PROTOCOL = HFACTIONCPX

FORM = CPX_WKSHT

CONTEXT

STUDYBOOK = CPX

REPEATING PAGE

CPX Worksheet

NODATA<I:3><ZYES>

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

Patient's Initials: ___ (first middle last) INITIALS

CPX(TYPE4)

CPXVIS<I:3><ACCPX> Visit: 1 Practice (if applicable) 2 Baseline 3 3-Month 4 12-Month 5 24-Month

CPX Tests submitted will have an exercise prescription returned. Disregard the prescription provided for Usual Care patients.

1 Date of test: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) CPXDT

2 Equipment: EQUIPTYP<I:3><ACEQUT>

1 Bike OR 2 Treadmill (Use same equipment type at each test.)

MOUTHSK<I:3><ACMTHS> 1 Mouthpiece OR 2 Mask OR 3 NA

CALIB<I:3><ZYESNO> Was the equipment calibrated prior to use? 0 No 1 Yes

What is the barometric pressure? _____ mm Hg BAROPRES<F:9:3>

LASTMEAL<I:3><ZYESNO>

3 Was the patient's last meal eaten > 3 hours prior to this test? 0 No 1 Yes

LASTMED<I:3><ZYNNA>

4 Was the patient's last dose of beta blockers taken between 3–10 hours ago?

2 NA 0 No → Consider rescheduling test. 1 Yes

5 Rest ECG: ECGRHYTH<I:3><ACRECG>

Rhythm (check only one):

1 Sinus 2 Atrial fibrillation 98 Other

ECGCOND<I:3><ACVCON>

Ventricular conduction (check only one):

1 Normal 2 LBBB 3 RBBB 4 IVCD 5 Paced

QRS interval: _____ ms QRSINT<I:4>

6 HR Data:

HR at peak exercise: _____ bpm PEAKHR<I:3>

Resting HR (after 5 minutes sitting rest, without mouthpiece): _____ bpm RESTHR <I:3>

HR reserve (peak HR – rest HR): _____ HRRES<I:3>

60% HR reserve (HR reserve x 0.6 + rest HR): _____ HR60R<F:9:3>

7 Borg RPE score at peak exercise: _____ (6–20) PKBORG<I:3>

8 Reason(s) for termination of testing (check all that apply):

STCPX2<I:3><ZYES> Symptom limited (dyspnea, fatigue) STCPX1<I:3><ZYES>

Angina/ischemia (complete all that apply)

HR when true cardiac angina occurred: _____ bpm OR NA HRANG<I:3> NAHRANG<I:3><ZYES>

HR when ischemic ECG changes occurred: _____ bpm OR NA HRISCECG<I:3> NAHRISC<I:3><ZYES>

STCPX3<I:3><ZYES> Serious arrhythmias (VT or SVT) STCPX4<I:3><ZYES>

Changes in blood pressure STCPX5<I:3><ZYES>

Orthopedic/extremity complaints (pains/cramps)

STCPX6<I:3><ZYES> Other (specify): _____ STCPXSP<V:100>

8b Based on the results of the test, is exercise training considered unsafe (i.e., precludes enrollment or causes interruption/termination of exercise training)? 0 No 1 Yes UNSAFE<I:3><ZYESNO>

ECTOPY<I:3><ZYESNO>

9 Did frequent ventricular ectopy occur (e.g., ≥ 7 PVCs/min, bi/tri-geminy, NSVT [≥ 3 beats])? 0 No 1 Yes

If Yes: When did it occur? (check all that apply)

During exercise ECTDUREX<ZYES> During recovery ECTDUREC<ZYES>

10 Was metabolic data measured? No Yes METABOLC<I:3><ZYESNO>

Record exercise start time in minutes and seconds, allowing patient at least 2 minutes equilibration on the gas exchange machine prior to exercise start.

Exercise start time: ___:___ minutes:seconds STRTMIN<I:3> STRTSEC<I:3>

Exercise end time: ___:___ minutes:seconds ENDMIN<I:3> ENDSEC<I:3>

Example:

Exercise start time: 2:10 minutes:seconds
(exercise starts 10 seconds after the 2-minute equilibration)
Exercise end time: 7:10 minutes:seconds
(patient exercised for 5 minutes)

11 Fax completed form, breath-by-breath and 15-second averaged analysis to **919-681-9274**.

12 Specify where the prescribed training HR should be faxed:

_____ (fax # specified by site) FAXNO<V:20>

13 Signature of person administering exercise test:

_____ SIGN<ZYES>

For CPX Lab Use Only

Peak VO_2: _____ mL/kg/min PKVO<F:9:3>

Absolute Peak VO_2: _____ mL/min ABSVO<F:9:3>

Exercise time: ___:___ minutes:seconds EXERMIN<I:3 EXERSEC<I:3>

RER: _____ RER<F:9:3>

Time to RER = 1.0: ___:___ minutes:seconds RERMIN<I:3> RERSEC<I:3>

$VeVCO_2$ slope: _____ VEVO<F:9:3>

HR at end of WL 2: _____ bpm WLHR<I:3>

1 Can the ventilatory threshold be read?

0 No → Set upper THR at 65% HRR VENTTH<I:3><ZYESNO>

1 Yes → Ventilatory threshold VO_2: _____ mL/kg/min VENTVO<F:9:3>

Heart rate: _____ bpm VENTHR<I:3>

HRRVT<I:3><ZYESNO> Is the HR at 70% HRR < 4 beats below HR at VT?

0 No → Set upper training HR 4 beats below HR at VT.

1 Yes → Set training HR range at 60–70% HRR.

2 Was the test terminated due to angina/ischemia?

0 No TESTTERM<I:3><ZYESNO>

1 Yes → Set upper training HR at 10 beats per min less than the HR where angina or ischemic ECG changes occurred, whichever is lower.

3 Prescribed training range: _____ (initial training HR) to _____ (max training HR) bpm PRETHRMN<I:3> PRETHRMX<I:3>

OR _____ to _____ kPE PREPEMN<I:3> PREPEMX<I:3>

All CPX testing results will be analyzed by the CPX Core Lab. Once the prescribed training heart rate has been calculated and recorded above, the core lab will fax the worksheet back to the number specified (item #12). Exercise training heart rates should be adjusted accordingly.

Annotation Final version 3.1_ 14 Aug 2003

CPX Worksheet

Patient Number: ___ ___ ___ (site #) - ___ ___ ___ ___ (patient #) Patient's Initials: ___ ___ ___ (first middle last)

Visit: ☐ Practice (if applicable) ☐ Baseline ☐ 3-Month ☐ 12-Month ☐ 24-Month

Exercise Recordings

Time (min:sec)	Heart Rate (bpm)	Blood Pressure	Borg RPE Score (6-20)	Time (min:sec)	Heart Rate (bpm)	Blood Pressure	Borg RPE Score (6-20)
Rest*		___ ___ ___/___ ___ ___ (systolic / diastolic)		10:00		___ ___ ___/___ ___ ___ (systolic / diastolic)	
START EXERCISE:				10:30			
0:30				11:00			
1:00				11:30			
1:30				12:00		___ ___ ___/___ ___ ___ (systolic / diastolic)	
2:00		___ ___ ___/___ ___ ___ (systolic / diastolic)		12:30			
2:30				13:00			
3:00				13:30			
3:30				14:00		___ ___ ___/___ ___ ___ (systolic / diastolic)	
4:00		___ ___ ___/___ ___ ___ (systolic / diastolic)		14:30			
4:30				15:00			
5:00				15:30			
5:30				16:00		___ ___ ___/___ ___ ___ (systolic / diastolic)	
6:00		___ ___ ___/___ ___ ___ (systolic / diastolic)		16:30			
6:30				17:00			
7:00				17:30			
7:30				18:00		___ ___ ___/___ ___ ___ (systolic / diastolic)	
8:00		___ ___ ___/___ ___ ___ (systolic / diastolic)		18:30			
8:30				19:00			
9:00				19:30			
9:30				20:00		___ ___ ___/___ ___ ___ (systolic / diastolic)	

Peak Exercise Data

Time: ___ ___ : ___ ___ (min : sec) Heart rate: _____ bpm Blood pressure: ___ ___ ___/___ ___ ___ (systolic / diastolic) RPE: _____

Recovery

Time (min:sec)	Heart Rate (bpm)	Blood Pressure	Time (min:sec)	Heart Rate (bpm)	Blood Pressure
1:00		___ ___ ___/___ ___ ___ (systolic / diastolic)	6:00		
2:00			7:00		___ ___ ___/___ ___ ___ (systolic / diastolic)
3:00		___ ___ ___/___ ___ ___ (systolic / diastolic)	8:00		
4:00			9:00		___ ___ ___/___ ___ ___ (systolic / diastolic)
5:00		___ ___ ___/___ ___ ___ (systolic / diastolic)	10:00		

*Resting HR measured after 5 minutes sitting rest, without mouthpiece.

PROTOCOL = HFACTION FORM = BASELINE CONTEXT

STUDYBOOK = DATA_FORMS

NODATA<I:3><ZYES>

HF ACTION

SUBJNO

Baseline

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last) INITIALS

Informed Consent

INFCNDT

Date informed consent form signed: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

INFCN(TYPE 1)

Treatment Preference Scale To be asked by study staff, immediately after obtaining consent.

"Some participants in this study would prefer to be assigned to one treatment over the other, while some participants don't have a preference. Although your treatment group will be determined entirely by chance, we are interested in your preference regarding these treatments. Would you prefer to be in the usual care group or the exercise training group?"

1 ☐ 1 Usual care 2 ☐ 2 Exercise training 3 ☐ 3 No preference 4 ☐ 4 Not applicable

TRPREF<I:3> <ACTPSA>

TPREF(TYPE 1)

Patient Status

Check the appropriate box for the patient status: PTSTAT<I:3><ACPTST>

STATUS(TYPE 1)

1 ☐ 1 Registry patient → Complete and submit the following:

- Informed Consent and Demographics, page 1
- Patient Survey, page 2
- KCCQ, pages 4, 5, and 6
- BDI, pages 7 and 8
- Current Medications, pages 13 and 14
- Medical History, page 15
- Supplemental Registry Form(s), if applicable

2 ☐ 2 Randomized patient → Complete and submit all baseline CRF pages, 1–17.

Demographics

1 Date of birth: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) DOBDT

DEMOG(TYPE 1)

2 Sex: 1 ☐ 1 Male 2 ☐ 2 Female GENDER<I:3><ZSEX>

3 Insurance (check only one): 1 ☐ 1 Medicare patient (part A only) 2 ☐ 2 Medicare patient (part A/B) 3 ☐ 3 Non-Medicare patient

INSUR<I:3><ACINSU>

Randomization

1 Date of randomization: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) RANDDT Not enterable if before 07APR2003

RANDVIT(TYPE 1)

2 Treatment group assignment: 1 ☐ 1 Usual care group 2 ☐ 2 Exercise training group TASSIGN<I:3><ACTASS>

After randomization, please ask the patient the following question:

TRSAT<I:3><ACTSAT>

3 "You have been assigned to the [usual care/exercise training group]. How satisfied are you with this treatment assignment?"

1 ☐ 1 Very satisfied 2 ☐ 2 Somewhat satisfied 3 ☐ 3 Neither satisfied nor dissatisfied 4 ☐ 4 Somewhat dissatisfied 5 ☐ 5 Very dissatisfied

Vital Signs

BPSYS <I:3> BPDIA <I:3>

1 Blood pressure (sitting): ___ ___ ___ / ___ ___ ___ mmHg (systolic / diastolic)

2 Heart rate: HRATE<I:3> bpm

3 Height: HT<F:9:3> 1 ☐ 1 in 2 ☐ 2 cm HGTU<ZHGTU>

4 Weight: WT<F:9:3> 1 ☐ 1 lb 2 ☐ 2 kg WGTU<ZWGTU>

CRF Annotation Version 6.0_11May2004

HF ACTION

Baseline

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Patient Survey

The following information is very important for the HF-ACTION trial. Please carefully read and answer the questions below.

SURVEY(TYPE 1)

1 Please check only one of the following options to indicate your ethnicity:

1 ☐ Hispanic or Latino *(a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race)*

2 ☐ Not Hispanic or Latino ETHNIC<I:3><ACETH>

2 Check as many of the categories below as you need to indicate your race:

☐ American Indian or Alaska Native *(a person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment)* AMERIND<I:3><ZYES>

☐ Asian *(a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam)* ASIAN<I:3><ZYES>

☐ Black or African American *(a person having origins in any of the black racial groups of Africa)* BLACK<I:3><ZYES>

☐ Native Hawaiian or other Pacific Islander *(a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands)* NATHWN<I:3><ZYES>

☐ White *(a person having origins in any of the original peoples of Europe, the Middle East, or North Africa)* WHITE<I:3><ZYES>

EDUCAT<I:3><ACEDU>

3 Please check only one of the following to indicate your highest level of education:

1 ☐ Less than high school
2 ☐ High school graduate or equivalent *(e.g., GED)*
3 ☐ Completed some college, but no degree
4 ☐ Completed associate degree/diploma program
5 ☐ College graduate *(e.g., B.A., B.S.)*
6 ☐ Completed graduate school *(e.g., M.S., M.D., Ph.D.)*

4 Check one of the following to indicate your current marital status: MARITST<I:3><ACMAR>

1 ☐ Married
2 ☐ Widowed
3 ☐ Divorced
4 ☐ Separated
5 ☐ Single–never married
6 ☐ Living with a partner
9 ☐ Decline to answer

5 Check one of the following to indicate your most recent annual household income before taxes: EARN<I:3><ACEARN>

1 ☐ less than $15,000
2 ☐ $15,000-$24,999
3 ☐ $25,000-$34,999
4 ☐ $35,000-$49,999
5 ☐ $50,000-$74,999
6 ☐ $75,000-$99,999
7 ☐ $100,000 or more
9 ☐ Decline to answer

6 Check one of the following to indicate your current employment status: EMPLOYST<I:3><ACEMP>

1 ☐ Employed/self-employed full-time *(> 30 hours week)*
2 ☐ Employed part-time *(specify hours per week)*: _____
3 ☐ Student
4 ☐ Homemaker
5 ☐ Volunteer
6 ☐ Disabled
7 ☐ Unemployed
8 ☐ Retired

PARTT2<F:9:3>

7 How many days have you lost from work and/or your usual activities in the past 30 days due to problems with your health?

_____ days LOSTWK2<F:9:3>

PATIENT SELF-REPORT FORM

CRF Annotation Version 6.0_11May2004

WHITE and YELLOW — Duke Clinical Research Institute • PINK — retain at site

This panel had been moved into production using multisite. Therefore the database format for Items PARTT and LOSTWK could not be changed. New items PARTT2 and LOSTWK2 were created. The old items will be null in the database.

EuroQoL Questionnaire

By placing a checkmark in one box in each group below, please indicate which statement best describes your own health state today.

EURO(TYPE 3)

1 Mobility: EURO1<I:3><ACER1O>

1 ☐ I have no problems in walking about.
2 ☐ I have some problems in walking about.
3 ☐ I am confined to bed.

2 Self-care: EURO2<I:3><ACER2O>

1 ☐ I have no problems with self-care.
2 ☐ I have some problems washing or dressing myself.
3 ☐ I am unable to wash or dress myself.

3 Usual activities *(e.g. work, study, housework, family or leisure activities)*: EURO3<I:3><ACER3O>

1 ☐ I have no problems with performing my usual activities.
2 ☐ I have some problems with performing my usual activities.
3 ☐ I am unable to perform my usual activities.

4 Pain/discomfort: EURO4<I:3><ACER4O>

1 ☐ I have no pain or discomfort.
2 ☐ I have moderate pain or discomfort.
3 ☐ I have extreme pain or discomfort.

5 Anxiety/depression: EURO5<I:3><ACER5O>

1 ☐ I am not anxious or depressed.
2 ☐ I am moderately anxious or depressed.
3 ☐ I am extremely anxious or depressed.

STOP → **Please let your study coordinator know that you are ready for the EuroQoL Thermometer worksheet.**

PATIENT SELF-REPORT FORM

Pain Assessment

1 How much bodily pain have you had during the past 4 weeks *(check only one)*? PAIN1<I:3><ACP1N>

1 ☐ None 2 ☐ Very mild 3 ☐ Mild 4 ☐ Moderate 5 ☐ Severe 6 ☐ Very severe

2 During the past 4 weeks, how much did pain interfere with your normal work *(including both work outside the home and housework)*? PAIN2<I:3><ACP2N>

1 ☐ Not at all 2 ☐ A little bit 3 ☐ Moderately 4 ☐ Quite a bit 5 ☐ Extremely

EuroQol Thermometer Response

Response to the EuroQoL thermometer: ___ ___ ___ (0-100) THERM<I:3>

CRF Annotation Version 6.0_11May2004

Kansas City Cardiomyopathy Questionnaire (KCCQ)

PATIENT SELF-REPORT FORM

The following questions refer to your heart failure and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answers that best apply to you.

1 **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** *(shortness of breath or fatigue)* in your ability to do the following activities over the past 2 weeks.

(Check only one box on each line.)

KCCQ1(TYPE 3)

<ACKCCA>

Activity	1 Extremely Limited	2 Quite a Bit Limited	3 Moderately Limited	4 Slightly Limited	5 Not at All Limited	6 Limited for Other Reasons or Did Not Do the Activity
KCCQ1A<I:3> Dressing yourself:	1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5	6 ☐6
KCCQ1B<I:3> Showering/bathing:	☐1	☐2	☐3	☐4	☐5	☐6
KCCQ1C<I:3> Walking 1 block on level ground:	☐1	☐2	☐3	☐4	☐5	☐6
KCCQ1D<I:3> Doing yard work, housework or carrying groceries:	☐1	☐2	☐3	☐4	☐5	☐6
KCCQ1E<I:3> Climbing a flight of stairs without stopping:	☐1	☐2	☐3	☐4	☐5	☐6
KCCQ1F<I:3> Hurrying or jogging *(as if to catch a bus)*:	☐1	☐2	☐3	☐4	☐5	☐6

2 Compared with 2 weeks ago, have your symptoms of **heart failure** *(shortness of breath, fatigue, or ankle swelling)* changed?

My symptoms of heart failure have become... KCCQ2<I:3><ACHFSY>

Much worse	Slightly worse	Not changed	Slightly better	Much better	I've had no symptoms over the last 2 weeks
1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5	6 ☐6

3 Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in the morning? KCCQ3<I:3><ACSWFT>

Every morning	3 or more times a week, but not every morning	1-2 times a week	Less than once a week	Never over the past 2 weeks
1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5

4 Over the past 2 weeks, how much has **swelling** in your feet, ankles or legs bothered you? It has been... KCCQ4<I:3><ACSWM>

Extremely bothersome	**Moderately** bothersome	**Somewhat** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no swelling**
1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5	6 ☐6

CRF Annotation Version 6.0_11May2004

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

KCCQ5<I:3><ACAVSH>

KCCQ2(TYPE3)

5 Over the past 2 weeks, on average, how many times has **fatigue** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1-2 times a week	Less than once a week	Never over the past 2 weeks
1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5	6 ☐6	7 ☐7

KCCQ6<I:3><ACMUFT>

6 Over the past 2 weeks, how much has your **fatigue** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no fatigue**
1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5	6 ☐6

KCCQ7<I:3><ACAVSH>

7 Over the past 2 weeks, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1-2 times a week	Less than once a week	Never over the past 2 weeks
1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5	6 ☐6	7 ☐7

KCCQ8<I:3><ACMUSH>

8 Over the past 2 weeks, how much has your **shortness of breath** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no shortness of breath**
1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5	6 ☐6

KCCQ9<I:3><ACAVFS>

9 Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

Every night	3 or more times a week, but not every night	1-2 times a week	Less than once a week	Never over the past 2 weeks
1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5

KCCQ10<I:3><ACHFHF>

10 **Heart failure** symptoms can worsen for a number of reasons. How sure are you that you know what to do or who to call, if your **heart failure** gets worse?

Not at all sure	**Not very** sure	**Somewhat** sure	**Mostly** sure	**Completely** sure
1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5

KCCQ11<I:3><ACHFUN>

11 How well do you understand what things you are able to do to keep your **heart failure** symptoms from getting worse *(for example, weighing yourself, eating a low-salt diet etc.)*?

Do not understand at all	Do not understand very well	Somewhat understand	Mostly understand	Completely understand
1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5

PATIENT SELF-REPORT FORM

CRF Annotation Version 6.0_11May2004

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

KCCQ3(TYPE3)

12 Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not limited** my enjoyment of life at all
1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5

KCCQ12<I:3><ACHFLM>

13 If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

Not at all satisfied	**Mostly** dissatisfied	**Somewhat** satisfied	**Mostly** satisfied	**Completely** satisfied
1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5

KCCQ13<I:3><ACHFLF>

14 Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of your **heart failure**?

I felt that way **all of the time**	I felt that way **most of the time**	I **occasionally** felt that way	I **rarely** felt that way	I **never** felt that way
1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5

KCCQ14<I:3><ACHFDC>

15 How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks.

(Check only one box on each line.)

<ACHFLS>

Activity	Severely Limited	Limited Quite a Bit	Moderately Limited	Slightly Limited	Did Not Limit at All	Does Not Apply or Did Not Do for Other Reasons
KCCQ15A <I:3> Hobbies, recreational activities:	1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5	6 ☐6
KCCQ15B <I:3> Intimate relationships with loved ones:	1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5	6 ☐6
KCCQ15C <I:3> Visiting family or friends out of your home:	1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5	6 ☐6
KCCQ15D <I:3> Working or doing household chores:	1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5	6 ☐6

PATIENT SELF-REPORT FORM

CRF Annotation Version 6.0_11May2004

Beck Depression Inventory (BDI)

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the **one statement** in each group that best describes the way you have been feeling during the **past one week, including today**. Check the box beside the statement you have picked. If several statements within a group seem to apply equally well, check the highest numbered box for that group. Be sure that you do not choose more than one statement for any group, including item 16, Changes in Sleeping Pattern and item 18, Changes in Appetite.

BDI1(TYPE 3)

1 Sadness: BDI1<I:3><ACB1D>

0 ☐ I do not feel sad.
1 ☐ I feel sad much of the time.
2 ☐ I am sad all of the time.
3 ☐ I am so sad or unhappy that I can't stand it.

2 Pessimism: BDI2<I:3><ACB2D>

☐ I am not discouraged about my future.
☐ I feel more discouraged about my future than I used to be.
☐ I do not expect things to work out for me.
☐ I feel my future is hopeless and will only get worse.

3 Past Failure: BDI3<I:3><ACB3D>

☐ I do not feel like a failure.
☐ I have failed more than I should have.
☐ As I look back, I see a lot of failures.
☐ I feel I am a total failure as a person.

4 Loss of Pleasure: BDI4<I:3><ACB4D>

☐ I get as much pleasure as I ever did from the things I enjoy.
☐ I don't enjoy things as much as I used to.
☐ I get very little pleasure from the things I used to enjoy.
☐ I can't get any pleasure from the things I used to enjoy.

5 Guilty Feelings: BDI5<I:3><ACB5D>

☐ I don't feel particularly guilty.
☐ I feel guilty over many things I have done or should have done.
☐ I feel quite guilty most of the time.
☐ I feel guilty all of the time.

6 Punishment Feelings: BDI6<I:3><ACB6D>

☐ I don't feel I am being punished.
☐ I feel I may be punished.
☐ I expect to be punished.
☐ I feel I am being punished.

7 Self-Dislike: BDI7<I:3><ACB7D>

☐ I feel the same about myself as ever.
☐ I have lost confidence in myself.
☐ I am disappointed in myself.
☐ I dislike myself.

8 Self-Criticalness: BDI8<I:3><ACB8D>

☐ I don't criticize or blame myself more than usual.
☐ I am more critical of myself than I used to be.
☐ I criticize myself for all of my faults.
☐ I blame myself for everything that happens.

9 Suicidal Thoughts or Wishes: BDI9<I:3><ACB9D>

☐ I don't have any thoughts of killing myself.
☐ I have thoughts of killing myself, but I would not carry them out.
☐ I would like to kill myself.
☐ I would kill myself if I had the chance.

10 Crying: BDI10<I:3><ACB10D>

☐ I don't cry any more than I used to.
☐ I cry more than I used to.
☐ I cry over every little thing.
☐ I feel like crying, but I can't.

11 Agitation: BDI11<I:3><ACB11D>

☐ I am no more restless or wound up than usual.
☐ I feel more restless or wound up than usual.
☐ I am so restless or agitated that it's hard to stay still.
☐ I am so restless or agitated that I have to keep moving or doing something.

12 Loss of Interest: BDI12<I:3><ACB12D>

☐ I have not lost interest in other people or activities.
☐ I am less interested in other people or things than before.
☐ I have lost most of my interest in other people or things.
☐ It's hard to get interested in anything.

PATIENT SELF-REPORT FORM

CRF Annotation Version 6.0_11May2004

Beck Depression Inventory (BDI) (continued)

13 Indecisiveness: BDI13<I:3><ACB13D>

0 ☐ I make decisions about as well as ever.
1 ☐ I find it more difficult to make decisions than usual.
2 ☐ I have much greater difficulty in making decisions than I used to.
3 ☐ I have trouble making any decisions.

14 Worthlessness: BDI14<I:3><ACB14D>

☐ I do not feel I am worthless.
☐ I don't consider myself as worthwhile and useful as I used to.
☐ I feel more worthless as compared to other people.
☐ I feel utterly worthless.

15 Loss of Energy: BDI15<I:3><ACB15D>

☐ I have as much energy as ever.
☐ I have less energy than I used to have.
☐ I don't have enough energy to do very much.
☐ I don't have enough energy to do anything.

16 Changes in Sleeping Pattern *(check only one)*: BDI16<I:3><ACB16D>

0 ☐ I have not experienced any change in my sleeping pattern.
1 ☐ I sleep somewhat more than usual.
2 ☐ I sleep somewhat less than usual.
3 ☐ I sleep a lot more than usual.
4 ☐ I sleep a lot less than usual.
5 ☐ I sleep most of the day.
6 ☐ I wake up 1–2 hours early and can't get back to sleep.

17 Irritability: BDI17<I:3><ACB17D>

☐ I am no more irritable than usual.
☐ I am more irritable than usual.
☐ I am much more irritable than usual.
☐ I am irritable all the time.

18 Changes in Appetite *(check only one)*: BDI2(TYPE3)

0 ☐ I have not experienced any change in my appetite.
1 ☐ My appetite is somewhat less than usual. BDI18<I:3><ACB18D>
2 ☐ My appetite is somewhat greater than usual.
3 ☐ My appetite is much less than before.
4 ☐ My appetite is much greater than usual.
5 ☐ I have no appetite at all.
6 ☐ I crave food all the time.

19 Concentration Difficulty: BDI19<I:3><ACB19D>

☐ I can concentrate as well as ever.
☐ I can't concentrate as well as usual.
☐ It's hard to keep my mind on anything for very long.
☐ I find I can't concentrate on anything.

20 Tiredness or Fatigue: BDI20<I:3><ACB20D>

☐ I am no more tired or fatigued than usual.
☐ I get more tired or fatigued more easily than usual.
☐ I am too tired or fatigued to do a lot of the things I used to do.
☐ I am too tired or fatigued to do most of the things I used to do.

21 Loss of Interest in Sex: BDI21<I:3><ACB21D>

☐ I have not noticed any recent change in my interest in sex.
☐ I am less interested in sex than I used to be.
☐ I am much less interested in sex now.
☐ I have lost interest in sex completely.

PATIENT SELF-REPORT FORM

CRF Annotation Version 6.0_11May2004

HF ACTION

Baseline

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Perceived Social Support Scale (PSSS)

PSSS (TYPE 4)PS

We are interested in how you feel about the following statements. Read each statement carefully.
Please check the box that most closely corresponds to how you feel about each statement, from very strongly disagree to very strongly agree.

PSSSQ<I:3><ACDSSQ>

PSSSA<I:3><ACDSSR>

	Very Strongly Disagree	Strongly Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree	Very Strongly Agree
1= **1** There is a special person who is around when I am in need:	1 ☐1	2 ☐2	3 ☐3	4 ☐4	5 ☐5	6 ☐6	7 ☐7
2= **2** There is a special person with whom I can share joys and sorrows:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
3= **3** My family really tries to help me:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
4= **4** I get the emotional help and support I need from my family:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
5= **5** I have a special person who is a real source of comfort to me:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
6= **6** My friends really try to help me:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
7= **7** I can count on my friends when things go wrong:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
8= **8** I can talk about my problems with my family:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
9= **9** I have friends with whom I can share my joys and sorrows:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
10= **10** There is a special person in my life who cares about my feelings:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
11= **11** My family is willing to help me make decisions:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
12= **12** I can talk about my problems with my friends:	☐1	☐2	☐3	☐4	☐5	☐6	☐7

CRF Annotation Version 6.0_11May2004

PATIENT SELF-REPORT FORM

PATIENT SELF-REPORT FORM

Stages of Change

Physical activity or exercise includes activities such as walking briskly, jogging, bicycling, swimming, or any other activity in which the exertion is at least as intense as these activities.

STAGE(TYPE 3)

For activity to be regular, it must add up to a total of 30 minutes or more per day and be done at least 5 days per week. For example, you could take one 30-minute walk or take three 10-minute walks for a daily total of 30 minutes.

For each of the following questions, please check "Yes" or "No." <ZYESNO>

STAGE1 <I:3>
1 I am currently physically active. 0 ☐0 No 1 ☐1 Yes

STAGE2 <I:3>
2 I intend to become more physically active in the next 6 months. 0 ☐0 No 1 ☐1 Yes

STAGE3 <I:3>
3 I currently engage in regular physical activity. 0 ☐0 No 1 ☐1 Yes

STAGE4 <I:3>
4 I have been regularly physically active for the past 6 months. 0 ☐0 No 1 ☐1 Yes

Exercise Self-Efficacy

Physical activity or exercise includes activities such as walking briskly, jogging, bicycling, swimming, or any other activity in which the exertion is at least as intense as these activities.

EXSELF(TYPE 3)

Check the box that indicates how confident you are that you could be physically active in each of the following situations:

1 When I am tired: EXSELF1<I:3><ACEXSA>
1 ☐1 Not at all confident 2 ☐2 Slightly confident 3 ☐3 Moderately confident 4 ☐4 Very confident 5 ☐5 Extremely confident

2 When I am in a bad mood: EXSELF2<I:3><ACEXSA>
1 ☐1 Not at all confident 2 ☐2 Slightly confident 3 ☐3 Moderately confident 4 ☐4 Very confident 5 ☐5 Extremely confident

3 When I feel I don't have time: EXSELF3<I:3><ACEXSA>
1 ☐1 Not at all confident 2 ☐2 Slightly confident 3 ☐3 Moderately confident 4 ☐4 Very confident 5 ☐5 Extremely confident

4 When I am on vacation: EXSELF4<I:3><ACEXSA>
1 ☐1 Not at all confident 2 ☐2 Slightly confident 3 ☐3 Moderately confident 4 ☐4 Very confident 5 ☐5 Extremely confident

5 When it is raining or snowing: EXSELF5<I:3><ACEXSA>
1 ☐1 Not at all confident 2 ☐2 Slightly confident 3 ☐3 Moderately confident 4 ☐4 Very confident 5 ☐5 Extremely confident

CRF Annotation Version 6.0_11May2004

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Decisional Balance

Please rate how important each of these statements is in your decision of whether to be physically active. In each case, think about how you feel right now, not how you have felt in the past or would like to feel.

DECBAL(TYPE 3)

<ACDEB>

		Not at All Important	Slightly Important	Moderately Important	Very Important	Extremely Important
DECIS1<I:3>	1 I would have more energy for my family and friends if I exercised regularly.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
DECIS2<I:3>	2 Regular exercise would help me relieve tension.	☐	☐	☐	☐	☐
DECIS3<I:3>	3 I think I would be too tired to do my daily work after exercising.	☐	☐	☐	☐	☐
DECIS4<I:3>	4 I would feel more confident if I exercised regularly.	☐	☐	☐	☐	☐
DECIS5<I:3>	5 I would sleep more soundly if I exercised regularly.	☐	☐	☐	☐	☐
DECIS6<I:3>	6 I would feel good about myself if I kept my commitment to exercise regularly.	☐	☐	☐	☐	☐
DECIS7<I:3>	7 I would find it difficult to find an exercise activity that I enjoy that is not affected by bad weather.	☐	☐	☐	☐	☐
DECIS8<I:3>	8 I would like my body better if I exercised regularly.	☐	☐	☐	☐	☐
DECIS9<I:3>	9 It would be easier for me to perform routine physical tasks if I exercised regularly.	☐	☐	☐	☐	☐
DECIS10<I:3>	10 I would feel less stressed if I exercised regularly.	☐	☐	☐	☐	☐
DECIS11<I:3>	11 I feel uncomfortable when I exercise because I get out of breath and my heart beats very fast.	☐	☐	☐	☐	☐
DECIS12<I:3>	12 I would feel more comfortable with my body if I exercised regularly.	☐	☐	☐	☐	☐
DECIS13<I:3>	13 Regular exercise would take too much of my time.	☐	☐	☐	☐	☐
DECIS14<I:3>	14 Regular exercise would help me have a more positive outlook on life.	☐	☐	☐	☐	☐
DECIS15<I:3>	15 I would have less time for my family and friends if I exercised regularly.	☐	☐	☐	☐	☐
DECIS16<I:3>	16 At the end of the day, I am too exhausted to exercise.	☐	☐	☐	☐	☐

PATIENT SELF-REPORT FORM

Barrier Scale

BARRIER(TYPE 3)

Please indicate the extent to which you anticipate that the following might interfere with your participation in this study:

<ACBR>

		Not at All	Somewhat	A Lot
BAR1<I:3>	1 Finances:	1 ☐	2 ☐	3 ☐
BAR2<I:3>	2 Child care:	☐	☐	☐
BAR3<I:3>	3 Weather:	☐	☐	☐
BAR4<I:3>	4 Vacation:	☐	☐	☐
BAR5<I:3>	5 Pain:	☐	☐	☐
BAR6<I:3>	6 Boredom:	1 ☐	2 ☐	3 ☐
BAR7<I:3>	7 Fatigue:	☐	☐	☐
BAR8<I:3>	8 Transportation:	☐	☐	☐
BAR9<I:3>	9 Work:	☐	☐	☐
BAR10<I:3>	10 Household responsibilities:	☐	☐	☐

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PAQ(TYPE 3)

HF ACTION

Baseline

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Physical Activity Questionnaire (PAQ)

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the last 7 days. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous physical activities** that you did in the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

1 During the last 7 days, on how many days did you do **vigorous physical activities** like heavy lifting, digging, aerobics, or fast bicycling?

VIGDAY<I:3>
_____ days → Continue to question 2.

OR ☐ No vigorous physical activities → Skip to question 3.

NOVIG<ZYES>

2 How much time did you usually spend doing **vigorous physical activities** on one of those days?

___ ___ ___ minutes per day VIGMIN<I:3>

OR ☐ Don't know/not sure UNKVIG<ZYES>

Think about all the **moderate physical activities** that you did in the last 7 days. Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3 During the last 7 days, on how many days did you do **moderate physical activities** like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

MODDAY<I:3>
_____ days → Continue to question 4.

OR ☐ No moderate physical activities → Skip to question 5.

NOMOD<ZYES>

4 How much time did you usually spend doing **moderate physical activities** on one of those days?

___ ___ ___ minutes per day MODMIN<I:3>

OR ☐ Don't know/not sure UNKMOD<ZYES>

Think about the time you spent **walking** in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5 During the last 7 days, on how many days did you **walk** for at least 10 minutes at a time?

_____ days → Continue to question 6. WALKD<I:3>

OR ☐ No walking → Skip to question 7.

NOWALK<ZYES>

6 How much time did you usually spend **walking** on one of those days?

___ ___ ___ minutes per day WALKMIN<I:3>

OR ☐ Don't know/not sure UNKWALK<ZYES>

The last question is about the time you spent **sitting on weekdays** during the last 7 days. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7 During the last 7 days, how much time did you spend **sitting on a weekday**?

___ ___ hours per day SITHR<I:3>

OR ☐ Don't know/not sure UNKSIT<ZYES>

PATIENT SELF-REPORT FORM

CRF Annotation Version 6.0_11May2004

WHITE and YELLOW — Duke Clinical Research Institute • PINK — retain at site

Current Medications

Check "No" or "Yes" for each medication and provide the total daily dose, if applicable.

CMED(TYPE 3)

1 ACE inhibitor: ACE<I:3><ZYESNO> NOACE<I:3><ACNOAC>

0 No → Reason for not using (check only one): 1 Contraindicated 2 Intolerance 3 MD preference 4 Patient preference

1 Yes → If Yes: Check only one and provide the TOTAL DAILY DOSE: ACEVAL<I:5>

YESACE<I:3><ACYESA>

1 Benazepril: _____ mg 6 Quinapril: _____ mg
2 Captopril: _____ mg 7 Ramipril: _____ mg
3 Enalapril: _____ mg 8 Trandolapril: _____ mg
4 Fosinopril: _____ mg 98 Other (specify): ACEOTH<V:50> _____ mg
5 Lisinopril: _____ mg

2 Angiotensin receptor blocker: ANGIO<ZYESNO> LOSAR<I:3><ZYES> IRBE<I:3><ZYES> CAND<I:3><ZYES> VALSAR<I:3><ZYES>

0 No

1 Yes → If Yes: Check all that apply: ☐ Valsartan ☐ Losartan ☐ Irbesartan ☐ Candesartan

ARBOT<I:3><ZYES> ☐ Other (specify): ANGOTH<V:50>

3 Beta blocker: BETA<I:3><ZYESNO> NOBETA<I:3><ACNOAC>

0 No → Reason for not using (check only one): 1 Contraindicated 2 Intolerance 3 MD preference 4 Patient preference

1 Yes → If Yes: Check only one and provide the TOTAL DAILY DOSE:

YESBET<I:3><ACBET> BETVAL<I:5>

1 Atenolol: _____ mg 4 Metoprolol immediate release: _____ mg
2 Bisoprolol: _____ mg 5 Metoprolol XL: _____ mg
3 Carvedilol: _____ mg 98 Other (specify): BETOTH<V:50> _____ mg

4 Aspirin: ASPIRIN<I:3><ZYESNO> NOASPIR<I:3><ACNOAC>

0 No → Reason for not using (check only one): 1 Contraindicated 2 Intolerance 3 MD preference 4 Patient preference

1 Yes → If Yes: Dose: _____ mg ASPVAL<I:5>

5 Loop diuretic: LOOPD<I:3><ZYESNO>

0 No

1 Yes → If Yes: Check only one and provide the TOTAL DAILY DOSE:

YESLOOP<I:3><ACLOOP> LOOPVAL<I:5>

1 Furosemide: _____ mg 3 Torsemide: _____ mg
2 Bumetanide: _____ mg 98 Other (specify): LOOPOTH<V:50> _____ mg

6 Antiarrhythmic: ARRHYT<I:3><ZYESNO>

0 No

1 Yes → If Yes: Check all that apply: ☐ Amiodarone AMIOD<I:3><ZYES> ☐ Sotalol SOTA<I:3><ZYES> ☐ Dofetilide DOFET<I:3><ZYES> ☐ Other (specify): ARROTSP<V:50> ARROTH<I:3><ZYES>

7 Lipid-lowering agent: LLWA<I:3><ZYESNO>

0 No

1 Yes → If Yes: Check only one: 1 HMG-CoA reductase inhibitor → Check all that apply: ☐ Atorvastatin ☐ Pravastatin ☐ Simvastatin ☐ Other HMGCOA<ZYES> ATOR<I:3><ZYES> PRAV<I:3><ZYES> SIMV<I:3><ZYES> OTLIP<I:3><ZYES>

OTHLLAGT<ZYES> 2 Other lipid-lowering agent

8 Selective serotonin reuptake inhibitor: SSRI<I:3><ZYESNO>

0 No

1 Yes → Check all that apply: ☐ Sertraline ☐ Citalopram ☐ Paroxetine ☐ Fluoxetine ☐ Other SERT<I:3><ZYES> PARO<I:3><ZYES> SSRIOT<I:3><ZYES> CITAL<I:3><ZYES> FLUOX<I:3><ZYES>

CRF Annotation Version 6.0_11May2004

Current Medications

CURMEDS<I:3><ACCMQ>

Check "No" or "Yes" for each medication.

MEDSANS<I:3><ZYESNO>

CMEDS(TYPE 4)PS

9	Tricyclic antidepressant:	[0] 0 No	[1] 1 Yes
10	Other antidepressant *(excluding SSRIs and TCAs)*:	[ ] 0 No	[ ] 1 Yes
11	Antipsychotic:	[ ] 0 No	[ ] 1 Yes
12	Clopidogrel:	[ ] 0 No	[ ] 1 Yes
13	Coumadin:	[ ] 0 No	[ ] 1 Yes
14	Digoxin:	[ ] 0 No	[ ] 1 Yes
15	Nitrate:	[ ] 0 No	[ ] 1 Yes
16	Calcium channel blocker:	[ ] 0 No	[ ] 1 Yes
17	Spironolactone:	[ ] 0 No	[ ] 1 Yes
18	Eplerenone:	[ ] 0 No	[ ] 1 Yes
19	Non-loop diuretic *(excluding aldosterone antagonist)*:	[ ] 0 No	[ ] 1 Yes
20	Potassium:	[ ] 0 No	[ ] 1 Yes
21	Insulin:	[ ] 0 No	[ ] 1 Yes
22	Glitazone:	[ ] 0 No	[ ] 1 Yes
23	Other oral diabetic agent:	[ ] 0 No	[ ] 1 Yes
24	Thyroid replacement:	[ ] 0 No	[ ] 1 Yes
25	NSAID:	[ ] 0 No	[ ] 1 Yes
26	COX-2 inhibitor:	[ ] 0 No	[ ] 1 Yes
27	Sildenafil:	[ ] 0 No	[ ] 1 Yes

CMEDS2 (TYPE 4) PS

Reserved for potential new drugs. **Do not complete unless instructed by the Duke Clinical Research Institute (DCRI).**

CRMDOTH<I:3><ACOTH>

CURMDSP<V:50>

CMOTHA<I:3><ZYESNO>

28	Other: _____	[0] 0 No	[1] 1 Yes
29	Other: _____	[ ] 0 No	[ ] 1 Yes

Baseline

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Medical History

1 Congestive heart failure:
CONGHF<I:3><ACCHF>
Type: [1] 1 Ischemic [2] 2 Non-ischemic

MEDHX1 (TYPE 1)

Ejection fraction: Baseline: _____% BASEF<F:9:3>
Screening *(if Registry patient)*: _____% SCRENEF<F:9:3>

CNYHA<I:3><ACYHA>
Current NYHA heart failure class *(check only one)*:
[1] I [2] II [3] III [4] IV

Put in conversion procedure
So that 1 can not be entered
For baseline

2 Angina: ANGIN<ZYESNO>
[0] 0 No
[1] 1 Yes → If Yes: Current Canadian Cardiovascular Society (CCS) Angina Class *(check only one)*: ANGICL<I:3><ACCLAS>
[0] No angina [1] I [2] II [3] III [4] IV

3 Myocardial infarction *(MI)*: MI<I:3><ZYESNO>
[0] 0 No
[1] 1 Yes → If Yes: Date of most recent MI: RMIDT
___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

All are <ZYESNO>

4 Cardiac procedures *(check "No" or "Yes" for each)*:

CARDPR1	CABG:	[0] 0 No [1] 1 Yes
CARDPR2	Valve surgery:	[0] 0 No [1] 1 Yes
CARDPR3	PCI:	[0] 0 No [1] 1 Yes
CARDPR4	Pacemaker:	[0] 0 No [1] 1 Yes
CARDPR5	AICD:	[0] 0 No [1] 1 Yes
CARDPR6	Bi-ventricular pacemaker:	[0] 0 No [1] 1 Yes
CARDPR7	Other procedure:	[0] 0 No [1] 1 Yes

➥ Specify: CARDOTH<V:50>

5 Arrhythmias: ARR<I:3><ZYESNO>
[0] 0 No
[1] 1 Yes → If Yes: Check all that apply:
- ATRIAL<I:3><ZYES> Atrial fibrillation/atrial flutter
- BRADY<I:3><ZYES> Symptomatic bradycardia
- VTACH<I:3><ZYES> Sustained ventricular tachycardia/ventricular fibrillation
- OTARR<I:3><ZYES> Other *(specify)*: ARRSP<V:50>

6 Hypertension: HYPTN<I:3><ZYESNO>
[0] 0 No [1] 1 Yes

7 Hyperlipidemia: HLIPID<I:3><ZYESNO>
[0] 0 No [1] 1 Yes

MEDHX2 (TYPE 1)

8 Peripheral vascular disease *(PVD)*: PVD<I:3><ZYESNO>
[0] 0 No
CLAUD<I:3><ZYES>
[1] 1 Yes → If Yes: Check all that apply:
- ☐ Claudication
- ☐ Revascularization

REVASC<I:3><ZYES>

9 Stroke: STRK<I:3><ZYESNO>
[0] 0 No [1] 1 Yes

10 Diabetes: DIABET<I:3><ZYESNO>
[0] 0 No [1] 1 Yes

COPD<I:3><ZYESNO>

11 Chronic obstructive pulmonary disease:
[0] 0 No [1] 1 Yes

CANCER<I:3><ZYESNO>

12 Cancer in last 5 years *(excluding minor skin cancer)*:
[0] 0 No [1] 1 Yes

13 Depression: DEPRES<I:3><ZYESNO>
[0] 0 No [1] 1 Yes

14 Cigarette smoking *(check only one)*: SMOKE<I:3><ACSMOK>
[0] 0 Never
[1] 1 Current smoker
[2] 2 Quit → If Quit: Provide month and year quit:
SMOKM<V:3><ACMON> ___ ___ (month / year) SMOKY <V:4>
SEE BELOW

15 Alcohol use: ALCOHOL<I:3><ZYESNO>
[0] 0 No
[1] 1 Yes → If Yes: Specify:
Average # of drinks per week: _____ OR AVDRIN<I:3>
☐ Patient no longer drinks *(past history of alcohol use only)* NODRINK<I:3><ZYES>

16 How many times has the patient been hospitalized in the past 6 months? _____ hospitalizations HOSPNM<I:3>

Of these hospitalizations, how many were related to heart failure? _____ HFHOSP<I:3>

<ACMON>
JAN JUL
FEB AUG
MAR SEP
APR OCT
MAY NOV
JUN DEC

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Labs

LABTEST<I:3><ACLBT> LABND<I:3><ZYES> LABVAL<F:9:3> LABUNIT<I:3><ACUNIT>

LABS (TYPE 2)PS

CHEMISTRY:

1= **1** Sodium: ☐1 Not done OR Value: _____ Units: 1 mmol/L OR mEq/L

2= **2** Potassium: ☐1 Not done OR Value: _____ Units: 2 mg/dL / 3 µmol/L

3= **3** Blood urea nitrogen: ☐1 Not done OR Value: _____ Units: 4 mmol/L / ☐ mg/dL

4= **4** Creatinine: ☐1 Not done OR Value: _____ Units: ☐ mg/dL / ☐ µmol/L

5= **5** Glucose: ☐1 Not done OR Value: _____ Units: ☐ mmol/L / ☐ mg/dL

LIPID:

6= **6** Total cholesterol: ☐1 Not done OR Value: _____ Units: ☐ mmol/L / ☐ mg/dL

7= **7** Low-density lipoprotein: ☐1 Not done OR Value: _____ Units: ☐ mmol/L / ☐ mg/dL

8= **8** High-density lipoprotein: ☐1 Not done OR Value: _____ Units: ☐ mmol/L / ☐ mg/dL

HEMATOLOGY:

9= **9** Hemoglobin *(Hgb)*: ☐1 Not done OR Value: _____ Units: 5 g/dL OR grams % / 6 g/L / ☐ mmol/L

10= **10** Hematocrit *(Hct)*: ☐1 Not done OR Value: _____ Units: 7 % / 8 L/L

DIABETIC ASSESSMENT:

11= **11** Hemoglobin A1c: ☐1 Not done OR Value: _____ Units: %

NATURETIC PEPTIDE:

12= **12** BNP: ☐1 Not done OR Value: _____ Units: 9 pg/mL

13= **13** Pro-BNP: ☐1 Not done OR Value: _____ Units: pg/mL

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Quality of Life—Reason for Missing Data Complete only for randomized patients.

Are all quality-of-life forms complete? 0 No → If No:
- 1 Patient died
- 2 Patient refused
- 3 Patient withdrew consent
- 4 Patient missed visit
- 5 Patient sick
- 98 Other

1 Yes

QOLL<I:3><ZYESNO>

QOLREA<I:3><ACQOLR>

QOLR (TYPE 3)

6–Minute Walk Test

1 Did the patient attempt the 6-minute walk at this visit? SIXMIN<I:3><ZYESNO>

WALKT (TYPE 3)

0 No → If No: Specify primary reason: NOSIX<I:3><ACNSIX>
- 1 Patient was too critically ill.
- 2 Patient cannot walk for technical reasons (e.g., a patient who is an amputee).
- 3 Not done due to oversight.
- 4 Patient refused
- 5 Patient died
- 6 Patient withdrew consent
- 7 Patient missed visit

1 Yes → If Yes: Date of 6-minute walk: WALKDT ___ / ___ / ___ (day / month / year)

Start walk time: WALKTM ___ : ___ (00:00 to 23:59)

Total distance walked: DISTM<F:9:3> _____ DISTMU<I:3><ACDSMU> 1 Feet 2 Meter(s)

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

SNON<I:3><ZYES> None SANG<I:3><ZYES> Angina SLGTH<I:3><ZYES> Light-headedness SSYN<I:3><ZYES> Syncope

Borg Rating of Perceived Exertion (RPE) Scale: _____ (6-20) BRPE<I:3>

QOLTM<I:3><ACQTM>

2 Were the QOL instruments completed before or after the 6-minute walk? Check only one:
- 1 Before
- 2 < 30 mins after
- 3 30-60 mins after
- 4 > 60 mins after

Patient Expectations Evaluation Administered after the patient's exercise CPX test.

Response to the evaluation of patient expectation question: _____ (single digit) CPXEV<I:3>

PATINS (TYPE 1)

Investigator's Signature

I have reviewed and found all **baseline** data pertaining to this patient to be complete and accurate.

SIG (TYPE 3)

BSIGDT

Investigator's signature: BSIG<I:3><ZYES> _____ Date: ___ / ___ / ___ (day / month / year)

PROTOCOL= HFACTION
STUDYBOOK= DATA_FORMS
FORM= 3MONTH

CONTEXT
NODATA<ZYES>

HF-ACTION

3-Month

VISITDT

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

SUBJNO

Patient's Initials: ___ ___ ___ (first middle last)

INITIALS

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

PATIENT SELF-REPORT FORM

EuroQoL Questionnaire

By placing a checkmark in one box in each group below, please indicate which statement best describes your own health state today.

See annotation on p.3 of Baseline

1 Mobility:

- ☐ 1 I have no problems in walking about.
- ☐ 2 I have some problems in walking about.
- ☐ 3 I am confined to bed.

2 Self-care:

- ☐ 1 I have no problems with self-care.
- ☐ 2 I have some problems washing or dressing myself.
- ☐ 3 I am unable to wash or dress myself.

3 Usual activities *(e.g. work, study, housework, family or leisure activities)*:

- ☐ 1 I have no problems with performing my usual activities.
- ☐ 2 I have some problems with performing my usual activities.
- ☐ 3 I am unable to perform my usual activities.

4 Pain/discomfort:

- ☐ 1 I have no pain or discomfort.
- ☐ 2 I have moderate pain or discomfort.
- ☐ 3 I have extreme pain or discomfort.

5 Anxiety/depression:

- ☐ 1 I am not anxious or depressed.
- ☐ 2 I am moderately anxious or depressed.
- ☐ 3 I am extremely anxious or depressed.

STOP → **Please let your study coordinator know that you are ready for the EuroQoL Thermometer worksheet.**

Pain Assessment

1 How much bodily pain have you had during the past 4 weeks *(check only one)*?

☐ 1 None ☐ 2 Very mild ☐ 3 Mild ☐ 4 Moderate ☐ 5 Severe ☐ 6 Very severe

2 During the past 4 weeks, how much did pain interfere with your normal work *(including both work outside the home and housework)*?

☐ 1 Not at all ☐ 2 A little bit ☐ 3 Moderately ☐ 4 Quite a bit ☐ 5 Extremely

EuroQol Thermometer Response

Response to the EuroQoL thermometer: ___ ___ ___ *(0-100)*

See annotation p.4 of Baseline

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Kansas City Cardiomyopathy Questionnaire (KCCQ)

PATIENT SELF-REPORT FORM

The following questions refer to your heart failure and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answers that best apply to you.

1 **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** *(shortness of breath or fatigue)* in your ability to do the following activities over the past 2 weeks.

(Check only one box on each line.)

Activity	Extremely Limited	Quite a Bit Limited	Moderately Limited	Slightly Limited	Not at All Limited	Limited for Other Reasons or Did Not Do the Activity
Dressing yourself:	☐1	☐2	☐3	☐4	☐5	☐6
Showering/bathing:	☐1	☐2	☐3	☐4	☐5	☐6
Walking 1 block on level ground:	☐1	☐2	☐3	☐4	☐5	☐6
Doing yard work, housework or carrying groceries:	☐1	☐2	☐3	☐4	☐5	☐6
Climbing a flight of stairs without stopping:	☐1	☐2	☐3	☐4	☐5	☐6
Hurrying or jogging *(as if to catch a bus)*:	☐1	☐2	☐3	☐4	☐5	☐6

2 Compared with 2 weeks ago, have your symptoms of **heart failure** *(shortness of breath, fatigue, or ankle swelling)* changed? My symptoms of heart failure have become...

Much worse	Slightly worse	Not changed	Slightly better	Much better	I've had no symptoms over the last 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6

3 Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in the morning?

Every morning	3 or more times a week, but not every morning	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5

4 Over the past 2 weeks, how much has **swelling** in your feet, ankles or legs bothered you? It has been...

Extremely bothersome	**Moderately** bothersome	**Somewhat** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no swelling**
☐1	☐2	☐3	☐4	☐5	☐6

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

5 Over the <u>past 2 weeks</u>, on average, how many times has **fatigue** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

6 Over the <u>past 2 weeks</u>, how much has your **fatigue** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no fatigue**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

7 Over the <u>past 2 weeks</u>, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

8 Over the <u>past 2 weeks</u>, how much has your **shortness of breath** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no shortness of breath**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

9 Over the <u>past 2 weeks</u>, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

Every night	3 or more times a week, but not every night	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10 **Heart failure** symptoms can worsen for a number of reasons. How sure are you that you know what to do or who to call, if your **heart failure** gets worse?

Not at all sure	**Not very** sure	**Somewhat** sure	**Mostly** sure	**Completely** sure
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11 How well do you understand what things you are able to do to keep your **heart failure** symptoms from getting **worse** *(for example, weighing yourself, eating a low-salt diet etc.)*?

Do not understand at all	Do not understand very well	Somewhat understand	Mostly understand	Completely understand
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

PATIENT SELF-REPORT FORM

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

12 Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not limited** my enjoyment of life at all
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

13 If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

Not at all satisfied	**Mostly** dissatisfied	**Somewhat** satisfied	**Mostly** satisfied	**Completely** satisfied
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

14 Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of your **heart failure**?

I felt that way **all of the time**	I felt that way **most of the time**	I **occasionally** felt that way	I **rarely** felt that way	I **never** felt that way
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

15 How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks.

(Check only one box on each line.)

Activity	Severely Limited	Limited Quite a Bit	Moderately Limited	Slightly Limited	Did Not Limit at All	Does Not Apply or Did Not Do for Other Reasons
Hobbies, recreational activities:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Intimate relationships with loved ones:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Visiting family or friends out of your home:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Working or doing household chores:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

PATIENT SELF-REPORT FORM

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Beck Depression Inventory (BDI)

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the past one week, including today. Check the box beside the statement you have picked. If several statements within a group seem to apply equally well, check the highest numbered box for that group. Be sure that you do not choose more than one statement for any group, including item 16, Changes in Sleeping Pattern and item 18, Changes in Appetite.

1 Sadness:
- ☐ 0 I do not feel sad.
- ☐ 1 I feel sad much of the time.
- ☐ 2 I am sad all of the time.
- ☐ 3 I am so sad or unhappy that I can't stand it.

2 Pessimism:
- ☐ 0 I am not discouraged about my future.
- ☐ 1 I feel more discouraged about my future than I used to be.
- ☐ 2 I do not expect things to work out for me.
- ☐ 3 I feel my future is hopeless and will only get worse.

3 Past Failure:
- ☐ 0 I do not feel like a failure.
- ☐ 1 I have failed more than I should have.
- ☐ 2 As I look back, I see a lot of failures.
- ☐ 3 I feel I am a total failure as a person.

4 Loss of Pleasure:
- ☐ 0 I get as much pleasure as I ever did from the things I enjoy.
- ☐ 1 I don't enjoy things as much as I used to.
- ☐ 2 I get very little pleasure from the things I used to enjoy.
- ☐ 3 I can't get any pleasure from the things I used to enjoy.

5 Guilty Feelings:
- ☐ 0 I don't feel particularly guilty.
- ☐ 1 I feel guilty over many things I have done or should have done.
- ☐ 2 I feel quite guilty most of the time.
- ☐ 3 I feel guilty all of the time.

6 Punishment Feelings:
- ☐ 0 I don't feel I am being punished.
- ☐ 1 I feel I may be punished.
- ☐ 2 I expect to be punished.
- ☐ 3 I feel I am being punished.

7 Self-Dislike:
- ☐ 0 I feel the same about myself as ever.
- ☐ 1 I have lost confidence in myself.
- ☐ 2 I am disappointed in myself.
- ☐ 3 I dislike myself.

8 Self-Criticalness:
- ☐ 0 I don't criticize or blame myself more than usual.
- ☐ 1 I am more critical of myself than I used to be.
- ☐ 2 I criticize myself for all of my faults.
- ☐ 3 I blame myself for everything that happens.

9 Suicidal Thoughts or Wishes:
- ☐ 0 I don't have any thoughts of killing myself.
- ☐ 1 I have thoughts of killing myself, but I would not carry them out.
- ☐ 2 I would like to kill myself.
- ☐ 3 I would kill myself if I had the chance.

10 Crying:
- ☐ 0 I don't cry any more than I used to.
- ☐ 1 I cry more than I used to.
- ☐ 2 I cry over every little thing.
- ☐ 3 I feel like crying, but I can't.

11 Agitation:
- ☐ 0 I am no more restless or wound up than usual.
- ☐ 1 I feel more restless or wound up than usual.
- ☐ 2 I am so restless or agitated that it's hard to stay still.
- ☐ 3 I am so restless or agitated that I have to keep moving or doing something.

12 Loss of Interest:
- ☐ 0 I have not lost interest in other people or activities.
- ☐ 1 I am less interested in other people or things than before.
- ☐ 2 I have lost most of my interest in other people or things.
- ☐ 3 It's hard to get interested in anything.

PATIENT SELF-REPORT FORM

See annotation p.8 of Baseline

3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Beck Depression Inventory (BDI) (continued)

13 Indecisiveness:

- 0 I make decisions about as well as ever.
- 1 I find it more difficult to make decisions than usual.
- 2 I have much greater difficulty in making decisions than I used to.
- 3 I have trouble making any decisions.

14 Worthlessness:

- 0 I do not feel I am worthless.
- 1 I don't consider myself as worthwhile and useful as I used to.
- 2 I feel more worthless as compared to other people.
- 3 I feel utterly worthless.

15 Loss of Energy:

- 0 I have as much energy as ever.
- 1 I have less energy than I used to have.
- 2 I don't have enough energy to do very much.
- 3 I don't have enough energy to do anything.

16 Changes in Sleeping Pattern *(check only one)*:

- 0 I have not experienced any change in my sleeping pattern.
- 1a I sleep somewhat more than usual.
- 1b I sleep somewhat less than usual.
- 2a I sleep a lot more than usual.
- 2b I sleep a lot less than usual.
- 3a I sleep most of the day.
- 3b I wake up 1–2 hours early and can't get back to sleep.

17 Irritability:

- 0 I am no more irritable than usual.
- 1 I am more irritable than usual.
- 2 I am much more irritable than usual.
- 3 I am irritable all the time.

18 Changes in Appetite *(check only one)*:

- 0 I have not experienced any change in my appetite.
- 1a My appetite is somewhat less than usual.
- 1b My appetite is somewhat greater than usual.
- 2a My appetite is much less than before.
- 2b My appetite is much greater than usual.
- 3a I have no appetite at all.
- 3b I crave food all the time.

19 Concentration Difficulty:

- 0 I can concentrate as well as ever.
- 1 I can't concentrate as well as usual.
- 2 It's hard to keep my mind on anything for very long.
- 3 I find I can't concentrate on anything.

20 Tiredness or Fatigue:

- 0 I am no more tired or fatigued than usual.
- 1 I get more tired or fatigued more easily than usual.
- 2 I am too tired or fatigued to do a lot of the things I used to do.
- 3 I am too tired or fatigued to do most of the things I used to do.

21 Loss of Interest in Sex:

- 0 I have not noticed any recent change in my interest in sex.
- 1 I am less interested in sex than I used to be.
- 2 I am much less interested in sex now.
- 3 I have lost interest in sex completely.

OUTPUT (TYPE 3)

PATIENT SELF-REPORT FORM

Productivity Assessment

1 How many days have you lost from work and/or your usual activities in the past 30 days due to problems with your health?

LOSTWK<F:9:3> days

HF-ACTION

3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Medical History

FUNYHA<I:3><ACYHA> MEDHX3 (TYPE 3)

1 Current NYHA heart failure class *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

ANGICL<I:3><ACCLAS>

2 Current Canadian Cardiovascular Society (CCS) angina class *(check only one)*: ☐ No angina ☐ I ☐ II ☐ III ☐ IV

Current Medications

CMEDLOOP(TYPE 3)

Check "No" or "Yes"; if "Yes", provide the total daily dose.

1 Loop diuretic: ☐ 0 No LOOPD<I:3><ZYESNO>

☐ 1 Yes → If Yes: Check only one and provide the **total daily dose**:

YESLOOP<I:3><ACLOOP>

☐ 1 Furosemide: _____ mg LOOPVAL<I:5>

☐ 2 Bumetanide: _____ mg

☐ 3 Torsemide: _____ mg

☐ 98 Other, *(specify)*: _____ _____ mg LOOPOTH<V:50>

Check "No" or "Yes" for each medication. NOWMEDS<I:3><ACMEDS> CMEDS3(TYPE 4)PS

MEDRESP<I:3><ZYESNO>

2 Spironolactone: ☐ 0 No ☐ 1 Yes

3 Eplerenone: ☐ 0 No ☐ 1 Yes

4 Non-loop diuretic: ☐ 0 No ☐ 1 Yes
(excluding aldosterone antagonist)

5 Potassium: ☐ 0 No ☐ 1 Yes

6 ACE inhibitor: ☐ 0 No ☐ 1 Yes

7 Angiotensin receptor blocker: ☐ 0 No ☐ 1 Yes

8 Beta blocker: ☐ 0 No ☐ 1 Yes

9 Aspirin: ☐ 0 No ☐ 1 Yes

10 Antiarrhythmic: ☐ 0 No ☐ 1 Yes

11 Lipid-lowering agent: ☐ 0 No ☐ 1 Yes

12 Clopidogrel: ☐ 0 No ☐ 1 Yes

13 Coumadin: ☐ 0 No ☐ 1 Yes

14 Digoxin: ☐ 0 No ☐ 1 Yes

15 Nitrate: ☐ 0 No ☐ 1 Yes

16 Calcium channel blocker: ☐ 0 No ☐ 1 Yes

17 Insulin: ☐ 0 No ☐ 1 Yes

18 Glitazone: ☐ 0 No ☐ 1 Yes

19 Other oral diabetic agent: ☐ 0 No ☐ 1 Yes

20 Thyroid replacement: ☐ 0 No ☐ 1 Yes

21 Selective serotonin reuptake inhibitor: ☐ 0 No ☐ 1 Yes

22 Tricyclic antidepressant: ☐ 0 No ☐ 1 Yes

23 Other antidepressant: ☐ 0 No ☐ 1 Yes
(excluding SSRIs and TCAs)

24 Antipsychotic: ☐ 0 No ☐ 1 Yes

25 NSAID: ☐ 0 No ☐ 1 Yes

26 COX-2 inhibitor: ☐ 0 No ☐ 1 Yes

27 Sildenafil: ☐ 0 No ☐ 1 Yes

CMEDS2(TYPE4)PS

See annotation p.14

Reserved for potential new drugs. **Do not complete unless instructed by the Duke Clinical Research Institute (DCRI).**

28 Other: _____ ☐ 0 No ☐ 1 Yes

29 Other: _____ ☐ 0 No ☐ 1 Yes

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Quality of Life—Reason for Missing Data

Are all quality-of-life forms complete?

- ☐ 0 No → If No:
  - ☐ 1 Patient died
  - ☐ 2 Patient refused
  - ☐ 3 Patient withdrew consent
  - ☐ 4 Patient missed visit
  - ☐ 5 Patient sick
  - ☐ 98 Other

OR

- ☐ 1 Yes

6–Minute Walk Test

1 Did the patient attempt the 6-minute walk at this visit?

- ☐ 0 No → If No: Specify primary reason:
  - ☐ Patient was too critically ill
  - ☐ Patient cannot walk for technical reasons *(e.g., a patient who is an amputee)*
  - ☐ Not done due to oversight
  - ☐ Patient refused
  - ☐ Patient died
  - ☐ Patient withdrew consent
  - ☐ Patient missed visit

OR

- ☐ 1 Yes → If Yes:

Date of 6-minute walk: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Start walk time: ___ ___ : ___ ___ (00:00 to 23:59)

Total distance walked: _____ ☐ 1 Feet ☐ 2 Meter(s)

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

☐ None ☐ Angina ☐ Light-headedness ☐ Syncope

Borg Rating of Perceived Exertion (RPE) Scale: _____ (6-20)

2 Were the QOL instruments completed before or after the 6-minute walk? Check only one:

- ☐ 1 Before
- ☐ 2 < 30 mins after
- ☐ 3 30–60 mins after
- ☐ 4 > 60 mins after

CRF ANNOTATION VERSION 6.0_11May2004

HF-ACTION

3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

1 Has the patient had any **non-urgent** outpatient visits since the last study visit? *(Do not include protocol-specified follow-up visits.)* ☐0 No ☐1 Yes → Complete the table below.

NONURG<ZYESNO>

OUTPAT (TYPE 4) PS

	Provider Type	Number of Office/Clinic Visits	Number of Home Visits
1= 1.1	Cardiologist: PROVIDER<I:3><ACPROV>	OFFVIS<I:3>	HOMVIS<I:3>
2= 1.2	Orthopedic surgeon:		
3= 1.3	Other specialist:		
4= 1.4	Primary care physician:		
5= 1.5	Physician extenders *(includes NPs, PAs, etc.)*:		
6= 1.6	OT or PT:		
7= 1.7	Mental health provider:		
8= 1.8	Nurse *(includes RNs, LPNs, nurse's aides or other equivalent)*:		
9= 1.9	Other *(specify)*: OTHPROSP<V:50>		OUTPATOT (TYPE 4)

2 Has the patient had any outpatient **cardiac** procedures/tests *(including ICD firing)* or **orthopedic** procedures/tests since the last study visit?
☐0 No ☐1 Yes → Compete the table below

OTPTPROC<ZYESNO>

OUTPAT2 (TYPE4)R

Procedure Code*	Number	Procedure Code*	Number	Procedure Code*	Number
PROCCODE<V:100>	PROCOUNT<I:3>				

*See choices on opposite page. Record one per row. If a procedure/test is not listed, please record it in the table above.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

CRF ANNOTATION VERSION 6.0_11May2004

3-Month

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

3 Has the patient required any **urgent/emergency care** on an outpatient basis since the last study visit? ☐0 No ☐1 Yes → Complete the table below.

URGENT<ZYESNO>

OUTPAT3 (TYPE4)PS

Outpatient Service Type	Number of Visits Due to Heart Failure*	Number of Visits Due to Cardiovascular Disease* (other than heart failure)	Number of Visits Due to Non-Cardiovascular Disease*	Number of Visits Due to Unknown Cause*	Number of Visits Due to a Cardiovascular Event Occurring During or Within 3 Hours After Exercise
SERVTYPE<I:3><ACSERV>					
1= **3.1** Emergency room, hospital < 24 hours, or observation unit:	HFVISIT<I:3>	CVVISIT<I:3>	NCVVISIT<I:3>	UNKVISIT<I:3>	EXVISIT<I:3>
2= **3.2** Heart failure clinic/office:					
3= **3.3** Stand-alone urgent care facility:					

NOER<I:3><ACNOER>
1= No ER visit to date
2= Previously recorded

NOUCHF<I:3><ACNOHF>
1=No urgent clinic visit for HF to date
2= Previously recorded

3.4 Date of 1st ER visit *(for any reason since randomization)*: ___ ___ / ___ ERDT / ___ ___ ___ ___ (day / month / year) OR ☐1 No ER visit to date

3.5 Date of 1st urgent clinic visit due to heart failure exacerbation *(since randomization)*: ___ ___ / ___ UCHFDT ___ ___ (day / month / year) OR ☐1 No urgent clinic visit for HF to date

OUTPAT4 (TYPE 4)

Other Types of Resource Utilization

1 Number of days on home IV infusion for heart failure since the last study visit: _____ days

IVDAYS<I:3>

RESUTIL (TYPE 4)

2 Since the last study visit, how many days did the patient live in each of the following...

Their home: HOMEDY<I:3> _____ days

Caregiver's home *(e.g., family and friends)*: CAREGVDY<I:3> _____ days

Assisted living: ASSTLVDY<I:3> _____ days

Skilled nursing facility: _____ days SKNURSDY<I:3>

Acute care hospital: ACCAREDY<I:3> _____ days

Rehabilitation center: REHABDY<I:3> _____ days

Other *(specify)*: DAYSSP<V:50> _____ OTHERDY<I:3> _____ days

*Primary diagnosis

CRF ANNOTATION VERSION 6.0_11May2004

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First page should have page rep 0

3-Month

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Hospitalization Record only hospitalizations for ≥ 24 hours.

Has the patient been hospitalized for any reason since the last completed study visit? HOSPNO (TYPE 3)

(Only include completed hospitalizations. Wait until the next study visit to record hospital information if the patient is currently hospitalized.)

☐0 No ☐1 Yes → If Yes: How many hospitalizations? HOSCOUNT<I:3>

INHOSP<ZYESNO>

HOSPITAL (TYPE 4) R

	Hospitalization:	Primary Reason for Hospitalization*	Primary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Secondary Cardiac Procedure*	Discharge Destination*
HOSPNUM<I:3>	PLANNED<I:3><ACHOS>				DISCHDES<I:3>
1 Hospitalization: Admission date: ___/___/___ (day/month/year) ADMITDT Discharge date: ___/___/___ DISCHDT	☐ Planned ☐ Unplanned	HOSPREA<I:3>	PRIMPROC<I:3>	SECPROC<I:3>	
Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes EXERHOSP<ZYESNO>					
CARDHOSP<ZYESNO>		HOSREAOT<V:100>	PRIMPROT<V:100>	SECPROT<V:100>	DISDESOT<V:100>
Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.					
2 Hospitalization: Admission date: ___/___/___ (day/month/year) Discharge date: ___/___/___	☐ Planned ☐ Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes					
Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.					
3 Hospitalization: Admission date: ___/___/___ (day/month/year) Discharge date: ___/___/___	☐ Planned ☐ Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes					
Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.					

DCRI MedDRA
MEDRCODE<V:8>
MEDRTEXT<V:100>
WORKFLOW<V:5>
~~CODETM~~
CODER<V:20>
CONFLVL<V:2>
MATCHES<V:4>

*See choices on opposite page. If a diagnosis/procedure/discharge destination is not listed, please record it in the table above.
If more than 3 hospitalizations occurred, complete an Additional Hospitalization form.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Telephone Log

TELELOG (TYPE 4)R

1 Date of call: ___/___/___ (day/month/year) TELEDT

TELENUM<I:3>

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

PROVCONT<I:3>

Changes to medications other than diuretics: _____ OTHMEDCH<I:3>

Diuretic dose increases: _____ DIURINCR<I:3>

Diuretic dose decreases: _____ DIURDECR<I:3>

Exercise Training Group: Is patient performing the training as prescribed?

TRAINING<ZYESNO>

☐0 No → **If No: Indicate primary reason code*:** _____ NQTRNCOD<I:3>

☐1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐0 No ☐1 Yes UPHYSACT<ZYESNO>

---

2 Date of call: ___/___/___ (day/month/year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐0 No → **If No: Indicate primary reason code*:** _____

☐1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐0 No ☐1 Yes

---

3 Date of call: ___/___/___ (day/month/year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐0 No → **If No: Indicate primary reason code*:** _____

☐1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐0 No ☐1 Yes

*See choices on opposite page.

If more than 3 telephone calls were completed, complete an Additional Telephone Log form.

WHITE and YELLOW — Duke Clinical Research Institute • PINK — retain at site

PROTOCOL= HFACTION
STUDYBOOK= DATA_FORMS
FORM = 6MONTH

CONTEXT

NODATA<ZYES>

6-Month

VISITDT

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

Patient's Initials: ___ ___ ___ (first middle last) INITIALS

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

EuroQoL Questionnaire

By placing a checkmark in one box in each group below, please indicate which statement best describes your own health state today.

See annotation p.3 of Baseline

1 Mobility:

- ☐ 1 I have no problems in walking about.
- ☐ 2 I have some problems in walking about.
- ☐ 3 I am confined to bed.

2 Self-care:

- ☐ 1 I have no problems with self-care.
- ☐ 2 I have some problems washing or dressing myself.
- ☐ 3 I am unable to wash or dress myself.

3 Usual activities *(e.g. work, study, housework, family or leisure activities)*:

- ☐ 1 I have no problems with performing my usual activities.
- ☐ 2 I have some problems with performing my usual activities.
- ☐ 3 I am unable to perform my usual activities.

4 Pain/discomfort:

- ☐ 1 I have no pain or discomfort.
- ☐ 2 I have moderate pain or discomfort.
- ☐ 3 I have extreme pain or discomfort.

5 Anxiety/depression:

- ☐ 1 I am not anxious or depressed.
- ☐ 2 I am moderately anxious or depressed.
- ☐ 3 I am extremely anxious or depressed.

STOP → **Please let your study coordinator know that you are ready for the EuroQoL Thermometer worksheet.**

PATIENT SELF-REPORT FORM

Pain Assessment

1 How much bodily pain have you had during the past 4 weeks *(check only one)*?

☐ 1 None ☐ 2 Very mild ☐ 3 Mild ☐ 4 Moderate ☐ 5 Severe ☐ 6 Very severe

2 During the past 4 weeks, how much did pain interfere with your normal work *(including both work outside the home and housework)*?

☐ 1 Not at all ☐ 2 A little bit ☐ 3 Moderately ☐ 4 Quite a bit ☐ 5 Extremely

EuroQol Thermometer Response

Response to the EuroQoL thermometer: ___ ___ ___ (0-100)

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Kansas City Cardiomyopathy Questionnaire (KCCQ)

PATIENT SELF-REPORT FORM

The following questions refer to your heart failure and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answers that best apply to you.

1 **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** *(shortness of breath or fatigue)* in your ability to do the following activities over the past 2 weeks.

(Check only one box on each line.)

Activity	Extremely Limited	Quite a Bit Limited	Moderately Limited	Slightly Limited	Not at All Limited	Limited for Other Reasons or Did Not Do the Activity
Dressing yourself:	☐1	☐2	☐3	☐4	☐5	☐6
Showering/bathing:	☐1	☐2	☐3	☐4	☐5	☐6
Walking 1 block on level ground:	☐1	☐2	☐3	☐4	☐5	☐6
Doing yard work, housework or carrying groceries:	☐1	☐2	☐3	☐4	☐5	☐6
Climbing a flight of stairs without stopping:	☐1	☐2	☐3	☐4	☐5	☐6
Hurrying or jogging *(as if to catch a bus)*:	☐1	☐2	☐3	☐4	☐5	☐6

2 Compared with 2 weeks ago, have your symptoms of **heart failure** *(shortness of breath, fatigue, or ankle swelling)* changed? My symptoms of heart failure have become...

Much worse	Slightly worse	Not changed	Slightly better	Much better	I've had no symptoms over the last 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6

3 Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in the morning?

Every morning	3 or more times a week, but not every morning	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5

4 Over the past 2 weeks, how much has **swelling** in your feet, ankles or legs bothered you? It has been...

Extremely bothersome	**Moderately** bothersome	**Somewhat** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no swelling**
☐1	☐2	☐3	☐4	☐5	☐6

HF ACTION

6-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

5 Over the <u>past 2 weeks</u>, on average, how many times has **fatigue** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

6 Over the <u>past 2 weeks</u>, how much has your **fatigue** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no fatigue**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

7 Over the <u>past 2 weeks</u>, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

8 Over the <u>past 2 weeks</u>, how much has your **shortness of breath** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no shortness of breath**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

9 Over the <u>past 2 weeks</u>, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

Every night	3 or more times a week, but not every night	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10 **Heart failure** symptoms can worsen for a number of reasons. How sure are you that you know what to do or who to call, if your **heart failure** gets worse?

Not at all sure	**Not very** sure	**Somewhat** sure	**Mostly** sure	**Completely** sure
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11 How well do you understand what things you are able to do to keep your **heart failure** symptoms from getting **worse** *(for example, weighing yourself, eating a low-salt diet etc.)*?

Do not understand at all	Do not understand very well	Somewhat understand	Mostly understand	Completely understand
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

PATIENT SELF-REPORT FORM

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

12 Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not limited** my enjoyment of life at all
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

13 If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

Not at all satisfied	**Mostly** dissatisfied	**Somewhat** satisfied	**Mostly** satisfied	**Completely** satisfied
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

14 Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of your **heart failure**?

I felt that way **all of the time**	I felt that way **most of the time**	I **occasionally** felt that way	I **rarely** felt that way	I **never** felt that way
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

15 How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks.

(Check only one box on each line.)

Activity	Severely Limited	Limited Quite a Bit	Moderately Limited	Slightly Limited	Did Not Limit at All	Does Not Apply or Did Not Do for Other Reasons
Hobbies, recreational activities:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Intimate relationships with loved ones:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Visiting family or friends out of your home:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Working or doing household chores:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

PATIENT SELF-REPORT FORM

See annotation p.7 of Baseline

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Beck Depression Inventory (BDI)

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the past one week, including today. Check the box beside the statement you have picked. If several statements within a group seem to apply equally well, check the highest numbered box for that group. Be sure that you do not choose more than one statement for any group, including item 16, Changes in Sleeping Pattern and item 18, Changes in Appetite.

1 Sadness:
- ☐ 0 I do not feel sad.
- ☐ 1 I feel sad much of the time.
- ☐ 2 I am sad all of the time.
- ☐ 3 I am so sad or unhappy that I can't stand it.

2 Pessimism:
- ☐ 0 I am not discouraged about my future.
- ☐ 1 I feel more discouraged about my future than I used to be.
- ☐ 2 I do not expect things to work out for me.
- ☐ 3 I feel my future is hopeless and will only get worse.

3 Past Failure:
- ☐ 0 I do not feel like a failure.
- ☐ 1 I have failed more than I should have.
- ☐ 2 As I look back, I see a lot of failures.
- ☐ 3 I feel I am a total failure as a person.

4 Loss of Pleasure:
- ☐ 0 I get as much pleasure as I ever did from the things I enjoy.
- ☐ 1 I don't enjoy things as much as I used to.
- ☐ 2 I get very little pleasure from the things I used to enjoy.
- ☐ 3 I can't get any pleasure from the things I used to enjoy.

5 Guilty Feelings:
- ☐ 0 I don't feel particularly guilty.
- ☐ 1 I feel guilty over many things I have done or should have done.
- ☐ 2 I feel quite guilty most of the time.
- ☐ 3 I feel guilty all of the time.

6 Punishment Feelings:
- ☐ 0 I don't feel I am being punished.
- ☐ 1 I feel I may be punished.
- ☐ 2 I expect to be punished.
- ☐ 3 I feel I am being punished.

7 Self-Dislike:
- ☐ 0 I feel the same about myself as ever.
- ☐ 1 I have lost confidence in myself.
- ☐ 2 I am disappointed in myself.
- ☐ 3 I dislike myself.

8 Self-Criticalness:
- ☐ 0 I don't criticize or blame myself more than usual.
- ☐ 1 I am more critical of myself than I used to be.
- ☐ 2 I criticize myself for all of my faults.
- ☐ 3 I blame myself for everything that happens.

9 Suicidal Thoughts or Wishes:
- ☐ 0 I don't have any thoughts of killing myself.
- ☐ 1 I have thoughts of killing myself, but I would not carry them out.
- ☐ 2 I would like to kill myself.
- ☐ 3 I would kill myself if I had the chance.

10 Crying:
- ☐ 0 I don't cry any more than I used to.
- ☐ 1 I cry more than I used to.
- ☐ 2 I cry over every little thing.
- ☐ 3 I feel like crying, but I can't.

11 Agitation:
- ☐ 0 I am no more restless or wound up than usual.
- ☐ 1 I feel more restless or wound up than usual.
- ☐ 2 I am so restless or agitated that it's hard to stay still.
- ☐ 3 I am so restless or agitated that I have to keep moving or doing something.

12 Loss of Interest:
- ☐ 0 I have not lost interest in other people or activities.
- ☐ 1 I am less interested in other people or things than before.
- ☐ 2 I have lost most of my interest in other people or things.
- ☐ 3 It's hard to get interested in anything.

PATIENT SELF-REPORT FORM

Beck Depression Inventory (BDI) (continued)

13 Indecisiveness:

- ☐ 0 I make decisions about as well as ever.
- ☐ 1 I find it more difficult to make decisions than usual.
- ☐ 2 I have much greater difficulty in making decisions than I used to.
- ☐ 3 I have trouble making any decisions.

14 Worthlessness:

- ☐ 0 I do not feel I am worthless.
- ☐ 1 I don't consider myself as worthwhile and useful as I used to.
- ☐ 2 I feel more worthless as compared to other people.
- ☐ 3 I feel utterly worthless.

15 Loss of Energy:

- ☐ 0 I have as much energy as ever.
- ☐ 1 I have less energy than I used to have.
- ☐ 2 I don't have enough energy to do very much.
- ☐ 3 I don't have enough energy to do anything.

16 Changes in Sleeping Pattern *(check only one)*:

- ☐ 0 I have not experienced any change in my sleeping pattern.
- ☐ 1a I sleep somewhat more than usual.
- ☐ 1b I sleep somewhat less than usual.
- ☐ 2a I sleep a lot more than usual.
- ☐ 2b I sleep a lot less than usual.
- ☐ 3a I sleep most of the day.
- ☐ 3b I wake up 1–2 hours early and can't get back to sleep.

17 Irritability:

- ☐ 0 I am no more irritable than usual.
- ☐ 1 I am more irritable than usual.
- ☐ 2 I am much more irritable than usual.
- ☐ 3 I am irritable all the time.

18 Changes in Appetite *(check only one)*:

- ☐ 0 I have not experienced any change in my appetite.
- ☐ 1a My appetite is somewhat less than usual.
- ☐ 1b My appetite is somewhat greater than usual.
- ☐ 2a My appetite is much less than before.
- ☐ 2b My appetite is much greater than usual.
- ☐ 3a I have no appetite at all.
- ☐ 3b I crave food all the time.

19 Concentration Difficulty:

- ☐ 0 I can concentrate as well as ever.
- ☐ 1 I can't concentrate as well as usual.
- ☐ 2 It's hard to keep my mind on anything for very long.
- ☐ 3 I find I can't concentrate on anything.

20 Tiredness or Fatigue:

- ☐ 0 I am no more tired or fatigued than usual.
- ☐ 1 I get more tired or fatigued more easily than usual.
- ☐ 2 I am too tired or fatigued to do a lot of the things I used to do.
- ☐ 3 I am too tired or fatigued to do most of the things I used to do.

21 Loss of Interest in Sex:

- ☐ 0 I have not noticed any recent change in my interest in sex.
- ☐ 1 I am less interested in sex than I used to be.
- ☐ 2 I am much less interested in sex now.
- ☐ 3 I have lost interest in sex completely.

See annotation p. 23 of 3-Month

PATIENT SELF-REPORT FORM

Productivity Assessment

1 How many days have you lost from work and/or your usual activities in the past 30 days due to problems with your health?

_____ days

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Physical Activity Questionnaire (PAQ)

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the last 7 days. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous physical activities** that you did in the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

1 During the last 7 days, on how many days did you do **vigorous physical activities** like heavy lifting, digging, aerobics, or fast bicycling?

_____ days → **Continue to question 2.**

OR ☐ No vigorous physical activities → **Skip to question 3.**

2 How much time did you usually spend doing **vigorous physical activities** on one of those days?

___ ___ ___ minutes per day

OR ☐ Don't know/not sure

Think about all the **moderate physical activities** that you did in the last 7 days. Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3 During the last 7 days, on how many days did you do **moderate physical activities** like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ days → **Continue to question 4.**

OR ☐ No moderate physical activities → **Skip to question 5.**

4 How much time did you usually spend doing **moderate physical activities** on one of those days?

___ ___ ___ minutes per day

OR ☐ Don't know/not sure

Think about the time you spent **walking** in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5 During the last 7 days, on how many days did you **walk** for at least 10 minutes at a time?

_____ days → **Continue to question 6.**

OR ☐ No walking → **Skip to question 7.**

6 How much time did you usually spend **walking** on one of those days?

___ ___ ___ minutes per day

OR ☐ Don't know/not sure

The last question is about the time you spent **sitting on weekdays** during the last 7 days. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7 During the last 7 days, how much time did you spend **sitting on a weekday**?

___ ___ hours per day

OR ☐ Don't know/not sure

PATIENT SELF-REPORT FORM

Medical History

1 **Current NYHA heart failure class** *(check only one)*: ☐ I ☐ II ☐ III ☐ IV See annotation p.24 of 3-Month

2 **Current Canadian Cardiovascular Society (CCS) angina class** *(check only one)*: ☐ No angina ☐ I ☐ II ☐ III ☐ IV

Current Medications

Check "No" or "Yes" for each medication and provide the total daily dose, if applicable. See annotation p.13 of Baseline

1 **ACE inhibitor:**

☐ 0 No → **Reason for not using** *(check only one)*: ☐ 1 Contraindicated ☐ 2 Intolerance ☐ 3 MD preference ☐ 4 Patient preference

☐ 1 Yes → **If Yes: Check only one and provide the TOTAL DAILY DOSE:**

- ☐ 1 Benazepril: _____ mg
- ☐ 2 Captopril: _____ mg
- ☐ 3 Enalapril: _____ mg
- ☐ 4 Fosinopril: _____ mg
- ☐ 5 Lisinopril: _____ mg
- ☐ 6 Quinapril: _____ mg
- ☐ 7 Ramipril: _____ mg
- ☐ 8 Trandolapril: _____ mg
- ☐ 98 Other *(specify)*: _____ _____ mg

2 **Angiotensin receptor blocker:**

☐ 0 No

☐ 1 Yes → **If Yes: Check all that apply:** ☐ Valsartan ☐ Losartan ☐ Irbesartan ☐ Candesartan ☐ Other *(specify)*: _____

3 **Beta blocker:**

☐ 0 No → **Reason for not using** *(check only one)*: ☐ 1 Contraindicated ☐ 2 Intolerance ☐ 3 MD preference ☐ 4 Patient preference

☐ 1 Yes → **If Yes: Check only one and provide the TOTAL DAILY DOSE:**

- ☐ 1 Atenolol: _____ mg
- ☐ 2 Bisoprolol: _____ mg
- ☐ 3 Carvedilol: _____ mg
- ☐ 4 Metoprolol immediate release: _____ mg
- ☐ 5 Metoprolol XL: _____ mg
- ☐ 98 Other *(specify)*: _____ _____ mg

4 **Aspirin:**

☐ 0 No → **Reason for not using** *(check only one)*: ☐ 1 Contraindicated ☐ 2 Intolerance ☐ 3 MD preference ☐ 4 Patient preference

☐ 1 Yes → **If Yes: Dose:** _____ mg

5 **Loop diuretic:**

☐ 0 No

☐ 1 Yes → **If Yes: Check only one and provide the TOTAL DAILY DOSE:**

- ☐ 1 Furosemide: _____ mg
- ☐ 2 Bumetanide: _____ mg
- ☐ 3 Torsemide: _____ mg
- ☐ 98 Other *(specify)*: _____ _____ mg

6 **Antiarrhythmic:**

☐ 0 No

☐ 1 Yes → **If Yes: Check all that apply:** ☐ Amiodarone ☐ Sotalol ☐ Dofetilide ☐ Other *(specify)*: _____

7 **Lipid-lowering agent:**

☐ 0 No

☐ 1 Yes → **If Yes: Check only one:** ☐ 1 HMG-CoA reductase inhibitor → **Check all that apply:** ☐ Atorvastatin ☐ Pravastatin ☐ Simvastatin ☐ Other

☐ 2 Other lipid-lowering agent

8 **Selective serotonin reuptake inhibitor:**

☐ 0 No

☐ 1 Yes → **Check all that apply:** ☐ Sertraline ☐ Citalopram ☐ Paroxetine ☐ Fluoxetine ☐ Other

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Current Medications

Check "No" or "Yes" for each medication.

9	Tricyclic antidepressant:	☐ 0 No	☐ 1 Yes
10	Other antidepressant *(excluding SSRIs and TCAs)*:	☐ 0 No	☐ 1 Yes
11	Antipsychotic:	☐ 0 No	☐ 1 Yes
12	Clopidogrel:	☐ 0 No	☐ 1 Yes
13	Coumadin:	☐ 0 No	☐ 1 Yes
14	Digoxin:	☐ 0 No	☐ 1 Yes
15	Nitrate:	☐ 0 No	☐ 1 Yes
16	Calcium channel blocker:	☐ 0 No	☐ 1 Yes
17	Spironolactone:	☐ 0 No	☐ 1 Yes
18	Eplerenone:	☐ 0 No	☐ 1 Yes
19	Non-loop diuretic *(excluding aldosterone antagonist)*:	☐ 0 No	☐ 1 Yes
20	Potassium:	☐ 0 No	☐ 1 Yes
21	Insulin:	☐ 0 No	☐ 1 Yes
22	Glitazone:	☐ 0 No	☐ 1 Yes
23	Other oral diabetic agent:	☐ 0 No	☐ 1 Yes
24	Thyroid replacement:	☐ 0 No	☐ 1 Yes
25	NSAID:	☐ 0 No	☐ 1 Yes
26	COX-2 inhibitor:	☐ 0 No	☐ 1 Yes
27	Sildenafil:	☐ 0 No	☐ 1 Yes

Reserved for potential new drugs. **Do not complete unless instructed by the Duke Clinical Research Institute (DCRI).**

28	Other: _____	☐ 0 No	☐ 1 Yes
29	Other: _____	☐ 0 No	☐ 1 Yes

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Quality of Life—Reason for Missing Data

Are all quality-of-life forms complete?

- ☐ 0 No → **If No:**
  - ☐ 1 Patient died
  - ☐ 2 Patient refused
  - ☐ 3 Patient withdrew consent
  - ☐ 4 Patient missed visit
  - ☐ 5 Patient sick
  - ☐ 98 Other

OR

- ☐ 1 Yes

See annotation p.26 of 3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

1 Has the patient had any **non-urgent** outpatient visits since the last study visit? *(Do not include protocol-specified follow-up visits.)* ☐ 0 No ☐ 1 Yes → **Complete the table below.**

	Provider Type	Number of Office/Clinic Visits	Number of Home Visits
1.1	Cardiologist:		
1.2	Orthopedic surgeon:		
1.3	Other specialist:		
1.4	Primary care physician:		
1.5	Physician extenders *(includes NPs, PAs, etc.)*:		
1.6	OT or PT:		
1.7	Mental health provider:		
1.8	Nurse *(includes RNs, LPNs, nurse's aides or other equivalent)*:		
1.9	Other *(specify)*: _____		

2 Has the patient had any outpatient **cardiac** procedures/tests *(including ICD firing)* or **orthopedic** procedures/tests since the last study visit?
☐ 0 No ☐ 1 Yes → **Compete the table below.**

Procedure Code*	Number	Procedure Code*	Number	Procedure Code*	Number

*See choices on opposite page. Record one per row. If a procedure/test is not listed, please record it in the table above.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

See annotation p.27 of 3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

3 Has the patient required any **urgent/emergency care** on an outpatient basis since the last study visit? ☐0 No ☐1 Yes → Complete the table below.

	Outpatient Service Type	Number of Visits Due to Heart Failure*	Number of Visits Due to Cardiovascular Disease* (other than heart failure)	Number of Visits Due to Non-Cardiovascular Disease*	Number of Visits Due to Unknown Cause*	Number of Visits Due to a Cardiovascular Event Occurring During or Within 3 Hours After Exercise
3.1	Emergency room, hospital < 24 hours, or observation unit:					
3.2	Heart failure clinic/office:					
3.3	Stand-alone urgent care facility:					

3.4 Date of 1st ER visit *(for any reason since randomization)*: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐1 No ER visit to date ☐2 Previously recorded

3.5 Date of 1st urgent clinic visit due to heart failure exacerbation *(since randomization)*: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐1 No urgent clinic visit for HF to date ☐2 Previously recorded

Other Types of Resource Utilization

1 Number of days on home IV infusion for heart failure since the last study visit: _____ days

2 Since the last study visit, how many days did the patient live in each of the following...

Their home: _____ days

Caregiver's home *(e.g., family and friends)*: _____ days

Assisted living: _____ days

Skilled nursing facility: _____ days

Acute care hospital: _____ days

Rehabilitation center: _____ days

Other *(specify)*: _____ _____ days

*Primary diagnosis

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Hospitalization Record only hospitalizations for ≥ 24 hours.

Has the patient been hospitalized for any reason since the last completed study visit?

(Only include completed hospitalizations. Wait until the next study visit to record hospital information if the patient is currently hospitalized.)

☐0 No ☐1 Yes → If Yes: How many hospitalizations? _____

	Hospitalization:	Primary Reason for Hospitalization*	Primary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Secondary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Discharge Destination*
1 Hospitalization: Admission date: ___/___/___ (day/month/year) Discharge date: ___/___/___ Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
2 Hospitalization: Admission date: ___/___/___ Discharge date: ___/___/___ Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
3 Hospitalization: Admission date: ___/___/___ Discharge date: ___/___/___ Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				

*See choices on opposite page. If a diagnosis/procedure/discharge destination is not listed, please record it in the table above.

If more than 3 hospitalizations occurred, complete an Additional Hospitalization form.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

This is a repeating page
First page should have page rep 0

See annotation p.29 of 3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Telephone Log

1 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → If ≥ 1: How many of the contacts resulted in:

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

2 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → If ≥ 1: How many of the contacts resulted in:

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

3 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → If ≥ 1: How many of the contacts resulted in:

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

*See choices on opposite page.

If more than 3 telephone calls were completed, complete an Additional Telephone Log form.

WHITE and YELLOW — Duke Clinical Research Institute • PINK — retain at site

CRF ANNOTATION VERSION 6.0_11May2004

CONTEXT

NODATA<ZYES>

PROTOCOL = HFACTION
STUDYBOOK = DATA_FORMS
FORM = 9MONTH

VISITDT

SUBJNO

INITIALS

HF ACTION

9-Month

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

Patient's Initials: ___ ___ ___ (first middle last)

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

EuroQoL Questionnaire

By placing a checkmark in one box in each group below, please indicate which statement best describes your own health state today.

See annotation p.3 of Baseline

1 Mobility:

- ☐ 1 I have no problems in walking about.
- ☐ 2 I have some problems in walking about.
- ☐ 3 I am confined to bed.

2 Self-care:

- ☐ 1 I have no problems with self-care.
- ☐ 2 I have some problems washing or dressing myself.
- ☐ 3 I am unable to wash or dress myself.

3 Usual activities *(e.g. work, study, housework, family or leisure activities)*:

- ☐ 1 I have no problems with performing my usual activities.
- ☐ 2 I have some problems with performing my usual activities.
- ☐ 3 I am unable to perform my usual activities.

4 Pain/discomfort:

- ☐ 1 I have no pain or discomfort.
- ☐ 2 I have moderate pain or discomfort.
- ☐ 3 I have extreme pain or discomfort.

5 Anxiety/depression:

- ☐ 1 I am not anxious or depressed.
- ☐ 2 I am moderately anxious or depressed.
- ☐ 3 I am extremely anxious or depressed.

STOP → **Please let your study coordinator know that you are ready for the EuroQoL Thermometer worksheet.**

PATIENT SELF-REPORT FORM

Pain Assessment

1 How much bodily pain have you had during the past 4 weeks *(check only one)*?

☐ 1 None ☐ 2 Very mild ☐ 3 Mild ☐ 4 Moderate ☐ 5 Severe ☐ 6 Very severe

2 During the past 4 weeks, how much did pain interfere with your normal work *(including both work outside the home and housework)*?

☐ 1 Not at all ☐ 2 A little bit ☐ 3 Moderately ☐ 4 Quite a bit ☐ 5 Extremely

EuroQol Thermometer Response

Response to the EuroQoL thermometer: ___ ___ ___ *(0-100)*

HF ACTION

9-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Kansas City Cardiomyopathy Questionnaire (KCCQ)

The following questions refer to your heart failure and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answers that best apply to you.

1 **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** *(shortness of breath or fatigue)* in your ability to do the following activities over the past 2 weeks.

(Check only one box on each line.)

Activity	Extremely Limited	Quite a Bit Limited	Moderately Limited	Slightly Limited	Not at All Limited	Limited for Other Reasons or Did Not Do the Activity
Dressing yourself:	☐1	☐2	☐3	☐4	☐5	☐6
Showering/bathing:	☐1	☐2	☐3	☐4	☐5	☐6
Walking 1 block on level ground:	☐1	☐2	☐3	☐4	☐5	☐6
Doing yard work, housework or carrying groceries:	☐1	☐2	☐3	☐4	☐5	☐6
Climbing a flight of stairs without stopping:	☐1	☐2	☐3	☐4	☐5	☐6
Hurrying or jogging *(as if to catch a bus)*:	☐1	☐2	☐3	☐4	☐5	☐6

2 Compared with 2 weeks ago, have your symptoms of **heart failure** *(shortness of breath, fatigue, or ankle swelling)* changed? My symptoms of heart failure have become...

Much worse	Slightly worse	Not changed	Slightly better	Much better	I've had no symptoms over the last 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6

3 Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in the morning?

Every morning	3 or more times a week, but not every morning	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5

4 Over the past 2 weeks, how much has **swelling** in your feet, ankles or legs bothered you? It has been...

Extremely bothersome	**Moderately** bothersome	**Somewhat** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no swelling**
☐1	☐2	☐3	☐4	☐5	☐6

PATIENT SELF-REPORT FORM

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

5 Over the <u>past 2 weeks</u>, on average, how many times has **fatigue** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6	☐7

6 Over the <u>past 2 weeks</u>, how much has your **fatigue** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no fatigue**
☐1	☐2	☐3	☐4	☐5	☐6

7 Over the <u>past 2 weeks</u>, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6	☐7

8 Over the <u>past 2 weeks</u>, how much has your **shortness of breath** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no shortness of breath**
☐1	☐2	☐3	☐4	☐5	☐6

9 Over the <u>past 2 weeks</u>, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

Every night	3 or more times a week, but not every night	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5

10 **Heart failure** symptoms can worsen for a number of reasons. How sure are you that you know what to do or who to call, if your **heart failure** gets worse?

Not at all sure	**Not very** sure	**Somewhat** sure	**Mostly** sure	**Completely** sure
☐1	☐2	☐3	☐4	☐5

11 How well do you understand what things you are able to do to keep your **heart failure** symptoms from getting **worse** *(for example, weighing yourself, eating a low-salt diet etc.)*?

Do not understand at all	Do not understand very well	Somewhat understand	Mostly understand	Completely understand
☐1	☐2	☐3	☐4	☐5

PATIENT SELF-REPORT FORM

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

12 Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not limited** my enjoyment of life at all
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

13 If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

Not at all satisfied	**Mostly** dissatisfied	**Somewhat** satisfied	**Mostly** satisfied	**Completely** satisfied
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

14 Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of your **heart failure**?

I felt that way **all of the time**	I felt that way **most of the time**	I **occasionally** felt that way	I **rarely** felt that way	I **never** felt that way
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

15 How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks.

(Check only one box on each line.)

Activity	Severely Limited	Limited Quite a Bit	Moderately Limited	Slightly Limited	Did Not Limit at All	Does Not Apply or Did Not Do for Other Reasons
Hobbies, recreational activities:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Intimate relationships with loved ones:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Visiting family or friends out of your home:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Working or doing household chores:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

PATIENT SELF-REPORT FORM

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Beck Depression Inventory (BDI)

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the past one week, including today. Check the box beside the statement you have picked. If several statements within a group seem to apply equally well, check the highest numbered box for that group. Be sure that you do not choose more than one statement for any group, including item 16, Changes in Sleeping Pattern and item 18, Changes in Appetite.

1 Sadness:
- ☐ 0 I do not feel sad.
- ☐ 1 I feel sad much of the time.
- ☐ 2 I am sad all of the time.
- ☐ 3 I am so sad or unhappy that I can't stand it.

2 Pessimism:
- ☐ 0 I am not discouraged about my future.
- ☐ 1 I feel more discouraged about my future than I used to be.
- ☐ 2 I do not expect things to work out for me.
- ☐ 3 I feel my future is hopeless and will only get worse.

3 Past Failure:
- ☐ 0 I do not feel like a failure.
- ☐ 1 I have failed more than I should have.
- ☐ 2 As I look back, I see a lot of failures.
- ☐ 3 I feel I am a total failure as a person.

4 Loss of Pleasure:
- ☐ 0 I get as much pleasure as I ever did from the things I enjoy.
- ☐ 1 I don't enjoy things as much as I used to.
- ☐ 2 I get very little pleasure from the things I used to enjoy.
- ☐ 3 I can't get any pleasure from the things I used to enjoy.

5 Guilty Feelings:
- ☐ 0 I don't feel particularly guilty.
- ☐ 1 I feel guilty over many things I have done or should have done.
- ☐ 2 I feel quite guilty most of the time.
- ☐ 3 I feel guilty all of the time.

6 Punishment Feelings:
- ☐ 0 I don't feel I am being punished.
- ☐ 1 I feel I may be punished.
- ☐ 2 I expect to be punished.
- ☐ 3 I feel I am being punished.

7 Self-Dislike:
- ☐ 0 I feel the same about myself as ever.
- ☐ 1 I have lost confidence in myself.
- ☐ 2 I am disappointed in myself.
- ☐ 3 I dislike myself.

8 Self-Criticalness:
- ☐ 0 I don't criticize or blame myself more than usual.
- ☐ 1 I am more critical of myself than I used to be.
- ☐ 2 I criticize myself for all of my faults.
- ☐ 3 I blame myself for everything that happens.

9 Suicidal Thoughts or Wishes:
- ☐ 0 I don't have any thoughts of killing myself.
- ☐ 1 I have thoughts of killing myself, but I would not carry them out.
- ☐ 2 I would like to kill myself.
- ☐ 3 I would kill myself if I had the chance.

10 Crying:
- ☐ 0 I don't cry any more than I used to.
- ☐ 1 I cry more than I used to.
- ☐ 2 I cry over every little thing.
- ☐ 3 I feel like crying, but I can't.

11 Agitation:
- ☐ 0 I am no more restless or wound up than usual.
- ☐ 1 I feel more restless or wound up than usual.
- ☐ 2 I am so restless or agitated that it's hard to stay still.
- ☐ 3 I am so restless or agitated that I have to keep moving or doing something.

12 Loss of Interest:
- ☐ 0 I have not lost interest in other people or activities.
- ☐ 1 I am less interested in other people or things than before.
- ☐ 2 I have lost most of my interest in other people or things.
- ☐ 3 It's hard to get interested in anything.

PATIENT SELF-REPORT FORM

Beck Depression Inventory (BDI) (continued)

13 Indecisiveness:

- ☐ 0 I make decisions about as well as ever.
- ☐ 1 I find it more difficult to make decisions than usual.
- ☐ 2 I have much greater difficulty in making decisions than I used to.
- ☐ 3 I have trouble making any decisions.

14 Worthlessness:

- ☐ 0 I do not feel I am worthless.
- ☐ 1 I don't consider myself as worthwhile and useful as I used to.
- ☐ 2 I feel more worthless as compared to other people.
- ☐ 3 I feel utterly worthless.

15 Loss of Energy:

- ☐ 0 I have as much energy as ever.
- ☐ 1 I have less energy than I used to have.
- ☐ 2 I don't have enough energy to do very much.
- ☐ 3 I don't have enough energy to do anything.

16 Changes in Sleeping Pattern *(check only one)*:

- ☐ 0 I have not experienced any change in my sleeping pattern.
- ☐ 1a I sleep somewhat more than usual.
- ☐ 1b I sleep somewhat less than usual.
- ☐ 2a I sleep a lot more than usual.
- ☐ 2b I sleep a lot less than usual.
- ☐ 3a I sleep most of the day.
- ☐ 3b I wake up 1–2 hours early and can't get back to sleep.

17 Irritability:

- ☐ 0 I am no more irritable than usual.
- ☐ 1 I am more irritable than usual.
- ☐ 2 I am much more irritable than usual.
- ☐ 3 I am irritable all the time.

18 Changes in Appetite *(check only one)*:

- ☐ 0 I have not experienced any change in my appetite.
- ☐ 1a My appetite is somewhat less than usual.
- ☐ 1b My appetite is somewhat greater than usual.
- ☐ 2a My appetite is much less than before.
- ☐ 2b My appetite is much greater than usual.
- ☐ 3a I have no appetite at all.
- ☐ 3b I crave food all the time.

19 Concentration Difficulty:

- ☐ 0 I can concentrate as well as ever.
- ☐ 1 I can't concentrate as well as usual.
- ☐ 2 It's hard to keep my mind on anything for very long.
- ☐ 3 I find I can't concentrate on anything.

20 Tiredness or Fatigue:

- ☐ 0 I am no more tired or fatigued than usual.
- ☐ 1 I get more tired or fatigued more easily than usual.
- ☐ 2 I am too tired or fatigued to do a lot of the things I used to do.
- ☐ 3 I am too tired or fatigued to do most of the things I used to do.

21 Loss of Interest in Sex:

- ☐ 0 I have not noticed any recent change in my interest in sex.
- ☐ 1 I am less interested in sex than I used to be.
- ☐ 2 I am much less interested in sex now.
- ☐ 3 I have lost interest in sex completely.

See annotation p.23 of 3-Month

PATIENT SELF-REPORT FORM

Productivity Assessment

1 How many days have you lost from work and/or your usual activities in the past 30 days due to problems with your health?

_____ days

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Medical History

1 Current NYHA heart failure class *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

2 Current Canadian Cardiovascular Society (CCS) angina class *(check only one)*: ☐ No angina ☐ I ☐ II ☐ III ☐ IV

Current Medications

Check "No" or "Yes"; if "Yes", provide the total daily dose.

1 Loop diuretic: ☐$_0$ No
☐$_1$ Yes → If Yes: Check only one and provide the **total daily dose**:
☐$_1$ Furosemide: _____ mg ☐$_3$ Torsemide: _____ mg
☐$_2$ Bumetanide: _____ mg ☐$_{98}$ Other, *(specify)*: _____ _____ mg

Check "No" or "Yes" for each medication.

2 Spironolactone: ☐$_0$ No ☐$_1$ Yes

3 Eplerenone: ☐$_0$ No ☐$_1$ Yes

4 Non-loop diuretic: ☐$_0$ No ☐$_1$ Yes
(excluding aldosterone antagonist)

5 Potassium: ☐$_0$ No ☐$_1$ Yes

6 ACE inhibitor: ☐$_0$ No ☐$_1$ Yes

7 Angiotensin receptor blocker: ☐$_0$ No ☐$_1$ Yes

8 Beta blocker: ☐$_0$ No ☐$_1$ Yes

9 Aspirin: ☐$_0$ No ☐$_1$ Yes

10 Antiarrhythmic: ☐$_0$ No ☐$_1$ Yes

11 Lipid-lowering agent: ☐$_0$ No ☐$_1$ Yes

12 Clopidogrel: ☐$_0$ No ☐$_1$ Yes

13 Coumadin: ☐$_0$ No ☐$_1$ Yes

14 Digoxin: ☐$_0$ No ☐$_1$ Yes

15 Nitrate: ☐$_0$ No ☐$_1$ Yes

16 Calcium channel blocker: ☐$_0$ No ☐$_1$ Yes

17 Insulin: ☐$_0$ No ☐$_1$ Yes

18 Glitazone: ☐$_0$ No ☐$_1$ Yes

19 Other oral diabetic agent: ☐$_0$ No ☐$_1$ Yes

20 Thyroid replacement: ☐$_0$ No ☐$_1$ Yes

21 Selective serotonin reuptake inhibitor: ☐$_0$ No ☐$_1$ Yes

22 Tricyclic antidepressant: ☐$_0$ No ☐$_1$ Yes

23 Other antidepressant: ☐$_0$ No ☐$_1$ Yes
(excluding SSRIs and TCAs)

24 Antipsychotic: ☐$_0$ No ☐$_1$ Yes

25 NSAID: ☐$_0$ No ☐$_1$ Yes

26 COX-2 inhibitor: ☐$_0$ No ☐$_1$ Yes

27 Sildenafil: ☐$_0$ No ☐$_1$ Yes

Reserved for potential new drugs. **Do not complete unless instructed by the Duke Clinical Research Institute (DCRI).**

28 Other: _____ ☐$_0$ No ☐$_1$ Yes

29 Other: _____ ☐$_0$ No ☐$_1$ Yes

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Quality of Life—Reason for Missing Data

Are all quality-of-life forms complete?

- ☐ 0 No → **If No:**
  - ☐ 1 Patient died
  - ☐ 2 Patient refused
  - ☐ 3 Patient withdrew consent
  - ☐ 4 Patient missed visit
  - ☐ 5 Patient sick
  - ☐ 98 Other

OR

- ☐ 1 Yes

See annotation p.26 of 3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

1 Has the patient had any **non-urgent** outpatient visits since the last study visit? *(Do not include protocol-specified follow-up visits.)* ☐0 No ☐1 Yes → **Complete the table below.**

	Provider Type	Number of Office/Clinic Visits	Number of Home Visits
1.1	Cardiologist:		
1.2	Orthopedic surgeon:		
1.3	Other specialist:		
1.4	Primary care physician:		
1.5	Physician extenders *(includes NPs, PAs, etc.)*:		
1.6	OT or PT:		
1.7	Mental health provider:		
1.8	Nurse *(includes RNs, LPNs, nurse's aides or other equivalent)*:		
1.9	Other *(specify)*: _____		

2 Has the patient had any outpatient **cardiac** procedures/tests *(including ICD firing)* or **orthopedic** procedures/tests since the last study visit?
☐0 No ☐1 Yes → **Compete the table below.**

Procedure Code*	Number	Procedure Code*	Number	Procedure Code*	Number

*See choices on opposite page. Record one per row. If a procedure/test is not listed, please record it in the table above.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

See annotation p.27 of 3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

3 Has the patient required any **urgent/emergency care** on an outpatient basis since the last study visit? ☐0 No ☐1 Yes → Complete the table below.

	Outpatient Service Type	Number of Visits Due to Heart Failure*	Number of Visits Due to Cardiovascular Disease* (other than heart failure)	Number of Visits Due to Non-Cardiovascular Disease*	Number of Visits Due to Unknown Cause*	Number of Visits Due to a Cardiovascular Event Occurring During or Within 3 Hours After Exercise
3.1	Emergency room, hospital < 24 hours, or observation unit:					
3.2	Heart failure clinic/office:					
3.3	Stand-alone urgent care facility:					

3.4 Date of 1st ER visit *(for any reason since randomization)*: ___/___/___ (day/month/year) OR ☐1 No ER visit to date ☐2 Previously recorded

3.5 Date of 1st urgent clinic visit due to heart failure exacerbation *(since randomization)*: ___/___/___ (day/month/year) OR ☐1 No urgent clinic visit for HF to date ☐2 Previously recorded

Other Types of Resource Utilization

1 Number of days on home IV infusion for heart failure since the last study visit: _____ days

2 Since the last study visit, how many days did the patient live in each of the following...

Their home: _____ days

Caregiver's home *(e.g., family and friends)*: _____ days

Assisted living: _____ days

Skilled nursing facility: _____ days

Acute care hospital: _____ days

Rehabilitation center: _____ days

Other *(specify)*: _____ _____ days

*Primary diagnosis

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

This is a repeating page
First page should have page rep 0

See annotation p.28 of 3-Month

9–Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Hospitalization Record only hospitalizations for ≥ 24 hours.

Has the patient been hospitalized for any reason since the last completed study visit?

(Only include completed hospitalizations. Wait until the next study visit to record hospital information if the patient is currently hospitalized.)

☐0 No ☐1 Yes → **If Yes: How many hospitalizations?** _____

	Hospitalization:	Primary Reason for Hospitalization*	Primary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Secondary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Discharge Destination*
1 Hospitalization: Admission date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Discharge date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
2 Hospitalization: Admission date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Discharge date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
3 Hospitalization: Admission date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Discharge date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				

*See choices on opposite page. If a diagnosis/procedure/discharge destination is not listed, please record it in the table above.
If more than 3 hospitalizations occurred, complete an Additional Hospitalization form.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

This is a repeating page
First page should have page rep 0

See annotation p.29 of 3-Month

HF-ACTION

9-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Telephone Log

1 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

2 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

3 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

*See choices on opposite page.

If more than 3 telephone calls were completed, complete an Additional Telephone Log form.

WHITE and YELLOW — Duke Clinical Research Institute • PINK — retain at site

PROTOCOL=HFACTION
STUDYBOOK = DATA_FORMS
FORM = 12MONTH
NODATA<ZYES>
CONTEXT

HF ACTION

12-Month

VISITDT

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

Patient's Initials: INITIALS (first middle last)

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

EuroQoL Questionnaire

By placing a checkmark in one box in each group below, please indicate which statement best describes your own health state today.

See annotation p.3 of Baseline

1 Mobility:

- ☐1 I have no problems in walking about.
- ☐2 I have some problems in walking about.
- ☐3 I am confined to bed.

2 Self-care:

- ☐1 I have no problems with self-care.
- ☐2 I have some problems washing or dressing myself.
- ☐3 I am unable to wash or dress myself.

3 Usual activities *(e.g. work, study, housework, family or leisure activities)*:

- ☐1 I have no problems with performing my usual activities.
- ☐2 I have some problems with performing my usual activities.
- ☐3 I am unable to perform my usual activities.

4 Pain/discomfort:

- ☐1 I have no pain or discomfort.
- ☐2 I have moderate pain or discomfort.
- ☐3 I have extreme pain or discomfort.

5 Anxiety/depression:

- ☐1 I am not anxious or depressed.
- ☐2 I am moderately anxious or depressed.
- ☐3 I am extremely anxious or depressed.

STOP → **Please let your study coordinator know that you are ready for the EuroQoL Thermometer worksheet.**

PATIENT SELF-REPORT FORM

Pain Assessment

1 How much bodily pain have you had during the past 4 weeks *(check only one)*?

☐1 None ☐2 Very mild ☐3 Mild ☐4 Moderate ☐5 Severe ☐6 Very severe

2 During the past 4 weeks, how much did pain interfere with your normal work *(including both work outside the home and housework)*?

☐1 Not at all ☐2 A little bit ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

EuroQol Thermometer Response

Response to the EuroQoL thermometer: ___ ___ ___ *(0-100)*

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Kansas City Cardiomyopathy Questionnaire (KCCQ)

PATIENT SELF-REPORT FORM

The following questions refer to your heart failure and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answers that best apply to you.

1 **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** *(shortness of breath or fatigue)* in your ability to do the following activities over the past 2 weeks.

(Check only one box on each line.)

Activity	Extremely Limited	Quite a Bit Limited	Moderately Limited	Slightly Limited	Not at All Limited	Limited for Other Reasons or Did Not Do the Activity
Dressing yourself:	☐1	☐2	☐3	☐4	☐5	☐6
Showering/bathing:	☐1	☐2	☐3	☐4	☐5	☐6
Walking 1 block on level ground:	☐1	☐2	☐3	☐4	☐5	☐6
Doing yard work, housework or carrying groceries:	☐1	☐2	☐3	☐4	☐5	☐6
Climbing a flight of stairs without stopping:	☐1	☐2	☐3	☐4	☐5	☐6
Hurrying or jogging *(as if to catch a bus)*:	☐1	☐2	☐3	☐4	☐5	☐6

2 Compared with 2 weeks ago, have your symptoms of **heart failure** *(shortness of breath, fatigue, or ankle swelling)* changed? My symptoms of heart failure have become...

Much worse	Slightly worse	Not changed	Slightly better	Much better	I've had no symptoms over the last 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6

3 Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in the morning?

Every morning	3 or more times a week, but not every morning	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5

4 Over the past 2 weeks, how much has **swelling** in your feet, ankles or legs bothered you? It has been...

Extremely bothersome	**Moderately** bothersome	**Somewhat** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no swelling**
☐1	☐2	☐3	☐4	☐5	☐6

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

5 Over the <u>past 2 weeks</u>, on average, how many times has **fatigue** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

6 Over the <u>past 2 weeks</u>, how much has your **fatigue** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no fatigue**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

7 Over the <u>past 2 weeks</u>, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

8 Over the <u>past 2 weeks</u>, how much has your **shortness of breath** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no shortness of breath**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

9 Over the <u>past 2 weeks</u>, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

Every night	3 or more times a week, but not every night	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10 **Heart failure** symptoms can worsen for a number of reasons. How sure are you that you know what to do or who to call, if your **heart failure** gets worse?

Not at all sure	**Not very** sure	**Somewhat** sure	**Mostly** sure	**Completely** sure
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11 How well do you understand what things you are able to do to keep your **heart failure** symptoms from getting **worse** *(for example, weighing yourself, eating a low-salt diet etc.)*?

Do not understand at all	Do not understand very well	Somewhat understand	Mostly understand	Completely understand
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

PATIENT SELF-REPORT FORM

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

12 Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not limited** my enjoyment of life at all
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

13 If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

Not at all satisfied	**Mostly** dissatisfied	**Somewhat** satisfied	**Mostly** satisfied	**Completely** satisfied
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

14 Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of your **heart failure**?

I felt that way **all of the time**	I felt that way **most of the time**	I **occasionally** felt that way	I **rarely** felt that way	I **never** felt that way
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

15 How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks.

(Check only one box on each line.)

Activity	Severely Limited	Limited Quite a Bit	Moderately Limited	Slightly Limited	Did Not Limit at All	Does Not Apply or Did Not Do for Other Reasons
Hobbies, recreational activities:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Intimate relationships with loved ones:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Visiting family or friends out of your home:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Working or doing household chores:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

PATIENT SELF-REPORT FORM

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Beck Depression Inventory (BDI)

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the past one week, including today. Check the box beside the statement you have picked. If several statements within a group seem to apply equally well, check the highest numbered box for that group. Be sure that you do not choose more than one statement for any group, including item 16, Changes in Sleeping Pattern and item 18, Changes in Appetite.

1 Sadness:
- ☐ 0 I do not feel sad.
- ☐ 1 I feel sad much of the time.
- ☐ 2 I am sad all of the time.
- ☐ 3 I am so sad or unhappy that I can't stand it.

2 Pessimism:
- ☐ 0 I am not discouraged about my future.
- ☐ 1 I feel more discouraged about my future than I used to be.
- ☐ 2 I do not expect things to work out for me.
- ☐ 3 I feel my future is hopeless and will only get worse.

3 Past Failure:
- ☐ 0 I do not feel like a failure.
- ☐ 1 I have failed more than I should have.
- ☐ 2 As I look back, I see a lot of failures.
- ☐ 3 I feel I am a total failure as a person.

4 Loss of Pleasure:
- ☐ 0 I get as much pleasure as I ever did from the things I enjoy.
- ☐ 1 I don't enjoy things as much as I used to.
- ☐ 2 I get very little pleasure from the things I used to enjoy.
- ☐ 3 I can't get any pleasure from the things I used to enjoy.

5 Guilty Feelings:
- ☐ 0 I don't feel particularly guilty.
- ☐ 1 I feel guilty over many things I have done or should have done.
- ☐ 2 I feel quite guilty most of the time.
- ☐ 3 I feel guilty all of the time.

6 Punishment Feelings:
- ☐ 0 I don't feel I am being punished.
- ☐ 1 I feel I may be punished.
- ☐ 2 I expect to be punished.
- ☐ 3 I feel I am being punished.

7 Self-Dislike:
- ☐ 0 I feel the same about myself as ever.
- ☐ 1 I have lost confidence in myself.
- ☐ 2 I am disappointed in myself.
- ☐ 3 I dislike myself.

8 Self-Criticalness:
- ☐ 0 I don't criticize or blame myself more than usual.
- ☐ 1 I am more critical of myself than I used to be.
- ☐ 2 I criticize myself for all of my faults.
- ☐ 3 I blame myself for everything that happens.

9 Suicidal Thoughts or Wishes:
- ☐ 0 I don't have any thoughts of killing myself.
- ☐ 1 I have thoughts of killing myself, but I would not carry them out.
- ☐ 2 I would like to kill myself.
- ☐ 3 I would kill myself if I had the chance.

10 Crying:
- ☐ 0 I don't cry any more than I used to.
- ☐ 1 I cry more than I used to.
- ☐ 2 I cry over every little thing.
- ☐ 3 I feel like crying, but I can't.

11 Agitation:
- ☐ 0 I am no more restless or wound up than usual.
- ☐ 1 I feel more restless or wound up than usual.
- ☐ 2 I am so restless or agitated that it's hard to stay still.
- ☐ 3 I am so restless or agitated that I have to keep moving or doing something.

12 Loss of Interest:
- ☐ 0 I have not lost interest in other people or activities.
- ☐ 1 I am less interested in other people or things than before.
- ☐ 2 I have lost most of my interest in other people or things.
- ☐ 3 It's hard to get interested in anything.

PATIENT SELF-REPORT FORM

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Beck Depression Inventory (BDI) (continued)

13 Indecisiveness:

- 0 I make decisions about as well as ever.
- 1 I find it more difficult to make decisions than usual.
- 2 I have much greater difficulty in making decisions than I used to.
- 3 I have trouble making any decisions.

14 Worthlessness:

- 0 I do not feel I am worthless.
- 1 I don't consider myself as worthwhile and useful as I used to.
- 2 I feel more worthless as compared to other people.
- 3 I feel utterly worthless.

15 Loss of Energy:

- 0 I have as much energy as ever.
- 1 I have less energy than I used to have.
- 2 I don't have enough energy to do very much.
- 3 I don't have enough energy to do anything.

16 Changes in Sleeping Pattern *(check only one)*:

- 0 I have not experienced any change in my sleeping pattern.
- 1a I sleep somewhat more than usual.
- 1b I sleep somewhat less than usual.
- 2a I sleep a lot more than usual.
- 2b I sleep a lot less than usual.
- 3a I sleep most of the day.
- 3b I wake up 1–2 hours early and can't get back to sleep.

17 Irritability:

- 0 I am no more irritable than usual.
- 1 I am more irritable than usual.
- 2 I am much more irritable than usual.
- 3 I am irritable all the time.

18 Changes in Appetite *(check only one)*:

- 0 I have not experienced any change in my appetite.
- 1a My appetite is somewhat less than usual.
- 1b My appetite is somewhat greater than usual.
- 2a My appetite is much less than before.
- 2b My appetite is much greater than usual.
- 3a I have no appetite at all.
- 3b I crave food all the time.

19 Concentration Difficulty:

- 0 I can concentrate as well as ever.
- 1 I can't concentrate as well as usual.
- 2 It's hard to keep my mind on anything for very long.
- 3 I find I can't concentrate on anything.

20 Tiredness or Fatigue:

- 0 I am no more tired or fatigued than usual.
- 1 I get more tired or fatigued more easily than usual.
- 2 I am too tired or fatigued to do a lot of the things I used to do.
- 3 I am too tired or fatigued to do most of the things I used to do.

21 Loss of Interest in Sex:

- 0 I have not noticed any recent change in my interest in sex.
- 1 I am less interested in sex than I used to be.
- 2 I am much less interested in sex now.
- 3 I have lost interest in sex completely.

OUTPUT 2 (TYPE 3)

PATIENT SELF-REPORT FORM

Productivity Assessment

1 How many days have you lost from work and/or your usual activities in the past 30 days due to problems with your health?

LOSTWK<F:9:3>

_____ days

EMPLOYST<I:3><ACEMP>

2 Check one of the following to indicate your current employment status:

- 1 Employed/self-employed full-time *(> 30 hours week)*
- 2 Employed part-time *(specify hours per week)*: _____
- 3 Student
- 4 Homemaker
- 5 Volunteer
- 6 Disabled
- 7 Unemployed
- 8 Retired

PARTT<F:9:3>

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

PATIENT SELF-REPORT FORM

Stages of Change

Physical activity or exercise includes activities such as walking briskly, jogging, bicycling, swimming, or any other activity in which the exertion is at least as intense as these activities.

For activity to be regular, it must add up to a total of 30 minutes or more per day and be done at least 5 days per week. For example, you could take one 30-minute walk or take three 10-minute walks for a daily total of 30 minutes.

For each of the following questions, please check "Yes" or "No."

1 I am currently physically active. ☐0 No ☐1 Yes

2 I intend to become more physically active in the next 6 months. ☐0 No ☐1 Yes

3 I currently engage in regular physical activity. ☐0 No ☐1 Yes

4 I have been regularly physically active for the past 6 months. ☐0 No ☐1 Yes

Exercise Self-Efficacy

Physical activity or exercise includes activities such as walking briskly, jogging, bicycling, swimming, or any other activity in which the exertion is at least as intense as these activities.

Check the box that indicates how confident you are that you could be physically active in each of the following situations:

1 When I am tired:
☐1 Not at all confident ☐2 Slightly confident ☐3 Moderately confident ☐4 Very confident ☐5 Extremely confident

2 When I am in a bad mood:
☐1 Not at all confident ☐2 Slightly confident ☐3 Moderately confident ☐4 Very confident ☐5 Extremely confident

3 When I feel I don't have time:
☐1 Not at all confident ☐2 Slightly confident ☐3 Moderately confident ☐4 Very confident ☐5 Extremely confident

4 When I am on vacation:
☐1 Not at all confident ☐2 Slightly confident ☐3 Moderately confident ☐4 Very confident ☐5 Extremely confident

5 When it is raining or snowing:
☐1 Not at all confident ☐2 Slightly confident ☐3 Moderately confident ☐4 Very confident ☐5 Extremely confident

12-Month

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Decisional Balance

Please rate how important each of these statements is in your decision of whether to be physically active. In each case, think about how you feel right now, not how you have felt in the past or would like to feel.

		Not at All Important	Slightly Important	Moderately Important	Very Important	Extremely Important
1	I would have more energy for my family and friends if I exercised regularly.	☐	☐	☐	☐	☐
2	Regular exercise would help me relieve tension.	☐	☐	☐	☐	☐
3	I think I would be too tired to do my daily work after exercising.	☐	☐	☐	☐	☐
4	I would feel more confident if I exercised regularly.	☐	☐	☐	☐	☐
5	I would sleep more soundly if I exercised regularly.	☐	☐	☐	☐	☐
6	I would feel good about myself if I kept my commitment to exercise regularly.	☐	☐	☐	☐	☐
7	I would find it difficult to find an exercise activity that I enjoy that is not affected by bad weather.	☐	☐	☐	☐	☐
8	I would like my body better if I exercised regularly.	☐	☐	☐	☐	☐
9	It would be easier for me to perform routine physical tasks if I exercised regularly.	☐	☐	☐	☐	☐
10	I would feel less stressed if I exercised regularly.	☐	☐	☐	☐	☐
11	I feel uncomfortable when I exercise because I get out of breath and my heart beats very fast.	☐	☐	☐	☐	☐
12	I would feel more comfortable with my body if I exercised regularly.	☐	☐	☐	☐	☐
13	Regular exercise would take too much of my time.	☐	☐	☐	☐	☐
14	Regular exercise would help me have a more positive outlook on life.	☐	☐	☐	☐	☐
15	I would have less time for my family and friends if I exercised regularly.	☐	☐	☐	☐	☐
16	At the end of the day, I am too exhausted to exercise.	☐	☐	☐	☐	☐

PATIENT SELF-REPORT FORM

Barrier Scale

Please indicate the extent to which you anticipate that the following might interfere with your continuing participation in this study:

		Not at All	Somewhat	A Lot			Not at All	Somewhat	A Lot
1	Finances:	☐	☐	☐	6	Boredom:	☐	☐	☐
2	Child care:	☐	☐	☐	7	Fatigue:	☐	☐	☐
3	Weather:	☐	☐	☐	8	Transportation:	☐	☐	☐
4	Vacation:	☐	☐	☐	9	Work:	☐	☐	☐
5	Pain:	☐	☐	☐	10	Household responsibilities:	☐	☐	☐

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Physical Activity Questionnaire (PAQ)

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the last 7 days. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous physical activities** that you did in the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

1 During the last 7 days, on how many days did you do **vigorous physical activities** like heavy lifting, digging, aerobics, or fast bicycling?

_____ days → **Continue to question 2.**

OR ☐ No vigorous physical activities → **Skip to question 3.**

2 How much time did you usually spend doing **vigorous physical activities** on one of those days?

___ ___ ___ minutes per day

OR ☐ Don't know/not sure

Think about all the **moderate physical activities** that you did in the last 7 days. Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3 During the last 7 days, on how many days did you do **moderate physical activities** like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ days → **Continue to question 4.**

OR ☐ No moderate physical activities → **Skip to question 5.**

4 How much time did you usually spend doing **moderate physical activities** on one of those days?

___ ___ ___ minutes per day

OR ☐ Don't know/not sure

Think about the time you spent **walking** in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5 During the last 7 days, on how many days did you **walk** for at least 10 minutes at a time?

_____ days → **Continue to question 6.**

OR ☐ No walking → **Skip to question 7.**

6 How much time did you usually spend **walking** on one of those days?

___ ___ ___ minutes per day

OR ☐ Don't know/not sure

The last question is about the time you spent **sitting on weekdays** during the last 7 days. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7 During the last 7 days, how much time did you spend **sitting on a weekday**?

___ ___ hours per day

OR ☐ Don't know/not sure

PATIENT SELF-REPORT FORM

Medical History

1 **Current NYHA heart failure class** *(check only one)*: ☐ I ☐ II ☐ III ☐ IV See annotation p.24 of 3-Month

2 **Current Canadian Cardiovascular Society (CCS) angina class** *(check only one)*: ☐ No angina ☐ I ☐ II ☐ III ☐ IV

Current Medications

Check "No" or "Yes" for each medication and provide the total daily dose, if applicable. See annotation p.13 of Baseline

1 **ACE inhibitor:**

☐ 0 No → **Reason for not using** *(check only one)*: ☐ 1 Contraindicated ☐ 2 Intolerance ☐ 3 MD preference ☐ 4 Patient preference

☐ 1 Yes → **If Yes: Check only one and provide the TOTAL DAILY DOSE:**

- ☐ 1 Benazepril: _____ mg
- ☐ 2 Captopril: _____ mg
- ☐ 3 Enalapril: _____ mg
- ☐ 4 Fosinopril: _____ mg
- ☐ 5 Lisinopril: _____ mg
- ☐ 6 Quinapril: _____ mg
- ☐ 7 Ramipril: _____ mg
- ☐ 8 Trandolapril: _____ mg
- ☐ 98 Other *(specify)*: _____ _____ mg

2 **Angiotensin receptor blocker:**

☐ 0 No

☐ 1 Yes → **If Yes: Check all that apply:** ☐ Valsartan ☐ Losartan ☐ Irbesartan ☐ Candesartan ☐ Other *(specify)*: _____

3 **Beta blocker:**

☐ 0 No → **Reason for not using** *(check only one)*: ☐ 1 Contraindicated ☐ 2 Intolerance ☐ 3 MD preference ☐ 4 Patient preference

☐ 1 Yes → **If Yes: Check only one and provide the TOTAL DAILY DOSE:**

- ☐ 1 Atenolol: _____ mg
- ☐ 2 Bisoprolol: _____ mg
- ☐ 3 Carvedilol: _____ mg
- ☐ 4 Metoprolol immediate release: _____ mg
- ☐ 5 Metoprolol XL: _____ mg
- ☐ 98 Other *(specify)*: _____ _____ mg

4 **Aspirin:**

☐ 0 No → **Reason for not using** *(check only one)*: ☐ 1 Contraindicated ☐ 2 Intolerance ☐ 3 MD preference ☐ 4 Patient preference

☐ 1 Yes → **If Yes: Dose:** _____ mg

5 **Loop diuretic:**

☐ 0 No

☐ 1 Yes → **If Yes: Check only one and provide the TOTAL DAILY DOSE:**

- ☐ 1 Furosemide: _____ mg
- ☐ 2 Bumetanide: _____ mg
- ☐ 3 Torsemide: _____ mg
- ☐ 98 Other *(specify)*: _____ _____ mg

6 **Antiarrhythmic:**

☐ 0 No

☐ 1 Yes → **If Yes: Check all that apply:** ☐ Amiodarone ☐ Sotalol ☐ Dofetilide ☐ Other *(specify)*: _____

7 **Lipid-lowering agent:**

☐ 0 No

☐ 1 Yes → **If Yes: Check only one:** ☐ 1 HMG-CoA reductase inhibitor → **Check all that apply:** ☐ Atorvastatin ☐ Pravastatin ☐ Simvastatin ☐ Other

☐ 2 Other lipid-lowering agent

8 **Selective serotonin reuptake inhibitor:**

☐ 0 No

☐ 1 Yes → **Check all that apply:** ☐ Sertraline ☐ Citalopram ☐ Paroxetine ☐ Fluoxetine ☐ Other

Current Medications

Check "No" or "Yes" for each medication.

9	Tricyclic antidepressant:	☐ 0 No	☐ 1 Yes
10	Other antidepressant *(excluding SSRIs and TCAs)*:	☐ 0 No	☐ 1 Yes
11	Antipsychotic:	☐ 0 No	☐ 1 Yes
12	Clopidogrel:	☐ 0 No	☐ 1 Yes
13	Coumadin:	☐ 0 No	☐ 1 Yes
14	Digoxin:	☐ 0 No	☐ 1 Yes
15	Nitrate:	☐ 0 No	☐ 1 Yes
16	Calcium channel blocker:	☐ 0 No	☐ 1 Yes
17	Spironolactone:	☐ 0 No	☐ 1 Yes
18	Eplerenone:	☐ 0 No	☐ 1 Yes
19	Non-loop diuretic *(excluding aldosterone antagonist)*:	☐ 0 No	☐ 1 Yes
20	Potassium:	☐ 0 No	☐ 1 Yes
21	Insulin:	☐ 0 No	☐ 1 Yes
22	Glitazone:	☐ 0 No	☐ 1 Yes
23	Other oral diabetic agent:	☐ 0 No	☐ 1 Yes
24	Thyroid replacement:	☐ 0 No	☐ 1 Yes
25	NSAID:	☐ 0 No	☐ 1 Yes
26	COX-2 inhibitor:	☐ 0 No	☐ 1 Yes
27	Sildenafil:	☐ 0 No	☐ 1 Yes

Reserved for potential new drugs. **Do not complete unless instructed by the Duke Clinical Research Institute (DCRI).**

28	Other: _____	☐ 0 No	☐ 1 Yes
29	Other: _____	☐ 0 No	☐ 1 Yes

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Quality of Life—Reason for Missing Data

Are all quality-of-life forms complete? ☐ 0 No → If No:

OR

☐ 1 Yes

- ☐ 1 Patient died
- ☐ 2 Patient refused
- ☐ 3 Patient withdrew consent
- ☐ 4 Patient missed visit
- ☐ 5 Patient sick
- ☐ 98 Other

6–Minute Walk Test

1 Did the patient attempt the 6-minute walk at this visit?

☐ 0 No → If No: **Specify primary reason:**

OR

☐ 1 Yes → If Yes:

- ☐ Patient was too critically ill
- ☐ Patient cannot walk for technical reasons *(e.g., a patient who is an amputee)*
- ☐ Not done due to oversight
- ☐ Patient refused
- ☐ Patient died
- ☐ Patient withdrew consent
- ☐ Patient missed visit

Date of 6-minute walk: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Start walk time: ___ ___ : ___ ___ (00:00 to 23:59)

Total distance walked: _____ ☐ 1 Feet ☐ 2 Meter(s)

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

☐ None ☐ Angina ☐ Light-headedness ☐ Syncope

Borg Rating of Perceived Exertion (RPE) Scale: _____ *(6-20)*

2 Were the QOL instruments completed before or after the 6-minute walk? Check only one:

- ☐ 1 Before
- ☐ 2 < 30 mins after
- ☐ 3 30–60 mins after
- ☐ 4 > 60 mins after

See annotation p.26 of 3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

1 Has the patient had any **non-urgent** outpatient visits since the last study visit? *(Do not include protocol-specified follow-up visits.)* ☐ 0 No ☐ 1 Yes → **Complete the table below.**

	Provider Type	Number of Office/Clinic Visits	Number of Home Visits
1.1	Cardiologist:		
1.2	Orthopedic surgeon:		
1.3	Other specialist:		
1.4	Primary care physician:		
1.5	Physician extenders *(includes NPs, PAs, etc.)*:		
1.6	OT or PT:		
1.7	Mental health provider:		
1.8	Nurse *(includes RNs, LPNs, nurse's aides or other equivalent)*:		
1.9	Other *(specify)*: _____		

2 Has the patient had any outpatient **cardiac** procedures/tests *(including ICD firing)* or **orthopedic** procedures/tests since the last study visit?
☐ 0 No ☐ 1 Yes → Compete the table below.

Procedure Code*	Number	Procedure Code*	Number	Procedure Code*	Number

*See choices on opposite page. Record one per row. If a procedure/test is not listed, please record it in the table above.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

3 Has the patient required any **urgent/emergency care** on an outpatient basis since the last study visit? ☐ 0 No ☐ 1 Yes → Complete the table below.

	Outpatient Service Type	Number of Visits Due to Heart Failure*	Number of Visits Due to Cardiovascular Disease* (other than heart failure)	Number of Visits Due to Non-Cardiovascular Disease*	Number of Visits Due to Unknown Cause*	Number of Visits Due to a Cardiovascular Event Occurring During or Within 3 Hours After Exercise
3.1	Emergency room, hospital < 24 hours, or observation unit:					
3.2	Heart failure clinic/office:					
3.3	Stand-alone urgent care facility:					

3.4 Date of 1st ER visit *(for any reason since randomization)*: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ 1 No ER visit to date ☐ 2 Previously recorded

3.5 Date of 1st urgent clinic visit due to heart failure exacerbation *(since randomization)*: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ 1 No urgent clinic visit for HF to date ☐ 2 Previously recorded

Other Types of Resource Utilization

1 Number of days on home IV infusion for heart failure since the last study visit: _____ days

2 Since the last study visit, how many days did the patient live in each of the following...

Their home: _____ days

Caregiver's home *(e.g., family and friends)*: _____ days

Assisted living: _____ days

Skilled nursing facility: _____ days

Acute care hospital: _____ days

Rehabilitation center: _____ days

Other *(specify)*: _____ _____ days

*Primary diagnosis

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Hospitalization Record only hospitalizations for ≥ 24 hours.

Has the patient been hospitalized for any reason since the last completed study visit?

(Only include completed hospitalizations. Wait until the next study visit to record hospital information if the patient is currently hospitalized.)

☐ 0 No ☐ 1 Yes → **If Yes: How many hospitalizations?** _____

	Hospitalization:	Primary Reason for Hospitalization*	Primary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Secondary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Discharge Destination*
1 Hospitalization: Admission date: ___/___/___ (day/month/year) Discharge date: ___/___/___ (day/month/year) **Did the event leading to this hospitalization occur during or within 3 hours after exercise?** ☐ 0 No ☐ 1 Yes **Did a cardiovascular event cause or occur during this hospitalization?** ☐ 0 No ☐ 1 Yes → **If Yes: Complete the Cardiovascular Event forms.**	☐ Planned ☐ Unplanned				
2 Hospitalization: Admission date: ___/___/___ (day/month/year) Discharge date: ___/___/___ (day/month/year) **Did the event leading to this hospitalization occur during or within 3 hours after exercise?** ☐ 0 No ☐ 1 Yes **Did a cardiovascular event cause or occur during this hospitalization?** ☐ 0 No ☐ 1 Yes → **If Yes: Complete the Cardiovascular Event forms.**	☐ Planned ☐ Unplanned				
3 Hospitalization: Admission date: ___/___/___ (day/month/year) Discharge date: ___/___/___ (day/month/year) **Did the event leading to this hospitalization occur during or within 3 hours after exercise?** ☐ 0 No ☐ 1 Yes **Did a cardiovascular event cause or occur during this hospitalization?** ☐ 0 No ☐ 1 Yes → **If Yes: Complete the Cardiovascular Event forms.**	☐ Planned ☐ Unplanned				

*See choices on opposite page. If a diagnosis/procedure/discharge destination is not listed, please record it in the table above.

If more than 3 hospitalizations occurred, complete an Additional Hospitalization form.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

This is a repeating page
First page should have page rep 0

See annotation p.29 of 3-Month

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Telephone Log

1 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

2 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

3 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

*See choices on opposite page.

If more than 3 telephone calls were completed, complete an Additional Telephone Log form.

WHITE and YELLOW — Duke Clinical Research Institute • PINK — retain at site

PROTOCOL =HFACTION NODATA <ZYES> CONTEXT
STUDYBOOK = DATA_FORMS
FORM = 15MONTH

HF-ACTION

15-Month

VISITDT

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

Patient's Initials: ___ ___ ___ (first middle last) INITIALS

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

Medical History

1 Current NYHA heart failure class *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

See annotation p.24 of 3-Month

2 Current Canadian Cardiovascular Society (CCS) angina class *(check only one)*: ☐ No angina ☐ I ☐ II ☐ III ☐ IV

Current Medications

Check "No" or "Yes"; if "Yes", provide the total daily dose.

1 Loop diuretic: ☐$_0$ No

☐$_1$ Yes → If Yes: Check only one and provide the **total daily dose**:

☐$_1$ Furosemide: _____ mg ☐$_3$ Torsemide: _____ mg

☐$_2$ Bumetanide: _____ mg ☐$_{98}$ Other, *(specify)*: _____ _____ mg

Check "No" or "Yes" for each medication.

2 Spironolactone:	☐$_0$ No	☐$_1$ Yes
3 Eplerenone:	☐$_0$ No	☐$_1$ Yes
4 Non-loop diuretic: *(excluding aldosterone antagonist)*	☐$_0$ No	☐$_1$ Yes
5 Potassium:	☐$_0$ No	☐$_1$ Yes
6 ACE inhibitor:	☐$_0$ No	☐$_1$ Yes
7 Angiotensin receptor blocker:	☐$_0$ No	☐$_1$ Yes
8 Beta blocker:	☐$_0$ No	☐$_1$ Yes
9 Aspirin:	☐$_0$ No	☐$_1$ Yes
10 Antiarrhythmic:	☐$_0$ No	☐$_1$ Yes
11 Lipid-lowering agent:	☐$_0$ No	☐$_1$ Yes
12 Clopidogrel:	☐$_0$ No	☐$_1$ Yes
13 Coumadin:	☐$_0$ No	☐$_1$ Yes
14 Digoxin:	☐$_0$ No	☐$_1$ Yes
15 Nitrate:	☐$_0$ No	☐$_1$ Yes
16 Calcium channel blocker:	☐$_0$ No	☐$_1$ Yes
17 Insulin:	☐$_0$ No	☐$_1$ Yes
18 Glitazone:	☐$_0$ No	☐$_1$ Yes
19 Other oral diabetic agent:	☐$_0$ No	☐$_1$ Yes
20 Thyroid replacement:	☐$_0$ No	☐$_1$ Yes
21 Selective serotonin reuptake inhibitor:	☐$_0$ No	☐$_1$ Yes
22 Tricyclic antidepressant:	☐$_0$ No	☐$_1$ Yes
23 Other antidepressant: *(excluding SSRIs and TCAs)*	☐$_0$ No	☐$_1$ Yes
24 Antipsychotic:	☐$_0$ No	☐$_1$ Yes
25 NSAID:	☐$_0$ No	☐$_1$ Yes
26 COX-2 inhibitor:	☐$_0$ No	☐$_1$ Yes
27 Sildenafil:	☐$_0$ No	☐$_1$ Yes

Reserved for potential new drugs. **Do not complete unless instructed by the Duke Clinical Research Institute (DCRI).**

28 Other: _____ ☐$_0$ No ☐$_1$ Yes

29 Other: _____ ☐$_0$ No ☐$_1$ Yes

WHITE and YELLOW — Duke Clinical Research Institute • PINK — retain at site

See annotation p.26 of 3-Month

15–Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

1 Has the patient had any **non-urgent** outpatient visits since the last study visit? *(Do not include protocol-specified follow-up visits.)* ☐ 0 No ☐ 1 Yes → **Complete the table below.**

	Provider Type	Number of Office/Clinic Visits	Number of Home Visits
1.1	Cardiologist:		
1.2	Orthopedic surgeon:		
1.3	Other specialist:		
1.4	Primary care physician:		
1.5	Physician extenders *(includes NPs, PAs, etc.)*:		
1.6	OT or PT:		
1.7	Mental health provider:		
1.8	Nurse *(includes RNs, LPNs, nurse's aides or other equivalent)*:		
1.9	Other *(specify)*: _____		

2 Has the patient had any outpatient **cardiac** procedures/tests *(including ICD firing)* or **orthopedic** procedures/tests since the last study visit?
☐ 0 No ☐ 1 Yes → **Compete the table below.**

Procedure Code*	Number	Procedure Code*	Number	Procedure Code*	Number

*See choices on opposite page. Record one per row. If a procedure/test is not listed, please record it in the table above.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

3 Has the patient required any **urgent/emergency care** on an outpatient basis since the last study visit? ☐0 No ☐1 Yes → Complete the table below.

	Outpatient Service Type	Number of Visits Due to Heart Failure*	Number of Visits Due to Cardiovascular Disease* (other than heart failure)	Number of Visits Due to Non-Cardiovascular Disease*	Number of Visits Due to Unknown Cause*	Number of Visits Due to a Cardiovascular Event Occurring During or Within 3 Hours After Exercise
3.1	Emergency room, hospital < 24 hours, or observation unit:					
3.2	Heart failure clinic/office:					
3.3	Stand-alone urgent care facility:					

3.4 Date of 1st ER visit *(for any reason since randomization)*: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐1 No ER visit to date ☐2 Previously recorded

3.5 Date of 1st urgent clinic visit due to heart failure exacerbation *(since randomization)*: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐1 No urgent clinic visit for HF to date ☐2 Previously recorded

Other Types of Resource Utilization

1 Number of days on home IV infusion for heart failure since the last study visit: _____ days

2 Since the last study visit, how many days did the patient live in each of the following...

Their home: _____ days

Caregiver's home *(e.g., family and friends)*: _____ days

Assisted living: _____ days

Skilled nursing facility: _____ days

Acute care hospital: _____ days

Rehabilitation center: _____ days

Other *(specify)*: _____ _____ days

*Primary diagnosis

This is a repeating page
First page should have page rep 0

See annotation p.28 of 3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Hospitalization Record only hospitalizations for ≥ 24 hours.

Has the patient been hospitalized for any reason since the last completed study visit?

(Only include completed hospitalizations. Wait until the next study visit to record hospital information if the patient is currently hospitalized.)

☐0 No ☐1 Yes → **If Yes: How many hospitalizations?** _____

	Hospitalization:	Primary Reason for Hospitalization*	Primary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Secondary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Discharge Destination*
1 Hospitalization: Admission date: ___/___/___ (day/month/year) Discharge date: ___/___/___ Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
2 Hospitalization: Admission date: ___/___/___ Discharge date: ___/___/___ Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
3 Hospitalization: Admission date: ___/___/___ Discharge date: ___/___/___ Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				

*See choices on opposite page. If a diagnosis/procedure/discharge destination is not listed, please record it in the table above.

If more than 3 hospitalizations occurred, complete an Additional Hospitalization form.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

This is a repeating page
First page should have page rep 0

See annotation p.29 of 3-Month

HF-ACTION

15-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Telephone Log

1 Date of call: ___/___/___ (day/month/year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → If ≥ 1: How many of the contacts resulted in:

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐0 No → If No: Indicate primary reason code*: _____

☐1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐0 No ☐1 Yes

2 Date of call: ___/___/___ (day/month/year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → If ≥ 1: How many of the contacts resulted in:

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐0 No → If No: Indicate primary reason code*: _____

☐1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐0 No ☐1 Yes

3 Date of call: ___/___/___ (day/month/year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → If ≥ 1: How many of the contacts resulted in:

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐0 No → If No: Indicate primary reason code*: _____

☐1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐0 No ☐1 Yes

*See choices on opposite page.

If more than 3 telephone calls were completed, complete an Additional Telephone Log form.

WHITE and YELLOW – Duke Clinical Research Institute • PINK – retain at site

NODATA <ZYES> CONTEXT

PROTOCOL = HFACTION
STUDYBOOK = DATA_FORMS
FORM = 18MONTH

VISITDT

18-Month

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (SUBJNO) (site # / patient #) Patient's Initials: ___ ___ ___ (INITIALS) (first middle last)

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

Medical History

1 Current NYHA heart failure class *(check only one)*: ☐ I ☐ II ☐ III ☐ IV See annotation p. 24 of 3-Month

2 Current Canadian Cardiovascular Society (CCS) angina class *(check only one)*: ☐ No angina ☐ I ☐ II ☐ III ☐ IV

Current Medications

Check "No" or "Yes"; if "Yes", provide the total daily dose.

1 Loop diuretic: ☐ 0 No See annotation p.24 of 3-Month

☐ 1 Yes → If Yes: Check only one and provide the **total daily dose**:

☐ 1 Furosemide: _____ mg ☐ 3 Torsemide: _____ mg

☐ 2 Bumetanide: _____ mg ☐ 98 Other, *(specify)*: _____ _____ mg

Check "No" or "Yes" for each medication.

2	Spironolactone:	☐ 0 No	☐ 1 Yes	**16** Calcium channel blocker:	☐ 0 No ☐ 1 Yes
3	Eplerenone:	☐ 0 No	☐ 1 Yes	**17** Insulin:	☐ 0 No ☐ 1 Yes
4	Non-loop diuretic: *(excluding aldosterone antagonist)*	☐ 0 No	☐ 1 Yes	**18** Glitazone:	☐ 0 No ☐ 1 Yes
				19 Other oral diabetic agent:	☐ 0 No ☐ 1 Yes
5	Potassium:	☐ 0 No	☐ 1 Yes	**20** Thyroid replacement:	☐ 0 No ☐ 1 Yes
6	ACE inhibitor:	☐ 0 No	☐ 1 Yes	**21** Selective serotonin reuptake inhibitor:	☐ 0 No ☐ 1 Yes
7	Angiotensin receptor blocker:	☐ 0 No	☐ 1 Yes	**22** Tricyclic antidepressant:	☐ 0 No ☐ 1 Yes
8	Beta blocker:	☐ 0 No	☐ 1 Yes	**23** Other antidepressant: *(excluding SSRIs and TCAs)*	☐ 0 No ☐ 1 Yes
9	Aspirin:	☐ 0 No	☐ 1 Yes	**24** Antipsychotic:	☐ 0 No ☐ 1 Yes
10	Antiarrhythmic:	☐ 0 No	☐ 1 Yes	**25** NSAID:	☐ 0 No ☐ 1 Yes
11	Lipid-lowering agent:	☐ 0 No	☐ 1 Yes	**26** COX-2 inhibitor:	☐ 0 No ☐ 1 Yes
12	Clopidogrel:	☐ 0 No	☐ 1 Yes	**27** Sildenafil:	☐ 0 No ☐ 1 Yes
13	Coumadin:	☐ 0 No	☐ 1 Yes		
14	Digoxin:	☐ 0 No	☐ 1 Yes		
15	Nitrate:	☐ 0 No	☐ 1 Yes		

Reserved for potential new drugs. **Do not complete unless instructed by the Duke Clinical Research Institute (DCRI).**

28 Other: _____ ☐ 0 No ☐ 1 Yes

29 Other: _____ ☐ 0 No ☐ 1 Yes

18–Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

1 Has the patient had any **non-urgent** outpatient visits since the last study visit? *(Do not include protocol-specified follow-up visits.)* ☐0 No ☐1 Yes → **Complete the table below.**

	Provider Type	Number of Office/Clinic Visits	Number of Home Visits
1.1	Cardiologist:		
1.2	Orthopedic surgeon:		
1.3	Other specialist:		
1.4	Primary care physician:		
1.5	Physician extenders *(includes NPs, PAs, etc.)*:		
1.6	OT or PT:		
1.7	Mental health provider:		
1.8	Nurse *(includes RNs, LPNs, nurse's aides or other equivalent)*:		
1.9	Other *(specify)*: _____		

2 Has the patient had any outpatient **cardiac** procedures/tests *(including ICD firing)* or **orthopedic** procedures/tests since the last study visit?
☐0 No ☐1 Yes → **Compete the table below.**

Procedure Code*	Number	Procedure Code*	Number	Procedure Code*	Number

*See choices on opposite page. Record one per row. If a procedure/test is not listed, please record it in the table above.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

See annotation p.27 of 3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

3 Has the patient required any **urgent/emergency care** on an outpatient basis since the last study visit? ☐0 No ☐1 Yes → Complete the table below.

	Outpatient Service Type	Number of Visits Due to Heart Failure*	Number of Visits Due to Cardiovascular Disease* (other than heart failure)	Number of Visits Due to Non-Cardiovascular Disease*	Number of Visits Due to Unknown Cause*	Number of Visits Due to a Cardiovascular Event Occurring During or Within 3 Hours After Exercise
3.1	Emergency room, hospital < 24 hours, or observation unit:					
3.2	Heart failure clinic/office:					
3.3	Stand-alone urgent care facility:					

3.4 Date of 1st ER visit *(for any reason since randomization)*: ___/___/___ (day/month/year) OR ☐1 No ER visit to date ☐2 Previously recorded

3.5 Date of 1st urgent clinic visit due to heart failure exacerbation *(since randomization)*: ___/___/___ (day/month/year) OR ☐1 No urgent clinic visit for HF to date ☐2 Previously recorded

Other Types of Resource Utilization

1 Number of days on home IV infusion for heart failure since the last study visit: _____ days

2 Since the last study visit, how many days did the patient live in each of the following...

Their home: _____ days

Caregiver's home *(e.g., family and friends)*: _____ days

Assisted living: _____ days

Skilled nursing facility: _____ days

Acute care hospital: _____ days

Rehabilitation center: _____ days

Other *(specify)*: _____ _____ days

*Primary diagnosis

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Hospitalization Record only hospitalizations for ≥ 24 hours.

Has the patient been hospitalized for any reason since the last completed study visit?

(Only include completed hospitalizations. Wait until the next study visit to record hospital information if the patient is currently hospitalized.)

☐0 No ☐1 Yes → **If Yes: How many hospitalizations?** _____

	Hospitalization:	Primary Reason for Hospitalization*	Primary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Secondary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Discharge Destination*
1 Hospitalization: Admission date: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) Discharge date: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
2 Hospitalization: Admission date: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) Discharge date: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
3 Hospitalization: Admission date: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) Discharge date: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				

*See choices on opposite page. If a diagnosis/procedure/discharge destination is not listed, please record it in the table above.

If more than 3 hospitalizations occurred, complete an Additional Hospitalization form.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

This is a repeating page
First page should have page rep 0

See annotation p.29 of 3-Month

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Telephone Log

1 Date of call: ___/___/___ (day/month/year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → If ≥ 1: How many of the contacts resulted in:

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

2 Date of call: ___/___/___ (day/month/year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → If ≥ 1: How many of the contacts resulted in:

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

3 Date of call: ___/___/___ (day/month/year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → If ≥ 1: How many of the contacts resulted in:

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

*See choices on opposite page.

If more than 3 telephone calls were completed, complete an Additional Telephone Log form.

WHITE and YELLOW — Duke Clinical Research Institute • PINK — retain at site

PROTOCOL = HFACTION
STUDYBOOK = DATA_FORMS
FORM = 21MONTH

CONTEXT

NODATA<ZYES>

HF-ACTION 21-Month

VISITDT

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (SUBJNO)
site # patient #

Patient's Initials: ___ ___ ___ (INITIALS)
first middle last

Date of visit: ___/___/___ ___ ___ ___
day month year

Medical History

1 Current NYHA heart failure class *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

See annotation p.24 of 3-Month

2 Current Canadian Cardiovascular Society (CCS) angina class *(check only one)*: ☐ No angina ☐ I ☐ II ☐ III ☐ IV

Current Medications

Check "No" or "Yes"; if "Yes", provide the total daily dose.

1 Loop diuretic: ☐$_0$ No

☐$_1$ Yes → If Yes: Check only one and provide the **total daily dose**:

☐$_1$ Furosemide: _____ mg ☐$_3$ Torsemide: _____ mg

☐$_2$ Bumetanide: _____ mg ☐$_{98}$ Other, *(specify)*: _____ _____ mg

Check "No" or "Yes" for each medication.

2 Spironolactone: ☐$_0$ No ☐$_1$ Yes

3 Eplerenone: ☐$_0$ No ☐$_1$ Yes

4 Non-loop diuretic: ☐$_0$ No ☐$_1$ Yes
(excluding aldosterone antagonist)

5 Potassium: ☐$_0$ No ☐$_1$ Yes

6 ACE inhibitor: ☐$_0$ No ☐$_1$ Yes

7 Angiotensin receptor blocker: ☐$_0$ No ☐$_1$ Yes

8 Beta blocker: ☐$_0$ No ☐$_1$ Yes

9 Aspirin: ☐$_0$ No ☐$_1$ Yes

10 Antiarrhythmic: ☐$_0$ No ☐$_1$ Yes

11 Lipid-lowering agent: ☐$_0$ No ☐$_1$ Yes

12 Clopidogrel: ☐$_0$ No ☐$_1$ Yes

13 Coumadin: ☐$_0$ No ☐$_1$ Yes

14 Digoxin: ☐$_0$ No ☐$_1$ Yes

15 Nitrate: ☐$_0$ No ☐$_1$ Yes

16 Calcium channel blocker: ☐$_0$ No ☐$_1$ Yes

17 Insulin: ☐$_0$ No ☐$_1$ Yes

18 Glitazone: ☐$_0$ No ☐$_1$ Yes

19 Other oral diabetic agent: ☐$_0$ No ☐$_1$ Yes

20 Thyroid replacement: ☐$_0$ No ☐$_1$ Yes

21 Selective serotonin reuptake inhibitor: ☐$_0$ No ☐$_1$ Yes

22 Tricyclic antidepressant: ☐$_0$ No ☐$_1$ Yes

23 Other antidepressant: ☐$_0$ No ☐$_1$ Yes
(excluding SSRIs and TCAs)

24 Antipsychotic: ☐$_0$ No ☐$_1$ Yes

25 NSAID: ☐$_0$ No ☐$_1$ Yes

26 COX-2 inhibitor: ☐$_0$ No ☐$_1$ Yes

27 Sildenafil: ☐$_0$ No ☐$_1$ Yes

Reserved for potential new drugs. **Do not complete unless instructed by the Duke Clinical Research Institute (DCRI).**

28 Other: _____ ☐$_0$ No ☐$_1$ Yes

29 Other: _____ ☐$_0$ No ☐$_1$ Yes

See annotation p.26 of 3-Month

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

1 Has the patient had any **non-urgent** outpatient visits since the last study visit? *(Do not include protocol-specified follow-up visits.)* ☐ 0 No ☐ 1 Yes → **Complete the table below.**

	Provider Type	Number of Office/Clinic Visits	Number of Home Visits
1.1	Cardiologist:		
1.2	Orthopedic surgeon:		
1.3	Other specialist:		
1.4	Primary care physician:		
1.5	Physician extenders *(includes NPs, PAs, etc.)*:		
1.6	OT or PT:		
1.7	Mental health provider:		
1.8	Nurse *(includes RNs, LPNs, nurse's aides or other equivalent)*:		
1.9	Other *(specify)*: _____		

2 Has the patient had any outpatient **cardiac** procedures/tests *(including ICD firing)* or **orthopedic** procedures/tests since the last study visit?
☐ 0 No ☐ 1 Yes → **Compete the table below.**

Procedure Code*	Number	Procedure Code*	Number	Procedure Code*	Number

*See choices on opposite page. Record one per row. If a procedure/test is not listed, please record it in the table above.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

See annotation p.27 of 3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

3 Has the patient required any **urgent/emergency care** on an outpatient basis since the last study visit? ☐ 0 No ☐ 1 Yes → Complete the table below.

	Outpatient Service Type	Number of Visits Due to Heart Failure*	Number of Visits Due to Cardiovascular Disease* (other than heart failure)	Number of Visits Due to Non-Cardiovascular Disease*	Number of Visits Due to Unknown Cause*	Number of Visits Due to a Cardiovascular Event Occurring During or Within 3 Hours After Exercise
3.1	Emergency room, hospital < 24 hours, or observation unit:					
3.2	Heart failure clinic/office:					
3.3	Stand-alone urgent care facility:					

3.4 Date of 1st ER visit *(for any reason since randomization)*: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) OR ☐ 1 No ER visit to date ☐ 2 Previously recorded

3.5 Date of 1st urgent clinic visit due to heart failure exacerbation *(since randomization)*: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) OR ☐ 1 No urgent clinic visit for HF to date ☐ 2 Previously recorded

Other Types of Resource Utilization

1 Number of days on home IV infusion for heart failure since the last study visit: _____ days

2 Since the last study visit, how many days did the patient live in each of the following...

Their home: _____ days

Caregiver's home *(e.g., family and friends)*: _____ days

Assisted living: _____ days

Skilled nursing facility: _____ days

Acute care hospital: _____ days

Rehabilitation center: _____ days

Other *(specify)*: _____ _____ days

*Primary diagnosis

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Hospitalization Record only hospitalizations for ≥ 24 hours.

Has the patient been hospitalized for any reason since the last completed study visit?

(Only include completed hospitalizations. Wait until the next study visit to record hospital information if the patient is currently hospitalized.)

☐0 No ☐1 Yes → **If Yes: How many hospitalizations?** _____

	Hospitalization:	Primary Reason for Hospitalization*	Primary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Secondary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Discharge Destination*
1 Hospitalization: Admission date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Discharge date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
2 Hospitalization: Admission date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Discharge date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
3 Hospitalization: Admission date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Discharge date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				

* See choices on opposite page. If a diagnosis/procedure/discharge destination is not listed, please record it in the table above.
If more than 3 hospitalizations occurred, complete an Additional Hospitalization form.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

This is a repeating page
First page should have page rep 0

See annotation p.29 of 3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Telephone Log

1 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → If ≥ 1: How many of the contacts resulted in:

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

2 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → If ≥ 1: How many of the contacts resulted in:

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

3 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → If ≥ 1: How many of the contacts resulted in:

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

*See choices on opposite page.

If more than 3 telephone calls were completed, complete an Additional Telephone Log form.

WHITE and YELLOW – Duke Clinical Research Institute • PINK – retain at site

PROTOCOL = HFACTION
STUDYBOOK = DATA_FORMS
FORM = 24MONTH

CONTEXT

NODATA<ZYES>

HF ACTION

24-Month

VISITDT

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

Patient's Initials: ___ ___ ___ (first middle last) INITIALS

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

EuroQoL Questionnaire

By placing a checkmark in one box in each group below, please indicate which statement best describes your own health state today.

See annotation p.3 of Baseline

1 Mobility:

- ☐ 1 I have no problems in walking about.
- ☐ 2 I have some problems in walking about.
- ☐ 3 I am confined to bed.

2 Self-care:

- ☐ 1 I have no problems with self-care.
- ☐ 2 I have some problems washing or dressing myself.
- ☐ 3 I am unable to wash or dress myself.

3 Usual activities *(e.g. work, study, housework, family or leisure activities)*:

- ☐ 1 I have no problems with performing my usual activities.
- ☐ 2 I have some problems with performing my usual activities.
- ☐ 3 I am unable to perform my usual activities.

4 Pain/discomfort:

- ☐ 1 I have no pain or discomfort.
- ☐ 2 I have moderate pain or discomfort.
- ☐ 3 I have extreme pain or discomfort.

5 Anxiety/depression:

- ☐ 1 I am not anxious or depressed.
- ☐ 2 I am moderately anxious or depressed.
- ☐ 3 I am extremely anxious or depressed.

STOP → **Please let your study coordinator know that you are ready for the EuroQoL Thermometer worksheet.**

PATIENT SELF-REPORT FORM

Pain Assessment

1 How much bodily pain have you had during the past 4 weeks *(check only one)*?

☐ 1 None ☐ 2 Very mild ☐ 3 Mild ☐ 4 Moderate ☐ 5 Severe ☐ 6 Very severe

2 During the past 4 weeks, how much did pain interfere with your normal work *(including both work outside the home and housework)*?

☐ 1 Not at all ☐ 2 A little bit ☐ 3 Moderately ☐ 4 Quite a bit ☐ 5 Extremely

EuroQol Thermometer Response

Response to the EuroQoL thermometer: ___ ___ ___ *(0-100)*

HF-ACTION

24-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Kansas City Cardiomyopathy Questionnaire (KCCQ)

The following questions refer to your heart failure and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answers that best apply to you.

1 **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** *(shortness of breath or fatigue)* in your ability to do the following activities over the past 2 weeks.

(Check only one box on each line.)

Activity	Extremely Limited	Quite a Bit Limited	Moderately Limited	Slightly Limited	Not at All Limited	Limited for Other Reasons or Did Not Do the Activity
Dressing yourself:	☐1	☐2	☐3	☐4	☐5	☐6
Showering/bathing:	☐1	☐2	☐3	☐4	☐5	☐6
Walking 1 block on level ground:	☐1	☐2	☐3	☐4	☐5	☐6
Doing yard work, housework or carrying groceries:	☐1	☐2	☐3	☐4	☐5	☐6
Climbing a flight of stairs without stopping:	☐1	☐2	☐3	☐4	☐5	☐6
Hurrying or jogging *(as if to catch a bus)*:	☐1	☐2	☐3	☐4	☐5	☐6

2 Compared with 2 weeks ago, have your symptoms of **heart failure** *(shortness of breath, fatigue, or ankle swelling)* **changed?**
My symptoms of heart failure have become...

Much worse	Slightly worse	Not changed	Slightly better	Much better	I've had no symptoms over the last 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6

3 Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in the morning?

Every morning	3 or more times a week, but not every morning	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5

4 Over the past 2 weeks, how much has **swelling** in your feet, ankles or legs bothered you? It has been...

Extremely bothersome	**Moderately** bothersome	**Somewhat** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no swelling**
☐1	☐2	☐3	☐4	☐5	☐6

PATIENT SELF-REPORT FORM

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

5 Over the past 2 weeks, on average, how many times has **fatigue** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

6 Over the past 2 weeks, how much has your **fatigue** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no fatigue**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

7 Over the past 2 weeks, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

8 Over the past 2 weeks, how much has your **shortness of breath** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no shortness of breath**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

9 Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

Every night	3 or more times a week, but not every night	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10 **Heart failure** symptoms can worsen for a number of reasons. How sure are you that you know what to do or who to call, if your **heart failure** gets worse?

Not at all sure	**Not very** sure	**Somewhat** sure	**Mostly** sure	**Completely** sure
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11 How well do you understand what things you are able to do to keep your **heart failure** symptoms from getting **worse** (*for example, weighing yourself, eating a low-salt diet etc.*)?

Do not understand at all	Do not understand very well	Somewhat understand	Mostly understand	Completely understand
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

PATIENT SELF-REPORT FORM

24-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

12 Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not limited** my enjoyment of life at all
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

13 If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

Not at all satisfied	**Mostly** dissatisfied	**Somewhat** satisfied	**Mostly** satisfied	**Completely** satisfied
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

14 Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of your **heart failure**?

I felt that way **all of the time**	I felt that way **most of the time**	I **occasionally** felt that way	I **rarely** felt that way	I **never** felt that way
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

15 How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks.

(Check only one box on each line.)

Activity	Severely Limited	Limited Quite a Bit	Moderately Limited	Slightly Limited	Did Not Limit at All	Does Not Apply or Did Not Do for Other Reasons
Hobbies, recreational activities:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Intimate relationships with loved ones:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Visiting family or friends out of your home:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Working or doing household chores:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

PATIENT SELF-REPORT FORM

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Beck Depression Inventory (BDI)

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the past one week, including today. Check the box beside the statement you have picked. If several statements within a group seem to apply equally well, check the highest numbered box for that group. Be sure that you do not choose more than one statement for any group, including item 16, Changes in Sleeping Pattern and item 18, Changes in Appetite.

1 Sadness:
- ☐ 0 I do not feel sad.
- ☐ 1 I feel sad much of the time.
- ☐ 2 I am sad all of the time.
- ☐ 3 I am so sad or unhappy that I can't stand it.

2 Pessimism:
- ☐ 0 I am not discouraged about my future.
- ☐ 1 I feel more discouraged about my future than I used to be.
- ☐ 2 I do not expect things to work out for me.
- ☐ 3 I feel my future is hopeless and will only get worse.

3 Past Failure:
- ☐ 0 I do not feel like a failure.
- ☐ 1 I have failed more than I should have.
- ☐ 2 As I look back, I see a lot of failures.
- ☐ 3 I feel I am a total failure as a person.

4 Loss of Pleasure:
- ☐ 0 I get as much pleasure as I ever did from the things I enjoy.
- ☐ 1 I don't enjoy things as much as I used to.
- ☐ 2 I get very little pleasure from the things I used to enjoy.
- ☐ 3 I can't get any pleasure from the things I used to enjoy.

5 Guilty Feelings:
- ☐ 0 I don't feel particularly guilty.
- ☐ 1 I feel guilty over many things I have done or should have done.
- ☐ 2 I feel quite guilty most of the time.
- ☐ 3 I feel guilty all of the time.

6 Punishment Feelings:
- ☐ 0 I don't feel I am being punished.
- ☐ 1 I feel I may be punished.
- ☐ 2 I expect to be punished.
- ☐ 3 I feel I am being punished.

7 Self-Dislike:
- ☐ 0 I feel the same about myself as ever.
- ☐ 1 I have lost confidence in myself.
- ☐ 2 I am disappointed in myself.
- ☐ 3 I dislike myself.

8 Self-Criticalness:
- ☐ 0 I don't criticize or blame myself more than usual.
- ☐ 1 I am more critical of myself than I used to be.
- ☐ 2 I criticize myself for all of my faults.
- ☐ 3 I blame myself for everything that happens.

9 Suicidal Thoughts or Wishes:
- ☐ 0 I don't have any thoughts of killing myself.
- ☐ 1 I have thoughts of killing myself, but I would not carry them out.
- ☐ 2 I would like to kill myself.
- ☐ 3 I would kill myself if I had the chance.

10 Crying:
- ☐ 0 I don't cry any more than I used to.
- ☐ 1 I cry more than I used to.
- ☐ 2 I cry over every little thing.
- ☐ 3 I feel like crying, but I can't.

11 Agitation:
- ☐ 0 I am no more restless or wound up than usual.
- ☐ 1 I feel more restless or wound up than usual.
- ☐ 2 I am so restless or agitated that it's hard to stay still.
- ☐ 3 I am so restless or agitated that I have to keep moving or doing something.

12 Loss of Interest:
- ☐ 0 I have not lost interest in other people or activities.
- ☐ 1 I am less interested in other people or things than before.
- ☐ 2 I have lost most of my interest in other people or things.
- ☐ 3 It's hard to get interested in anything.

PATIENT SELF-REPORT FORM

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Beck Depression Inventory (BDI) (continued)

13 Indecisiveness:

- ☐ 0 I make decisions about as well as ever.
- ☐ 1 I find it more difficult to make decisions than usual.
- ☐ 2 I have much greater difficulty in making decisions than I used to.
- ☐ 3 I have trouble making any decisions.

14 Worthlessness:

- ☐ 0 I do not feel I am worthless.
- ☐ 1 I don't consider myself as worthwhile and useful as I used to.
- ☐ 2 I feel more worthless as compared to other people.
- ☐ 3 I feel utterly worthless.

15 Loss of Energy:

- ☐ 0 I have as much energy as ever.
- ☐ 1 I have less energy than I used to have.
- ☐ 2 I don't have enough energy to do very much.
- ☐ 3 I don't have enough energy to do anything.

16 Changes in Sleeping Pattern *(check only one)*:

- ☐ 0 I have not experienced any change in my sleeping pattern.
- ☐ 1a I sleep somewhat more than usual.
- ☐ 1b I sleep somewhat less than usual.
- ☐ 2a I sleep a lot more than usual.
- ☐ 2b I sleep a lot less than usual.
- ☐ 3a I sleep most of the day.
- ☐ 3b I wake up 1–2 hours early and can't get back to sleep.

17 Irritability:

- ☐ 0 I am no more irritable than usual.
- ☐ 1 I am more irritable than usual.
- ☐ 2 I am much more irritable than usual.
- ☐ 3 I am irritable all the time.

18 Changes in Appetite *(check only one)*:

- ☐ 0 I have not experienced any change in my appetite.
- ☐ 1a My appetite is somewhat less than usual.
- ☐ 1b My appetite is somewhat greater than usual.
- ☐ 2a My appetite is much less than before.
- ☐ 2b My appetite is much greater than usual.
- ☐ 3a I have no appetite at all.
- ☐ 3b I crave food all the time.

19 Concentration Difficulty:

- ☐ 0 I can concentrate as well as ever.
- ☐ 1 I can't concentrate as well as usual.
- ☐ 2 It's hard to keep my mind on anything for very long.
- ☐ 3 I find I can't concentrate on anything.

20 Tiredness or Fatigue:

- ☐ 0 I am no more tired or fatigued than usual.
- ☐ 1 I get more tired or fatigued more easily than usual.
- ☐ 2 I am too tired or fatigued to do a lot of the things I used to do.
- ☐ 3 I am too tired or fatigued to do most of the things I used to do.

21 Loss of Interest in Sex:

- ☐ 0 I have not noticed any recent change in my interest in sex.
- ☐ 1 I am less interested in sex than I used to be.
- ☐ 2 I am much less interested in sex now.
- ☐ 3 I have lost interest in sex completely.

See annotation p.61

PATIENT SELF-REPORT FORM

Productivity Assessment

1 How many days have you lost from work and/or your usual activities in the past 30 days due to problems with your health?

_____ days

2 Check one of the following to indicate your current employment status:

- ☐ 1 Employed/self-employed full-time *(> 30 hours week)*
- ☐ 2 Employed part-time *(specify hours per week)*: _____
- ☐ 3 Student
- ☐ 4 Homemaker
- ☐ 5 Volunteer
- ☐ 6 Disabled
- ☐ 7 Unemployed
- ☐ 8 Retired

See annotation p.12 of Baseline

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Physical Activity Questionnaire (PAQ)

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the last 7 days. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous physical activities** that you did in the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

1 During the last 7 days, on how many days did you do **vigorous physical activities** like heavy lifting, digging, aerobics, or fast bicycling?

_____ days → **Continue to question 2.**

OR ☐ No vigorous physical activities → **Skip to question 3.**

2 How much time did you usually spend doing **vigorous physical activities** on one of those days?

___ ___ ___ minutes per day

OR ☐ Don't know/not sure

Think about all the **moderate physical activities** that you did in the last 7 days. Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3 During the last 7 days, on how many days did you do **moderate physical activities** like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ days → **Continue to question 4.**

OR ☐ No moderate physical activities → **Skip to question 5.**

4 How much time did you usually spend doing **moderate physical activities** on one of those days?

___ ___ ___ minutes per day

OR ☐ Don't know/not sure

Think about the time you spent **walking** in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5 During the last 7 days, on how many days did you **walk** for at least 10 minutes at a time?

_____ days → **Continue to question 6.**

OR ☐ No walking → **Skip to question 7.**

6 How much time did you usually spend **walking** on one of those days?

___ ___ ___ minutes per day

OR ☐ Don't know/not sure

The last question is about the time you spent **sitting on weekdays** during the last 7 days. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7 During the last 7 days, how much time did you spend **sitting on a weekday**?

___ ___ hours per day

OR ☐ Don't know/not sure

PATIENT SELF-REPORT FORM

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Medical History

1 Current NYHA heart failure class *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

2 Current Canadian Cardiovascular Society (CCS) angina class *(check only one)*: ☐ No angina ☐ I ☐ II ☐ III ☐ IV

Current Medications

Check "No" or "Yes"; if "Yes", provide the total daily dose.

1 Loop diuretic: ☐$_0$ No
☐$_1$ Yes → If Yes: Check only one and provide the **total daily dose**:
☐$_1$ Furosemide: _____ mg ☐$_3$ Torsemide: _____ mg
☐$_2$ Bumetanide: _____ mg ☐$_{98}$ Other, *(specify)*: _____ _____ mg

Check "No" or "Yes" for each medication.

2 Spironolactone: ☐$_0$ No ☐$_1$ Yes

3 Eplerenone: ☐$_0$ No ☐$_1$ Yes

4 Non-loop diuretic: ☐$_0$ No ☐$_1$ Yes
(excluding aldosterone antagonist)

5 Potassium: ☐$_0$ No ☐$_1$ Yes

6 ACE inhibitor: ☐$_0$ No ☐$_1$ Yes

7 Angiotensin receptor blocker: ☐$_0$ No ☐$_1$ Yes

8 Beta blocker: ☐$_0$ No ☐$_1$ Yes

9 Aspirin: ☐$_0$ No ☐$_1$ Yes

10 Antiarrhythmic: ☐$_0$ No ☐$_1$ Yes

11 Lipid-lowering agent: ☐$_0$ No ☐$_1$ Yes

12 Clopidogrel: ☐$_0$ No ☐$_1$ Yes

13 Coumadin: ☐$_0$ No ☐$_1$ Yes

14 Digoxin: ☐$_0$ No ☐$_1$ Yes

15 Nitrate: ☐$_0$ No ☐$_1$ Yes

16 Calcium channel blocker: ☐$_0$ No ☐$_1$ Yes

17 Insulin: ☐$_0$ No ☐$_1$ Yes

18 Glitazone: ☐$_0$ No ☐$_1$ Yes

19 Other oral diabetic agent: ☐$_0$ No ☐$_1$ Yes

20 Thyroid replacement: ☐$_0$ No ☐$_1$ Yes

21 Selective serotonin reuptake inhibitor: ☐$_0$ No ☐$_1$ Yes

22 Tricyclic antidepressant: ☐$_0$ No ☐$_1$ Yes

23 Other antidepressant: ☐$_0$ No ☐$_1$ Yes
(excluding SSRIs and TCAs)

24 Antipsychotic: ☐$_0$ No ☐$_1$ Yes

25 NSAID: ☐$_0$ No ☐$_1$ Yes

26 COX-2 inhibitor: ☐$_0$ No ☐$_1$ Yes

27 Sildenafil: ☐$_0$ No ☐$_1$ Yes

Reserved for potential new drugs. **Do not complete unless instructed by the Duke Clinical Research Institute (DCRI).**

28 Other: _____ ☐$_0$ No ☐$_1$ Yes

29 Other: _____ ☐$_0$ No ☐$_1$ Yes

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Quality of Life—Reason for Missing Data

Are all quality-of-life forms complete?

- ☐ 0 No → If No:
  - ☐ 1 Patient died
  - ☐ 2 Patient refused
  - ☐ 3 Patient withdrew consent
  - ☐ 4 Patient missed visit
  - ☐ 5 Patient sick
  - ☐ 98 Other

  OR

- ☐ 1 Yes

6–Minute Walk Test

1 Did the patient attempt the 6-minute walk at this visit?

- ☐ 0 No → If No: Specify primary reason:
  - ☐ Patient was too critically ill
  - ☐ Patient cannot walk for technical reasons *(e.g., a patient who is an amputee)*
  - ☐ Not done due to oversight
  - ☐ Patient refused
  - ☐ Patient died
  - ☐ Patient withdrew consent
  - ☐ Patient missed visit

  OR

- ☐ 1 Yes → If Yes: Date of 6-minute walk: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

  Start walk time: ___ ___ : ___ ___ (00:00 to 23:59)

  Total distance walked: _____ ☐ 1 Feet ☐ 2 Meter(s)

  Did the patient experience any of the following symptoms? *(check all that apply)*
  ☐ None ☐ Angina ☐ Light-headedness ☐ Syncope

  Borg Rating of Perceived Exertion (RPE) Scale: _____ *(6–20)*

2 Were the QOL instruments completed before or after the 6-minute walk? Check only one:

- ☐ 1 Before
- ☐ 2 < 30 mins after
- ☐ 3 30–60 mins after
- ☐ 4 > 60 mins after

See annotation p.26 of 3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

1 Has the patient had any **non-urgent** outpatient visits since the last study visit? *(Do not include protocol-specified follow-up visits.)* ☐ 0 No ☐ 1 Yes → Complete the table below.

	Provider Type	Number of Office/Clinic Visits	Number of Home Visits
1.1	Cardiologist:		
1.2	Orthopedic surgeon:		
1.3	Other specialist:		
1.4	Primary care physician:		
1.5	Physician extenders *(includes NPs, PAs, etc.)*:		
1.6	OT or PT:		
1.7	Mental health provider:		
1.8	Nurse *(includes RNs, LPNs, nurse's aides or other equivalent)*:		
1.9	Other *(specify)*: _____		

2 Has the patient had any outpatient **cardiac** procedures/tests *(including ICD firing)* or **orthopedic** procedures/tests since the last study visit?
☐ 0 No ☐ 1 Yes → Compete the table below.

Procedure Code*	Number	Procedure Code*	Number	Procedure Code*	Number

*See choices on opposite page. Record one per row. If a procedure/test is not listed, please record it in the table above.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

See annotation p.27 of 3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

3 Has the patient required any **urgent/emergency care** on an outpatient basis since the last study visit? ☐0 No ☐1 Yes → Complete the table below.

	Outpatient Service Type	Number of Visits Due to Heart Failure*	Number of Visits Due to Cardiovascular Disease* (other than heart failure)	Number of Visits Due to Non-Cardiovascular Disease*	Number of Visits Due to Unknown Cause*	Number of Visits Due to a Cardiovascular Event Occurring During or Within 3 Hours After Exercise
3.1	Emergency room, hospital < 24 hours, or observation unit:					
3.2	Heart failure clinic/office:					
3.3	Stand-alone urgent care facility:					

3.4 Date of 1st ER visit *(for any reason since randomization)*: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐1 No ER visit to date ☐2 Previously recorded

3.5 Date of 1st urgent clinic visit due to heart failure exacerbation *(since randomization)*: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐1 No urgent clinic visit for HF to date ☐2 Previously recorded

Other Types of Resource Utilization

1 Number of days on home IV infusion for heart failure since the last study visit: _____ days

2 Since the last study visit, how many days did the patient live in each of the following...

Their home: _____ days

Caregiver's home *(e.g., family and friends)*: _____ days

Assisted living: _____ days

Skilled nursing facility: _____ days

Acute care hospital: _____ days

Rehabilitation center: _____ days

Other *(specify)*: _____ _____ days

*Primary diagnosis

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Hospitalization Record only hospitalizations for ≥ 24 hours.

Has the patient been hospitalized for any reason since the last completed study visit?

(Only include completed hospitalizations. Wait until the next study visit to record hospital information if the patient is currently hospitalized.)

☐0 No ☐1 Yes → **If Yes: How many hospitalizations?** _____

	Hospitalization:	Primary Reason for Hospitalization*	Primary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Secondary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Discharge Destination*
1 Hospitalization: Admission date: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) Discharge date: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
2 Hospitalization: Admission date: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) Discharge date: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
3 Hospitalization: Admission date: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) Discharge date: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				

*See choices on opposite page. If a diagnosis/procedure/discharge destination is not listed, please record it in the table above.

If more than 3 hospitalizations occurred, complete an Additional Hospitalization form.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

This is a repeating page
First page should have page rep 0

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Telephone Log

1 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

2 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

3 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

*See choices on opposite page.

If more than 3 telephone calls were completed, complete an Additional Telephone Log form.

WHITE and YELLOW — Duke Clinical Research Institute • PINK — retain at site

PROTOCOL = HFACTION
STUDYBOOK = DATA_FORMS
FORM = FINAL VISIT

NODATA<ZYES>

CONTEXT

HF ACTION

Final Visit

VISITDT

SUBJNO

Patient Number: ___ ___ ___ - ___ ___ ___ ___
site # patient #

Patient's Initials: ___ ___ ___ INITIALS
first middle last

Date of visit: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
day month year

EuroQoL Questionnaire

By placing a checkmark in one box in each group below, please indicate which statement best describes your own health state today.

See annotation p. 3 of Baseline

1 Mobility:

- ☐ 1 I have no problems in walking about.
- ☐ 2 I have some problems in walking about.
- ☐ 3 I am confined to bed.

2 Self-care:

- ☐ 1 I have no problems with self-care.
- ☐ 2 I have some problems washing or dressing myself.
- ☐ 3 I am unable to wash or dress myself.

3 Usual activities *(e.g. work, study, housework, family or leisure activities)*:

- ☐ 1 I have no problems with performing my usual activities.
- ☐ 2 I have some problems with performing my usual activities.
- ☐ 3 I am unable to perform my usual activities.

4 Pain/discomfort:

- ☐ 1 I have no pain or discomfort.
- ☐ 2 I have moderate pain or discomfort.
- ☐ 3 I have extreme pain or discomfort.

5 Anxiety/depression:

- ☐ 1 I am not anxious or depressed.
- ☐ 2 I am moderately anxious or depressed.
- ☐ 3 I am extremely anxious or depressed.

STOP → **Please let your study coordinator know that you are ready for the EuroQoL Thermometer worksheet.**

PATIENT SELF-REPORT FORM

Pain Assessment

1 How much bodily pain have you had during the past 4 weeks *(check only one)*?

☐ 1 None ☐ 2 Very mild ☐ 3 Mild ☐ 4 Moderate ☐ 5 Severe ☐ 6 Very severe

2 During the past 4 weeks, how much did pain interfere with your normal work *(including both work outside the home and housework)*?

☐ 1 Not at all ☐ 2 A little bit ☐ 3 Moderately ☐ 4 Quite a bit ☐ 5 Extremely

EuroQol Thermometer Response

Response to the EuroQoL thermometer: ___ ___ ___
(0-100)

Kansas City Cardiomyopathy Questionnaire (KCCQ)

The following questions refer to your heart failure and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answers that best apply to you.

1 **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** *(shortness of breath or fatigue)* in your ability to do the following activities over the past 2 weeks.

(Check only one box on each line.)

Activity	Extremely Limited	Quite a Bit Limited	Moderately Limited	Slightly Limited	Not at All Limited	Limited for Other Reasons or Did Not Do the Activity
Dressing yourself:	☐1	☐2	☐3	☐4	☐5	☐6
Showering/bathing:	☐1	☐2	☐3	☐4	☐5	☐6
Walking 1 block on level ground:	☐1	☐2	☐3	☐4	☐5	☐6
Doing yard work, housework or carrying groceries:	☐1	☐2	☐3	☐4	☐5	☐6
Climbing a flight of stairs without stopping:	☐1	☐2	☐3	☐4	☐5	☐6
Hurrying or jogging *(as if to catch a bus)*:	☐1	☐2	☐3	☐4	☐5	☐6

2 Compared with 2 weeks ago, have your symptoms of **heart failure** *(shortness of breath, fatigue, or ankle swelling)* changed? My symptoms of heart failure have become...

Much worse	Slightly worse	Not changed	Slightly better	Much better	I've had no symptoms over the last 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6

3 Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in the morning?

Every morning	3 or more times a week, but not every morning	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5

4 Over the past 2 weeks, how much has **swelling** in your feet, ankles or legs bothered you? It has been...

Extremely bothersome	**Moderately** bothersome	**Somewhat** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no swelling**
☐1	☐2	☐3	☐4	☐5	☐6

PATIENT SELF-REPORT FORM

See annotation p. 5 of Baseline

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

5 Over the <u>past 2 weeks</u>, on average, how many times has **fatigue** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

6 Over the <u>past 2 weeks</u>, how much has your **fatigue** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no fatigue**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

7 Over the <u>past 2 weeks</u>, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

8 Over the <u>past 2 weeks</u>, how much has your **shortness of breath** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no shortness of breath**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

9 Over the <u>past 2 weeks</u>, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

Every night	3 or more times a week, but not every night	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10 **Heart failure** symptoms can worsen for a number of reasons. How sure are you that you know what to do or who to call, if your **heart failure** gets worse?

Not at all sure	**Not very** sure	**Somewhat** sure	**Mostly** sure	**Completely** sure
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11 How well do you understand what things you are able to do to keep your **heart failure** symptoms from getting **worse** *(for example, weighing yourself, eating a low-salt diet etc.)*?

Do not understand at all	Do not understand very well	Somewhat understand	Mostly understand	Completely understand
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

PATIENT SELF-REPORT FORM

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

12 Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not limited** my enjoyment of life at all
☐1	☐2	☐3	☐4	☐5

13 If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

Not at all satisfied	**Mostly** dissatisfied	**Somewhat** satisfied	**Mostly** satisfied	**Completely** satisfied
☐1	☐2	☐3	☐4	☐5

14 Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of your **heart failure**?

I felt that way **all of the time**	I felt that way **most of the time**	I **occasionally** felt that way	I **rarely** felt that way	I **never** felt that way
☐1	☐2	☐3	☐4	☐5

15 How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks.

(Check only one box on each line.)

Activity	Severely Limited	Limited Quite a Bit	Moderately Limited	Slightly Limited	Did Not Limit at All	Does Not Apply or Did Not Do for Other Reasons
Hobbies, recreational activities:	☐1	☐2	☐3	☐4	☐5	☐6
Intimate relationships with loved ones:	☐1	☐2	☐3	☐4	☐5	☐6
Visiting family or friends out of your home:	☐1	☐2	☐3	☐4	☐5	☐6
Working or doing household chores:	☐1	☐2	☐3	☐4	☐5	☐6

PATIENT SELF-REPORT FORM

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Beck Depression Inventory (BDI)

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the past one week, including today. Check the box beside the statement you have picked. If several statements within a group seem to apply equally well, check the highest numbered box for that group. Be sure that you do not choose more than one statement for any group, including item 16, Changes in Sleeping Pattern and item 18, Changes in Appetite.

1 Sadness:
- ☐ 0 I do not feel sad.
- ☐ 1 I feel sad much of the time.
- ☐ 2 I am sad all of the time.
- ☐ 3 I am so sad or unhappy that I can't stand it.

2 Pessimism:
- ☐ 0 I am not discouraged about my future.
- ☐ 1 I feel more discouraged about my future than I used to be.
- ☐ 2 I do not expect things to work out for me.
- ☐ 3 I feel my future is hopeless and will only get worse.

3 Past Failure:
- ☐ 0 I do not feel like a failure.
- ☐ 1 I have failed more than I should have.
- ☐ 2 As I look back, I see a lot of failures.
- ☐ 3 I feel I am a total failure as a person.

4 Loss of Pleasure:
- ☐ 0 I get as much pleasure as I ever did from the things I enjoy.
- ☐ 1 I don't enjoy things as much as I used to.
- ☐ 2 I get very little pleasure from the things I used to enjoy.
- ☐ 3 I can't get any pleasure from the things I used to enjoy.

5 Guilty Feelings:
- ☐ 0 I don't feel particularly guilty.
- ☐ 1 I feel guilty over many things I have done or should have done.
- ☐ 2 I feel quite guilty most of the time.
- ☐ 3 I feel guilty all of the time.

6 Punishment Feelings:
- ☐ 0 I don't feel I am being punished.
- ☐ 1 I feel I may be punished.
- ☐ 2 I expect to be punished.
- ☐ 3 I feel I am being punished.

7 Self-Dislike:
- ☐ 0 I feel the same about myself as ever.
- ☐ 1 I have lost confidence in myself.
- ☐ 2 I am disappointed in myself.
- ☐ 3 I dislike myself.

8 Self-Criticalness:
- ☐ 0 I don't criticize or blame myself more than usual.
- ☐ 1 I am more critical of myself than I used to be.
- ☐ 2 I criticize myself for all of my faults.
- ☐ 3 I blame myself for everything that happens.

9 Suicidal Thoughts or Wishes:
- ☐ 0 I don't have any thoughts of killing myself.
- ☐ 1 I have thoughts of killing myself, but I would not carry them out.
- ☐ 2 I would like to kill myself.
- ☐ 3 I would kill myself if I had the chance.

10 Crying:
- ☐ 0 I don't cry any more than I used to.
- ☐ 1 I cry more than I used to.
- ☐ 2 I cry over every little thing.
- ☐ 3 I feel like crying, but I can't.

11 Agitation:
- ☐ 0 I am no more restless or wound up than usual.
- ☐ 1 I feel more restless or wound up than usual.
- ☐ 2 I am so restless or agitated that it's hard to stay still.
- ☐ 3 I am so restless or agitated that I have to keep moving or doing something.

12 Loss of Interest:
- ☐ 0 I have not lost interest in other people or activities.
- ☐ 1 I am less interested in other people or things than before.
- ☐ 2 I have lost most of my interest in other people or things.
- ☐ 3 It's hard to get interested in anything.

PATIENT SELF-REPORT FORM

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Beck Depression Inventory (BDI) (continued)

13 Indecisiveness:

- ☐ 0 I make decisions about as well as ever.
- ☐ 1 I find it more difficult to make decisions than usual.
- ☐ 2 I have much greater difficulty in making decisions than I used to.
- ☐ 3 I have trouble making any decisions.

14 Worthlessness:

- ☐ 0 I do not feel I am worthless.
- ☐ 1 I don't consider myself as worthwhile and useful as I used to.
- ☐ 2 I feel more worthless as compared to other people.
- ☐ 3 I feel utterly worthless.

15 Loss of Energy:

- ☐ 0 I have as much energy as ever.
- ☐ 1 I have less energy than I used to have.
- ☐ 2 I don't have enough energy to do very much.
- ☐ 3 I don't have enough energy to do anything.

16 Changes in Sleeping Pattern *(check only one)*:

- ☐ 0 I have not experienced any change in my sleeping pattern.
- ☐ 1a I sleep somewhat more than usual.
- ☐ 1b I sleep somewhat less than usual.
- ☐ 2a I sleep a lot more than usual.
- ☐ 2b I sleep a lot less than usual.
- ☐ 3a I sleep most of the day.
- ☐ 3b I wake up 1–2 hours early and can't get back to sleep.

17 Irritability:

- ☐ 0 I am no more irritable than usual.
- ☐ 1 I am more irritable than usual.
- ☐ 2 I am much more irritable than usual.
- ☐ 3 I am irritable all the time.

18 Changes in Appetite *(check only one)*:

- ☐ 0 I have not experienced any change in my appetite.
- ☐ 1a My appetite is somewhat less than usual.
- ☐ 1b My appetite is somewhat greater than usual.
- ☐ 2a My appetite is much less than before.
- ☐ 2b My appetite is much greater than usual.
- ☐ 3a I have no appetite at all.
- ☐ 3b I crave food all the time.

19 Concentration Difficulty:

- ☐ 0 I can concentrate as well as ever.
- ☐ 1 I can't concentrate as well as usual.
- ☐ 2 It's hard to keep my mind on anything for very long.
- ☐ 3 I find I can't concentrate on anything.

20 Tiredness or Fatigue:

- ☐ 0 I am no more tired or fatigued than usual.
- ☐ 1 I get more tired or fatigued more easily than usual.
- ☐ 2 I am too tired or fatigued to do a lot of the things I used to do.
- ☐ 3 I am too tired or fatigued to do most of the things I used to do.

21 Loss of Interest in Sex:

- ☐ 0 I have not noticed any recent change in my interest in sex.
- ☐ 1 I am less interested in sex than I used to be.
- ☐ 2 I am much less interested in sex now.
- ☐ 3 I have lost interest in sex completely.

See annotation p.61 for OUTPUT2

PATIENT SELF-REPORT FORM

Productivity Assessment

1 How many days have you lost from work and/or your usual activities in the past 30 days due to problems with your health?

_____ days

2 Check one of the following to indicate your current employment status:

- ☐ 1 Employed/self-employed full-time *(> 30 hours week)*
- ☐ 2 Employed part-time *(specify hours per week)*: _____
- ☐ 3 Student
- ☐ 4 Homemaker
- ☐ 5 Volunteer
- ☐ 6 Disabled
- ☐ 7 Unemployed
- ☐ 8 Retired

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Perceived Social Support Scale (PSSS)

PATIENT SELF-REPORT FORM

We are interested in how you feel about the following statements. Read each statement carefully.
Please check the box that most closely corresponds to how you feel about each statement, from very strongly disagree to very strongly agree.

	Very Strongly Disagree	Strongly Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree	Very Strongly Agree
1 There is a special person who is around when I am in need:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
2 There is a special person with whom I can share joys and sorrows:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
3 My family really tries to help me:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
4 I get the emotional help and support I need from my family:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
5 I have a special person who is a real source of comfort to me:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
6 My friends really try to help me:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
7 I can count on my friends when things go wrong:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
8 I can talk about my problems with my family:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
9 I have friends with whom I can share my joys and sorrows:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
10 There is a special person in my life who cares about my feelings:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
11 My family is willing to help me make decisions:	☐1	☐2	☐3	☐4	☐5	☐6	☐7
12 I can talk about my problems with my friends:	☐1	☐2	☐3	☐4	☐5	☐6	☐7

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See annotation p. 12 of Baseline

Final Visit

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Physical Activity Questionnaire (PAQ)

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the last 7 days. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous physical activities** that you did in the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

1 During the last 7 days, on how many days did you do **vigorous physical activities** like heavy lifting, digging, aerobics, or fast bicycling?

_____ days → **Continue to question 2.**

OR ☐ No vigorous physical activities → **Skip to question 3.**

2 How much time did you usually spend doing **vigorous physical activities** on one of those days?

___ ___ ___ minutes per day

OR ☐ Don't know/not sure

Think about all the **moderate physical activities** that you did in the last 7 days. Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3 During the last 7 days, on how many days did you do **moderate physical activities** like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ days → **Continue to question 4.**

OR ☐ No moderate physical activities → **Skip to question 5.**

4 How much time did you usually spend doing **moderate physical activities** on one of those days?

___ ___ ___ minutes per day

OR ☐ Don't know/not sure

Think about the time you spent **walking** in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5 During the last 7 days, on how many days did you **walk** for at least 10 minutes at a time?

_____ days → **Continue to question 6.**

OR ☐ No walking → **Skip to question 7.**

6 How much time did you usually spend **walking** on one of those days?

___ ___ ___ minutes per day

OR ☐ Don't know/not sure

The last question is about the time you spent **sitting on weekdays** during the last 7 days. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7 During the last 7 days, how much time did you spend **sitting on a weekday**?

___ ___ hours per day

OR ☐ Don't know/not sure

PATIENT SELF-REPORT FORM

See annotation p. 24 of 3-Month

Final Visit

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Medical History

1 Current NYHA heart failure class *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

2 Current Canadian Cardiovascular Society (CCS) angina class *(check only one)*: ☐ No angina ☐ I ☐ II ☐ III ☐ IV

Current Medications

Check "No" or "Yes"; if "Yes", provide the total daily dose.

1 Loop diuretic: ☐$_0$ No
☐$_1$ Yes → If Yes: Check only one and provide the **total daily dose**:
☐$_1$ Furosemide: _____ mg ☐$_3$ Torsemide: _____ mg
☐$_2$ Bumetanide: _____ mg ☐$_{98}$ Other, *(specify)*: _____ _____ mg

Check "No" or "Yes" for each medication.

2 Spironolactone: ☐$_0$ No ☐$_1$ Yes

3 Eplerenone: ☐$_0$ No ☐$_1$ Yes

4 Non-loop diuretic: ☐$_0$ No ☐$_1$ Yes
(excluding aldosterone antagonist)

5 Potassium: ☐$_0$ No ☐$_1$ Yes

6 ACE inhibitor: ☐$_0$ No ☐$_1$ Yes

7 Angiotensin receptor blocker: ☐$_0$ No ☐$_1$ Yes

8 Beta blocker: ☐$_0$ No ☐$_1$ Yes

9 Aspirin: ☐$_0$ No ☐$_1$ Yes

10 Antiarrhythmic: ☐$_0$ No ☐$_1$ Yes

11 Lipid-lowering agent: ☐$_0$ No ☐$_1$ Yes

12 Clopidogrel: ☐$_0$ No ☐$_1$ Yes

13 Coumadin: ☐$_0$ No ☐$_1$ Yes

14 Digoxin: ☐$_0$ No ☐$_1$ Yes

15 Nitrate: ☐$_0$ No ☐$_1$ Yes

16 Calcium channel blocker: ☐$_0$ No ☐$_1$ Yes

17 Insulin: ☐$_0$ No ☐$_1$ Yes

18 Glitazone: ☐$_0$ No ☐$_1$ Yes

19 Other oral diabetic agent: ☐$_0$ No ☐$_1$ Yes

20 Thyroid replacement: ☐$_0$ No ☐$_1$ Yes

21 Selective serotonin reuptake inhibitor: ☐$_0$ No ☐$_1$ Yes

22 Tricyclic antidepressant: ☐$_0$ No ☐$_1$ Yes

23 Other antidepressant: ☐$_0$ No ☐$_1$ Yes
(excluding SSRIs and TCAs)

24 Antipsychotic: ☐$_0$ No ☐$_1$ Yes

25 NSAID: ☐$_0$ No ☐$_1$ Yes

26 COX-2 inhibitor: ☐$_0$ No ☐$_1$ Yes

27 Sildenafil: ☐$_0$ No ☐$_1$ Yes

Reserved for potential new drugs. **Do not complete unless instructed by the Duke Clinical Research Institute (DCRI).**

28 Other: _____ ☐$_0$ No ☐$_1$ Yes

29 Other: _____ ☐$_0$ No ☐$_1$ Yes

Quality of Life—Reason for Missing Data

Are all quality-of-life forms complete? ☐ 0 No → If No:
- ☐ 1 Patient died
- ☐ 2 Patient refused
- ☐ 3 Patient withdrew consent
- ☐ 4 Patient missed visit
- ☐ 5 Patient sick
- ☐ 98 Other

OR

☐ 1 Yes

6–Minute Walk Test

1 Did the patient attempt the 6-minute walk at this visit?

☐ 0 No → If No: Specify primary reason:
- ☐ Patient was too critically ill
- ☐ Patient cannot walk for technical reasons *(e.g., a patient who is an amputee)*
- ☐ Not done due to oversight
- ☐ Patient refused
- ☐ Patient died
- ☐ Patient withdrew consent
- ☐ Patient missed visit

OR

☐ 1 Yes → If Yes: Date of 6-minute walk: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Start walk time: ___ ___ : ___ ___ (00:00 to 23:59)

Total distance walked: _____ ☐ 1 Feet ☐ 2 Meter(s)

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

☐ None ☐ Angina ☐ Light-headedness ☐ Syncope

Borg Rating of Perceived Exertion (RPE) Scale: _____ (6–20)

2 Were the QOL instruments completed before or after the 6-minute walk? Check only one:
- ☐ 1 Before
- ☐ 2 < 30 mins after
- ☐ 3 30–60 mins after
- ☐ 4 > 60 mins after

Final Visit

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

1 Has the patient had any **non-urgent** outpatient visits since the last study visit? *(Do not include protocol-specified follow-up visits.)* ☐ 0 No ☐ 1 Yes → **Complete the table below.**

	Provider Type	Number of Office/Clinic Visits	Number of Home Visits
1.1	Cardiologist:		
1.2	Orthopedic surgeon:		
1.3	Other specialist:		
1.4	Primary care physician:		
1.5	Physician extenders *(includes NPs, PAs, etc.)*:		
1.6	OT or PT:		
1.7	Mental health provider:		
1.8	Nurse *(includes RNs, LPNs, nurse's aides or other equivalent)*:		
1.9	Other *(specify)*: _____		

2 Has the patient had any outpatient **cardiac** procedures/tests *(including ICD firing)* or **orthopedic** procedures/tests since the last study visit?
☐ 0 No ☐ 1 Yes → Compete the table below.

Procedure Code*	Number	Procedure Code*	Number	Procedure Code*	Number

*See choices on opposite page. Record one per row. If a procedure/test is not listed, please record it in the table above.

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Outpatient Log

3 Has the patient required any **urgent/emergency care** on an outpatient basis since the last study visit? ☐ 0 No ☐ 1 Yes → Complete the table below.

	Outpatient Service Type	Number of Visits Due to Heart Failure*	Number of Visits Due to Cardiovascular Disease* (other than heart failure)	Number of Visits Due to Non-Cardiovascular Disease*	Number of Visits Due to Unknown Cause*	Number of Visits Due to a Cardiovascular Event Occurring During or Within 3 Hours After Exercise
3.1	Emergency room, hospital < 24 hours, or observation unit:					
3.2	Heart failure clinic/office:					
3.3	Stand-alone urgent care facility:					

3.4 Date of 1st ER visit *(for any reason since randomization)*: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ 1 No ER visit to date ☐ 2 Previously recorded

3.5 Date of 1st urgent clinic visit due to heart failure exacerbation *(since randomization)*: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ 1 No urgent clinic visit for HF to date ☐ 2 Previously recorded

Other Types of Resource Utilization

1 Number of days on home IV infusion for heart failure since the last study visit: _____ days

2 Since the last study visit, how many days did the patient live in each of the following...

Their home: _____ days

Caregiver's home *(e.g., family and friends)*: _____ days

Assisted living: _____ days

Skilled nursing facility: _____ days

Acute care hospital: _____ days

Rehabilitation center: _____ days

Other *(specify)*: _____ _____ days

*Primary diagnosis

See annotation p. 28 of 3-Month

Final Visit

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Hospitalization Record only hospitalizations for ≥ 24 hours.

Has the patient been hospitalized for any reason since the last completed study visit?

*(For the final visit, record **ALL** hospitalizations including those ongoing.)*

☐0 No ☐1 Yes → If Yes: How many hospitalizations? _____

	Hospitalization:	Primary Reason for Hospitalization*	Primary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Secondary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Discharge Destination*
1 Hospitalization: Admission date: ___/___/___ (day/month/year) Discharge date: ___/___/___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
2 Hospitalization: Admission date: ___/___/___ (day/month/year) Discharge date: ___/___/___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
3 Hospitalization: Admission date: ___/___/___ (day/month/year) Discharge date: ___/___/___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				

* See choices on opposite page. If a diagnosis/procedure/discharge destination is not listed, please record it in the table above.
If more than 3 hospitalizations occurred, complete an Additional Hospitalization form.

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This is a repeating page
First page should have page rep 0

See annotation p.29 of 3-Month

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Telephone Log

1 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

2 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

3 Date of call: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

*See choices on opposite page.

If more than 3 telephone calls were completed, complete an Additional Telephone Log form.

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CRF ANNOTATION VERSION 6.0_11May2004

PROTOCOL = HFACTION
STUDYBOOK = DATA_FORMS
FORMS = YEAR 3

CONTEXT

NODATA<ZYES>

HF-ACTION

Year 3

VISITDT

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #)

SUBJNO

Patient's Initials: ___ ___ ___ (first middle last)

INITIALS

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

EuroQoL Questionnaire

By placing a checkmark in one box in each group below, please indicate which statement best describes your own health state today.

See annotation p. 3 of Baseline

1 Mobility:

- ☐ 1 I have no problems in walking about.
- ☐ 2 I have some problems in walking about.
- ☐ 3 I am confined to bed.

2 Self-care:

- ☐ 1 I have no problems with self-care.
- ☐ 2 I have some problems washing or dressing myself.
- ☐ 3 I am unable to wash or dress myself.

3 Usual activities *(e.g. work, study, housework, family or leisure activities)*:

- ☐ 1 I have no problems with performing my usual activities.
- ☐ 2 I have some problems with performing my usual activities.
- ☐ 3 I am unable to perform my usual activities.

4 Pain/discomfort:

- ☐ 1 I have no pain or discomfort.
- ☐ 2 I have moderate pain or discomfort.
- ☐ 3 I have extreme pain or discomfort.

5 Anxiety/depression:

- ☐ 1 I am not anxious or depressed.
- ☐ 2 I am moderately anxious or depressed.
- ☐ 3 I am extremely anxious or depressed.

STOP → **Please let your study coordinator know that you are ready for the EuroQoL Thermometer worksheet.**

PATIENT SELF-REPORT FORM

Pain Assessment

1 How much bodily pain have you had during the past 4 weeks *(check only one)*?

☐ 1 None ☐ 2 Very mild ☐ 3 Mild ☐ 4 Moderate ☐ 5 Severe ☐ 6 Very severe

2 During the past 4 weeks, how much did pain interfere with your normal work *(including both work outside the home and housework)*?

☐ 1 Not at all ☐ 2 A little bit ☐ 3 Moderately ☐ 4 Quite a bit ☐ 5 Extremely

EuroQol Thermometer Response

Response to the EuroQoL thermometer: ___ ___ ___ *(0-100)*

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Kansas City Cardiomyopathy Questionnaire (KCCQ)

The following questions refer to your heart failure and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answers that best apply to you.

1 **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** *(shortness of breath or fatigue)* in your ability to do the following activities over the past 2 weeks.

(Check only one box on each line.)

Activity	Extremely Limited	Quite a Bit Limited	Moderately Limited	Slightly Limited	Not at All Limited	Limited for Other Reasons or Did Not Do the Activity
Dressing yourself:	☐1	☐2	☐3	☐4	☐5	☐6
Showering/bathing:	☐1	☐2	☐3	☐4	☐5	☐6
Walking 1 block on level ground:	☐1	☐2	☐3	☐4	☐5	☐6
Doing yard work, housework or carrying groceries:	☐1	☐2	☐3	☐4	☐5	☐6
Climbing a flight of stairs without stopping:	☐1	☐2	☐3	☐4	☐5	☐6
Hurrying or jogging *(as if to catch a bus)*:	☐1	☐2	☐3	☐4	☐5	☐6

2 Compared with 2 weeks ago, have your symptoms of **heart failure** *(shortness of breath, fatigue, or ankle swelling)* changed? My symptoms of heart failure have become...

Much worse	Slightly worse	Not changed	Slightly better	Much better	I've had no symptoms over the last 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6

3 Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in the morning?

Every morning	3 or more times a week, but not every morning	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5

4 Over the past 2 weeks, how much has **swelling** in your feet, ankles or legs bothered you? It has been...

Extremely bothersome	**Moderately** bothersome	**Somewhat** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no swelling**
☐1	☐2	☐3	☐4	☐5	☐6

PATIENT SELF-REPORT FORM

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

5 Over the <u>past 2 weeks</u>, on average, how many times has **fatigue** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6	☐7

6 Over the <u>past 2 weeks</u>, how much has your **fatigue** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no fatigue**
☐1	☐2	☐3	☐4	☐5	☐6

7 Over the <u>past 2 weeks</u>, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5	☐6	☐7

8 Over the <u>past 2 weeks</u>, how much has your **shortness of breath** bothered you? It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no shortness of breath**
☐1	☐2	☐3	☐4	☐5	☐6

9 Over the <u>past 2 weeks</u>, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

Every night	3 or more times a week, but not every night	1–2 times a week	Less than once a week	Never over the past 2 weeks
☐1	☐2	☐3	☐4	☐5

10 **Heart failure** symptoms can worsen for a number of reasons. How sure are you that you know what to do or who to call, if your **heart failure** gets worse?

Not at all sure	**Not very** sure	**Somewhat** sure	**Mostly** sure	**Completely** sure
☐1	☐2	☐3	☐4	☐5

11 How well do you understand what things you are able to do to keep your **heart failure** symptoms from getting **worse** *(for example, weighing yourself, eating a low-salt diet etc.)*?

Do not understand at all	Do not understand very well	Somewhat understand	Mostly understand	Completely understand
☐1	☐2	☐3	☐4	☐5

PATIENT SELF-REPORT FORM

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Kansas City Cardiomyopathy Questionnaire (KCCQ) (continued)

12 Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not limited** my enjoyment of life at all
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

13 If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

Not at all satisfied	**Mostly** dissatisfied	**Somewhat** satisfied	**Mostly** satisfied	**Completely** satisfied
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

14 Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of your **heart failure**?

I felt that way **all of the time**	I felt that way **most of the time**	I **occasionally** felt that way	I **rarely** felt that way	I **never** felt that way
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

15 How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks.

(Check only one box on each line.)

Activity	Severely Limited	Limited Quite a Bit	Moderately Limited	Slightly Limited	Did Not Limit at All	Does Not Apply or Did Not Do for Other Reasons
Hobbies, recreational activities:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Intimate relationships with loved ones:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Visiting family or friends out of your home:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Working or doing household chores:	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

PATIENT SELF-REPORT FORM

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Beck Depression Inventory (BDI)

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the **one statement** in each group that best describes the way you have been feeling during the **past one week, including today**. Check the box beside the statement you have picked. If several statements within a group seem to apply equally well, check the highest numbered box for that group. Be sure that you do not choose more than one statement for any group, including item 16, Changes in Sleeping Pattern and item 18, Changes in Appetite.

1 Sadness:
- ☐ 0 I do not feel sad.
- ☐ 1 I feel sad much of the time.
- ☐ 2 I am sad all of the time.
- ☐ 3 I am so sad or unhappy that I can't stand it.

2 Pessimism:
- ☐ 0 I am not discouraged about my future.
- ☐ 1 I feel more discouraged about my future than I used to be.
- ☐ 2 I do not expect things to work out for me.
- ☐ 3 I feel my future is hopeless and will only get worse.

3 Past Failure:
- ☐ 0 I do not feel like a failure.
- ☐ 1 I have failed more than I should have.
- ☐ 2 As I look back, I see a lot of failures.
- ☐ 3 I feel I am a total failure as a person.

4 Loss of Pleasure:
- ☐ 0 I get as much pleasure as I ever did from the things I enjoy.
- ☐ 1 I don't enjoy things as much as I used to.
- ☐ 2 I get very little pleasure from the things I used to enjoy.
- ☐ 3 I can't get any pleasure from the things I used to enjoy.

5 Guilty Feelings:
- ☐ 0 I don't feel particularly guilty.
- ☐ 1 I feel guilty over many things I have done or should have done.
- ☐ 2 I feel quite guilty most of the time.
- ☐ 3 I feel guilty all of the time.

6 Punishment Feelings:
- ☐ 0 I don't feel I am being punished.
- ☐ 1 I feel I may be punished.
- ☐ 2 I expect to be punished.
- ☐ 3 I feel I am being punished.

7 Self-Dislike:
- ☐ 0 I feel the same about myself as ever.
- ☐ 1 I have lost confidence in myself.
- ☐ 2 I am disappointed in myself.
- ☐ 3 I dislike myself.

8 Self-Criticalness:
- ☐ 0 I don't criticize or blame myself more than usual.
- ☐ 1 I am more critical of myself than I used to be.
- ☐ 2 I criticize myself for all of my faults.
- ☐ 3 I blame myself for everything that happens.

9 Suicidal Thoughts or Wishes:
- ☐ 0 I don't have any thoughts of killing myself.
- ☐ 1 I have thoughts of killing myself, but I would not carry them out.
- ☐ 2 I would like to kill myself.
- ☐ 3 I would kill myself if I had the chance.

10 Crying:
- ☐ 0 I don't cry any more than I used to.
- ☐ 1 I cry more than I used to.
- ☐ 2 I cry over every little thing.
- ☐ 3 I feel like crying, but I can't.

11 Agitation:
- ☐ 0 I am no more restless or wound up than usual.
- ☐ 1 I feel more restless or wound up than usual.
- ☐ 2 I am so restless or agitated that it's hard to stay still.
- ☐ 3 I am so restless or agitated that I have to keep moving or doing something.

12 Loss of Interest:
- ☐ 0 I have not lost interest in other people or activities.
- ☐ 1 I am less interested in other people or things than before.
- ☐ 2 I have lost most of my interest in other people or things.
- ☐ 3 It's hard to get interested in anything.

PATIENT SELF-REPORT FORM

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Beck Depression Inventory (BDI) (continued)

13 Indecisiveness:

- ☐ 0 I make decisions about as well as ever.
- ☐ 1 I find it more difficult to make decisions than usual.
- ☐ 2 I have much greater difficulty in making decisions than I used to.
- ☐ 3 I have trouble making any decisions.

14 Worthlessness:

- ☐ 0 I do not feel I am worthless.
- ☐ 1 I don't consider myself as worthwhile and useful as I used to.
- ☐ 2 I feel more worthless as compared to other people.
- ☐ 3 I feel utterly worthless.

15 Loss of Energy:

- ☐ 0 I have as much energy as ever.
- ☐ 1 I have less energy than I used to have.
- ☐ 2 I don't have enough energy to do very much.
- ☐ 3 I don't have enough energy to do anything.

16 Changes in Sleeping Pattern *(check only one)*:

- ☐ 0 I have not experienced any change in my sleeping pattern.
- ☐ 1a I sleep somewhat more than usual.
- ☐ 1b I sleep somewhat less than usual.
- ☐ 2a I sleep a lot more than usual.
- ☐ 2b I sleep a lot less than usual.
- ☐ 3a I sleep most of the day.
- ☐ 3b I wake up 1–2 hours early and can't get back to sleep.

17 Irritability:

- ☐ 0 I am no more irritable than usual.
- ☐ 1 I am more irritable than usual.
- ☐ 2 I am much more irritable than usual.
- ☐ 3 I am irritable all the time.

18 Changes in Appetite *(check only one)*:

- ☐ 0 I have not experienced any change in my appetite.
- ☐ 1a My appetite is somewhat less than usual.
- ☐ 1b My appetite is somewhat greater than usual.
- ☐ 2a My appetite is much less than before.
- ☐ 2b My appetite is much greater than usual.
- ☐ 3a I have no appetite at all.
- ☐ 3b I crave food all the time.

19 Concentration Difficulty:

- ☐ 0 I can concentrate as well as ever.
- ☐ 1 I can't concentrate as well as usual.
- ☐ 2 It's hard to keep my mind on anything for very long.
- ☐ 3 I find I can't concentrate on anything.

20 Tiredness or Fatigue:

- ☐ 0 I am no more tired or fatigued than usual.
- ☐ 1 I get more tired or fatigued more easily than usual.
- ☐ 2 I am too tired or fatigued to do a lot of the things I used to do.
- ☐ 3 I am too tired or fatigued to do most of the things I used to do.

21 Loss of Interest in Sex:

- ☐ 0 I have not noticed any recent change in my interest in sex.
- ☐ 1 I am less interested in sex than I used to be.
- ☐ 2 I am much less interested in sex now.
- ☐ 3 I have lost interest in sex completely.

See annotation p.61 for OUTPUT2

PATIENT SELF-REPORT FORM

Productivity Assessment

1 How many days have you lost from work and/or your usual activities in the past 30 days due to problems with your health?

_____ days

2 Check one of the following to indicate your current employment status:

- ☐ 1 Employed/self-employed full-time *(> 30 hours week)*
- ☐ 2 Employed part-time *(specify hours per week)*: _____
- ☐ 3 Student
- ☐ 4 Homemaker
- ☐ 5 Volunteer
- ☐ 6 Disabled
- ☐ 7 Unemployed
- ☐ 8 Retired

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Physical Activity Questionnaire (PAQ)

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the last 7 days. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous physical activities** that you did in the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

1 During the last 7 days, on how many days did you do **vigorous physical activities** like heavy lifting, digging, aerobics, or fast bicycling?

_____ days → **Continue to question 2.**

OR ☐ No vigorous physical activities → **Skip to question 3.**

2 How much time did you usually spend doing **vigorous physical activities** on one of those days?

___ ___ ___ minutes per day

OR ☐ Don't know/not sure

Think about all the **moderate physical activities** that you did in the last 7 days. Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3 During the last 7 days, on how many days did you do **moderate physical activities** like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ days → **Continue to question 4.**

OR ☐ No moderate physical activities → **Skip to question 5.**

4 How much time did you usually spend doing **moderate physical activities** on one of those days?

___ ___ ___ minutes per day

OR ☐ Don't know/not sure

Think about the time you spent **walking** in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5 During the last 7 days, on how many days did you **walk** for at least 10 minutes at a time?

_____ days → **Continue to question 6.**

OR ☐ No walking → **Skip to question 7.**

6 How much time did you usually spend **walking** on one of those days?

___ ___ ___ minutes per day

OR ☐ Don't know/not sure

The last question is about the time you spent **sitting on weekdays** during the last 7 days. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7 During the last 7 days, how much time did you spend **sitting on a weekday**?

___ ___ hours per day

OR ☐ Don't know/not sure

PATIENT SELF-REPORT FORM

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Medical History

1 Current NYHA heart failure class *(check only one)*: ☐ I ☐ II ☐ III ☐ IV

2 Current Canadian Cardiovascular Society (CCS) angina class *(check only one)*: ☐ No angina ☐ I ☐ II ☐ III ☐ IV

Current Medications

Check "No" or "Yes"; if "Yes", provide the total daily dose.

1 Loop diuretic: ☐$_0$ No
☐$_1$ Yes → If Yes: Check only one and provide the **total daily dose**:
☐$_1$ Furosemide: _____ mg ☐$_3$ Toremide: _____ mg
☐$_2$ Bumetanide: _____ mg ☐$_{98}$ Other, *(specify)*: _____ _____ mg

Check "No" or "Yes" for each medication.

2 Spironolactone: ☐$_0$ No ☐$_1$ Yes

3 Eplerenone: ☐$_0$ No ☐$_1$ Yes

4 Non-loop diuretic: ☐$_0$ No ☐$_1$ Yes
(excluding aldosterone antagonist)

5 Potassium: ☐$_0$ No ☐$_1$ Yes

6 ACE inhibitor: ☐$_0$ No ☐$_1$ Yes

7 Angiotensin receptor blocker: ☐$_0$ No ☐$_1$ Yes

8 Beta blocker: ☐$_0$ No ☐$_1$ Yes

9 Aspirin: ☐$_0$ No ☐$_1$ Yes

10 Antiarrhythmic: ☐$_0$ No ☐$_1$ Yes

11 Lipid-lowering agent: ☐$_0$ No ☐$_1$ Yes

12 Clopidogrel: ☐$_0$ No ☐$_1$ Yes

13 Coumadin: ☐$_0$ No ☐$_1$ Yes

14 Digoxin: ☐$_0$ No ☐$_1$ Yes

15 Nitrate: ☐$_0$ No ☐$_1$ Yes

16 Calcium-channel blocker: ☐$_0$ No ☐$_1$ Yes

17 Insulin: ☐$_0$ No ☐$_1$ Yes

18 Glitazone: ☐$_0$ No ☐$_1$ Yes

19 Other oral diabetic agent: ☐$_0$ No ☐$_1$ Yes

20 Thyroid replacement: ☐$_0$ No ☐$_1$ Yes

21 Selective serotonin reuptake inhibitor: ☐$_0$ No ☐$_1$ Yes

22 Tricyclic antidepressant: ☐$_0$ No ☐$_1$ Yes

23 Other antidepressant: ☐$_0$ No ☐$_1$ Yes
(excluding SSRIs and TCAs)

24 Antipsychotic: ☐$_0$ No ☐$_1$ Yes

25 NSAID: ☐$_0$ No ☐$_1$ Yes

26 COX-2 inhibitor: ☐$_0$ No ☐$_1$ Yes

27 Sildenafil: ☐$_0$ No ☐$_1$ Yes

Reserved for potential new drugs. **Do not complete unless instructed by the Duke Clinical Research Institute (DCRI).**

28 Other: _____ ☐$_0$ No ☐$_1$ Yes

29 Other: _____ ☐$_0$ No ☐$_1$ Yes

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Quality of Life—Reason for Missing Data

Are all quality-of-life forms complete? ☐ 0 No → If No:

- ☐ 1 Patient died
- ☐ 2 Patient refused
- ☐ 3 Patient withdrew consent
- ☐ 4 Patient missed visit
- ☐ 5 Patient sick
- ☐ 98 Other

OR

☐ 1 Yes

6–Minute Walk Test

1 Did the patient attempt the 6-minute walk at this visit?

☐ 0 No → If No: Specify primary reason:

- ☐ Patient was too critically ill
- ☐ Patient cannot walk for technical reasons *(e.g., a patient who is an amputee)*
- ☐ Not done due to oversight
- ☐ Patient refused
- ☐ Patient died
- ☐ Patient withdrew consent
- ☐ Patient missed visit

OR

☐ 1 Yes → If Yes: Date of 6-minute walk: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Start walk time: ___ ___ : ___ ___ (00:00 to 23:59)

Total distance walked: _____ ☐ 1 Feet ☐ 2 Meter(s)

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

☐ None ☐ Angina ☐ Light-headedness ☐ Syncope

Borg Rating of Perceived Exertion (RPE) Scale: _____ *(6–20)*

2 Were the QOL instruments completed before or after the 6-minute walk? Check only one:

- ☐ 1 Before
- ☐ 2 < 30 mins after
- ☐ 3 30–60 mins after
- ☐ 4 > 60 mins after

See annotation p.26 of 3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

1 Has the patient had any **non-urgent** outpatient visits since the last study visit? *(Do not include protocol-specified follow-up visits.)* ☐ 0 No ☐ 1 Yes → **Complete the table below.**

	Provider Type	Number of Office/Clinic Visits	Number of Home Visits
1.1	Cardiologist:		
1.2	Orthopedic surgeon:		
1.3	Other specialist:		
1.4	Primary care physician:		
1.5	Physician extenders *(includes NPs, PAs, etc.)*:		
1.6	OT or PT:		
1.7	Mental health provider:		
1.8	Nurse *(includes RNs, LPNs, nurse's aides or other equivalent)*:		
1.9	Other *(specify)*: _____		

2 Has the patient had any outpatient **cardiac** procedures/tests *(including ICD firing)* or **orthopedic** procedures/tests since the last study visit?
☐ 0 No ☐ 1 Yes → **Compete the table below.**

Procedure Code*	Number	Procedure Code*	Number	Procedure Code*	Number

*See choices on opposite page. Record one per row. If a procedure/test is not listed, please record it in the table above.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Outpatient Log

3 Has the patient required any **urgent/emergency care** on an outpatient basis since the last study visit? ☐ 0 No ☐ 1 Yes → Complete the table below.

	Outpatient Service Type	Number of Visits Due to Heart Failure*	Number of Visits Due to Cardiovascular Disease* (other than heart failure)	Number of Visits Due to Non-Cardiovascular Disease*	Number of Visits Due to Unknown Cause*	Number of Visits Due to a Cardiovascular Event Occurring During or Within 3 Hours After Exercise
3.1	Emergency room, hospital < 24 hours, or observation unit:					
3.2	Heart failure clinic/office:					
3.3	Stand-alone urgent care facility:					

3.4 Date of 1st ER visit *(for any reason since randomization)*: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ 1 No ER visit to date ☐ 2 Previously recorded

3.5 Date of 1st urgent clinic visit due to heart failure exacerbation *(since randomization)*: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) OR ☐ 1 No urgent clinic visit for HF to date ☐ 2 Previously recorded

Other Types of Resource Utilization

1 Number of days on home IV infusion for heart failure since the last study visit: _____ days

2 Since the last study visit, how many days did the patient live in each of the following...

Their home: _____ days

Caregiver's home *(e.g., family and friends)*: _____ days

Assisted living: _____ days

Skilled nursing facility: _____ days

Acute care hospital: _____ days

Rehabilitation center: _____ days

Other *(specify)*: _____ _____ days

*Primary diagnosis

See annotation p.28 of 3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Hospitalization Record only hospitalizations for ≥ 24 hours.

Has the patient been hospitalized for any reason since the last completed study visit?

(Only include completed hospitalizations. Wait until the next study visit to record hospital information if the patient is currently hospitalized.)

☐ 0 No ☐ 1 Yes → **If Yes: How many hospitalizations?** _____

	Hospitalization:	Primary Reason for Hospitalization*	Primary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Secondary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Discharge Destination*
1 Hospitalization: Admission date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Discharge date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐ 0 No ☐ 1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐ 0 No ☐ 1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
2 Hospitalization: Admission date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Discharge date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐ 0 No ☐ 1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐ 0 No ☐ 1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
3 Hospitalization: Admission date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Discharge date: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐ 0 No ☐ 1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐ 0 No ☐ 1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				

*See choices on opposite page. If a diagnosis/procedure/discharge destination is not listed, please record it in the table above.

If more than 3 hospitalizations occurred, complete an Additional Hospitalization form.

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.

This is a repeating page
First page should have page rep 0

See annotation p.29 of 3-Month

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # – patient #) Patient's Initials: ___ ___ ___ (first middle last)

Telephone Log

1 Date of call: ___/___/___ (day/month/year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → If ≥ 1: How many of the contacts resulted in:

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

2 Date of call: ___/___/___ (day/month/year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → If ≥ 1: How many of the contacts resulted in:

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

3 Date of call: ___/___/___ (day/month/year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → If ≥ 1: How many of the contacts resulted in:

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

*See choices on opposite page.

If more than 3 telephone calls were completed, complete an Additional Telephone Log form.

WHITE and YELLOW – Duke Clinical Research Institute • PINK – retain at site

CONTEXT

PROTOCOL = HFACTION NODATA<ZYES>
STUDYBOOK = DATA_FORMS
FORM= STUDY COMP

HF-ACTION Study Completion/Death

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) SUBJNO Patient's Initials: ___ ___ ___ (first middle last) INITIALS

Study Completion

STUDCOMP (TYPE 1)

1 Did the patient complete the study? COMPLETE<ZYESNO>

- 0 No → **If No: Reason** (check only one): NOCMPREA<I:3><ACCOMP>
  - 1 Patient lost to follow-up
  - 2 Patient withdrew consent
  - 3 Patient died → **Complete section below and submit the discharge summary, autopsy report, and/or brief summary describing the out-of-hospital death with case report form.**
- 1 Yes

DCRI MedDRA
MEDRCODE<V:8>,CONFLVL<V:2>
MEDRTEXT<V:100>,MATCHES<V:4>
WORKFLOW<V:5>
CODETM
CODER<V:20>

2 Did the patient have a permanent disability related to study intervention? PERMDIS<I:3><ACDIS>

0 No 2 NA, patient in the Usual Care group 1 Yes → **If Yes: Check all that apply:**

- Musculoskeletal PERMMUSC<ZYES>
- Stroke PERMSTRO<ZYES>
- Other, (specify): _____ PERMSP<V:100>

PERMOTH<ZYES>

Death

DEATHLOC<I:3><ACINOT>

1 Check only one: Inpatient **OR** Outpatient

DEATH (TYPE 1)

2 Date of death: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) DEATHDT

DCRI MedDRA
MEDRCODE<V:8>,CONFLVL<V:2>
MEDRTEXT<V:100>,MATCHES<V:4>
WORKFLOW<V:5>
CODETM
CODER<V:20>

DEATHCAU<I:3><ACDEAT>

3 Cause of death (check only one):

1 Cardiovascular death → **Check only one:** DEACARD<I:3><ACCREA>

- 1 Sudden death
- 2 Pump failure
- 3 Fatal myocardial infarction
- 4 CVA
- 5 Cardiovascular procedure-related death → **Specify:** _____ CVPROCSP<V:100>
- 98 Other cardiovascular death → **Specify:** _____ OTHCVSP<V:100>

DCRI MedDRA
MEDRCOD2<V:8>,CONFLVL2<V:2>
MEDRTXT2<V:100>,MATCHES2<V:4>
WORKFLW2<V:5>
CODETM2
CODER2<V:20>

2 Non-cardiovascular death → **Specify:** _____ NONCVSP<V:100>

3 Unknown

DCRI MedDRA
MEDRCOD3<V:8>,CONFLVL3<V:2>
MEDRTXT3<V:100>,MATCHES3<V:4>
WORKFLW3<V:5>
CODETM3
CODER3<V:20>

4 Was an autopsy performed? 0 No 1 Yes AUTOPSY<ZYESNO>

5 Was death the direct result of exercise training (during or within three hours after training)?

0 No DEATHEX<I:3><ACDTH>

1 Yes → **If Yes:** Please fax this page within 5 days of knowledge of the patient's death to DCRI Safety Surveillance at (919) 668-7138 and provide a brief narrative of the event. DEATHSM1<V:200>no verification

_____ DEATHSM2<V:200>no verification

_____

_____ DEATHSM3<V:100>no verification

2 Unable to determine

Investigator's Signature

I have reviewed and found all the case report form data pertaining to this patient to be complete and accurate.

See annotation p.17 of Baseline

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

PROTOCOL = HFACTION
STUDYBOOK = DATA_FORMS
FORM= CARDIO EVT

NODATA<ZYES>

CONTEXT

Cardiovascular Event Form

This is a repeating page
First page should have page rep 0

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

Patient's Initials: ___ ___ ___ (first middle last) INITIALS

CVISIT<I:3><ACCVIS>

Visit: 1 3-Month 2 6-Month 3 9-Month 4 12-Month 5 15-Month 6 18-Month 7 21-Month 8 24-Month 9 Year 3 10 Final

CARDVIST (TYPE 4)

Complete the first item of EACH section for ALL patients.

Congestive Heart Failure (CHF)

CHFEVENT (TYPE 4)

1 Did the patient experience a worsening of congestive heart failure?

0 No 1 Yes → If Yes: Date documented: ___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year) WCHEDT

WCHFEVNT<ZYESNO>

2 What evidence was there of worsening congestive heart failure (check all that apply)? All are <ZYES>

- WFATIGUE Worsening/increasing fatigue
- WGASTRO Gastrointestinal distress
- WEDEMA Peripheral edema
- WOTHER Other
- WDYSPNEA Dyspnea
- Elevated JVD WJVD
- Ascites/hepatomegaly/hepatojugular reflux WAHH
- WORTHOP Orthopnea
- WRALES Rales
- Renal hypoperfusion/worsening renal function WRENAL

3 Was the patient treated with intravenous diuretics? 0 No 1 Yes TREDIUR<ZYESNO>

4 Was the patient treated with intravenous inotropic agents? 0 No 1 Yes TREINO<ZYESNO>

5 Was the patient treated with an intravenous vasodilator? 0 No 1 Yes TREVASO<ZYESNO>

6 Was there significant augmentation (50% increase) of oral therapy? 0 No 1 Yes TREORAL<ZYESNO>

Send copy of the Hospital Discharge Summary.

Myocardial Infarction (MI)

MIEVENT (TYPE 4)

1 Did the patient experience a myocardial infarction?

0 No 1 Yes → If Yes: Date documented: ___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year) MIDT

MIEVNT<ZYESNO>

2 Was the clinical presentation consistent with an MI? 0 No 1 Yes CLNCALMI<ZYESNO>

3 Were there ECGs done? 0 No 1 Yes → If Yes: Send copies of ECGs surrounding the event.

Send copy of the Hospital Discharge Summary.

ECGS<ZYESNO>

4 Peak CK: Date and time: ___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year) PEAKCKDT ___ ___ : ___ ___ (00:00 to 23:59) CKTM OR 0 Not done CKND<ZYES>

Value: _____ CKVAL<F:9:3> 1 IU/L OR U/L OR mIU/mL 2 µkat/L CKUNIT<I:3><ACPKCK>

Upper limit of normal value: _____ ULNCK<F:9:3>

5 Peak CK-MB: Date and time: ___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year) PKCKMBDT ___ ___ : ___ ___ (00:00 to 23:59) CKMBTM OR 0 Not done CKMBND<ZYES>

Value: _____ CKMBVAL<F:9:3> 1 IU/L OR U/L OR mIU/mL 3 mcg/L OR µg/L OR ng/mL 2 µkat/L 4 % CKMBUNIT<I:3><ACMB>

Upper limit of normal value: _____ ULNCKMB<F:9:3>

6 Peak Troponin: Date and time: ___ ___ (day) / ___ ___ ___ (month) / ___ ___ ___ ___ (year) PKTROPDT ___ ___ : ___ ___ (00:00 to 23:59) TROPTM OR 0 Not done TROPND<ZYES>

Check only one: 1 Troponin I 2 Troponin T TROPTYPE<I:3><ACTROP>

Value: _____ ng/mL OR 1 Positive 2 Negative TROPVAL<F:9:3> TROPUNIT<I:3><ACTUNT>

Upper limit of normal value: _____ ULNTROP<F:9:3>

Cardiovascular Event Form

This is a repeating page
First page should have page rep 0

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Unstable Angina

UNSTANG (TYPE 4)

Did unstable angina occur? UANG<ZYESNO>

☐ 0 No

☐ 1 Yes → If Yes: Date documented: UANGDT ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Serious Adverse Arrhythmias/Cardiac Arrest

SAARRH (TYPE 4)

Did the patient have any serious adverse arrhythmias, including cardiac arrest?

☐ 0 No SAA<ZYESNO>

☐ 1 Yes → If Yes: Date documented: SAADT ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Check "No" or "Yes" for each:

VENTTACH<ZYESNO>	Sustained ventricular tachycardia > 30 seconds:	☐ 0 No ☐ 1 Yes
VENTFIB<ZYESNO>	Ventricular fibrillation:	☐ 0 No ☐ 1 Yes
SUPTACH<ZYESNO>	Supraventricular tachycardia with rapid ventricular response > 30 seconds:	☐ 0 No ☐ 1 Yes
CARREST<ZYESNO>	Cardiac arrest:	☐ 0 No ☐ 1 Yes
BRADYCRD<ZYESNO>	Bradycardia *(heart rate < 50, symptomatic and not felt to be related to medication)*:	☐ 0 No ☐ 1 Yes

Stroke

OTHEVENT (TYPE 4)

Did a stroke occur? STROKE<ZYESNO>

☐ 0 No

☐ 1 Yes → If Yes: Date documented: STROKEDT ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

STRKTYPE<I:3><ACSTK>

Classification *(check only one)*: ☐ 1 Ischemic ☐ 2 Hemorrhagic ☐ 99 Unknown

Send copy of the Hospital Discharge Summary, reports of any CT and MRI scans and neurological consults done.

Transient Ischemic Attack (TIA)

Did a transient ischemic attack occur? TIA<ZYESNO>

☐ 0 No

☐ 1 Yes → If Yes: Date documented: TIADT ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

This is a repeating page
First page should have page rep 0

NODATA<YES>

CONTEXT

PROTOCOL= HFACTION
STUDYBOOK = DATA_FORMS
FORM = TRAIN WKSHEET

Supervised Exercise Training Worksheet

For Cardiac Rehabilitation Programs

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

Patient's Initials: ___ ___ ___ (first middle last) INITIALS

SESSNUMB<I:3>

WKSHEET (TYPE 4)

Session #: _____ (1 - 36 of the initial supervised training sessions)

TRAINVIS<I:3><ACTRAN>

OR Visit: 1 6-Month 2 9-Month 3 12-Month 4 15-Month 5 18-Month 6 21-Month 7 24-Month
8 27-Month 9 30-Month 10 33-Month 11 Year 3 12 39-Month 13 42-Month 14 45-Month 15 Final

(Protocol requires supervised exercise training sessions to be held once every three months, beginning at month 6.)

ADDSESS<ZYES>

OR 1 Additional supervised session *(per MD discretion)*

Visit date and time: ___ ___ / ___ ___ ___ ___ (day / month / year) TRAINDT

___ ___ : ___ ___ (00:00 to 23:59) TRAINTM

1 Weight: _____ 1 lb OR 2 kg TWEIGHT<F:9:3> TWTUNIT<ZWGTU>

2 Training heart rate range *(assigned by CPX Core Lab)*: _____ to _____ bpm THRMIN<I:3> THRMAX<I:3>

OR **RPE target training range***: _____ to _____ *(if applicable)* TRPEMIN<I:3> TRPEMAX<I:3>

3 Resting heart rate: _____ bpm RESTHR<I:3>

4 Resting BP: ___ ___ ___ / ___ ___ ___ (systolic / diastolic) TBPSYS<I:3> TBPDIA<I:3>

5 Warm up: 0 Yes 1 No WARMUP<ZYESNO>

6 Exercise(s) performed *(check all that apply)*: FREEWALK<ZYES>

Treadmill exercise TREAD<ZYES>

Total exercise duration: ___ ___ min** TREADDUR<F:9:3>

Speed: ___.___ mph SPEED<F:9:3> SPEEDUNT <I:3>ACSPUT 1=mph 2=km/h

Incline: ___ ___.___ % INCLINE<F:9:3>

Heart rate: ___ ___ ___ bpm TREADHR<I:3>

Borg RPE: ___ (6-20) TREADRPE<I:3>

Bicycle exercise† BIKE<ZYES>

Total exercise duration: ___ ___ min** BIKEDUR<F:9:3>

___ ___ ___ Watts OR ___ ___ ___ ___ kpm/min BIKEWATT<I:3> BIKEKPM<F:9:3>

Heart rate: ___ ___ ___ bpm BIKEHR<I:3>

Borg RPE: ___ (6-20) BIKERPE<I:3>

Free walk exercise

Total exercise duration: ___ ___ min** WALKDUR<F:9:3>

Heart rate: ___ ___ ___ bpm WALKHR<I:3>

Borg RPE: ___ (6-20) WALKRPE<I:3>

* *For special circumstances making measurement of target heart rate invalid, record RPE range.*

** *Total exercise duration does not include time for warm up and cool down.*

† *Recumbent bike allowed only during 1st 2 weeks of training unless prescribed.*

* *Heart rate should be obtained using Polar heart rate monitor.*

7 Cool down: 0 Yes 1 No COOLDOWN<ZYESNO>

8 Did patient achieve and maintain training heart rate? 0 Yes 1 No → **Record reason below.** GETTRHR<ZYESNO>.

9 Did patient achieve exercise duration? 0 Yes 1 No → **Record reason below.** GETTRDUR<ZYESNO>

All are <ZYES>

10 If patient did not achieve and maintain training heart rate or exercise duration, check all that apply to indicate the reason(s):

Angina TANGINA	ICD discharge TICD	Leg fatigue TLEGFAT	Lack of motivation TMOTIV
Dyspnea TDYSP	Presyncope/syncope TSYNC	Fatigue TFATIGUE	Exercise-related fall or injury TINJURY
Arrhythmia TARRH	Claudication TCLAUD	Musculoskeletal complaint TMUSC	Hypoglycemia THYPOGLY
			Other *(please specify)*: _____ TOTHER

TRAINSP<V:100>

Cardiac Rehab Staff Signature: _____ REHABSIG<ZYES> **Facility Name:** _____ FACILNAM<V:50>

Cardiac Rehab Staff:

Batch in sets of 3 and forward or fax completed forms to: _____ CORDSIG<ZYES>
Study Coordinator and fax number

HF-ACTION Study Coordinator: Submit a copy of each completed worksheet to the DCRI with the CRFs.

Additional Hospitalization

See annotation p. 28 OF 3-Month for HOSPITAL

Patient Number: ___ ___ ___ – ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Hospitalization Record only hospitalizations for ≥ 24 hours.

	Hospitalization:	Primary Reason for Hospitalization*	Primary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Secondary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Discharge Destination*
1 Hospitalization: Admission date: ___/___/___ (day/month/year) Discharge date: ___/___/___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
2 Hospitalization: Admission date: ___/___/___ (day/month/year) Discharge date: ___/___/___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
3 Hospitalization: Admission date: ___/___/___ (day/month/year) Discharge date: ___/___/___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				

*See choices on opposite page. If a diagnosis/procedure/discharge destination is not listed, please record it in the table above.
If more than 3 hospitalizations occurred, complete an Additional Hospitalization form.

Additional Telephone Log

See annotation p. 29 of 3-Month

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Telephone Log

1 Date of call: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

2 Date of call: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

3 Date of call: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Since the last call, how many times has the patient's provider been contacted **due to changes in the patient's health/symptoms** *(including contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)*?

_____ contacts → **If ≥ 1: How many of the contacts resulted in:**

Changes to medications other than diuretics: _____

Diuretic dose increases: _____

Diuretic dose decreases: _____

Exercise Training Group: Is patient performing the training as prescribed?

☐ 0 No → If No: Indicate primary reason code*: _____

☐ 1 Yes

Usual Care Group: Is patient performing physical activity *(formal or non-formal)*? ☐ 0 No ☐ 1 Yes

*See choices on opposite page.

If more than 3 telephone calls were completed, complete an Additional Telephone Log form.

WHITE and YELLOW — Duke Clinical Research Institute • PINK — retain at site

PROTOCOL = HFACTION
STUDYBOOK = DATA_FORMS
FORM= COMPLIANCE

NODATA<ZYES>

CONTEXT

This is a repeating page

Exercise Compliance

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

Patient's Initials: INITIALS (first middle last)

Visit: ☐ 3-Month ☐ 6-Month ☐ 9-Month ☐ 12-Month ☐ 15-Month ☐ 18-Month ☐ 21-Month ☐ 24-Month ☐ Year 3 ☐ Final

Same as CARDVIST p.128

Home Exercise Compliance Complete for exercise training group only.

HOMEXCOM (TYPE 4)

Date Interval	Primary Target Training Intensity	Total Number of Days of Exercise During Interval	Average Heart Rate (bpm) OR RPE*	Average Exercise Duration (minutes)	Compliance Comments (choose one compliance code letter per item)	Patient-Reported Symptom Frequency	Primary Mode of Exercise During this Time Period
___/___/___ (day/month/year) BEGINDT	____ to ____ bpm THRMIN<I:3> THRMAX<I:3>	EXERDAY<I:3> ____	____ bpm AVGHR<F:9:3>	____ AVGDUR<F:9:3>	Frequency (a or b): ____ COMPFREQ<V:3>	a: ____ SYMFREQA<I:3>	1 ☐ Treadmill
to	OR		OR		Intensity (c, d, or e): ____ COMPINT<V:3>	b: ____ SYMFREQB<I:3>	2 ☐ Bike
___/___/___ (day/month/year) ENDDT	RPE* range (6–20): ____ to ____ TRPEMIN<I:3> TRPEMAX<I:3>		Average RPE*: ____ AVGRPE<F:9:3>		Duration (f, g, h, or i): ____ COMPDUR<V:3>	c: ____ SYMFREQC<I:3>	3 ☐ Free walk
					Exercise mode (j or k): ____ COMPMODE<V:3>	d: ____ SYMFREQD<I:3>	98 ☐ Other
						e: ____ SYMFREQE<I:3>	EQUIP<I:3><ACEQUI>

Supervised Exercise Training

Did the patient have additional supervised training sessions since the last complete study visit?

ADDSUPEX<ZYESNO>

☐ 0 No

☐ 1 Yes → If Yes: Submit a copy of each Supervised Exercise Training Worksheet.

*Use RPE only for special circumstances making measurement of the target heart rate invalid.

This is a repeating page

PROTOCOL = HFACTION NODATA<ZYES> CONTEXT
STUDYBOOK = DATA_FORMS
FORM= MISSED VISIT

Missed Visit Form

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # – patient #) SUBJNO Patient's Initials: ___ ___ ___ (first middle last) INITIALS

Missed Visit

INSTRUCTIONS: Complete this form only if the patient missed an entire study visit but is continuing in the trial. Complete one form per missed visit. MVISITFM (TYPE 4)

Missed visit *(check only one)*: MISSVIS<I:3><ACMISS>

- 1 ☐ 3-Month
- 2 ☐ 6-Month
- 3 ☐ 9-Month
- 4 ☐ 12-Month
- 5 ☐ 15-Month
- 6 ☐ 18-Month
- 7 ☐ 21-Month
- 8 ☐ 24-Month
- 9 ☐ Year 3

HF-ACTION Study Coordinator: Submit the original of each form to the DCRI with the next batch of CRF pages. Maintain a copy in the patient's CRF binder in place of the monthly visit pages.

Note: A missed visit form may not be submitted for the final visit.

Complete and submit the following if the patient withdraws consent *(verbally or written)*, the patient dies, or when the study is complete:

- Final Visit, pages 113–126 and
- Study Completion/Death, page 127.

CRF Annotation Version 6.0_11May2004

This is a repeating page

VISITDT

CONTEXT

PROTOCOL=HFACTION

STUDYBOOK=DATA_FORMS

FORM=FU PRESCRIP

Exercise Training Prescription Form
Follow-up Prescription

NODATA<ZYES>

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

Patient's Initials: ___ ___ ___ (first middle last) INITIALS

Dear HF-ACTION Study Coordinator:

After recent communication with a study staff member from your site about the patient indicated above, it was determined that the patient's training intensity needs to be modified.

ETPCHG(Type4)

1 Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ETPREVDT

2 Prior training intensity: PRHRMIN<I:3> to PRHRMAX<I:3> bpm

OR

PRRPEMIN<I:3> to PRRPEMAX<I:3> RPE

3 **Revised training intensity:** RVHRMIN<I:3> to RVHRMAX<I:3> bpm

OR

RVRPEMIN<I:3> to RVRPEMAX<I:3> RPE

4 Reason for modification: MODREAS<I:3><ACMODR>

(check only one)

1 ☐ Change in beta blocker
2 ☐ Other medication change
3 ☐ Atrial fibrillation
4 ☐ Atrial/ventricular ectopy
98 ☐ Other *(specify)*: MODREASP<V:200>

Instructions:

Site Study Coordinator: Please notify the patient and your exercise training staff of the above modifications. Also, maintain a copy of this follow-up prescription form in the patient's study records.

HR Compliance Core Lab: Please fax completed form to DCRI at 919-668-7100.

CRF Annotation Version 6.0_11May2004

CRF page 134.__

This is a repeating page
First page should have a page rep 1

PROTOCOL=HFACTION FORM=HOSPFORM

STUDYBOOK=CEC

Endpoint Classification–Hospitalization

Enter this page ☐

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

SUBJNO

Patient's Initials: ___ ___ ___ (first middle last)

INITIALS

REVTYPE<I:3><ACREVU>

Review type: 1 ☐ Committee members 2 ☐ Fellow 3 ☐ Coordinator 4 ☐ Committee meeting 5 ☐ Full committee
6 ☐ QA 7 ☐ Re-review

REVIEW1(TYPE 4)

Review codes: #CECODER1<I:2>CECODER2<I:2>

Released codes: CECODER3<I:2>___ CECODER4<I:2>

6

Endpoint Classification Hospitalization Form

1 Date of hospitalization: ___ / CECHSPDT ___ ___ (day / month / year)

CECHOSP (TYPE 4)

2 Primary cause of hospitalization (check only one):

1 ☐ Worsening heart failure CECHSPCA<I:3><ACCAUS>
2 ☐ Unstable angina
3 ☐ Myocardial infarction DNUMBHOS<I:6>
4 ☐ Cardiovascular procedure
5 ☐ Resuscitated cardiac arrest
6 ☐ Arrhythmia (check only one):

Atrial: ARRHTYPE<I:3><ACATYP>
1 ☐ Supraventricular tachycardia
2 ☐ Atrial fibrillation/atrial flutter

Ventricular:
3 ☐ Ventricular tachycardia
4 ☐ Ventricular fibrillation

Conduction disorder:
5 ☐ Bradycardia
6 ☐ Heart block
7 ☐ Sick sinus node syndrome

7 ☐ Other cardiovascular (check only one):
1 ☐ CVA (stroke) OTHCVTYP<I:3><ACOTYP>
2 ☐ Transient ischemic attack
3 ☐ Vascular: Peripheral vascular disease
4 ☐ Presyncope
5 ☐ Syncope
6 ☐ Chest pain
7 ☐ Hypotension
8 ☐ Hypertension
9 ☐ CV drugs
10 ☐ CV procedure related complication
98 ☐ Other

8 ☐ Non-Cardiovascular

3 Events that occurred during the hospitalization:

3.1 Did an episode of worsening heart failure occur during the hospitalization? CECHSPHF<ZYESNO>
☐ No
☐ Yes → If Yes: Date occurred: ___ ___ / CECHFDT ___ ___ (day / month / year)

DNUMBCHF<I:6>

3.2 Did a myocardial infarction occur during the hospitalization? CECHSPMI<ZYESNO>
☐ No
☐ Yes → If Yes: Date occurred: ___ ___ / CECMIDT ___ ___ (day / month / year)

DNUMBMI<I:6>

3.3 Did a stroke occur during the hospitalization? CECHSPST<ZYESNO>
☐ No
☐ Yes → If Yes: Date occurred: ___ ___ / CECSTRDT ___ ___ (day / month / year)

DNUMBSTK<I:6>

This is not entered

Additional data needed or rationale: _____

Reviewer (signature): _____ HSPREVSG<ZYES> Date: ___ / HSPREVDT ___ ___ (day / month / year)

CRF page 2.___

CRF ANNOTATION VERSION 6.0_11May2004

PROTOCOL=HFACTION

CONTEXT NODATA<ZYES>

STUDYBOOK=CEC
FORM= DEATHFORM

Endpoint Classification–Death

Enter this page ☐

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

Patient's Initials: ___ ___ ___ (first middle last) INITIALS

REVTYPE<I:3><ACREVU>

Review type: ☐1 Committee members ☐4 Committee meeting ☐5 Full committee ☐6 QA ☐7 Re-Review REVIEW1(TYPE 4)

CECODER1<I:2> CECODER2<I:2>

Review codes: #___ ___ #___ ___

CECODER3<I:2> CECODER4<I:2>

Released codes: #___ ___ #___ ___

Death Form

CECDTHDT

1 Date of death: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year)

DNUMBDTH<I:6>

CECDEATH(TYPE4)

2 Cause of death (check only one): CECDTHCA<I:3><ACECDT>

1 ☐1 Cardiovascular Death

(check only one): CECCVDTH<I:3><ACCREA>

1 ☐1 Sudden death
2 ☐2 Pump failure
3 ☐3 Fatal myocardial infarction
4 ☐4 CVA
5 ☐5 Cardiovascular procedure-related death → Specify: _____ CECPRCSP<V:100>
98 ☐98 Other cardiovascular death → Specify: _____ CECOTHSP<V:100>

2 ☐2 Non-Cardiovascular Death → Specify: _____ CECNONSP<V:100>

3 ☐3 Unknown

Additional data needed or rationale: _____ This is not entered

_____

_____

_____

Reviewer (signature): _____ DEAREVSG<ZYES>

Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) DEAREVDT

CRF page 1

CRF ANNOTATION VERSION 6.0_11May2004

FORM = CPX_MISSED VISIT CONTEXT

REPEATING PAGE

PROTOCOL = HFACTIONCPX

STUDYBOOK = CPX PAGEID = 999

CPX Worksheet
Missed Visit

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (SUBJNO) (site # / patient #) Patient's Initials: ___ (INITIALS) (first middle last)

Missed Visit

This form is being utilized to capture the primary reason a patient did not complete a protocol-specified CPX.

Please fill out this form for **any patient who did not complete a protocol-specified CPX due on or after 01 March 2007,** according to the following instructions:

- If the patient was randomized on or after 01 December 2006 and missed the 3-Month and/or 12-Month CPX
- If the patient was randomized on or after 01 March 2006 and missed the 12-Month CPX
- If the patient was randomized on or after 01 March 2005 and missed the 24-Month CPX

CPXMISSV(TYPE4)

1 Date form completed: ___/___/___ (FRMCOMDT) (day / month / year)

2 Benchmark CPX visit missed (check only one): (CPXVISMS<I:3><ACPXMS>)

- [3] 3 3-month
- [4] 4 12-month
- [5] 5 24-month

3 Reason CPX study did not occur (check only one): (NOCPXREA<I:3><ACNORE>)

- [1] 1 Patient was too critically ill
- [2] 2 Patient could not walk/bike for technical reasons (e.g., a patient who is an amputee, has physical limitations due to stroke, etc.)
- [3] 3 Not done due to oversight
- [4] 4 Patient refused
- [5] 5 Patient died
- [6] 6 Patient withdrew consent for study
- [7] 7 Patient missed visit
- [8] 8 Patient only being followed by phone (e.g., patient who has moved and can no longer come to study visits; patient refuses to come in for office visits, etc.)
- [9] 9 Patient currently lost to follow-up
- [10] 10 Physician/physiologist decision
- [98] 98 Other (specify) _____ (NOCPXOTH<V:250>)

Please fax completed form to 1-919-684-4573

Annotation Final version 1.0_ 30 July 2007

PROTOCOL = **HFACTION**
STUDYBOOK = **DATA_FORMS**
FORM= **POST FV CONTACT**

PAGEID = 999

CONTEXT **NODATA<ZYES>**

Post Final Visit Contact Form

Subject Number: ___ ___ ___ - ___ ___ ___ ___ (site # / subject #) **SUBJNO**

Subject's Initials: ___ ___ ___ (first middle last) **INITIALS**

Post Final Visit Contact

INSTRUCTIONS: Complete this form if additional primary endpoint data is discovered following completion of the final visit (FV) for any subject who had not reached 4 years of trial participation at the time of his/her final visit.

NOTE: This form **is expected** for any HF-ACTION subject whose final visit was in December 2007 or January 2008 and who, at the time of that final visit, had not reached 4 years of trial participation. Please complete and fax this form to DCRI no later than March 31, 2008.

POSTFVC (TYPE 1)

1 Has the subject been hospitalized for any reason since the last completed study visit? **BEENHOSP<I:3><XYNUNK>**

0 No → If No: As of (date): ___ ___ (day) / ___ ___ (month) / ___ ___ ___ ___ (year) **FOLLOWDT**

1 Yes → If Yes: Number of hospitalizations: ___ **NMBRHOSP<I:3>**

- Complete Additional Hospitalization form(s) and FedEx to DCRI Forms Management.
- Complete an additional end-of-study Rapid Report Form (RRF) and fax it to the EQOL group at **1-919-668-7051.**

99 Unknown

2 Is the subject currently alive? **CURALIVE<I:3><XYNUNK>**

0 No → If No: Date of death: ___ ___ (day) / ___ ___ (month) / ___ ___ ___ ___ (year) **DTDEATH**

Location of death (check only one): **LOCDEATH<I:3><ACINOT>**

1 Inpatient

2 Outpatient

Cause of death (check only one): **CAUDEATH<I:3><ACDEAT>**

1 Cardiovascular death → Check only one: **CVDEATH<I:3><ACCREA>**

- 1 Sudden death
- 2 Pump failure
- 3 Fatal myocardial infarction
- 4 CVA
- 5 Cardiovascular procedure-related death (specify) **CVPRODSP<V:100>**
- 98 Other cardiovascular death (specify) **OTHCVDSP<V:100>**

2 Non-cardiovascular death (specify) **NONCVDSP<V:100>**

3 Unknown

1 Yes → If Yes: Last date known alive: ___ ___ (day) / ___ ___ (month) / ___ ___ ___ ___ (year) **LSTALVDT**

99 Unknown

DCRI MEDRA
MEDRCODE<V:8>,CONFLVL<V:2>
MEDRTEXT<V:100>,MATCHES<V:4>
WORKFLOW<V:5>
CODETM
CODER<V:20>

DCRI MEDRA
MEDRCOD2<V:8>,CONFLVL2<V:2>
MEDRTXT2<V:100>,MATCHES2<V:4>
WORKFLW2<V:5>
CODETM2
CODER2<V:20>

DCRI MEDRA
MEDRCOD3<V:8>,CONFLVL3<V:2>
MEDRTXT3<V:100>,MATCHES3<V:4>
WORKFLW3<V:5>
CODETM3
CODER3<V:20>

Please fax completed form to DCRI Forms Management at
1-919-668-7100

CRF ANNOTATION VERSION 7.0_06Dec2007

This is a repeating page
First page should have page rep 1

Additional Hospitalization

See annotation p. 28 OF 3-Month for HOSPITAL

Patient Number: ___ ___ ___ - ___ ___ ___ ___ (site # / patient #) Patient's Initials: ___ ___ ___ (first middle last)

Hospitalization Record only hospitalizations for ≥ 24 hours.

	Hospitalization:	Primary Reason for Hospitalization*	Primary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Secondary Cardiac Procedure* (code/description)* Record a zero if patient did not have cardiac procedures.	Discharge Destination*
1 Hospitalization: Admission date: ___/___/___ (day/month/year) Discharge date: ___/___/___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
2 Hospitalization: Admission date: ___/___/___ (day/month/year) Discharge date: ___/___/___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				
3 Hospitalization: Admission date: ___/___/___ (day/month/year) Discharge date: ___/___/___ (day/month/year) Did the event leading to this hospitalization occur during or within 3 hours after exercise? ☐0 No ☐1 Yes Did a cardiovascular event cause or occur during this hospitalization? ☐0 No ☐1 Yes → If Yes: Complete the Cardiovascular Event forms.	☐ Planned ☐ Unplanned				

*See choices on opposite page. If a diagnosis/procedure/discharge destination is not listed, please record it in the table above.
If more than 3 hospitalizations occurred, complete an Additional Hospitalization form.

PAGEID = 999