n* = 52)	*P*-value*
Age (years)	64.9 ± 9.8	68.4 ± 9.2	0.04
Female gender, *n* (%)	21 (23.1)	9 (17.3)	0.4
Previous AMI, *n* (%)	34 (37.4)	31 (59.6)	0.01
Log EuroSCORE, *n* (%)	10.2 ± 7.4	21.9 ± 4.8	<0.0001
Previous cardiac surgery, *n* (%)	9 (9.9)	12 (23.1)	0.03
Coronary artery disease, *n* (%)	44 (48.3)	37 (71.2)	0.03
Atrial fibrillation, *n* (%)	29 (32)	37 (17.3)	0.01
Chronic renal failure, *n* (%)	16 (17.6)	30 (57.7)	<0.0001
COPD, *n* (%)	3 (3.3)	11 (21.2)	0.0005
Cerebrovascular disease, *n* (%)	6 (6.6)	5 (9.6)	0.5
Diabetes, *n* (%)	9 (9.9)	14 (26.9)	0.007
NYHA functional class, *n* (%)			
I	4 (4.4)	0	0.1
II	26 (28.6)	8 (15.4)	
III	47 (51.6)	35 (63.3)	
IV	14 (15.4)	9 (17.3)	

AMI: acute myocardial infarction; COPD: chronic obstructive pulmonary disease; NYHA: New York Heart Association.
*Student's unpaired *t*-test for continuous data; Chi-square test for categorical data.

Table 3: Perioperative results

	Surgery (*n* = 91)	MitraClip (*n* = 52)	*P*-value*
In-hospital mortality, *n* (%)	6 (6.6)	0	0.01
Acute kidney injury, *n* (%)	28 (30.7)	16 (30.7)	1
Need for CVVH, *n* (%)	2 (2.2)	3 (5.8)	0.2
LCOS, *n* (%)	3 (3.3)	4 (7.7)	0.2
Major infection/sepsis, *n* (%)	15 (16.5)	3 (3.8)	0.02
Stroke, *n* (%)	2 (2.2)	0	0.2
AMI, *n* (%)	0	0	Na
Discharge MR ≥ 3+, *n* (%)	0	5 (9.6)	0.002

CVVH: continuous veno-venous haemofiltration; LCOS: low cardiac output syndrome; AMI: acute myocardial infarction; MR: mitral regurgitation.
*Chi-square test.

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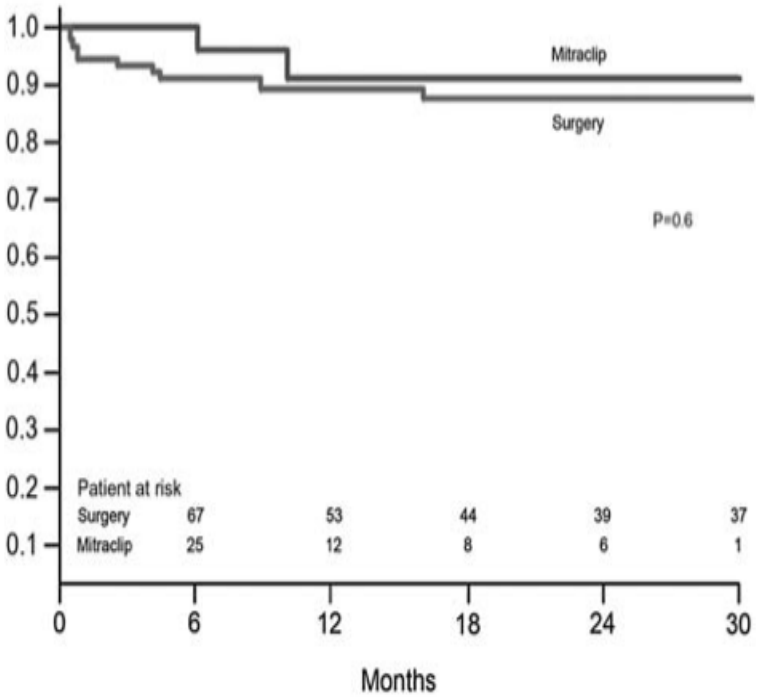
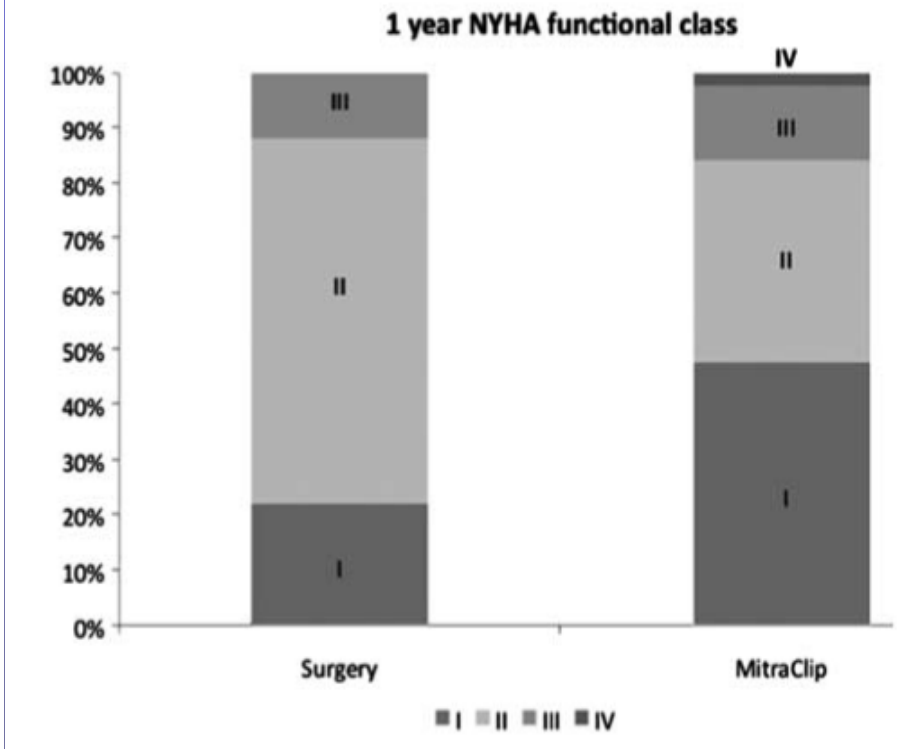




Left Cardiac Chambers Reverse Remodeling after Percutaneous Mitral Valve Repair with the MitraClip System

Salvatore Scandura, MD, Gian Paolo Ussia, MD, FSCAI, Piera Capranzano, MD, Anna Caggegi, MD, Kunal Sarkar, MD, Valeria Cammalleri, MD, Sarah Mangiafico, MD, Marta Chiarandà, MD, Sebastiano Immè, MD, Fabio Di Pasqua, MD, Anna Maria Pistritto, MD, Giovanni Millan, MD, and Corrado Tamburino, MD, PhD, FESC, FSCAI, *Catania, Italy*

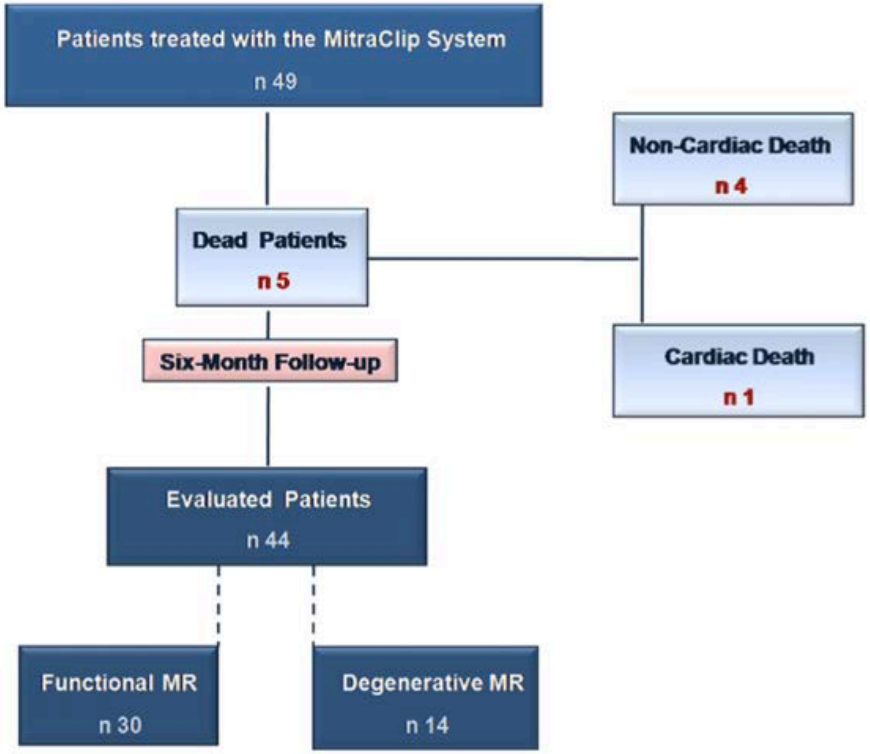
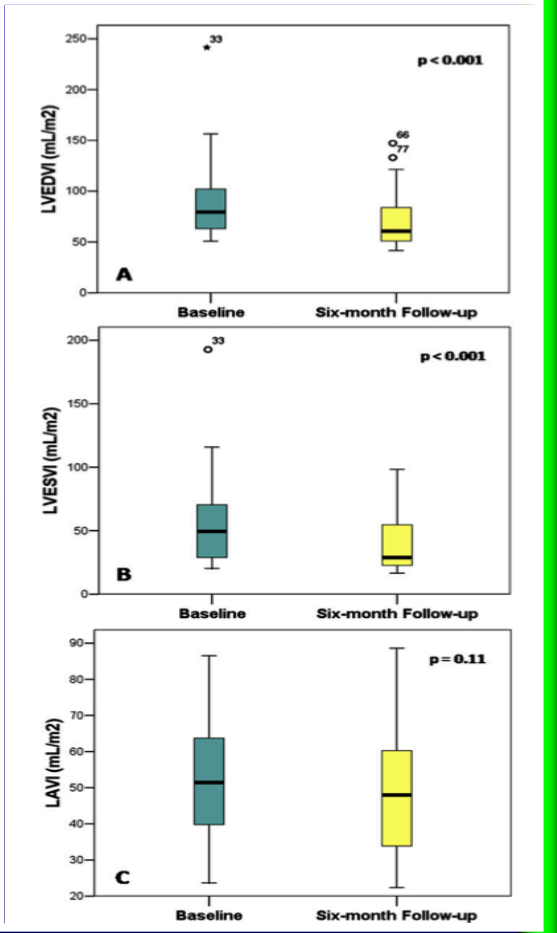


Figure 1 Study flow diagram.



ACCESS-EU Phase I

Demographics and Co-morbidities	EVEREST II RCT Device Patients N=178	EVEREST II High Surgical Risk Cohort N=211	ACCESS EU – MitraClip Patients N=567
Age (mean ± SD), years	67 ± 13	76 ± 10	74 ± 10
Logistic EuroSCORE, (%)			
Mean ± SD	NA	NA	23 ± 18
Logistic EuroSCORE ≥ 20%, (%)	NA	NA	45
STS Mortality Risk, (%)			
Mean ± SD	5 ± 4	12 ± 8	NA
STS Mortality Risk ≥ 12%, (%)	6	48	NA
Male Gender, (%)	64	61	64
Coronary Artery Disease, (%)	47	81	63
Previous Cardiovascular Surgery, (%)	23	58	37
Myocardial Infarction, (%)	22	49	32
Cerebrovascular Disease, (%)	8	21	13
Moderate to Severe Renal Failure, (%)	3	31	42
Atrial Fibrillation, (%)	33	64	68
NYHA Functional Class III or IV, (%)	50	86	85

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Demographics and Co-morbities

Age (mean ± SD), years	67 ± 13	76 ± 10	74 ± 10
Logistic EuroSCORE, (%)			
Mean ± SD	NA	NA	23 ± 18
Mitral Regurgitation Grade ≥ 3+, (%)	96	86	98
Ejection Fraction < 40%, (%)	6	28	53
Functional MR, (%)	27	71	77
Ischemic	NA	NA	42
Non-ischemic	NA	NA	58
Degenerative MR, (%)	73	29	23

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Site reported 1 Yr Safety Events

1-Year Events*	All Patients N=567	Logistic EuroSCORE ≥20% N=253	Logistic EuroSCORE <20% N=314	p-value
Death	98 (17.3%)	58 (22.9%)	40 (12.7%)	<0.05
Stroke	6 (1.1%)	4 (1.6%)	2 (0.6%)	ns
Myocardial Infarction	8 (1.4%)	5 (2.0%)	3 (1.0%)	ns
Renal Failure	49 (8.6%)	29 (11.5%)	20 (6.4%)	<0.05
Respiratory Failure	5 (0.9%)	4 (1.6%)	1 (0.3%)	ns
Need for Resuscitation	12 (2.1%)	9 (3.6%)	3 (1.0%)	<0.05
Cardiac Tamponade	7 (1.2%)	4 (1.6%)	3 (1.0%)	ns
Bleeding Complications	27 (4.8%)	16 (6.3%)	11 (3.5%)	ns

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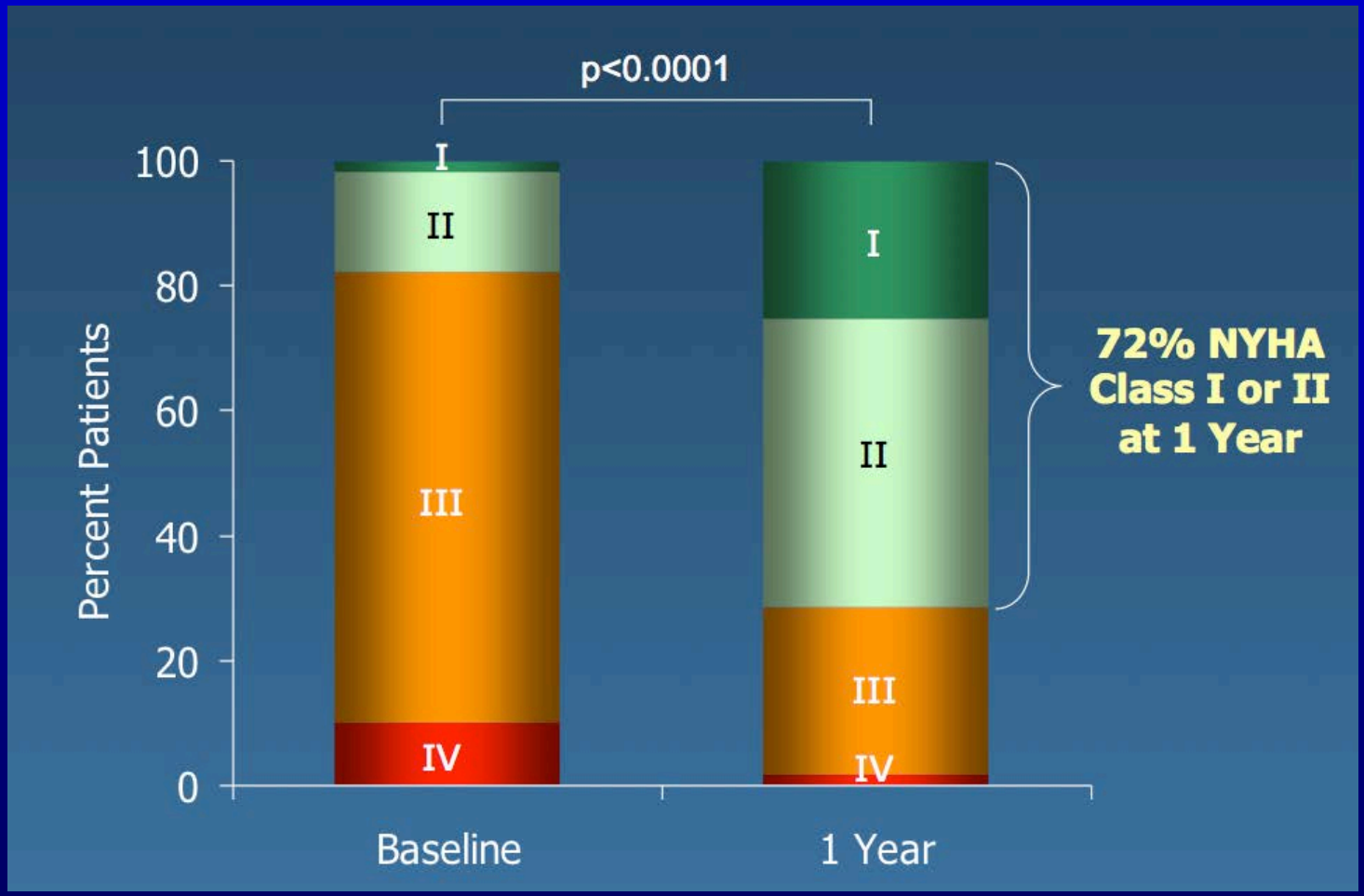
NYHA Class



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TURIN'S EXPERIENCE

FIRST 10 CASES

Baseline Demographics and Co-morbidities

	N=10
Age (mean)	67,6
Gender, males	8
NYHA III-IV	2
CCS	1 (class II)
Previous HF hosp. < 6 months	7
History of CAD	8
Previous STEMI	5
Previous cardiovascular surgery	4 (only CABGs)
Previous stroke	1
Hypertension	7
Diabetes mellitus	5
Dyslipedmia	
COPD	
Moderate-severe renal failure (GFR ≤ 59)	
Previous cancer	1

Mitral regurgitation etiology was FUNCTIONAL in ALL patients

Baseline echocardiografic parameters

		N=10
Ejection fraction % (mean)		26,8%
LVES volume (ml, mean)		171
LVED volume (ml, mean)		237
LA volume (ml, mean)		129
Mitral regurgitantion severity		
	3+/4+	1 pt
	4+/4+	9 pts
PISA radium (mm, mean)		9
EROA (cm^2, mean)		0,56
Mitral valve anulus (mm, mean)		43
Mitral valve area (cm^2, mean)		5,3
Coaptation depth ETE (mm ,mean)		10,7
Coaptation lenght ETE (mm, mean)		3,35
PAPs exstimated (mmHg, mean)		49
PAPs exstimated ≥ 55 mmHg (nr.)		5

Baseline EKG characteristics

	N=10
Synus rythm	5
P wave duration	81 msec
Complete LBBB	2
QRS duration (mean)	134 msec
Signs of LVH	4
Pathological Q waves	2

ATRIAL FIBRILLATION

Paroxysmal n=4

Persistent n=1

Permanent n=3

Implantable devices

Pace maker only	1 pt
ICD only	5 pts
CRT-D	3 pts

Hospitalizations 6-m pre M.Clip

2 PTS → 3 EPISODES

2 PTS → 2 EPISODES

3 PTS → 1 EPISODES

Risk stratification

Logistic EuroSCORE (mean) 26,88

(4 patients < 20)

Addictive EuroSCORE (mean) 10,6

EuroSCORE II (mean) 14,52

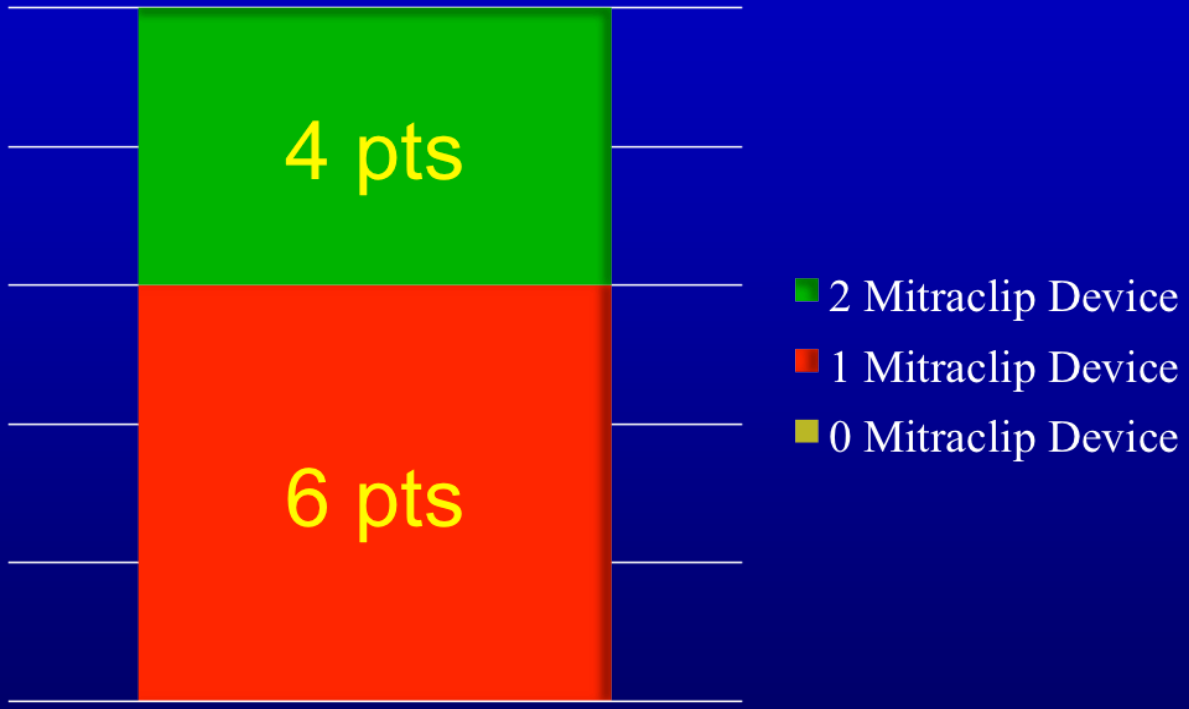
STS Score (mean) 18,23

Procedure-related datas

	N=10
Vein puncture –Interatrial Septum (IAS) puncture time (mean)	42.2 min
Vein puncture – 1 st clip opening time	114.5 min
IAS puncture – 1 st clip opening time	71.3 min
1 st clip opening - 1 st clip release time	42.9 min
Mean procedural time	3 h 21 min
1 clip positioning	3 h 9 min
2 clips positioning	3 h 40 min
DAP fluoroscopy	215,58 Gy*cm^2
DAP fluorography	2,67 Gy*cm^2
DAP total	218,26 Gy*cm^2

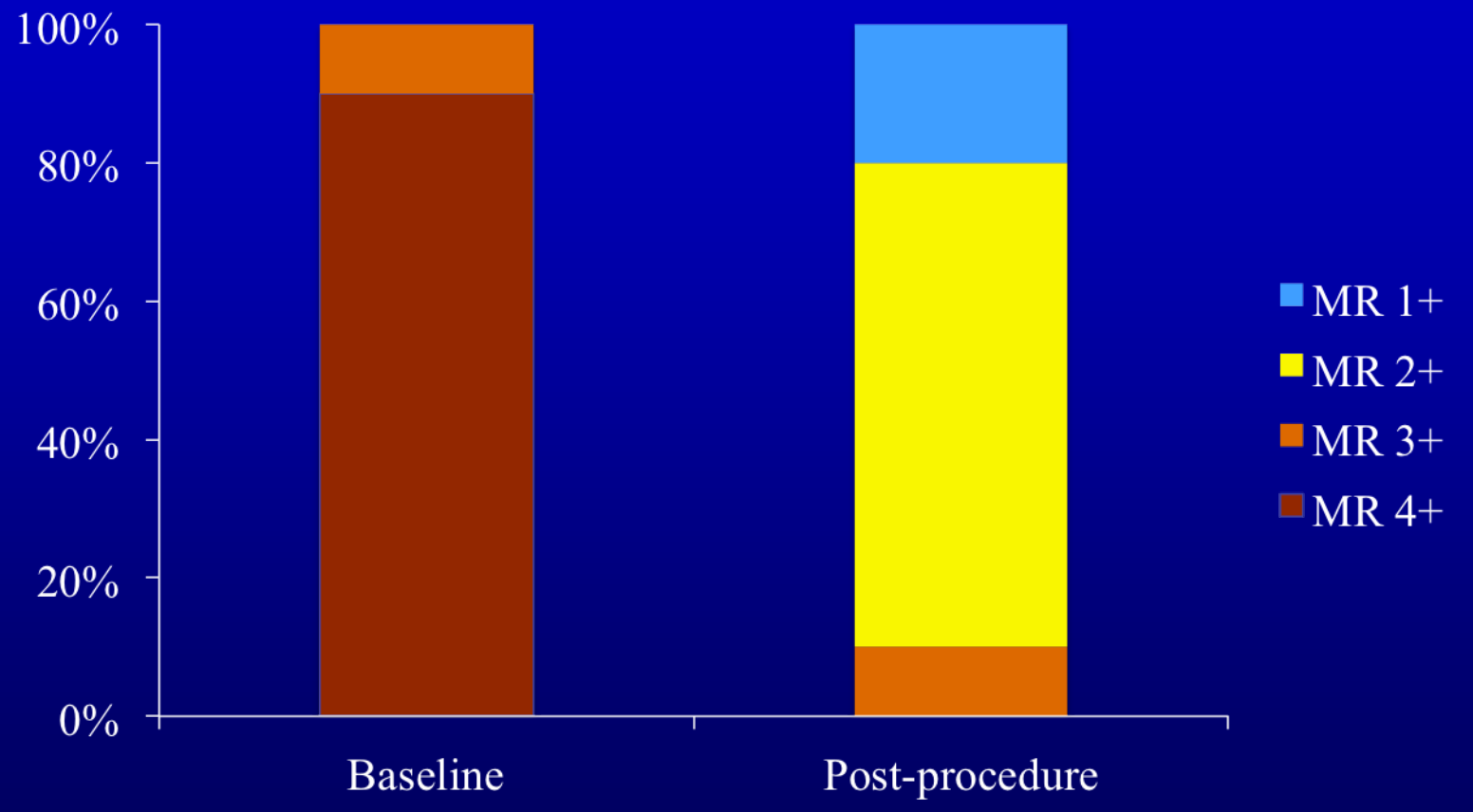
Mitraclip success implant rate

At least 1 clip was successfully implanted in all 10 patients



In one case a chordal rupture with consequent massive mitral regurgitation occurred during device positioning, solved with clip implantation (mild MR left).

Periprocedure mitral regurgitation grade



Mean transvalvular anterograde gradient after device implantation was 3,05 mmHg

In-hospital complications

	N=10
Death	0
Stroke/TIA	0
Reoperation of mitral valve	0
CV surgery	0
Myocardial infarction	0
Inotropes post-operation	6
Reintubation	0
Bleeding/transfusions	1
Ventricular tachycardia	1
Acute renal injury	1
Angina	1
Paroxysmal atrial fibrillation (peri-procedure)	2
Pneumonia	1

Hospitalization datas

	N=9
ICU stay (days, mean)	6,9
Post-operative period (days, mean)	7,9
Total hospitalization (days, mean)	15,3

3 patients were discharged at home, 6 was transferred for a cardiological rehabilitation period.

Events at follow-up

1 month follow-up for 9 patients

6 months follow-up for 4 patients

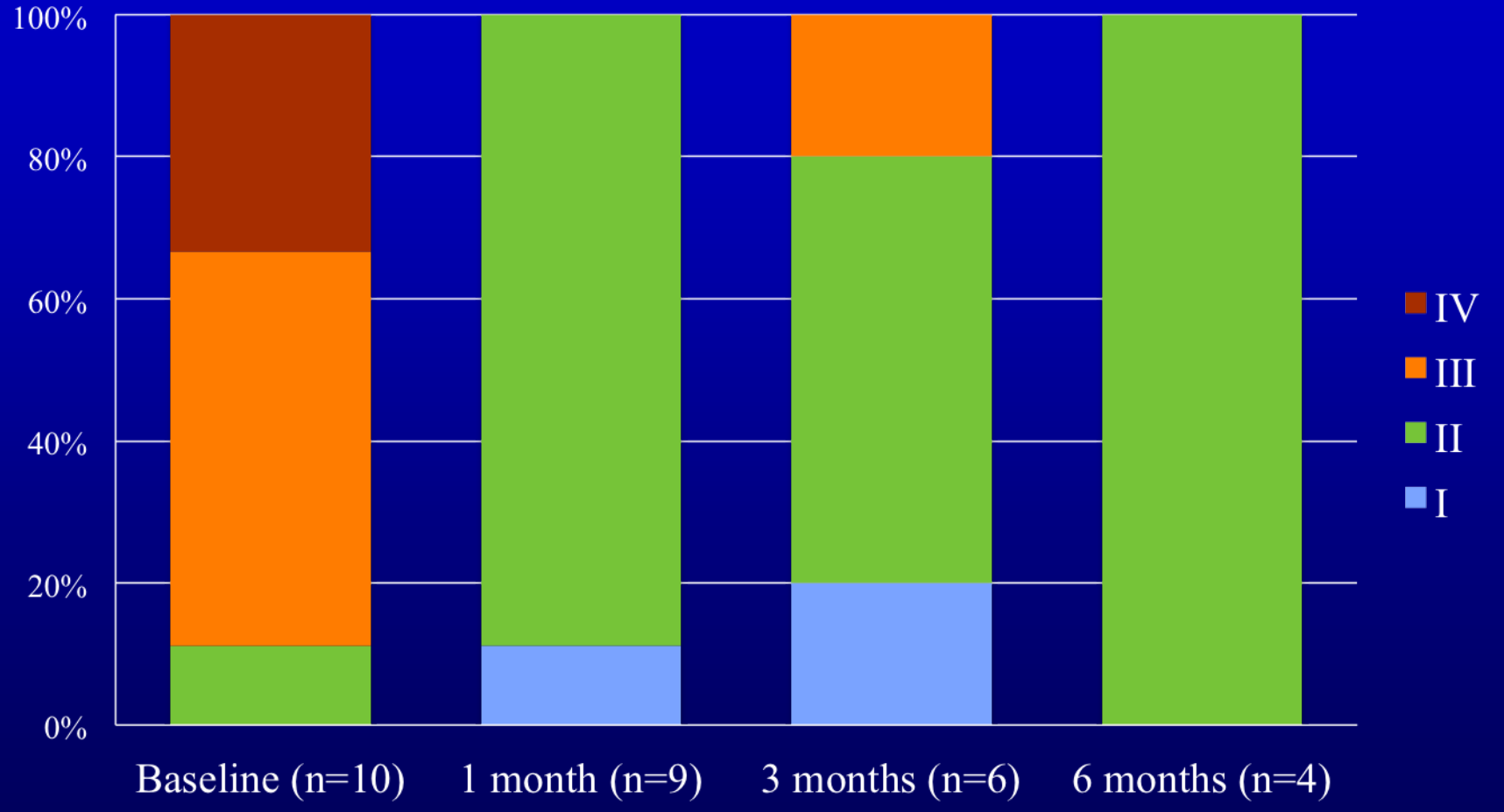
2 patients died

- 1 during an hospitalization for heart failure 74 days after clip implantation
- 1 because of road accident (not clearly known cause) 71 days after intervention

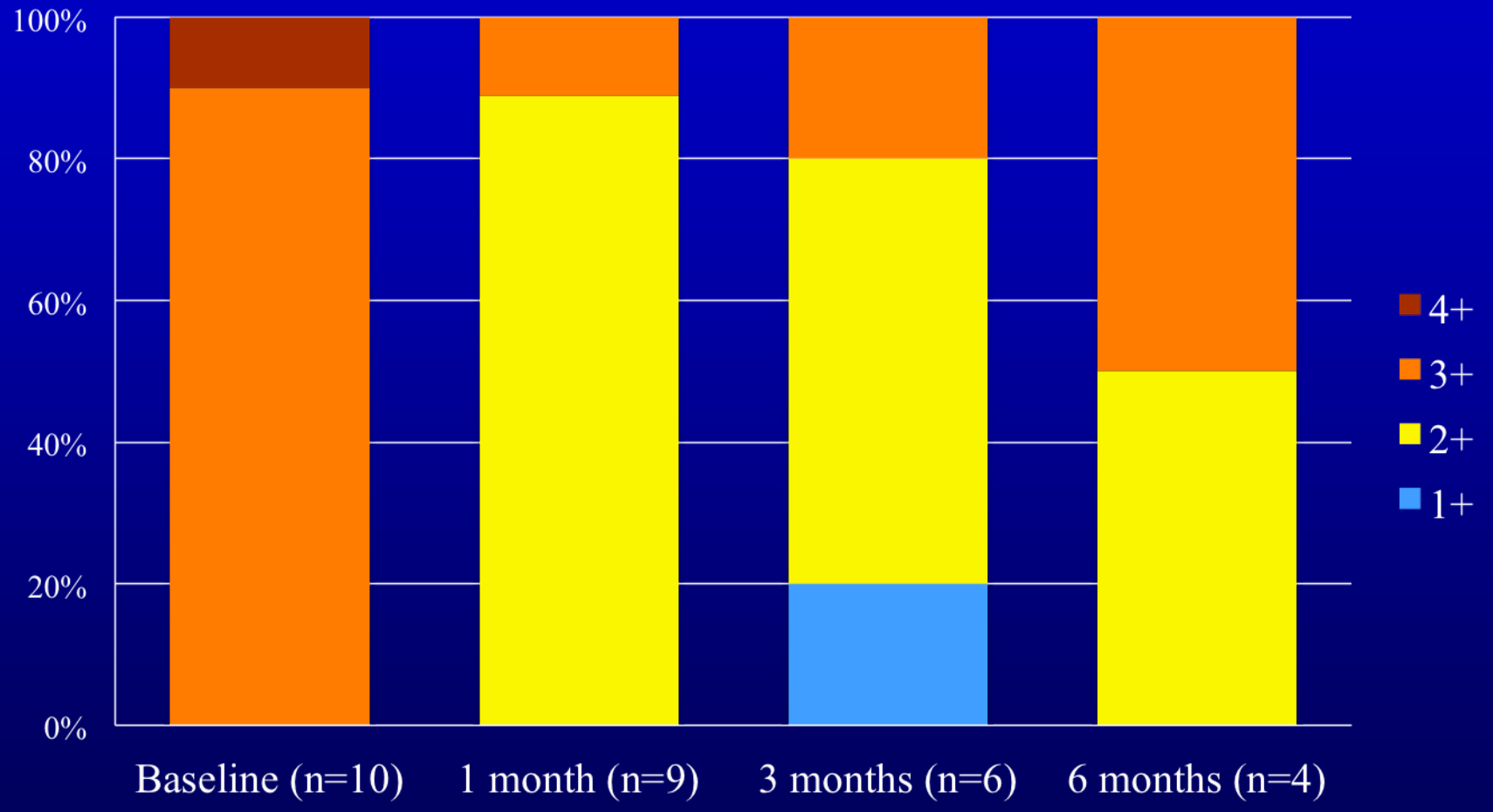
We registered 1 cardiac hospitalization for worsening heart failure (at two months)

1 non cardiac hospitalization (acute colecistitis)

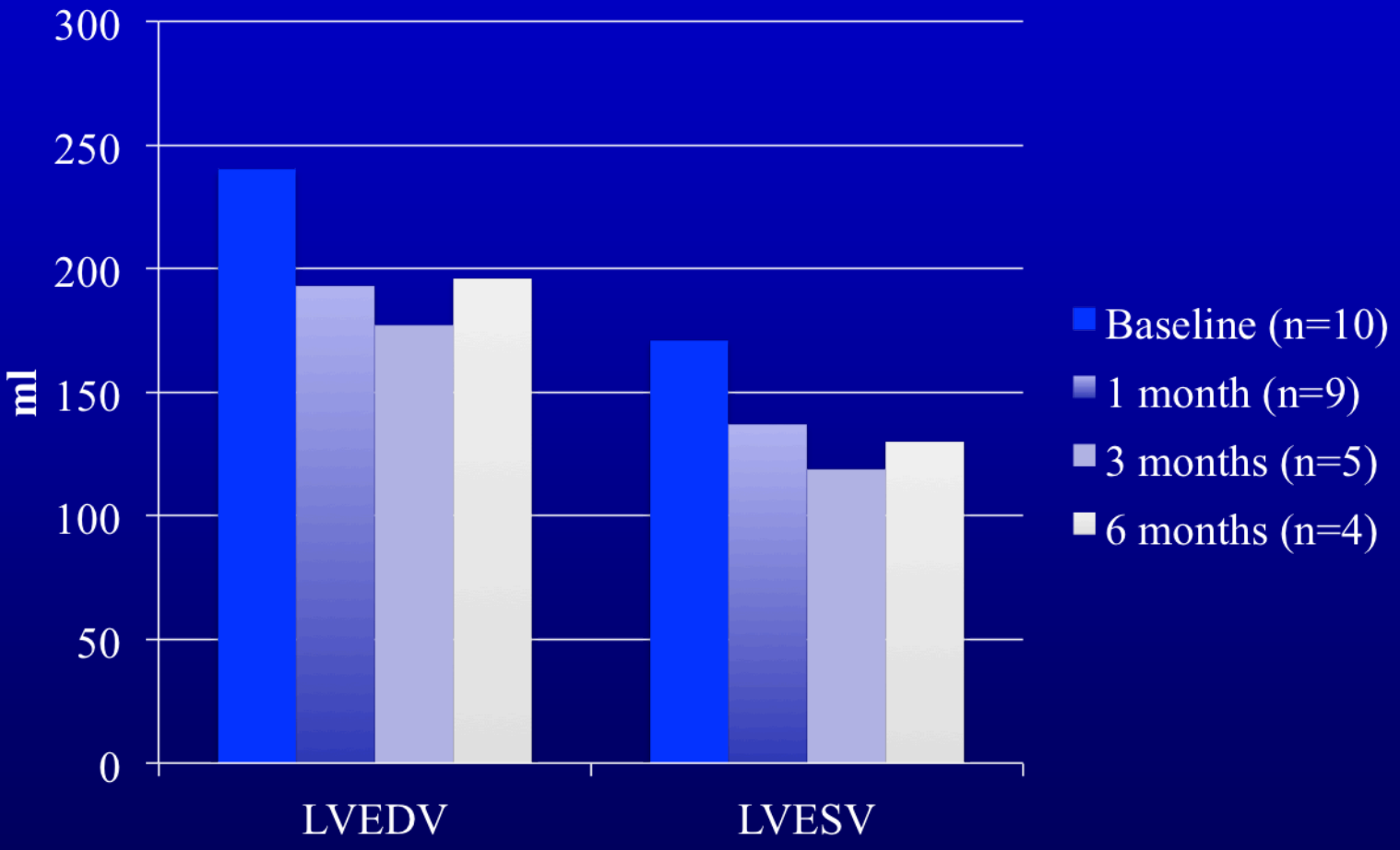
NYHA functional class – follow up



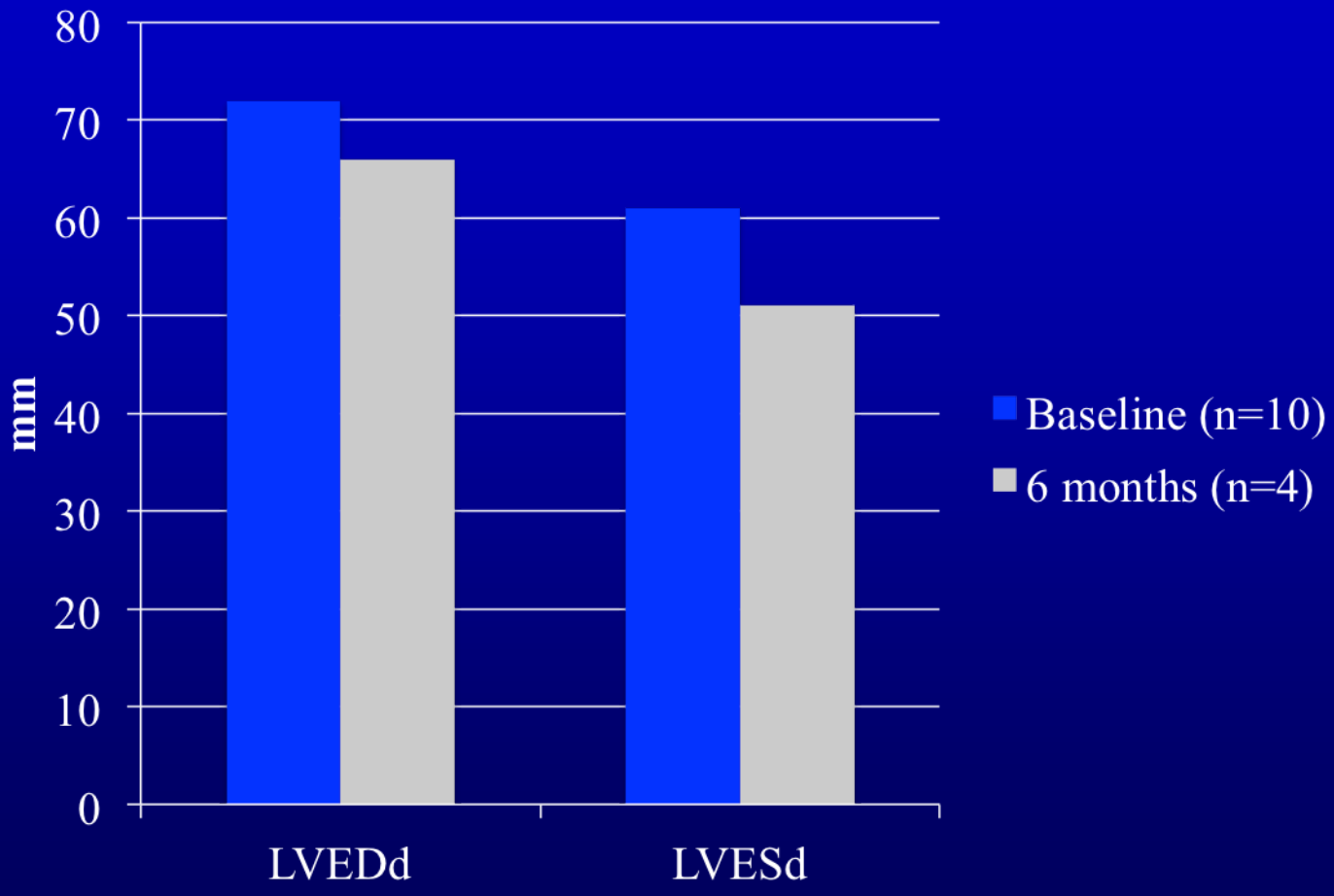
Mitral regurgitation grade – follow up



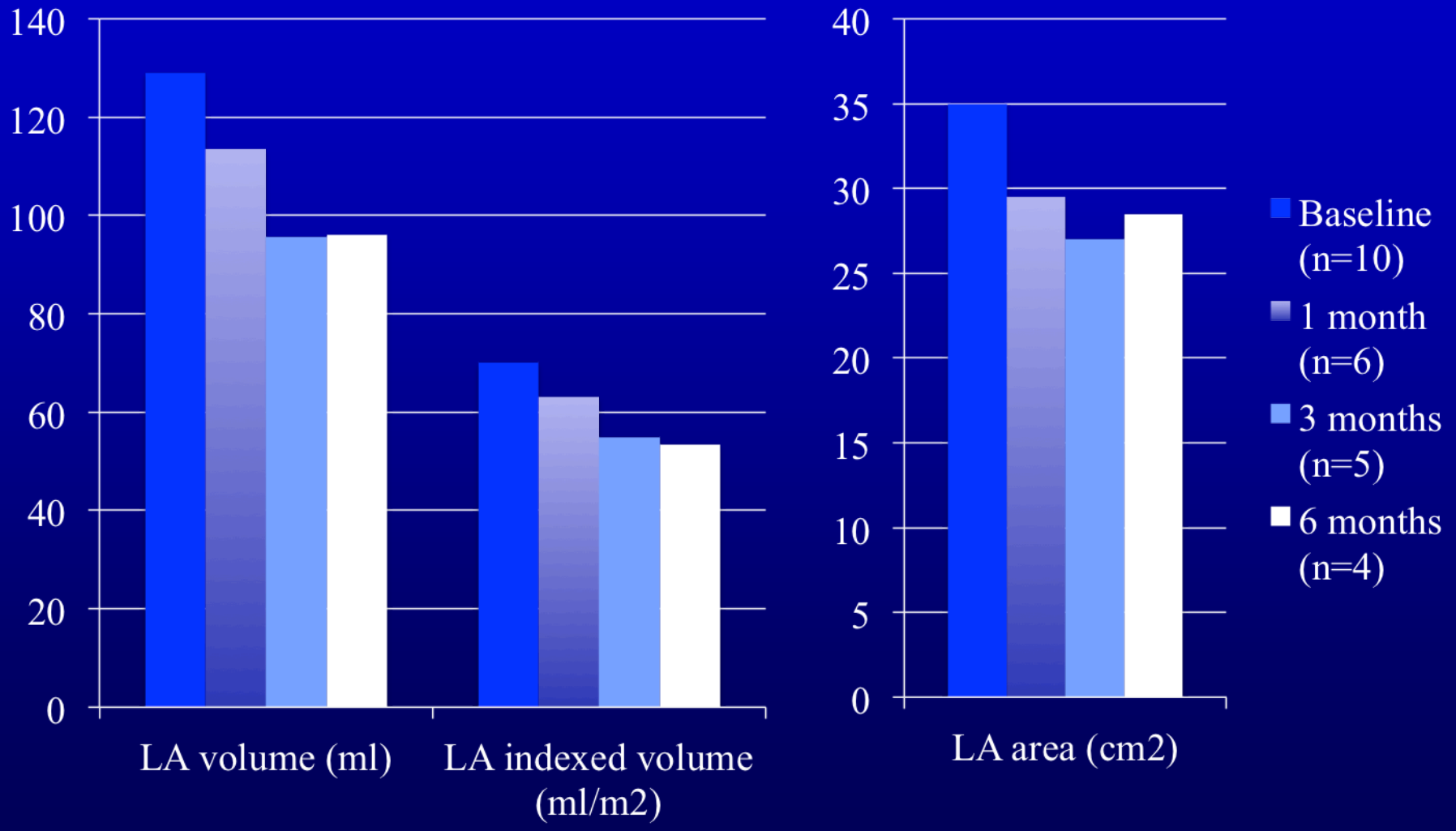
LVED and LVES volumes – follow up



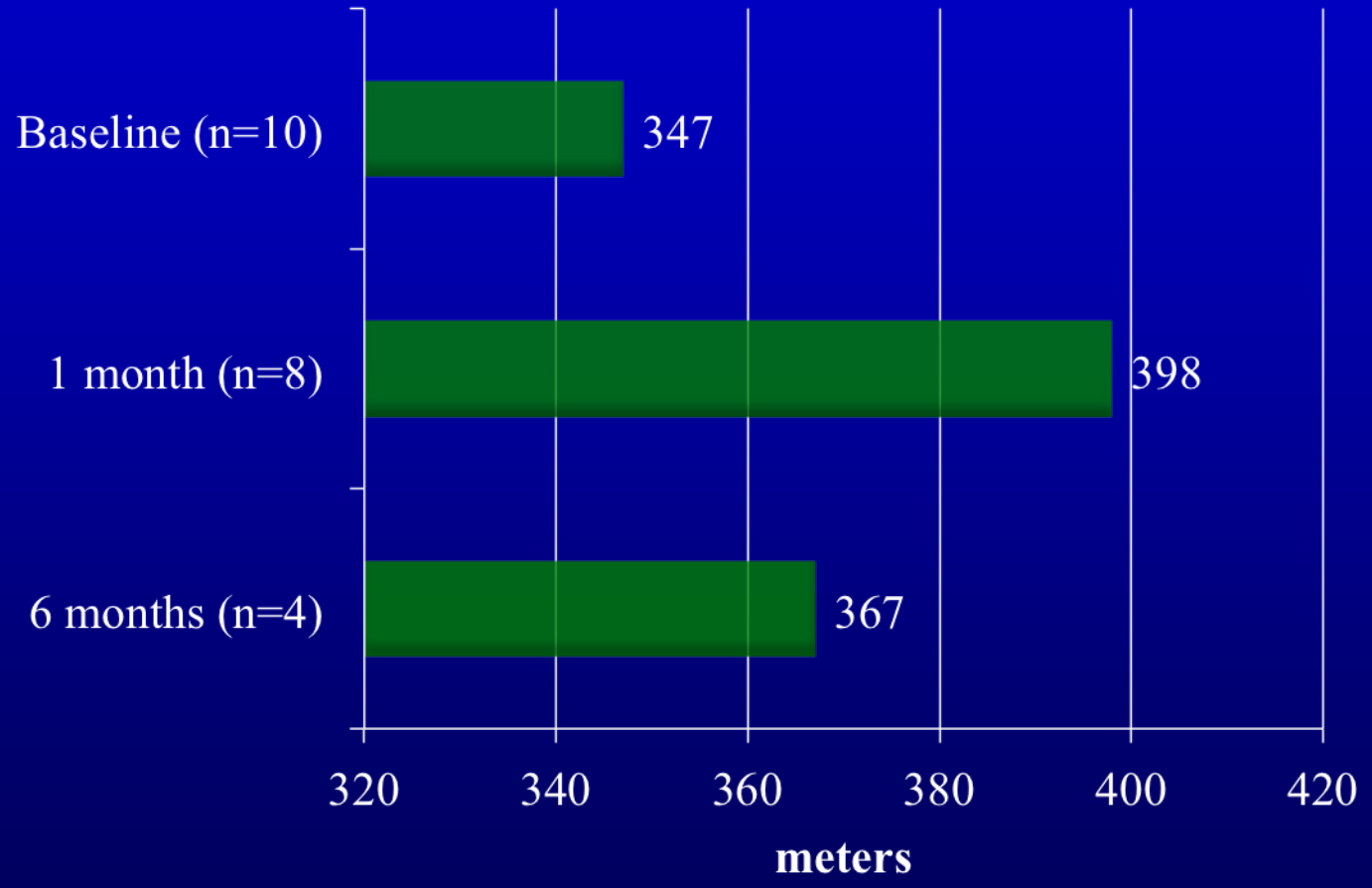
LVED and LVES diameters – follow up



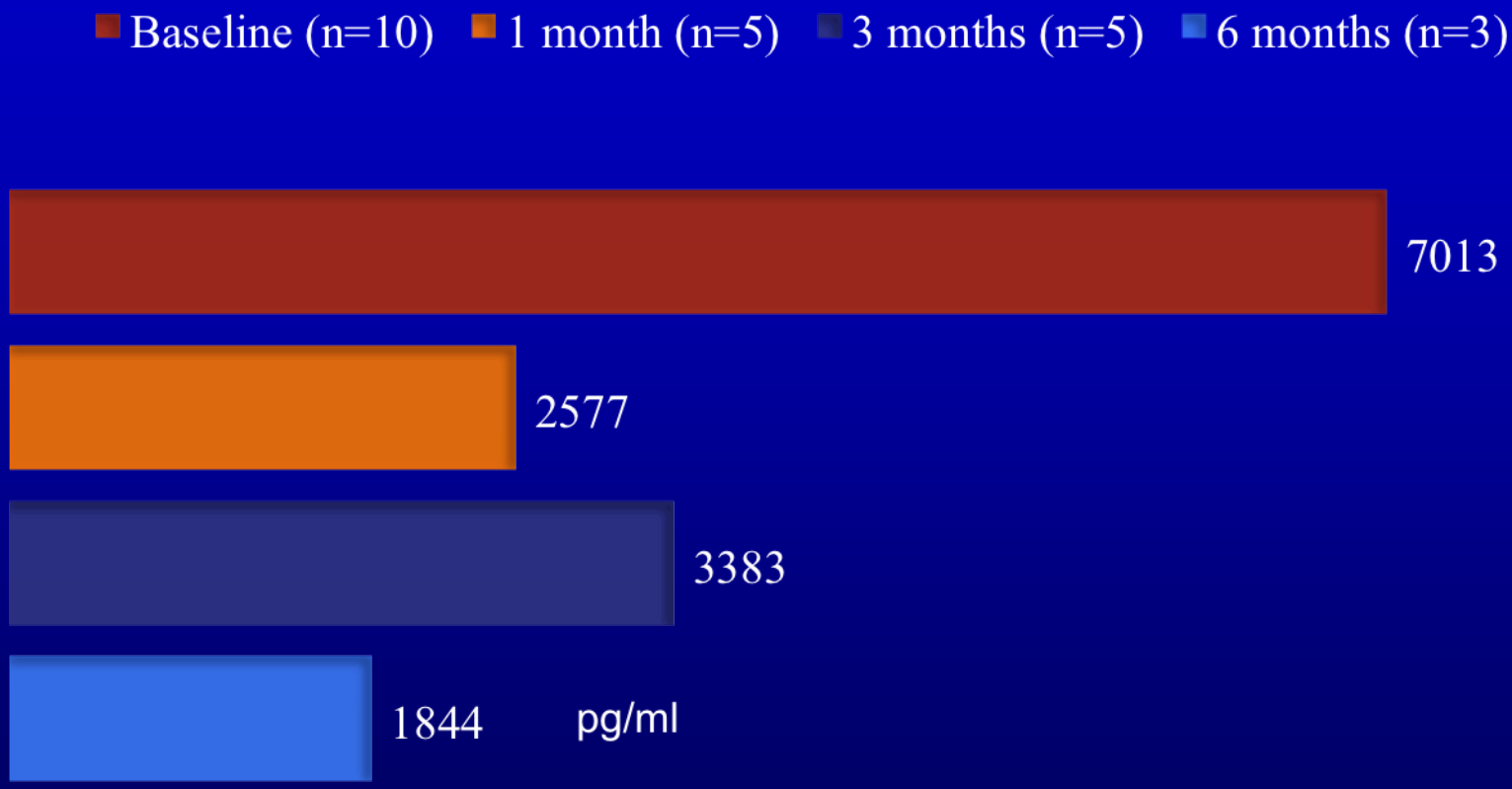
Left atrium dimensions – follow up



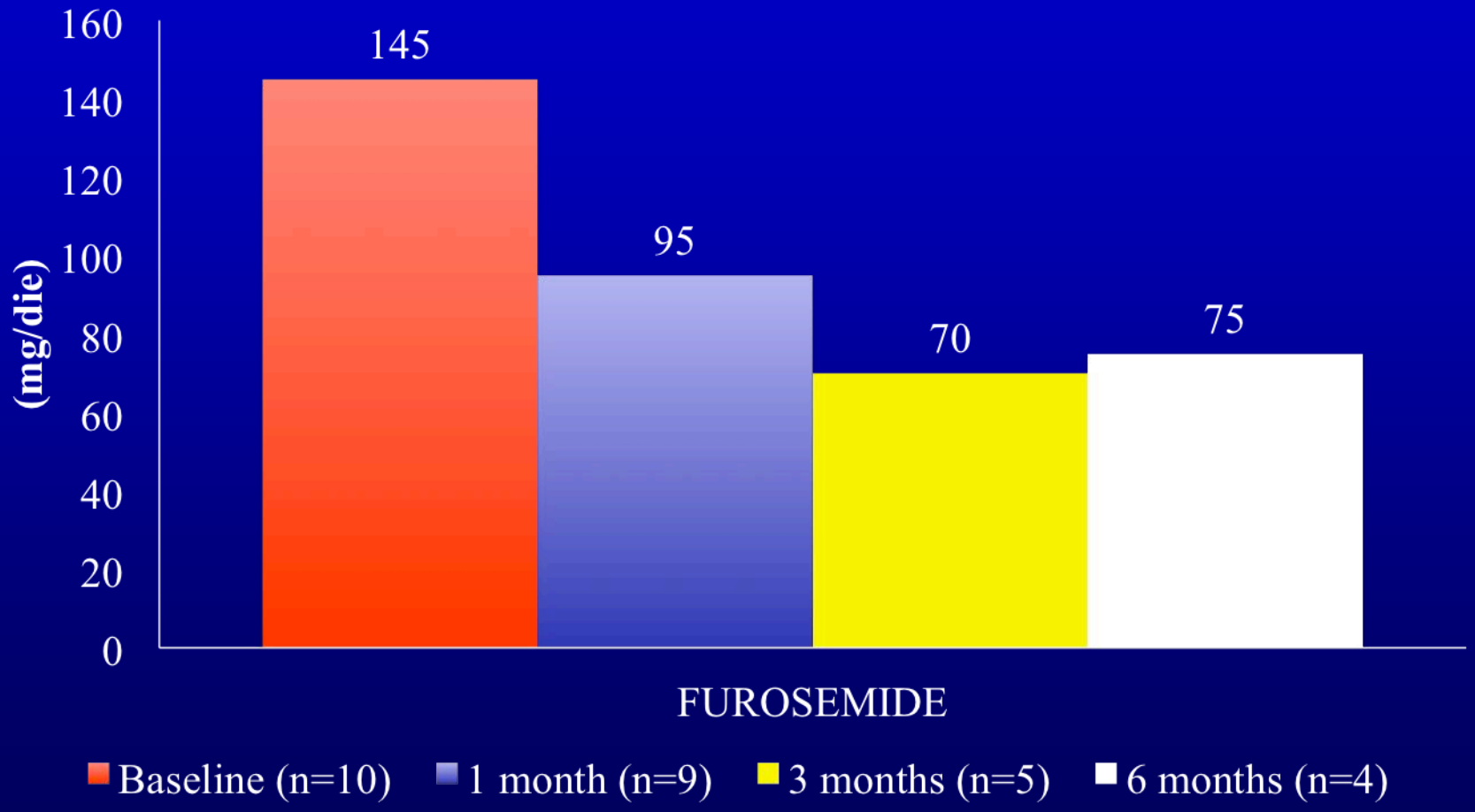
Six-minute walk test

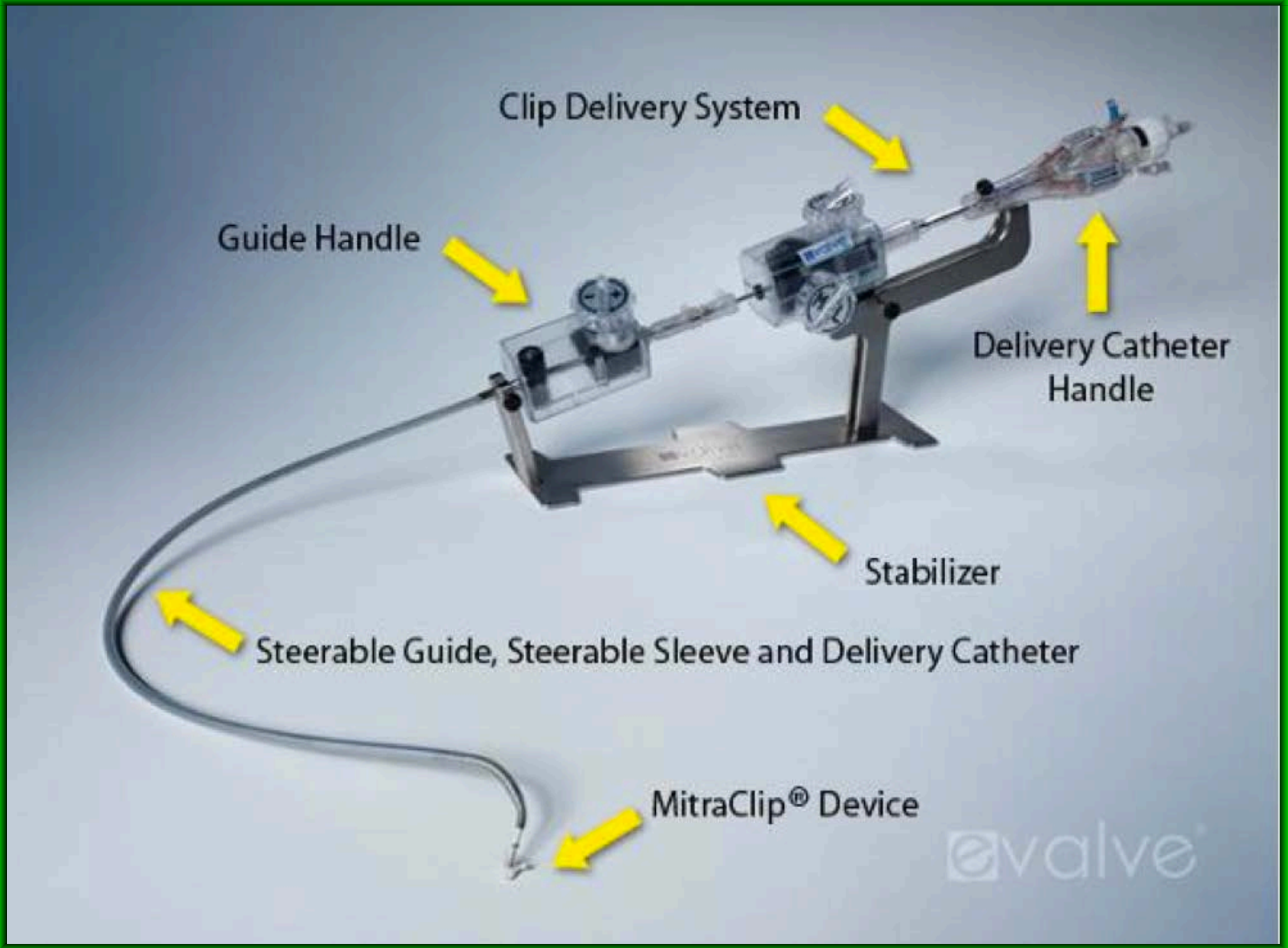


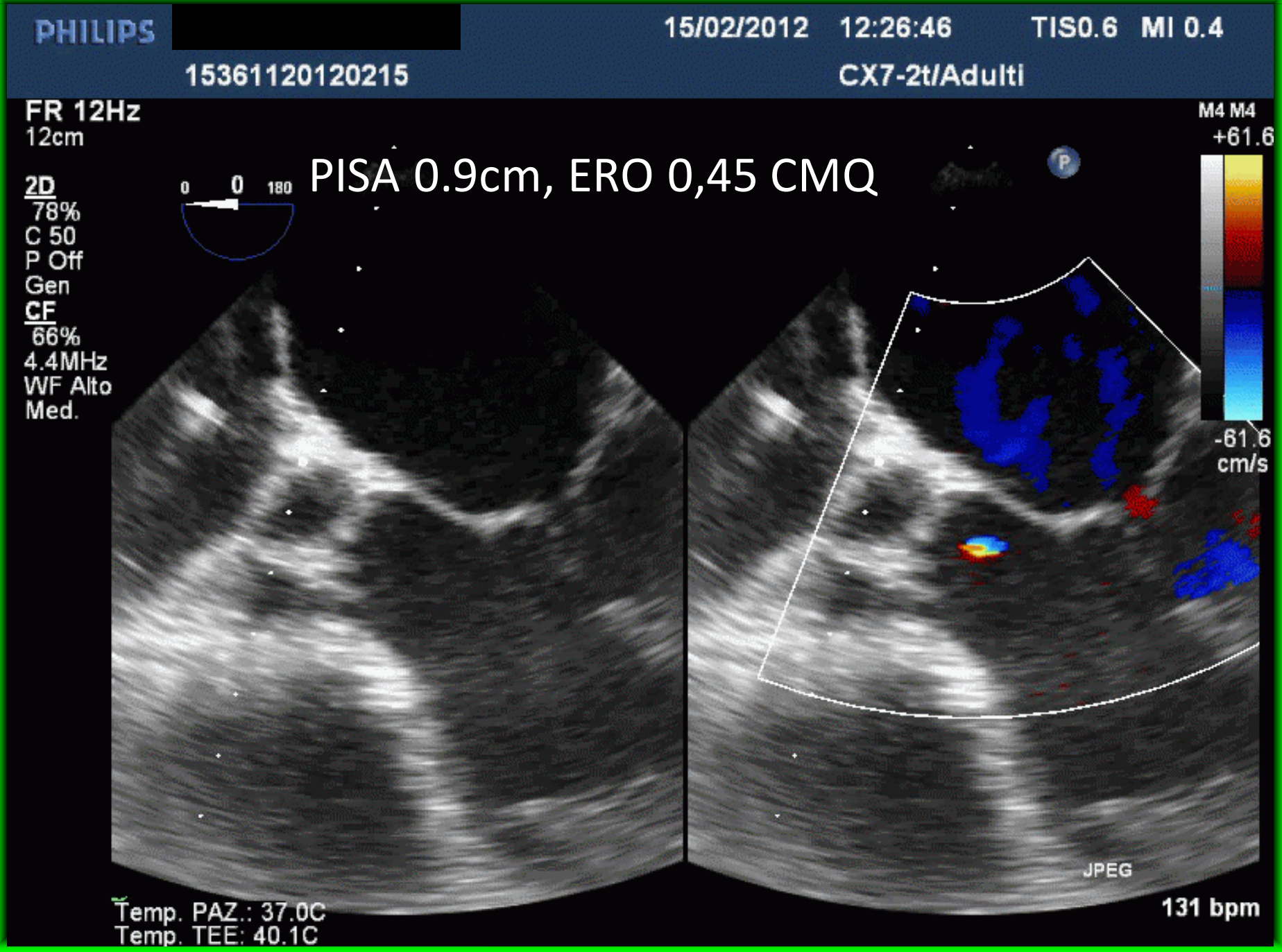
NTproBNP levels



Medical therapy – diuretic dose at follow up




Clip Delivery System
Guide Handle
Delivery Catheter Handle
Stabilizer
Steerable Guide, Steerable Sleeve and Delivery Catheter
MitraClip® Device
evalve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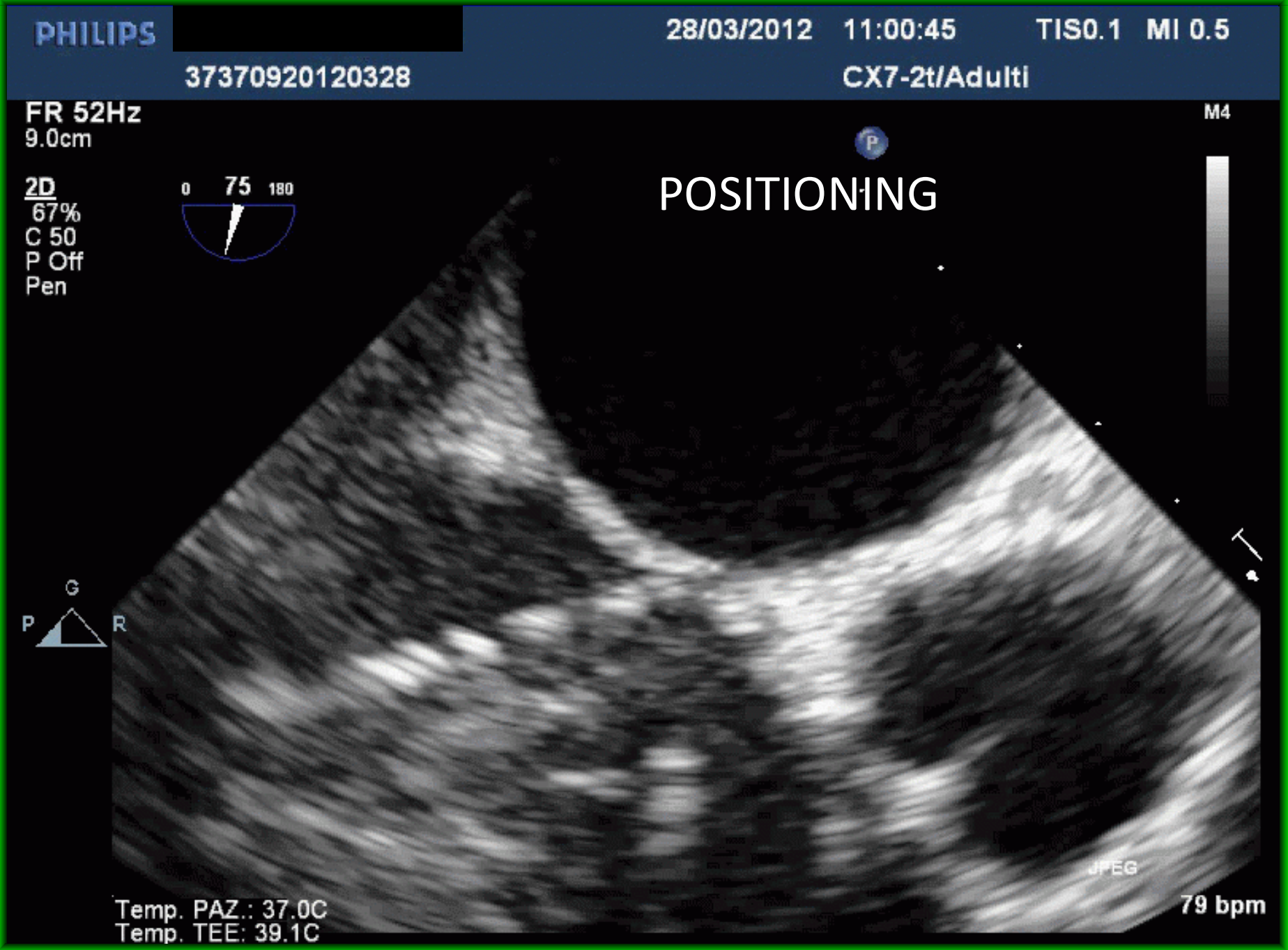
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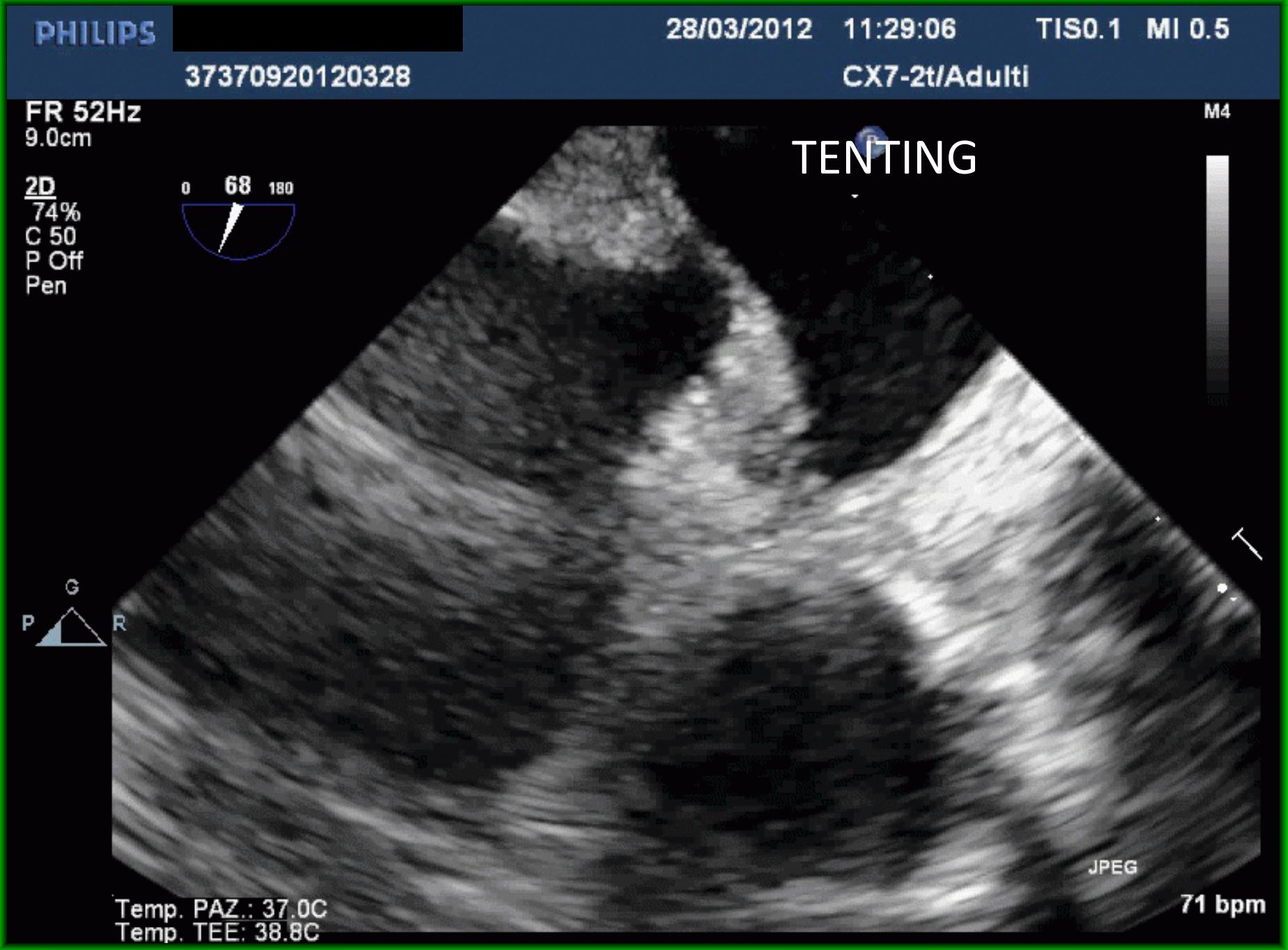
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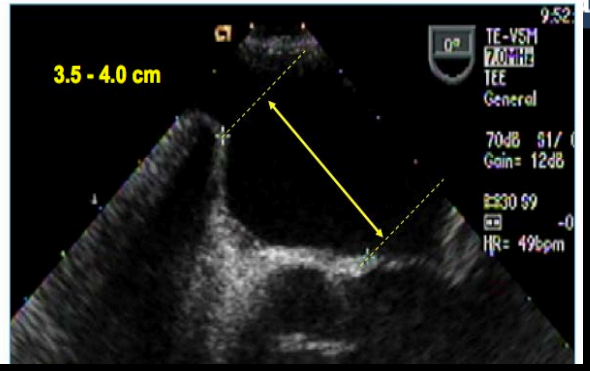
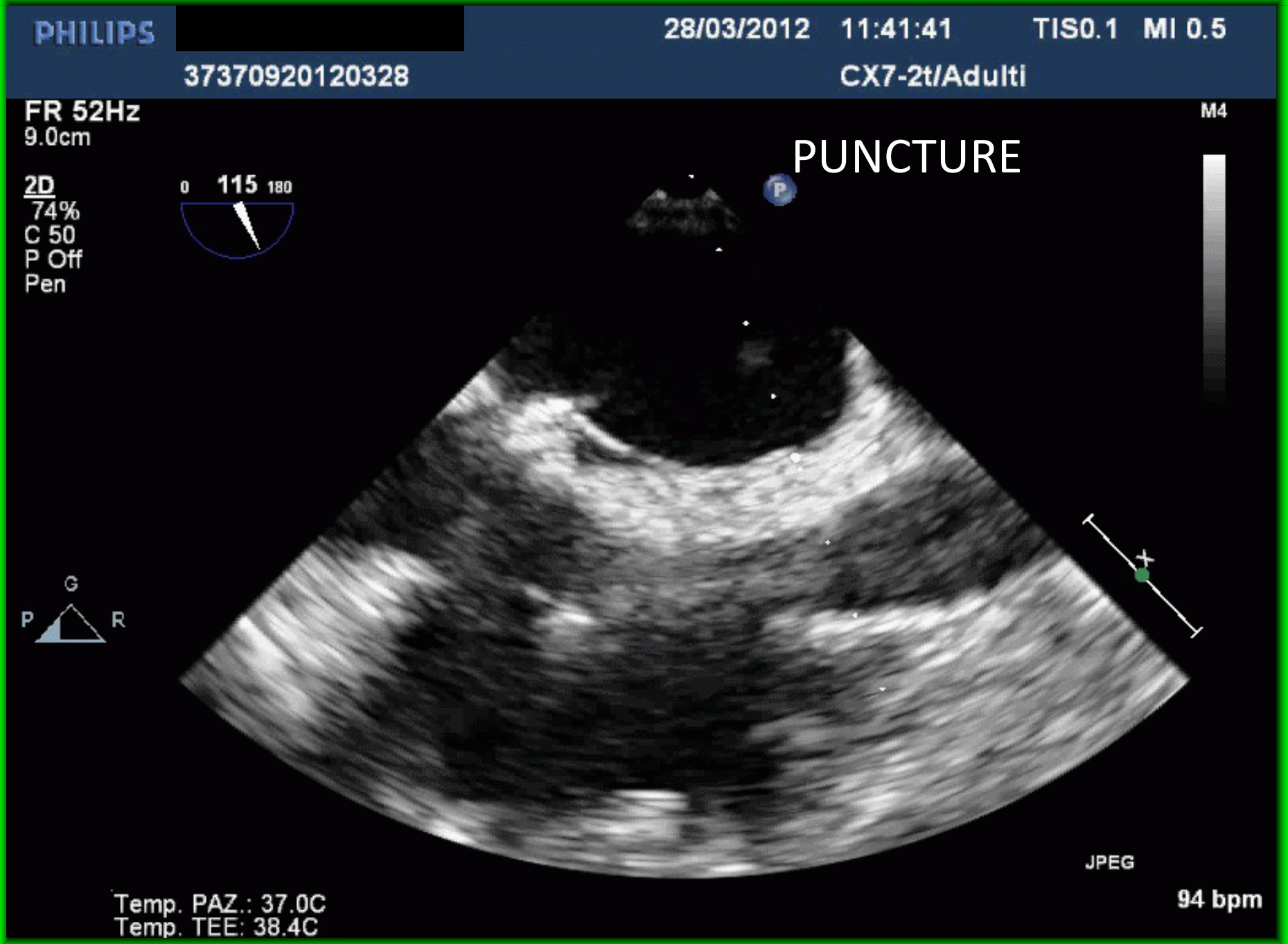
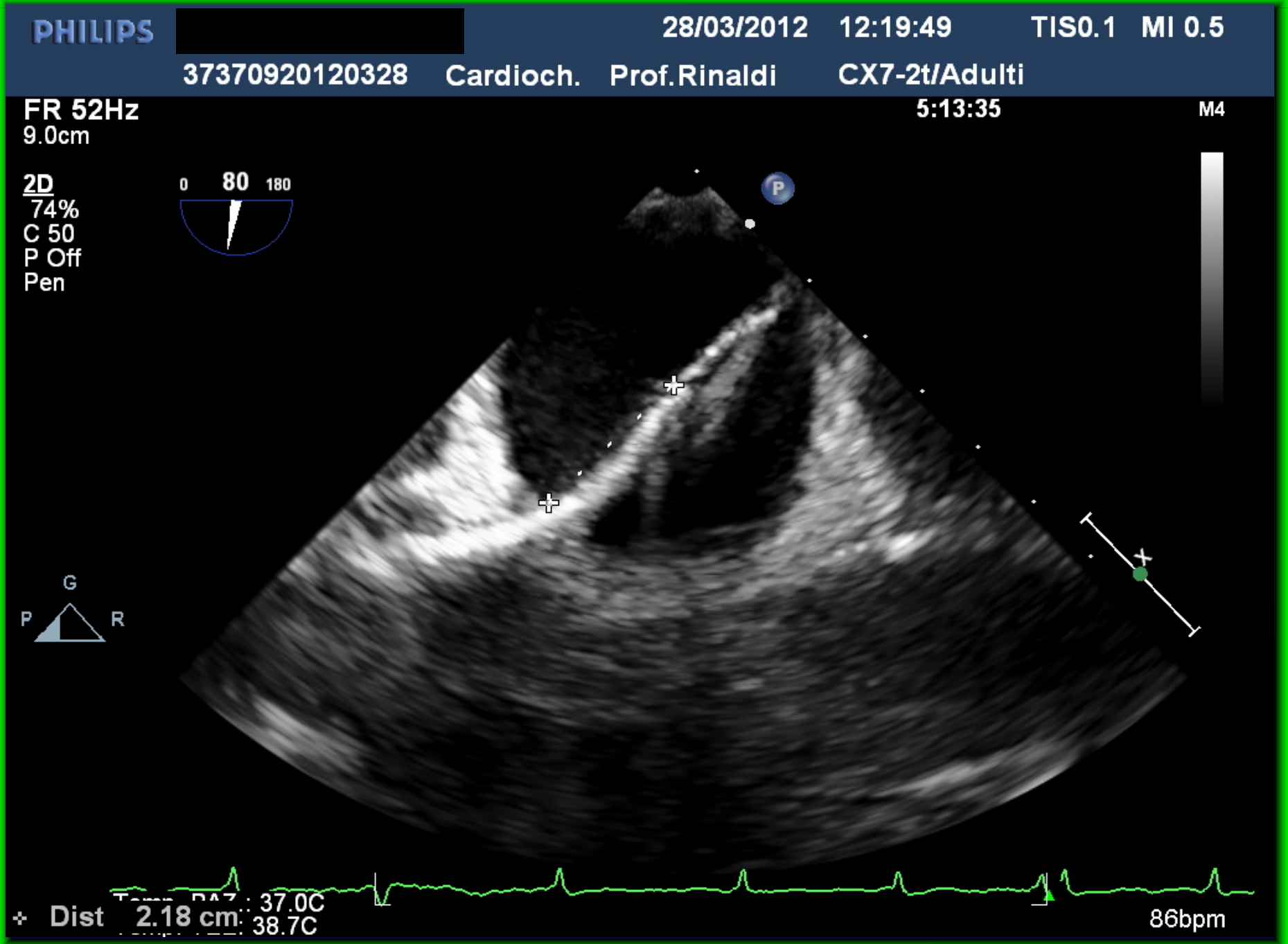
37370920120328
CX7-2t/Adulti
FR 52Hz
9.0cm
2D
74%
C 50
P Off
Pen
0 68 180
M4
TENTING
G
P
R
JPEG
Temp. PAZ.: 37.0C
Temp. TEE: 38.8C
71 bpm

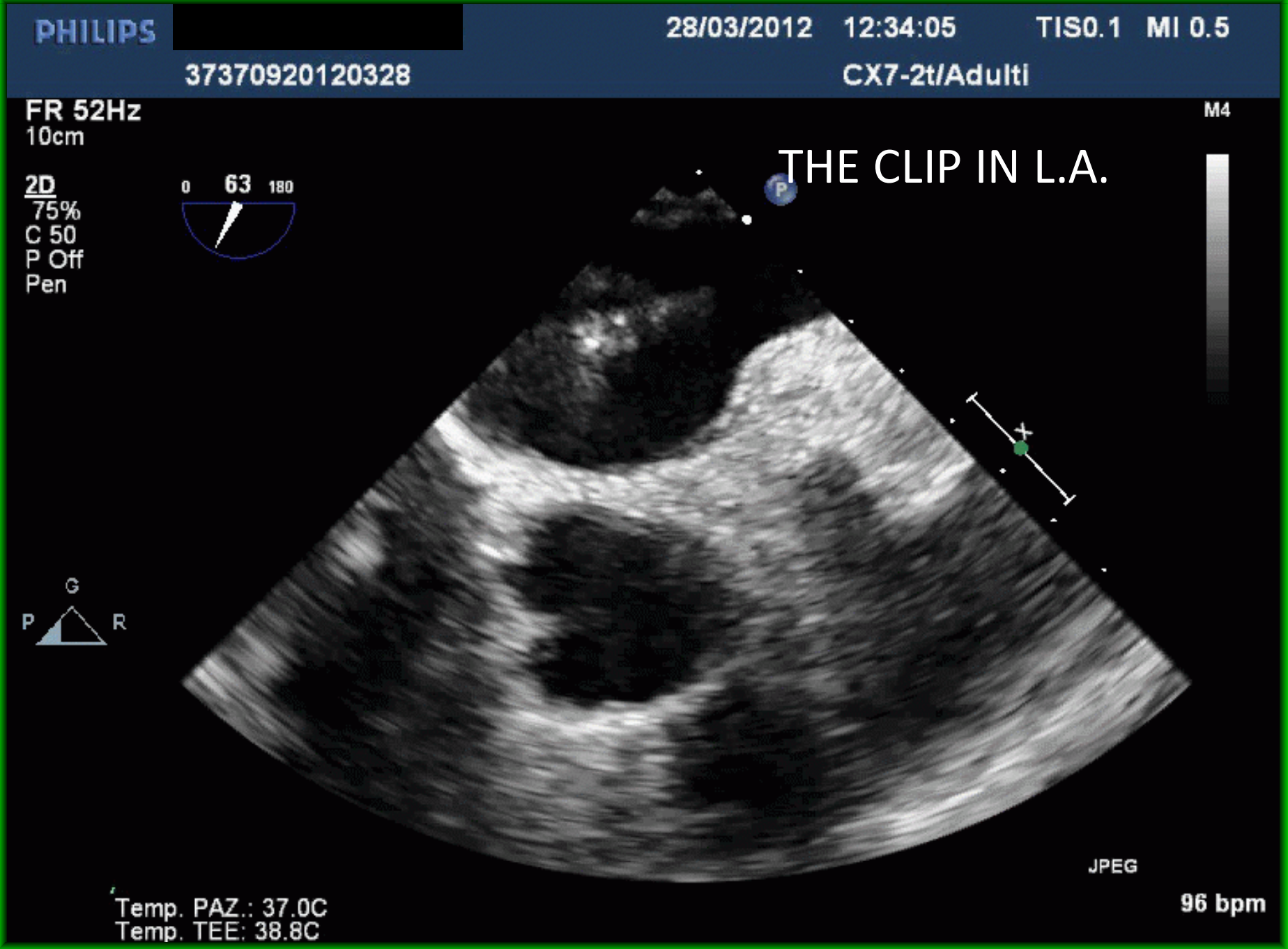
Tenting: "Superior" Aspect of Fossa

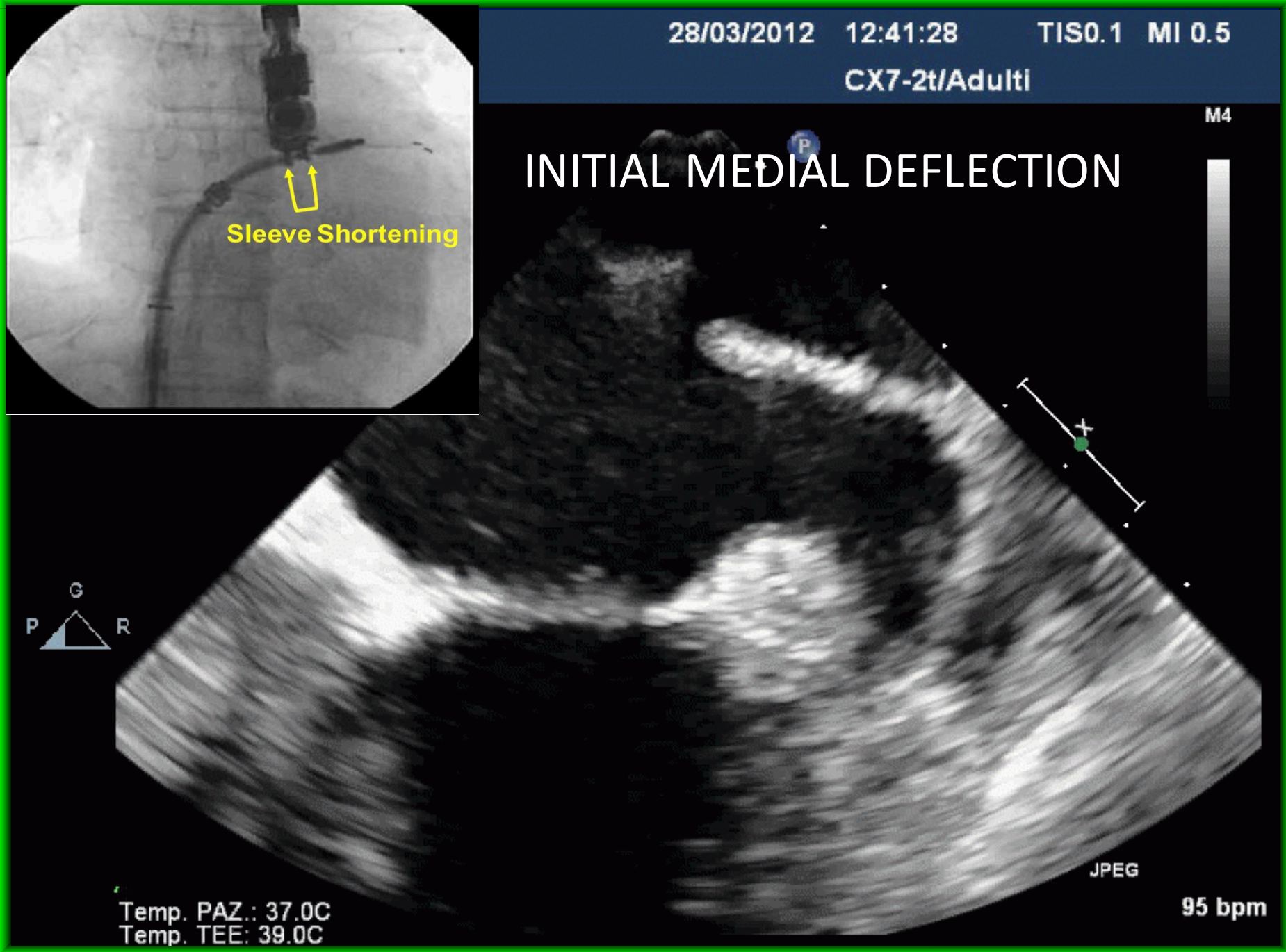
Echo view: 4 Chamber or 5 Chamber, Height 3.5-4.0cm

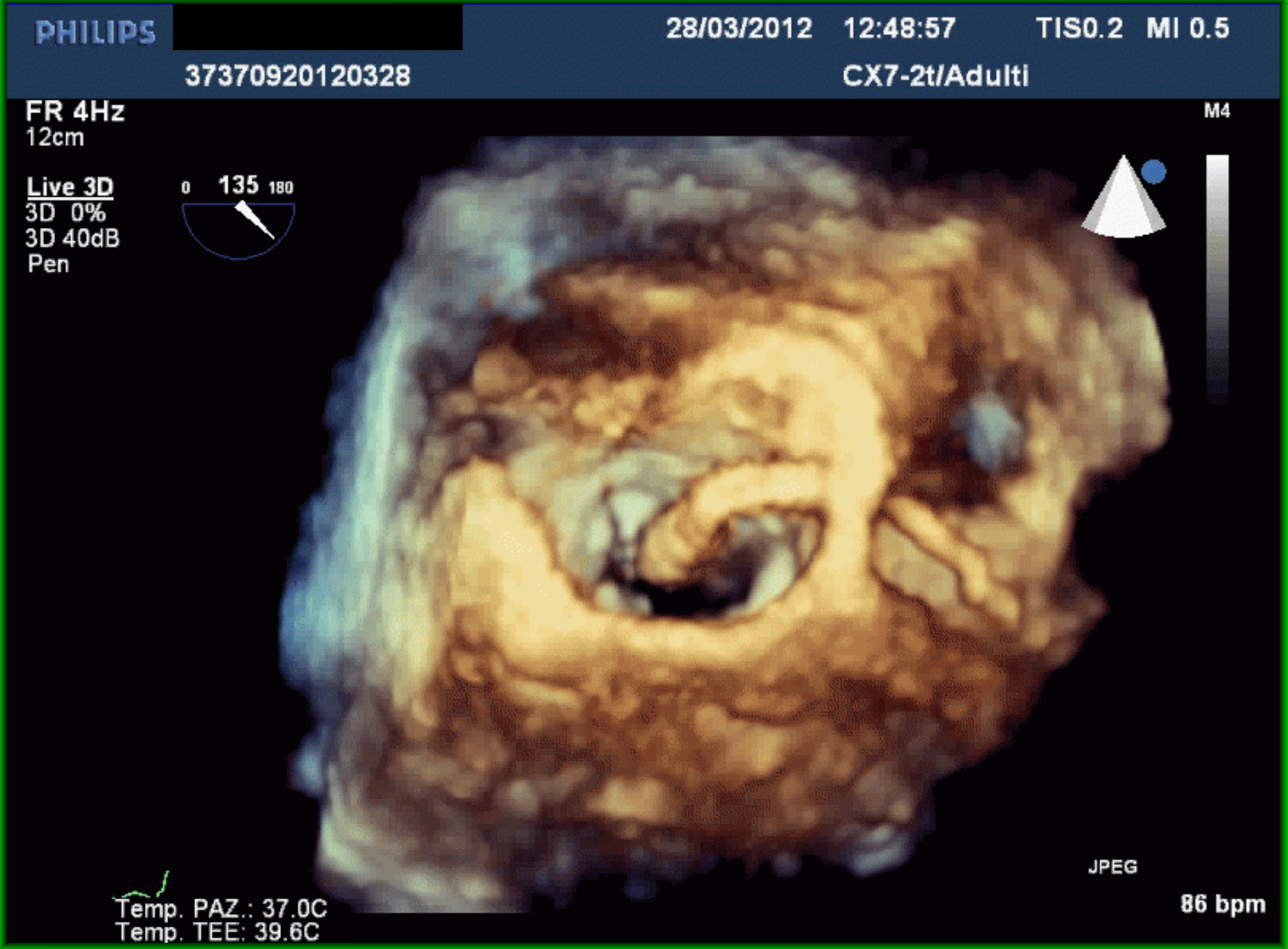


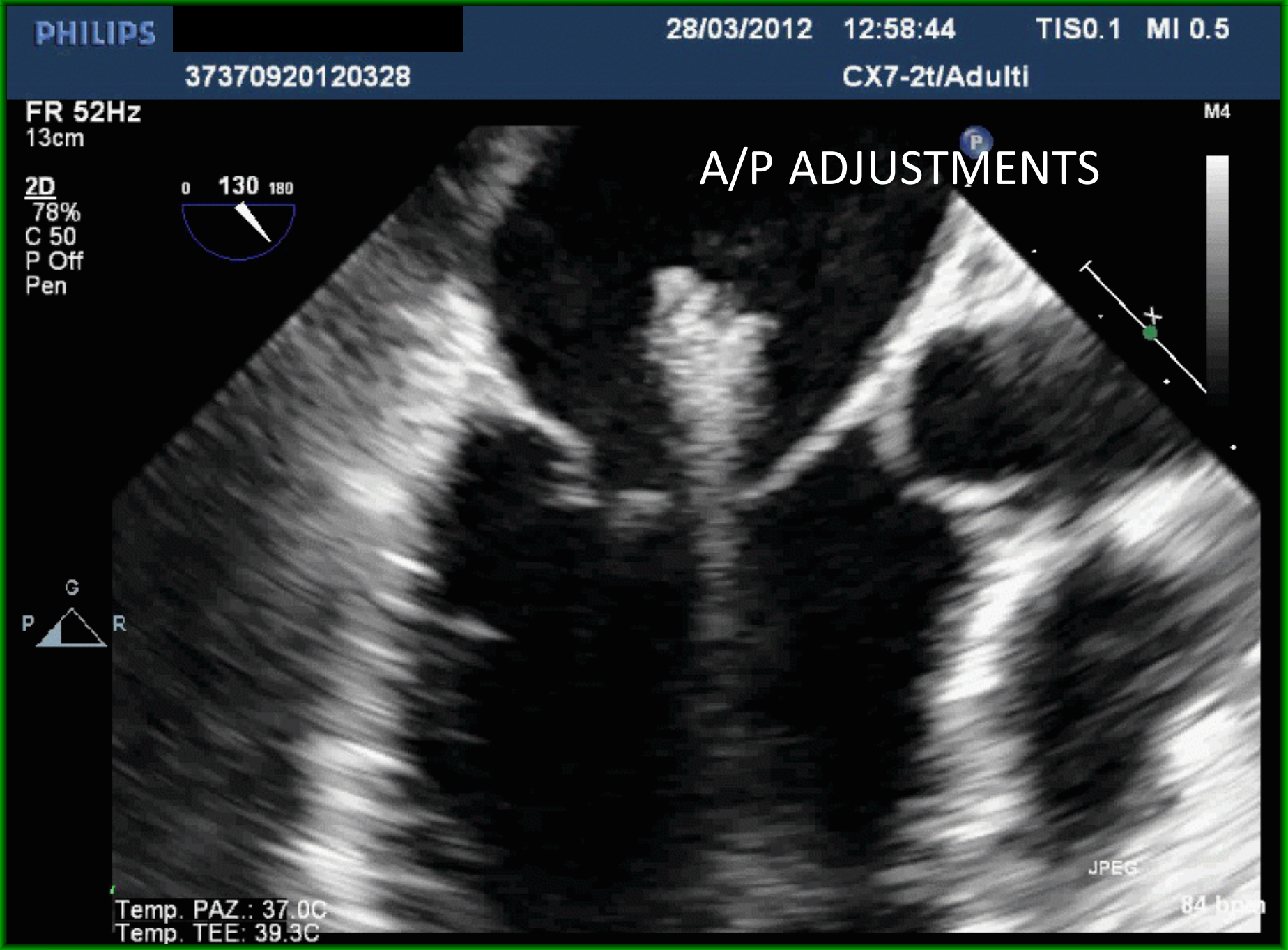

PHILIPS
[redacted]
28/03/2012 11:41:41 TIS0.1 MI 0.5
37370920120328
CX7-2t/Adulti
FR 52Hz
9.0cm
2D
74%
C 50
P Off
Pen
0 115 180
M4
PUNCTURE
P
G
P
R
JPEG
Temp. PAZ.: 37.0C
Temp. TEE: 38.4C
94 bpm

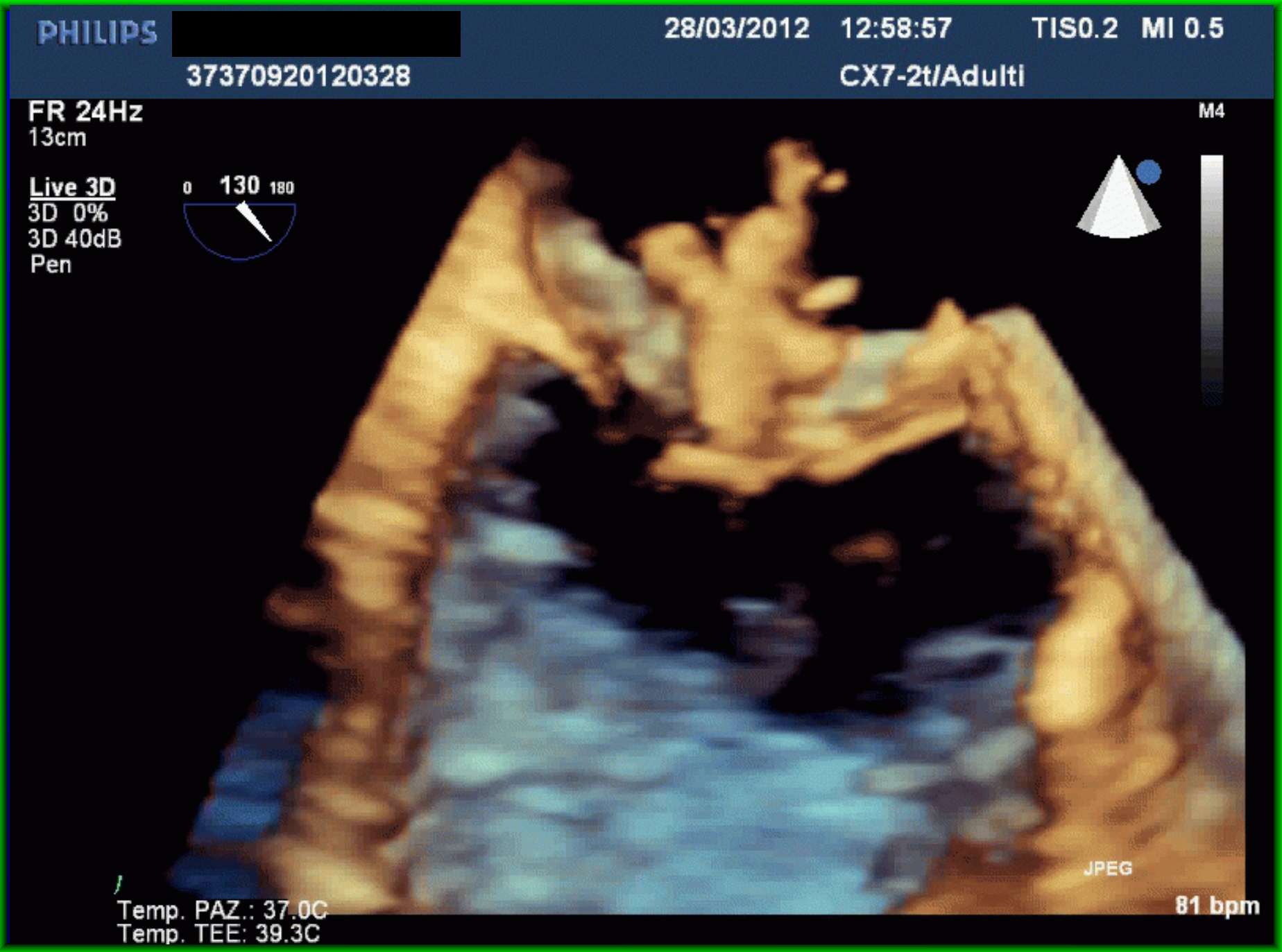

PHILIPS
28/03/2012 12:19:49 TIS0.1 MI 0.5
37370920120328 Cardioch. Prof.Rinaldi CX7-2t/Adulti
FR 52Hz
9.0cm
5:13:35
M4
2D
74%
C 50
P Off
Pen
0 80 180
G
P R
Dist 2.18 cm
37.0C
38.7C
86bpm

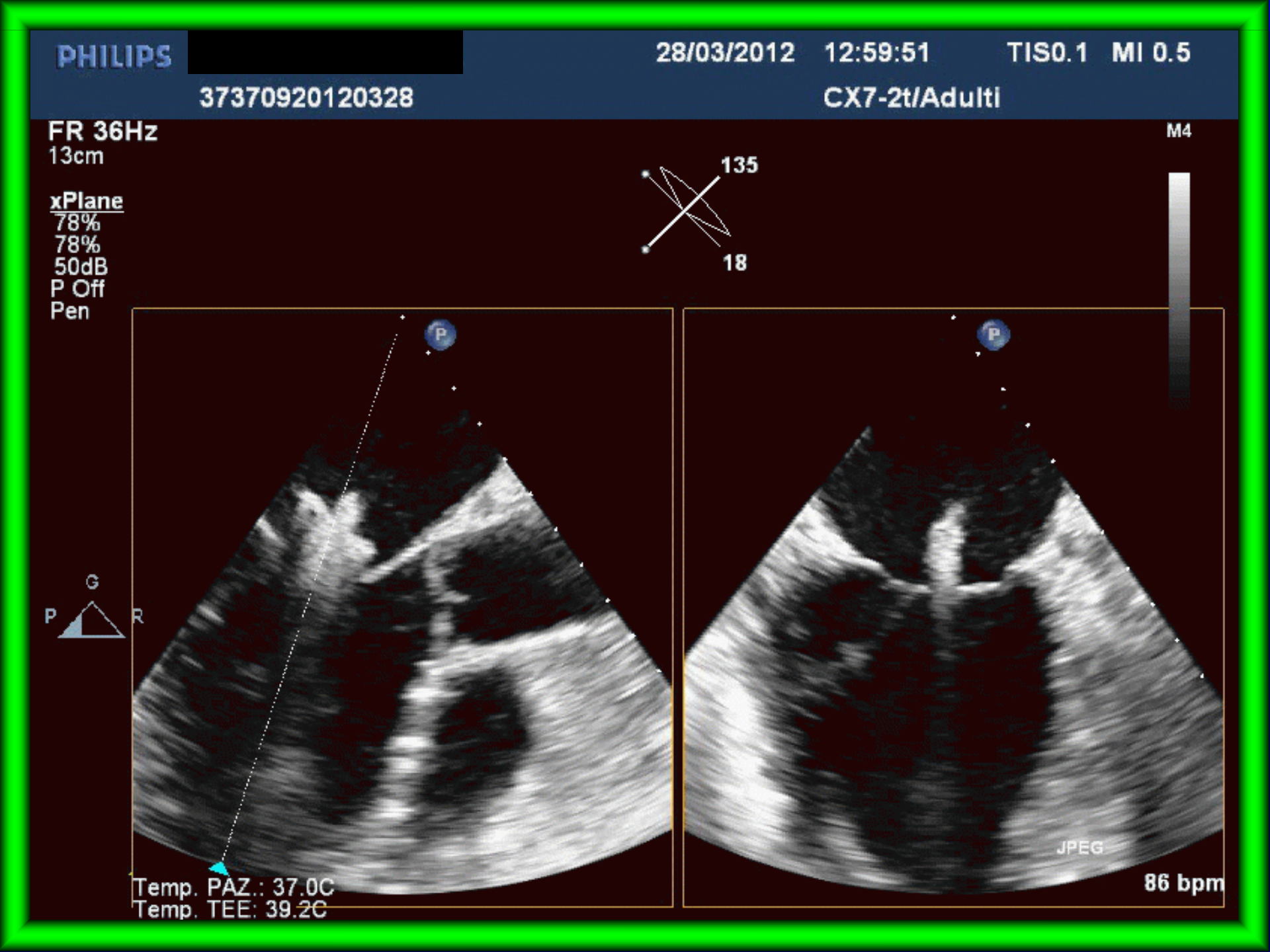

PHILIPS
[redacted]
28/03/2012 12:34:05 TIS0.1 MI 0.5
37370920120328
CX7-2t/Adulti
FR 52Hz
10cm
2D
75%
C 50
P Off
Pen
0 63 180
M4
THE CLIP IN L.A.
G
P R
JPEG
Temp. PAZ.: 37.0C
Temp. TEE: 38.8C
96 bpm


28/03/2012 12:41:28 TIS0.1 MI 0.5
CX7-2t/Adulti
M4
INITIAL MEDIAL DEFLECTION
Sleeve Shortening
G
P
R
JPEG
Temp. PAZ.: 37.0C
Temp. TEE: 39.0C
95 bpm


PHILIPS
28/03/2012 12:48:57 TIS0.2 MI 0.5
37370920120328
CX7-2t/Adulti
FR 4Hz
12cm
M4
Live 3D
3D 0%
3D 40dB
Pen
0 135 180
JPEG
86 bpm
Temp. PAZ.: 37.0C
Temp. TEE: 39.6C

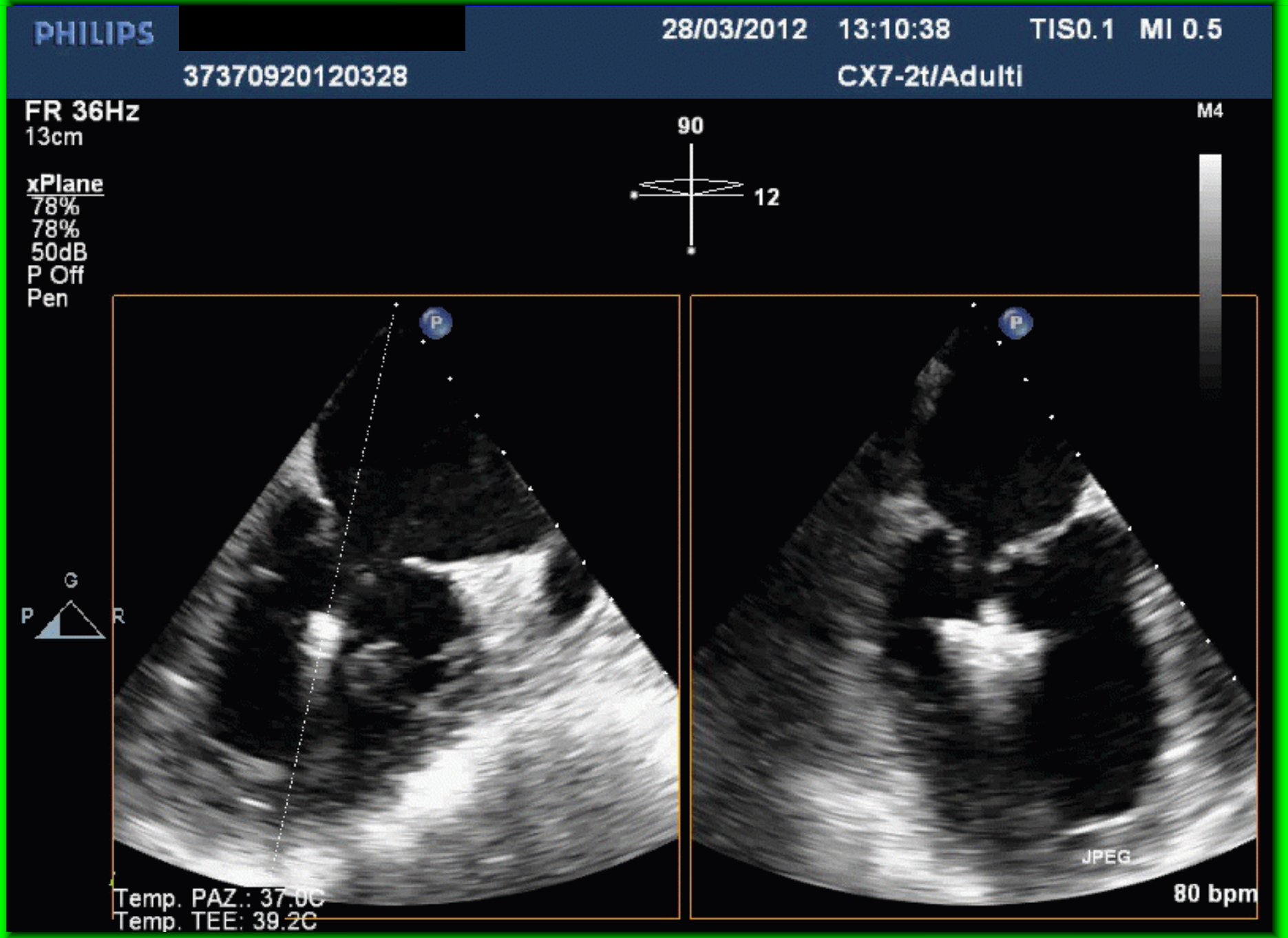

PHILIPS
28/03/2012 12:58:44 TIS0.1 MI 0.5
37370920120328
CX7-2t/Adulti
FR 52Hz
13cm
2D
78%
C 50
P Off
Pen
0 130 180
M4
A/P ADJUSTMENTS
G
P
R
JPEG
Temp. PAZ.: 37.0C
Temp. TEE: 39.3C
84 bpm

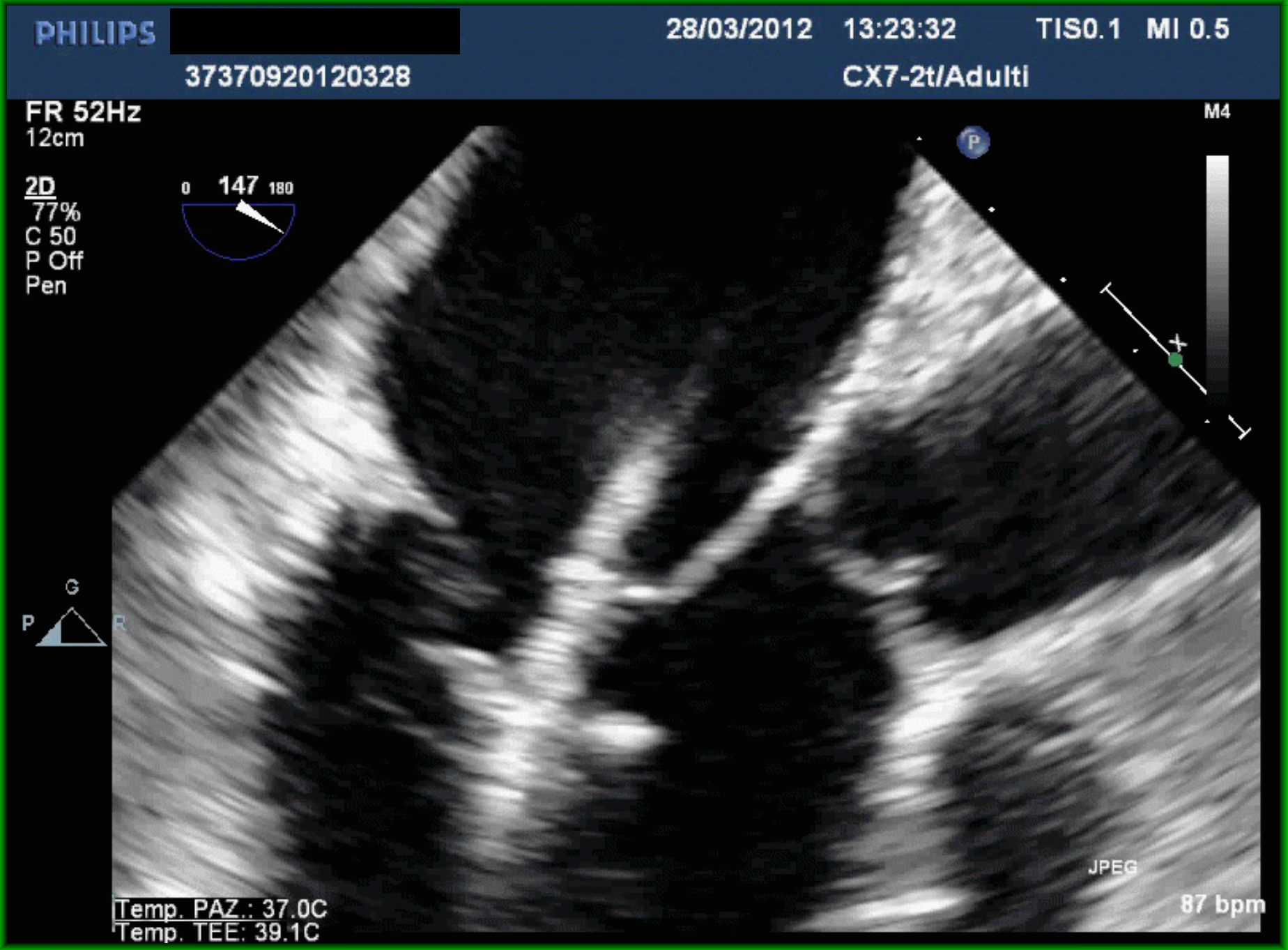

PHILIPS
[redacted]
28/03/2012 12:58:57 TIS0.2 MI 0.5
37370920120328
CX7-2t/Adulti
FR 24Hz
13cm
M4
Live 3D
3D 0%
3D 40dB
Pen
0 130 180
JPEG
Temp. PAZ.: 37.0C
Temp. TEE: 39.3C
81 bpm


PHILIPS
28/03/2012 12:59:51 TIS0.1 MI 0.5
37370920120328
CX7-2t/Adulti
FR 36Hz
13cm
xPlane
78%
78%
50dB
P Off
Pen
135
18
M4
G
P
R
Temp. PAZ.: 37.0C
Temp. TEE: 39.2C
JPEG
86 bpm

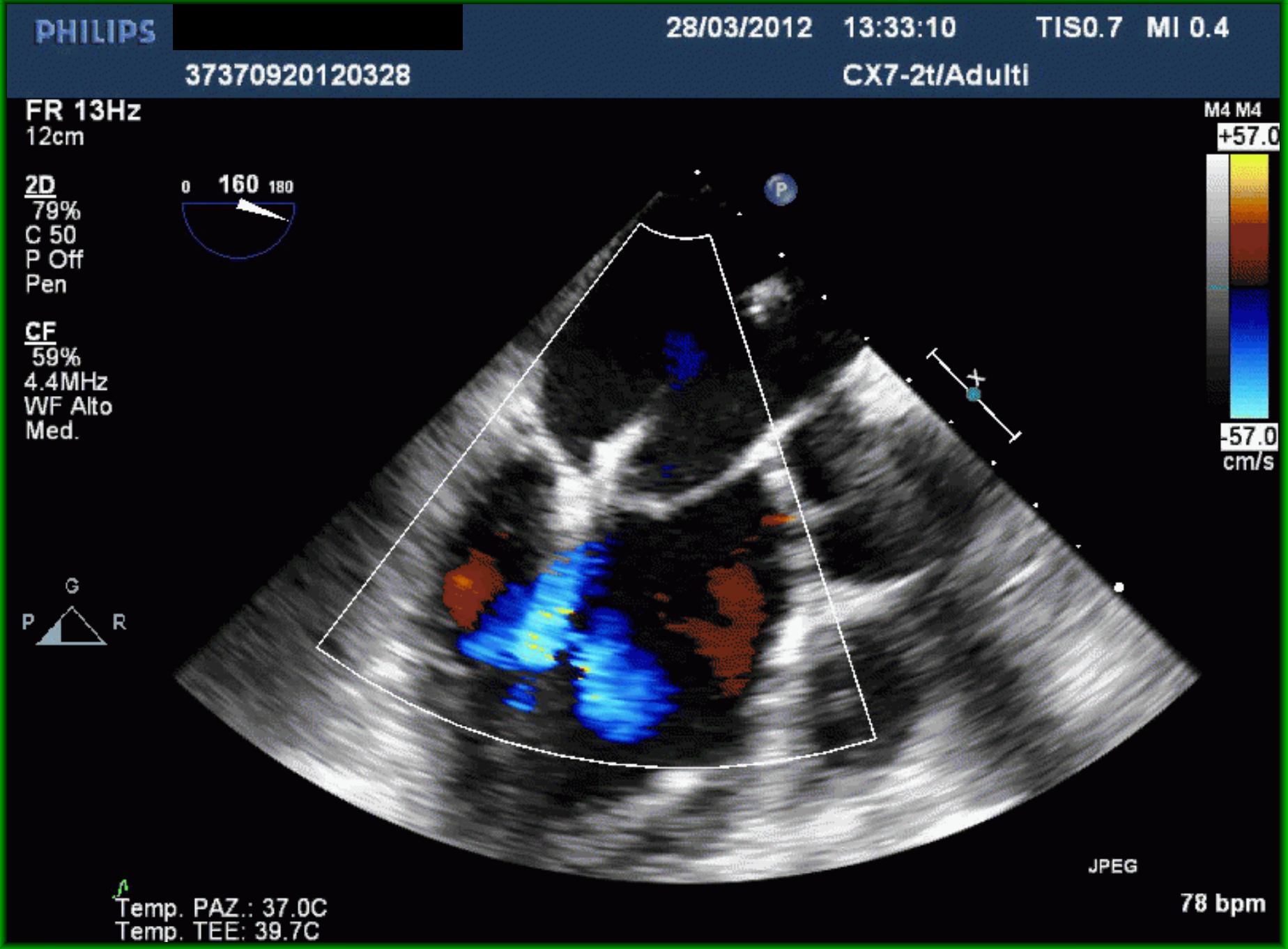

PHILIPS
28/03/2012 13:02:11 TIS0.2 MI 0.5
37370920120328
CX7-2t/Adulti
FR 5Hz
9.9cm
Live 3D
3D 0%
3D 40dB
Pen
M4
0 135 180
Clip opened and aligned
JPEG
Temp. PAZ.: 37.0C
Temp. TEE: 39.6C
79 bpm

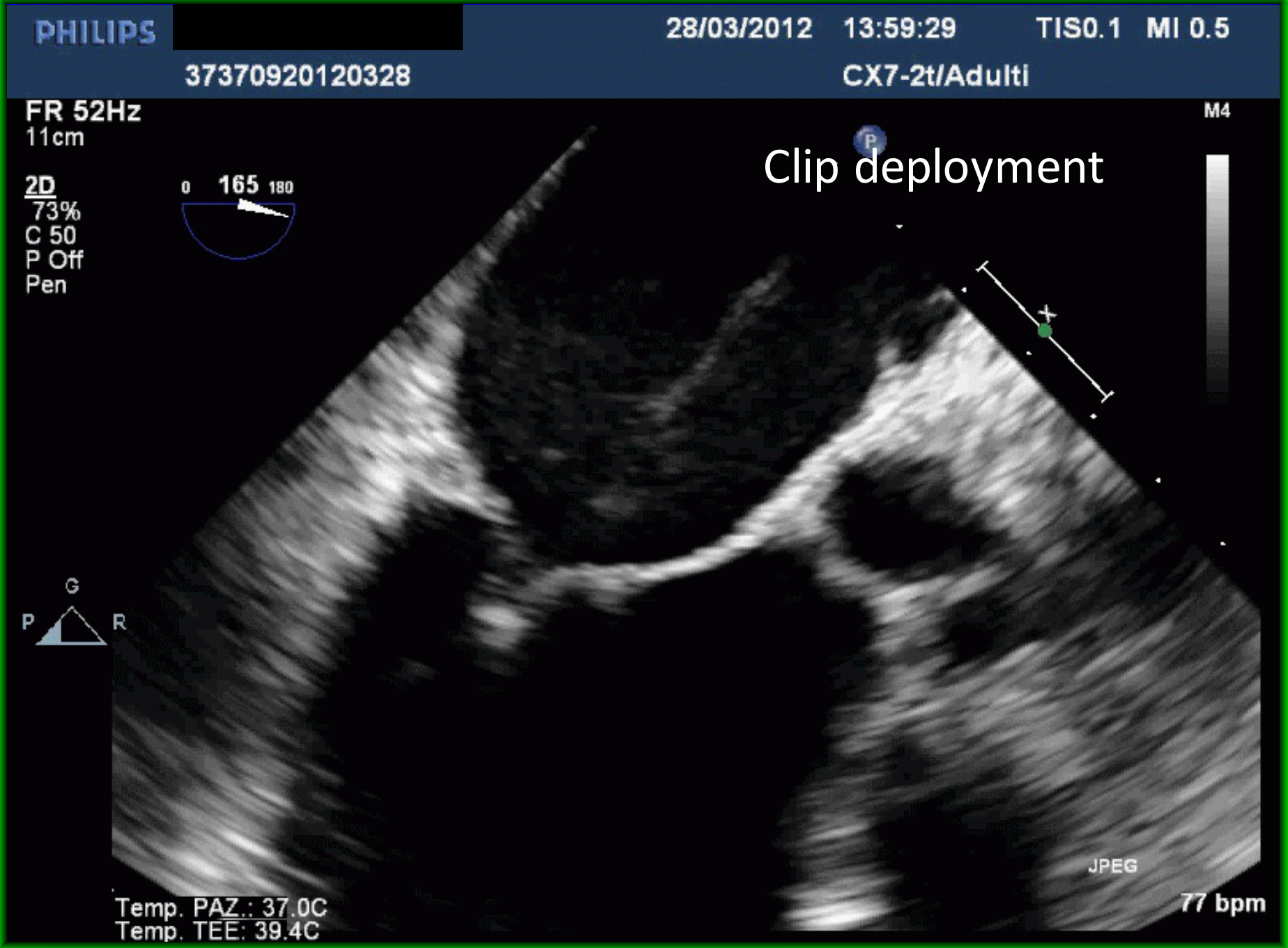

PHILIPS
[redacted]
28/03/2012 13:07:28 TIS0.2 MI 0.5
37370920120328
CX7-2t/Adulti
FR 28Hz
11cm
Live 3D
3D 0%
3D 40dB
Pen
0 160 180
M4
Clip into LV
JPEG
Temp. PAZ.: 37.0C
Temp. TEE: 39.3C
92 bpm

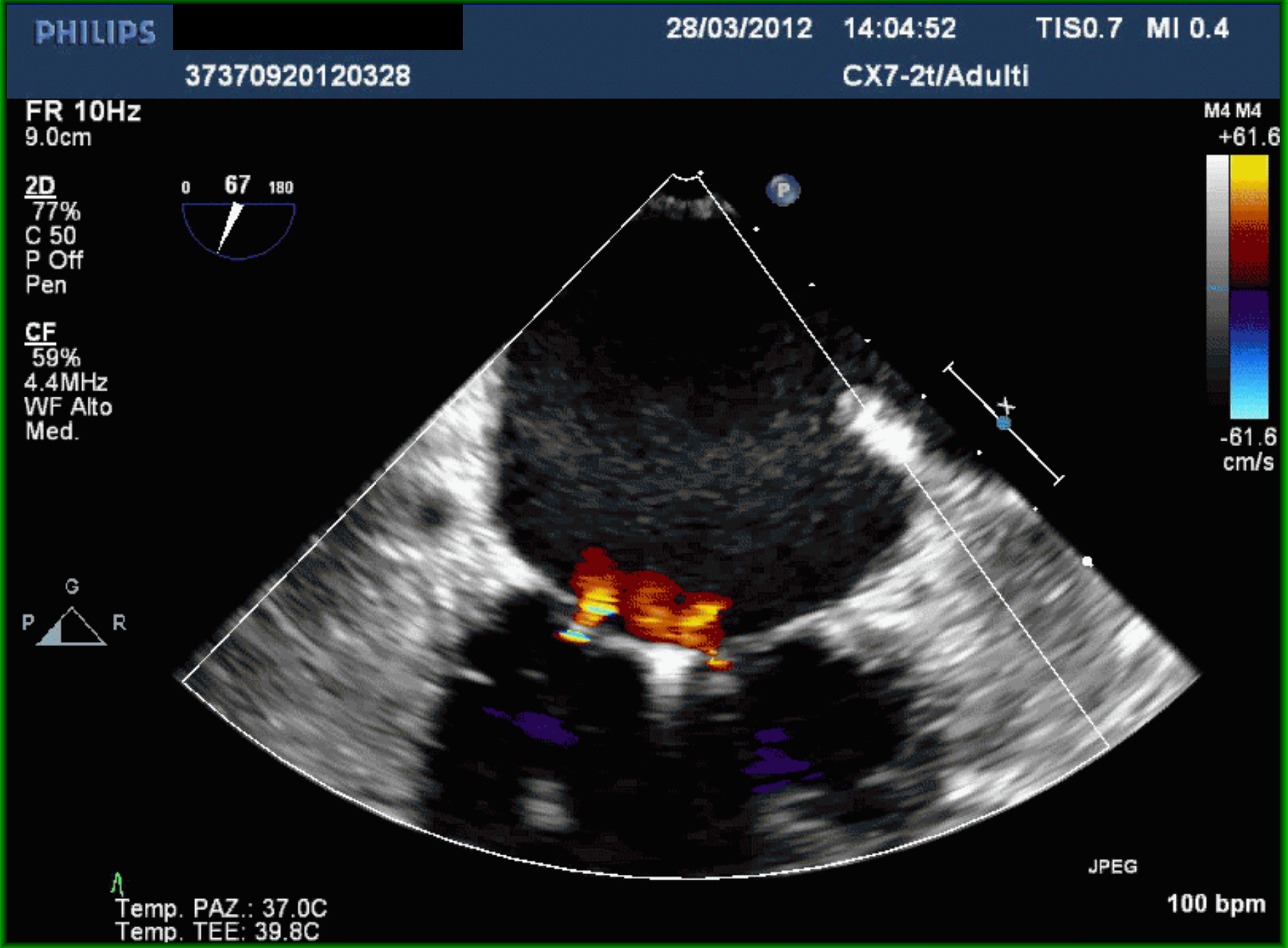

PHILIPS
[redacted]
28/03/2012 13:10:38 TIS0.1 MI 0.5
37370920120328
CX7-2t/Adulti
FR 36Hz
13cm
xPlane
78%
78%
50dB
P Off
Pen
90
12
M4
G
P
R
Temp. PAZ.: 37.0C
Temp. TEE: 39.2C
JPEG
80 bpm

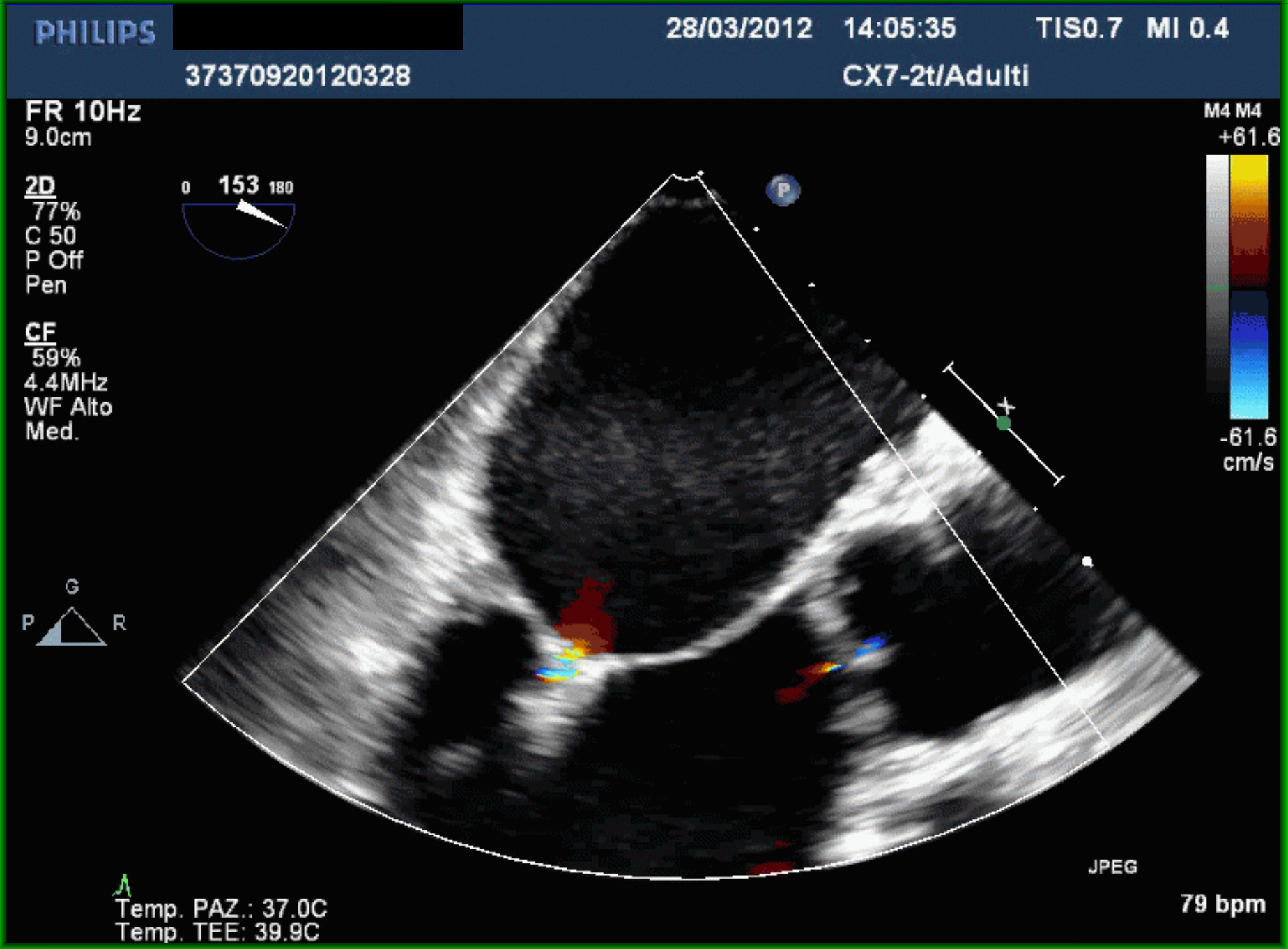

PHILIPS
[redacted]
28/03/2012 13:23:32 TIS0.1 MI 0.5
37370920120328
CX7-2t/Adulti
FR 52Hz
12cm
M4
2D
77%
C 50
P Off
Pen
0 147 180
G
P
R
JPEG
Temp. PAZ.: 37.0C
Temp. TEE: 39.1C
87 bpm


PHILIPS
[redacted]
28/03/2012 13:25:42 TIS0.1 MI 0.5
37370920120328
CX7-2t/Adulti
FR 52Hz
12cm
2D
77%
C 50
P Off
Pen
0 145 180
M4
Grippers down
G
P
R
JPEG
Temp. PAZ.: 37.0C
Temp. TEE: 39.2C
75 bpm

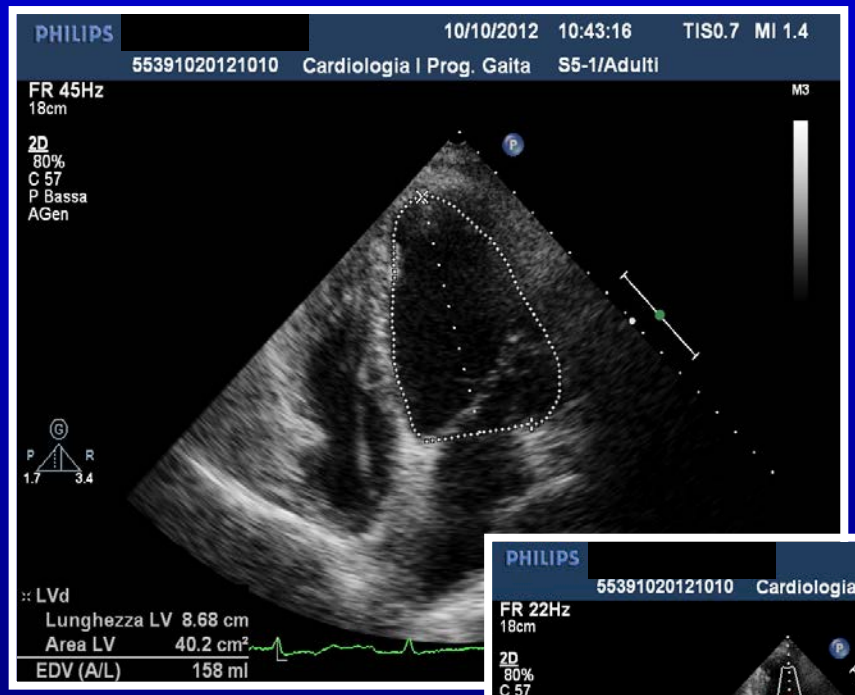

PHILIPS
[redacted]
28/03/2012 13:33:10 TIS0.7 MI 0.4
37370920120328
CX7-2t/Adulti
FR 13Hz
12cm
2D
79%
C 50
P Off
Pen
0 160 180
CF
59%
4.4MHz
WF Alto
Med.
M4 M4
+57.0
-57.0
cm/s
G
P
R
JPEG
Temp. PAZ.: 37.0C
Temp. TEE: 39.7C
78 bpm

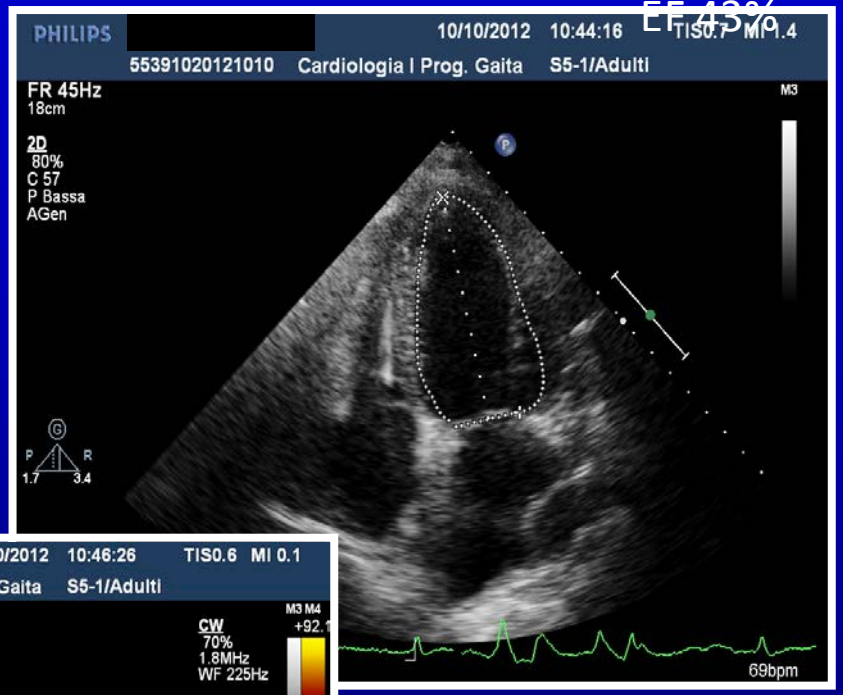

PHILIPS
28/03/2012 13:59:29 TIS0.1 MI 0.5
37370920120328
CX7-2t/Adulti
FR 52Hz
11cm
2D
73%
C 50
P Off
Pen
0 165 180
M4
Clip deployment
G
P
R
JPEG
Temp. PAZ.: 37.0C
Temp. TEE: 39.4C
77 bpm

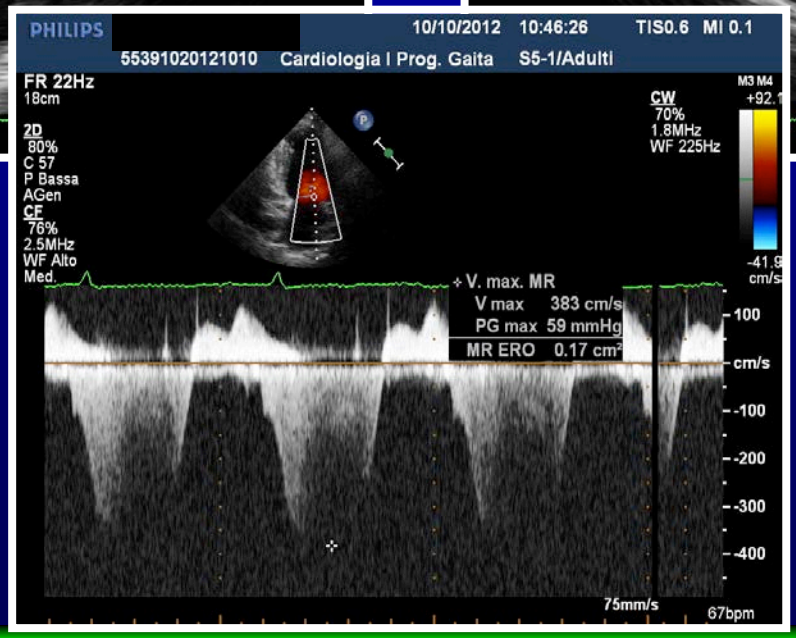

PHILIPS
28/03/2012 14:04:52 TIS0.7 MI 0.4
37370920120328
CX7-2t/Adulti
FR 10Hz
9.0cm
2D
77%
C 50
P Off
Pen
0 67 180
CF
59%
4.4MHz
WF Alto
Med.
M4 M4
+61.6
-61.6
cm/s
G
P R
JPEG
Temp. PAZ.: 37.0C
Temp. TEE: 39.8C
100 bpm

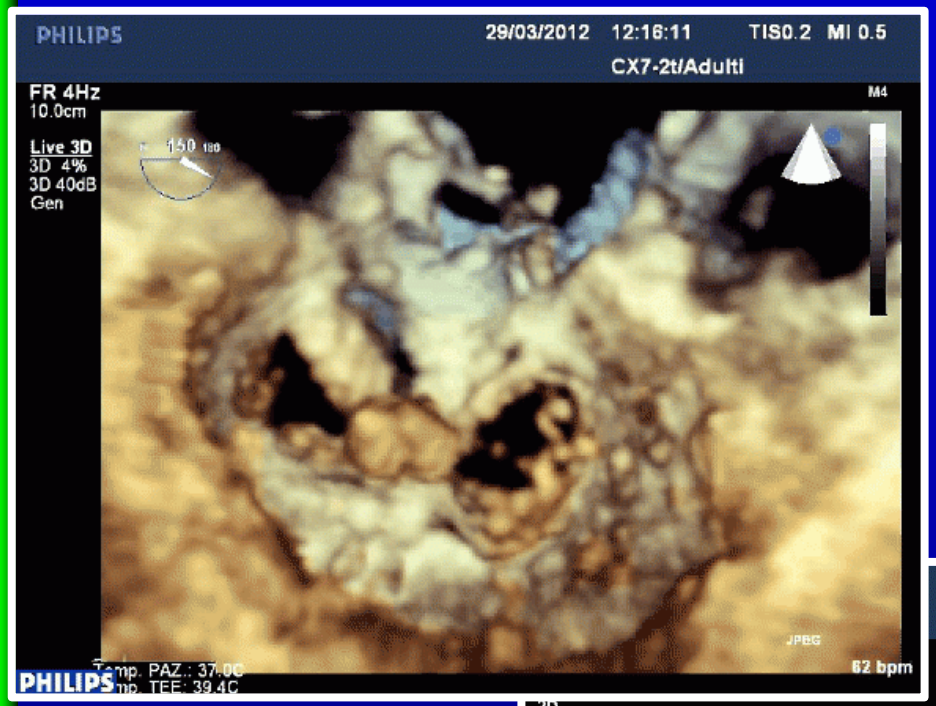

PHILIPS
[redacted]
28/03/2012 14:05:35 TIS0.7 MI 0.4
37370920120328
CX7-2t/Adulti
FR 10Hz
9.0cm
2D
77%
C 50
P Off
Pen
CF
59%
4.4MHz
WF Alto
Med.
0 153 180
M4 M4
+61.6
-61.6
cm/s
G
P R
JPEG
Temp. PAZ.: 37.0C
Temp. TEE: 39.9C
79 bpm

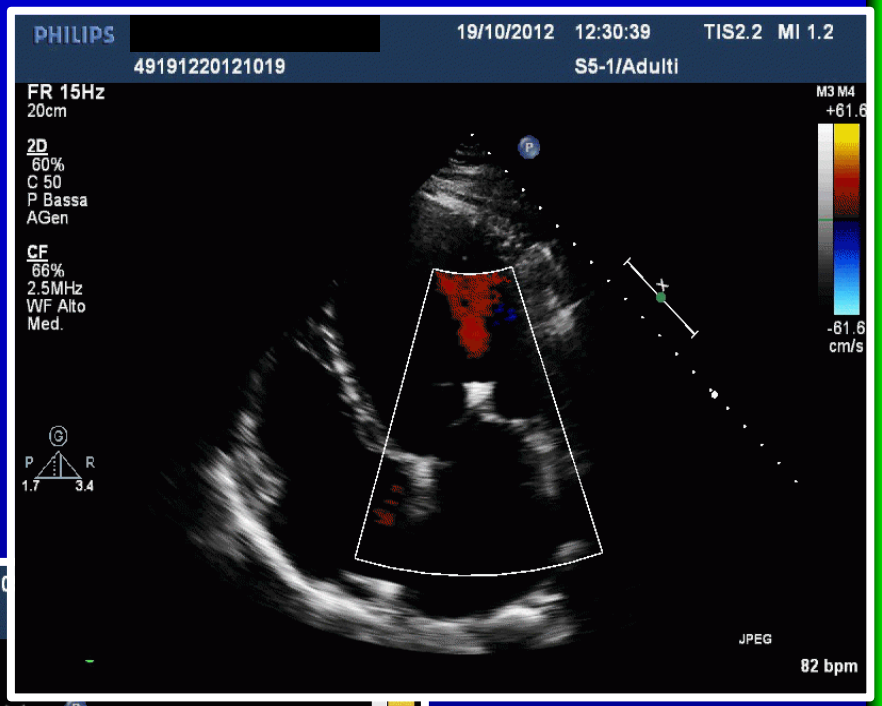
6 M. F.UP: EF 43%

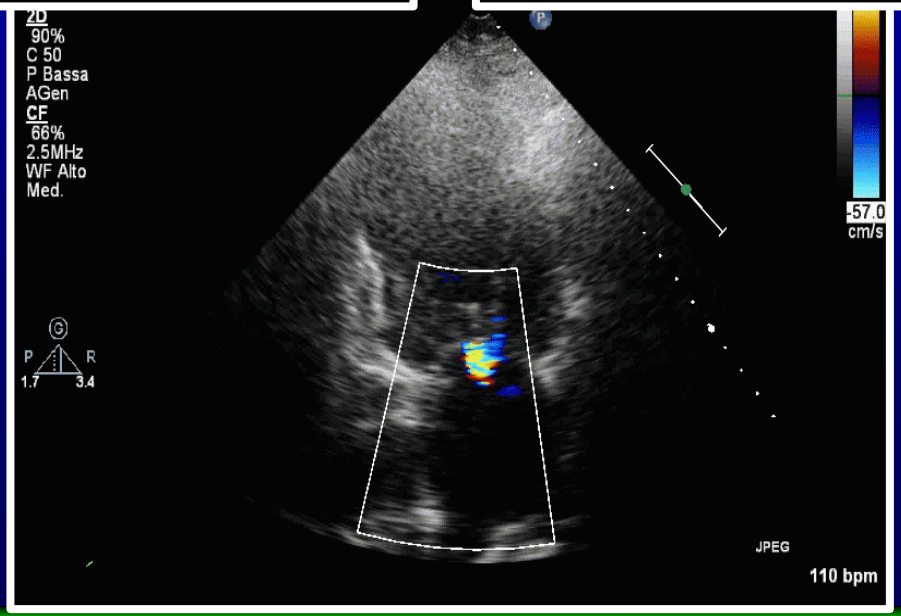

PHILIPS
10/10/2012 10:43:16 TIS0.7 MI 1.4
55391020121010 Cardiologia I Prog. Gaita S5-1/Adulti
FR 45Hz
18cm
2D
80%
C 57
P Bassa
AGen
M3
:: LVd
Lunghezza LV 8.68 cm
Area LV 40.2 cm²
EDV (A/L) 158 ml


EF 43%
PHILIPS
10/10/2012 10:44:16
55391020121010 Cardiologia I Prog. Gaita S5-1/Adulti
FR 45Hz
18cm
2D
80%
C 57
P Bassa
AGen
M3
69bpm


PHILIPS
10/10/2012 10:46:26 TIS0.6 MI 0.1
55391020121010 Cardiologia I Prog. Gaita S5-1/Adulti
FR 22Hz
18cm
2D
80%
C 57
P Bassa
AGen
CF
76%
2.5MHz
WF Alto
Med.
CW
70%
1.8MHz
WF 225Hz
M3 M4
V. max. MR
V max 383 cm/s
PG max 59 mmHg
MR ERO 0.17 cm²
100
cm/s
-100
-200
-300
-400
75mm/s
67bpm


PHILIPS
29/03/2012 12:16:11 TIS0.2 MI 0.5
CX7-2t/Adulti
FR 4Hz
10.0cm
Live 3D
3D 4%
3D 40dB
Gen
M4
JPEG
82 bpm
PHILIPS


PHILIPS
19/10/2012 12:30:39 TIS2.2 MI 1.2
49191220121019
S5-1/Adulti
FR 15Hz
20cm
2D
60%
C 50
P Bassa
AGen
CF
66%
2.5MHz
WF Alto
Med.
M3 M4
+61.6
-61.6
cm/s
JPEG
82 bpm


2D
90%
C 50
P Bassa
AGen
CF
66%
2.5MHz
WF Alto
Med.
-57.0
cm/s
JPEG
110 bpm

All is well that ends well but remember…

- Small super selected group
- Core Lab –
- Follow up ++

Final Remarks

- There is an unmet need for an alternative intervention for pts with a functional mitral regurgitation and heart failure.
- In our (small) case series Mitraclip proved to be safe and effective in this highly selected patient category.
- There is a need for a RCT comparing Mitraclip tx against best medical tx in pts with FMR and HF.

?

?

Thanks for your kind attention

…by THE TEAM !!

Mitraclip for FMR

- Surgical treatment of FMR is associated with
  - High hospital mortality
  - High recurrence rate
  - Long hospital stay
  - Unproven survival benefit
- Mitraclip for FMR
  - Procedure more simple than for DMR
  - Improvement of symptoms at low risk
  - HRR suggests survival benefit
  - Failure does not modify the surgical option

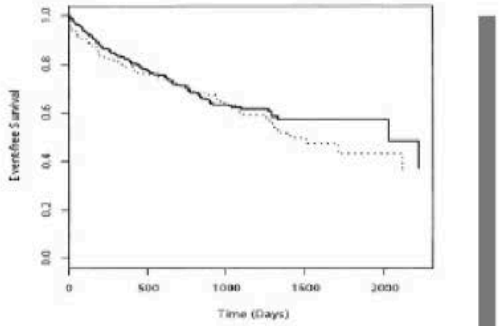
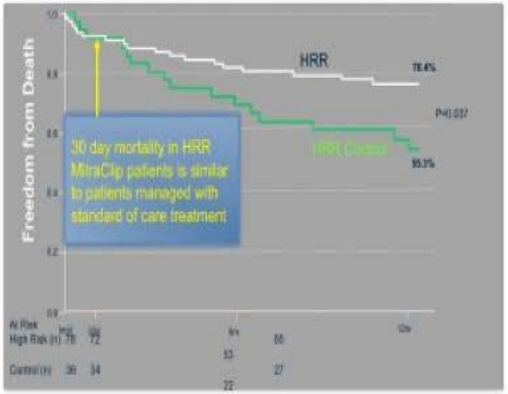
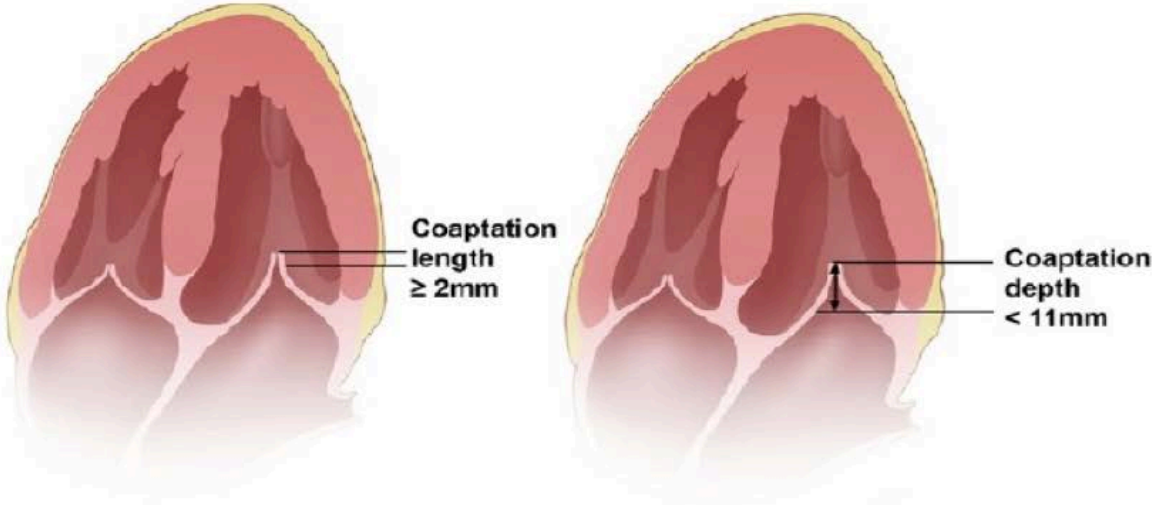


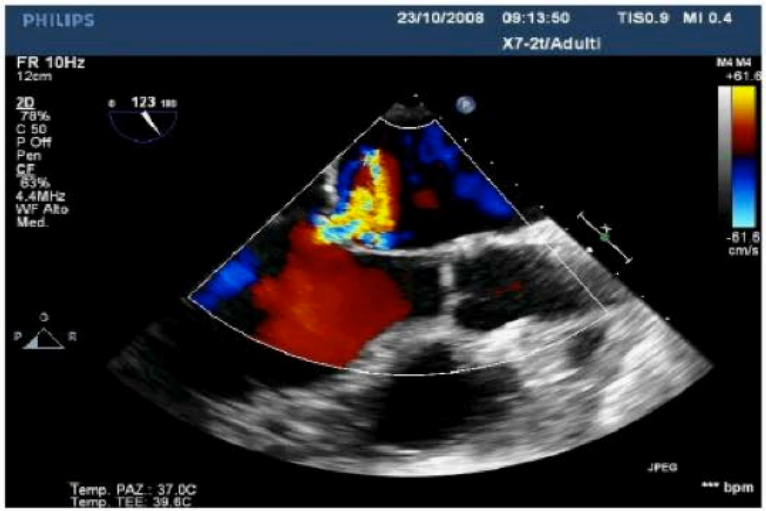
Figure 1. Event-free survival for non-mitral-valve annuloplasty (MVA) group **(solid line)** and MVA group **(dotted line)**.



Is the patient's anatomy eligible for MitraClip procedure ?

Functional MR





Screening process

TEE is mandatory for patient screening

- Significant MR?
- No severe mitral annular calcification?
- No severe leaflet restriction?
- No too severe flail leaflet?
- No cleft between A2/P2?
- No prior surgery of mitral valve?
- No intracardiac mass or thrombus?
- No presence of mitral stenosis?
- All echo views for procedure guidance are obtainable?

YES! → Good chance for technical / procedural success!

STEP_1

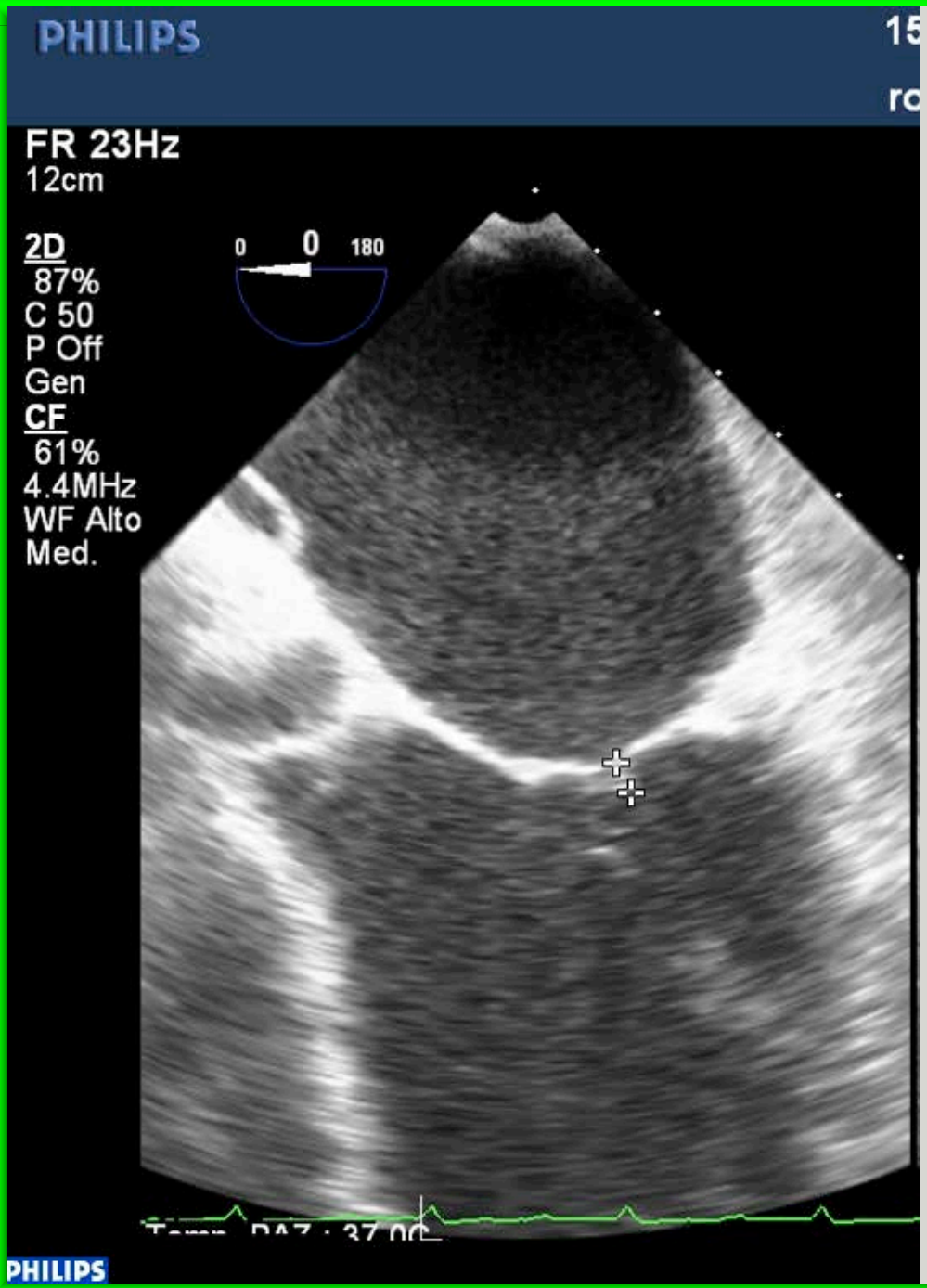
Abbott Vascular

Transesophageal Echo (TEE) Assessment Sheet

MitraClip Mitral Valve Repair System

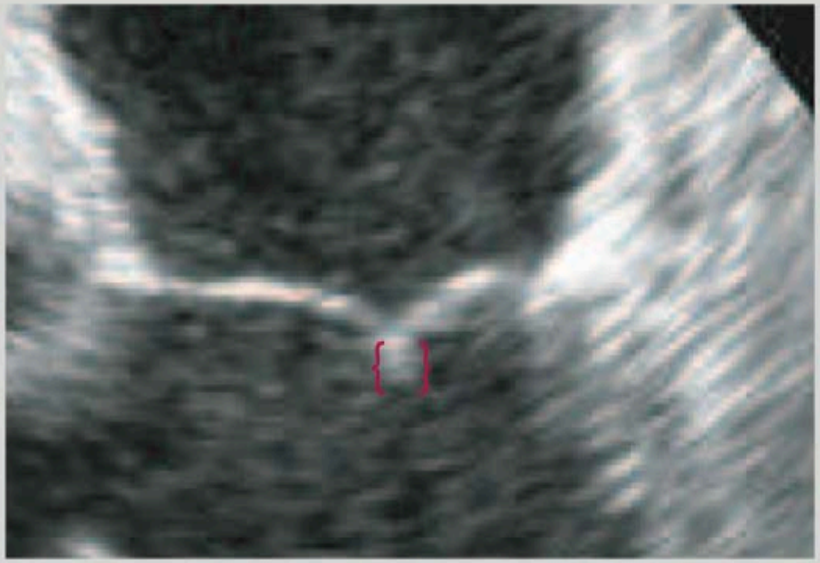
Anatomic dimensions for FUNCTIONAL MR

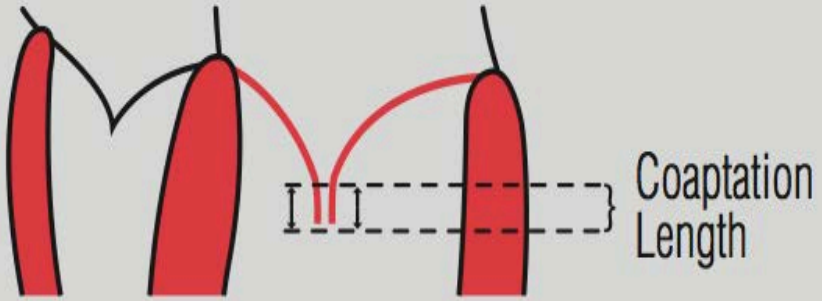
Mitral valve coaptation length Reference value* (length): ≥ 2 mm	Measurement (mm)	Reference View / Image Number
Mitral valve coaptation depth Reference value* (depth): < 11 mm	Measurement (mm)	Reference View / Image Number

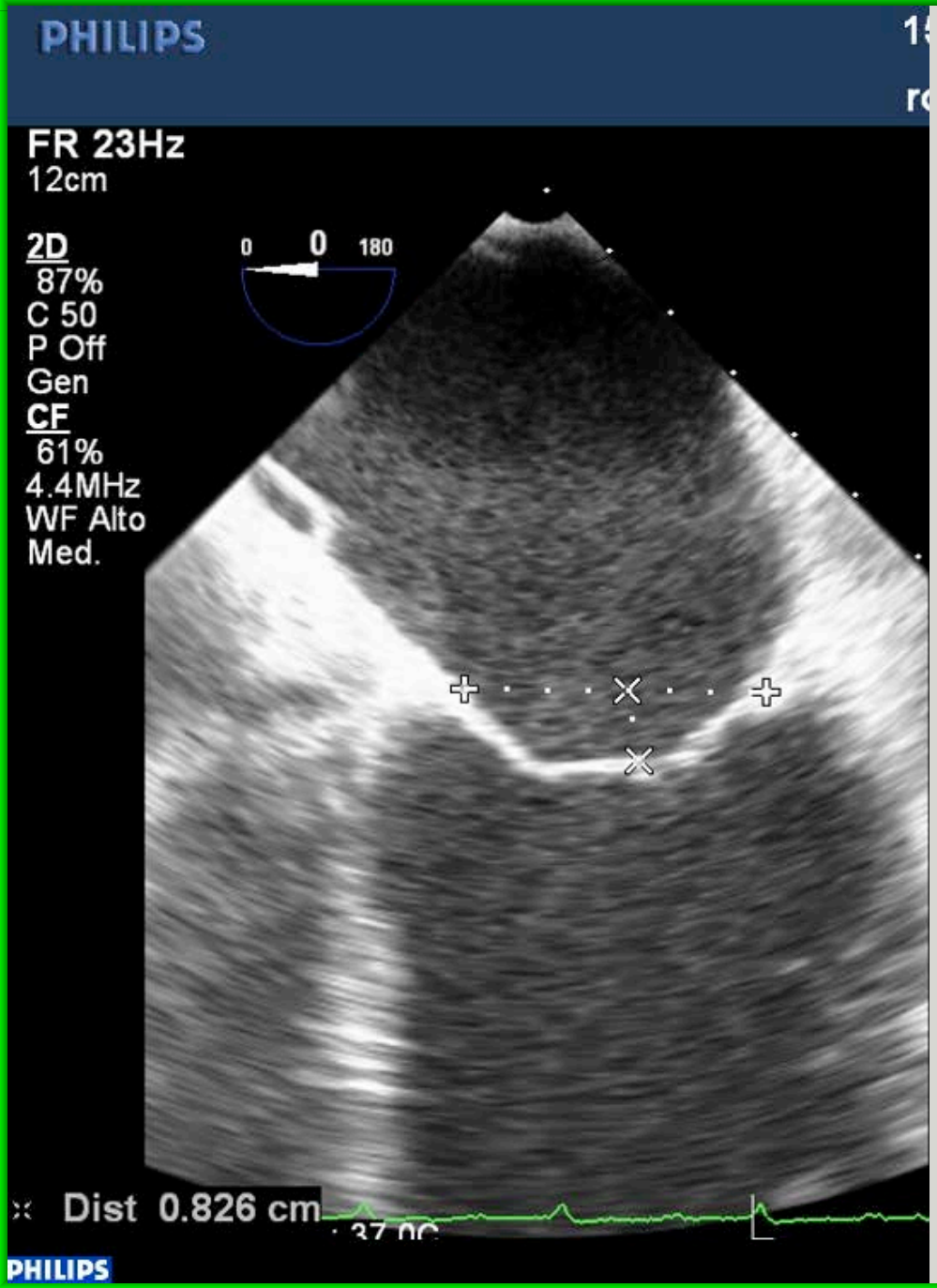


FMR Coaptation Length

The measurement should be taken in the 4C view where the coaptation length is shortest.

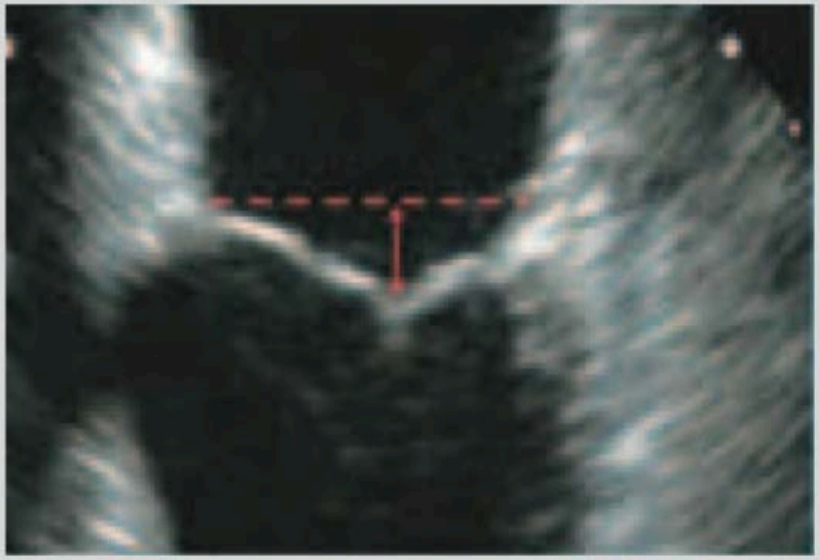


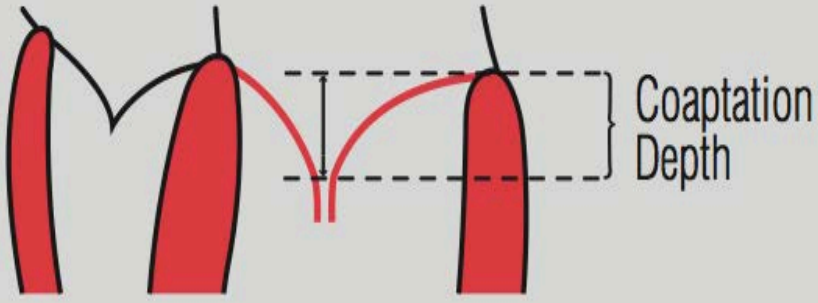




FMR Coaptation Depth

The measurement should be taken in the 4C view where the coaptation depth is greatest.





STEP_2

Abbott Vascular

Transesophageal Echo (TEE) Assessment Sheet

MitraClip Mitral Valve Repair System

Additional TEE Assessments				
Mitral valve orifice area (> 4 cm^2 required)	Measurement (cm^2)			Reference View / Image Number
Primary regurgitant jet originates from malcoaptation of A2/P2 scallops	☐ Yes	☐ No	☐ Not Evaluable	
Clinically significant secondary jet	☐ Yes	☐ No	☐ Not Evaluable	
Severe mitral annular calcification	☐ Yes	☐ No	☐ Not Evaluable	
Calcification in grasping area of A2 or P2 scallops	☐ Yes	☐ No	☐ Not Evaluable	
Leaflet anatomy or additional considerations that may preclude Clip placement *(Describe in comments)*	☐ Yes	☐ No	☐ Not Evaluable	
Presence of significant cleft or leaflet perforation	☐ Yes	☐ No	☐ Not Evaluable	
Lack of both primary and secondary chordal support	☐ Yes	☐ No	☐ Not Evaluable	
Restricted Posterior Leaflet	☐ Yes	☐ No	☐ Not Evaluable	
Leaflet thickness Reference value*: ≤ 5 mm	Measurement (mm)			Reference View / Image Number

Unmet need: Euro Heart Survey

2/3 of symptomatic MR patients >70 are denied surgery

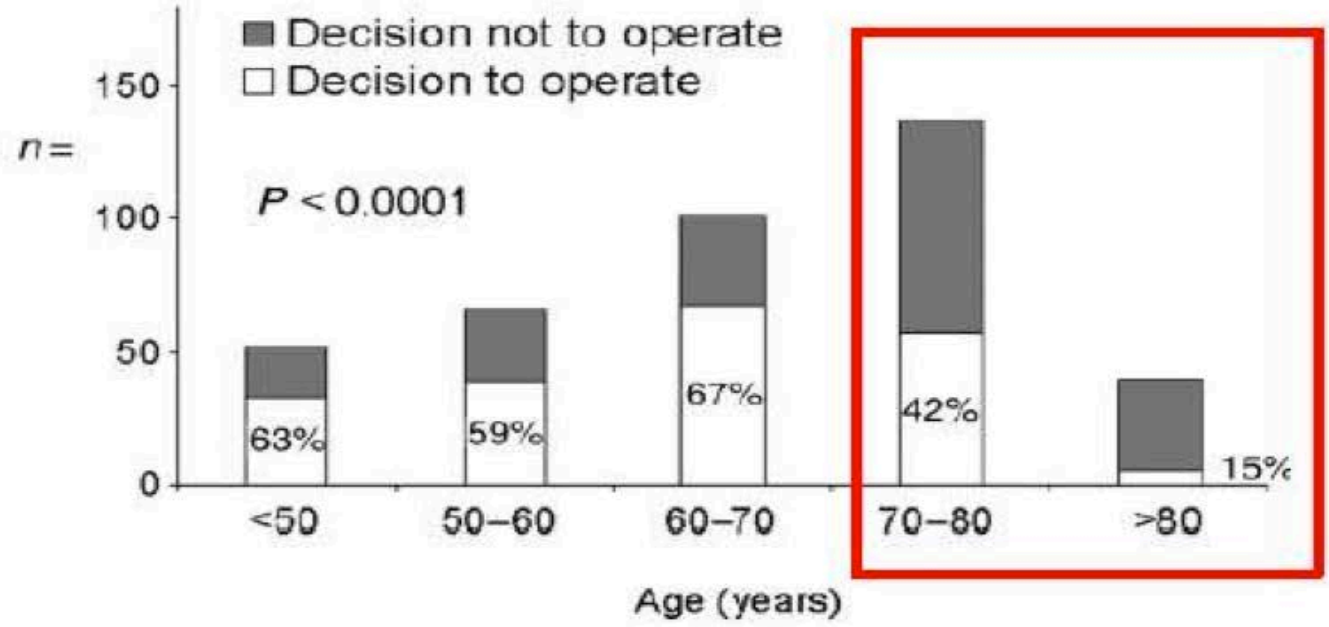


Figure 2 Decision to operate according to age range.

Mirabel et al, European Heart J 2007;28:1358-1365

STEP_3
Additional screening consideration

1. HAEMODYNAMIC INSTABILITY
2. CONTRAINDICATIONS TO DAT

3. TEE IMAGE QUALITY
4. INFORMED CONSENT !!