STUDYBOOK = ESCAPE
FORM = BASELINE

CONTEXT

Baseline

INVSITE <V:4> SUBJNO <V:5>

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #)

Patient Initials: __ INITIALS __ __

PATID<V:10> CONCANTINATION OF INVSITE & SUBJNO

Minnesota Living with Heart Failure

Instructions: These questions concern how your heart failure (heart condition) has prevented you from living as you wanted during the last month. The items listed below describe different ways some people are affected. If you are sure an item does not apply to you or is not related to your heart failure then circle 0 (meaning "No") and go onto the next item. If an item does apply to you, then circle the number rating of how much it prevented you from living as you wanted. Remember to think about ONLY THE LAST MONTH.

LWHFQUES (TYPE 3)

Did your heart failure prevent you from living as you wanted during the LAST MONTH by:

	No					Very Much
		Very Little →				
SWELL <ESRATE> 1. causing swelling in your ankles, legs, etc?	0 = 0	1 = 1	2 = 2	3 = 3	4 = 4	5 = 5
WORK <ESRATE> 2. making your working around the house or yard difficult?	0	1	2	3	4	5
FRIENDS <ESRATE> 3. making your relating to or doing things with your friends difficult?	0	1	2	3	4	5
REST <ESRATE> 4. making you sit or lie down to rest during the day?	0	1	2	3	4	5
ENERGY <ESRATE> 5. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
DIFF <ESRATE> 6. making your working to earn a living difficult?	0	1	2	3	4	5
WALKC <ESRATE> 7. making your walking or climbing stairs difficult?	0	1	2	3	4	5
BREATH <ESRATE> 8. making you short of breath?	0	1	2	3	4	5
SLEEP <ESRATE> 9. making your sleeping well at night difficult?	0	1	2	3	4	5
EAT <ESRATE> 10. making you eat less of the foods you like?	0	1	2	3	4	5
AWAY <ESRATE> 11. making your going places away from home difficult?	0	1	2	3	4	5
SEX <ESRATE> 12. making your sexual activities difficult?	0	1	2	3	4	5
HOBBIE <ESRATE> 13. making your recreational pastimes, sports, or hobbies difficult?	0	1	2	3	4	5
REMEM <ESRATE> 14. making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
EFFECT <ESRATE> 15. giving you side effects from medications?	0	1	2	3	4	5
WORRY <ESRATE> 16. making you worry?	0	1	2	3	4	5
DEPRS <ESRATE> 17. making you feel depressed?	0	1	2	3	4	5
COST <ESRATE> 18. costing you money for medical care?	0	1	2	3	4	5
LOSS <ESRATE> 19. making you feel a loss of self-control in your life?	0	1	2	3	4	5
STAY <ESRATE> 20. making you stay in a hospital?	0	1	2	3	4	5
BURDEN <ESRATE> 21. making you feel you are a burden to your family or friends?	0	1	2	3	4	5

Baseline Physician Assessment

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Heart Failure Clinical Assessment -- Symptoms

Does the patient have any of the following?

SYMPTOMS (TYPE3)

	No	Yes
Fatigue:	0	1
At rest FREST <ZYESNO>	☐	☐
Any activity FANYACT <ZYESNO>	☐	☐
Routine daily activity FDAYACT <ZYESNO>	☐	☐

	No	Yes
Dyspnea:	0	1
At rest DREST <ZYESNO>	☐	☐
Walking in room DWALKRM <ZYESNO>	☐	☐
Walking < 1 block DWALKBK <ZYESNO>	☐	☐

Orthopnea *(check only one)*: ORTHOP <ESMSR>
- 1 Needs only 1 pillow
- 2 Occasional orthopnea with 1 pillow
- 3 Needs 2 pillows most of the time
- 4 Needs 3 pillows most of the time
- 5 Needs 4 pillows most of the time *(sitting up)*

PHYSDAY <ESINHS>

Gastrointestinal distress *(check only one)*: GIDIST <ESWITN> 0 None 1 Occasional 2 Constant

NYHA classification *(check only one)*: NYHA <ZCLASS> 1 I 2 II 3 III 4 IV

Heart Failure Clinical Assessment—Physical Exam

PHYSEXAM (TYPE 3)

Heart rate (supine): HRSUP <I:3> ___ bpm **Heart rate (standing after 3 minutes):** HRSTAND <I:3> ___ bpm

Blood pressure manual cuff *(supine)*: SUPSYSBP <I:3> ___ (systolic) / SUPDIABP <I:3> ___ (diastolic) mmHg

PHYSDAY <ESINHS>

Blood pressure manual cuff *(standing after 3 minutes)*: STSYSBP <I:3> ___ (systolic) / STDIABP <I:3> ___ (diastolic) mmHg

Weight: WT <F:9:3> ___ ___ ___ . ___ WTUNIT <ZWGTU> 1 lb 2 kg

Respiratory rate: RESP <I:2> breaths/minute

Temperature: TEMP <F:9:3> ___ ___ ___ . ___ TEMPUNIT <ZTMPU> 1 C 2 F

Jugular venous pulsation *(cm above the right atrium)*: JVP <ESJVP> 1 < 8 2 8 -12 3 12–16 4 >16 0 Cannot measure

Rales: RALES <ESRALE> 0 None 1 < 1/3 2 1/3 - 2/3 3 > 2/3

Auscultation: S3 <ZYESNO>: 0 No 1 Yes

Estimated P2-PAS: ESTPZPAS <ESPAS> 1 < 40 2 40-50 3 51-60 4 > 60

Hepatomegaly *(check only one)*: HEPMEG <ESHEPA> 0 Absent 1 2-4 finger breadths 2 > 4 finger breadths

Hepatojugular reflux: HEPREFLX <ZYESNO> 0 No 1 Yes

Ascites *(check only one)*: ASCITES <ESACIT> 0 None 1 Trace 2 Moderate 3 Massive

Peripheral edema *(check only one)*: PEREDMA <ESEDMA> 0 0 1 1+ 2 2+ 3 3+ 4 4+

Extremities *(check only one)*: EXTREM <ESEXTR> 1 Cool 2 Lukewarm 3 Warm

Valsalva maneuver *(check only one)*: VALMAN <ESVAL> 1 Normal 2 Absent overshoot 3 Square-wave 4 Uncertain **OR** 5 Not applicable

Clinical profile *(check only one)*: CLINPRO <ESPRO> 1 Dry/warm 2 Wet/warm 3 Dry/cold 4 Wet/cold

Baseline Physician Assessment

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Heart Failure Clinical Assessment—Estimate of Hemodynamic Status

HEMSTAT (TYPE 3)

RAP <ESRAP>
Right atrial pressure (mmHg) *(check only one)*: [1] < 8 [2] 8 -12 [3] 13 - 16 [4] >16

RAPCERT <ESCERT>
Certainty of assessment *(check only one)*: [1] 1 [2] 2 [3] 3 [4] 4 [5] 5
not very sure ——— *very sure*

CROSSDT <DATE>

WEDGPRES <ESWEDG>
Pulmonary capillary wedge pressure (mmHg) *(check only one)*: [1] < 12 [2] 12 - 22 [3] 23 - 30 [4] >30

WEDGCERT <ESCERT>
Certainty of assessment *(check only one)*: [1] 1 [2] 2 [3] 3 [4] 4 [5] 5
not very sure ——— *very sure*

CARDINDX <ESCAR>
Cardiac index (L/min • m^2) *(check only one)*: [1] < 1.8 [2] 1.8 - 2.2 [3] 2.3 - 2.5 [4] > 2.5

CARDCERT <ESCERT>
Certainty of assessment *(check only one)*: [1] 1 [2] 2 [3] 3 [4] 4 [5] 5
not very sure ——— *very sure*

Physician Estimate of Likelihood of Death over next 6 months

Check only one:
- ☐ 0 - 25%
- ☐ 26 - 50%
- ☐ 51 - 75%
- ☐ 76 - 100%

This is not entered

Physician Estimate of Readmission over next 6 months

Check only one:
- ☐ 0 - 25%
- ☐ 26 - 50%
- ☐ 51 - 75%
- ☐ 76 - 100%

This is not entered

Signature (Physician who performed assessment)

PHYSDAY <ESINHS> SIGNATUR (TYPE 4)

SIGTYPE <ZSIGTY>
1= **Investigator's signature:** SIGNANS <ZYES> 1 = YES, IF SIGNED **Date performed:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SIGDT <DATE>
2= Study Coordinator

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Demographics

Date of birth: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) → (Date Example: 03/OCT/1930) DOBDT <DATE>

Sex: [1] Male [2] Female GENDER <ZSEX> DEMOG (TYPE 1)

Race (check only one): [1] Caucasian [2] Black [3] Asian [4] Hispanic [5] Native American [98] Other (specify): _____ RACE<ZRACE> RACETX <V:40>

Height: ___ ___ ___ [1] inch [2] cm HT <I:3> HTUNIT<ZHGTU>

Randomization

Enrolling hospital admission date and time: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) ___:___ (00:00–23:59) HOSADMDT <DATE> HOSADMTM <DATETIME> RANDO (TYPE 1)

Was the patient transferred from another hospital? TRANSFER <ZYESNO>

[0] No

[1] Yes → If Yes, date of admission: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) TRNADMDT <DATE>

Did the patient meet all the inclusion and exclusion criteria? [0] No [1] Yes INCEXC <ZYESNO>

Randomization date and time: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00–23:59) RANDODT <DATE> RANDOTM <DATETIME>

Was patient randomized to PAC? [0] No [1] Yes RANPAC <ZYESNO>

Socioeconomic Information

Does the patient live alone? [0] No [1] Yes LIVEALN <ZYESNO> SOCIO (TYPE 1)

Patient's residence (check only one): [1] Home [2] Assisted living [3] Skilled nursing facility RESIDNCE <ESRES>

Education (highest level completed): [1] Grade school [3] Some high school [5] High school [2] Technical school [4] Undergraduate school [6] Graduate school EDUCATN <ESED>

Insurance status (check only one): [0] None [1] Private [2] Medicare [3] Medicaid [4] Private and Medicare [5] Medicare and Medicaid INSURANC <ESINS>

Household income level (US$): [1] < 25,000 [2] 25–49,999 [3] 50–74,999 [4] 75–99,999 [5] ≥ 100,000 INCOME <ESINC>

Resuscitation orders (check only one): [1] Attempt cardiopulmonary resuscitation [2] Attempt cardiopulmonary resuscitation but do not intubate [3] Do not attempt cardiopulmonary resuscitation RESUSORD <ESRESU>

Clinical History

Estimated date of initial diagnosis of heart failure: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) INDIAGDT <DATE> CLINHIS1 (TYPE 1)

Number of hospitalizations within prior 12 months (specify): ___ <I:2> NUMHOSP

Date of last hospital admission: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) LSTADMDT <DATE>

Date of last LVEF: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) LSTLVDT <DATE>

Value of last LVEF: EF ___ % (record whole number) EF <I:3>

Quantitative method of LV function (check only one): [1] Radionuclide ventriculogram [2] Ventricular angiography [3] Echocardiogram LVMETH <ESLV>

Clinical History (continued)

Primary etiology of heart failure *(rank up to 3 in order of importance with 1 being most important)*: CLINHIS2 (TYPE 2) PS

ETIOHF <ESHF>

1 = Alcoholic ETIOHFRK <I:1>
2 = Cytotoxic drug therapy <I:1>
3 = Familial <I:1>
4 = Hypertensive <I:1>
5 = Idiopathic <I:1>
6 = Ischemic <I:1>
7 = Peripartum <I:1>
8 = Valvular <I:1>
9 = Other/uncertain <I:1>

Does the patient have a documented history of any of the following? CLINHIS3 (TYPE 2) PS

DOCHIST <ESHIST>

	No	Yes
DOCHISYN <ZYESNO>		
Ischemic heart disease:		
1 = Angina pectoris	0	1
2 = Myocardial infarction (MI)	0	1
3 = Percutaneous transluminal coronary intervention (PTCI)	0	1
4 = Coronary artery bypass graft (CABG)	0	1
Valvular heart disease:		
5 = Primary tricuspid regurgitation	0	1
6 = Mitral stenosis	0	1
7 = Primary mitral regurgitation	0	1
8 = Aortic stenosis	0	1
9 = Aortic regurgitation	0	1
10 = **Peripheral vascular disease:**	0	1
11 = **Chronic obstructive pulmonary disease:**	0	1
12 = **Chronic steroid use:**	0	1
13 = **Diabetes:**	0	1
14 = Insulin dependent	0	1
15 = Controlled by oral agents	0	1
16 = **Gout:**	0	1
17 = **Hepatic disease:**	0	1
18 = **Hypertension:**	0	1
Cerebrovascular disease:		
19 = TIA	0	1
20 = Stroke	0	1
Arrhythmias:		
21 = Atrial fibrillation	0	1
22 = Sustained ventricular tachycardia	0	1
23 = Torsades de pointe	0	1
24 = Ventricular fibrillation	0	1
25 = Cardiac arrest/Rhythm unknown	0	1
26 = **Implantable cardiac defibrillator:**	0	1
27 = **Pacemaker placement:**	0	1
28 = **Malignancy:**	0	1
29 = **Depression** *(treated with prescription medications)*:	0	1

CLINHIS4 (TYPE 1)

CIGSMOK <ESSMOK>
Cigarette smoking *(check only one)*: 1 Current 2 Quit < 6 months ago 3 Quit ≥ 6 months ago 0 Never

HRTTRAN <ESHRT>
Heart transplant status *(check only one)*: 1 Ineligible 2 Active evaluation 3 No evaluation planned

RENAL <ESREN>
Renal insufficiency *(check only one)*: 1 History of creatinine > 3.5 mg/dL 2 History of chronic dialysis 0 Neither

Left Heart Catheterization Results

Date of last left heart catheterization before randomization: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) OR 1 Not applicable

LSTCTHDT <DATE> LSTCTHNA <ZYES>

Vessels with > 70% stenosis *(check all that apply)*: 1 LM 1 LAD 1 LCX 1 RCA

STENLM <ZYES> STNLCX <ZYES> STENLAD <ZYES> STENRCA <ZYES>

LHCATH (TYPE 1)

ECG (Record results of ECG closest to time of randomization.)

ECG (TYPE 3)

Date and time: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00–23:59)

ECGDT <DATE> ECGTM <DATETIME>

Rate: ___ ___ ___ bpm

RATE <I:3>

RHYTHM <ESRHY>

Rhythm *(check only one)*: 1 Sinus bradycardia 3 Normal sinus rhythm 5 Sinus tachycardia 2 Atrial fibrillation/flutter 4 Paced rhythm 98 Other

Specific abnormalities *(check all that apply)*: 1 RBBB 1 LBBB 1 Not applicable

ABNRBBB <ZYES> ABNNA <ZYES> ABNLBBB <ZYES>

Current Medications (Include all medications patient was taking prior to hospitalization.)

ACE inhibitor: [0] No → If No, specify reason *(check all that apply)*: ACE1 (TYPE 3)

ACE <ZYESNO>

- ANGIO <ZYES> [1] Angioedema, anaphylaxis, neutropenia
- COUGH <ZYES> [1] Cough
- HYPRKAL <ZYES> [1] Hyperkalemia
- RNL <ZYES> [1] Renal artery stenosis
- RNLDYS <ZYES> [1] Renal dysfunction
- SYMP <ZYES> [1] Symptomatic hypotension
- OTHAE <ZYES> [1] Other adverse events such as taste disturbance, rash, and gastrointestinal upset

ACE2 (TYPE 3)

[1] Yes → If Yes:

		Total daily dose:
[1] Benazepril	BENAZ <ZYES>	BENAZDS <F:9:3> mg
[1] Captopril	CAPTO <ZYES>	CAPTODS <F:9:3> mg
[1] Enalapril	ENALA <ZYES>	ENALADS <F:9:3> mg
[1] Fosinopril	FOSINO <ZYES>	FOSINODS <F:9:3> mg
[1] Lisinopril	LISINO <ZYES>	LISINODS <F:9:3> mg
[1] Quinapril	QUINA <ZYES>	QUINADS <F:9:3> mg
[1] Ramipril	RAMI <ZYES>	RAMIDS <F:9:3> mg
[1] Trandolapril	TRANDO <ZYES>	TRANDODS <F:9:3> mg
[1] Other *(specify)*: OTHACESP <V:60>	OTHACE <ZYES>	OTHACEDS <F:9:3> mg

ANGIODIG (TYPE 3)

Angiotensin II antagonist : [0] No [1] Yes → If Yes:

ANGIOT <ZYESNO>

		Total daily dose:
[1] Candesartan	CANDE <ZYES>	CANDEDS <F:9:3> mg
[1] Losartan	LOSAR <ZYES>	LOSARDS <F:9:3> mg
[1] Valsartan	VALSAR <ZYES>	VALSARDS <F:9:3> mg
[1] Other *(specify)*: OTHANGSP <V:60>	OTHANG <ZYES>	OTHANGDS <F:9:3> mg

DIGOXIN <ZYESNO>

Digoxin: [0] No [1] Yes → **If Yes, specify total dose and frequency:** DIGDS <F:10:4> mg [1] QD [2] QOD [98] Other DIGFQ <ESFQ>

DIUR1 (TYPE 3)

Diuretic: (loop) [0] No [1] Yes → If Yes:

DIULOOP <ZYESNO>

		Total daily dose:
[1] Bumetanide	BUMETA <ZYES>	BUMETADS <F:9:3> mg
[1] Ethacrynic acid	ETHACR <ZYES>	ETHACRDS <F:9:3> mg
[1] Furosemide	FUROSE <ZYES>	FUROSEDS <F:9:3> mg
[1] Torsemide	TORSE <ZYES>	TORSEDS <F:9:3> mg
[1] Other *(specify)*: OTHDILSP <V:60>	OTHDIL <ZYES>	OTHDILDS <F:9:3> mg

Diuretic: (potassium sparing) [0] No [1] Yes → If Yes:

DIUPOT <ZYESNO>

		Total daily dose:
[1] Amiloride	AMILO <ZYES>	AMILODS <F:9:3> mg
[1] Spironolactone	SPIRO <ZYES>	SPIRODS <F:9:3> mg
[1] Triamterene	TRIAM <ZYES>	TRIAMDS <F:9:3> mg
[1] Other *(specify)*: OTHDIPSP <V:60>	OTHDIP <ZYES>	OTHDIPDS <F:9:3> mg

DIURCCB (TYPE 3)

Diuretic: (thiazide) [0] No [1] Yes → If Yes:

DIUTHIA <ZYESNO>

		Total daily dose:
[1] Chlorothiazide (diuril)	CHLORO <ZYES>	CHLORODS <F:9:3> mg
[1] Hydrochlorothiazide (HCTZ)	HCTZ <ZYES>	HCTZDS <F:9:3> mg
[1] Metolazone (zaroxolyn)	METOLA <ZYES>	METOLADS <F:9:3> mg
[1] Other *(specify)*: OTHDITSP <V:60>	OTHDIT <ZYES>	OTHDITDS <F:9:3> mg

Calcium channel blocker: [0] No [1] Yes → If Yes:

CCBLK <ZYESNO>

		Total daily dose:
[1] Amlodipine	AMLODI <ZYES>	AMLODIDS <F:9:3> mg
[1] Other *(specify)*: OTHCCBSP <V:60>	OTHCCB <ZYES>	OTHCCBDS <F:9:3> mg

Current Medications (cont.) (Include all medications patient was taking prior to hospitalization.)

BBANTIAR (TYPE 3)

Beta blocker: [0] No [1] Yes → If Yes: BBLOCK <ZYESNO>

		Total daily dose:
[1] Atenolol	ATENO <ZYES>	ATENODS <F:9:3> mg
[1] Bisoprolol	BISO <ZYES>	BISODS <F:9:3> mg
[1] Carvedilol	CARVE <ZEYS>	CARVEDS <F:9:3> mg
[1] Metoprolol	METO <ZYES>	METODS <F:9:3> mg
[1] Propranolol	PROP <ZYES>	PROPDS <F:9:3> mg
[1] Other (specify): OTHBBSP <V:60>	OTHBB <ZYES>	OTHBBDS <F:9:3> mg

Antiarrhythmics: [0] No [1] Yes → If Yes: ANTIARRH <ZYESNO>

		Total daily dose:
[1] Amiodarone	AMIOD <ZYES>	AMIODDS <F:9:3> mg
[1] Dofetilide	DOFET <ZYES>	DOFETDS <F:9:3> mg
[1] Sotalol	SOTA <ZYES>	SOTADS <F:9:3> mg
[1] Other (specify): OTHAASP <V:60>	OTHAA <ZYES>	OTHAADS <F:9:3> mg

NIHYPOT (TYPE 3)

Nitrates: [0] No [1] Yes → If Yes: NITRA <ZYESNO>

		Total daily dose:
[1] Isosorbide dinitrate	DINIT <ZYES>	DINITDS <F:9:3> mg
[1] Isosorbide mononitrate	MONONI <ZYES>	MONONIDS <F:9:3> mg
[1] Topical nitroglycerin	TOPNIT <ZYES>	TOPNITDS <F:9:3> mg

Hydralazine: [0] No [1] Yes → If Yes, total daily dose: HYDRA <ZYESNO> — HYDRADS <F:9:3> mg

Potassium: [0] No [1] Yes → If Yes, total daily dose: POTAS <ZYESNO> — POTASDS <F:9:3> mEq

MEDS (TYPE 4) PS

MED <ESMED> MEDRSP <ZYESNO>

1= Statins:	[0] No [1] Yes	12= Antidepressants:	[ ] No [ ] Yes
2= Other lipid lowering agents:	[ ] No [ ] Yes	13= Benzodiazepines:	[ ] No [ ] Yes
3= Magnesium:	[ ] No [ ] Yes	14= Allopurinol:	[ ] No [ ] Yes
4= Estrogen replacement therapy:	[ ] No [ ] Yes	15= Colchicine:	[ ] No [ ] Yes
5= Testosterone replacement therapy:	[ ] No [ ] Yes	16= Enoxaparin:	[ ] No [ ] Yes
6= Insulin:	[ ] No [ ] Yes	17= Warfarin:	[ ] No [ ] Yes
7= Oral diabetic agents:	[ ] No [ ] Yes	18= Vitamin E:	[ ] No [ ] Yes
8= Aspirin (daily):	[ ] No [ ] Yes	19= CoEnzyme Q10:	[ ] No [ ] Yes
9= Other antiplatelet agents:	[ ] No [ ] Yes	20= Other antioxidants:	[ ] No [ ] Yes
10= NSAIDs:	[ ] No [ ] Yes	21= Multi-vitamin:	[ ] No [ ] Yes
11= Thyroid replacement therapy:	[ ] No [ ] Yes		

OTHINV (TYPE 3)

Other investigational study drug: [0] No [1] Yes → If Yes, specify study drug: OTHINVSP <V:100> OTHINVS <ZYESNO>

Current/Intermittent Infusions (Include all medications patient was taking prior to hospitalization.)

INFUS (TYPE 4) PS

		Current infusion rate:	
1= Amrinone:	[0] No [1] Yes → If Yes: INFRSP <ZYESNO>	INFUDS <F:9:3> mcg/kg/min	INFUDAY <I:2> # days/month
2= Dobutamine:	[ ] No [ ] Yes → If Yes:	_____ mcg/kg/min	_____ # days/month
3= Dopamine:	[ ] No [ ] Yes → If Yes:	_____ mcg/kg/min	_____ # days/month
4= Milrinone:	[ ] No [ ] Yes → If Yes:	_____ mcg/kg/min	_____ # days/month

INFUNM <ESINF>

5= Nitroglycerin
6= Nitroprusside
7= Natracor

Inpatient Medication Summary (Medications taken from hospital admission to randomization.)

INPTMED1 (TYPE 4) PS

IVINFMED <ESIV> Intravenous Infusions:	IVINFRSP <ZYESNO>	Start dose: IVINFSDS <F:9:3>	Highest dose: IVINFHDS <F:9:3>	Total # Days: (record whole number) IVINFDAY <I:4>
1= Amrinone	[0] No [1] Yes → If Yes:	_____ mcg/kg/min	_____ mcg/kg/min	_____
2= Dobutamine	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	_____ mcg/kg/min	_____
3= Dopamine	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	_____ mcg/kg/min	_____
4= Milrinone	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	_____ mcg/kg/min	_____
5= Nitroglycerin	☐ No ☐ Yes → If Yes:	_____ mcg/min	_____ mcg/min	_____
6= Nitroprusside	☐ No ☐ Yes → If Yes:	_____ mcg/min	_____ mcg/min	_____

INPTMED2 (TYPE 4) PS

MEDNAME <ESMDNM>	MEDNMRSP <ZYESNO>	Highest total daily dose: MEDTOTAL <F:9:3>	Highest single daily dose: MEDSINGL <F:9:3>	Total # Days: (record whole number) MEDNUM <I:4>
ACE inhibitors:				
1= Benazepril	[0] No [1] Yes → If Yes:	_____ mg	_____ mg	_____
2= Captopril	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
3= Enalapril	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
4= Fosinopril	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
5= Lisinopril	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
6= Quinapril	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
7= Ramipril	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
8= Trandolapril	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
9= Other	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
Angiotensin II antagonist:				
10=Candesartan	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
11=Losartan	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
12=Valsartan	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
13=Other	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
14= **Hydralazine:**	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
15= **Isosorbide dinitrate:**	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
16= **Isosorbide mononitrate:**	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
17= **Topical nitroglycerin:**	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____

INPTMED3 (TYPE 4) PS

MEDNM <ESNAME>	MEDNAMRE <ZYESNO>	Highest total daily dose: PO MEDTOTPO <F:9:3>	Highest total daily dose: IV MEDTOTIV <F:9:3>	Total # Days: (record whole number) PO MEDDAYPO <I:4>	Total # Days: (record whole number) IV MEDDAYIV <I:4>
Diuretic (loop):					
1= Bumetanide	[0] No [1] Yes → If Yes:	_____ mg	_____ mg	_____	_____
2= Ethacrynic acid	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____	_____
3= Furosemide	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____	_____
4= Torsemide	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____	_____
5= Other	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____	_____
Diuretic (potassium sparing):					
6= Amiloride	☐ No ☐ Yes → If Yes:	_____ mg		_____	
7= Spironolactone	☐ No ☐ Yes → If Yes:	_____ mg		_____	
8= Triamterene	☐ No ☐ Yes → If Yes:	_____ mg		_____	
9= Other	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____	_____
Diuretic (thiazide):					
10=Chlorothiazide (diuril)	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____	_____
11=Hydrochlorothiazide (HCTZ)	☐ No ☐ Yes → If Yes:	_____ mg		_____	
12=Metolazone (zaroxolyn)	☐ No ☐ Yes → If Yes:	_____ mg		_____	
13=Other	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____	_____

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Visual Analog Scale Scores (Complete the Visual Analog Scale Worksheet)

VISUAL (TYPE 3)

Examination date: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) VISUALDT <DATE>

Worst symptom: ___ <I:3> ___ → Corresponding to (Check only one): WRSTSYM WRSTSYMP <ESWRST>

- [1] Abdominal discomfort
- [2] Breathing
- [3] Body swelling
- [4] Fatigue

Breathing: ___ ___ ___ <I:3> OR [1] Not applicable if breathing was selected as worst symptom BREATHING BRTHNGNA <ZYES>

Global: ___ <I:3> ___ GLOBAL

Time Trade-Off Scores

TIMETRAD (TYPE 3)

Examination date: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) TIMEDT <DATE>

Score: ___ ___ months TIMESCRN <F:9:3> [1] or 1 day ONEDAY <ZYES> Indifferent = 1 INDIFF<ZYES>

*TIMESCR <I:2>

6 Minute Walk Exercise Test

WALK (TYPE 3)

Did the patient attempt the 6-minute walk test? WALKTST <ZYESNO>

[0] No → If No, specify primary reason: WALKRENO <ESWLK>

- [1] The patient was too critically ill to be taken out of bed and exercised.
- [2] Patient cannot walk for technical reasons (e.g., a patient who is an amputee).
- [3] Not done due to oversight.

[1] Yes → If Yes, complete below.

Examination date: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) WALKDT <DATE>

Start time of walk: ___ ___ : ___ ___ (00:00–23:59) WALKSTTM <DATETIME>

End time of walk: ___ ___ : ___ ___ (00:00–23:59) WALKEDTM <DATETIME>

Total distance walked: ___ <F:9:3> ___ WALKDIS [1] Feet [2] Meters WALKUNIT <ESWKUT>

Did the patient experience any of the following symptoms *(check all that apply)*:

- [1] Angina ANGINA <ZYES>
- [1] Light headedness LGTHEAD <ZYES>
- [1] Syncope SYNCOPE <ZYES>

Borg Dyspnea score: ___ <F:9:3> ___ *(Transcribe score from worksheet.)* BORGSCOR

*TIMESCR is to be deleted from the page section

Echocardiogram Data

ECHO (TYPE 3)

Examination date and time: ECHODT <DATE>
___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
ECHOTM <DATETIME> ___ ___:___ ___ (00:00–23:59)

Blood pressure *(closest to start of ECHO)*: ECOSYSBP <I:3>___ ___ / ___ ECODIABP <I:3>___ (systolic / diastolic)

- Send ECHO tape to Brigham Core Lab

Cardiopulmonary Exercise (CPX)

CPX (TYPE 3)

Did the patient attempt cardiopulmonary exercise testing?

CPX <ZYESNO>

[0] No → **If No, specify primary reason:**

CPXRE <ESCPX>

[1] The patient was too critically ill to be taken out of bed and exercised.

[2] The patient was unable to walk > 50 meters on the 6 minute walk.

[3] Patient cannot walk for technical reasons (e.g., a patient who is an amputee).

[4] Not done due to oversight.

[1] Yes → **If Yes, complete below.**

Examination date: CPXDT <DATE>
___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

CPXTYPE <ESCPXT>

Type of exercise *(patient should perform same type of exercise throughout study)*: [1] Bicycle [2] Treadmill

Peak cardiovascular responses:

- **VO_2** (ml/kg/min): VO2 <F:9:3>
- **VCO_2** (ml/kg/min): VCO2 <F:9:3>
- **VE max** (L/min): VEMAX <F:9:3>
- **VE/VCO_2** (25 watts or end of first workload on treadmill): VEVCO2 <F:9:3>
- **VO_2 @ R = 1.0:** VO2R <F:9:3>
- **Heart rate** (bpm): HRTRATE <I:3>
- **Systolic BP** (max): SYSBP <I:3>
- **Diastolic BP** (max): DIABP <I:3>
- **Duration of exercise** (min): DUREX <F:9:3> DUREXS <F:9:3>
- **Respiratory exchange ratio:** REXCHNG <F:9:3>

DUREXDM <F:9:3> := DUREX+(DUREXS/60)

CPXTERM <ESTERM>

Reason for termination of testing *(check primary reason)*:

[1] Patient completed testing
[2] Symptom limited (e.g., dyspnea, fatigue)
[3] Angina
[4] Serious arrhythmia
[5] Blood pressure changes
[6] No longer able to walk (e.g., leg cramps)
[98] Other

Laboratory (Prior to randomization)

LABDT <DATE>

LAB (TYPE 4) PS

Date of collection: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

LABDAY <ESINHS>

Value	Value
1 = LAB <ESLAB> **Hemoglobin (Hgb)** _____ LABVAL <F:9:3> ☐1 g/L ☐2 mmol/L ☐3 g/dL	10 = **AST/SGOT** _____ IU/L OR U/L OR mIU/mL
2 = **Platelets** _____ ☐4 10^9/L OR 10^3/mm³ ☐5 /mm³	11 = **Total protein** _____ ☐ g/dL ☐ g/L
3 = **Hematocrit (Hct)** _____ ☐6 L/L ☐7 %	12 = **Albumin** _____ ☐ g/dL ☐ g/L
4 = **WBC** _____ ☐ 10^9/L OR 10^3/mm³ ☐ /mm³	13 = **Total bilirubin** _____ ☐ mg/dL ☐ µmol/L
5 = **Sodium** _____ 8 mmol/L OR mEq/L	14 = **Direct bilirubin** _____ ☐ mg/dL ☐ µmol/L
6 = **Potassium** _____ mmol/L OR mEq/L	**CK** (ULN = CKULN <F:9:3>) CKVAL <F:9:3> IU/L OR U/L OR mIU/mL ENZYMES (TYPE 3) CKND <ZYES> ☐1 Not Done
7 = **BUN** _____ 9 mg/dL	**CK-MB** (ULN = CKMBULN <F:9:3>) CKMBVAL <F:9:3> ☐12 mcg/L OR µg/L OR ng/mL ☐ IU/L OR U/L OR mIU/mL ☐ % CKMBUNT <ESLUNT> CKMBND <ZYES> ☐1 Not Done
8 = **Creatinine** _____ mg/dL	**Troponin** ☐1 I ☐2 T TROPTYP <ESTRO> TROPVAL <F:9:3> ng/mL OR ☐1 Positive ☐2 Negative TROPPN <ZPOSNE> (ULN = TROPULN <F:9:3>) ☐1 Not Done TROPND<ZYES>
9 = **ALT/SGPT** _____ 10 IU/L OR U/L OR mIU/mL	

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Annotated the same as Page 11

Laboratory

Day 3 Value
LABDAY <ESINHS>
☐ 1 Also Optimal Day Value (QPTDAY <ZYES>)
☐ 1 Discharge Day record on page 29 (DISDAY <ZYES>)
LABQUES (TYPE 4)

Date of collection: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

WBC _____ ☐ $10^9/_L$ OR $10^3/_{mm^3}$ ☐ $/_{mm^3}$

Sodium _____ $mmol/_L$ OR $mEq/_L$

Potassium _____ $mmol/_L$ OR $mEq/_L$

BUN _____ $mg/_{dL}$

Creatinine _____ $mg/_{dL}$

Day 5 Value
☐ Also Optimal Day Value
☐ Discharge Day record on page 29
LABQUES (TYPE 4)

Date of collection: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

WBC _____ ☐ $10^9/_L$ OR $10^3/_{mm^3}$ ☐ $/_{mm^3}$

Sodium _____ $mmol/_L$ OR $mEq/_L$

Potassium _____ $mmol/_L$ OR $mEq/_L$

BUN _____ $mg/_{dL}$

Creatinine _____ $mg/_{dL}$

Day 7 Value
☐ Also Optimal Day Value
☐ Discharge Day record on page 29
LABQUES (TYPE 4)

Date of collection: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

WBC _____ ☐ $10^9/_L$ OR $10^3/_{mm^3}$ ☐ $/_{mm^3}$

Sodium _____ $mmol/_L$ OR $mEq/_L$

Potassium _____ $mmol/_L$ OR $mEq/_L$

BUN _____ $mg/_{dL}$

Creatinine _____ $mg/_{dL}$

Optimal Day Value
☐ 1 Recorded elsewhere (RECELS <ZYES>)
☐ Discharge Day record on page 29
LABQUES (TYPE 4)

Date of collection: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

WBC _____ ☐ $10^9/_L$ OR $10^3/_{mm^3}$ ☐ $/_{mm^3}$

Sodium _____ $mmol/_L$ OR $mEq/_L$

Potassium _____ $mmol/_L$ OR $mEq/_L$

BUN _____ $mg/_{dL}$

Creatinine _____ $mg/_{dL}$

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Inpatient Medication Summary (Medications taken after randomization.)

INPTMED1 (TYPE 4) PS

		Start dose:	Highest dose:	Total # Days: (record whole number)
Intravenous Infusions:				
Amrinone	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	_____ mcg/kg/min	_____
Dobutamine	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	_____ mcg/kg/min	_____
Dopamine	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	_____ mcg/kg/min	_____
Milrinone	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	_____ mcg/kg/min	_____
Nitroglycerin	☐ No ☐ Yes → If Yes:	_____ mcg/min	_____ mcg/min	_____
Nitroprusside	☐ No ☐ Yes → If Yes:	_____ mcg/min	_____ mcg/min	_____

INPTMED2 (TYPE 4) PS

		Highest total daily dose:	Highest single daily dose:	Total # Days: (record whole number)
ACE inhibitors:				
Benazepril	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
Captopril	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
Enalapril	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
Fosinopril	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
Lisinopril	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
Quinapril	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
Ramipril	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
Trandolapril	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
Other	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
Angiotensin II antagonist:				
Candesartan	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
Losartan	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
Valsartan	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
Other	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
Hydralazine:	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
Isosorbide dinitrate:	☐ No ☐ Yes → If Yes	_____ mg	_____ mg	_____
Isosorbide mononitrate:	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____
Topical nitroglycerin:	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____

INPTMED3 (TYPE 4) PS

		Highest total daily dose:		Total # Days: (record whole number)	
		PO	IV	PO	IV
Diuretic (loop):					
Bumetanide	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____	_____
Ethacrynic acid	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____	_____
Furosemide	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____	_____
Torsemide	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____	_____
Other	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____	_____
Diuretic (potassium sparing):					
Amiloride	☐ No ☐ Yes → If Yes:	_____ mg		_____	
Spironolactone	☐ No ☐ Yes → If Yes:	_____ mg		_____	
Triamterene	☐ No ☐ Yes → If Yes:	_____ mg		_____	
Other	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____	_____
Diuretic (thiazide):					
Chlorothiazide (diuril)	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____	_____
Hydrochlorothiazide (HCTZ)	☐ No ☐ Yes → If Yes:	_____ mg		_____	
Metolazone (zaroxolyn)	☐ No ☐ Yes → If Yes:	_____ mg		_____	
Other	☐ No ☐ Yes → If Yes:	_____ mg	_____ mg	_____	_____

PAC Details

Did the patient receive a PAC at any time during the index hospitalization? PACDTLS (TYPE 1)

0 **No** → If No, check primary reason: PAC <ESPACN>

- 1 Randomized to CLIN
- 2 Randomized to PAC but catheter not placed due to *(check only one)*: CATHNOT <ESNOPA>
  - 1 Abnormal anatomy
  - 2 Other technical difficulties
  - 3 Change in patient condition
  - 4 Physician preference
  - 5 Withdrawal of consent
  - 6 Death → Complete page 70, Event Notification Form AND Death Form (insert page)
  - 7 Other clinical event

PACRECV <ZYESNO>

1 **Yes** → If Yes, check all that apply:

- 1 Randomized to PAC (initial placement) PACRAN<ZYES>

→ Was the PAC removed before the optimization of therapy (initial randomized insertion only)? PACREMVD <ZYESNO>

- 0 No
- 1 Yes → If Yes, check primary reason: REMVDRE <ESREMV>
  - 1 PAC associated complications
  - 2 Technical problems *(e.g., balloon rupture, clot in catheter)*
  - 3 Change in patient condition
  - 4 Death → Complete page 70, Event Notification Form AND Death Form (insert page)
  - 98 Other *(specify)*: _____ OTHRESP <V:100>

PACCROSS <ZYES>

1 Crossover from CLIN to PAC (initial placement) → Complete Physician Estimate of Hemodynamic Status—Crossover Form (insert page)

PACADD <ZYES>

1 Additional PAC placement → Complete the **Additional PAC Insertion Form** (insert page) for **each** PAC placement

Patient Number: ___ ___ - ___ ___ ___ (site # - patient #) Patient Initials: ___ ___ ___

This is not entered

PAC Insertion Details

☐ Not applicable

PAC insertion date and time: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) PACINSDT <DATE> PACINSTM <DATETIME> ___ ___ : ___ (00:00-23:59) PACINSRT (TYPE 3)

Type of catheter *(see codes in instructions)*: ___ ___ ___ CATHTYP <I:3>

Reason for PAC:

[1] Initial PAC due to randomization PACRAND <ZYES>

OR

Check up to 3 reasons:

[1] Acute coronary syndrome CORONARY <ZYES>
[1] Assess transplant eligibility ASSESELI <ZYES>
[1] Diagnostic uncertainty regarding hemodynamic profile DIAGNOS <ZYES>
[1] Inability to wean inotropes INABLTY <ZYES>
[1] Need for increasing dose of inotropes INOTROP <ZYES>
[1] Need for mechanical ventilation MECHVENT <ZYES>

[1] Progressive oliguric renal insufficiency RENINSU <ZYES>
[1] Refractory symptomatic hypotension HYPOTN <ZYES>
→ Blood pressure: <I:3> __ / __ <I:3> HYPSYSBP HYPDIABP
[1] Sepsis SEPSIS <ZYES>
[1] Worsening pulmonary edema WRSEDEMA <ZYES>
[1] Other *(specify)*: _____ OTHREAS <ZYES> OTHRSSP <V:100>

Name of attending physician who performed or supervised PAC insertion: _____

This is not entered

Complications of PAC (Check Yes or No to each complication)

PACCOMP1 (TYPE 4) PS

	PACCOMP <ESCCOM>	PCOMRSP <ZYESNO>	Date of occurrence: PCOMPDT <DATE>
1	PAC associated bleeding requiring surgical intervention:	[0] No [1] Yes →	___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year)
2	PAC associated bleeding requiring transfusion:	[0] No [1] Yes →	___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year)
3	PAC associated pulmonary emboli:	[0] No [1] Yes →	___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year)
4	PAC associated cannulation of carotid artery:	[0] No [1] Yes →	___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year)
5	PAC associated VT > 30 seconds or VF:	[0] No [1] Yes →	___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year)
6	PAC associated thrombosis of a blood vessel:	[0] No [1] Yes →	___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year)
7	PAC associated complete heart block requiring pacemaker:	[0] No [1] Yes →	___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year)
8	PAC associated perforation or rupture of pulmonary artery:	[0] No [1] Yes →	___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year)
9	PAC associated pneumothorax:	[0] No [1] Yes →	___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year)
10	PAC knotting:	[0] No [1] Yes →	___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year)
11	PAC associated valvular trauma:	[0] No [1] Yes →	___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year)
12	PAC associated infection:	[0] No [1] Yes →	___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year)

→ If Yes, check all that apply:

[1] Elevated WBC ELWBC <ZYES>
[1] Temperature >38° Celsius TEMP38 <ZYES>
[1] Positive blood cultures POSBLDCX <ZYES>
[1] Need for IV antibiotics IVANTI <ZYES>
[1] Need for pressors due to sepsis PRESSORS <ZYES>
[1] Positive catheter tip culture POSCTHCX <ZYES>
[1] Positive urine culture POSURNCXZ <ZYES>
[1] Infiltrate on chest x-ray INFIL <ZYES>
[1] Endocarditis ENDOCARD <ZYES>

PACCOMP2 (TYPE 3)

PAC associated event requiring CPR: CPRREQ <ZYESNO> [0] No [1] Yes → If Yes, complete Event Notification Form

→ If Yes, date of occurrence: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) EVNTDT <DATE>

→ If Yes, date of resolution: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) EVNTRSDT <DATE> OR [1] Ongoing EVNTONGO <ZYES>

PAC associated pulmonary infarction/hemorrhage: INFHEM <ZYESNO> [0] No [1] Yes → If Yes, complete Event Notification Form

PACCOMP3 (TYPE 3)

→ If Yes, date of occurrence: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) INFDT <DATE>

→ If Yes, date of resolution: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) INFRSDT <DATE> OR [1] Ongoing INFONGO <ZYES>

ESCAPE

SAME AS PAGE 15

Additional PAC Insertion Form

Patient Number: ___ ___ - ___ ___ ___ (site # - patient #) Patient Initials: ___ ___ ___

PAC Insertion Details (Index hospitalization)

PACINSRT (TYPE 3)

PAC insertion date and time: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00–23:59)

Type of catheter *(see codes in instructions)*: _____ _____ _____

Reason for PAC:

☐ Initial PAC due to randomization

OR

Check up to 3 reasons:

☐ Acute coronary syndrome
☐ Assess transplant eligibility
☐ Diagnostic uncertainty regarding hemodynamic profile
☐ Inability to wean inotropes
☐ Need for increasing dose of inotropes
☐ Need for mechanical ventilation
☐ Progressive oliguric renal insufficiency
☐ Refractory symptomatic hypotension
→ Blood pressure: ___ ___ ___ / ___ ___ ___
☐ Sepsis
☐ Worsening pulmonary edema
☐ Other *(specify)*: _____

Name of physician who performed or supervised PAC insertion: _____

Complications of PAC (Index hospitalization only)

PACCOMP1 (TYPE 4) PS

Check Yes or No to each complication. Date of occurrence: (day / month / year)

PAC associated bleeding requiring surgical intervention:	☐ No	☐ Yes →	___ ___ / ___ ___ ___ / ___ ___ ___ ___
PAC associated bleeding requiring transfusion:	☐ No	☐ Yes →	___ ___ / ___ ___ ___ / ___ ___ ___ ___
PAC associated pulmonary emboli:	☐ No	☐ Yes →	___ ___ / ___ ___ ___ / ___ ___ ___ ___
PAC associated cannulation of carotid artery:	☐ No	☐ Yes →	___ ___ / ___ ___ ___ / ___ ___ ___ ___
PAC associated VT > 30 seconds or VF:	☐ No	☐ Yes →	___ ___ / ___ ___ ___ / ___ ___ ___ ___
PAC associated thrombosis of a blood vessel:	☐ No	☐ Yes →	___ ___ / ___ ___ ___ / ___ ___ ___ ___
PAC associated complete heart block requiring pacemaker:	☐ No	☐ Yes →	___ ___ / ___ ___ ___ / ___ ___ ___ ___
PAC associated perforation or rupture of pulmonary artery:	☐ No	☐ Yes →	___ ___ / ___ ___ ___ / ___ ___ ___ ___
PAC associated pneumothorax:	☐ No	☐ Yes →	___ ___ / ___ ___ ___ / ___ ___ ___ ___
PAC knotting:	☐ No	☐ Yes →	___ ___ / ___ ___ ___ / ___ ___ ___ ___
PAC associated valvular trauma:	☐ No	☐ Yes →	___ ___ / ___ ___ ___ / ___ ___ ___ ___
PAC associated infection:	☐ No	☐ Yes →	___ ___ / ___ ___ ___ / ___ ___ ___ ___

→ If Yes, check all that apply:

☐ Elevated WBC
☐ Temperature >38° Celsius
☐ Positive blood cultures
☐ Need for IV antibiotics
☐ Need for pressors due to sepsis
☐ Positive catheter tip culture
☐ Positive urine culture
☐ Infiltrate on chest x-ray
☐ Endocarditis

PACCOMP2 (TYPE 3)

PAC associated event requiring CPR: ☐ No ☐ Yes → **If Yes, complete Event Notification Form**

→ If Yes, date of occurrence: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

→ If Yes, date of resolution: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR ☐ Ongoing

PAC associated pulmonary infarction/hemorrhage: ☐ No ☐ Yes → **If Yes, complete Event Notification Form**

PACCOMP3 (TYPE 3)

→ If Yes, date of occurrence: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

→ If Yes, date of resolution: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR ☐ Ongoing

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Complications During Hospitalization

COMP <ESCOM> | COMPRSP <ZYNNA> | COMP (TYPE 4) PS

		No	Yes	NA	If Yes, date of first occurrence: COMPDT <DATE>
	ICD firing:				
1=	Ventricular tachycardia/fibrillation	0	1	2	__ __ / __ __ __ / __ __ __ __ (day / month / year)
2=	Inappropriate firing	0	1	2	__ __ / __ __ __ / __ __ __ __ (day / month / year)
3=	**Cardiogenic shock** (SBP < 60 mmHg requiring vasopressors)	0	1		__ __ / __ __ __ / __ __ __ __ (day / month / year)
4=	**Ischemia/Angina**	0	1		__ __ / __ __ __ / __ __ __ __ (day / month / year)
5=	**Myocardial infarction**	0	1		__ __ / __ __ __ / __ __ __ __ (day / month / year) → Complete MI Form
6=	**New atrial fibrillation/flutter**	0	1		__ __ / __ __ __ / __ __ __ __ (day / month / year)
7=	**Pulmonary embolism**	0	1		__ __ / __ __ __ / __ __ __ __ (day / month / year)
8=	**Stroke**	0	1		__ __ / __ __ __ / __ __ __ __ (day / month / year)
9=	**TIA**	0	1		__ __ / __ __ __ / __ __ __ __ (day / month / year)
	Cardiac arrest:				
10=	Bradycardic arrest	0	1		__ __ / __ __ __ / __ __ __ __ (day / month / year)
11=	Ventricular fibrillation	0	1		__ __ / __ __ __ / __ __ __ __ (day / month / year)
12=	Ventricular tachycardia > 30 seconds	0	1		__ __ / __ __ __ / __ __ __ __ (day / month / year)
13=	EMD/PEA	0	1		__ __ / __ __ __ / __ __ __ __ (day / month / year)
14=	Undetermined cause	0	1		__ __ / __ __ __ / __ __ __ __ (day / month / year)
15=	Other	0	1		__ __ / __ __ __ / __ __ __ __ (day / month / year)
	Infection:				
16=	Sepsis	0	1		__ __ / __ __ __ / __ __ __ __ (day / month / year)
17=	Other infection requiring antibiotics	0	1		__ __ / __ __ __ / __ __ __ __ (day / month / year)

Procedures During Hospitalization

PROC <ESPROC> | PROCRSP <ZYESNO> | PROC (TYPE 4) PS

		No	Yes	If Yes, date of first occurrence: PROCDT <DATE>
1=	**ICD implantation**	0	1	__ __ / __ __ __ / __ __ __ __ (day / month / year)
2=	**CABG**	0	1	__ __ / __ __ __ / __ __ __ __ (day / month / year)
3=	**Left heart catheterization**	0	1	__ __ / __ __ __ / __ __ __ __ (day / month / year)
4=	**Cardiopulmonary resuscitation**	0	1	__ __ / __ __ __ / __ __ __ __ (day / month / year)
5=	**Cardioversion**	0	1	__ __ / __ __ __ / __ __ __ __ (day / month / year)
6=	**Intra-aortic balloon pump**	0	1	__ __ / __ __ __ / __ __ __ __ (day / month / year)
7=	**Left ventricular assist device**	0	1	__ __ / __ __ __ / __ __ __ __ (day / month / year)
8=	**Mechanical ventilation**	0	1	__ __ / __ __ __ / __ __ __ __ (day / month / year)
9=	**PTCI**	0	1	__ __ / __ __ __ / __ __ __ __ (day / month / year)
10=	**Permanent pacemaker**	0	1	__ __ / __ __ __ / __ __ __ __ (day / month / year)
11=	**Temporary pacemaker**	0	1	__ __ / __ __ __ / __ __ __ __ (day / month / year)
12=	**Other cardiac procedure/operation**	0	1	__ __ / __ __ __ / __ __ __ __ (day / month / year)

13 = PULMONARY ARTERY CATHETERIZATION

ESCAPE

Index Hospitalization

Patient Number: ___ ___ - ___ ___ ___ (site #, patient #)   Patient Initials: ___ ___ ___

Daily Summary of Volume Status and PAC Insertion Site Status

VOLUME (TYPE 2)

Date:	Net Fluid Status:	Insertion Site Status:
VOLDT <DATE> ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SEQNUM <I:1>	VOLSIGN <ESSIGN> [1] + [2] - VOLNET <F:9:3> cc	SITESTAT <ZYNNA> Erythema: No [0] Yes [1] NA [2]; SITEST <ZYESNO> Exudate: No [0] Yes [1]
___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐ + ☐ - ______ cc	Erythema: No ☐ Yes ☐ NA ☐; Exudate: No ☐ Yes ☐
___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐ + ☐ - ______ cc	Erythema: No ☐ Yes ☐ NA ☐; Exudate: No ☐ Yes ☐
___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐ + ☐ - ______ cc	Erythema: No ☐ Yes ☐ NA ☐; Exudate: No ☐ Yes ☐
___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐ + ☐ - ______ cc	Erythema: No ☐ Yes ☐ NA ☐; Exudate: No ☐ Yes ☐
___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐ + ☐ - ______ cc	Erythema: No ☐ Yes ☐ NA ☐; Exudate: No ☐ Yes ☐
___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐ + ☐ - ______ cc	Erythema: No ☐ Yes ☐ NA ☐; Exudate: No ☐ Yes ☐
___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	☐ + ☐ - ______ cc	Erythema: No ☐ Yes ☐ NA ☐; Exudate: No ☐ Yes ☐

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Heart Failure Clinical Assessment—Symptoms

Does the patient have any of the following?

SYMPTOMS (TYPE 3)

	No	Yes
Fatigue:		
At rest	☐	☐
Any activity	☐	☐
Routine daily activity	☐	☐

	No	Yes
Dyspnea:		
At rest	☐	☐
Walking in room	☐	☐
Walking < 1 block	☐	☐

Orthopnea *(check only one)*:
- ☐ Needs only 1 pillow
- ☐ Occasional orthopnea with 1 pillow
- ☐ Needs 2 pillows most of the time
- ☐ Needs 3 pillows most of the time
- ☐ Needs 4 pillows most of the time *(sitting up)*

Gastrointestinal distress *(check only one)*: ☐ None ☐ Occasional ☐ Constant

NYHA classification *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

Heart Failure Clinical Assessment—Physical Exam

Heart rate (supine): ___ ___ ___ bpm **Heart rate (standing after 3 minutes):** ___ ___ ___ bpm

Blood pressure manual cuff *(supine)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg

Blood pressure manual cuff *(standing after 3 minutes)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg

Weight: ___ ___ ___ . ___ ☐ lb ☐ kg

Respiratory rate: ___ ___ breaths/minute

Temperature: ___ ___ ___ . ___ ☐ C ☐ F

Jugular venous pulsation *(cm above the right atrium)*: ☐ < 8 ☐ 8–12 ☐ 12–16 ☐ >16 ☐ Cannot measure

Rales: ☐ None ☐ < 1/3 ☐ 1/3–2/3 ☐ > 2/3

Auscultation: S3: ☐ No ☐ Yes
Estimated P2-PAS: ☐ < 40 ☐ 40–50 ☐ 51–60 ☐ > 60

Hepatomegaly *(check only one)*: ☐ Absent ☐ 2–4 finger breadths ☐ > 4 finger breadths

Hepatojugular reflux: ☐ No ☐ Yes

Ascites *(check only one)*: ☐ None ☐ Trace ☐ Moderate ☐ Massive

Peripheral edema *(check only one)*: ☐ 0 ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+

Extremities *(check only one)*: ☐ Cool ☐ Lukewarm ☐ Warm

Valsalva maneuver *(check only one)*: ☐ Normal ☐ Absent overshoot ☐ Square-wave ☐ Uncertain **OR** ☐ Not applicable

Clinical profile *(check only one)*: ☐ Dry/warm ☐ Wet/warm ☐ Dry/cold ☐ Wet/cold

Signature (Physician who performed assessment)

SAME AS PAGE 3

SIGNATUR (TYPE 4)

Investigator's signature: _____ **Date performed:** ___ ___ (day) / ___ ___ (month) / ___ ___ ___ ___ (year)

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Heart Failure Clinical Assessment—Symptoms

SYMPTOMS (TYPE 3)

Does the patient have any of the following?

	No	Yes
Fatigue:		
At rest	☐	☐
Any activity	☐	☐
Routine daily activity	☐	☐

	No	Yes
Dyspnea:		
At rest	☐	☐
Walking in room	☐	☐
Walking < 1 block	☐	☐

Orthopnea *(check only one)*:
- ☐ Needs only 1 pillow
- ☐ Occasional orthopnea with 1 pillow
- ☐ Needs 2 pillows most of the time
- ☐ Needs 3 pillows most of the time
- ☐ Needs 4 pillows most of the time *(sitting up)*

Gastrointestinal distress *(check only one)*: ☐ None ☐ Occasional ☐ Constant

NYHA classification *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

Heart Failure Clinical Assessment—Physical Exam

Heart rate (supine): ___ ___ ___ bpm **Heart rate (standing after 3 minutes):** ___ ___ ___ bpm

Blood pressure manual cuff *(supine)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) **mmHg**

Blood pressure manual cuff *(standing after 3 minutes)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) **mmHg**

Weight: ___ ___ ___ . ___ ☐ **lb** ☐ **kg**

Respiratory rate: ___ ___ **breaths/minute**

Temperature: ___ ___ ___ . ___ ☐ **C** ☐ **F**

Jugular venous pulsation *(cm above the right atrium)*: ☐ < 8 ☐ 8–12 ☐ 12–16 ☐ >16 ☐ Cannot measure

Rales: ☐ None ☐ < 1/3 ☐ 1/3–2/3 ☐ > 2/3

Auscultation: S3: ☐ No ☐ Yes
Estimated P2-PAS: ☐ < 40 ☐ 40–50 ☐ 51–60 ☐ > 60

Hepatomegaly *(check only one)*: ☐ Absent ☐ 2–4 finger breadths ☐ > 4 finger breadths

Hepatojugular reflux: ☐ No ☐ Yes

Ascites *(check only one)*: ☐ None ☐ Trace ☐ Moderate ☐ Massive

Peripheral edema *(check only one)*: ☐ 0 ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+

Extremities *(check only one)*: ☐ Cool ☐ Lukewarm ☐ Warm

Valsalva maneuver *(check only one)*: ☐ Normal ☐ Absent overshoot ☐ Square-wave ☐ Uncertain **OR** ☐ Not applicable

Clinical profile *(check only one)*: ☐ Dry/warm ☐ Wet/warm ☐ Dry/cold ☐ Wet/cold

Signature (Physician who performed assessment)

SAME AS PAGE 3

SIGNATUR (TYPE 4)

Investigator's signature: _____ **Date performed:** ___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year)

Patient Number: ___ ___ (site #) - ___ ___ ___ (patient #) Patient Initials: ___ ___ ___

Heart Failure Clinical Assessment—Symptoms

Does the patient have any of the following?

SYMPTOMS (TYPE 3)

	No	Yes		No	Yes
Fatigue:			**Dyspnea:**		
At rest	☐	☐	At rest	☐	☐
Any activity	☐	☐	Walking in room	☐	☐
Routine daily activity	☐	☐	Walking < 1 block	☐	☐

Orthopnea *(check only one)*:
- ☐ Needs only 1 pillow
- ☐ Occasional orthopnea with 1 pillow
- ☐ Needs 2 pillows most of the time
- ☐ Needs 3 pillows most of the time
- ☐ Needs 4 pillows most of the time *(sitting up)*

Gastrointestinal distress *(check only one)*: ☐ None ☐ Occasional ☐ Constant

NYHA classification *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

Heart Failure Clinical Assessment—Physical Exam

Heart rate (supine): ___ ___ ___ bpm **Heart rate (standing after 3 minutes):** ___ ___ ___ bpm

Blood pressure manual cuff *(supine)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg

Blood pressure manual cuff *(standing after 3 minutes)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg

Weight: ___ ___ ___ . ___ ☐ lb ☐ kg

Respiratory rate: ___ ___ breaths/minute

Temperature: ___ ___ ___ . ___ ☐ C ☐ F

Jugular venous pulsation *(cm above the right atrium)*: ☐ < 8 ☐ 8–12 ☐ 12–16 ☐ >16 ☐ Cannot measure

Rales: ☐ None ☐ < 1/3 ☐ 1/3–2/3 ☐ > 2/3

Auscultation: S3: ☐ No ☐ Yes
Estimated P2-PAS: ☐ < 40 ☐ 40–50 ☐ 51–60 ☐ > 60

Hepatomegaly *(check only one)*: ☐ Absent ☐ 2–4 finger breadths ☐ > 4 finger breadths

Hepatojugular reflux: ☐ No ☐ Yes

Ascites *(check only one)*: ☐ None ☐ Trace ☐ Moderate ☐ Massive

Peripheral edema *(check only one)*: ☐ 0 ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+

Extremities *(check only one)*: ☐ Cool ☐ Lukewarm ☐ Warm

Valsalva maneuver *(check only one)*: ☐ Normal ☐ Absent overshoot ☐ Square-wave ☐ Uncertain **OR** ☐ Not applicable

Clinical profile *(check only one)*: ☐ Dry/warm ☐ Wet/warm ☐ Dry/cold ☐ Wet/cold

Signature (Physician who performed assessment)

SAME AS PAGE 3

SIGNATUR (TYPE 4)

Investigator's signature: _____ **Date performed:** ___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year)

Optimal-Day Physician Assessment

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Heart Failure Clinical Assessment—Symptoms

Does the patient have any of the following? SYMPTOMS (TYPE 3)

	No	Yes
Fatigue:		
At rest	☐	☐
Any activity	☐	☐
Routine daily activity	☐	☐

	No	Yes
Dyspnea:		
At rest	☐	☐
Walking in room	☐	☐
Walking < 1 block	☐	☐

Orthopnea *(check only one)*:
- ☐ Needs only 1 pillow
- ☐ Occasional orthopnea with 1 pillow
- ☐ Needs 2 pillows most of the time
- ☐ Needs 3 pillows most of the time
- ☐ Needs 4 pillows most of the time *(sitting up)*

Gastrointestinal distress *(check only one)*: ☐ None ☐ Occasional ☐ Constant

NYHA classification *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

Heart Failure Clinical Assessment—Physical Exam

Heart rate (supine): ___ ___ ___ bpm **Heart rate (standing after 3 minutes):** ___ ___ ___ bpm

Blood pressure manual cuff *(supine)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) **mmHg**

Blood pressure manual cuff *(standing after 3 minutes)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) **mmHg**

Weight: ___ ___ ___ . ___ ☐ **lb** ☐ **kg**

Respiratory rate: ___ ___ **breaths/minute**

Temperature: ___ ___ ___ . ___ ☐ **C** ☐ **F**

Jugular venous pulsation *(cm above the right atrium)*: ☐ < 8 ☐ 8–12 ☐ 12–16 ☐ >16 ☐ Cannot measure

Rales: ☐ None ☐ < 1/3 ☐ 1/3–2/3 ☐ > 2/3

Auscultation: S3: ☐ No ☐ Yes
Estimated P2-PAS: ☐ < 40 ☐ 40–50 ☐ 51–60 ☐ > 60

Hepatomegaly *(check only one)*: ☐ Absent ☐ 2–4 finger breadths ☐ > 4 finger breadths

Hepatojugular reflux: ☐ No ☐ Yes

Ascites *(check only one)*: ☐ None ☐ Trace ☐ Moderate ☐ Massive

Peripheral edema *(check only one)*: ☐ 0 ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+

Extremities *(check only one)*: ☐ Cool ☐ Lukewarm ☐ Warm

Valsalva maneuver *(check only one)*: ☐ Normal ☐ Absent overshoot ☐ Square-wave ☐ Uncertain **OR** ☐ Not applicable

Clinical profile *(check only one)*: ☐ Dry/warm ☐ Wet/warm ☐ Dry/cold ☐ Wet/cold

Signature (Physician who performed assessment)

SAME AS PAGE 3 SIGNATUR (TYPE 4)

Investigator's signature: _____ **Date performed:** ___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year)

STUDYBOOK=ESCAPE
FORM=DISCHARGE

SAME AS PAGE 2

Discharge Physician Assessment

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Heart Failure Clinical Assessment—Symptoms

SYMPTOMS (TYPE 3)

Does the patient have any of the following?

	No	Yes
Fatigue:		
At rest	☐	☐
Any activity	☐	☐
Routine daily activity	☐	☐

	No	Yes
Dyspnea:		
At rest	☐	☐
Walking in room	☐	☐
Walking < 1 block	☐	☐

Orthopnea *(check only one)*:
- ☐ Needs only 1 pillow
- ☐ Occasional orthopnea with 1 pillow
- ☐ Needs 2 pillows most of the time
- ☐ Needs 3 pillows most of the time
- ☐ Needs 4 pillows most of the time *(sitting up)*

Gastrointestinal distress *(check only one)*: ☐ None ☐ Occasional ☐ Constant

NYHA classification *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

Heart Failure Clinical Assessment—Physical Exam

Heart rate (supine): ___ ___ ___ **bpm** **Heart rate (standing after 3 minutes):** ___ ___ ___ **bpm**

Blood pressure manual cuff *(supine)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) **mmHg**

Blood pressure manual cuff *(standing after 3 minutes)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) **mmHg**

Weight: ___ ___ ___ . ___ ☐ **lb** ☐ **kg**

Respiratory rate: ___ ___ **breaths/minute**

Temperature: ___ ___ ___ . ___ ☐ **C** ☐ **F**

Jugular venous pulsation *(cm above the right atrium)*: ☐ < 8 ☐ 8–12 ☐ 12–16 ☐ >16 ☐ Cannot measure

Rales: ☐ None ☐ < 1/3 ☐ 1/3–2/3 ☐ > 2/3

Auscultation: S3: ☐ No ☐ Yes
Estimated P2-PAS: ☐ < 40 ☐ 40–50 ☐ 51–60 ☐ > 60

Hepatomegaly *(check only one)*: ☐ Absent ☐ 2–4 finger breadths ☐ > 4 finger breadths

Hepatojugular reflux: ☐ No ☐ Yes

Ascites *(check only one)*: ☐ None ☐ Trace ☐ Moderate ☐ Massive

Peripheral edema *(check only one)*: ☐ 0 ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+

Extremities *(check only one)*: ☐ Cool ☐ Lukewarm ☐ Warm

Valsalva maneuver *(check only one)*: ☐ Normal ☐ Absent overshoot ☐ Square-wave ☐ Uncertain **OR** ☐ Not applicable

Clinical profile *(check only one)*: ☐ Dry/warm ☐ Wet/warm ☐ Dry/cold ☐ Wet/cold

Discharge Physician Assessment

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Heart Failure Clinical Assessment—Estimate of Hemodynamic Status

Right atrial pressure (mmHg) (check only one): ☐ < 8 ☐ 8–12 ☐ 13–16 ☐ >16 THIS NOT ENTERED

Certainty of assessment (check only one): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
not very sure ——— very sure

Pulmonary capillary wedge pressure (mmHg) (check only one): ☐ < 12 ☐ 12–22 ☐ 23–30 ☐ >30

Certainty of assessment (check only one): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
not very sure ——— very sure

Cardiac index (L/min • m^2) (check only one): ☐ < 1.8 ☐ 1.8–2.2 ☐ 2.3–2.5 ☐ > 2.5

Certainty of assessment (check only one): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
not very sure ——— very sure.

Physician Estimate of Likelihood of Death over next 6 months

PHYDTH <ESEST> PHYSEST (TYPE 3)

Check only one:
1 ☐ 0–25%
2 ☐ 26–50%
3 ☐ 51–75%
4 ☐ 76–100%

Physician Estimate of Readmission over next 6 months

PHYREADM <ESEST>

Check only one:
1 ☐ 0–25%
2 ☐ 26–50%
3 ☐ 51–75%
4 ☐ 76–100%

Signature (Physician who performed assessment)

SAME AS PAGE 3 SIGNATUR (TYPE 4)

Investigator's signature: _____ Date performed: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
day / month / year

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Visual Analog Scale Scores (Complete the Visual Analog Scale Worksheet)

VISUAL (TYPE 3)

Examination date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Worst symptom: ___ ___ ___ → Corresponding to *(Check only one)*:

- ☐ Abdominal discomfort
- ☐ Breathing
- ☐ Body swelling
- ☐ Fatigue

Breathing: ___ ___ ___ OR ☐ Not applicable if breathing was selected as worst symptom

Global: ___ ___ ___

Time Trade-Off Scores

Examination date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

THIS NOT ENTERED

Score: ___ ___ months

6 Minute Walk Exercise Test

WALK (TYPE 3)

Did the patient attempt the 6-minute walk test?

☐ No → If No, specify primary reason:

- ☐ The patient was too critically ill to be taken out of bed and exercised.
- ☐ Patient cannot walk for technical reasons (e.g., a patient who is an amputee).
- ☐ Not done due to oversight.

☐ Yes → If Yes, complete below.

Examination date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Start time of walk: ___ ___ : ___ ___ (00:00–23:59)

End time of walk: ___ ___ : ___ ___ (00:00–23:59)

Total distance walked: _____ ☐ Feet ☐ Meters

Did the patient experience any of the following symptoms *(check all that apply)*:

- ☐ Angina
- ☐ Light headedness
- ☐ Syncope

Borg Dyspnea score: _____ *(Transcribe score from worksheet.)*

Echocardiogram Data

ECHO (TYPE 3)

Examination date and time: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00–23:59)

Blood pressure *(closest to start of ECHO)*: ___ ___ ___ / ___ ___ ___ (systolic / diastolic)

● Send ECHO tape to Brigham Core Lab

Cardiopulmonary Exercise (CPX)

CPX (TYPE 3)

Did the patient attempt cardiopulmonary exercise testing?

☐ No → If No, specify primary reason:

- ☐ The patient was too critically ill to be taken out of bed and exercised.
- ☐ The patient was unable to walk > 50 meters on the 6 minute walk.
- ☐ Patient cannot walk for technical reasons (e.g., a patient who is an amputee).
- ☐ Not done due to oversight.

☐ Yes → If Yes, complete below.

Examination date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year.)

Type of exercise *(patient should perform same type of exercise throughout study)*: ☐ Bicycle ☐ Treadmill

Peak cardiovascular responses:

- VO_2 (ml/kg/min): _____
- VCO_2 (ml/kg/min): _____
- VE max (L/min): _____
- VE/VCO_2 (25 watts or end of first workload on treadmill) _____
- VO_2 @ R = 1.0: _____
- Heart rate (bpm): _____
- Systolic BP (max): _____
- Diastolic BP (max): _____
- Duration of exercise (min): _____
- Respiratory exchange ratio: _____

Reason for termination of testing *(check primary reason)*:

- ☐ Patient completed testing
- ☐ Symptom limited (e.g., dyspnea, fatigue)
- ☐ Angina
- ☐ Serious arrhythmia
- ☐ Blood pressure changes
- ☐ No longer able to walk (e.g., leg cramps)
- ☐ Other

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Laboratory

■ Optimal Day Value

LAB (TYPE 4) PS

Date of collection: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year)

	Value		Value	
Hemoglobin (Hgb)	_____	☐ g/L ☐ mmol/L ☐ g/dL	AST/SGOT	_____	IU/L OR U/L OR mIU/mL
Platelets	_____	☐ 10^9/L OR 10^3/mm³ ☐ /mm³	Total protein	_____	☐ g/dL ☐ g/L
Hematocrit (Hct)	_____	☐ L/L ☐ %	Albumin	_____	☐ g/dL ☐ g/L
WBC	_____	☐ 10^9/L OR 10^3/mm³ ☐ /mm³	Total bilirubin	_____	☐ mg/dL ☐ µmol/L
Sodium	_____	mmol/L OR mEq/L	Direct bilirubin	_____	☐ mg/dL ☐ µmol/L
Potassium	_____	mmol/L OR mEq/L	CK (ULN =_____)	_____	IU/L OR U/L OR mIU/mL ☐ Not Done
BUN	_____	mg/dL	CK-MB (ULN =_____)	_____	☐ mcg/L OR µg/L OR ng/mL ☐ IU/L OR U/L OR mIU/mL ☐ % ☐ Not Done
Creatinine	_____	mg/dL	Troponin ☐ I ☐ T (ULN =_____)	_____ ng/mL OR	☐ Positive ☐ Negative ☐ Not Done
ALT/SGPT	_____	IU/L OR U/L OR mIU/mL			

Discharge Medications

ACE inhibitor: ☐ No → If No, specify reason *(check all that apply)*: ACE1 (TYPE 3)

- ☐ Angioedema, anaphylaxis, neutropenia
- ☐ Cough
- ☐ Hyperkalemia
- ☐ Renal artery stenosis
- ☐ Renal dysfunction
- ☐ Symptomatic hypotension
- ☐ Other adverse events such as taste disturbance, rash, and gastrointestinal upset

ACE2 (TYPE 3)

☐ Yes → If Yes:

	Total daily dose:
☐ Benazepril	_____ mg
☐ Captopril	_____ mg
☐ Enalapril	_____ mg
☐ Fosinopril	_____ mg
☐ Lisinopril	_____ mg
☐ Quinapril	_____ mg
☐ Ramipril	_____ mg
☐ Trandolapril	_____ mg
☐ Other *(specify)*: _____	_____ mg

Angiotensin II antagonist: ANGIODIG (TYPE 3)

☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Candesartan	_____ mg
☐ Losartan	_____ mg
☐ Valsartan	_____ mg
☐ Other *(specify)*: _____	_____ mg

Digoxin: ☐ No ☐ Yes → **If Yes, specify total dose and frequency:** _____ mg ☐ QD ☐ QOD ☐ Other

Diuretic: (loop) ☐ No ☐ Yes → If Yes: DIUR1 (TYPE 3)

	Total daily dose:
☐ Bumetanide	_____ mg
☐ Ethacrynic acid	_____ mg
☐ Furosemide	_____ mg
☐ Torsemide	_____ mg
☐ Other *(specify)*: _____	_____ mg

Diuretic: (potassium sparing) ☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Amiloride	_____ mg
☐ Spironolactone	_____ mg
☐ Triamterene	_____ mg
☐ Other *(specify)*: _____	_____ mg

Diuretic: (thiazide) ☐ No ☐ Yes → If Yes: DIURCCB (TYPE 3)

	Total daily dose:
☐ Chlorothiazide (diuril)	_____ mg
☐ Hydrochlorothiazide (HCTZ)	_____ mg
☐ Metolazone (zaroxolyn)	_____ mg
☐ Other *(specify)*: _____	_____ mg

Calcium channel blocker: ☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Amlodipine	_____ mg
☐ Other *(specify)*: _____	_____ mg

Discharge Medications (cont.)

BBANTIAR (TYPE 3)

			Total daily dose:
Beta blocker:	☐ No ☐ Yes → If Yes:	☐ Atenolol	_____ mg
		☐ Bisoprolol	_____ mg
		☐ Carvedilol	_____ mg
		☐ Metoprolol	_____ mg
		☐ Propranolol	_____ mg
		☐ Other *(specify)*: _____	_____ mg

			Total daily dose:
Antiarrhythmics:	☐ No ☐ Yes → If Yes:	☐ Amiodarone	_____ mg
		☐ Dofetilide	_____ mg
		☐ Sotalol	_____ mg
		☐ Other *(specify)*: _____	_____ mg

NIHYPOT (TYPE 3)

			Total daily dose:
Nitrates:	☐ No ☐ Yes → If Yes:	☐ Isosorbide dinitrate	_____ mg
		☐ Isosorbide mononitrate	_____ mg
		☐ Topical nitroglycerin _____ mg	
Hydralazine:	☐ No ☐ Yes → If Yes, total daily dose:		_____ mg
Potassium:	☐ No ☐ Yes → If Yes, total daily dose:		_____ mEq

MEDS (TYPE 4) PS

Statins:	☐ No ☐ Yes	**Antidepressants:**	☐ No ☐ Yes
Other lipid lowering agents:	☐ No ☐ Yes	**Benzodiazepines:**	☐ No ☐ Yes
Magnesium:	☐ No ☐ Yes	**Allopurinol:**	☐ No ☐ Yes
Estrogen replacement therapy:	☐ No ☐ Yes	**Colchicine:**	☐ No ☐ Yes
Testosterone replacement therapy:	☐ No ☐ Yes	**Enoxaparin:**	☐ No ☐ Yes
Insulin:	☐ No ☐ Yes	**Warfarin:**	☐ No ☐ Yes
Oral diabetic agents:	☐ No ☐ Yes	**Vitamin E:**	☐ No ☐ Yes
Aspirin (daily):	☐ No ☐ Yes	**CoEnzyme Q10:**	☐ No ☐ Yes
Other antiplatelet agents:	☐ No ☐ Yes	**Other antioxidants:**	☐ No ☐ Yes
NSAIDs:	☐ No ☐ Yes	**Multi-vitamin:**	☐ No ☐ Yes
Thyroid replacement therapy:	☐ No ☐ Yes		

Current/Intermittent Infusions

INFUS (TYPE 4) PS

Amrinone:	☐ No ☐ Yes → If Yes: _____ mcg/kg/min	_____ # days/month	
Dobutamine:	☐ No ☐ Yes → If Yes: _____ mcg/kg/min	_____ # days/month	
Dopamine:	☐ No ☐ Yes → If Yes: _____ mcg/kg/min	_____ # days/month	
Milrinone:	☐ No ☐ Yes → If Yes: _____ mcg/kg/min	_____ # days/month	

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Nurse/Study Coordinator Estimate of Likelihood of Death over next 6 months

NRSDTH <ESEST> NURSEEST (TYPE 3)

Check only one: [1] 0-25% [2] 26-50% [3] 51-75% [4] 76-100%

Nurse/Study Coordinator Estimate of Readmission over next 6 months

NRSREADM <ESEST>

Check only one: [1] 0-25% [2] 26-50% [3] 51-75% [4] 76-100%

ECG (Record results of ECG closest to time of discharge.)

ECG (TYPE 3)

Date and time: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) SAME AS PAGE 5 ___ ___ : ___ (00:00-23:59)

Rate: ___ ___ ___ bpm

Rhythm *(check only one)*: ☐ Sinus bradycardia ☐ Normal sinus rhythm ☐ Sinus tachycardia ☐ Atrial fibrillation/flutter ☐ Paced rhythm ☐ Other

Specific abnormalities *(check all that apply)*: ☐ RBBB ☐ LBBB ☐ Not applicable

Endpoint Summary: Index Hospitalization

ENDPTSUM (TYPE 3)

Number of days since randomization the patient was in:

ICU/CCU: ICUNUM <I:3>

Step down unit: STPNUM <I:3>

Regular ward: WRDNUM <I:3>

HOSPADM <ZYESNO>

NUMTIMES <I:2>

CRDOPPRO <ZYESNO>

Since randomization has the patient died?

PTDIED <ZYESNO>

[0] No → **If No, transplant status** *(check only one)*: TRNSTAT <ESSTAT>

[1] Ineligible

[2] Active evaluation

[3] Listed

[4] Received transplant → **Date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) RECDT <DATE>

[5] Accepted, but waiting to detemine need after discharge

[6] Not evaluated

[1] Yes → **If Yes, complete page 70, Event Notification Form and the Death Form (insert page)**

→ **If Yes, DO NOT complete remainder of this page.**

Discharge Summary

DISCHARG (TYPE 1)

Patient status: PTSTAT <ESDISC> [1] Discharged home [2] Discharged to assisted living [3] Discharged to skilled nursing facility

Discharge date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) DISCHDT <DATE>

On discharge, was the patient relieved of congestion?

RELIEV <ZYESNO>

[0] No → **If No, diuresis was limited by** *(check only one)*: DIULMIT <ESDIUR>

[1] Yes

[1] Renal dysfunction

[2] Hypotension

[98] Other

Discharge Instructions for Sodium and Fluid Restriction:

Sodium restriction: SODRES <F:9:3> ___ mg/day

Fluid restriction: FLDRES <F:9:3> ___ L/day

Was the patient given a diuretic plan for weight gain? PLAN <ZYESNO> [0] No [1] Yes → **If Yes, for every 2 lb weight gain patient:** *(check all that apply)*

[1] Increases loop diuretics INCLOOP <ZYES>

[1] Adds thiazide/metolazone ADDTHMET <ZYES>

2-Week Follow-Up

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Contact Status

CONTACT (TYPE 3)

Date of contact: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) CONTDT <DATE>

MODEC<ESCON>

Mode of contact *(check only one)*:

1 Clinic visit
2 Telephone call
3 Rehospitalization
4 Continuous hospitalization since randomization
5 Lost to follow-up → Date of last contact: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) LSTCONDT <DATE>
98 Other *(specify)*: _____ OTHMDESP <V:100>

Resuscitation Orders

Resuscitation orders *(check only one)*: RESUSORD <ESRESU>

1 Attempt cardiopulmonary resuscitation
2 Attempt cardiopulmonary resuscitation but do not intubate
3 Do not attempt cardiopulmonary resuscitation

Endpoint Summary *(SKIP this box for patients with a continuous hospitalization since randomization.)*

ENDPTSUM (TYPE 3)

Since the last visit was the patient admitted to the hospital or emergency department for more than 24 hours?

☐ No
☐ Yes → **If Yes, number of times:** ___ ___

SAME AS PAGE 32

→ **If Yes, complete the Rehospitalization Form (insert page) for each hospital admission**

Since the last visit has the patient undergone a cardiovascular operation or procedure (e.g., CABG, PAC, mechanical ventilation)?

☐ No
☐ Yes → **If Yes, complete the CV Procedures/Mechanical Ventilation Form (insert page)**

Since the last visit has the patient died?

☐ No → **If No, transplant status** *(check only one)*:

☐ Ineligible
☐ Active evaluation
☐ Listed
☐ Received transplant → **Date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
☐ Accepted, but waiting to detemine need after discharge
☐ Not evaluated

☐ Yes → **If Yes, complete page 70, Event Notification Form and the Death Form (insert page)**

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Heart Failure Clinical Assessment – Symptoms

SYMPTOMS (TYPE3)

Does the patient have any of the following?

	No	Yes
Fatigue:		
At rest	☐	☐
Any activity	☐	☐
Routine daily activity	☐	☐
Dyspnea:		
At rest	☐	☐
Walking in room	☐	☐
Walking < 1 block	☐	☐

Orthopnea *(check only one)*:
- ☐ Needs only 1 pillow
- ☐ Occasional orthopnea with 1 pillow
- ☐ Needs 2 pillows most of the time
- ☐ Needs 3 pillows most of the time
- ☐ Needs 4 pillows most of the time *(sitting up)*

Gastrointestinal distress *(check only one)*: ☐ None ☐ Occasional ☐ Constant

NYHA classification *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

Heart Failure Clinical Assessment – Physical Exam

PHYSEXAM (TYPE 3)

Heart rate (supine): ___ ___ ___ bpm **Heart rate (standing after 3 minutes):** ___ ___ ___ bpm

Blood pressure manual cuff *(supine)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg

Blood pressure manual cuff *(standing after 3 minutes)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg

Weight: ___ ___ ___ . ___ ☐ lb ☐ kg

Respiratory rate: ___ ___ breaths/minute

Temperature: ___ ___ ___ . ___ ☐ C ☐ F

Jugular venous pulsation *(cm above the right atrium)*: ☐ < 8 ☐ 8–12 ☐ 12–16 ☐ >16 ☐ Cannot measure

Rales: ☐ None ☐ < 1/3 ☐ 1/3–2/3 ☐ > 2/3

Auscultation: S3: ☐ No ☐ Yes
Estimated P2-PAS: ☐ < 40 ☐ 40–50 ☐ 51–60 ☐ > 60

Hepatomegaly *(check only one)*: ☐ Absent ☐ 2–4 finger breadths ☐ > 4 finger breadths

Hepatojugular reflux: ☐ No ☐ Yes

Ascites *(check only one)*: ☐ None ☐ Trace ☐ Moderate ☐ Massive

Peripheral edema *(check only one)*: ☐ 0 ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+

Extremities *(check only one)*: ☐ Cool ☐ Lukewarm ☐ Warm

Valsalva maneuver *(check only one)*: ☐ Normal ☐ Absent overshoot ☐ Square-wave ☐ Uncertain **OR** ☐ Not applicable

Clinical profile *(check only one)*: ☐ Dry/warm ☐ Wet/warm ☐ Dry/cold ☐ Wet/cold

Signature (Physician who performed assessment)

SAME AS PAGE 3

SIGNATUR (TYPE 4)

Investigator's signature: _____ **Date performed:** ___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year)

Patient Number: ___ ___ (site #) - ___ ___ ___ (patient #) Patient Initials: ___ ___ ___

Current Medications

ACE inhibitor: ☐ No → If No, specify reason *(check all that apply)*: ACE1 (TYPE 3)

- ☐ Angioedema, anaphylaxis, neutropenia
- ☐ Cough
- ☐ Hyperkalemia
- ☐ Renal artery stenosis
- ☐ Renal dysfunction
- ☐ Symptomatic hypotension
- ☐ Other adverse events such as taste disturbance, rash, and gastrointestinal upset

ACE2 (TYPE 3)

☐ Yes → If Yes:

	Total daily dose:
☐ Benazepril	_____ mg
☐ Captopril	_____ mg
☐ Enalapril	_____ mg
☐ Fosinopril	_____ mg
☐ Lisinopril	_____ mg
☐ Quinapril	_____ mg
☐ Ramipril	_____ mg
☐ Trandolapril	_____ mg
☐ Other *(specify)*: _____	_____ mg

Angiotensin II antagonist: ☐ No ☐ Yes → If Yes: ANGIODIG (TYPE 3)

	Total daily dose:
☐ Candesartan	_____ mg
☐ Losartan	_____ mg
☐ Valsartan	_____ mg
☐ Other *(specify)*: _____	_____ mg

Digoxin: ☐ No ☐ Yes → **If Yes, specify total dose and frequency:** _____ mg ☐ QD ☐ QOD ☐ Other

Diuretic: (loop) ☐ No ☐ Yes → If Yes: DIUR1 (TYPE 3)

	Total daily dose:
☐ Bumetanide	_____ mg
☐ Ethacrynic acid	_____ mg
☐ Furosemide	_____ mg
☐ Torsemide	_____ mg
☐ Other *(specify)*: _____	_____ mg

Diuretic: (potassium sparing) ☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Amiloride	_____ mg
☐ Spironolactone	_____ mg
☐ Triamterene	_____ mg
☐ Other *(specify)*: _____	_____ mg

Diuretic: (thiazide) ☐ No ☐ Yes → If Yes: DIURCCB (TYPE 3)

	Total daily dose:
☐ Chlorothiazide (diuril)	_____ mg
☐ Hydrochlorothiazide (HCTZ)	_____ mg
☐ Metolazone (zaroxolyn)	_____ mg
☐ Other *(specify)*: _____	_____ mg

Calcium channel blocker: ☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Amlodipine	_____ mg
☐ Other *(specify)*: _____	_____ mg

Current Medications (cont.)

BBANTIAR (TYPE 3)

Beta blocker: ☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Atenolol	_____ mg
☐ Bisoprolol	_____ mg
☐ Carvedilol	_____ mg
☐ Metoprolol	_____ mg
☐ Propranolol	_____ mg
☐ Other (specify): _____	_____ mg

Antiarrhythmics: ☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Amiodarone	_____ mg
☐ Dofetilide	_____ mg
☐ Sotalol	_____ mg
☐ Other (specify): _____	_____ mg

NIHYPOT (TYPE 3)

		Total daily dose:
Nitrates:	☐ No ☐ Yes → If Yes:	
	☐ Isosorbide dinitrate	_____ mg
	☐ Isosorbide mononitrate	_____ mg
	☐ Topical nitroglycerin	_____ mg
Hydralazine:	☐ No ☐ Yes → If Yes, total daily dose:	_____ mg
Potassium:	☐ No ☐ Yes → If Yes, total daily dose:	_____ mEq

MEDS (TYPE 4) PS

Statins:	☐ No ☐ Yes	**Antidepressants:**	☐ No ☐ Yes
Other lipid lowering agents:	☐ No ☐ Yes	**Benzodiazepines:**	☐ No ☐ Yes
Magnesium:	☐ No ☐ Yes	**Allopurinol:**	☐ No ☐ Yes
Estrogen replacement therapy:	☐ No ☐ Yes	**Colchicine:**	☐ No ☐ Yes
Testosterone replacement therapy:	☐ No ☐ Yes	**Enoxaparin:**	☐ No ☐ Yes
Insulin:	☐ No ☐ Yes	**Warfarin:**	☐ No ☐ Yes
Oral diabetic agents:	☐ No ☐ Yes	**Vitamin E:**	☐ No ☐ Yes
Aspirin (daily):	☐ No ☐ Yes	**CoEnzyme Q10:**	☐ No ☐ Yes
Other antiplatelet agents:	☐ No ☐ Yes	**Other antioxidants:**	☐ No ☐ Yes
NSAIDs:	☐ No ☐ Yes	**Multi-vitamin:**	☐ No ☐ Yes
Thyroid replacement therapy:	☐ No ☐ Yes		

INFUSIN (TYPE 4) PS

		INFUDG <ESINF>	INFDGRSP <ZYESNO>	Current infusion rate: INFDGDS	Check box if intermittent: INFINT <ZYES>	INFNUMDY
1=	**Amrinone:**	[0] No	[1] Yes → If Yes:	<F:9:3> mcg/kg/min	[1] Intermittent →	<I:2> # days/month
2=	**Dobutamine:**	[0] No	[1] Yes → If Yes:	_____ mcg/kg/min	[1] Intermittent →	_____ # days/month
3=	**Dopamine:**	[0] No	[1] Yes → If Yes:	_____ mcg/kg/min	[1] Intermittent →	_____ # days/month
4=	**Milrinone:**	[0] No	[1] Yes → If Yes:	_____ mcg/kg/min	[1] Intermittent →	_____ # days/month
5=	**Nitroglycerin:**	[0] No	[1] Yes → If Yes:	_____ mcg/min		
6=	**Nitroprusside:**	[0] No	[1] Yes → If Yes:	_____ mcg/min		

7= Natracor

Laboratory

LAB (TYPE 4) PS

Date of collection: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Value			Value		
Hemoglobin (Hgb)	_____	☐ g/L ☐ mmol/L ☐ g/dL	AST/SGOT	_____	IU/L OR U/L OR mIU/mL
Platelets	_____	☐ 10^9/L OR 10^3/mm³ ☐ /mm³	Total protein	_____	☐ g/dL ☐ g/L
Hematocrit (Hct)	_____	☐ L/L ☐ %	Albumin	_____	☐ g/dL ☐ g/L
WBC	_____	☐ 10^9/L OR 10^3/mm³ ☐ /mm³	Total bilirubin	_____	☐ mg/dL ☐ µmol/L
Sodium	_____	mmol/L OR mEq/L	Direct bilirubin	_____	☐ mg/dL ☐ µmol/L
Potassium	_____	mmol/L OR mEq/L	ENZYMES (TYPE 3) CK (ULN =_____)	_____	IU/L OR U/L OR mIU/mL ☐ Not Done
BUN	_____	mg/dL	CK-MB (ULN =_____)	_____	☐ mcg/L OR µg/L OR ng/mL ☐ IU/L OR U/L OR mIU/mL ☐ % ☐ Not Done
Creatinine	_____	mg/dL	Troponin ☐ I ☐ T (ULN =_____)	_____	ng/mL OR ☐ Positive ☐ Negative ☐ Not Done
ALT/SGPT	_____	IU/L OR U/L OR mIU/mL			

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Follow-Up Summary

FOLLOW (TYPE 3)

Follow-Up Instructions for Sodium and Fluid Restriction:

SODIUM

Sodium restriction: F:9:3> ___ mg/day

FLUID

Fluid restriction: <F:9:3> L/day

WTPLAN <ZYESNO>

Was the patient given a diuretic plan for weight gain? [0] No [1] Yes → If Yes, for every 2 lb weight gain patient:
(check all that apply)

[1] Increases loop diuretics INCDIU <ZYES>

[1] Adds thiazide/metolazone ADDSTHI <ZYES>

Visual Analog Scale Scores (Complete the Visual Analog Scale Worksheet insert pages)

VISUAL (TYPE 3)

Examination date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SAME AS PAGE 9

Worst symptom: ___ ___ ___ → Corresponding to *(check only one)*:

- ☐ Abdominal discomfort
- ☐ Breathing
- ☐ Body swelling
- ☐ Fatigue

Breathing: ___ ___ ___ OR ☐ Not applicable if breathing was selected as worst symptom

Global: ___ ___ ___

Nurse/Study Coordinator Estimate of Likelihood of Death over next 6 months

Check only one:

- ☐ 0–25%
- ☐ 26–50%
- ☐ 51–75%
- ☐ 76–100%

THIS NOT ENTERED

Nurse/Study Coordinator Estimate of Readmission over next 6 months

Check only one:

- ☐ 0–25%
- ☐ 26–50%
- ☐ 51–75%
- ☐ 76–100%

THIS NOT ENTERED

Signature

SIGNATUR (TYPE 4)

The data recorded on CRF pages 1–38 have been reviewed by me or my delegate and are accurate and complete to the best of my knowledge.

SAME AS PAGE 3

Investigator's signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

STUDYBOOK=ESCAPE
FORM=1-MONTH FOLLOW-UP

SAME AS PAGE 1

1-Month Follow-Up

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Minnesota Living with Heart Failure

Instructions: These questions concern how your heart failure (heart condition) has prevented you from living as you wanted during the last month. The items listed below describe different ways some people are affected. If you are sure an item does not apply to you or is not related to your heart failure then circle 0 (meaning "No") and go onto the next item. If an item does apply to you, then circle the number rating of how much it prevented you from living as you wanted. Remember to think about ONLY THE LAST MONTH.

LWHFQUES (TYPE 3)

Did your heart failure prevent you from living as you wanted during the LAST MONTH by:

	No	Very Little →				Very Much
1. causing swelling in your ankles, legs, etc?	0	1	2	3	4	5
2. making your working around the house or yard difficult?	0	1	2	3	4	5
3. making your relating to or doing things with your friends difficult?	0	1	2	3	4	5
4. making you sit or lie down to rest during the day?	0	1	2	3	4	5
5. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
6. making your working to earn a living difficult?	0	1	2	3	4	5
7. making your walking or climbing stairs difficult?	0	1	2	3	4	5
8. making you short of breath?	0	1	2	3	4	5
9. making your sleeping well at night difficult?	0	1	2	3	4	5
10. making you eat less of the foods you like?	0	1	2	3	4	5
11. making your going places away from home difficult?	0	1	2	3	4	5
12. making your sexual activities difficult?	0	1	2	3	4	5
13. making your recreational pastimes, sports, or hobbies difficult?	0	1	2	3	4	5
14. making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
15. giving you side effects from medications?	0	1	2	3	4	5
16. making you worry?	0	1	2	3	4	5
17. making you feel depressed?	0	1	2	3	4	5
18. costing you money for medical care?	0	1	2	3	4	5
19. making you feel a loss of self-control in your life?	0	1	2	3	4	5
20. making you stay in a hospital?	0	1	2	3	4	5
21. making you feel you are a burden to your family or friends?	0	1	2	3	4	5

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Contact Status

Date of contact: ___ ___ (day) / ___ ___ (month) / ___ ___ ___ ___ (year)

SAME AS PAGE 33

CONTACT (TYPE 3)

Mode of contact *(check only one)*:

- ☐ Clinic visit
- ☐ Telephone call
- ☐ Rehospitalization
- ☐ Continuous hospitalization since randomization
- ☐ Lost to follow-up → **Date of last contact:** ___ ___ (day) / ___ ___ (month) / ___ ___ ___ ___ (year)
- ☐ Other *(specify)*: _____

Resuscitation Orders

Resuscitation orders *(check only one)*:

- ☐ Attempt cardiopulmonary resuscitation
- ☐ Attempt cardiopulmonary resuscitation but do not intubate
- ☐ Do not attempt cardiopulmonary resuscitation

Endpoint Summary *(SKIP this box for patients with a continuous hospitalization since randomization.)*

SAME AS PAGE 32

ENDPTSUM (TYPE 3)

Since the last visit was the patient admitted to the hospital or emergency department for more than 24 hours?

- ☐ No
- ☐ Yes → **If Yes, number of times:** ___ ___
  → **If Yes, complete the Rehospitalization Form (insert page) for each hospital admission**

Since the last visit has the patient undergone a cardiovascular operation or procedure (e.g., CABG, PAC, mechanical ventilation)?

- ☐ No
- ☐ Yes → **If Yes, complete the CV Procedures/Mechanical Ventilation Form (insert page)**

Since the last visit has the patient died?

- ☐ No → **If No, transplant status** *(check only one)*:
  - ☐ Ineligible
  - ☐ Active evaluation
  - ☐ Listed
  - ☐ Received transplant → **Date:** ___ ___ (day) / ___ ___ (month) / ___ ___ ___ ___ (year)
  - ☐ Accepted, but waiting to detemine need after discharge
  - ☐ Not evaluated
- ☐ Yes → **If Yes, complete page 70, Event Notification Form and the Death Form (insert page)**

SAME AS PAGE 2 Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Heart Failure Clinical Assessment—Symptoms

SYMPTOMS (TYPE 3)

Does the patient have any of the following?

	No	Yes
Fatigue:		
At rest	☐	☐
Any activity	☐	☐
Routine daily activity	☐	☐

	No	Yes
Dyspnea:		
At rest	☐	☐
Walking in room	☐	☐
Walking < 1 block	☐	☐

Orthopnea *(check only one)*:
- ☐ Needs only 1 pillow
- ☐ Occasional orthopnea with 1 pillow
- ☐ Needs 2 pillows most of the time
- ☐ Needs 3 pillows most of the time
- ☐ Needs 4 pillows most of the time *(sitting up)*

Gastrointestinal distress *(check only one)*: ☐ None ☐ Occasional ☐ Constant

NYHA classification *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

Heart Failure Clinical Assessment—Physical Exam

PHYSEXAM (TYPE 3)

Heart rate (supine): ___ ___ ___ bpm **Heart rate (standing after 3 minutes):** ___ ___ ___ bpm

Blood pressure manual cuff *(supine)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg

Blood pressure manual cuff *(standing after 3 minutes)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg

Weight: ___ ___ ___ . ___ ☐ lb ☐ kg

Respiratory rate: ___ ___ breaths/minute

Temperature: ___ ___ ___ . ___ ☐ C ☐ F

Jugular venous pulsation *(cm above the right atrium)*: ☐ < 8 ☐ 8–12 ☐ 12–16 ☐ >16 ☐ Cannot measure

Rales: ☐ None ☐ < 1/3 ☐ 1/3–2/3 ☐ > 2/3

Auscultation: S3: ☐ No ☐ Yes
Estimated P2-PAS: ☐ < 40 ☐ 40–50 ☐ 51–60 ☐ > 60

Hepatomegaly *(check only one)*: ☐ Absent ☐ 2–4 finger breadths ☐ > 4 finger breadths

Hepatojugular reflux: ☐ No ☐ Yes

Ascites *(check only one)*: ☐ None ☐ Trace ☐ Moderate ☐ Massive

Peripheral edema *(check only one)*: ☐ 0 ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+

Extremities *(check only one)*: ☐ Cool ☐ Lukewarm ☐ Warm

Valsalva maneuver *(check only one)*: ☐ Normal ☐ Absent overshoot ☐ Square-wave ☐ Uncertain **OR** ☐ Not applicable

Clinical profile *(check only one)*: ☐ Dry/warm ☐ Wet/warm ☐ Dry/cold ☐ Wet/cold

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Heart Failure Clinical Assessment—Estimate of Hemodynamic Status

Right atrial pressure (mmHg) *(check only one)*: ☐ < 8 ☐ 8–12 ☐ 13–16 ☐ >16 THIS NOT ENTERED

Certainty of assessment *(check only one)*: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
not very sure ——— *very sure*

Pulmonary capillary wedge pressure (mmHg) *(check only one)*: ☐ < 12 ☐ 12–22 ☐ 23–30 ☐ >30

Certainty of assessment *(check only one)*: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
not very sure ——— *very sure*

Cardiac index (L/min • m^2) *(check only one)*: ☐ < 1.8 ☐ 1.8–2.2 ☐ 2.3–2.5 ☐ > 2.5

Certainty of assessment *(check only one)*: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
not very sure ——— *very sure.*

Physician Estimate of Likelihood of Death over next 6 months

SAME AS PAGE 26 PHYSEST (TYPE 3)

Check only one:
☐ 0–25%
☐ 26–50%
☐ 51–75%
☐ 76–100%

Physician Estimate of Readmission over next 6 months

Check only one:
☐ 0–25%
☐ 26–50%
☐ 51–75%
☐ 76–100%

Signature (Physician who performed assessment)

SAME AS PAGE 3 SIGNATUR (TYPE 4)

Investigator's signature: _____ Date performed: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Current Medications

ACE inhibitor: ☐ No → If No, specify reason *(check all that apply)*: ACE1 (TYPE 3)

- ☐ Angioedema, anaphylaxis, neutropenia
- ☐ Cough
- ☐ Hyperkalemia
- ☐ Renal artery stenosis
- ☐ Renal dysfunction
- ☐ Symptomatic hypotension
- ☐ Other adverse events such as taste disturbance, rash, and gastrointestinal upset

ACE2 (TYPE 3)

☐ Yes → If Yes:

	Total daily dose:
☐ Benazepril	_____ mg
☐ Captopril	_____ mg
☐ Enalapril	_____ mg
☐ Fosinopril	_____ mg
☐ Lisinopril	_____ mg
☐ Quinapril	_____ mg
☐ Ramipril	_____ mg
☐ Trandolapril	_____ mg
☐ Other *(specify)*: _____	_____ mg

Angiotensin II antagonist: ANGIODIG (TYPE 3)

☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Candesartan	_____ mg
☐ Losartan	_____ mg
☐ Valsartan	_____ mg
☐ Other *(specify)*: _____	_____ mg

Digoxin: ☐ No ☐ Yes → **If Yes, specify total dose and frequency:** _____ mg ☐ QD ☐ QOD ☐ Other

Diuretic: (loop) ☐ No ☐ Yes → If Yes: DIUR1 (TYPE 3)

	Total daily dose:
☐ Bumetanide	_____ mg
☐ Ethacrynic acid	_____ mg
☐ Furosemide	_____ mg
☐ Torsemide	_____ mg
☐ Other *(specify)*: _____	_____ mg

Diuretic: (potassium sparing) ☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Amiloride	_____ mg
☐ Spironolactone	_____ mg
☐ Triamterene	_____ mg
☐ Other *(specify)*: _____	_____ mg

Diuretic: (thiazide) ☐ No ☐ Yes → If Yes: DIURCCB (TYPE 3)

	Total daily dose:
☐ Chlorothiazide (diuril)	_____ mg
☐ Hydrochlorothiazide (HCTZ)	_____ mg
☐ Metolazone (zaroxolyn)	_____ mg
☐ Other *(specify)*: _____	_____ mg

Calcium channel blocker: ☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Amlodipine	_____ mg
☐ Other *(specify)*: _____	_____ mg

Current Medications (cont.)

BBANTIAR (TYPE 3)

			Total daily dose:
Beta blocker:	☐ No ☐ Yes → If Yes:	☐ Atenolol	_____ mg
		☐ Bisoprolol	_____ mg
		☐ Carvedilol	_____ mg
		☐ Metoprolol	_____ mg
		☐ Propranolol	_____ mg
		☐ Other *(specify)*: _____	_____ mg

			Total daily dose:
Antiarrhythmics:	☐ No ☐ Yes → If Yes:	☐ Amiodarone	_____ mg
		☐ Dofetilide	_____ mg
		☐ Sotalol	_____ mg
		☐ Other *(specify)*: _____	_____ mg

NIHYPOT (TYPE 3)

			Total daily dose:
Nitrates:	☐ No ☐ Yes → If Yes:	☐ Isosorbide dinitrate	_____ mg
		☐ Isosorbide mononitrate	_____ mg
		☐ Topical nitroglycerin	_____ mg
Hydralazine:	☐ No ☐ Yes → If Yes, total daily dose:		_____ mg
Potassium:	☐ No ☐ Yes → If Yes, total daily dose:		_____ mEq

MEDS (TYPE 4) PS

Statins:	☐ No ☐ Yes	**Antidepressants:**	☐ No ☐ Yes
Other lipid lowering agents:	☐ No ☐ Yes	**Benzodiazepines:**	☐ No ☐ Yes
Magnesium:	☐ No ☐ Yes	**Allopurinol:**	☐ No ☐ Yes
Estrogen replacement therapy:	☐ No ☐ Yes	**Colchicine:**	☐ No ☐ Yes
Testosterone replacement therapy:	☐ No ☐ Yes	**Enoxaparin:**	☐ No ☐ Yes
Insulin:	☐ No ☐ Yes	**Warfarin:**	☐ No ☐ Yes
Oral diabetic agents:	☐ No ☐ Yes	**Vitamin E:**	☐ No ☐ Yes
Aspirin (daily):	☐ No ☐ Yes	**CoEnzyme Q10:**	☐ No ☐ Yes
Other antiplatelet agents:	☐ No ☐ Yes	**Other antioxidants:**	☐ No ☐ Yes
NSAIDs:	☐ No ☐ Yes	**Multi-vitamin:**	☐ No ☐ Yes
Thyroid replacement therapy:	☐ No ☐ Yes		

SAME AS PAGE 36

INFUSIN (TYPE 4) PS

		Current infusion rate:	Check box if intermittent:
Amrinone:	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	☐ Intermittent → _____ # days/month
Dobutamine:	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	☐ Intermittent → _____ # days/month
Dopamine:	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	☐ Intermittent → _____ # days/month
Milrinone:	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	☐ Intermittent → _____ # days/month
Nitroglycerin:	☐ No ☐ Yes → If Yes:	_____ mcg/min	
Nitroprusside:	☐ No ☐ Yes → If Yes:	_____ mcg/min	

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Laboratory

LAB (TYPE 4) PS

Date of collection: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Value		Value	
Hemoglobin (Hgb)	_____ ☐ g/L ☐ mmol/L ☐ g/dL	AST/SGOT	_____ IU/L OR U/L OR mIU/mL
Platelets	_____ ☐ 10^9/L OR 10^3/mm³ ☐ /mm³	Total protein	_____ ☐ g/dL ☐ g/L
Hematocrit (Hct)	_____ ☐ L/L ☐ %	Albumin	_____ ☐ g/dL ☐ g/L
WBC	_____ ☐ 10^9/L OR 10^3/mm³ ☐ /mm³	Total bilirubin	_____ ☐ mg/dL ☐ µmol/L
Sodium	_____ mmol/L OR mEq/L	Direct bilirubin	_____ ☐ mg/dL ☐ µmol/L
Potassium	_____ mmol/L OR mEq/L	ENZYMES (TYPE 3) CK (ULN =_____)	_____ IU/L OR U/L OR mIU/mL ☐ Not Done
BUN	_____ mg/dL	CK-MB (ULN =_____)	_____ ☐ mcg/L OR µg/L OR ng/mL ☐ IU/L OR U/L OR mIU/mL ☐ % ☐ Not Done
Creatinine	_____ mg/dL	Troponin ☐ I ☐ T (ULN =_____)	_____ ng/mL OR ☐ Positive ☐ Negative ☐ Not Done
ALT/SGPT	_____ IU/L OR U/L OR mIU/mL		

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Follow-Up Summary

Follow-Up Instructions for Sodium and Fluid Restriction: SAME AS PAGE 38 FOLLOW (TYPE 3)

Sodium restriction: _____ mg/day

Fluid restriction: _____ L/day

Was the patient given a diuretic plan for weight gain? ☐ No ☐ Yes → If Yes, for every 2 lb weight gain patient:
(check all that apply)

☐ Increases loop diuretics
☐ Adds thiazide/metolazone

Visual Analog Scale Scores (Complete the Visual Analog Scale Worksheet insert pages)

Examination date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year.) SAME AS PAGE 9 VISUAL (TYPE 3)

Worst symptom: ___ ___ ___ → Corresponding to *(check only one)*:

☐ Abdominal discomfort
☐ Breathing
☐ Body swelling
☐ Fatigue

Breathing: ___ ___ ___ OR ☐ Not applicable if breathing was selected as worst symptom

Global: ___ ___ ___

Congestion Score (See instructions on facing page.)

Congestion score: CONGSCOR <I:1> CONGEST (TYPE 1)

Time Trade-Off Scores

Examination date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SAME AS PAGE 9 TIMETRAD (TYPE 3)

Score: ___ ___ months ☐ or 1 day

Nurse/Study Coordinator Estimate of Likelihood of Death over next 6 months

Check only one: SAME AS PAGE 32 NURSEEST (TYPE 3)

☐ 0–25%
☐ 26–50%
☐ 51–75%
☐ 76–100%

Nurse/Study Coordinator Estimate of Readmission over next 6 months

Check only one:

☐ 0–25%
☐ 26–50%
☐ 51–75%
☐ 76–100%

Signature

The data recorded on CRF pages 39–46 have been reviewed by me or my delegate and are accurate and complete to the best of my knowledge. SIGNATUR (TYPE 4)

SAME AS PAGE 3

Investigator's signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

STUDYBOOK=ESCAPE
FORM=2-MONTH FOLLOW-UP

2-Month Follow-Up

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) **Patient Initials:** ___ ___ ___

Contact Status

Date of contact: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

SAME AS PAGE 33

CONTACT (TYPE 3)

Mode of contact *(check only one)*:

- ☐ Clinic visit
- ☐ Telephone call
- ☐ Rehospitalization
- ☐ Continuous hospitalization since randomization
- ☐ Lost to follow-up → **Date of last contact:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
- ☐ Other *(specify)*: _____

Resuscitation Orders

Resuscitation orders *(check only one)*:

- ☐ Attempt cardiopulmonary resuscitation
- ☐ Attempt cardiopulmonary resuscitation but do not intubate
- ☐ Do not attempt cardiopulmonary resuscitation

Endpoint Summary *(SKIP this box for patients with a continuous hospitalization since randomization.)*

SAME AS PAGE 32

ENDPTSUM (TYPE 3)

Since the last visit was the patient admitted to the hospital or emergency department for more than 24 hours?

- ☐ No
- ☐ Yes → **If Yes, number of times:** ___ ___
  → **If Yes, complete the Rehospitalization Form (insert page) for each hospital admission**

Since the last visit has the patient undergone a cardiovascular operation or procedure (e.g., CABG, PAC, mechanical ventilation)?

- ☐ No
- ☐ Yes → **If Yes, complete the CV Procedures/Mechanical Ventilation Form (insert page)**

Since the last visit has the patient died?

- ☐ No → **If No, transplant status** *(check only one)*:
  - ☐ Ineligible
  - ☐ Active evaluation
  - ☐ Listed
  - ☐ Received transplant → **Date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
  - ☐ Accepted, but waiting to detemine need after discharge
  - ☐ Not evaluated
- ☐ Yes → **If Yes, complete page 70, Event Notification Form and the Death Form (insert page)**

SAME AS PAGE 2

2-Month Physician Assessment

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Heart Failure Clinical Assessment – Symptoms

SYMPTOMS (TYPE 3)

Does the patient have any of the following?

	No	Yes
Fatigue:		
At rest	☐	☐
Any activity	☐	☐
Routine daily activity	☐	☐
Dyspnea:		
At rest	☐	☐
Walking in room	☐	☐
Walking < 1 block	☐	☐

Orthopnea *(check only one)*:
- ☐ Needs only 1 pillow
- ☐ Occasional orthopnea with 1 pillow
- ☐ Needs 2 pillows most of the time
- ☐ Needs 3 pillows most of the time
- ☐ Needs 4 pillows most of the time *(sitting up)*

Gastrointestinal distress *(check only one)*: ☐ None ☐ Occasional ☐ Constant

NYHA classification *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

Heart Failure Clinical Assessment – Physical Exam

PHYSEXAM (TYPE 3)

Heart rate (supine): ___ ___ ___ bpm **Heart rate (standing after 3 minutes):** ___ ___ ___ bpm

Blood pressure manual cuff *(supine)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg

Blood pressure manual cuff *(standing after 3 minutes)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg

Weight: ___ ___ ___ . ___ ☐ lb ☐ kg

Respiratory rate: ___ ___ breaths/minute

Temperature: ___ ___ ___ . ___ ☐ C ☐ F

Jugular venous pulsation *(cm above the right atrium)*: ☐ < 8 ☐ 8–12 ☐ 12–16 ☐ >16 ☐ Cannot measure

Rales: ☐ None ☐ < 1/3 ☐ 1/3–2/3 ☐ > 2/3

Auscultation: S3: ☐ No ☐ Yes
Estimated P2-PAS: ☐ < 40 ☐ 40–50 ☐ 51–60 ☐ > 60

Hepatomegaly *(check only one)*: ☐ Absent ☐ 2–4 finger breadths ☐ > 4 finger breadths

Hepatojugular reflux: ☐ No ☐ Yes

Ascites *(check only one)*: ☐ None ☐ Trace ☐ Moderate ☐ Massive

Peripheral edema *(check only one)*: ☐ 0 ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+

Extremities *(check only one)*: ☐ Cool ☐ Lukewarm ☐ Warm

Valsalva maneuver *(check only one)*: ☐ Normal ☐ Absent overshoot ☐ Square-wave ☐ Uncertain **OR** ☐ Not applicable

Clinical profile *(check only one)*: ☐ Dry/warm ☐ Wet/warm ☐ Dry/cold ☐ Wet/cold

Signature (Physician who performed assessment)

SAME AS PAGE 3

SIGNATUR (TYPE 4)

Investigator's signature: _____ **Date performed:** ___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year)

Current Medications

ACE inhibitor: ☐ No → If No, specify reason *(check all that apply)*: ACE1 (TYPE 3)

- ☐ Angioedema, anaphylaxis, neutropenia
- ☐ Cough
- ☐ Hyperkalemia
- ☐ Renal artery stenosis
- ☐ Renal dysfunction
- ☐ Symptomatic hypotension
- ☐ Other adverse events such as taste disturbance, rash, and gastrointestinal upset

ACE2 (TYPE 3)

☐ Yes → If Yes:

	Total daily dose:
☐ Benazepril	_____ mg
☐ Captopril	_____ mg
☐ Enalapril	_____ mg
☐ Fosinopril	_____ mg
☐ Lisinopril	_____ mg
☐ Quinapril	_____ mg
☐ Ramipril	_____ mg
☐ Trandolapril	_____ mg
☐ Other *(specify)*: _____	_____ mg

Angiotensin II antagonist: ANGIODIG (TYPE 3)

☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Candesartan	_____ mg
☐ Losartan	_____ mg
☐ Valsartan	_____ mg
☐ Other *(specify)*: _____	_____ mg

Digoxin: ☐ No ☐ Yes → **If Yes, specify total dose and frequency:** _____ mg ☐ QD ☐ QOD ☐ Other

Diuretic (loop): ☐ No ☐ Yes → If Yes: DIUR1 (TYPE 3)

	Total daily dose:
☐ Bumetanide	_____ mg
☐ Ethacrynic acid	_____ mg
☐ Furosemide	_____ mg
☐ Torsemide	_____ mg
☐ Other *(specify)*: _____	_____ mg

Diuretic (potassium sparing): ☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Amiloride	_____ mg
☐ Spironolactone	_____ mg
☐ Triamterene	_____ mg
☐ Other *(specify)*: _____	_____ mg

Diuretic (thiazide): ☐ No ☐ Yes → If Yes: DIURCCB (TYPE 3)

	Total daily dose:
☐ Chlorothiazide (diuril)	_____ mg
☐ Hydrochlorothiazide (HCTZ)	_____ mg
☐ Metolazone (zaroxolyn)	_____ mg
☐ Other *(specify)*: _____	_____ mg

Calcium channel blocker: ☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Amlodipine	_____ mg
☐ Other *(specify)*: _____	_____ mg

Current Medications (cont.)

BBANTIAR (TYPE 3)

			Total daily dose:
Beta blocker:	☐ No ☐ Yes → If Yes:	☐ Atenolol	_____ mg
		☐ Bisoprolol	_____ mg
		☐ Carvedilol	_____ mg
		☐ Metoprolol	_____ mg
		☐ Propranolol	_____ mg
		☐ Other *(specify)*: _____	_____ mg

			Total daily dose:
Antiarrhythmics:	☐ No ☐ Yes → If Yes:	☐ Amiodarone	_____ mg
		☐ Dofetilide	_____ mg
		☐ Sotalol	_____ mg
		☐ Other *(specify)*: _____	_____ mg

NIHYPOT (TYPE 3)

			Total daily dose:
Nitrates:	☐ No ☐ Yes → If Yes:	☐ Isosorbide dinitrate	_____ mg
		☐ Isosorbide mononitrate	_____ mg
		☐ Topical nitroglycerin	_____ mg
Hydralazine:	☐ No ☐ Yes → If Yes, total daily dose:		_____ mg
Potassium:	☐ No ☐ Yes → If Yes, total daily dose:		_____ mEq

MEDS (TYPE 4) PS

Statins:	☐ No ☐ Yes	**Antidepressants:**	☐ No ☐ Yes
Other lipid lowering agents:	☐ No ☐ Yes	**Benzodiazepines:**	☐ No ☐ Yes
Magnesium:	☐ No ☐ Yes	**Allopurinol:**	☐ No ☐ Yes
Estrogen replacement therapy:	☐ No ☐ Yes	**Colchicine:**	☐ No ☐ Yes
Testosterone replacement therapy:	☐ No ☐ Yes	**Enoxaparin:**	☐ No ☐ Yes
Insulin:	☐ No ☐ Yes	**Warfarin:**	☐ No ☐ Yes
Oral diabetic agents:	☐ No ☐ Yes	**Vitamin E:**	☐ No ☐ Yes
Aspirin (daily):	☐ No ☐ Yes	**CoEnzyme Q10:**	☐ No ☐ Yes
Other antiplatelet agents:	☐ No ☐ Yes	**Other antioxidants:**	☐ No ☐ Yes
NSAIDs:	☐ No ☐ Yes	**Multi-vitamin:**	☐ No ☐ Yes
Thyroid replacement therapy:	☐ No ☐ Yes		

INFUSIN (TYPE 4) PS

SAME AS PAGE 36

		Current infusion rate:	Check box if intermittent:
Amrinone:	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	☐ Intermittent → _____ # days/month
Dobutamine:	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	☐ Intermittent → _____ # days/month
Dopamine:	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	☐ Intermittent → _____ # days/month
Milrinone:	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	☐ Intermittent → _____ # days/month
Nitroglycerin:	☐ No ☐ Yes → If Yes:	_____ mcg/min	
Nitroprusside:	☐ No ☐ Yes → If Yes:	_____ mcg/min	

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Laboratory

LAB (TYPE 4) PS

Date of collection: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Value			Value		
Hemoglobin (Hgb)	_____	☐ g/L ☐ mmol/L ☐ g/dL	AST/SGOT	_____	IU/L OR U/L OR mIU/mL
Platelets	_____	☐ 10^9/L OR 10^3/mm³ ☐ /mm³	Total protein	_____	☐ g/dL ☐ g/L
Hematocrit (Hct)	_____	☐ L/L ☐ %	Albumin	_____	☐ g/dL ☐ g/L
WBC	_____	☐ 10^9/L OR 10^3/mm³ ☐ /mm³	Total bilirubin	_____	☐ mg/dL ☐ µmol/L
Sodium	_____	mmol/L OR mEq/L	Direct bilirubin	_____	☐ mg/dL ☐ µmol/L
Potassium	_____	mmol/L OR mEq/L	CK (ULN =_____)	_____	IU/L OR U/L OR mIU/mL ☐ Not Done
BUN	_____	mg/dL	CK-MB (ULN =_____)	_____	☐ mcg/L OR µg/L OR ng/mL ☐ IU/L OR U/L OR mIU/mL ☐ % ☐ Not Done
Creatinine	_____	mg/dL	Troponin ☐ I ☐ T (ULN =_____)	_____	ng/mL OR ☐ Positive ☐ Negative ☐ Not Done
ALT/SGPT	_____	IU/L OR U/L OR mIU/mL			

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Follow-Up Summary

Follow-Up Instructions for Sodium and Fluid Restriction: SAME AS PAGE 38 FOLLOW (TYPE 3)

Sodium restriction: _____ mg/day

Fluid restriction: _____ L/day

Was the patient given a diuretic plan for weight gain? ☐ No ☐ Yes → If Yes, for every 2 lb weight gain patient:
(check all that apply)

- ☐ Increases loop diuretics
- ☐ Adds thiazide/metolazone

Visual Analog Scale Scores (Complete the Visual Analog Scale Worksheet insert pages)

Examination date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SAME AS PAGE 9 VISUAL (TYPE 3)

Worst symptom: ___ ___ ___ → Corresponding to *(check only one)*:

- ☐ Abdominal discomfort
- ☐ Breathing
- ☐ Body swelling
- ☐ Fatigue

Breathing: ___ ___ ___ OR ☐ Not applicable if breathing was selected as worst symptom

Global: ___ ___ ___

Time Trade-Off Scores

Examination date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SAME AS PAGE 9 TIMETRAD (TYPE 3)

Score: ___ ___ months ☐ or 1 day

Nurse/Study Coordinator Estimate of Likelihood of Death over next 6 months

Check only one:

- ☐ 0–25%
- ☐ 26–50%
- ☐ 51–75%
- ☐ 76–100%

THIS NOT ENTERED

Nurse/Study Coordinator Estimate of Readmission over next 6 months

Check only one:

- ☐ 0–25%
- ☐ 26–50%
- ☐ 51–75%
- ☐ 76–100%

THIS NOT ENTERED

Signature

SAME AS PAGE 3 SIGNATUR (TYPE 4)

The data recorded on CRF pages 47–52 have been reviewed by me or my delegate and are accurate and complete to the best of my knowledge.

Investigator's signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

3-Month Follow-Up

SAME AS PAGE 1 Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Minnesota Living with Heart Failure

Instructions: These questions concern how your heart failure (heart condition) has prevented you from living as you wanted during the last month. The items listed below describe different ways some people are affected. If you are sure an item does not apply to you or is not related to your heart failure then circle 0 (meaning "No") and go onto the next item. If an item does apply to you, then circle the number rating of how much it prevented you from living as you wanted. Remember to think about ONLY THE LAST MONTH.

LWHFQUES (TYPE 3)

Did your heart failure prevent you from living as you wanted during the LAST MONTH by:

	No	Very Little →				Very Much
1. causing swelling in your ankles, legs, etc?	0	1	2	3	4	5
2. making your working around the house or yard difficult?	0	1	2	3	4	5
3. making your relating to or doing things with your friends difficult?	0	1	2	3	4	5
4. making you sit or lie down to rest during the day?	0	1	2	3	4	5
5. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
6. making your working to earn a living difficult?	0	1	2	3	4	5
7. making your walking or climbing stairs difficult?	0	1	2	3	4	5
8. making you short of breath?	0	1	2	3	4	5
9. making your sleeping well at night difficult?	0	1	2	3	4	5
10. making you eat less of the foods you like?	0	1	2	3	4	5
11. making your going places away from home difficult?	0	1	2	3	4	5
12. making your sexual activities difficult?	0	1	2	3	4	5
13. making your recreational pastimes, sports, or hobbies difficult?	0	1	2	3	4	5
14. making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
15. giving you side effects from medications?	0	1	2	3	4	5
16. making you worry?	0	1	2	3	4	5
17. making you feel depressed?	0	1	2	3	4	5
18. costing you money for medical care?	0	1	2	3	4	5
19. making you feel a loss of self-control in your life?	0	1	2	3	4	5
20. making you stay in a hospital?	0	1	2	3	4	5
21. making you feel you are a burden to your family or friends?	0	1	2	3	4	5

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Contact Status

Date of contact: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SAME AS PAGE 33 CONTACT (TYPE 3)

Mode of contact *(check only one)*:

- ☐ Clinic visit
- ☐ Telephone call
- ☐ Rehospitalization
- ☐ Continuous hospitalization since randomization
- ☐ Lost to follow-up → **Date of last contact:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
- ☐ Other *(specify)*: _____

Resuscitation Orders

Resuscitation orders *(check only one)*:

- ☐ Attempt cardiopulmonary resuscitation
- ☐ Attempt cardiopulmonary resuscitation but do not intubate
- ☐ Do not attempt cardiopulmonary resuscitation

Endpoint Summary *(SKIP this box for patients with a continuous hospitalization since randomization.)*

SAME AS PAGE 32 ENDPTSUM (TYPE 3)

Since the last visit was the patient admitted to the hospital or emergency department for more than 24 hours?

- ☐ No
- ☐ Yes → **If Yes, number of times:** ___ ___
  → **If Yes, complete the Rehospitalization Form (insert page) for each hospital admission**

Since the last visit has the patient undergone a cardiovascular operation or procedure (e.g., CABG, PAC, mechanical ventilation)?

- ☐ No
- ☐ Yes → **If Yes, complete the CV Procedures/Mechanical Ventilation Form (insert page)**

Since the last visit has the patient died?

- ☐ No → **If No, transplant status** *(check only one)*:
  - ☐ Ineligible
  - ☐ Active evaluation
  - ☐ Listed
  - ☐ Received transplant → **Date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
  - ☐ Accepted, but waiting to detemine need after discharge
  - ☐ Not evaluated
- ☐ Yes → **If Yes, complete page 70, Event Notification Form and the Death Form (insert page)**

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Heart Failure Clinical Assessment—Symptoms

SYMPTOMS (TYPE 3)

Does the patient have any of the following?

	No	Yes
Fatigue:		
At rest	☐	☐
Any activity	☐	☐
Routine daily activity	☐	☐

	No	Yes
Dyspnea:		
At rest	☐	☐
Walking in room	☐	☐
Walking < 1 block	☐	☐

Orthopnea *(check only one)*:
- ☐ Needs only 1 pillow
- ☐ Occasional orthopnea with 1 pillow
- ☐ Needs 2 pillows most of the time
- ☐ Needs 3 pillows most of the time
- ☐ Needs 4 pillows most of the time *(sitting up)*

Gastrointestinal distress *(check only one)*: ☐ None ☐ Occasional ☐ Constant

NYHA classification *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

Heart Failure Clinical Assessment—Physical Exam

PHYSEXAM (TYPE 3)

Heart rate (supine): ___ ___ ___ bpm **Heart rate (standing after 3 minutes):** ___ ___ ___ bpm

Blood pressure manual cuff *(supine)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg

Blood pressure manual cuff *(standing after 3 minutes)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg

Weight: ___ ___ ___ . ___ ☐ lb ☐ kg

Respiratory rate: ___ ___ breaths/minute

Temperature: ___ ___ ___ . ___ ☐ C ☐ F

Jugular venous pulsation *(cm above the right atrium)*: ☐ < 8 ☐ 8–12 ☐ 12–16 ☐ >16 ☐ Cannot measure

Rales: ☐ None ☐ < 1/3 ☐ 1/3–2/3 ☐ > 2/3

Auscultation: S3: ☐ No ☐ Yes
Estimated P2-PAS: ☐ < 40 ☐ 40–50 ☐ 51–60 ☐ > 60

Hepatomegaly *(check only one)*: ☐ Absent ☐ 2–4 finger breadths ☐ > 4 finger breadths

Hepatojugular reflux: ☐ No ☐ Yes

Ascites *(check only one)*: ☐ None ☐ Trace ☐ Moderate ☐ Massive

Peripheral edema *(check only one)*: ☐ 0 ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+

Extremities *(check only one)*: ☐ Cool ☐ Lukewarm ☐ Warm

Valsalva maneuver *(check only one)*: ☐ Normal ☐ Absent overshoot ☐ Square-wave ☐ Uncertain **OR** ☐ Not applicable

Clinical profile *(check only one)*: ☐ Dry/warm ☐ Wet/warm ☐ Dry/cold ☐ Wet/cold

Signature (Physician who performed assessment)

SAME AS PAGE 3

SIGNATUR (TYPE 4)

Investigator's signature: _____ **Date performed:** ___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year)

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Current Medications

ACE inhibitor: ☐ No → If No, specify reason *(check all that apply)*: ACE1 (TYPE 3)

- ☐ Angioedema, anaphylaxis, neutropenia
- ☐ Cough
- ☐ Hyperkalemia
- ☐ Renal artery stenosis
- ☐ Renal dysfunction
- ☐ Symptomatic hypotension
- ☐ Other adverse events such as taste disturbance, rash, and gastrointestinal upset

ACE2 (TYPE 3)

☐ Yes → If Yes:

	Total daily dose:
☐ Benazepril	_____ mg
☐ Captopril	_____ mg
☐ Enalapril	_____ mg
☐ Fosinopril	_____ mg
☐ Lisinopril	_____ mg
☐ Quinapril	_____ mg
☐ Ramipril	_____ mg
☐ Trandolapril	_____ mg
☐ Other *(specify)*: _____	_____ mg

Angiotensin II antagonist: ☐ No ☐ Yes → If Yes: ANGIODIG (TYPE 3)

	Total daily dose:
☐ Candesartan	_____ mg
☐ Losartan	_____ mg
☐ Valsartan	_____ mg
☐ Other *(specify)*: _____	_____ mg

Digoxin: ☐ No ☐ Yes → **If Yes, specify total dose and frequency:** _____ mg ☐ QD ☐ QOD ☐ Other

Diuretic: (loop) ☐ No ☐ Yes → If Yes: DIUR1 (TYPE 3)

	Total daily dose:
☐ Bumetanide	_____ mg
☐ Ethacrynic acid	_____ mg
☐ Furosemide	_____ mg
☐ Torsemide	_____ mg
☐ Other *(specify)*: _____	_____ mg

Diuretic: (potassium sparing) ☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Amiloride	_____ mg
☐ Spironolactone	_____ mg
☐ Triamterene	_____ mg
☐ Other *(specify)*: _____	_____ mg

Diuretic: (thiazide) ☐ No ☐ Yes → If Yes: DIURCCB (TYPE 3)

	Total daily dose:
☐ Chlorothiazide (diuril)	_____ mg
☐ Hydrochlorothiazide (HCTZ)	_____ mg
☐ Metolazone (zaroxolyn)	_____ mg
☐ Other *(specify)*: _____	_____ mg

Calcium channel blocker: ☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Amlodipine	_____ mg
☐ Other *(specify)*: _____	_____ mg

Current Medications (cont.)

BBANTIAR (TYPE 3)

			Total daily dose:
Beta blocker:	☐ No ☐ Yes → If Yes:	☐ Atenolol	_____ mg
		☐ Bisoprolol	_____ mg
		☐ Carvedilol	_____ mg
		☐ Metoprolol	_____ mg
		☐ Propranolol	_____ mg
		☐ Other *(specify)*: _____	_____ mg

			Total daily dose:
Antiarrhythmics:	☐ No ☐ Yes → If Yes:	☐ Amiodarone	_____ mg
		☐ Dofetilide	_____ mg
		☐ Sotalol	_____ mg
		☐ Other *(specify)*: _____	_____ mg

NIHYPOT (TYPE 3)

			Total daily dose:
Nitrates:	☐ No ☐ Yes → If Yes:	☐ Isosorbide dinitrate	_____ mg
		☐ Isosorbide mononitrate	_____ mg
		☐ Topical nitroglycerine	_____ mg
Hydralazine:	☐ No ☐ Yes → If Yes, total daily dose:		_____ mg
Potassium:	☐ No ☐ Yes → If Yes, total daily dose:		_____ mEq

MEDS (TYPE 4) PS

Statins:	☐ No ☐ Yes	**Antidepressants:**	☐ No ☐ Yes
Other lipid lowering agents:	☐ No ☐ Yes	**Benzodiazepines:**	☐ No ☐ Yes
Magnesium:	☐ No ☐ Yes	**Allopurinol:**	☐ No ☐ Yes
Estrogen replacement therapy:	☐ No ☐ Yes	**Colchicine:**	☐ No ☐ Yes
Testosterone replacement therapy:	☐ No ☐ Yes	**Enoxaparin:**	☐ No ☐ Yes
Insulin:	☐ No ☐ Yes	**Warfarin:**	☐ No ☐ Yes
Oral diabetic agents:	☐ No ☐ Yes	**Vitamin E:**	☐ No ☐ Yes
Aspirin (daily):	☐ No ☐ Yes	**CoEnzyme Q10:**	☐ No ☐ Yes
Other antiplatelet agents:	☐ No ☐ Yes	**Other antioxidants:**	☐ No ☐ Yes
NSAIDs:	☐ No ☐ Yes	**Multi-vitamin:**	☐ No ☐ Yes
Thyroid replacement therapy:	☐ No ☐ Yes		

SAME AS PAGE 36

INFUSIN (TYPE 4) PS

		Current infusion rate:	Check box if intermittent:
Amrinone:	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	☐ Intermittent → _____ # days/month
Dobutamine:	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	☐ Intermittent → _____ # days/month
Dopamine:	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	☐ Intermittent → _____ # days/month
Milrinone:	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	☐ Intermittent → _____ # days/month
Nitroglycerin:	☐ No ☐ Yes → If Yes:	_____ mcg/min	
Nitroprusside:	☐ No ☐ Yes → If Yes:	_____ mcg/min	

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Laboratory

LAB (TYPE 4) PS

Date of collection: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Value			Value		
Hemoglobin (Hgb)	_____	☐ g/L ☐ mmol/L ☐ g/dL	AST/SGOT	_____	IU/L OR U/L OR mIU/mL
Platelets	_____	☐ 10^9/L OR 10^3/mm³ ☐ /mm³	Total protein	_____	☐ g/dL ☐ g/L
Hematocrit (Hct)	_____	☐ L/L ☐ %	Albumin	_____	☐ g/dL ☐ g/L
WBC	_____	☐ 10^9/L OR 10^3/mm³ ☐ /mm³	Total bilirubin	_____	☐ mg/dL ☐ µmol/L
Sodium	_____	mmol/L OR mEq/L	Direct bilirubin	_____	☐ mg/dL ☐ µmol/L
Potassium	_____	mmol/L OR mEq/L	CK (ULN =_____)	_____	ENZYMES (TYPE 3) IU/L OR U/L OR mIU/mL ☐ Not Done
BUN	_____	mg/dL	CK-MB (ULN =_____)	_____	☐ mcg/L OR µg/L OR ng/mL ☐ IU/L OR U/L OR mIU/mL ☐ % ☐ Not Done
Creatinine	_____	mg/dL	Troponin ☐ I ☐ T (ULN =_____)	_____ ng/mL OR	☐ Positive ☐ Negative ☐ Not Done
ALT/SGPT	_____	IU/L OR U/L OR mIU/mL			

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Visual Analog Scale Scores (Complete the Visual Analog Scale Worksheet insert pages)

VISUAL (TYPE 3)

Examination date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Worst symptom: ___ ___ ___ → Corresponding to *(check only one)*:

- ☐ Abdominal discomfort
- ☐ Breathing
- ☐ Body swelling
- ☐ Fatigue

Breathing: ___ ___ ___ OR ☐ Not applicable if breathing was selected as worst symptom

Global: ___ ___ ___

Time Trade-Off Scores

TIMETRAD (TYPE 3)

Examination date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Score: ___ ___ months ☐ or 1 day

6-Minute Walk Exercise Test

WALK (TYPE 3)

Did the patient attempt the 6-minute walk test?

☐ No → If No, specify primary reason:

- ☐ The patient was too critically ill to be taken out of bed and exercised.
- ☐ Patient cannot walk for technical reasons (e.g., a patient who is an amputee).
- ☐ Not done due to oversight.

☐ Yes → If Yes, complete below.

Examination date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Start time of walk: ___ ___ : ___ ___ (00:00–23:59)

End time of walk: ___ ___ : ___ ___ (00:00–23:59)

Total distance walked: _____ ☐ Feet ☐ Meters

Did the patient experience any of the following symptoms *(check all that apply)*:

- ☐ Angina
- ☐ Light headedness
- ☐ Syncope

Borg Dyspnea score: _____ *(Transcribe score from worksheet.)*

Echocardiogram Data

ECHO (TYPE 3)

Examination date and time: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00–23:59)

Blood pressure *(closest to start of ECHO)*: ___ ___ ___ / ___ ___ ___ (systolic / diastolic)

- Send ECHO tape to Brigham Core Lab

Cardiopulmonary Exercise (CPX)

CPX (TYPE 3)

Did the patient attempt cardiopulmonary exercise testing?

☐ No → If No, specify primary reason:

- ☐ The patient was too critically ill to be taken out of bed and exercised.
- ☐ The patient was unable to walk > 50 meters on the 6 minute walk.
- ☐ Patient cannot walk for technical reasons (e.g., a patient who is an amputee).
- ☐ Not done due to oversight.

☐ Yes → If Yes, complete below.

Examination date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year.)

Type of exercise *(patient should perform same type of exercise throughout study)*: ☐ Bicycle ☐ Treadmill

Peak cardiovascular responses:

- VO_2 (ml/kg/min): _____
- VCO_2 (ml/kg/min): _____
- VE max (L/min): _____
- VE/VCO_2 (25 watts or end of first workload on treadmill) _____
- VO_2 @ R = 1.0: _____
- Heart rate (bpm): _____
- Systolic BP (max): _____
- Diastolic BP (max): _____
- Duration of exercise (min): _____
- Respiratory exchange ratio: _____

Reason for termination of testing *(check primary reason)*:

- ☐ Patient completed testing
- ☐ Symptom limited (e.g., dyspnea, fatigue)
- ☐ Angina
- ☐ Serious arrhythmia
- ☐ Blood pressure changes
- ☐ No longer able to walk (e.g., leg cramps)
- ☐ Other

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Follow-Up Summary

Follow-Up Instructions for Sodium and Fluid Restriction: SAME AS PAGE 38 FOLLOW (TYPE 3)

Sodium restriction: _____ mg/day

Fluid restriction: _____ L/day

Was the patient given a diuretic plan for weight gain? ☐ No ☐ Yes → If Yes, for every 2 lb weight gain patient:
(check all that apply)

- ☐ Increases loop diuretics
- ☐ Adds thiazide/metolazone

Nurse/Study Coordinator Estimate of Likelihood of Death over next 6 months

Check only one:

- ☐ 0–25%
- ☐ 26–50%
- ☐ 51–75%
- ☐ 76–100%

THIS NOT ENTERED

Nurse/Study Coordinator Estimate of Readmission over next 6 months

Check only one:

- ☐ 0–25%
- ☐ 26–50%
- ☐ 51–75%
- ☐ 76–100%

THIS NOT ENTERED

Signature

SAME AS PAGE 3 SIGNATUR (TYPE 4)

The data recorded on CRF pages 53–61 have been reviewed by me or my delegate and are accurate and complete to the best of my knowledge.

Investigator's signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

ESCAPE

6-Month Follow-Up

SAME AS PAGE 1

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Minnesota Living with Heart Failure

Instructions: These questions concern how your heart failure (heart condition) has prevented you from living as you wanted during the last month. The items listed below describe different ways some people are affected. If you are sure an item does not apply to you or is not related to your heart failure then circle 0 (meaning "No") and go onto the next item. If an item does apply to you, then circle the number rating of how much it prevented you from living as you wanted. Remember to think about ONLY THE LAST MONTH.

LWHFQUES (TYPE 3)

Did your heart failure prevent you from living as you wanted during the LAST MONTH by:

	No	Very Little →				Very Much
1. causing swelling in your ankles, legs, etc?	0	1	2	3	4	5
2. making your working around the house or yard difficult?	0	1	2	3	4	5
3. making your relating to or doing things with your friends difficult?	0	1	2	3	4	5
4. making you sit or lie down to rest during the day?	0	1	2	3	4	5
5. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
6. making your working to earn a living difficult?	0	1	2	3	4	5
7. making your walking or climbing stairs difficult?	0	1	2	3	4	5
8. making you short of breath?	0	1	2	3	4	5
9. making your sleeping well at night difficult?	0	1	2	3	4	5
10. making you eat less of the foods you like?	0	1	2	3	4	5
11. making your going places away from home difficult?	0	1	2	3	4	5
12. making your sexual activities difficult?	0	1	2	3	4	5
13. making your recreational pastimes, sports, or hobbies difficult?	0	1	2	3	4	5
14. making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
15. giving you side effects from medications?	0	1	2	3	4	5
16. making you worry?	0	1	2	3	4	5
17. making you feel depressed?	0	1	2	3	4	5
18. costing you money for medical care?	0	1	2	3	4	5
19. making you feel a loss of self-control in your life?	0	1	2	3	4	5
20. making you stay in a hospital?	0	1	2	3	4	5
21. making you feel you are a burden to your family or friends?	0	1	2	3	4	5

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Contact Status

SAME AS PAGE 33

CONTACT (TYPE 3)

Date of contact: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Mode of contact *(check only one)*:

- ☐ Clinic visit
- ☐ Telephone call
- ☐ Rehospitalization
- ☐ Continuous hospitalization since randomization
- ☐ Lost to follow-up → **Date of last contact:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
- ☐ Other *(specify)*: _____

Resuscitation Orders

Resuscitation orders *(check only one)*:

- ☐ Attempt cardiopulmonary resuscitation
- ☐ Attempt cardiopulmonary resuscitation but do not intubate
- ☐ Do not attempt cardiopulmonary resuscitation

Endpoint Summary *(SKIP this box for patients with a continuous hospitalization since randomization.)*

SAME AS PAGE 32

ENDPTSUM (TYPE 3)

Since the last visit was the patient admitted to the hospital or emergency department for more than 24 hours?

- ☐ No
- ☐ Yes → **If Yes, number of times:** ___ ___
  → **If Yes, complete the Rehospitalization Form (insert page) for each hospital admission**

Since the last visit has the patient undergone a cardiovascular operation or procedure (e.g., CABG, PAC, mechanical ventilation)?

- ☐ No
- ☐ Yes → **If Yes, complete the CV Procedures/Mechanical Ventilation Form (insert page)**

Since the last visit has the patient died?

- ☐ No → **If No, transplant status** *(check only one)*:
  - ☐ Ineligible
  - ☐ Active evaluation
  - ☐ Listed
  - ☐ Received transplant → **Date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
  - ☐ Accepted, but waiting to detemine need after discharge
  - ☐ Not evaluated
- ☐ Yes → **If Yes, complete page 70, Event Notification Form and the Death Form (insert page)**

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Heart Failure Clinical Assessment – Symptoms

SYMPTOMS (TYPE3)

Does the patient have any of the following?

	No	Yes
Fatigue:		
At rest	☐	☐
Any activity	☐	☐
Routine daily activity	☐	☐

	No	Yes
Dyspnea:		
At rest	☐	☐
Walking in room	☐	☐
Walking < 1 block	☐	☐

Orthopnea *(check only one)*:
- ☐ Needs only 1 pillow
- ☐ Occasional orthopnea with 1 pillow
- ☐ Needs 2 pillows most of the time
- ☐ Needs 3 pillows most of the time
- ☐ Needs 4 pillows most of the time *(sitting up)*

Gastrointestinal distress *(check only one)*: ☐ None ☐ Occasional ☐ Constant

NYHA classification *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

Heart Failure Clinical Assessment – Physical Exam

PHYSEXAM (TYPE 3)

Heart rate (supine): ___ ___ ___ bpm **Heart rate (standing after 3 minutes):** ___ ___ ___ bpm

Blood pressure manual cuff *(supine)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg

Blood pressure manual cuff *(standing after 3 minutes)*: ___ ___ ___ (systolic) / ___ ___ ___ (diastolic) mmHg

Weight: ___ ___ ___ . ___ ☐ lb ☐ kg

Respiratory rate: ___ ___ breaths/minute

Temperature: ___ ___ ___ . ___ ☐ C ☐ F

Jugular venous pulsation *(cm above the right atrium)*: ☐ < 8 ☐ 8–12 ☐ 12–16 ☐ >16 ☐ Cannot measure

Rales: ☐ None ☐ < 1/3 ☐ 1/3–2/3 ☐ > 2/3

Auscultation: S3: ☐ No ☐ Yes
Estimated P2-PAS: ☐ < 40 ☐ 40–50 ☐ 51–60 ☐ > 60

Hepatomegaly *(check only one)*: ☐ Absent ☐ 2–4 finger breadths ☐ > 4 finger breadths

Hepatojugular reflux: ☐ No ☐ Yes

Ascites *(check only one)*: ☐ None ☐ Trace ☐ Moderate ☐ Massive

Peripheral edema *(check only one)*: ☐ 0 ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+

Extremities *(check only one)*: ☐ Cool ☐ Lukewarm ☐ Warm

Valsalva maneuver *(check only one)*: ☐ Normal ☐ Absent overshoot ☐ Square-wave ☐ Uncertain **OR** ☐ Not applicable

Clinical profile *(check only one)*: ☐ Dry/warm ☐ Wet/warm ☐ Dry/cold ☐ Wet/cold

Signature (Physician who performed assessment)

SAME AS PAGE 3

SIGNATUR (TYPE 4)

Investigator's signature: _____ **Date performed:** ___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year)

Current Medications

ACE inhibitor: ☐ No → If No, specify reason *(check all that apply)*: ACE1 (TYPE 3)

- ☐ Angioedema, anaphylaxis, neutropenia
- ☐ Cough
- ☐ Hyperkalemia
- ☐ Renal artery stenosis
- ☐ Renal dysfunction
- ☐ Symptomatic hypotension
- ☐ Other adverse events such as taste disturbance, rash, and gastrointestinal upset

ACE2 (TYPE 3)

☐ Yes → If Yes:

	Total daily dose:
☐ Benazepril	_____ mg
☐ Captopril	_____ mg
☐ Enalapril	_____ mg
☐ Fosinopril	_____ mg
☐ Lisinopril	_____ mg
☐ Quinapril	_____ mg
☐ Ramipril	_____ mg
☐ Trandolapril	_____ mg
☐ Other *(specify)*: _____	_____ mg

Angiotensin II antagonist: ANGIODIG (TYPE 3)

☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Candesartan	_____ mg
☐ Losartan	_____ mg
☐ Valsartan	_____ mg
☐ Other *(specify)*: _____	_____ mg

Digoxin: ☐ No ☐ Yes → **If Yes, specify total dose and frequency:** _____ mg

☐ QD ☐ QOD ☐ Other

Diuretic: (loop) ☐ No ☐ Yes → If Yes: DIUR1 (TYPE 3)

	Total daily dose:
☐ Bumetanide	_____ mg
☐ Ethacrynic acid	_____ mg
☐ Furosemide	_____ mg
☐ Torsemide	_____ mg
☐ Other *(specify)*: _____	_____ mg

Diuretic: (potassium sparing) ☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Amiloride	_____ mg
☐ Spironolactone	_____ mg
☐ Triamterene	_____ mg
☐ Other *(specify)*: _____	_____ mg

Diuretic: (thiazide) ☐ No ☐ Yes → If Yes: DIURCCB (TYPE 3)

	Total daily dose:
☐ Chlorothiazide (diuril)	_____ mg
☐ Hydrochlorothiazide (HCTZ)	_____ mg
☐ Metolazone (zaroxolyn)	_____ mg
☐ Other *(specify)*: _____	_____ mg

Calcium channel blocker: ☐ No ☐ Yes → If Yes:

	Total daily dose:
☐ Amlodipine	_____ mg
☐ Other *(specify)*: _____	_____ mg

Current Medications (cont.)

BBANTIAR (TYPE 3)

			Total daily dose:
Beta blocker:	☐ No ☐ Yes → If Yes:	☐ Atenolol	_____ mg
		☐ Bisoprolol	_____ mg
		☐ Carvedilol	_____ mg
		☐ Metoprolol	_____ mg
		☐ Propranolol	_____ mg
		☐ Other *(specify)*: _____	_____ mg

			Total daily dose:
Antiarrhythmics:	☐ No ☐ Yes → If Yes:	☐ Amiodarone	_____ mg
		☐ Dofetilide	_____ mg
		☐ Sotalol	_____ mg
		☐ Other *(specify)*: _____	_____ mg

NIHYPOT (TYPE 3)

			Total daily dose:
Nitrates:	☐ No ☐ Yes → If Yes:	☐ Isosorbide dinitrate	_____ mg
		☐ Isosorbide mononitrate	_____ mg
		☐ Topical nitroglycerin	_____ mg
Hydralazine:	☐ No ☐ Yes → If Yes, total daily dose:		_____ mg
Potassium:	☐ No ☐ Yes → If Yes, total daily dose:		_____ mEq

MEDS (TYPE 4) PS

Statins:	☐ No ☐ Yes	**Antidepressants:**	☐ No ☐ Yes
Other lipid lowering agents:	☐ No ☐ Yes	**Benzodiazepines:**	☐ No ☐ Yes
Magnesium:	☐ No ☐ Yes	**Allopurinol:**	☐ No ☐ Yes
Estrogen replacement therapy:	☐ No ☐ Yes	**Colchicine:**	☐ No ☐ Yes
Testosterone replacement therapy:	☐ No ☐ Yes	**Enoxaparin:**	☐ No ☐ Yes
Insulin:	☐ No ☐ Yes	**Warfarin:**	☐ No ☐ Yes
Oral diabetic agents:	☐ No ☐ Yes	**Vitamin E:**	☐ No ☐ Yes
Aspirin (daily):	☐ No ☐ Yes	**CoEnzyme Q10:**	☐ No ☐ Yes
Other antiplatelet agents:	☐ No ☐ Yes	**Other antioxidants:**	☐ No ☐ Yes
NSAIDs:	☐ No ☐ Yes	**Multi-vitamin:**	☐ No ☐ Yes
Thyroid replacement therapy:	☐ No ☐ Yes		

SAME AS PAGE 36

INFUSIN (TYPE 4) PS

		Current infusion rate:	Check box if intermittent:
Amrinone:	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	☐ Intermittent → _____ # days/month
Dobutamine:	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	☐ Intermittent → _____ # days/month
Dopamine:	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	☐ Intermittent → _____ # days/month
Milrinone:	☐ No ☐ Yes → If Yes:	_____ mcg/kg/min	☐ Intermittent → _____ # days/month
Nitroglycerin:	☐ No ☐ Yes → If Yes:	_____ mcg/min	
Nitroprusside:	☐ No ☐ Yes → If Yes:	_____ mcg/min	

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Laboratory

LAB (TYPE 4) PS

Date of collection: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Value			Value		
Hemoglobin (Hgb)	_____	☐ g/L ☐ mmol/L ☐ g/dL	AST/SGOT	_____	IU/L OR U/L OR mIU/mL
Platelets	_____	☐ 10^9/L OR 10^3/mm³ ☐ /mm³	Total protein	_____	☐ g/dL ☐ g/L
Hematocrit (Hct)	_____	☐ L/L ☐ %	Albumin	_____	☐ g/dL ☐ g/L
WBC	_____	☐ 10^9/L OR 10^3/mm³ ☐ /mm³	Total bilirubin	_____	☐ mg/dL ☐ µmol/L
Sodium	_____	mmol/L OR mEq/L	Direct bilirubin	_____	☐ mg/dL ☐ µmol/L
Potassium	_____	mmol/L OR mEq/L	CK (ULN =_____)	_____	ENZYMES (TYPE 3) IU/L OR U/L OR mIU/mL ☐ Not Done
BUN	_____	mg/dL	CK-MB (ULN =_____)	_____	☐ mcg/L OR µg/L OR ng/mL ☐ IU/L OR U/L OR mIU/mL ☐ % ☐ Not Done
Creatinine	_____	mg/dL	Troponin ☐ I ☐ T (ULN =_____)	_____ ng/mL OR	☐ Positive ☐ Negative ☐ Not Done
ALT/SGPT	_____	IU/L OR U/L OR mIU/mL			

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Visual Analog Scale Scores (Complete the Visual Analog Scale Worksheet insert pages)

VISUAL (TYPE 3)

Examination date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Worst symptom: ___ ___ ___ → Corresponding to *(check only one)*:

- ☐ Abdominal discomfort
- ☐ Breathing
- ☐ Body swelling
- ☐ Fatigue

Breathing: ___ ___ ___ OR ☐ Not applicable if breathing was selected as worst symptom

Global: ___ ___ ___

Time Trade-Off Scores

TIMETRAD (TYPE 3)

Examination date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Score: ___ ___ months ☐ or 1 day

6-Minute Walk Exercise Test

WALK (TYPE 3)

Did the patient attempt the 6-minute walk test?

☐ No → If No, specify primary reason:

- ☐ The patient was too critically ill to be taken out of bed and exercised.
- ☐ Patient cannot walk for technical reasons (e.g., a patient who is an amputee).
- ☐ Not done due to oversight.

☐ Yes → If Yes, complete below.

Examination date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Start time of walk: ___ ___ : ___ ___ (00:00–23:59)

End time of walk: ___ ___ : ___ ___ (00:00–23:59)

Total distance walked: _____ ☐ Feet ☐ Meters

Did the patient experience any of the following symptoms *(check all that apply)*:

- ☐ Angina
- ☐ Light headedness
- ☐ Syncope

Borg Dyspnea score: _____ *(Transcribe score from worksheet.)*

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Follow-Up Summary

Follow-Up Instructions for Sodium and Fluid Restriction: SAME AS PAGE 38 FOLLOW (TYPE 3)

Sodium restriction: _____ mg/day

Fluid restriction: _____ L/day

Was the patient given a diuretic plan for weight gain? ☐ No ☐ Yes → If Yes, for every 2 lb weight gain patient: *(check all that apply)*

- ☐ Increases loop diuretics
- ☐ Adds thiazide/metolazone

Nurse/Study Coordinator Estimate of Likelihood of Death over next 6 months

Check only one:

- ☐ 0–25%
- ☐ 26–50%
- ☐ 51–75%
- ☐ 76–100%

THIS NOT ENTERED

Nurse/Study Coordinator Estimate of Readmission over next 6 months

Check only one:

- ☐ 0–25%
- ☐ 26–50%
- ☐ 51–75%
- ☐ 76–100%

THIS NOT ENTERED

Signature

SAME AS PAGE 3 SIGNATUR (TYPE 4)

The data recorded on CRF pages 62–70 have been reviewed by me or my delegate and are accurate and complete to the best of my knowledge.

Investigator's signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Complete and submit the Early Withdrawl/Study Completion page 70.

Early Withdrawal/Study Completion

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Early Withdrawal/Study Completion

Date patient ended the study: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

STYCOMDT <DATE>

STDYCOMP (TYPE 1)

Did the patient complete the study?

COMPSTDY <ZYESNO>

[1] Yes

[0] No → If No, choose primary reason:

NOCOMPRE <ESCORE>

[1] Cardiac transplantation

[2] Consent withdrawn

[3] Lost to follow-up

[4] Protocol violation

[5] Physician decision

[6] Early study termination

Signature

SAME AS PAGE 3

SIGNATUR (TYPE 4)

I have reviewed and found all data pertaining to this subject to be complete and accurate.

Responsible investigator's signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Study coordinator's signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

STUDYBOOK=ESCAPE
FORM=REHOSPITALIZATION

Rehospitalization Form

Patient Number: ___ ___ - ___ ___ ___ (site # - patient #) Patient Initials: ___ ___ ___

Rehospitalization Form (Patient readmitted to hospital OR in emergency department > 24 hours.)

Date of admission: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) HSPADMDT <DATE> REHOSP1 (TYPE 3)

Date of discharge: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) HSPDISDT <DATE>

REHOSP2 (TYPE 3)

Primary reason for rehospitalization *(check only one)*:

HOSPRE <ESHSRE>
1 Heart failure exacerbation → **Complete CHF Form**

2 Acute coronary syndrome *(check only one)*:
ACUTESYN <ESSYN>
- 1 Myocardial infarction → **Complete MI Form**
- 2 Unstable angina
- 3 Chest pain unspecified

3 Other cardiovascular *(check only one)*:
OTHCAR <ESOTHC>
- 1 Procedure related → **Complete CV Procedures/ Mechanical Ventilation Form**
- 2 Stroke
- 3 Transient ischemic attack
- 4 Pulmonary embolism
- 98 Other

4 Arrhythmia *(check only one)*:
ARRH <ESARRH>
- 1 Sudden death with resuscitation
- 2 Supraventricular arrhythmia
- 3 Ventricular arrhythmia
- 4 ICD firing
- 5 AV block
- 6 Syncope

5 Cancer

6 Non-cardiovascular

7 Unable to determine

Secondary reason for rehospitalization *(check all that apply)*:

HRTFAIL <ZYES>
1 Heart failure exacerbation

ACCORSYN <ZYES>
1 Acute coronary syndrome *(check only one)*:
ACUTETYP <ESSYN>
- 1 Myocardial infarction
- 2 Unstable angina
- 3 Chest pain unspecified

OTHRCAR <ZYES>
1 Other cardiovascular *(check only one)*:
OTHCARS <ESOTHC>
- 1 Procedure related → **Complete CV Procedures/ Mechanical Ventilation Form**
- 2 Stroke
- 3 Transient ischemic attack
- 4 Pulmonary embolism
- 98 Other

ARRYTH <ZYES>
1 Arrhythmia *(check only one)*: ARRYH <ESARRH>
- 1 Sudden death with resuscitation
- 2 Supraventricular arrhythmia
- 3 Ventricular arrhythmia
- 4 ICD firing
- 5 AV block
- 6 Syncope

CANCER <ZYES>
1 Cancer

NONCAR <ZYES>
1 Non-cardiovascular

UNDETR <ZYES>
1 Unable to determine

CV Procedures/Mechanical Ventilation

Did the patient undergo any cardiovascular procedures during the rehospitalization? REHOSP3 (TYPE 3)

CARPROC <ZYESNO>
1 Yes → **If Yes, Complete page D of the CRF**

0 No

CHF Form

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

CHF Form (To be completed if worsening CHF was the reason for hospitalization.)

CHF (TYPE 3)

Date of CHF exacerbation: CHFDT <DATE> ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year)

What evidence was there of worsening CHF *(check all that apply)*:

- [1] Worsening/increasing fatigue — FATWRS <ZYES>
- [1] Dyspnea — DYSP <ZYES>
- [1] Orthopnea — ORTOP <ZYES>
- [1] Gastrointestinal distress — GIDISST <ZYES>
- [1] Elevated JVP — ELVATJVP <ZYES>
- [1] Rales — RALE <ZYES>
- [1] Peripheral edema — PEDEMA <ZYES>
- [1] Ascites/hepatomegaly/hepatojugular reflux — ASHEPRFL <ZYES>
- [1] Renal hypoperfusion/worsening renal function — RENWRS <ZYES>

Was the patient treated with intravenous diuretics? TXIVDIU <ZYESNO> [0] No [1] Yes

Was the patient treated with intravenous inotropic agents? TXIVINO <ZYESNO> [0] No [1] Yes

Was the patient treated with an intravenous vasodilator? TXIVVAS <ZYESNO> [0] No [1] Yes

MI Form

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

MI Form

Date and time of myocardial infarction: ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) MIDT <DATE> ___ ___ : ___ ___ (00:00 to 23:59) MITM <DATETIME> MI1 (TYPE 3)

Was the clinical presentation consistent with an MI? [0] No [1] Yes MICLIN <ZYESNO>

Were there ECG changes? [0] No [1] Yes → If Yes, check all that apply: ECGCHNG <ZYESNO>

- [1] New Q-wave NQWAVE <ZYES>
- [1] New left bundle branch block NLBBB <ZYES>
- [1] ST ↑ (> 1.0 mm) ≥ 2 leads STINC <ZYES>
- [1] ST ↓ (> 1.0 mm) ≥ 2 leads STDEC <ZYES>
- [1] T wave inversion TWAVE <ZYES>

→ If Yes, send a copy of the ECG with the most significant changes.

Peak CK: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) PKCKDT <DATE> ___ ___ : ___ ___ (00:00 to 23:59) PKCKTM <DATETIME>

Upper limit of normal = <F:9:3> PKCKULN

Value: <F:9:3> PKCKVAL ☐ IU/L OR U/L OR mIU/mL

Peak CK-MB: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) PKCMBDT <DATE> ___ ___ : ___ ___ (00:00 to 23:59) PKCMBTM <DATETIME> MI2 (TYPE 3)

Upper limit of normal = F:9:3> PKCMBULN

Value: <F:9:3> PKCMBVAL PKCMBUNT <ESLUNT>

- ☐ mcg/L OR µg/L OR ng/mL
- ☐ IU/L OR U/L OR mIU/mL
- ☐ %

Peak Troponin : ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) PKTROPDT <DATE> ___ ___ : ___ ___ (00:00 to 23:59) PKTROPTM <DATETIME>

PKTROTYP <ESTRO>

[1] I OR [2] T

Upper limit of normal = <F:9:3> PKTROULN

Value: <F:9:3> ng/mL PKTROVAL OR ☐ [1] Positive ☐ [2] Negative PKTROPN <ZPOSNE>

CV Procedures/Mechanical

Patient Number: ___ ___ (site #) - ___ ___ ___ (patient #) Patient Initials: ___ ___ ___

CV Procedures/Mechanical Ventilation Form

SAME AS PAGE 19

PROC (TYPE 4) PS

Were any of the following procedures performed? Answer ALL questions; Yes or No.

	No	Yes	→ If Yes, date:
Pulmonary artery catheterization	☐	☐	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year.)
Left heart catheterization	☐	☐	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
PTCI	☐	☐	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
CABG	☐	☐	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
ICD implantation	☐	☐	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
Permanent pacemaker	☐	☐	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
Temporary pacemaker	☐	☐	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
Left ventricular assist device	☐	☐	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
Intra-aortic balloon pump	☐	☐	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
Cardiopulmonary resuscitation	☐	☐	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
Cardioversion	☐	☐	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
Other cardiovascular procedure/operation	☐	☐	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

MECHVENT <ZYESNO>

PROCMV (TYPE 4)

Mechanical ventilation [0] No

[1] Yes → **If Yes, date of intubation:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) INTUBDT <DATE>

→ **If Yes, date of extubation:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) EXTUBDT <DATE>

STUDYBOOK=ESCAPE
FORM=DEATH FORM

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Death Form

Date of death: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) DTHDT <DATE>

DEATH (TYPE 3)

Primary cause of death *(check only one)*: DTHCAUS <ESDTH>

1 Pump failure → **Complete CHF Form if death occurred after index hospitalization**

2 Fatal myocardial infarction → **Complete MI Form**

3 Unexpected "sudden death" *(check only one)*: SUDNDTH <ESSUDN>
- 1 Identified arrhythmia
- 2 Witnessed cardiac arrest
- 3 Unwitnessed cardiac arrest
- 4 Sudden death associated with unexpected worsening of heart failure

4 Other cardiovascular *(check only one)*:

OTHCRD <ESOTHC>

- 1 Procedure related → **Complete CV Procedures/Mechanical Ventilation Form if death occurred after index hospitalization**
- 2 Stroke
- 4 Pulmonary embolism
- 98 Other

5 Cancer

6 Non-cardiovascular death

7 Unable to determine

Send a copy of the Discharge Summary and/or Autopsy Report

Event Notification Form

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Complete this form for ALL:

- Deaths;
- PAC-associated pulmonary infarction/hemorrhage; and
- PAC-associated complications requiring cardiopulmonary resuscitation.

Event Notification Form

Date completed: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) → (Date Example: 12/OCT/1930)

Sex: ☐ Female ☐ Male

Date of birth: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Did the patient die? ☐ No ☐ Yes → If Yes, date of death: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

→ If Yes, complete the Death Form (page E) of the Case Report Form (CRF).
(Note: DO NOT FAX the Death Form page in with this Event Notification Form.)

Did the patient experience a PAC-associated pulmonary infarction/hemorrhage?

☐ No ☐ Yes → If Yes, date of event: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Did the patient experience a PAC-associated complication requiring cardiopulmonary resuscitation?

☐ No ☐ Yes → If Yes, date of event: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

→ If Yes, complete the Complications of PAC section on page 15 or 15.___ of the CRF.
(Note: DO NOT FAX the Complications of PAC section in with this Event Notification Form.)

Name of person submitting form *(print)*: _____

Phone number: (_____) _____ - _____

FAX this page to the DCRI Safety Desk at (919) 668-7138 within 24 hours.

CALL the DCRI Safety Desk at (919) 668-8624 with any questions.

Physician Estimate of Hemodynamic Status—Crossover Form

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Estimate of Hemodynamic Status

SAME AS PAGE 3

HEMSTAT (TYPE 3)

Date patient crossed over to PAC placement: ___ ___ (day) / ___ ___ (month) / ___ ___ ___ ___ (year)

Right atrial pressure (mmHg) *(check only one)*: ☐ < 8 ☐ 8 -12 ☐ 13 - 16 ☐ >16

Certainty of assessment *(check only one)*: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
not very sure ——— *very sure*

Pulmonary capillary wedge pressure (mmHg) *(check only one)*: ☐ < 12 ☐ 12 - 22 ☐ 23 - 30 ☐ >30

Certainty of assessment *(check only one)*: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
not very sure ——— *very sure*

Cardiac index (L/min • m^2) *(check only one)*: ☐ < 1.8 ☐ 1.8 - 2.2 ☐ 2.3 - 2.5 ☐ > 2.5

Certainty of assessment *(check only one)*: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
not very sure ——— *very sure*

ESCAPE

THIS PAGE IS NOT ENTERED **Randomization Worksheet**

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

The physician must complete the Physician Assessment pages of the CRF prior to randomization.

Demographics (The following 5 questions will be asked during the randomization phone call.)

Date of birth: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) Sex: ☐ Female ☐ Male

Race *(check one)*: ☐ Caucasian ☐ Black ☐ Asian ☐ Hispanic ☐ Native American ☐ Other *(specify)*: _____

The Physician's Assessment (estimate) regarding cardiac index *(check one)*: ☐ ≤ 2.2 ☐ > 2.2

Has the written informed consent been obtained? ☐ No ☐ Yes

Inclusion Criteria (must answer "Yes" to questions 1–11 to be eligible)

		No	Yes
1	Is the patient ≥ 16 years of age?	☐	☐
2	Is the patient currently hospitalized under the care of the heart failure service of the investigating site?	☐	☐
3	Does the patient have NYHA Class IV heart failure symptoms?	☐	☐
4	Has the patient had one previous hospitalization for exacerbation of heart failure within 6 months prior to randomization?	☐	☐
5	Does the patient have documented LVEF < 30% within 12 months prior to randomization?	☐	☐
6	Does the patient have a documented history of heart failure for ≥ 3 months?	☐	☐
7	Has the patient had attempted therapy with angiotensin converting enzyme inhibitors and diuretics for ≥ 3 months prior to randomization?	☐	☐
8	Does the patient have a systolic blood pressure of ≤ 125 mmHg?	☐	☐
9	Does the patient have elevated filling pressures present, indicated by *one* of the following symptoms? • dyspnea *(at rest, or in supine position, or immediately upon routine activity within one room)*; • abdominal discomfort; • severe anorexia; or • nausea without apparent cause other than hepatosplanchnic congestion	☐	☐
10	Does the patient have *one* of the following signs? • jugular venous pulsation elevation > 10 cm above the right atrium; • square-wave valsalva response; • hepatomegaly, ascites, or edema in absence of other obvious causes; or • rales greater than 1/3 lung fields	☐	☐
11	Is the patient able to undergo placement of a pulmonary artery catheter within the next 12 hours?	☐	☐

Do Not Send This Form With CRF
File this **Worksheet** with the patient's study files.
To randomize a patient call: 1-800-388-9564

ESCAPE

THIS PAGE IS NOT ENTERED

Randomization Worksheet

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Exclusion Criteria (must answer "No" to questions 12-33 to be eligible)

		No	Yes
12	Does the patient have acute decompensation felt by the responsible heart failure physician to require or or be likely to require PAC during the next 24 hours for adequate management *(patient to be entered in PAC registry)*?	☐	☐
13	Does the patient have an active listing for cardiac transplant?	☐	☐
14	Is mechanical ventilation present or anticipated at the time of randomization?	☐	☐
15	Is a mechanical circulatory assist device, including intra-aortic balloon pump and left ventricular assist device present or anticipated at the time of randomization?	☐	☐
16	Has the patient received IV milrinone within 48 hours prior to randomization?	☐	☐
17	Is the patient currently receiving IV dopamine or dobutamine at > 3 mcg/kg/min OR has the patient received IV dopamine or dobutamine for > 24 hours prior to randomization?	☐	☐
18	Has the patient had an acute myocardial infarction or cardiac surgery within the last 6 weeks before randomization?	☐	☐
19	Is the patient currently hospitalized for acute coronary syndrome, including acute MI or unstable angina?	☐	☐
20	Does the patient have documented moderate to severe mitral stenosis or aortic stenosis?	☐	☐
21	Is there a revascularization procedure planned during this hospitalization?	☐	☐
22	Is there a surgical procedure planned during this hospitalization?	☐	☐
23	Does the patient have documented primary pulmonary hypertension?	☐	☐
24	Has the patient had a pulmonary infarct within one month before randomization?	☐	☐
25	Does the patient currently have pneumothorax?	☐	☐
26	Does the patient currently have a serum creatinine > 3.5 mg/dL?	☐	☐
27	Does the patient have a temperature > 37.8 degrees Celsius?	☐	☐
28	Does the patient have a WBC count > 13,000 mm^3?	☐	☐
29	Does the patient have an exacerbation of heart failure due to a primary factor requiring specific therapy such as severe anemia, clinical hypothyroidism, or active systemic infection?	☐	☐
30	Does the patient have any non-cardiac disease, such as cancer, that is likely to shorten life expectancy to < 1 year?	☐	☐
31	Is the patient unable to return to the heart failure program at the investigating site for all follow-up visits?	☐	☐
32	Is the patient a female who is pregnant or lactating *(Note: All females of childbearing potential should have a negative pregnancy test prior to randomization)*?	☐	☐
33	Is the patient a female of child bearing potential who is not using an accepted method of birth control?	☐	☐

Randomization

If the patient is eligible for ESCAPE, please call 1-800-388-9564 AND access code **856**.

Assigned patient number: ___ ___ ___

Assigned treatment allocation *(check one)*: ☐ Pulmonary artery catheter ☐ Clinical assessment

Randomization date and time: ___ ___ (day) / ___ ___ (month) / ___ ___ ___ ___ (year) ___ ___ : ___ ___ (00:00–23:59)

Signature

Signature: _____

Complete the Visual Analog Scales, Minnesota Living with Heart Failure, Time Trade-off, echocardiogram, cardiopulmonary exercise test, and the 6-minute walk **prior** to PAC placement **OR** clinical therapy.

ESCAPE

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

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Patient Contact Information (Please Print)

Patient Identification

Hospital name: _____

Patient name: _____ (last), _____ (First) _____ (Middle)

Social security number/
Resident identification number: _____ Medical record number: _____

Primary home address: _____

_____

_____

_____

Primary home phone number: _____ Best time to call: _____ ☐ AM ☐ PM

Business phone number: _____ Best time to call: _____ ☐ AM ☐ PM

Spouse or significant other: _____ (last), _____ (First) _____ (Middle)

Secondary Residence (vacation home, etc.)

Mailing address: _____

_____

_____

Phone number: _____ Best time to call: _____ ☐ AM ☐ PM

Alternative Contact (relative, friend or neighbor not living with patient)

Name: _____ (last), _____ (First) _____ (Middle)

Relationship to patient: _____

Mailing address: _____

_____

_____

Phone number: _____ Best time to call: _____ ☐ AM ☐ PM

Local/Referring Physician or Primary Care Physician/General Practitioner

Name: _____ (last), _____ (First) _____ (Middle)

Mailing address: _____

_____

_____

Physician's office phone number: _____

Contains Confidential Patient Information

Do not FAX or send this page to Coordinating Center

Visual Analog Scale Worksheet—Worst Symptom

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Date of Evaluation: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Check One: ☐ Baseline ☐ Discharge ☐ 2-Week Follow-up ☐ 1-Month Follow-up ☐ 2-Month Follow-up ☐ 3-Month Follow-up ☐ 6-Month Follow-up

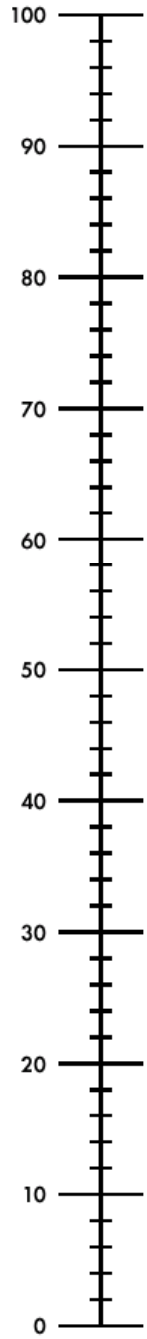
Patient Visual Analog Scale—Worst Symptom (use the same worst symptom each time)

Directions:

Which of the following bothers you the most?

(check only one):

- ☐ Abdominal discomfort
- ☐ Breathing
- ☐ Body swelling
- ☐ Fatigue



Best imaginable:
Patient feels comfortable and normal throughout the day.

Worst imaginable:
Symptom is the most severe the patient can imagine.

ESCAPE

Visual Analog Scale Worksheet—Breathing

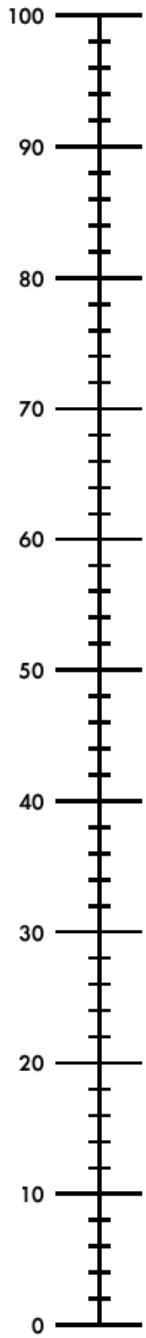
Patient number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Date of evaluation: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Check one: ☐ Baseline ☐ Discharge ☐ 2 Week Follow-Up ☐ 1 Month Follow-Up ☐ 2 Month Follow-Up ☐ 3 MonthFollow-Up ☐ 6 Month Follow-Up

Patient Visual Analog Scale – Breathing

Complete ONLY if breathing is NOT the worst symptom.



Best imaginable:
Breathing feels comfortable and normal throughout the day.

Worst imaginable:
I feel constant shortness of breath throughout the day.

File this **Worksheet** with the patient's study files.

ESCAPE

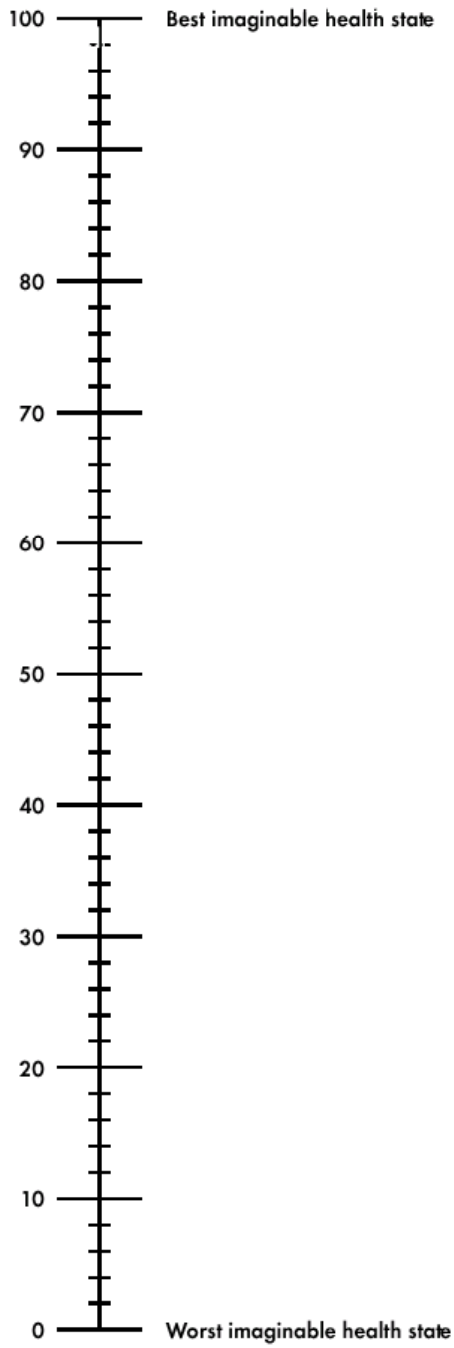
Visual Analog Scale Worksheet—Global

Patient Number: ___ ___ - ___ ___ ___ (site # / patient #) Patient Initials: ___ ___ ___

Date of Evaluation: ___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year)

Check one: ☐ Baseline ☐ Discharge ☐ 2 Week Follow-Up ☐ 1 Month Follow-Up ☐ 2 Month Follow-Up ☐ 3 MonthFollow-Up ☐ 6 Month Follow-Up

Patient Visual Analog Scale—Global



ESCAPE

THIS PAGE IS NOT ENTERED

Screening Log

Site number: ___ ___

Refer to the back of this form to obtain the reason(s) the patient was not enrolled into the study and record the corresponding number(s).

Date of Screening	Pt. Initials/ Sex	Race	Registry	Reason not Enrolled/ Comment
___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) MR # ______	___ ___ ___ ☐ M ☐ F		☐ Yes ☐ No	______ ______
___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) MR # ______	___ ___ ___ ☐ M ☐ F		☐ Yes ☐ No	______ ______
___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) MR # ______	___ ___ ___ ☐ M ☐ F		☐ Yes ☐ No	______ ______
___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) MR # ______	___ ___ ___ ☐ M ☐ F		☐ Yes ☐ No	______ ______
___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) MR # ______	___ ___ ___ ☐ M ☐ F		☐ Yes ☐ No	______ ______
___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) MR # ______	___ ___ ___ ☐ M ☐ F		☐ Yes ☐ No	______ ______
___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) MR # ______	___ ___ ___ ☐ M ☐ F		☐ Yes ☐ No	______ ______
___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) MR # ______	___ ___ ___ ☐ M ☐ F		☐ Yes ☐ No	______ ______
___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) MR # ______	___ ___ ___ ☐ M ☐ F		☐ Yes ☐ No	______ ______
___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) MR # ______	___ ___ ___ ☐ M ☐ F		☐ Yes ☐ No	______ ______
___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) MR # ______	___ ___ ___ ☐ M ☐ F		☐ Yes ☐ No	______ ______
___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) MR # ______	___ ___ ___ ☐ M ☐ F		☐ Yes ☐ No	______ ______
___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) MR # ______	___ ___ ___ ☐ M ☐ F		☐ Yes ☐ No	______ ______