

Case Report Form



FONDAZIONE I.R.C.A.B.

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General Data

			CRF1	Patient ID	<input type="text"/>
CRF2	Centre number	<input type="text"/>			
CRF2	Patient's initial	<input type="text"/> ⁿ <input type="text"/> ^s	CRF3	Sex	<input type="checkbox"/> M <input type="checkbox"/> F
CRF4	Date of birth	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/> ^{yy}	CRF5	Age	<input type="text"/> yrs

Patient's History

CRF8	Chronic Angina Pectoris	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF8	Date	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/>
CRF10	Myocardial Infarction (1st)	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF10	Date	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/>
CRF10	Myocardial Infarction (2nd)	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF11	Date	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/>
CRF12	Other evidence of CHD	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF12	Date	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/>
CRF14	CABG	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF14	Date	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/>
CRF16	PTCA	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF16	Date	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/>
CRF8	Hypertension	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF8	Date	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/>
CRF10	Dyabetes Mellitus	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF10	Date	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/>
		<input type="checkbox"/> Y <input type="checkbox"/> N		Date	<input type="text"/> ^{dd} <input type="text"/> ^{mm} <input type="text"/>
CRF7	Smoking (>5 sig/day)	<input type="checkbox"/> never <input type="checkbox"/> current <input type="checkbox"/> former (>1 year)			



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Inclusion Criteria

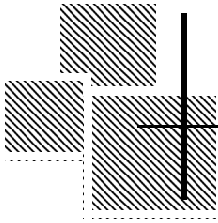
(all answers must be "yes")

- CRF8 Males or females admitted to hospital for symptoms due to unstable angina with acute ischemic ECG changes present at admission or developed thereafter, or with a documented history of coronary artery disease (hospital summary, invasive or non invasive diagnostic test) Y N
- CRF10 Stabilised symptoms: no angina episodes (with new ECG changes or > 20 min) in the last 24 hs after i.v. nitrates suspension Y N
- CRF12 No silent ST-T ischemic changes (total ischemic burden <20') in the last 24 hs after i.v. nitrates suspension Y N
- CRF12 Age ≤ 70 years Y N
- CRF12 Y N

Exclusion Criteria

(all answers must be "no")

- CRF8 ECG with persistent ST segment elevation and/or use of thrombolytic at admission Y N
- CRF10 CPK (with MB fraction > 10%) elevation more than twice the upper normal value Y N
- CRF12 Myocardial infarction within 2 months (i.e. excluding post MI unstable angina) Y N
- CRF12 Cardiac failure at admission or during hospitalization (any clinical relevant sign or symptoms) Y N
- CRF12 Severe impairment of left ventricle function: hypo/akinesia of ≥ 6/16 segments (AHA/ACC) or global EF ≤ 35% Y N
- CRF12 PTCA during the last 6 months Y N
- CRF12 CABG during the last 12 months Y N
- CRF12 Patients in whom a coronary angiogram or a rivascularization procedure has already been planned Y N
- CRF12 Inability to perform an ergometric stress test Y N
- CRF12 Atrial fibrillation, LBBB, repolarization abnormalities due to LVH and/or digoxin treatment, impairing functional tests Y N
- CRF12 Preexisting valvular disease of clinical relevance Y N
- CRF12 Unrelated disease which may limit life expectancy to < 6 months Y N
- CRF12 Poor thoracic acoustic window Y N



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Unstable Angina Data

CRF6 Date of onset or worsening of angina ^{dd} ^{mm}

CRF6 Type of angina Effort Rest angina Both

CRF6 Date of admission at hospital ^{dd} ^{mm} CRF6 Time ^{hrs}

CRF6 Symptoms at admission Worsening effort angina (Braunwald class I)
 Rest angina > 48 hours (Braunwald class II)

Angina during no°ep. Onset ECG type locat.

CRF20/21/22/23 Refractory angina Date ^{dd} ^{mm} ^{yy} Time ^{hrs} ^{min}

CRF10 Recurrent angina Date ^{dd} ^{mm} ^{yy} Time ^{hrs} ^{min}

Date ^{dd} ^{mm} ^{yy} Time ^{hrs} ^{min}

Definitions:

Angina during hospital phase: new episodes occurring between admission and randomization
 Refractory angina: with new ecg changes or longer than 20 minutes
 Recurrent angina: longer than 5 minutes without ECG changes
 ECG silent ischemia: silent ischemic episodes > 5 minutes detected either by ST-T monitoring device, conventional CCU

ECG legend (choose the more significant ECG correlated with admission symptoms)

type (if more than one code is appropriate) **location** (if more than one code is appropriate)

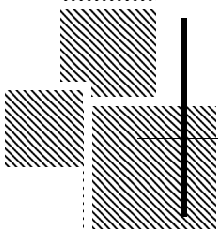
- | | | | | | |
|-------|---|---|-------|---|----------------------------|
| CRF8 | 1 | Transient ST elevation | CRF8 | 1 | Anterior or antero-lateral |
| CRF10 | 2 | ST depression > 1 mm in at least two contiguous leads | CRF10 | 2 | Inferior or infero-lateral |
| CRF14 | 3 | T wave inversion > 2 mm deep | CRF14 | 3 | Anterior and inferior |
| CRF16 | 4 | Any other ST depression | CRF16 | 4 | Lateral alone |
| CRF18 | | | | | |

Cardiac enzymes

CRF6 Date ^{dd} ^{mm}

CRF6 Troponin T/I Positive Negative CRF6 value ,

CRF6 CPK tot/ MB peak / U/L (MAX normal value _____)



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Drug Therapy

		Before	During	At	At
CRF37/38/39	Aspirin	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF40/41/42	Other Antiplatelet Drug	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF43/44/45	Heparin I.V./S.C Aptt Adj.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF46/47/48	Lmw Heparin 100 U/Kg Tid	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF49/50/51	Other Dosage Of	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF37/38/39	Lmw / S.C. Heparin	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF40/41/42	lib/liia Inhibitors	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF43/44/45	Thrombolytic Therapy	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF46/47/48	Oral Anticoagulants	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF49/50/51	Beta-Blockers	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF37/38/39	Nitrates I.V.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF40/41/42	Other Nitrates	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF43/44/45	Diltiazem / Verapamil	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF46/47/48	Dihydropiridine	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF49/50/51	Ace-Inhibitors	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF37/38/39	Diuretics	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF40/41/42	Other Antihypertensive	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF43/44/45	Lipid Lowering Drugs	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N

CRF6

RANDOMIZATION FORM

Date ^{dd} ^{mm}

CRF6

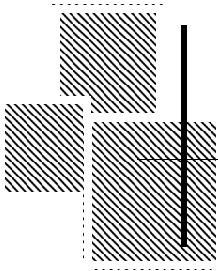
Hours since last angina episode or ST-T changes yrs

CRF6

Hours from I.V. nitrates stop yrs

CRF6

Randomized to Exercise stress test Dobutamine stress ECHO



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CRF6

Exercise Test (BRUCE PROTOCOL)

Date

dd	mm	
[][]	[][]	[][]

Ischemic Threshold (<1mm st)

Peak Values

CRF26/27

Exercise Duration

[][]

[][]

CRF26/27/28/29

BP/Heart rate

[][][][]

[][][][][][]

[][][][]

[][][][][][][]

mm Hg

Treadmill duke score

Exercise Duration (min) – (5 x mm depr/elev ST) – (4 x Treadmill Angina Index*)

*(Treadmill Angina Index 0 = No Angina 1 = Not Limiting Angina 2 = Limiting Angina)

CRF6

High (tds ≤ 10)

Intermediate (4 ≤ tds < 10)

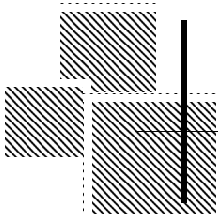
Low (tds < 4)

Exercise Test Protocol

- Performed in therapy, symptom limited
- ≥1 mm ST depression (J+80msec) in 3 consecutive beats is considered diagnostic for ischemia

Interruption criteria

- Strong chest pain, dispnea and/or intense fatigue - maximal heart rate
- ST depression >2 mm at first step, worsening or > 4 mm at any step
- ST elevation > 1 mm in two contiguous leads without Q
- Absence of rise in blood pressure - hypertensive response with SBP>240 or DBP>120 mmHg
- Worsening ventricular or sopraventricular arrhythmias (VPCs, NSVT, atrial fibrillation and flutter, ...)



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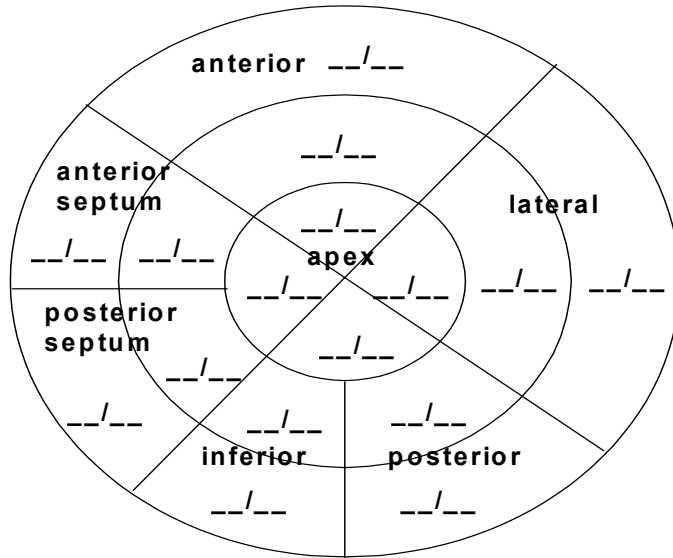
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CRF6

Dobutamine stress ECO

Date ^{dd} ^{mm}



WALL MOTION SCORE

- 1 = normal
- 2 = hypokinetic
- 3 = akinetic
- 4 = diskinetik

rest / stress

___ / ___

Ischemic Threshold (<1mm st)

Peak Values

CRF26/27

BP/Heart rate

/ / mm Hg

CRF26/27

Dobutamine dose

(γ /Kg/min) | (γ /Kg/min)

CRF26

DSE score

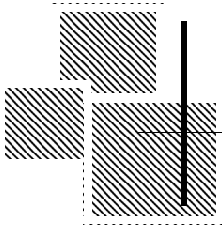
- High (nwma > 4 seg.)
- Intermediate (nwma in 2 seg. and hr < 100bpm)

Dobutamine Stress ECHO Protocol

- Performed in therapy
- ECG (12 lead continuous recording) and non invasive Blood Pressure monitoring
- Each step recorded on digital support or video-tape possibly in quad screen format for blinded review
- Dobutamine scheme:
 - 1st step 10 γ /Kg/min for 5 min
 - 2nd " 20 γ /Kg/min for 3 min
 - 3rd " 30 γ /Kg/min for 3 min
 - 4th " 40 γ /Kg/min for 3 min
- atropine 1 mg (0.25 mg i.v./min) if heart rate < 85% Max HR for sex and age

Interruption criteria

- New wall motion abnormalities (hypo/akinesia) in more than 4 segments; for this purpose the whole apex is considered 1 segment
- Large ST segment elevation in leads without Q waves



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Risk stratification

According to test score and LV Function Pts. are stratified in:

CRF26 **LOW RISK:** Low score and EF>40%
 - Patients are followed-up on medical therapy

CRF37 **MEDIUM RISK :** Medium score and EF>40%
 Low score and EF<40%
 - Cardiac catheterization is performed. Patients without coronary anatomy at risk are treated with optimal drug therapy (aspirin, beta-blocker or non dihydropiridinic calcium antagonist if contraindicated, nitrates, lipid lowering agents if indicated). Patients with high risk coronary anatomy (1. multivessel disease characterised by proximal stenosis >70% of two major coronary arteries, including proximal LAD – 2. left main stenosis > 50%) are discussed for myocardial revascularization

CRF37 **HIGH RISK:** High score
 Medium score and EF<40%

Coronary Angiogram

CRF37 (for patients at medium and high risk)

Date ^{dd} ^{mm}

	stenosis %	proximal	medium	distal
CRF37 Left main		<input type="text"/> %		
CRF40/41/42 Left anterior descending		<input type="text"/> %	<input type="text"/> %	<input type="text"/> %
CRF43/44/45 Circunflex		<input type="text"/> %	<input type="text"/> %	<input type="text"/> %
CRF46/47/48 Right coronary artery		<input type="text"/> %	<input type="text"/> %	<input type="text"/> %

Myocardial Revascularization

CRF26 Date ^{dd} ^{mm}

CRF26 PTCA Y N

CRF26 Vessel treated - Left anterior descending Y

CRF26 - Circunflex Y

CRF26 - Right Coronary artery Y N



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Follow-Up)

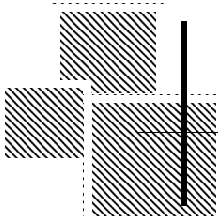
(all patients randomized)

Events	Hospital Phase	1 ST Month	6 TH Months
CRF37/38/39 Death	dd mm yy <input type="text"/>	dd mm yy <input type="text"/>	dd mm yy <input type="text"/>
CRF40/41/42 Myocardial Infarction	dd mm yy <input type="text"/>	dd mm yy <input type="text"/>	dd mm yy <input type="text"/>
CRF43/44/45 Non-Q AMI	dd mm yy <input type="text"/>	dd mm yy <input type="text"/>	dd mm yy <input type="text"/>
CRF46/47/48 Rehospitalization for UA	dd mm yy <input type="text"/>	dd mm yy <input type="text"/>	dd mm yy <input type="text"/>
CRF49/50/51 Persistent Angina	dd mm yy <input type="text"/>	dd mm yy <input type="text"/>	dd mm yy <input type="text"/>
CRF37/38/39 Cardiac Catheterisation	dd mm yy <input type="text"/>	dd mm yy <input type="text"/>	dd mm yy <input type="text"/>
CRF40/41/42	dd mm yy <input type="text"/>	dd mm yy <input type="text"/>	dd mm yy <input type="text"/>
Therapy			
CRF37/38 Aspirin		<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF40/41 Other Antiplatelet Drug		<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF43/44 Oral Anticoagulants		<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF46/47 Beta-Blockers		<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF49/50 Nitrates		<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF37/38 Diltiazem / Verapamil		<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF40/41 Dihydropiridine		<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF43/44 Ace-Inhibitors		<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF46/47		<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N

Clinical Events Definitions

- Acute myocardial infarction O or non-Q wave: characteristic prolonged chest pain associated with typical ECG ST-T changes and/or new Q waves (>0.04 s. in 2 contiguous leads) and/or significant CK tot / CKMB release (more than twice the upper normal limit).

- Persistent angina pectoris: recurrence of effort or spontaneous angina limiting daily life while on optimal medical therapy (including beta-blockers and/or calcium channel blockers, ASA, nitrates) requiring hospitalisation for coronary angiography and/or revascularisation procedures.



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Exercise Test

CRF6

(BRUCE PROTOCOL)

Date

dd mm

Ischemic Threshold (<1mm st)

Peak Values

CRF26/27

Exercise Duration

mm

mm

CRF26/27/28/29

BP/Heart rate

mm Hg

mm Hg

mm Hg

mm Hg

mm Hg

Treadmill duke score

Exercise Duration (min) - (5 x mm depr/elev ST) - (4 x Treadmill Angina Index*)

CRF6

High (tds ≤ 10)

Intermediate (4 ≤ tds < 10)

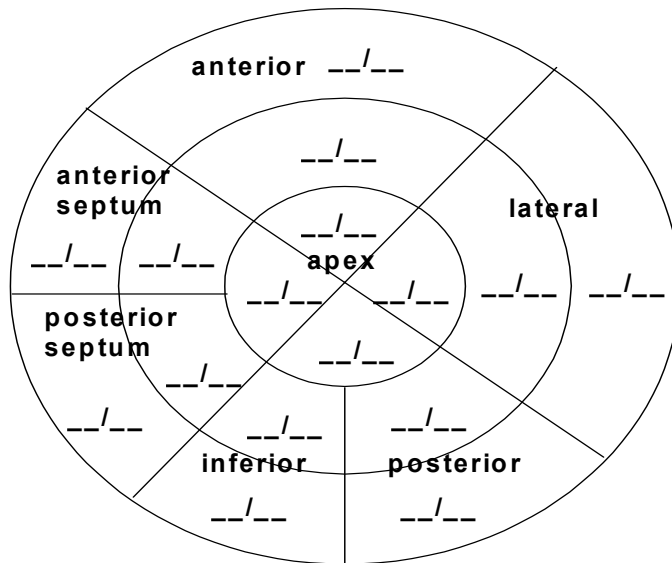
Low (tds < 4)

CRF6

Dobutamine stress ECO

Date

dd mm



WALL MOTION SCORE

- 1 = normal
- 2 = hypokinetic
- 3 = akinetic
- 4 = diskinctic

rest / stress

--- / ---

Ischemic Threshold (<1mm st)

Peak Values

CRF26/27

BP/Heart rate

mm Hg

mm Hg

mm Hg

mm Hg

mm Hg

CRF26/27

Dobutamine dose

(γ/Kg/min)

(γ/Kg/min)

(γ/Kg/min)

(γ/Kg/min)

CRF26

DSE score

High (nwma > 4 seg.)

Intermediate (nwma in 2 seg. and hr < 100bpm)