PROTOCOL = HFACTIONCPX FORM = CPX_WKS	CONTEXT
STUDYBOOK = CPX REPEATING F	
	CPA worksneer
NODATA <i:3><zyes> Pati</zyes></i:3>	tient Number:
CPXVIS <i:3><accpx> Visit: 1 Practice (if a</accpx></i:3>	
CPX Tests submitted will have an exercise prescription returned	
	ECTOPY <i:3><zyesno></zyesno></i:3>
1 Date of test:/ CPXDT /	9 Did frequent ventricular ectopy occur (e.g., ≥ 7 PVCs/min,
2 Equipment: EQUIPTYP <i:3><acequt></acequt></i:3>	bi/tri-geminy, NSVT [≥ 3 beats])? No Yes
	If Yes: When did it occur? (check all that apply)
MOUTHM SK<1:3>< 1 Mouthpiece or 2 Mask or 3 NAU B<1:3><7YESN	During exercise During recovery ECTDUREX <zyes> ECTDUREC<zyes></zyes></zyes>
ACMTHS> /as the equipment calibrated prior to use? No Yes	ECTDUREX <zyes> ECTDUREC<zyes> NO TO Was metabolic data measured? METABOLC<f3><zyesn< th=""></zyesn<></f3></zyes></zyes>
What is the barometric pressure?mm Hg BAROPRES <f:9:3></f:9:3>	Record exercise start time in minutes and seconds,
BAROPRES <f:9:3></f:9:3>	allowing patient at least 2 minutes equilibration on the
3 Was the patient's last meal eaten > 3 hours prior to this	gas exchange machine prior to exercise start. STRTMIN<1:3> STRTSEC<1:3> Exercise start time:minutes:seconds
test? No Yes	Exercise end time: minutes:seconds
4 Was the patient's last dose of beta blockers taken	Example:
between 3–10 hours ago?	Exercise start time: 2:10 minutes:seconds
2 NA 0_0 No \rightarrow Consider rescheduling test. 1_1 Yes	(exercise starts 10 seconds after the 2-minute equilibration) Exercise end time: 7:10 minutes:seconds
$\Sigma_1 \cap X = [0_0 \cap 0 \rightarrow Consider rescribedoning rest. [1_1]_1 res$	(patient exercised for 5 minutes)
5 <u>Rest ECG</u> : ECGRHYTH <i:3><acrecg></acrecg></i:3>	III F. S. Marker M. Lands, J. F. Marker, J.
Rhythm (check only one):	11 Fax completed form, breath-by-breath and 15-second
GCOND <i:3><acvcon>2 Atrial fibrillation 98,8 Other</acvcon></i:3>	averaged analysis to 919-681-9274.
Ventricular conduction (check only one):	12 Specify where the prescribed training HR should be faxed:
1_1 Normal 2_2 LBBB 3_3 RBBB 4_4 IVCD 5_5 Paced QRS interval: QRSINT 4_5	FAXNO <v:20> fax # specified by site</v:20>
GRS interval:	13 Signature of person administering exercise test:
6 HR Data:	SIGN <zyes></zyes>
HR at peak exercise:bpm	For CPX Lab Use Only
Resting HR RESTHR <i:3></i:3>	Peak VO2:mL/kg/min PKVO <f:9:3></f:9:3>
(after 5 minutes sitting rest, without mouthpiece): bpm	Absolute Peok VO EXERMIN<1:3 EXERSEC<1:3>
HR reserve (peak HR - rest HR): HRRES<1:3>	EXERMINAL:3 EXERSEC <i:3> Exercise time: minutes:seconds</i:3>
60% HR reserve (HR reserve x 0.6 + rest HR): HR60R <f:9:3></f:9:3>	RER: RER <f:9:3></f:9:3>
PKBORG <i:3> 7 Borg RPE score at peak exercise:(6-20)</i:3>	Time to RER = 1.0:RERMIN <i:3>REBSEC<!--13--></i:3>
	VeVCO2 slope: VEVO <f:9:3></f:9:3>
8 Reason(s) for termination of testing (check all that apply): CPX2 <i:3><zyes> STCPX1<i:3><zyes></zyes></i:3></zyes></i:3>	HR at end of WL 2: WLHR <i:3>bpm</i:3>
Symptom limited (dyspned, tangue)	1 Can the ventilatory threshold be read? VENTTH <i:3><zyesno< td=""></zyesno<></i:3>
Angina/ischemia (complete all Complete all C	$V_{FS} = 0$ No \rightarrow Set upper THR at 65% HRR VENTVO <e:9:3></e:9:3>
that apple 🖌	_1 Yes → Ventilatory threshold VO ₂ : mL/kg/min
HR when ischemic ECG changes occurred: HRISCECCA:35	HRRVT <i:3><zyesnos< td=""></zyesnos<></i:3>
CPX3 <i:3><zyes> Dpm OR NAHRISC<i:3><z< th=""><th></th></z<></i:3></zyes></i:3>	
Serious arrhythmias (VT or SVI) STCPX4 <i:3><zyes> Changes in blood pressure STCPX5<i:3><zyes></zyes></i:3></zyes></i:3>	\square_0 No → Set upper training HR 4 beats below HR at VT. 1 Yes → Set training HR range at 60–70% HRR.
Orthopedic/extremity complaints (pains/cramps)	2 Was the test terminated due to angina/ischemia?
STCPX6<1:3>24ES/section:STCPXSP <v:100></v:100>	✓ was the rest terminated due to angina/ischemia? □ No TESTTERM <i:3><zyesno></zyesno></i:3>
	$\Box_0 \text{ NO} \longrightarrow \text{Bet upper training HR at 10 beats per min less than the HR where}$
8b Based on the results of the test, is exercise training	engine as indexed FCC sharpers assumed which must is lawse
considered unsafe (i.e., precludes enrollment or causes	3 Prescribed training range: PRETHRMN<[:3> PRETHRMX<[:6] initial training HR
interruption/termination of exercise training/? No Yes UNSAFE <i:3><zyesno></zyesno></i:3>	
	prescribed training heart rate has been calculated and recorded above,

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CPX Worksheet

	فلي الم			Poti	ent Number:		patient #	Patient's	Initials:
			Vi	sit: Practice (if a	pplicable)	Baseline	3-Month	12-Mor	nth 24-Month
Exerc	ise Recor	dings							
Time	Heart Rate			Borg RPE Score	Time	Heart Rate			Borg RPE Score
(min:sec)	(bpm)	Blood Pre	ssure	(6-20)	(min:sec)	(bpm)	Blood Pre	essure	(6-20)
Rest*		/	diantolie		10:00		/_	diastolic	
	S	TART EXERCI	SE:		10:30				
0:30	-				11:00				
1:00					11:30				
1:30					12:00		/_	diastolic	
2:00		, ,			12:30		,		
			diantolic		13:00				
2:30					13:30				
3:00					14:00		/_		
3:30					14:30		systalic	diantolic	
4:00		/	diautolic		15:00				
4:30					15:30				
5:00					16:00		,		
5:30					16:30		nyatalic / -	diantolic	
6:00		/			17:00				
6:30		systalic	diantolic		17:30				
7:00					18:00				
7:30							/	diastolic	
8:00		/_			18:30				
8:30		systalic	diautolie		19:00				
9:00					19:30				
9:30					20:00		/_	diastolic	
							<i>,</i>		
Peak	Exercise	Data							
Time:	in 1000	Heart rate	:	bpm B	lood pressu	re:	diastolie	RPE: _	
Recov	ery								
Time	Heart	Rate			Time	Heart	Rate		
(min:sec)	(bp		Blo	od Pressure	(min:sec)	(bp		Blo	od Pressure
1:00				_/	6:00				
2:00			iyifa	ic diastolic	7:00				_/
3:00				/	8:00			systoli	c diastalic
			iyita	ie diastolie					,
4:00					9:00			iyitob	/
5:00			iyifa	ic diantolic	10:00				

*Resting HR measured after 5 minutes sitting rest, without mouthpiece. HF-ACTION_CPX V1.4 05AUG2003

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PROTOCOL = HFACTION	FORM = BASELINE	CONTEXT
STUDYBOOK = DATA FORMS	NODATA <i:3><zyes> SUBJN Patient Number: site #</zyes></i:3>	O Baseline INITIALS Patient # Potient's Initials: Ter riddle Tar
Date informed consent form signed:	NFCNDT //ye <i>a</i> r	INFCN(TYPE 1)
Treatment Preference Sca	e To be asked by study staff, immediately	after obtaining consent.
a preference. Although your treatment gra regarding these treatments. Would you pr 1_1 Usual care 2_2 Exercise training 3_	oup will be determined entirely by chance, refer to be in the usual care group or the ex 3 No preference 4_4 Not applicable TR	sercise training group?"
Patient Status		
Check the appropriate box for the patient 1□1 Registry patient → Complete and subr • Informed Conser • Patient Survey, p • KCCQ, pages 4, • BDI, pages 7 and 2□2 Randomized patient → Complete and	mit the following: nt and Demographics, page 1 • Curren bage 2 • Medice 5, and 6 • Supple d 8	STATUS(TYPE 1 at Medications, pages 13 and 14 al History, page 15 emental Registry Form(s), if applicable
	pages, r	
Demographics		
1 Date of birth:/		DEMOG(TYPE 1)
 2 Sex: 1 Male 2 Female 3 Insurance (check only one): 1 Medicare INSUR<i:3><acinsu></acinsu></i:3> 	R <i:3><zsex> potient (part A only) 22 Medicare patient (pa</zsex></i:3>	art A/B) 3 ₃ Non-Medicare patient
Randomization		
1 Date of randomization:/	h year RANDDT Not enterable 07APR2003	e if before RANDVIT(TYPE 1
2 Treatment group assignment: 1 ₁ Usu	al care group 🛛 🚬 Exercise training group T	ASSIGN <i:3><actass></actass></i:3>
	care/exercise training group]. How satisfied	are you with this treatment assignment?" _4 Somewhat dissatisfied 55 Very dissatisfied
Vital Signs BPSYS BP 1 Blood pressure (sitting): /	PDIA 3> Austolic mmHg	
2 Heart rate: <u>HRATE<i:3>bpm</i:3></u> 2 Height: <u>HT<f:9:3></f:9:3></u> in [a] or		
 3 Height: <u>HT<f:9:3></f:9:3></u> 1₁ in 2₂ cm 4 Weight: <u>WT<f:9:3></f:9:3></u> 1₁ lb 2₂ kg 		
CRF Annotation Version 6.0_11May2004	- Duke Clinical Research Institute •	PINK — retain at site
	2003 DCRI - Confidential	CPE page]

GTION	Patient Number:			Baseline
	Tohen Homber.	site #	patie <i>nt #</i>	foren s minors. Ire roldie last
Patient Survey The following information is very important for the HF-AC	TION trial Plagsa a	profully road	and answart	ha quastions halow
 Please check only one of the following options to indi 11 Hispanic or Latino (a person of Cuban, Mexican, Puerto Rica 22 Not Hispanic or Latino ETHNIC<i:3><aceth></aceth></i:3> 	cate your ethnicity:	-		SURVEY(TYPE 1)
2 □2 High school graduate or equivalent (e.g., GED) 5	is in any of the original pe ZYES> the Far East, Southeast As lands, Thailand, and Vietn of the black racial groups ing origins in any of the or Europe, the Middle East, WHIT	oples of North, C ia, or the Indian am) ASIAN< of Africa) BLA ginal peoples of or North Africa) E<1:3> <zye lucation: iate degree/di (e.g., B.A., B.S.)</zye 	subcontinent indu <1:3> <zyes> CK<1:3><zyi Hawaii, Guam, Si B> ploma program</zyi </zyes>	ding, for example, Cambodka, ES> amoa, or other Pacific Islands) NATHWN <i:3><zyes></zyes></i:3>
 4 Check one of the following to indicate your current management of the following to indicate your current of the f	arital status: MAF	lITST <i:3><</i:3>	ACMAR>	
 5 Check one of the following to indicate your most rece 1 1 less than \$15,000 2 15,000-\$24,999 3 3 \$25,000-\$34,999 7 7 100,000 or more 4 4 \$35,000-\$49,999 9 9 cline to answer 	nt annual househol	d income bef	ore taxes: E	ARN <i:3><acearn></acearn></i:3>
 6 Check one of the following to indicate your current en 11 Employed/self-employed full-time (> 30 hours week) 5 [22 Employed part-time (specify hours per week):6 [33 Student PARTT2<f:9:3> 7 [</f:9:3> 4 Homemaker 8 [5 Volunteer 6 Disabled	EMPLOYS	T <i:3><ace< td=""><td>MP></td></ace<></i:3>	MP>
7 How many days have you lost from work and/or you days LOSTWK2 <f:9:3></f:9:3>	ur usual activities in t	he past 30 d	ays due to pr	oblems with your health?

CRF Annotation Version 6.0_11May2004

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CRF, page 2

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.

CTION	Patient Number:	Baseline
EuroQoL Questionnaire	site ₹ patient	
By placing a checkmark in one box in each group below, p which statement best describes your own health state <u>toda</u>		EURO(TYPE 3)
 Mobility: EURO1<i:3><acer10></acer10></i:3> 1 _1 have no problems in walking about. 2 _2 have some problems in walking about. 3 _3 am confined to bed. 		
 2 Self-care: EURO2<i:3><acer2o></acer2o></i:3> 11 I have no problems with self-care. 22 I have some problems washing or dressing myself. 33 I am unable to wash or dress myself. 		PATIE
 Usual activities (e.g. work, study, housework, family or leisure administration of the problems with performing my usual activities. 2 2 1 have some problems with performing my usual activities 3 3 1 am unable to perform my usual activities. 		N T SEL
 4 Pain/discomfort: EURO4<i:3><acer4o></acer4o></i:3> 1 1 l have no pain or discomfort. 2 2 l have moderate pain or discomfort. 3 3 l have extreme pain or discomfort. 		F-REPO
 5 Anxiety/depression: EURO5<i:3><acer50></acer50></i:3> 1 1 am not anxious or depressed. 2 2 1 am moderately anxious or depressed. 3 3 1 am extremely anxious or depressed. 		ORT FOR
→ Please let your study coordinator know th	hat you are ready for the EuroQoL	Thermometer worksheet. z-
Pain Assessment 1 How much bodily pain have you had during the past 4 1 1 None 2 2 Very mild 3 3 Mild 4 4 Moderate 4		ACP1N>
2 During the past 4 weeks, how much did pain interference $1 \square_1$ Not at all $2 \square_2$ A little bit $3 \square_3$ Moderately $4 \square_4$ (ACP2N> : outside the home and housework)?
EuroQol Thermometer Response Response to the EuroQoL thermometer:	RM <i:3></i:3>	
CRF Annotation Version 6.0_11May2004		



Patient Number: ______ - _____ site # _____patient # **Baseline**

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 <u>past 2 weeks</u>.

	(Check only one bo							
	Activity		Extremely 1 Limited	Quite a Bit 2 Limited	<<<<<	A> Slightly 4 Limited	Not at All 5 Limited	Limited for Other Reasons or Did 6 Not Do the Activity
Q1A <i:3></i:3>	Dressing yours	self:	1	2 2	3 🗔	4 🗖 4	5 🗖 5	6 🔤
Q1B <l:3></l:3>	Showering/ba	thing:		 2	□_ ₃		□ ₅	_ 6
Q1C <i:3:< td=""><td>Walking 1 blo</td><td>ck on level ground:</td><td></td><td>2</td><td>3</td><td></td><td>5</td><td>6</td></i:3:<>	Walking 1 blo	ck on level ground:		 2	3		5	6
Q1D <i:3></i:3>	Doing yard wa or carrying gra	ork, housework oceries:			_ 3		□s	_ 6
Q1E <i:3></i:3>	Climbing a flig stairs without s				3	□₄	□s	_ 6
	Hurrying or jo	aaina						
Q1F :3	(as if to catch a bus			 2	3	4	5	6
Q1F <i:3></i:3>	(as if to catch a but		e your sympto	oms of hea	art failure (short (1:3> <achfsy< td=""><td></td><td>tigue, or ankle s</td><td>welling) changed?</td></achfsy<>		tigue, or ankle s	welling) changed?
	(as if to catch a but	s): <u>h 2 weeks aao</u> , hav	e your sympto	oms of hea KCCQ2<			l've had over the	welling) changed? no symptoms last 2 weeks
2	(as if to catch a but <u>Compared with</u> My symptoms Much worse 11 Over the <u>past</u>	s): <u>h 2 weeks aao</u> , hav of heart failure hav Slightly worse	re your sympto re become Not change 3 3	oms of hea KCCQ2< ed u have swe	Slightly better 4 4	Much better 55	l've had over the	no symptoms last 2 weeks
2	(as if to catch a but <u>Compared with</u> My symptoms Much worse 11 Over the <u>past</u>	s): h 2 weeks aao, hav of heart failure hav Slightly worse 2 22 2 weeks, how many	re your sympto re become Not change 3 3 3 y times did you o in the mornin reek, 1-2 tim	oms of hea KCCQ2< ed u have swe ug? KCC	Slightly better 4 4	Much better 5_5	l've had over the 6	no symptoms last 2 weeks
3	(as if to catch a but <u>Compared with</u> My symptoms Much worse 1 1 1 Over the <u>past</u> ankles or legs Every morning 1 1 1	s): <u>h 2 weeks aao</u> , hav of heart failure hav Slightly worse 22 2 weeks, how many when you woke up 3 or more times a w but not every mom	re your sympto re become Not change 3 3 3 y times did you o in the mornin reek, 1-2 tim ing a wee 3 3	oms of hea KCCQ2< ed u have swe ng? KCC nes ek	Slightly better 4 4 CQ3<1:3> <acs Less than once a week 4 4</acs 	Much better 5 5 set, WFT> Never over past 2 wee 5 5	l've had over the 6 the eks	no symptoms lost 2 weeks
3	(as if to catch a but <u>Compared with</u> My symptoms Much worse 1 1 1 Over the <u>past</u> ankles or legs Every morning 1 1 1	s): h 2 weeks aao, hav of heart failure hav Slightly worse 22 2 weeks, how many when you woke up 3 or more times a w but not every mom 22	re your sympto re become Not change 3 3 3 y times did you o in the mornin reek, 1-2 tim ing a wee 3 3	oms of hea KCCQ2< ed u have swe 19? KCC nes sk KC g in your fe	Slightly better 4 4 CQ3<1:3> <acs Less than once a week 4 4</acs 	Much better 5 5 set, WFT> Never over past 2 wee 5 5	l've had over the 6 the eks you? It has be	no symptoms lost 2 weeks

6		TION		Patient Number:		Poti	ient's Initials:
			- thu: 0	dianaatiya (K		atient#	174
				tionnaire (K			
		<u>veeks</u> , on average,	how many time	s has fatigue limite	d your ability to d	lo what you we	CO2(TYPI
1:3><	ACAVSH>	Several	At	3 or more	1-2	Less than	Never
	the	times	least once	times per week	times	once	over the
	time	per day	o day	but not every day	a week	a week	past 2 weeks
	1 🗆 ı	2 🗆 2	3 🗆 3	4 4	5 5	<mark>6</mark> _6	7 🗖
6	Over the <u>past 2 v</u>	veeks, how much h	as your fatigue	bothered you? It h	as been KCCC	Q6 <i:3><acm< td=""><td>UFT></td></acm<></i:3>	UFT>
	Extremely	Quite a bit	Moderately	Slightly	Not at all	l've had	ł
	bothersome	bothersome	bothersome	bothersome	bothersome	no fatig	Ve
	1 🗔	2	3 🔄	4	5	6	
		r				Q7 <i:3><aca\< td=""><td>/CH></td></aca\<></i:3>	/CH>
7	Over the <u>past 2 v</u>	<u>veeks</u> , on average,	how many time	s has shortness of			
	All of	Several	At	3 or more	1-2	Less than	Never
	the	times	least once	times per week	times	once	over the
	time	per day	a day	but not every day	a week	a week	past 2 weeks
	1 🗔	2	3	4	5 5	6	7
	• – – –	2	- 3	•4		0	
8	Over the past 2 v	veeks, how much h	as your shortn e	ess of breath both	ered you? It has b	CQ8 <i:3><acm een</acm </i:3>	NUSH>
	Extremely	Quite a bit	Moderately		Not at all	l've had i	no
	bothersome	bothersome	bothersome	bothersome	bothersome	shortness of	breath
	1 🗖 I	22	3 🔄 3	4 🖂	5 ₅	6 🗌 ₆	
							1
		<u>veeks</u> , on average, to prop you up bea		s have you been for ess of breath ?	• •	g up in a chair CQ9<1:3> <ac <="" td=""><td></td></ac>	
		3 or more times	1-2	Less than	Never		
	Every	a week, but	times	once	over the		
	night	not every night	a week	a week	post 2 weeks		
	1 Ŭ1	2 🛄	3 🗔	4	5 🗆 5		
		2	3 — 3	4	5		
10	Heart failure sy	mptoms can worse	n for a number	of reasons. How su	re are you that you	u know what to	o do or
	who to call, if you	ur heart failure ge	ets worse?		KCC	CQ10 <i:3><ac< td=""><td>:HFHF></td></ac<></i:3>	:HFHF>
	Not at all	Notvery	Somewhat	Mostly	Completely		
	sure	sure	sure	sure	sure		
	1 🗆 I	2 2	3 🗔	4	5 5		
		-	v	-	° °		
				ble to do to keep yo	our heart failure	symptoms from	n getting
	worse (for example,	weighing yourself, eating	a low-salt diet etc.)?	,	ксо	CQ11 <i:3><ac< td=""><td>HFUN></td></ac<></i:3>	HFUN>
	Do not understand	Do not understand	Somewhat	Mostly	Completely		
I I	at all	very well	understand	understand	understand		
	1 🗖 I	2 🗋 2	3 🗔	4 🗔	5 🗖 5		
		-	-				

100		TION	1				Baseli
-				Patient Number:		patient #	Potient's Initials: test rid
К	ansas City C	ardiomyop	athy Questi	onnaire (K	CCQ) (conti	nued)	
1	2 Over the <u>past 2 w</u>	<u>veeks</u> , how much h	as your heart fail	ure limited your a	enjoyment of	life?	KCCQ3(TYPE3
	limited my	It has limited my enjoyment of life	limited my	limited my	It has not lin my enjoyme	ent of	NOCOS(III EC
	enjoyment of life 1 🔤 ı	quite a bit 2 ^{_2} 2	enjoyment of life 3 🔲 3	enjoyment of life <mark>4</mark> — ₄	life at a <mark>5</mark> ⊡s	" KCCC	12 <i:3><achflm></achflm></i:3>
1	3 If you had to sper	nd the rest of your	life with your hea i	rt failure the way	y it is <u>right no</u> v	<u>w</u> , how wou	ld you feel about this?
	Not at all satisfied 1 🔄 1	Mostly dissatisfied 22	Somewhat satisfied 3 3	Mostly sotisfied 4	Complet satisfied 5s		Q13 <i:3><achflf></achflf></i:3>
						,	have to the sec
"	4 Over the <u>past 2 w</u> I felt that way	<u>veeks</u> , how often h Ifelt that way	ave you telt discou	raged or down in I rarely felt	the dumps be I never		our heart failure?
	,						
	all of the time	most of the time	felt that way	that way	that wa	NUUG	(14<1:3> <auhfdu></auhfdu>
	all of the time 1 🔲 1	most of the time 22	felt that way 3 🔲 3	that way	that wa <mark>5</mark>	NUUG	114 <i:3><auhfdu></auhfdu></i:3>
1	1 □1 5 How much does y	2 22 your heart failure cipation in the follo	3 3 a affect your lifesty owing activities ove Limited	4 □4	5 🗆s e how your he <u>s</u> .	y	
	1 □ı 5 How much does y limited your parti	2 2 your heart failure cipation in the follo n each line.)	3 3 a affect your lifesty owing activities ove Limited	4 4 e? Please indicate r the <u>past 2 week</u> <achfl< td=""><td>5 🗆s e how your he <u>s</u>- S></td><td>y eart failure</td><td>e may have Does Not Apply</td></achfl<>	5 🗆s e how your he <u>s</u> - S>	y eart failure	e may have Does Not Apply
	1 🗔 5 How much does y limited your parti (Check only one bax of	2 2 your heart failure cipation in the follo n each line.) Severely Limited	3 🗔 3 e affect your lifestyl owing activities ove Limited Quite	4 4 e? Please indicate r the <u>past 2 week</u> < <u>ACHFL</u> Moderately	5s e how your he <u>s</u> Slightly	y eart failure Did Not Limit at	e may have Does Not Apply or Did Not Do for
5 . A	1 1 5 How much does y limited your partic (Check only one bax of partic (Check only one bax of partic)) Activity Hobbies, recreation	2 2 your heart failure cipation in the follo n each line.) Severely Limited onal 1 1	3 🗔 3 e affect your lifestyl owing activities ove Limited Quite a Bit	4 4 e? Please indicate r the <u>past 2 week</u> < <u>ACHFL</u> Moderately Limited	5 _s e how your he <u>\$</u> S> Slightly Limited	Did Not Limit at All	e may have Does Not Apply or Did Not Do for Other Reasons
5A 5B 5C	1 1 5 How much does y limited your partic (Check only one box of partic (Check only one box of partic decivity) Activity Hobbies, recreation activities: Intimate relations	2 2 your heart failure cipation in the follo n each line.) Severely Limited onal 1 1 hips 1 1 friends	3 3 a affect your lifestyl owing activities ove Limited Quite a Bit 2 22	4 4 le? Please indicate r the <u>past 2 week</u> <achfl< b=""> Moderately Limited 3 3</achfl<>	5 _s e how your he s S Slightly Limited	Did Not Limit at All	e may have Does Not Apply or Did Not Do for Other Reasons 6 🗖 6

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Patient Number: site # Potient's Initials: Int made for

Baseline

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.

patient #

BDI1(TYPE 3)

 BDI1<i:3><acb1d></acb1d></i:3> 0 0 I do not feel sad. 1 1 I feel sad much of the time. 2 2 I am sad all of the time. 3 3 I am so sad or unhappy that I can't stand it. 	7 Self-Dislike: BDI7 <i:3><acb7d> 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.</acb7d></i:3>
BDI2 <i:3><acb2d> BDI2<i:3><acb2d> 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.</acb2d></i:3></acb2d></i:3>	 BDI8<i:3><acb8d></acb8d></i:3> Self-Criticalness: a l don't criticize or blame myself more than usual. a more critical of myself than I used to be. a I criticize myself for all of my faults. a I blame myself for everything that happens.
3 Past Failure: BDI3 <i:3><acb3d> 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.</acb3d></i:3>	 Suicidal Thoughts or Wishes: BDI9<i:3><acb9d></acb9d></i:3> 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.
4 Loss of Pleasure: BDI4 <i:3><acb4d> a l 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.</acb4d></i:3>	10 Crying: BDI10 <i:3><acb10d> 0 I don't cry any more than I used to. 1 I cry more than I used to. 1 I cry over every little thing. 2 I cry over every little thing. 3 I feel like crying, but I can't. BDI11<i:3><acb11d></acb11d></i:3></acb10d></i:3>
 Guilty Feelings: BDI5<i:3><acb5d></acb5d></i:3> 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 oll of the time. 	 Agiration: a m 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.
BDI6 <i:3><acb6d></acb6d></i:3>	12 Loss of Interest: BDI12 <i:3><acb12d></acb12d></i:3>

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CRF, page 7

Potien	nt Number: Potient's Initials:
Beck Depression Inventory (BDI) (continued) 13 Indecisiveness: BDI13<1:3> <acb13d> 0 0 I make decisions about as well as ever. 1 1 I find it more difficult to make decisions than usual. 2 1 have much greater difficulty in making decisions than 1 used to. 3 3 1 have much greater difficulty in making decisions than 1 used to. 3 3 1 have trouble making any decisions. 14 Worthlessness: BDI14<1:3><acb14d> 0 1 don't consider myself as worthwhile and useful as 1 used to. 2 1 feel more worthless as compared to other people. 3 1 feel utterly worthless. 15 Loss of Energy: BDI15<1:3><acb15d> 0 1 have as much energy as ever. 1 1 have less energy than 1 used to have. 2 1 don't have enough energy to do very much. 3 1 don't have enough energy to do anything. BD116 1:3><acb16d> 16 Changes in Sleeping Pattern (deck only one): 0 0 0 1 have not experienced any change in my sleeping pattern. 1 1a Isleep somewhat more than usual. 2 1.5 1.5<!--</th--><th>18 Changes in Appetite (check only one): BD12(TYPE3) 0 0 1 1 have not experienced any change in my appetite. 1 10 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 11 0 12 0 13 1 14 0 15 0 16 0 17 0 18 0 19 0 10 1 10 1 10 1 11 1 12 1 13 1 14 1 15 0 16 1 17 1 18 0 19 1 10 1 10 1 11 1 12 1 13 1 14 1 15 1 16 1 17 1</th></acb16d></acb15d></acb14d></acb13d>	18 Changes in Appetite (check only one): BD12(TYPE3) 0 0 1 1 have not experienced any change in my appetite. 1 10 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 10 0 11 0 12 0 13 1 14 0 15 0 16 0 17 0 18 0 19 0 10 1 10 1 10 1 11 1 12 1 13 1 14 1 15 0 16 1 17 1 18 0 19 1 10 1 10 1 11 1 12 1 13 1 14 1 15 1 16 1 17 1

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patient #

Baseline

Perceived Social Support Scale (PSSS)

We are interested in how you feel about the following statements. Read each statement carefully.

PSSS (TYPE 4)PS

Please check the box that most closely corresponds to how you feel about each statement, from very strongly disagree to very strongly agree.

	Very PSSSA <i:3><acdssr></acdssr></i:3>			ACDSSR>			Very
PSSSQ <i:3><acdssq></acdssq></i:3>	Strongly Disagree	Strongly Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree	Strongly Agree
1=	Discillee	Discidlee	Discillee	Heoligi	Adiee	Adies	Adiee
There is a special person who is around when I am in need:	1 🗆	2 🗆	<mark>3</mark> □3	4 🛛 4	5 _5	<mark>6</mark> 🗖	7 🗆 7
2=2 There is a special person with whom I can share joys and sorrows:		2	3	4	5	6	7
3= 3 My family really tries to help me:		\square_2	\square_3	4	5	□ ₆	7
4= I get the emotional help and support I need from my family:		_ 2	3	4	5	_ 6	7
I have a special person who is a real source of comfort to me: 6=		\square_2	\square_3	4	□ ₅	_ 6	7
6 My friends really try to help me:		 2	\square_3	4	5	_ 6	7
7=7 I can count on my friends when things go wrong:		 2	\square_3	 4	5	_ 6	7
8= 8 I can talk about my problems with my family:		_ 2	□₃	4	5	□ ₆	7
9= 9 I have friends with whom I can share my joys and sorrows:		_ 2	□₃	_ 4	5	□ ₆	7
10= 10 There is α special person in my life who cares about my feelings:		_ 2	□ ₃	4	5	_ 6	7
11 ⁻ My family is willing to help me make decisions:		 2	□ ₃	_ 4	5	_ 6	7
12=12 I can talk about my problems with my friends:		_ 2	3	4	5	□₀	7

PATIENT SELF-REPORT FORM

•

PINK — retain at site

	Baseline	
	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	
STAGE1 <i:3></i:3>	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> I I am currently physically active. 0 0 0 1 1 Yes</zyesno>	L W
STAGE2 <i:3> STAGE3 <i:3> STAGE4 <i:3></i:3></i:3></i:3>	 2 Lintend to become more physically active in the next 6 months.0 0 No 1 1 Yes 3 Lourrently engage in regular physical activity. 0 0 No 1 1 Yes 4 Lhave 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: When I am tired:	ELF-REPOR
	 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></acexsa></i:3> 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></acexsa></i:3> 	
	 1	

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	-22-	Gri	jon							I	Baseli	ine
		~			P	atient Number: _		patient #	F	atient's Ini	tiols:	ide int
	Decisiona	l Balanc	е									
	Please rate how to be physically you have felt in	active. In ea	ach case, think	about <u>how v</u> a			how	Not at All In	Slightly Ima	Moderately Important Veri	ery Important Extremely Important	Jean.
DECIS1	<l:3> 1 I would hav</l:3>	/e more ener	gy for my fan	nily and friend	siflex	cercised regular	ły.	1 🗌 :	2 🗌 3		5	
DECIS2	<123> Regular exe	ercise would	help me reliev	ve tension.								
	<1:3> 3 Ithink Iwo				rexer	cising.						
DECIS4	<l:3> 4 I would feel</l:3>											
DECIS5	<l:3> 5 I would slee</l:3>	ep more sou	ndly if Iexerci	sed regularly.								
DECIS6	<1:3> I would feel	l good abou	t myself if I ke	pt my commite	nent to	exercise regula	arly.					÷
DECIS7	<1:3> 7 I would find		find an exer									
DECIS8	<1 <mark>3</mark> 3> I would like	my body be	etter if Iexerci	sed regularly.								F
DECIS9	<l:3> 9 It would be</l:3>	easier for m	e to perform	routine physico	al tasks	if I exercised r	egularly.					
DECISI	10 I would feel											
DECIS1	1<1:3> 11 I feel uncon heart beats		en I exercise	because I get o	out of b	oreath and my						1
DECIS1	2< :3> 12 I would feel	I more comfo	ortable with m	ıy body if Iexe	ercised	regularly.						
DECIS1						• •						
DECIS1	4 41.3 > 14 Regular exe	ercise would	help me have	a more positiv	ve outle	ook on life.						
DECIS1	5<1:3> 15 I would hav											-
DECIS1	6 <i:3> 16 At the end of</i:3>	of the day, I	am too exhau	sted to exercis	e.							Ē
	Barrier Sc										R(TYP	E 3)
	Please indicate <acbr></acbr>	the extent to Not at All	somewhat	A Lot	he follo	wing might inte	-	ur partici Not at Al		in this st mewhat	udy: A Lot	
BAR1 <i< td=""><td>3> Finances:</td><td></td><td>2</td><td>3 🗌</td><td>6</td><td>Boredom: BA</td><td></td><td></td><td></td><td>newnar 2</td><td>3 🗌</td><td></td></i<>	3> Finances:		2	3 🗌	6	Boredom: BA				newnar 2	3 🗌	
BAR2 <i< td=""><td></td><td></td><td></td><td></td><td>7</td><td>Fatigue: BAR</td><td></td><td></td><td></td><td></td><td></td><td></td></i<>					7	Fatigue: BAR						
BAR3<	3 3 Weather:				8	Transportation						
BAR4<	4 Vacation				9	Work: BAR9						
BAR5 <i< td=""><td>1</td><td></td><td></td><td></td><td>10</td><td>Household res</td><td>ponsibilities: 10<1:3> —</td><td></td><td></td><td></td><td></td><td></td></i<>	1				10	Household res	ponsibilities: 10<1:3> —					
	RF Annotation V		11May2004			Research mann	ле - ги ч К	— retain	at site		000	. 1 1
	HF-ACTION FINAL 1.	U 29APR2003		200	3 DCR	— Confidential					CRF, pag	geil

CTION	tient Number: Patient's Initials:
Physical Activity Questionnaire (PAQ)	site # potient # Polient s minors. Int midde for
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 <u>last 7 days</u> . 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 <u>last 7 days</u>. 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 <u>last 7 days</u>, 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.</i:3> OR No vigorous physical activities → Skip to question 3. NOVIG<zyes></zyes> 2 How much time did you usually spend doing vigorous physical activities on one of those days? minutes per day VIGMIN<i:3></i:3> OR Don't know/not sure UNKVIG<zyes></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></i:3> OR OWALK<zyes></zyes> 6 How much time did you usually spend walking on one of those days? minutes per day minutes per day MALKMIN<i:3></i:3> MALK
 Think about all the moderate physical activities that you did in the <u>last 7 days</u>. 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 <u>last 7 days</u>, 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<:3> Continue to question 4. OR □ No moderate physical activities → Skip to question 5. 	 The last question is about the time you spent sitting on week-days during the <u>last 7 days</u>. 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 <u>last 7 days</u>, how much time did you spend sitting on a weekday? hours per day SITHR<i:3></i:3> OR Don't know/not sure UNKSIT<zyes></zyes>

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or 🗌 Don't know/not sure

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4 How much time did you usually spend doing moderate

MODMIN<I:3>

UNKMOD<ZYES>

physical activities on one of those days?

__ minutes per day

PAQ(TYPE 3)



Baseline

	Patient Number: Patient's Initials:	fest middle last
Current Me	edications	
	Yes" for each westerning and approved the test definition for any limited	
	CMED(I	YPE 3)
$\frac{0}{0}_{0} \operatorname{No} \rightarrow \operatorname{Rec}_{1}$ $\frac{1}{1}_{1} \operatorname{Yes} \rightarrow \operatorname{If} \mathbf{Y}$		preference
	3_3 Enalapril: mg 8_8 Trandolapril: mg 4_4 Fosinopril: mg 98% Other (specify): ACEOTH <v:50> mg 5_5 Lisinopril: mg</v:50>	
0 No	receptor blocker: ANGIO <zyesno> LOSAR<i:3><zyes> VALSAR<i:3><zyes> Yes: Check all that apply: Valsartan Losartan Irbesartan Candesartan ARBOT<i:3> Other (specfy): <u>ANGOTH<v:50></v:50></u> <zyes></zyes></i:3></zyes></i:3></zyes></i:3></zyesno>	
3 Beta blocker:		
-	eason for not using (check only one): 1_1 Contraindicated 2_2 Intolerance 3_3 MD preference 4_4 Patient p	reference
_	Yes: Check only one and provide the <u>TOTAL DAILY DOSE</u> :	
YESBET <i:3></i:3>		
<acbet></acbet>	2 Bisoprolol: mg 5 Metoprolol XL: mg 3 Carvedilol: mg 98 98 Other (specify): BETOTH <v:50> mg</v:50>	
	Yes: Dose: ^{mg} ASPVAL <i:5></i:5>	
	· LOOPD <i:3><zyesno></zyesno></i:3>	
	Yes: Check only one and provide the <u>TOTAL DAILY DOSE</u> :	
YESLOOP <i <acloop></acloop></i 	1:3> 1 FurosemideLOOPVAL #65> 3 Torsemide: mg 2 2 Bumetanide: mg 98.98 Other (specify): LOOPOTH <v:50> mg</v:50>	9
P_₀ No	tic: ARRHYT <i:3><zyesno> AMIOD<i:3><zyes> DOFET<i:3><zyes> Yes: Check all that apply: Amiodarone Sotalol Dofetilide Other (specify): SOTA<i:3><zyes> ARROTH<i:3><zyes></zyes></i:3></zyes></i:3></zyes></i:3></zyes></i:3></zyesno></i:3>	<v:50></v:50>
7 Lipid-lowering 0_0 No	g agent: LLWA <i:3><zyesno> HMGCOA<zyes> ATOR<i:3><zyes> PRA</zyes></i:3></zyes></zyesno></i:3>	\V <i:3><z`< td=""></z`<></i:3>
	OTHULAGT<7YES> 2 Other lipid-lowering agent	ravastatin)ther IP <i:3><z)< td=""></z)<></i:3>
8 Selective sero	otonin reuptake inhibitor: SSRI <i:3><zyesno></zyesno></i:3>	
0_₀ No _1 Yes → Chi	SERT <i:3><zyes> PARO<i:3><zyes> SSRIOT<i:3><zy< th=""> heck all that apply: Sertraline Citalopram Paraxetine Fluoxetine Other</zy<></i:3></zyes></i:3></zyes></i:3>	ES>
Annotation Vers	sion 6.0_11May2004 W - Dul CITAL <i:3><zyes> FLUOX<i:3><zyes></zyes></i:3></zyes></i:3>	_
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ACTION	Patient Number:	Potient's Initials:
Current Medications		pone in e
CURMED Check "No" or "Yes" for each medication.	S <i:3><accmq></accmq></i:3>	
9 Tricyclic antidepressant:	MEDSANS <i:3><zyesnc </zyesnc </i:3>	> CMEDS(TYPE
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 antagon	ist): 🗌 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
KIRSSERCE For potential new drugs. Do not con		ke Clinical Research Institute (D CMOTHA <i:3><zye< td=""></zye<></i:3>
28 Other: CURMDSP	<00:00>	0 ₀ No 1 ₁

CTION	Baseline
Park Park	ient Number: Potient's Initials:
Medical History	
Congestive heart failure: MEDHX1 CONGHF<1:3> <acchf> MEDHX1 Type: 1 Ischemic 2 2 Non-ischemic (TYPE 1)</acchf>	7 Hyperlipidemia: HLIPID <i:3><zyesno> MEDHX2 0-0 No ↓1 Yes (TYPE 1)</zyesno></i:3>
Ejection fraction: Baseline:% BASEF <f:9:3> Screening (<i>f</i> Registry patient):% CNYHA<i:3><acyha> SCRENEF<f:9:3> Current NYHA heart failure class (check only one): 1 1 2 11 3 111 4 N Put in conversion procedure So that 1 can not be entered</f:9:3></acyha></i:3></f:9:3>	 8 Peripheral vascular disease (PVD): PVD<i:3><zyesno></zyesno></i:3> 0 0 No CLAUD<i:3><zyes></zyes></i:3> 1 Yes → If Yes: Check all that apply: Claudication Revascularization REVASC<i:3><zyes></zyes></i:3>
For baseline 2 Angina: ANGIN <zyesno> $\bigcirc_0 N_0$ $\bigcirc_1 Y_{es} \rightarrow If Yes: Current Canadian Cardiovascular Society$</zyesno>	 9 Stroke: STRK<i:3><zyesno></zyesno></i:3> 0 0 No 1 Yes 10 Diabetes: DIABET<i:3><zyesno></zyesno></i:3>
(CCS) Angina Class (check only one): O No angina 1 2 1 3 11 4 N	COPD <i:3><zyesno></zyesno></i:3>
3 Myocardial infarction (MI): MI <i:3><zyesno> 0 No 1 Yes → If Yes: Date of most recent MI: RMIDT</zyesno></i:3>	CANCER <i:3><zyesno> 12 Cancer in last 5 years (excluding minor skin cancer): 0_0 No 1_1 Yes</zyesno></i:3>
All are <zyesno> CARDPR1 CABG: 0 0 No 1 Yes</zyesno>	13 Depression: DEPRES <i:3><zyesno> 0_0No 1_1Yes</zyesno></i:3>
CARDPR2 Valve surgery: 0 No 1 Yes CARDPR3 PCI: 0 No 1 Yes CARDPR4 Pacemaker: 0 No 1 Yes CARDPR5 AICD: 0 No 1 Yes CARDPR6 Bi-ventricular pacemaker: 0 No 1 Yes CARDPR7 Other procedure: 0 No 1 Yes	14 Cigarette smoking (check only one): SMOKE <i:3><acsmok> 0₀ Never 4₁ Current smoker 2₂ Quit → If Quit: Provide month and year quit: SMOKM<v:3><acmon> SMOKY <v:4></v:4></acmon></v:3></acsmok></i:3>
 Specify: <u>CARDOTH<v:50></v:50></u> 5 Arrhythmias: <u>ARR<i:3><zyesno></zyesno></i:3></u> 0₀ No ↓1 Yes → If Yes: Check all that apply: Atrial fibrillation/atrial flutter 	SEE BELOW ^{INDUM} Just 15 Alcohol use: ALCOHOL <i:3><zyesno> 0_0 No 1_1 Yes → If Yes: Specify: AVDRIN<i:3> Average # of drinks per week: OR Patient no longer drinks (past history of redepined on the longer drinks (past history of</i:3></zyesno></i:3>
BRADY <i:3><zyes> Symptomatic bradycardia VTACH<i:3><zyes> Sustained ventricular tachycardia/ ventricular fibrillation OTARR<i:3><zyes> Other (specify): <u>ARRSP<v:50></v:50></u></zyes></i:3></zyes></i:3></zyes></i:3>	alcohol use only) NODRINK <i:3><zyes> 16 How many times has the patient been hospitalized in the past 6 months? hospitalizationsHOSPNM<i:3></i:3></zyes></i:3>
6 Hypertension: HYPTN <i:3><zyesno> 0 1 Yes</zyesno></i:3>	Of these hospitalizations, how many were related to heart failure? HFHOSP <i:3> <acmon> JAN JUL FEB AUG</acmon></i:3>
CRF Annotation Version 6.0_11May2004 W - Duke Clinical Re HF-ACTION FINAL 1.0 29APR2003 2003 DCRI -	search Institute • PINK – retainAnBite OCT - Confidential MAY NOV page 15 JUN DEC

			on		Pot	ient Number:				Be Patient's Initial	aseline
		ıbs			T GI		site #	р Р	atient #	T diletti s mino	5: fret middle Tast
L 1=	CH Abt	EMISTRY: EST <i:3><aclbt> Sodium:</aclbt></i:3>	LABND <i:3< th=""><th>S><zye< th=""><th></th><th>LABVAL<</th><th></th><th></th><th>BUNIT<i:3 Immol/Lor</i:3 </th><th>><ACUNIT> mEq/L</th><th></th></zye<></th></i:3<>	S> <zye< th=""><th></th><th>LABVAL<</th><th></th><th></th><th>BUNIT<i:3 Immol/Lor</i:3 </th><th>><ACUNIT> mEq/L</th><th></th></zye<>		LABVAL<			BUNIT <i:3 Immol/Lor</i:3 	>< ACUNIT > mEq/L	
2=	2	Potassium:	□ ₁ Not done	OR	Value:			Units:	<mark>2</mark> mg/dL 3 μmol/L	LABS	(TYPE 2)PS
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		
	LIP	PID:									
6=	Ó	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		
	HE	MATOLOGY:									
9=	9	Hemoglobin (Hgb):	□ ₁ Not done	OR	Value: _			Units:	5 g/dL or 6 g/L mmol/L		
10=	10	Hematocrit (Ha):	□ ₁ Not done	OR	Value: _			Units:	7 % 8 l/l		
	DI/	ABETIC ASSESSMENT:									
11=		Hemoglobin A1c:	□ ₁ Not done	OR	Value:		_	Units:	%		
		TURETIC PEPTIDE:	_								
12=	12	BNP:	Not done	OR	Value: _		_	Units: 9	pg/mL		
13=	13	Pro-BNP:	□ ₁ Not done	OR	Value:		_	Units:	pg/mL		

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ACTION	Patient Number: Patient * Patient's Initials:
Quality of Life—Reason for Missing	
Are all quality-of-life forms complete? 0, No → If No: QOLL <i:3><zyesno> 1, Yes</zyesno></i:3>	 1 Patient die d 2 Patient refuse d 3 Patient withdrew consent 4 Patient missed visit 4 Patient sick 98% Other
1 Patient was too critically ill. 2 Patient cannot walk for technical in 3 Not done due to oversight. 1 Yes → If Yes: Date of 6-minute walk:/	IX <i:3><acnsix> 4 Patient refused (TYPE 3) reasons (e.g., a patient who is an amputee). 5 Patient died WALKDT 6 Patient withdrew consent month year 7 Patient missed visit</acnsix></i:3>
2 Were the QOL instruments completed before or after Dational Exponentians, Evaluation	QOLTM <i:3><acqtm> er the 6-minute walk? Check only one: 1₁Before 2₂ < 30 mins after 3₃ 30-60 mins after 4₄ < 60 mins after</acqtm></i:3>
Patient Expectations Evaluation Adm Response to the evaluation of patient expectation quest	
Investigator's Signature	
I have reviewed and found all baseline data pertaining Investigator's signature:BSIG <i:3><zyes></zyes></i:3>	ng to this patient to be complete and accurate. SIG (TYPE 3) BSIGDT Date:/

		PROTOCOL	= HFACT	ION	CC	ONTEX [®]	Т
		STUDYBOO	K= DATA	FORMS	NODATA <z`< th=""><th></th><th></th></z`<>		
	S-11/GUDELC	FORM= 3MC	ONTH			3-M	onth
4	VISITE	Potie	nt Number:	SUBJNO		s Initials: 👖	
Da	te of visit:///						
E.	uroQoL Questionnaire						
	placing a checkmark in one box in e ich statement best describes your ov		indicate	See ann	otation on p.3	of Baselir	ne
1	Mobility:						
	1 l have no problems in walking abo	ut.					
	2 I have some problems in walking a	out.					
	3 I am confined to bed.						
2	Self-care:						
	1 have no problems with self-care.						P
	2 I have some problems washing or	ressing myself.					2
	3 I am unable to wash or dress myse						
3	Usual activities (e.g. work, study, housewo						É
	1 I have no problems with performin						
	2 I have some problems with perform						60
	3 I am unable to perform my usual a	nvines.					-
4	Pain/discomfort:						
	1 have no pain or discomfort.						코
	2 I have moderate pain or discomfo						
	3 I have extreme pain or discomfort.						ATIENT SELF-REPORT F
5	Anxiety/depression:						Ŭ.
	1 I am not anxious or depressed.						Ĩ
	2 I am moderately anxious or depre	sed.					
	3 I am extremely anxious or depress						Ö
					_		22
	→ Please let your study coo	rdinator know that you	are ready f	or the EuroQoL	Thermometer	workshee	• 3
	_						
Po	ain Assessment						
,	How much bodily pain have you ha	during the part 4 week	t laborh and and	2			
•	\square_1 None \square_2 Very mild \square_3 Mil						
				,			
2	During the past 4 weeks, how much	did pain interfere with y	our normal wo	rk (including both we	ork outside the home	and housewor	k)?
	\square_1 Not at all \square_2 A little bit \square_3	Moderately 🗌 4 Quite a	bit5 Extre	emely			
Εų	vroQol Thermometer R	sponse					
Res	sponse to the EuroQoL thermometer:						
		(0-100)					
	WHITE and YEL	OW — Duke Clinical Res	earch Institute	e • PINK – ret	ain at site		

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See annotation p.4 of Baseline

patient #

site #

3-Month

1

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 <u>past 2 weeks</u>.

(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 yours	elf:		 2	3	4	5	6
Showering/bat	thing:		2	3	4	5	6
Walking 1 bloc	k on level ground:		2	3	4	5	6
Doing yard wo or carrying gro			2		4	5	6
Climbing a flig stairs without s			2	\square_3	4	5	6
Hurrying or jog (as if to catch a bus			2	3	4	5	6
	<u>h 2 weeks ago</u> , hav of heart failure hav		ns of hea	rt failvre (short	ness of breath,	fatigue, or ankl	e swelling) changed?
Much worse	Slightly worse	Not changed 3	I	Slightly better 4	Much better □_s		ad no symptoms he last 2 weeks
	<u>2 weeks</u> , how many when you woke up	-		lling in your fe	et,		
Every morning	3 or more times a we but not every morni	-	-	Less than once a week	Never ove past 2 we		
Over the <u>past 2</u>	2 weeks, how much	has swelling i	in your fe	et, ankles or leg	gs bothered	you? It has	been
Extremely bothersome	Moderately bothersome	Somewho bothersom		Slightly bothersome	Not at botherso		I've had swelling

HF-ACTION_3MO_1.2_16JUN2003

₩- M	3710N	Se	e annotation p.5 c	of Baseline		3-Mon
	-		Patient Number:		ntient # Pa	tient's Initials:
ansas City	Cardiomyop	athy Ques	tionnaire (K	CCQ) (continue	d)	
Over the past 2	weeks, on average,	how many time	s has fatigue limited	d your ability to d	o what you w	anted?
All of	Several	At	3 or more	1-2	Less than	Never
the	times	least once	times per week	times	once	over the
time	per day	a day	but not every day	a week	a week	past 2 weeks
		3		5	6	
Over the <u>past 2</u>	weeks, how much he	as your fatigue	bothered you? It ho	ıs been		
Extremely	Quite a bit	Moderately	Slightly	Not at all	l've ho	bd
bothersome	bothersome	bothersome	bothersome	bothersome	no fatig	gue
	2	3	4	5	6	
Over the <u>past 2</u>	<u>weeks</u> , on average, h	ow many times	has shortness of br e	eath limited your	ability to do wl	hat you wanted?
All of	Several	At	3 or more	1-2	Less than	Never
the	times	least once	times per week	times	once	over the
time	per day	a day	but not every day	a week	a week	past 2 weeks
				5	6	7
Extremely bothersome	Quite a bit bothersome	Moderately bothersome	Slightly bothersome	Not at all bothersome	l've had shortness o	
bothersome	bothersome	bothersome	bothersome	bothersome	shortness of	t breath
	<u>weeks</u> , on average, rs to prop you up bec			ced to sleep sitting	g up in a chair	or with
	3 or more times	1-2	Less than	Never		
Every	a week, but	times	once	over the		
night	not every night	a week	a week	past 2 weeks		
1	2	3	4	5		
Heart failure	symptoms can worse	n for a number	of reasons. How sur	e are you that yo	u know what t	o do or
	our heart failure ge	ts worse?				
		ts worse? Somewhat	Mostly	Completely		
who to call, if y	our heart failure ge		Mostly	Completely sure		
who to call, if y Not at all	our heart failure ge Not very	Somewhat				
who to call, if y Not at all sure 1 How well do yo	Not very Sure 2 Sure 2	Somewhat ^{sure} 3	sure ble to do to keep you	sure	symptoms fro	m getting
who to call, if y Not at all sure 1 How well do yo worse (for example	Not very sure 2 ou understand what the e, weighing yourself, eating	Somewhat sure 3 hings you are a a low-salt diet etc.)?	sure	sure s ur heart failure	symptoms from	m getting
who to call, if y Not at all sure 1 How well do yo worse (for example	Not very Sure 2 Sure 2	Somewhat sure 3 hings you are a a low-salt diet etc.)? Somewhat	sure ble to do to keep you Mostly	sure s ur heart failure Completely	symptoms fro	m getting
who to call, if y Not at all sure 1 How well do yo worse (for example	Not very sure 2 ou understand what the e, weighing yourself, eating	Somewhat sure 3 hings you are a a low-salt diet etc.)?	sure	sure s ur heart failure	symptoms fro	m getting

CRF ANNOTATION VERSION 6.0_11May2004

			3-Mo			
			Patient Number:		patient #	Patient's Initials:
nsas City (Cardiomyop	athy Quest	ionnaire (K	CCQ) (col	ntinued)	
Over the <u>past 2</u>	weeks, how much h	nas your heart fai	lure limited your	enjoyment o	of life?	
t has extremely limited my	It has limited my enjoyment of life	It has moderately limited my	 It has slightly limited my 	lt has not my enjoy		
enjoyment of life	quite a bit	enjoyment of life	enjoyment of life	life at	s all	
lf you had to spe	nd the rest of your	life with your hea	rt failure the wa	y it is <u>right n</u>	<u>iow</u> , how wou	ld you feel about this
Not at all	Mostly	Somewhat	Mostly	Compl	etely	
satisfied	dissatisfied	satisfied	satisfied	satisf	ied	
1	2	3	4		5	
Over the <u>past 2 v</u>						
I felt that way	I felt that way most of the time	felt that way	I rarely felt that way	I neve that v	vay	
I felt that way all of the time In How much does imited your part	I felt that way most of the time 		that way	that v	vay s	e may have Does Not Apply
I felt that way all of the time inted your part Check only one bax of	I felt that way most of the time 	e affect your lifesty	that way	that v	vay s heart failure	
I felt that way all of the time I How much does	I felt that way most of the time 	e affect your lifesty owing activities ove Limited Quite	that way 	that v e how your <u>is</u> . Slightly	heart failure Did Not Limit at	Does Not Apply or Did Not Do for
I felt that way all of the time inited your part Check only one bax of Activity Hobbies, recreat	I felt that way most of the time	e affect your lifesty owing activities ove Limited Quite	that way a the? Please indicate er the <u>past 2 week</u> Moderately Limited	that v e how your <u>is</u> . Slightly	heart failure Did Not Limit at	Does Not Apply or Did Not Do for
I felt that way all of the time inited your part Check only one box of Activity Hobbies, recreat activities:	I felt that way most of the time	e affect your lifesty owing activities ove Limited Quite	that way a the? Please indicate er the <u>past 2 week</u> Moderately Limited 3	that v e how your <u>is</u> . Slightly	heart failure Did Not Limit at	Does Not Apply or Did Not Do for

CRF ANNOTATION VERSION 6.0_11May2004

J	See annotation p.7 of	Baseline 3-Month
6	Po	tient Number: patient # Patient's Initials:
Be	eck Depression Inventory (BDI)	11 W T
Thi rec the wa	s questionnaire consists of 21 groups of statements. Please ad each group of statements carefully, and then pick out one statement in each group that best describes the by you have been feeling during the past one week , cluding 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 state- ment for any group, including item 16, Changes in Sleeping Pattern and item 18, Changes in Appetite.
1	Sadness: I do not feel sad. I feel sad much of the time. I am sad all of the time. I am so sad or unhappy that I can't stand it.	 Self-Dislike: 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.
2	Pessimism: 	 Self-Criticalness: O 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.
3	Past Failure: 	 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.
4	Loss of Pleasure: 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. 	10 Crying:
5	Guilty Feelings: 	 Agitation: 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.
6	Punishment Feelings: 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.	 12 Loss of Interest:

set if and if more difficulty in making decisions than usual.	Image:		ation p.8 of Baseline 3-Mo
 □ I nake decisions about as well as ever. □ I find it more difficult to make decisions than usual. □ I have nuch greater difficulty in making decisions than usual. □ I have nuch greater difficulty in making decisions than usual. □ I have nuch greater difficulty in making decisions. Worthlessness: □ I don't consider myself as worthwhile and useful as I used to. □ I for to consider myself as worthwhile and useful as I used to. □ I don't consider myself as worthwhile and useful as I used to. □ I for the worthless. □ I don't consider myself as worthwhile and useful as I used to. □ I have not experienced any change in my appetite is somewhat greater than usual. □ I have not experience as compared to other people. □ I have as much energy as ever. □ I have less energy than 1 used to have. □ I don't have enough energy to do anything. Changes in Sleeping Pattern (check only one): □ I have not experienced any change in my sleeping pattern. □ a listep somewhat less than usual. □ I have not experienced any change in my sleeping pattern. □ as I sleep a lot more than usual. □ as I sleep a lot more than usual. □ as I sleep nost of the day. □ as I wake up 1 - 2 hours early and can't get back to sleep. I transbility: □ an moch more irritable than usual. □ an moch more irritable than usual. □ an much more irritable than usual.<th>Indecisions about as well as ever. If had it more difficult to make decisions than usual. If have not experienced any change in my appetite. If have not decisions about as well as ever. If have not experienced any change in my appetite. If have not decisions about as well as ever. If have not experienced any change in my appetite. If how much greater difficulty in making decisions than usual. If how much greater than usual. If how not set rouble making any decisions. If how not experienced any change in my appetite is somewhat greater than usual. If how not consider myself as worthwhile and useful as 1 used to not feel 1 am worthless. If all ther to consider myself as worthwhile and useful as 1 used to not feel term worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to concentrate as well as usual. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all the to worthless. I</th><th></th><th></th>	Indecisions about as well as ever. If had it more difficult to make decisions than usual. If have not experienced any change in my appetite. If have not decisions about as well as ever. If have not experienced any change in my appetite. If have not decisions about as well as ever. If have not experienced any change in my appetite. If how much greater difficulty in making decisions than usual. If how much greater than usual. If how not set rouble making any decisions. If how not experienced any change in my appetite is somewhat greater than usual. If how not consider myself as worthwhile and useful as 1 used to not feel 1 am worthless. If all ther to consider myself as worthwhile and useful as 1 used to not feel term worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to concentrate as well as usual. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all ther to worthless. If all the to worthless. I		
 a have decisions about as well as ever. a have much greater difficult in making decisions than usual. b have nuch greater difficulty in making decisions than usual. b have nuch greater difficulty in making decisions than usual. b have nuch greater difficulty in making decisions. Worthlessness: a have trouble making any decisions. Worthlessness: b of the l am worthless. c have not experienced any worthwhile and useful as I used to. c have not everthless as compared to other people. c have not everthless. c have as much energy as ever. c have as much energy to do anything. Changes in Sleeping Pottern (check only one): a have lase strain usual. b al sleep somewhat more than usual. c have not experienced any change in my sleeping pattern. a listep somewhat less than usual. b al sleep somewhat less than usual. c have not experienced any change in my appetite. d am no more irritable than usual. c have not erritable than usual. c have not erritable than usual. c harm on more irritable than usual. c harm on more irritable than usual. c harm intribube (ith me usual. c harm on more irritable than usual. c harm harm on more irritable than usual. c harm on more irritable	Output (TYPE 3)	eck Depression Inventory (BDI) (a	ontinued)
 a l do not feel I am worthless. 1 do not feel I am worthless. 1 do not feel I am worthless. 1 do not feel I am worthless. 2 l feel utterly worthless. 3 I feel utterly worthless. 4 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. 4 Changes in Sleeping Pattern (check only one): 0 I have not experienced any change in my sleeping pattern. 1 I sleep somewhat less than usual. 2 I sleep a lot more than usual. 2 I sleep a lot less than usual. 2 I be post of the day. 3 I sleep nost of the day. 3 I sleep nost of the day. 3 I sleep nost of the day. 1 la more irritable than usual. 1 a more irritable	I do not feel 1 am worthless. I do not feel 1 am worthless. I don't consider myself as worthwhile and useful as I used to. I feel uterly worthless. I case of Energy: I have as much energy as ever. I howe less energy than 1 used to have. I don't have enough energy to do very much. I don't have enough energy to do anything. Changes in Sleeping Pattern (check only one): I sleep somewhat more than usual. I sleep a lot less than usual. I sleep a lot less than usual. I sleep a lot less than usual. I sleep a lot more initiable than usual. I wake up 1-2 hours early and can't get back to sleep. I rintability: I am more irritable than usual. I am intriable all the time. OUTPUT (TYPE 3)	 I find it more difficult to make decisions than usual. I have much greater difficulty in making decisions than I used to. 	 I have not experienced any change in my appetite. In My appetite is somewhat less than usual. My appetite is somewhat greater than usual. In My appetite is much less than before.
 J feel utterly worthless. J feel utterly worthless. J feel utterly worthless. J Loss of Energy: I can't concentrate as well as ever. I can't concentrate as well as usual. I can't concentrate as well as usual. J thave less energy than I used to have. I ton't have enough energy to do very much. J ton't have enough energy to do very much. J ton't have enough energy to do anything. Changes in Sleeping Pattern (check only one): I tave not experienced any change in my sleeping pattern. I tave not experienced any change in my sleeping pattern. I tave not experienced any change in my sleeping pattern. I tave not experienced any change in my sleeping pattern. I table p a lot less than usual. I sleep a lot less than usual. I tritability: I am no more irritable than usual. I am no more irritable than usual. I am much more irritable than usual. I am irritable altha usual. I am irritable altha usual. I am irritable than usual. I am irritable altha usual. I am irritable than usual.	 ☐ feel utterly worthless. ☐ Loss of Energy: ☐ I have as much energy as ever. ☐ I have less energy than I used to have. ☐ 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. 2 Changes in Sleeping Pattern (check only one): ☐ I have not experienced any change in my sleeping pattern. ☐ I sleep somewhat more than usual. ☐ I sleep somewhat less than usual. ☐ I sleep a lot more than usual. ☐ I sleep a lot more than usual. ☐ I sleep a lot less than usual. ☐ I sleep a lot more than usual. ☐ I have up 1-2 hours early and can't get back to sleep. / Irritability: ☐ I am no more irritable than usual. ☐ I am more irritable than usual. ☐ I am much more irritable than usual. ☐ I am much more irritable than usual. ☐ I am much more irritable than usual. ☐ I am irritable all the time. 	1 I don't consider myself as worthwhile and useful as	used to.
 a I find I can't concentrate on anything. Changes in Sleeping Pattern (check only one): a I an no more tired or fatigued than usual. a I sleep somewhat more than usual. b I sleep a lot more than usual. a I sleep a lot less than usual. b I sleep a lot less than usual. b I sleep a lot less than usual. b I sleep a lot less than usual. c I tritability: a I sleep more irritable than usual. b I more irritable than usual. c I am no more irritable than usual. c I am more irritable than usual. <l< td=""><td> □ I have as much energy as ever. □ I have less energy than I used to have. □ I have less energy than I used to have. □ I have enough energy to do very much. □ I don't have enough energy to do anything. 20 Tiredness or Fatigue: □ I am no more tired or fatigued than usual. □ I aper somewhat more than usual. □ I sleep somewhat less than usual. □ I sleep somewhat less than usual. □ I sleep nost of the day. □ I are no more irritable than usual. □ I cons of Interest in Sex: □ I have not experienced any can't get back to sleep. 21 Loss of Interest in Sex: □ I am no more irritable than usual. □ I am no more irritable than usual. □ I am irritable than usual. □ I</td><td></td><td>I can concentrate as well as ever. 1 can't concentrate as well as usual.</td></l<>	 □ I have as much energy as ever. □ I have less energy than I used to have. □ I have less energy than I used to have. □ I have enough energy to do very much. □ I don't have enough energy to do anything. 20 Tiredness or Fatigue: □ I am no more tired or fatigued than usual. □ I aper somewhat more than usual. □ I sleep somewhat less than usual. □ I sleep somewhat less than usual. □ I sleep nost of the day. □ I are no more irritable than usual. □ I cons of Interest in Sex: □ I have not experienced any can't get back to sleep. 21 Loss of Interest in Sex: □ I am no more irritable than usual. □ I am no more irritable than usual. □ I am irritable than usual. □ I		I can concentrate as well as ever. 1 can't concentrate as well as usual.
 6 Changes in Sleeping Pattern (check only one): 	 Changes in Sleeping Pattern (check only one): 0 I have not experienced any change in my sleeping pattern. 1 a I sleep somewhat more than usual. 1 b I sleep a lot more 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. 3 I am too tired or fatigued to do most of the things I used to do. 3 I am too tired or fatigued to do most of the things I used to do. 3 I am too tired or fatigued to do most of the things I used to do. 3 I am too tired or fatigued to do most of the things I used to do. 3 I am too tired or fatigued to do most of the things I used to do. 3 I am too tired or fatigued to do most of the things I used to do. 3 I am too tired or fatigued to do most of the things I used to do. 3 I am too tired or fatigued to do most of the things I used to do. 3 I am too tired or fatigued to do most of the things I used to do. 3 I am too tired or fatigued to do most of the things I used to do. 3 I am too tired or fatigued to do most of the things I used to do. 3 I am too tired or fatigued to do most of the things I used to do. 3 I am too tired or fatigued to do most of the things I used to do. 3 I am too tired or fatigued to do most of the things I used to do. 3 I am too tired or fatigued to do most of the things I used to do. 3 I am much more irritable than usual. 3 I am irritable all the time. OUTPUT (TYPE 3) 	I have less energy than I used to have. 1 don't have enough energy to do very much.	 a I find I can't concentrate on anything. 20 Tiredness or Fatigue:
 2_a I sleep a lot more than usual. 2_b I sleep a lot less than usual. 3_a I sleep most of the day. 3_b I wake up 1-2 hours early and can't get back to sleep. 7 Irritability: 0 I am no more irritable than usual. 1 am more irritable than usual. 2 I am much more irritable than usual. 3 I am irritable all the time. 	 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. 7 Irritability: 0 I am no more irritable than usual. 1 am more irritable than usual. 2 I am much more irritable than usual. 3 I am irritable all the time. 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. 	\Box_0 I have not experienced any change in my sleeping $\Box_{1\alpha}$ I sleep somewhat more than usual.	pattern. _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
7 Irritability:	7 Irritability: Image: mail of the second seco	2 _α I sleep a lot more than usual. 2 _b I sleep a lot less than usual. 3 _α I sleep most of the day.	leep.
□ 3 I am irritable all the time. OUTPUT (TYPE 3)	OUTPUT (TYPE 3)	 I am no more irritable than usual. I am more irritable than usual. I am much more irritable than usual. 	
	roductivity Assessment	∟ ₃ I am irritable all the time.	OUTPUT (TYPE 3)

LOSTWK<F:9:3

- AGTION			3-Month
	Patient Nu	mber: patient #	Patient's Initials:
Medical History			
FUNYHA Current NYHA heart failure class (check only or	<i:3><acyha></acyha></i:3>	III 🗌 IV	MEDHX3 (TYPE 3)
2 Current Canadian Cardiovascular Society (C	CS) angina class {check	ANGICL <i:3><acci only one): No angina I</acci </i:3>	_AS> _
Current Medications			
Check "No" or "Yes"; if "Yes", provide the total	daily dose.	C	MEDLOOP(TYPE 3)
Loop diuretic: □₀ No LOOPD <i:3>< □₁ Yes → If Yes: Check only</i:3>	one and provide the t	otal daily dose:	
YESLOOP <i:3><acloop> 11 Furosem</acloop></i:3>	<mark>.@O<u>PVAL<i:< u="">5≽</i:<></u></mark> g ide: mg	3 ₃ Torsemide: mg 98 ₉₈ Other, (specify <mark>: OOPOTH</mark> <	V:50> mg
Check "No" or "Yes" for each medication.	WMEDS <i:3><acm< td=""><td>IEDS></td><td>CMEDS3(TYPE 4)PS</td></acm<></i:3>	IEDS>	CMEDS3(TYPE 4)PS
2 Spironolactone:	P <i:3><zyesno></zyesno></i:3>	Calcium channel blocker:	o No o 1 Yes
3 Eplerenone:	_1 Yes 17	Insulin:	🗌 ₀ No 🔄 ₁ Yes
4 Non-loop diuretic:	_1 Yes 18	Glitazone:	🗋 ₀ No 🔄 1 Yes
(excluding aldosterone antagonist)		Other oral diabetic agent:	🔄 0 No 🔄 1 Yes
5 Potassium:	1 Yes 20	Thyroid replacement:	🗋 No 🔄 1 Yes
6 ACE inhibitor:		Selective serotonin	
7 Angiotensin receptor blocker:	1 Yes	reuptake inhibitor:	🗋 No 🔄 🔤 Yes
8 Beta blocker:	_, Yes 22	Tricyclic antidepressant:	o No o Yes
9 Aspirin:	_1 Yes 23	Other antidepressant:	o No o 1 Yes
10 Antiarrhythmic:	-	(excluding SSRIs and TCAs)	
11 Lipid-lowering agent:		Antipsychotic:	o No a Yes
12 Clopidogrel:		NSAID:	o No o 1 Yes
13 Coumadin:	26 , Yes	COX-2 inhibitor:	o No 1 Yes
14 Digoxin:	27	Sildenafil:	🗌 ₀ No 🔲 ₁ Yes
15 Nitrate:	1 Yes	See annotation p.14	CMEDS2(TYPE4)PS
Reserved for potential new drugs. Do not comp	olete unless instruct		
28 Other:			o No 1 Yes
29 Other:			o No 🛛 1 Yes

	10N	3-Month
	See annotation p.17 of Baseline except PATINS, SIG	Patient's Initials:
Quality of Life	—Reason for Missing Data	
Are all quality-of-life for 6-Minute Wall	rms complete?	
	mpt the 6-minute walk at this visit?	
On No → If No: Since Si	pecify 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 Patient missed visit tart walk time: :	
	id the patient experience any of the following symptoms? (check all that apply) None Angina Light-headedness Syncope org Rating of Perceived Exertion (RPE) Scale:	
	(6-20)	
2 Were the QOL instru	330-	re) mins after 60 mins after) mins after

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-				Patient Number:	r: Potient's Initials:	Initials for order to
	Outpatient Log					
	1 Has the patient had any non-urge	mt outportient visits sin	NONURG <zyesno> Has the patient had any non-urgent outpatient visits since the last study visit? (Do not include protocol-specified follow-up visits)</zyesno>	SNO> col-specified follow-up vis	$ \underset{dis.}{\overset{dis.}{\square}} \bigcup_{0} N_{D} \underset{v \in S}{\overset{OUTPAT}{\square}} (TYPE 4) PS $	t) PS able below.
1	Provider Type		Number of Office/Clinic Visits	lisits	Number of Home Visits	
	1.1 Cardiologist: pROVIDER 21:3>24CPROV>	3> <acprov></acprov>	OFFVIS <i:3></i:3>		HOMVIS <i:3></i:3>	
2	2= 1.2 Orthopedic surgeon:					
3	1.3 Other specialist:					
4	1.4 Primary care physician:					
2	1.5 Physician extenders (includes NPs, PAs, etc.);	i, PAs, etc.)t				
9	1.6 OT or PT:					
7=	7= 1.7 Mental health provider:					
# ©	1.8 Nurse (includes RNs, LPNs, nurse's aides or other equivalent);	des or other equivalent);				
6	1.9 Other (specify): OTHPROSP <v:50></v:50>	SP <v:50></v:50>			OUTPA	ОИТРАТОТ (ТҮРЕ 4
	2 Has the partient had any outpatient cardiac procedures/ tests (including ICD	t cardiac procedures table belowOTPTPF	Has the patient had any outpatient cardiac procedures/tests {including KD lining} or orthopedic procedures/tests since the last study visit? □₀ № □, Yes → Compete the table belowOTPTPROC <zyesno></zyesno>	orocedures/tests sir		OUTPAT2 (TYPE4)R
	Procedure Code*	Number	Procedure Code*	Number	Procedure Code*	Number
	PROCCODE <v:100></v:100>	PROCOUNT <i:3< td=""><td></td><td></td><td></td><td></td></i:3<>				
	*See choices on opposite page. Reco	rd one per row. If a p	*See choices on opposite page. Record one per row. If a procedure/test is not listed, please record it in the table above.	d it in the table abc	ove.	

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HF-ACTION_3MO_1.2_16JUN2003

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e

Patient's Initials: for eads for

site # patient # Patient Number:

Outpatient Log

3 Has the parient required any urgenVemergency care on an outparient basis since the last study visitive GeNE<2YESNO2+ Complete the table belowUTPAT3 (TYPE4) PS

			•					
		Number of Visits Due to OußERRV Heart Failure*	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 HF VISIT <i:3> hours, or observation unit:</i:3>	HFVISIT <i:3></i:3>	CVVISIT <i:3></i:3>	NCVVISIT <i:3> JNKVISIT<i:3></i:3></i:3>	UNKVISIT <i:3></i:3>	EXVISIT <i:3></i:3>	
3	3.2	Heart failure clinic/office:			NOER <i:3><acnoer></acnoer></i:3>			
3= 3.3	3.3	Stand-alone urgent care facility:			1= No ER visit to date		NOUCHF≺I:3> <acnohf> 1=No undent clinic visit for HF to date</acnohf>	
	3.4	Date of 1 st ER visit (for any reason since randomization):	nce randomization);		ORNO ER visit to date	colaca	2= Previously recorded OUTPAT4 (TYPE 4)	
	3.5	Date of 1 st urgent clinic visit due to heart failure	to heart failure	exacerbation (since randomization):	-/UCMED	" or	$\hfill \square_1$ No urgent clinic visit for HF to date	
	0th	Other Types of Resource Utilizatio	Utilization					
	z	1 Number of days on home IV infusion for heart failure since the last study visit:	n for heart failur	e since the last study visit:	days IVDAYS <i:3></i:3>		RESUTIL (TYPE 4)	
	7	Since the last study visit, how many days did the patient live in each of the following	days did the pat	tient live in each of the follo	wing			
		Caregiver's home (e.g., family and friends); CAREGUB/X<1:3>	iends): CAREG	⟨₽⟩Х <i:3></i:3>				
		0	days SKNURSDY<1:3> ACCAREDY<1:3>	SDY <i:3> i:3></i:3>				
		3> V:50>	2	OTHERDY <i:3> doys</i:3>				
•	Deimo	Deimener alianeerais						7

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LAN REPORT	This is a repeating page		Ċ	3-Month
	First page should have page rep 0		patient # Patient's Inihi	Patient's Initials: for eads for
Hospitalization Record only hospitalizations for 2 24 hours.				
Has the patient been hospitalized for any reason since the last completed study visit?	d study visit?		NdSOH	HOSPNO (TYPE 3)
(Only include completed hospitalizations. Wait until the next study visit to record hospital information if the patient is currently hospitalized.) $\Box_0 No = \Box_1 Yes \rightarrow 1f Yes; How many hospitalizations? HOSCOUNT<1:3>$	ation if the patient is currently hospitalized.) 1:3>		HOSPITAL (TVPF 4) R	4) R
HOSP <zyesno></zyesno>		Primary Cardiac	Secondary Cardiac	DISCHDES<
HOSPNUM<1:3>	PLANNED <i:3><achos></achos></i:3>		otion)*	Discharge
T	Hospitalization: tor Hospitalization	Record a zero if patient did not have cardiac procedures.	have cardiac procedures.	Destination [*]
I Hospitalization: Admission date:	Dlanned HOSPREA<1:3>	PRIMPROC <i:3></i:3>	SECPROC<1:3>	
Did the event leading to this hospitalization occur during or within 3 hours after exercise? □0 No □1 Yes EXERHOSP <zyesno> CARDHOSP<zyesno> Did a cardiovascular event cause or occur during this hospitalization? Did a cardiovascular event cause or occur during this hospitalization?</zyesno></zyesno>	HOSREAOT <v:100></v:100>		PRIMPROT <v:100> SECPROT<v:100> DISDESOT<v:100></v:100></v:100></v:100>	ISDESOT <v 100<="" td=""></v>
2 Hospitalization: Admission date:	DCRI MedDRA			
Did the event leading to this hospitalization occur during or within		/:8>		
3 hours after exercise? 0 No 1 Yes	MEDRTEXT <v:100></v:100>	:100>		
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ No \ \square_1 \ Yes \rightarrow If Yes$. Complete the Cardiovascular Event forms.	WORKFLOW <v:5></v:5>	V:5>		
3 Hospitalization: Admission date: <u></u>	Definition of the second secon			
cour during or	CONFLVL <v:2> MATCHES<v:4></v:4></v:2>	∧ ↔		
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ No = \square_1 \ \gamma_{es} \rightarrow If \ Yes: Complete the Cardiovascular Event forms.$				
* See choices on opposite page. If a diagnosis/procedure/discharge destination is not listed, please record it in the table above.	ation is not listed, please record it	t in the table above.		

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

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2		This is a repeating page First page should have page rep 0	3-Month
C		Potient Number:	t # Potient's Initials:
Te	elephone Log		
1 El	Date of call:/TEL∉DT		TELELOG (TYPE 4)R
		patient's provider been contacted due to changes	in the patient's
		atient, patient's family/friend, study personnel, and/or exercise trai	
	contacts \rightarrow If \geq 1: How many of t	the contacts resulted in:	
Ρ	ROVCONT <i:3> Changes to me</i:3>	edications other than divretics: OTHMEDCH <i:3< td=""><td>}></td></i:3<>	}>
		ncreases: DIURINCR <i:3></i:3>	
		ecreases: DIURDECR <i:3></i:3>	
	Exercise Training Group: Is patient perform TRAINING<7YESNO _₽ No → If No: II	ing the training as prescribed? Indicate primary reason code ?	
	Usual Care Group: Is patient performing phy	UPHYSACT <zyes (formal="" activity="" non-formal)?<="" or="" td="" ysical=""><td></td></zyes>	
2	Date of call:/		
		patient's provider been contacted due to changes	in the national c
		tlient, patient's family/friend, study personnel, and/or exercise trai	
			ina j•
	contacts → If ≥ 1: How many of t		
	-	edications other than diuretics: ncreases:	
		lecreases:	
	biotenie dose d		
	Exercise Training Group: Is patient perform	ing the training as prescribed?	
	₀ No → If No: I	ndicate primary reason code*:	
	1 Yes		
	Usual Care Group: Is patient performing phy	ysical activity (formal or non-formal)? 🔲 No 🔄 Yes	5
3	Date of call:/		
	Since the last call how many times has the a	patient's provider been contacted due to changes i	in the antiont/s
		attent, patient's family/friend, study personnel, and/or exercise trai	
			ner) r
	contacts → If ≥ 1: How many of t		
	•	edications other than diuretics:	
		ncreases:	
	Diuretic dose d	lecreases:	
	Exercise Training Group: Is patient perform	ing the training as prescribed?	
		ndicate primary reason code*:	
	, Yes		

		OTOCOL= HFACT		CONTEXT
	17 🔺 11 - X 1	JDYBOOK= DATA RM = 6MONTH	—	<zyes> 6-Mont</zyes>
	VISITDT	Patient Number: _	site # patient #	Potient's Initials: INTITA
te of visit:/	/			
	th year			
vroQoL Questio	nnaire			
placing a checkmark in ich statement best descr			See annotat	ion p.3 of Baseline
Mobility:				
1 have no problems i				
2 I have some problem				
3 I am confined to bed				
Self-care:				
1 have no problems v	with self-care.			
2 I have some problem		yself.		
3 I am unable to wash	or dress myself.			
Usual and March 1		ta ana b		
Usual activities (e.g. work				
	ns with performing my usu			
3 I am unable to perfor				
	,			
Pain/discomfort:				
1 have no pain or dis				2
2 I have moderate pair				
3 I have extreme pain	or discomfort.			
Anxiety/depression:				
1 I am not anxious or a	depressed.			
2 I am moderately anx	ious or depressed.			
3 I am extremely anxio	us or depressed.			
				2
→ Please let you	Jr study coordinator	know that you are ready	for the EuroQoL Ther	mometer worksneet.
ain Assessment				
How much bodily pain	have you had during (he past 4 weeks (check only or		
, None , Very m				
_1 None _2 Very m				
		interfere with your normal	work (including both work out	ide the home and housework)?
During the past 4 week	cs, how much did pain	-		ide the home and housework]?
During the past 4 week	ittle bit □ ₃ Moderate	interfere with your normal y y □_4 Quite a bit □ ₅ Ex		ide the home and housework)?
During the past 4 week	ittle bit □ ₃ Moderate	interfere with your normal y y □_4 Quite a bit □ ₅ Ex		ide the home and housework}?
During the past 4 week	as, how much did pain ittle bit 🛛 3 Moderate meter Respons	interfere with your normal y y4 Quite a bits Ex		ide the home and housework]?





Patient Number: _ site #

patient #

Patient's Initials: _______

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 your	self:		2	3	4	5	6
Showering/ba	ıthing:		2	3	4	5	6
Walking 1 blo	ck on level ground:		2	3	4	5	6
Doing yard we or carrying gr	ork, housework oceries:			\square_3	4	5	6
Climbing a flig stairs without				3	4	5	6
Hurrying or jo (as if to catch a bu			2	3	4	5	6
-	th 2 weeks ago, have of heart failure have		oms of hec	irt failure (short	tness of breath, :	fatigue, or ankle	swelling) changed?
Much worse	Slightly worse	Not change	ed	Slightly better 4	Much better □s		d no symptoms le last 2 weeks
	2 weeks, how many when you woke up i	-		elling in your fe	eet,		
Every morning	3 or more times a we but not every mornin 			Less than once a week	Never ove past 2 we		
Over the past	2 weeks, how much	has swelling	j in your fe	et, ankles or le	gs bothered	you? It has	been
Extremely bothersome	Moderately bothersome	Somew botherso		Slightly bothersome	Not at a		l've had swelling

CRF ANNOTATION VERSION 6.0_11May2004

	RON	See	annotation p.5 of I	Baseline		6-Mo
<u>عرا</u> 🗧			Particul March and			•
			Patient Number:	site# P	ntient #	ient's Initials:
nsas City (Cardiomyop	athy Ques	stionnaire (K	CCQ) (continue	d)	
Over the past 2 v	weeks, on average,	how many time	es has fatigue limite	d your ability to d	o what you w	anted?
All of	Several	At	3 or more	1-2	Less than	Never
the	times	least once	times per week	times	once	over the
time	per day	a day	but not every day	a week	a week	past 2 weeks
\Box_1		\square_3		5	6	7
Over the <u>past 2 v</u>	weeks, how much h	as your fatigu e	bothered you? It he	as been		
Extremely	Quite a bit	Moderately	Slightly	Not at all	l've ha	d
bothersome	bothersome	bothersome	bothersome	bothersome	no fatig	lue
\Box_1		\square_3	_ 4	5		
Over the <u>past 2 w</u>	<u>veeks</u> , on average, h	ow many times	has shortness of br	eath limited your	ability to do wł	nat you wanted?
All of	Several	At	3 or more	1-2	Less than	Never
the	times	least once	times per week	times	once	over the
time	per day	a day	but not every day	a week	a week	past 2 weeks
			Π.	Π.	Π.	
o	weeks have much h		ore of browth build			
Extremely	Quite a bit	Moderately	ess of breath bothe Slightly	Not at all	l've had	no
bothersome	bothersome	bothersome	bothersome	bothersome	shortness of	
\Box_1		3	4	5	6	
Over the past 2 v	weeks, on average,	how many time	s have you been for	ced to sleep sitting	g up in a chair	or with
	to prop you up bec	-				
	3 or more times	1-2	Less than	Never		
Every	a week, but	times	once	over the		
night	not every night	a week	a week	past 2 weeks		
	2	3	4	5		
			of reasons. How sur	e are you that yo	u know what t	o do or
	ymptoms can worse ur heart failure ge Not very		of reasons. How sur Mostly	e are you that you completely	u know what t	o do or
who to call, if yo	ur heart failure ge	ets worse?			u know what t	o do or
who to call, if you Not at all	ur heart failure ge Not very	ets worse? Somewhat	Mostly	Completely	u know what t	o do or
who to call, if you Not at all sure	ur heart failure ge Not very sure 2	sure	Mostly	Completely sure		
who to call, if you Not at all sure 	ur heart failure ge Not very sure 2	somewhat sure 3 hings you are a	Mostly ^{sure} 4 ble to do to keep yo	Completely sure		
who to call, if you Not at all sure 1 How well do you worse (for example,	ur heart failure ge Not very sure 2	somewhat sure 3 hings you are a	Mostly ^{sure} 4 ble to do to keep yo	Completely sure		
who to call, if you Not at all sure 1 How well do you worse (for example,	ur heart failure ge Not very sure 2 understand what th weighing yourself, eating	sure Somewhat sure 3 hings you are a	Mostly sure	Completely sure sure s		

CRF ANNOTATION VERSION 6.0_11May2004

≫FII\C	LION.	See annota	ation p.6 of Base	eline		6-Mo
			Potient Number:		patient #	Patient's Initials:
nsas City C	Cardiomyop	athy Questi	onnaire (K	CCQ) (cor	ntinued)	
Over the <u>past 2 v</u>	<u>veeks</u> , how much l	nas your heart fai	lure limited your (enjoyment o	f 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 my enjoyr life at	ment of	
\Box_1					5	
f you had to spe	nd the rest of your	life with your hea	rt failure the way	y it is <u>right n</u>	<u>ow</u> , how wou	ld you feel about this?
Not at all	Mostly	Somewhat	Mostly	Comple	etely	-
satisfied	dissatisfied	satisfied	satisfied	satisfi	ed	
	2	3	4	\Box_i	5	
Over the past 2 v	veeks, how often h	nave you felt discou	raaed or down in	the dumps	because of vo	ur heart failure ?
			•		,	
I felt that way	I felt that way	occasionally	l rarely felt	Ineve	r felf	
	I felt that way most of the time		I rarely felt that way	that w		
all of the time	most of the time	felt that way	that way	that w	ay s	
all of the time	most of the time	,	that way	that w	ay s	e may have Does Not Apply or Did Not Do for Other Reasons
all of the time	most of the time 	e affect your lifesty owing activities ove Limited Quite	that way a le? Please indicate or the <u>past 2 week</u> Moderately	that w that w show your l <u>s</u> .	beart failure Did Not Limit at	Does Not Apply or Did Not Do for
all of the time	most of the time 	e affect your lifesty owing activities ove Limited Quite	that way a le? Please indicate or the <u>past 2 week</u> Moderately	that w that w show your l <u>s</u> .	beart failure Did Not Limit at	Does Not Apply or Did Not Do for
all of the time	most of the time	e affect your lifesty owing activities ove Limited Quite	that way a le? Please indicate or the <u>past 2 week</u> Moderately Limited	that w that w show your l <u>s</u> .	beart failure Did Not Limit at	Does Not Apply or Did Not Do for
all of the time	most of the time	e affect your lifesty owing activities ove Limited Quite	that way 4 1e? Please indicate a the past 2 week Moderately Limited 3	that w that w show your l <u>s</u> .	beart failure Did Not Limit at	Does Not Apply or Did Not Do for



1 Sadness:



Potient Number: _______

Patient's Initials:

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.

patient #

7 Self-Dislike:

- I feel the same about myself as ever. , I do not feel sad. 1 I feel sad much of the time. I have lost confidence in myself. , I am disappointed in myself. I am sad all of the time. 3 I am so sad or unhappy that I can't stand it. 3 I dislike myself. 2 Pessimism: 8 Self-Criticalness: , I am not discouraged about my future. I don't criticize or blame myself more than usual. I feel more discouraged about my future than I used to be. I am more critical of myself than I used to be. 2 I do not expect things to work out for me. I criticize myself for all of my faults. I feel my future is hopeless and will only get worse. I blame myself for everything that happens. 3 Past Failure: 9 Suicidal Thoughts or Wishes: I do not feel like a failure. I don't have any thoughts of killing myself. 1 have failed more than I should have. 1 I have thoughts of killing myself, but I would not As I look back, I see a lot of failures. carry them out. a I feel I am a total failure as a person. I would like to kill myself. a I would kill myself if I had the chance. 4 Loss of Pleasure: 10 Crying: I get as much pleasure as I ever did from the things I enjoy. I don't cry any more than I used to. I don't enjoy things as much as I used to. I cry more than I used to. , I get very little pleasure from the things I used to enjoy. 2 I cry over every little thing. , I can't get any pleasure from the things I used to enjoy. , I feel like crying, but I can't. 5 Guilty Feelings: 11 Agitation: l don't feel particularly guilty. I am no more restless or wound up than usual. , I feel more restless or wound up than usual. , I feel guilty over many things I have done or should have done. 2 I am so restless or agitated that it's hard to stay still. I feel quite guilty most of the time. a I am so restless or agitated that I have to keep a I feel guilty all of the time. moving or doing something. 6 Punishment Feelings: 12 Loss of Interest: I don't feel I am being punished. I have not lost interest in other people or activities. 1 I feel I may be punished. 1 am less interested in other people or things I expect to be punished. than before. 1 feel I am being punished. I have lost most of my interest in other people or things.
 - 3 It's hard to get interested in anything.

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CRF ANNOTATION VERSION 6.0_11May2004
See annotation p.8	tient Number: Patient's Initials:
	site # patient # tou mi
eck Depression Inventory (BDI) (continued	
Indecisiveness:	18 Changes in Appetite (check only one):
o I make decisions about as well as ever.	o I have not experienced any change in my appetite.
1 find it more difficult to make decisions than usual.	My appetite is somewhat less than usual.
2 I have much greater difficulty in making decisions	My appetite is somewhat greater than usual.
than I used to.	2 ₂₀ My appetite is much less than before.
_a I have trouble making any decisions.	25 My appetite is much greater than usual.
Worthlessness:	
l do not feel I am worthless.	_{3a} I have no appetite at all.
\Box_0 to not reef tails worthess. \Box_1 I don't consider myself as worthwhile and useful as I used to.	₃₆ I crave food all the time.
 1 addit consider myself as wormwrite and useror as rosed to. 2 I feel more worthless as compared to other people. 	19 Concentration Difficulty:
1 reel more wormless as compared to other people.	Concentration Difficulty:
	1 can't concentrate as well as usual.
Loss of Energy:	\square_2 It's hard to keep my mind on anything for very long.
□ _o I have as much energy as ever.	1 find I can't concentrate on anything.
1 I have less energy than I used to have.	g i ind i control on on onyming.
I don't have enough energy to do very much.	20 Tiredness or Fatigue:
\square_3 I don't have enough energy to do anything.	I am no more tired or fatigued than usual.
3. contract on the group of the contract of of the co	I get more tired or fatigued more easily than usual.
Changes in Sleeping Pattern (check only one):	1 am too tired or fatigued to do a lot of the things
I have not experienced any change in my sleeping pattern.	L used to do.
	s I am too tired or fatigued to do most of the things I
1 _a I sleep somewhat more than usual.	used to do.
_{1b} I sleep somewhat less than usual.	
_{2e} I sleep a lot more than usual.	21 Loss of Interest in Sex:
2b I sleep a lot less than usual.	I have not noticed any recent change in my
3 ₃₀ I sleep most of the day.	interest in sex.
□ _{3b} I wake up 1 – 2 hours early and can't get back to sleep.	, I am less interested in sex than I used to be.
	I am much less interested in sex now.
/ Irritability:	3 I have lost interest in sex completely.
o I am no more irritable than usual.	
1 am more irritable than usual.	
2 am much more irritable than usual.	
3 I am irritable all the time.	See annotation p. 23 of 3-Month
roductivity Assessment	
How many days have you lost from work and/or your usual of	activities in the past 30 days due to problems with your health?

__ days

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Patient Number: _______ - ______ patient #

Potient's Initials:

Physical Activit	y 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 <u>last 7 days</u>. Please answer each question

Think about all the **vigorous physical activities** that you did in the <u>last 7 days</u>. 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.

 During the <u>last 7 days</u>, 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 <u>last 7 days</u>. 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 <u>last 7 days</u>, 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

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 the time you spent **walking** in the <u>last 7</u> <u>days</u>. 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 <u>last 7 days</u>, 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?

or Don't know/not sure

The last question is about the time you spent **sitting on weekdays** during the <u>last 7 days</u>. 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 <u>last 7 days</u>, how much time did you spend sitting on a weekday?

____ hours per day

or Don't know/not sure

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		Potient Number: = Potient # Potient's Initials:
Иe	dical History	/
с	urrent NYHA heart f	failure class (check only one):
C	urrent Canadian Ca	ardiovascular Society (CCS) angina class (check only one): No angina II III III IV
ur	rent Medica	tions
heck	k "No" or "Yes" for	r each medication and provide the total daily dose, if applicable. See annotation p.13 of Baseline
Α	CE inhibitor:	
		or not using (check only one): 🔄 Contraindicated 📃 Intolerance 🔄 MD preference 🔄 Patient preferen
	$_1$ Yes \rightarrow If Yes: Che	neck only one and provide the <u>TOTAL DAILY DOSE</u> :
		Benazepril: mg Guinapril: mg
		2 Captopril: mg Ramipril: mg
		₃ Enalapril: mg g Trandolapril: mg
		4 Fosinopril: mg go Other (specify): mg
		s Lisinopril: mg
А	angiotensin receptor	r blocker:
_	, No	
		heck all that apply: Valsartan Losartan Irbesartan Candesartan
	and the state of	
	eta blocker:	an anti-mine (2, 1, 1, 1, 1) Contraction to a literature in the International Contraction of the Providence of the Contraction
		or not using (check only one): 1 Contraindicated 2 Intolerance 3 MD preference 4 Patient preferen
		neck only one and provide the <u>TOTAL DAILY DOSE</u> :
		Atenolol: mg Metoprolol immediate release: mg Bisoprolol: mgs Metoprolol XL: mg
		3 Carvedilol: mg go ther (specify): mg
	spirin:	
		or not using (check only one): 🔄 Contraindicated 📃 2 Intolerance 🔄 3 MD preference 🔄 4 Patient preferen
	1 Yes → If Yes: Do	ose: mg
	oop diuretic:	
Lo	-	
		neck only one and provide the <u>TOTAL DAILY DOSE</u> :
		n Furosemide: mg a Torsemide: mg mg mg mg mg
		2 Bumetanide: mg Other (specify): mg
А	antiarrhythmic:	
	o No	
	, Yes → If Yes: Che	neck all that apply: Amiodarone Sotalol Dofetilide Other (specify):
_	ipid-lowering agent:	:
	_o No	
	1 Yes → If Yes: Che	heck only one: □, HMG-CoA reductase inhibitor → Check all that apply: □ Atorvastatin □ Pravastat □, Other lipid-lowering agent □ Simvastatin □ Other
S	elective serotonin re	euptake inhibitor:
_	No	
	•	that apply: Sertraline Citalopram Paroxetine Other
	w	VHITE and YELLOW - Duke Clinical Research Institute • PINK - retain at site
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See annotation p.14 of Baseline



6-Month

	Patie	nt Number:		patient #	Patient's Initials:	Ant middle last
Current Medications						
Check "No" or "Yes" for each medication.						
9 Tricyclic antidepressant:	o No	1 Yes				
10 Other antidepressant (excluding SSRIs and TCAs):	o No	1 Yes				
11 Antipsychotic:	o No	1 Yes				
12 Clopidogrel:	o No	1 Yes				
13 Coumadin:	o No	1 Yes				
14 Digoxin:	o No	Yes				
15 Nitrate:	o No	1 Yes				
16 Calcium channel blocker:	o No	1 Yes				
17 Spironolactone:	o No	1 Yes				
18 Eplerenone:	o No	1 Yes				
19 Non-loop diuretic (excluding aldosterone antagonist):	o No	1 Yes				
20 Potassium:	o No	1 Yes				
21 Insulin:	o No	1 Yes				
22 Glitazone:	o No	1 Yes				
23 Other oral diabetic agent:	o No	1 Yes				
24 Thyroid replacement:	o No	1 Yes				
25 NSAID:	o No	1 Yes				
26 COX-2 inhibitor:	o No	1 Yes				
27 Sildenafil:	o No	1 Yes				
Reserved for potential new drugs. Do not complete un	less inst	tructed by	the Duke Cli	nical Resear	ch Institute (I	DCRI).
28 Other:					O No	1 Yes
29 Other:						Yes

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6-Month

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	patient #
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Outpatient Log	
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Outpa	-
Outp	•
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Ĩ	Has the patient had any non-urgent outpatient visits sinc	visits since the last study visit? (Do not include protocol-specified follow-up visit⊥) No Yes → Complete the table below.	$\exists x_i \mid \bigcup_{0} N_{0} \bigcup_{1} Y_{es} \rightarrow Complete the table below.$
	Provider Type	Number of Office/Clinic Visits	Number of Home Visits
11	1.1 Cardiologist:		
1.2	Orthopedic surgeon:		
1.3	Other specialist:		
4.	Primary care physician:		
1.5	1.5 Physician extenders (includes NB2, PA2, etc.);		
1.6	1.6 OT or PT:		
1.7	Mental health provider:		
1.8	Nurse (includes RNs, LPNs, nurse's aides or other equivalent);		
1.9	1.9 Other (specify):		
7 7	Has the patient had any outpatient cardiac procedures/ $\square_0 \mathbb{N}_0 = \square_1 \mathbb{Y}_{es} \rightarrow \text{Compete the table below.}$	2 Has the patient had any outpatient cardiac procedures/tests (including KD lining) or orthopedic procedures/tests since the last study visit? $\square_0 \text{ No} = \square_1 \text{ Yes} \rightarrow \text{Compete the table below.}$	ice the last study visit?

e* 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.
Procedure Code*			"See choices on opposite page. Record one

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See annotation p.27 of 3-Month

6-Month

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Outpatient Log 3 Has the patient required any wegnet/senergency are on an outpatient basis since the last study visit?	Ş		л	See annotation p.27 of 3-Month		Patient Number:	- Potient # Potient's Initials
• on an outpatient basis since the last study visit? O	5	tpatient Log					
Number of Visits Due to Cardiovascular Disease* Number of Visits Due to Unknown (other than heart failure) Number of Visits Due Cardiovascular Disease* Due to Unknown (other than heart failure) Disease* Cause*		tas the patient required any urgen t	t/emergency car	e on an outpatient basis sir	nce the last study visit?	₀ No □ Yes ↓ C	omplete the ta
(other than heart failure) Disease* Cause* ^{by}			Number of Visits Due to	Number of Visits Due to Cardiovascular Disease*	Number of Visits Due to Non-Cardiovascular	Number of Visits Due to Unknown	Numb Cardiovascul
		Outpatient Service Type	Heart Failure*	(other than heart failure)	Disease*	Cause*	or Within
 	2	Emergency room, hospital < 24 hours, or observation unit:					
^{dyy} / _ mash / _ yor f	3.2						
^{dyy} / mode / mod	.3	Stand-alone urgent care facility:					
xacerbation (since randomization):	4		ince randomization)‡			te ded	
e since the last study visit: ent live in each of the following lays 	5.5		to heart failure	exacerbation (since randomizat	-/	O	urgent clinic visit viously recorded
Number of days on home IV infusion for heart failure since the last study visit:	ō	her Types of Resource	. Utilizatior				
	_	Number of days on home IV infusio	n for heart failur	e since the last study visit:	days		
op		ince the last study visit, how many	days did the pat	ient live in each of the follo	wing		
op							
days days days		Caregiver's home (e.g. family and th		days			
:days days days							
days days		Skilled nursing facility:	_ days				
days			ays				
			days				
		Other (specify):		days			

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GHION

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See annotation p.28 of 3-Month

Patient Number: _______ = _____ Patient # Patient's Initials

6-Month

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 partient is currently hospitalized.)

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If Yes:
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			Primary Cardiac Procedure*	Secondary Cardiac Procedure*	
	Hosnitelization:	Primary Reason for Hosnitalization*	(code/description)* Borond a zon if contract did act hours condition concedures	cription)* of here conding concedures	Discharge Destination*
1 Hospitalization: Admission date:/	Planned Unplanned		a put a source a portou	os sere control proceduros.	
Did the event leading to this hospitalization occur during or within 3 hours after exercise? \Box_0 No \Box_1 Yes					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \text{ No} = \square_1 \text{ Yes} \rightarrow \text{If Yes: Complete the Cardiovascular Event forms.}$					
2 <u>Hospitalization:</u> Admission date:	Planned Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? \square_0 No \square_1 Yes					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ No \ \square_1 \ \forall es \rightarrow If \ Yes: \ Complete \ the \ Cardiovascular \ Event forms.$					
3 Hospitalization: Admission date:	Planned Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? $\square_0 No \square_1 Yes$					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ No$ $\square_1 \ Yes \rightarrow If Yes: Complete the Cardiovascular Event forms.$					
* See choices on opposite page. If a diagnosis/procedure/discharge destination is not listed, please record it in the table above.	stination is not liste	ed, please record it in t	he table above.		

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

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2	JGTION	See annotation p.29 of 3-Month	6-Month
Ľ	مصريتها المستشير	Patient Number:	Patient's Initials:
-		site # potient	# Ant middle last
	Telephone Log		
1	1 Date of call://		
	Since the last call, how many times has the patient		
	health/symptoms (including contacts initiated by patient,)		/?
	contacts → If ≥ 1: How many of the o	ontacts resulted in: tions other than diuretics:	
	Diuretic dose increa		
	Diuretic dose decre		
	Exercise Training Group: Is patient performing t	· ·	
		ate primary reason code*:	
	1 Yes		
	Usual Care Group: Is patient performing physica	activity (formal or non-formal)? No Yes	
2	2 Data of calls		
1	2 Date of call:/		
	Since the last call, how many times has the patier	nt'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 \rightarrow If \geq 1: How many of the a	ontacts resulted in:	
		tions other than diuretics:	
	Diuretic dose increa	ases:	
	Diuretic dose decre	ases:	
	Exercise Training Group: Is patient performing t	he training as prescribed?	
		ate primary reason code*:	
	, Yes	,	
	Usual Care Group: Is patient performing physica	I activity (formal or non-formal)?	
3	3 Date of call:/		
	Since the last call, how many times has the patient	nt's provider been contacted due to changes in	the patient's
	health/symptoms (including contacts initiated by patient,)		
	contacts \rightarrow If \geq 1: How many of the o		
	-	tions other than diuretics:	
	Diuretic dose increa		
	Diuretic dose decre		
		1	
	Exercise Training Group: Is patient performing t		
		ate primary reason code*:	
	1 Yes		
	Usual Care Group: Is patient performing physica	I activity (formal or non-formal)? No Yes	
*Se	See choices on opposite page.		

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

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	PROTOCOL = HFACTI STUDYBOOK = DATA_ FORM = 9MONTH Patient Number: _		<zyes> 9-Month Patient's Initials: </zyes>
Date of visit:/	ar		
EuroQoL Questionnaire			
By placing a checkmark in one box in o which statement best describes your ov		See annotation	n p.3 of Baseline
Mobility: I have no problems in walking ab I have some problems in walking ab I am confined to bed. 			
Self-care: 1 have no problems with self-care. 2 have some problems washing or 3 a unable to wash or dress mystered			PATIE
3 Usual activities (e.g. work, study, housew □ ₁ have no problems with performin □ ₂ have some problems with perform □ ₃ am unable to perform my usual of	ng my usual activities. ming my usual activities.		NT SEL
Pain/discomfort:			F - R E P O
 Anxiety/depression: 1 am not anxious or depressed. 1 am moderately anxious or depression 1 am extremely anxious or depression 			RT FO
\rightarrow Please let your study co	ordinator know that you are ready	for the EuroQoL The	rmometer worksheet.
Pain Assessment			
	ad during the past 4 weeks (check only an ild4 Moderate5 Severe6		
2 During the past 4 weeks, how much \Box_1 Not at all \Box_2 A little bit \Box_3	h did pain interfere with your normal w ₃ Moderately □₄ Quite a bit □₅ Ext		tside the home and housework)?
EuroQol Thermometer R	esponse		
Response to the EuroQoL thermometer	(0-100)		
WHITE and YEL HF-ACTION_9MO_1.2_16JUN2003	LOW — Duke Clinical Research Institu 2003 DCRI — Confidential	ute • PINK — retain a	at site CRF, page 44

CRF ANNOTATION VERSION 6.0_11May2004

CONTEXT



9-Month

Potient Number: _______

Patient's Initials:

patient #

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 <u>past 2 weeks</u>.

(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 yourse	elf:	\Box_1	2	3	4	5	6
Showering/bat	hing:		2	3	4	5	6
Walking 1 bloc	k on level ground:		2	3	4	5	6
Doing yard wo or carrying gro			2	\square_3	4	5	6
Climbing a fligh stairs without st		$\Box_{\mathbf{l}}$	\square_2	\square_3	4	5	6
Hurrying or jog (as if to catch a bus)				3	4	5	6
My symptoms of	<u>n 2 weeks ago</u> , hav of heart failure hav	e become					
Much worse	Slightly worse	Not chang 3		Slightly better 4	Much better □_s		d no symptoms ne last 2 weeks
	<u>weeks</u> , how many when you woke up			e lling in your fe	eet,		
Every morning	3 or more times a w but not every morni	eek, 1-2 tin	nes	Less than once a week	Never ove past 2 we		
Over the <u>past 2</u>	<u>2 weeks</u> , how much	has swellin	g in your fe	et, ankles or le	gs bothered	you? It has	been
Extremely	Moderately	Somew	/hat	Slightly	Not at	all	I've had

<u></u>	grion	See annota	tion p.5 of Baselin	e		9-Mont
مر کی	-		Patient Number:	= p	atient # Pat	tient's Initials:
Kansas City	Cardiomyop	athy Ques	stionnaire (K	CCQ) (continue	d)	
5 Over the past 2	<u>2 weeks</u> , on average,	how many time	s has fatigue limited	d your ability to d	lo what you w	anted?
All of	Several	At	3 or more	1-2	Less than	Never
the	times	least once	times per week	times	once	over the
time	per day	a day	but not every day	a week	a week	past 2 weeks
	2	3	4	5	6	7
6 Over the past 2	2 weeks, how much h	as your fatigue	bothered you? It ho	ıs been		
Extremely	Quite a bit	Moderately	Slightly	Not at all	l've ho	d
bothersome	bothersome	bothersome	bothersome	bothersome	no fatiç	jue
	2	3	4	5	6	
7 Over the past 2	weeks, on average, h	ow many times	has shortness of br e	eath limited your	ability to do wł	nat you wanted?
All of	Several	At	3 or more	1-2	Less than	Never
the	times	least once	times per week	times	once	over the
time	per day	a day	but not every day	a week	a week	past 2 weeks
	2	3	4	5	6	□ ₇ 07
8 Over the past 2	2 weeks, how much h	as your shorin e	ess of breath bothe	ered you? It has b	een	
Extremely	Quite a bit	Moderately	Slightly	Not at all	l've had	no
bothersome	bothersome	bothersome	bothersome	bothersome	shortness of	f breath
		3	4	5	6	f breath
9 Over the past 2	weeks on average.	how many time	s have you been for	ced to sleep sitting	g up in a chair	or with
at least 2 willow	e meeks, on average,	,	,	···· · · · · · · · · · · · · · · · · ·		
ar least 3 pillov	vs to prop you up bec	-	•			7
ar least 3 pillov		-	•	Never		
er least 3 pillow	ws to prop you up bec	ause of shortn	ess of breath?			X -
	3 or more times	ause of shortn 1-2	ess of breath? Less than	Never		
Every	3 or more times a week, but	ause of shortn 1–2 times	ess of breath? Less than once	Never over the		or with C
Every night □_1 10 Heart failure	vs to prop you up bea 3 or more times a week, but not every night 2 symptoms can worse	tause of shortn 1–2 times a week 3 n for a number	ess of breath? Less than once a week	Never over the past 2 weeks	u know what t	
Every night □_1 10 Heart failure	a week, but not every night	tause of shortn 1–2 times a week 3 n for a number	ess of breath? Less than once a week	Never over the past 2 weeks	u know what t	
Every night □1 10 Heart failure	vs to prop you up bea 3 or more times a week, but not every night 2 symptoms can worse	tause of shortn 1–2 times a week 3 n for a number	ess of breath? Less than once a week	Never over the past 2 weeks	u know what t	
Every night 1 10 Heart failure who to call, if y	symptoms can worse	ause of shortn 1-2 times a week a s n for a number ets worse?	ess of breath? Less than once a week a 4 of reasons. How sur	Never over the past 2 weeks s e are you that you	u know what t	
Every night 1 10 Heart failure who to call, if y Not at all	vs to prop you up bea 3 or more times a week, but not every night 2 symptoms can worse your heart failure ge Not very	times a week a week a s n for a number ets worse? Somewhat	ess of breath? Less than once a week 4 of reasons. How sum Mostly	Never over the past 2 weeks s e are you that you Completely	u know what t	
Every night 1 10 Heart failure who to call, if y Not at all sure 1 1 How well do yo	ws to prop you up bed 3 or more times a week, but not every night 2 symptoms can worse your heart failure ge Not very sure 2 ou understand what the	ause of shortn 1-2 times a week 3 n for a number sts worse? Somewhat sure 3 hings you are a	ess of breath? Less than once a week a of reasons. How sur Mostly sure 4 ble to do to keep you	Never over the past 2 weeks s e are you that you Completely sure sure s		o do or
Every night 1 10 Heart failure who to call, if y Not at all sure 1 1 How well do yo	vs to prop you up bed 3 or more times a week, but not every night 2 symptoms can worse your heart failure ge Not very sure 2	ause of shortn 1-2 times a week 3 n for a number sts worse? Somewhat sure 3 hings you are a	ess of breath? Less than once a week a of reasons. How sur Mostly sure 4 ble to do to keep you	Never over the past 2 weeks s e are you that you Completely sure sure s		o do or
Every night 1 10 Heart failure who to call, if y Not at all sure 1 1 How well do yo worse (for example	ws to prop you up bed 3 or more times a week, but not every night 2 symptoms can worse your heart failure ge Not very sure 2 ou understand what the	ause of shortn 1-2 times a week 3 n for a number sts worse? Somewhat sure 3 hings you are a	ess of breath? Less than once a week a of reasons. How sur Mostly sure 4 ble to do to keep you	Never over the past 2 weeks s e are you that you Completely sure sure s		o do or
Every night 1 10 Heart failure who to call, if y Not at all sure 1 1 How well do yo worse (for example	vs to prop you up bed 3 or more times a week, but not every night 2 symptoms can worse your heart failure ge Not very sure 2 ou understand what the le, weighing yourself, eating	ause of shortn 1-2 times a week 3 n for a number ts worse? Somewhat sure 3 hings you are a a low-salt diet etc.}?	ess of breath? Less than once a week a of reasons. How sur Mostly sure 4 ble to do to keep you	Never over the past 2 weeks s e are you that you Completely sure sure sure		o do or

ショルし	TON	See annotat	ion p.6 of Baseli	ne		9-Mo
			Patient Number:	 site #	patient #	Patient's Initials:
nsas City (Cardiomyop	athy Questi	onnaire (K	CCQ) (con	tinued)	
Over the past 2 v	veeks, how much h	has your heart fai l	lure limited your e	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 l my enjoyn life at	nent of all	
If you had to spe	nd the rest of your	life with your hea	rt failure the way	y it is <u>right n</u> e	<u>ow</u> , how wou	ld you feel about this?
Not at all	Mostly	Somewhat	Mostly	Comple	tely	
satisfied	dissatisfied	satisfied	satisfied	satisfi s		
Over the <u>past 2 v</u> I felt that way	I felt that way	occasionally	I rarely felt	Inever		
I felt that way all of the time In How much does	most of the time	felt that way	that way	that w s e how your I	ay	e may have
I felt that way all of the time In How much does	most of the time	felt that way	that way	that w s e how your I	ay	e may have Does Not Apply
I felt that way all of the time I How much does imited your part	most of the time	 felt that way a a affect your lifesty owing activities over 	that way	that w s e how your I	ay neart failure	·
I felt that way all of the time In How much does imited your part (Check only one bax of	most of the time 	e affect your lifesty owing activities ove Limited Quite	that way 	that w s how your the s. Slightly	ay heart failure Did Not Limit at	Does Not Apply or Did Not Do for
I felt that way all of the time inited your part (Check only one bax of Activity Hobbies, recreati	most of the time	e affect your lifesty owing activities ove Limited Quite	that way 4 le? Please indicate or the <u>past 2 week</u> Moderately Limited	that w s how your the s. Slightly	Did Not Limit at All	Does Not Apply or Did Not Do for
I felt that way all of the time inited your part (Check only one bax of Activity Hobbies, recreations) activities:	most of the time	e affect your lifesty owing activities ove Limited Quite	that way 4 le? Please indicate or the <u>past 2 week</u> Moderately Limited	that w s how your the s. Slightly	Did Not Limit at All	Does Not Apply or Did Not Do for

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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.

patient #

Sadness: I do not feel sad. I feel sad much of the time. I am sad all of the time. I am so sad or unhappy that I can't stand it. 	 Self-Dislike: I feel the same about myself as ever. I have lost confidence in myself. I am disappointed in myself. I dislike myself.
Pessimism: 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.	 Self-Criticalness: 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.
 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: 1 act as much pleasure as Lever did from the things Legistry. 	 Suicidal Thoughts or Wishes: 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.
 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. 	 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.
 Guilty Feelings: I don't feel particularly guilty. I feel guilty over many things I have done or should have done I feel guilty most of the time. I feel guilty all of the time. 	11 Agitation: I am no more restless or wound up than usual. I am so 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.
 Punishment Feelings: 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. 	 Loss of Interest: 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. I have lost most of my interest in other people or things.

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See annotation p.8 of Baseline

9-Month

Patient Number: _____ - ___ Patient's Initials: _____

	sife# powerrw	Test market and
Beck Depression Inventory (BDI) (continued)		
 13 Indecisiveness: a I make decisions about as well as ever. find it more difficult to make decisions than usual. I have much greater difficulty in making decisions than I used to. I have trouble making any decisions. 14 Worthlessness: I do not feel I am worthless. I don't consider myself as worthwhile and useful as I used to. I feel more worthless. I feel utterly worthless. I feel utterly worthless. 	 18 Changes in Appetite (check only one): I have not experienced any change in my appetite My appetite is somewhat less than usual. My appetite is somewhat greater than usual. My appetite is much less than before. My appetite is much less than before. My appetite is much greater than usual. My appetite is much greater than usual. My appetite is much less than before. My appetite is much less than usual. My appetite is much less than usual. I have no appetite at all. I can't concentrate as well as usual. 	PATIEN
15 Loss of Energy: o I have as much energy as ever.	It's hard to keep my mind on anything for very lo 3 I find I can't concentrate on anything.	ing.
 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. I don't have enough energy to do anything. Changes in Sleeping Pattern (check only one): I have not experienced any change in my sleeping pattern. 	 20 Tiredness or Fatigue: a no more tired or fatigued than usual. a too tired or fatigued more easily than usual. a too tired or fatigued to do a lot of the things I used to do. 	
1 _a I sleep somewhat more than usual. 1 _b I sleep somewhat less than usual.	used to do. a most of the things	s∣ POR
 □_{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. 	 21 Loss of Interest in Sex: 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. 	T FORM
17 Irritability: am no more irritable than usual. 1 am more irritable than usual. 2 am much more irritable than usual. 3 am irritable all the time. 	☐ ₃ I have lost interest in sex completely. See annotation p.23 of 3-Month	
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

|--|--|

See annotation p.24 of 3-Month

9-Month

	Patient Number: patient #	Potient's Initials: Ant middle last
Medical History		
1 Current NYHA heart failure class (check or	niy ane): I III III IV	
2 Current Canadian Cardiovascular Societ	y (CCS) angina class (check only one): No angina 🗌 I	
Current Medications		
Check "No" or "Yes"; if "Yes", provide the t	otal daily dose.	
Loop diuretic: □₀ No		
	nly one and provide the total daily dose: semide: mg Torsemide: mg	
	etanide: mg Other, (specify):	mg
Check "No" or "Yes" for each medication.		
2 Spironolactone:	No Yes 16 Calcium channel blocker:	No Yes
3 Eplerenone:	No Yes 17 Insulin:	🔄 No 🔄 1 Yes
4 Non-loop diuretic:	No 18 Glitazone:	🗌 ₀ No 🔄 ₁ Yes
(excluding aldosterone antagonist)	19 Other oral diabetic agent:	🗆 No 🔄 1 Yes
5 Potassium:	No _, Yes 20 Thyroid replacement:	🗖 No 🗍 Yes
6 ACE inhibitor:		
7 Angiotensin receptor blocker:		🔄 0 No 🔄 1 Yes
8 Beta blocker:	No Yes 22 Tricyclic antidepressant:	🗌 No 🔲 1 Yes
9 Aspirin:	No 1 Yes 23 Other antidepressant:	🗋 0 No 🔄 1 Yes
10 Antiarrhythmic:	(excluding SSRIs and TCAs)	
11 Lipid-lowering agent:	24 Antipsychotic:	0 No 1 Yes
	25 NSAID:	🗆 No 🔄 1 Yes
12 Clopidogrel:	No1 Yes 26 COX-2 inhibitor:	No
13 Coumadin:	No 🔄 Yes	· ·
14 Digoxin:	27 Sildenafil:	
15 Nitrate:	No 🔄 Yes	
	omplete unless instructed by the Duke Clinical Resea	
28 Other:		o No 1 Yes
29 Other:		□ ₀ No □ ₁ Yes

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See annotation p.17 of Baseline for QOLR

9-Month

	Patient Number:	patient #	Patient's Initials:	Ant middle last
Quality of Life—Reason for Missing	Data			
Are all quality-of-life forms complete? $\square_0 \text{ No} \rightarrow \text{If No}$:	1 Patient died			
↓ • • • • • • • • • • • • • • • • • • •	2 Patient refused			
	3 Patient withdrew consent			
œ	4 Patient missed visit			
	5 Patient sick			
*	98 Other			
Yes				

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3 TION

See annotation p.26 of 3-Month

9-Month

				Patient Number:	1	nitials for add for
20	Outpatient Log					
÷	tas the patient had any non-urgent	outpatient visits sir	Has the patient had any non-urgent outpatient visits since the last study visit? (Do not include protocol-specified follow-up visits.) 🔤 No	col-specified follow-up visi	#±} □0 No □1 Yes → Complete the table below.	able below.
	Provider Type		Number of Office/ Clinic Visits	lisits	Number of Home Visits	
Ξ	Cardiologist:					
1.2	Orthopedic surgeon:					
1.3	Other specialist:					
1.4	Primary care physician:					
1.5	Physician extenders (includes NPs, PAs, etc.);	As, etc.)t				
1.6	OT or PT:					
1.7	Mental health provider:					
1.8	Nurse (includes RNs, LPNs, nurse's aides or ather equivalent);	ar other equivalent);				
1.9	Other (specify):					
4	tas the patient had any outpatient cardiac pro □ ₀ N₀ □ 1 Yes → Compete the table below.	a ar diac procedures able below.	Has the patient had any outpatient cardiac procedures/tests {including KD fining} or orthopedic procedures/tests since the last study visit? □_o No □_1 Yes → Compete the table below.	orocedures/tests sin	ce the last study visit?	
	Procedure Code*	Number	Procedure Code*	Number	Procedure Code*	Number
*See	choices on opposite page. Record	one per row. If a p	*See choices on opposite page. Record one per row. If a procedure/test is not listed, please record it in the table above.	d it in the table abo	we.	

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NON	See annotation p.

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Patient's Initials:	
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	10 miles
Patient Number:	

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3						
E E	Has the patient required any urgent/emergency care on an outpatient basis since the last study visit? 0, No 0, Yes → Complete the table below.	/emergency car	e on an outpatient basis sin	ce the last study visit?	No Trest C	mplete the table below.
		Number of		Number of Visits Due	Number of Visits	Number of Visits Due to a
	Outpatient Service Type	VISITS DUE TO Heart Failure*	Caraiovascuiar Disease (other than heart failure)	to Non-Caralovascular Disease*	Due to Unknown Cause*	caraiovascular 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);	ice randomization)‡ -	day //	orNo ER visit to date	de d	
3.5	Date of 1 st urgent clinic visit due to heart failure exacerbation (since randomization); $\frac{1}{4s}$	to heart failure (exacerbation (since randomizati		year OR No	$\hfill 1$ No urgent clinic visit for HF to date $\hfill 2$ Previously recorded
ð	Other Types of Resource Utilization	Utilization				
-	1 Number of days on home IV infusion for heart failure since the last study visit:	n for heart failur.	e since the last study visit: _	days		
7	Since the last study visit, how many days did the patient live in each of the following	days did the pati	ient live in each of the follov	ving		
	Their home: days					
	Caregiver's home (e.g. family and friends):		days			
	Assisted living: days					
	Skilled nursing facility:	days				
	Acute care hospital: da	days				
	Rehabilitation center: d	days				
	Other (specify):		days			

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9-Month

See annotation p.28 of 3-Month

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?

			Primary Cardiac Procedure*	Secondary Cardiac Procedure*	
		Primary Reason	(code/description)*	cription)*	Discharge
	Hospitalization:	for Hospitalization*	Record a zero if patient did not have cardiac procedures.	ot have cardiac procedures.	Destinction*
1 Hospitalization: Admission date:/	Planned Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? \square_0 No \square_1 Yes					
Did a cardiovascular event cause or occur during this hospitalization? $\Box_0 N_0 = \Box_1 Y_{es} \rightarrow$ If Yes: Complete the Cardiovascular Event forms.					
2 Hospitalization: Admission date:/	Planned Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? \square_0 No \square_1 Yes					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ N_0 \ \square_1 \ \gamma_{es} \rightarrow$ If Yes: Complete the Cardiovascular Event forms.					
3 Hospitalization: Admission date:/	Planned Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? $\square_0 \land 0 = \square_1 \lor_{es}$					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ No \ \square_1 \ \mbox{Yes} \rightarrow$ If Yes: Complete the Cardiovascular Event forms.					

* 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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CRF, page 54

	This is a repeating page First page should have page rep 0	9-Month
	See annotation p.29 of 3-Month Potient Number:	potient # Potient's Initials:
Telephone Log		
1 Date of call:/		
	nas the patient's provider been contacted due to c	hanges in the patient's
health/symptoms (including contacts initi	ated by patient, patient's family/friend, study personnel, and/or e	exercise trainer)?
contacts → If ≥ 1: How n	nany of the contacts resulted in:	
Chang	es to medications other than diuretics:	
Diureti	c dose increases:	
Diureti	c dose decreases:	
Exercise Training Group: Is patient	performing the training as prescribed?	
2 .	If No: Indicate primary reason code*:	
Usual Care Group: Is patient perform	ming physical activity (formal or non-formal)? 🗌 No	Yes
2 Date of call:/		
Since the last call, how many times I	nas the patient's provider been contacted due to c	hanges in the patient's
health/symptoms (including contacts initi	ated by patient, patient's family/friend, study personnel, and/or e	wercise trainer)?
contacts → If ≥ 1: How n	nany of the contacts resulted in:	
Chang	es to medications other than diuretics:	
Diureti	c dose increases:	
Diureti	c dose decreases:	
Exercise Training Group: Is patient	performing the training as prescribed?	
	If No: Indicate primary reason code*:	
, Yes		
Usual Care Group: Is patient perform	ming physical activity (formal or non-formal)?	1 Yes
3 Date of call:/		
Since the last call, how many times I	has the patient's provider been contacted due to a	hanges in the patient's
health/symptoms (including contacts initi	ated by patient, patient's family/friend, study personnel, and/or e	xercise trainer)?
contacts → If ≥ 1: How n	nany of the contacts resulted in:	
Chang	es to medications other than diuretics:	
Diureti	c dose increases:	
Diureti	c dose decreases:	
Exercise Training Groups Is patient	performing the training as prescribed?	
2 .	If No: Indicate primary reason code*:	
Usual Care Group: Is patient perform	ming physical activity (formal or non-formal)? 🗌 No	Yes
*See choices on opposite page.		

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

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9		PROTOCOL=HFACTIC STUDYBOOK = DATA_ FORM = 12MONTH Patient Number: SL	NN	DDATA <zye< th=""><th>CON</th><th>ITEXT Month INITIALS</th></zye<>	CON	ITEXT Month INITIALS
Date of visit:	///yev					
EuroQol	L Questionnaire					
	checkmark in one box in e ent best describes your ov	each group below, please indicate vn health state <u>today</u> .	See ann	otation p.3 o	f Baseline	
2 I have	e no problems in walking abo e some problems in walking o confined to bed.					
2 Self-care:	1					σ
	e no problems with self-care.	1 . W				A
	e some problems washing or unable to wash or dress myse					
						ΞN
	t ivities (e.g. work, study, housew e no problems with performin					-
	e some problems with perfor					S
□ ₃ l am u	unable to perform my usual o	activities.				
4 Pain/disc						
	e no pain or discomfort.					R
	e moderate pain or discomfo					
31 nave	e extreme pain or discomfort.					ŏ
5 Anxiety/	depression:					찐
	not anxious or depressed.					-
-	moderately anxious or depre					
3 i am o	extremely anxious or depress	.ea.				0
• • •	Please let your study co	ordinator know that you are ready t	for the Euro	QoL Thermo	meter works	heet.
Pain Ass	sessment					
		ad during the past 4 weeks (check only one Id Moderate Severe N				
		h did pain interfere with your normal wa Moderately Quite a bits Extr		both work outside	the home and hous	:ework)?
EuroQol	Thermometer R	esponse				
Response to t	the EuroQoL thermometer	(0-100)				
HF-ACTION_12MC	WHITE and YEL	LOW — Duke Clinical Research Institut 2003 DCRI — Confidential	te • PINK	— retain at si		CRF, page 56





Potient Number: ______ - ____

patient #

Potient's Initials: _______

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:		2	3	4	5	6
Showering/bathing:		2	3	4	5	6
Walking 1 block on level ground:		2	3	4	5	6
Doing yard work, housework or carrying groceries:		\square_2	\square_3	4	5	 6
Climbing a flight of stairs without stopping:			\square_3	4	5	6
Hurrying or jogging (as if to catch a bus):		 2	3	4	5	6
<u>Compared with 2 weeks ago</u> , hav My symptoms of heart failure hav		ms of hea	rt failure (shortr	ness of breath,	fatigue, or ankle	swelling) changed?
Much Slightly worse worse	Not change 3	d	Slightly better	Much better □_s		d no symptoms ne last 2 weeks
Over the <u>past 2 weeks</u> , how many ankles or legs when you woke up			lling in your fe	et,		
Every 3 or more times a w morning but not every morn 1 2	veek, 1-2 time	əs	Less than once a week	Never ove past 2 we		
Over the past 2 weeks, how much	h has swelling	in your fe	et, ankles or leg	s bothered	you? It has	been
Extremely Moderately bothersome bothersome	Somew bothersor		Slightly bothersome	Not at a botherso		I've had swelling

- AC	JION	See anno	tation p.5 of Base	ine		12-Mor
			Patient Number:	site# po	atient # Pat	ient's Initials:
ansas City (Cardiomyop	athy Ques	tionnaire (K	CCQ) (continue	d)	
Over the past 2	weeks, on average,	how many time	s has fatigue limited	d your ability to d	lo what you wa	anted?
All of	Several	At	3 or more	1-2	Less than	Never
the	times	least once	times per week	times	once	over the
time	per day	a day	but not every day	a week	a week	past 2 weeks
\Box_1			4	5	6	7
Over the <u>past 2</u>	weeks, how much he	as your fatigue	bothered you? It ha	s been		
Extremely	Quite a bit	Moderately	Slightly	Not at all	l've ha	d
bothersome	bothersome	bothersome	bothersome	bothersome	no fatig	lue
	2	3	4	5	6	
Over the <u>past 2 v</u>	<u>veeks</u> , on average, h	ow many times	has shortness of br e	eath limited your	ability to do wh	at you wanted?
All of	Several	At	3 or more	1-2	Less than	Never
the	times	least once	times per week	times	once	over the
time	per day	a day	but not every day	a week	a week	past 2 weeks
	2		4	5	6	7
Over the past 2	weeks, how much he	as your shorin	ess of breath bothe	red you? It has b	een	
Extremely	Quite a bit	Moderately	Slightly	Not at all	I've had	no
bothersome	bothersome	bothersome	bothersome	bothersome	shortness of	breath
\Box_1	2	3	4	5	6	
Over the past 2	<u>weeks</u> , on average,	how many time	s have you been for	ed to sleep sitting	g up in a chair	or with
-	<u>weeks</u> , on average, s to prop you up bec	-		ced to sleep sitting	g up in a chair	or with
-	-	-		:ed to sleep sitting Never	g up in a chair	or with
-	s to prop you up bec	ause of shortn	ess of breath?		g up in a chair	or with
at least 3 pillows Every	3 or more times a week, but	ause of shortn 1–2 times	ess of breath? Less than	Never over the	g up in a chair	or with
at least 3 pillows	s to prop you up bec 3 or more times	ause of shortn	ess of breath? Less than once	Never over the past 2 weeks	g up in a chair	or with
at least 3 pillows Every night	3 or more times a week, but not every night	ause of shortn 1–2 times a week a	ess of breath? Less than once a week 4	Never over the past 2 weeks	-	
at least 3 pillows Every night 1 Heart failure sy	s to prop you up bec 3 or more times a week, but not every night 2 ymptoms can worse	trause of shortn 1–2 times a week 3 n for a number	ess of breath? Less than once	Never over the past 2 weeks	-	
at least 3 pillows Every night 1 Heart failure sy	3 or more times a week, but not every night	trause of shortn 1–2 times a week 3 n for a number	ess of breath? Less than once a week 4	Never over the past 2 weeks	-	
et least 3 pillows Every night 1 Heart failure sy who to call, if yo	s to prop you up bec 3 or more times a week, but not every night 2 ymptoms can worse ur heart failure ge	ause of shortn 1-2 times a week a a s a week a s a to a number to so a number	ess of breath? Less than once a week a 4 of reasons. How sure	Never over the past 2 weeks s e are you that you	-	
at least 3 pillows Every night 	s to prop you up bec 3 or more times a week, but not every night 2 ymptoms can worse ur heart failure ge Not very	times a week a week a s n for a number of worse? Somewhat	ess of breath? Less than once a week 4 of reasons. How sum Mostly	Never over the past 2 weeks s e are you that you Completely	-	
at least 3 pillows Every night 1 Heart failure sy who to call, if yo Not at all sure 1	s to prop you up bec 3 or more times a week, but not every night 2 ymptoms can worse ur heart failure ge Not very sure 2	ause of short 1-2 times a week 3 n for a number sts worse? Somewhat sure 3	ess of breath? Less than once a week 4 of reasons. How sum Mostly	Never over the past 2 weeks s a are you that you Completely sure sure s	u know what to	o do or
et least 3 pillows Every night 1 Heart failure sy who to call, if yo Not at all sure 1 How well do you	s to prop you up bec 3 or more times a week, but not every night 2 ymptoms can worse ur heart failure ge Not very sure 2	ause of shortn 1-2 times a week 3 n for a number ts worse? Somewhat sure 3 hings you are a	ess of breath? Less than once a week a of reasons. How surve Mostly sure a sure a ble to do to keep you	Never over the past 2 weeks s a are you that you Completely sure sure s	u know what to	o do or
et least 3 pillows Every night 1 Heart failure sy who to call, if yo Not at all sure 1 How well do you worse (for example,	s to prop you up bec 3 or more times a week, but not every night 2 ymptoms can worse our heart failure ge Not very sure 2 u understand what the	ause of shortn 1-2 times a week 3 n for a number ts worse? Somewhat sure 3 hings you are a	ess of breath? Less than once a week a of reasons. How surve Mostly sure a sure a ble to do to keep you	Never over the past 2 weeks s a are you that you Completely sure sure s	u know what to	o do or
et least 3 pillows Every night 1 Heart failure sy who to call, if yo Not at all sure 1 How well do you worse (for example,	s to prop you up bec 3 or more times a week, but not every night 2 ymptoms can worse ur heart failure ge Not very sure 2 u understand what the weighing yourself, eating	ause of short 1-2 times a week 3 n for a number ts worse? Somewhat sure 3 hings you are a a low-salt diet etc.)?	ess of breath? Less than once a week a of reasons. How sure Mostly sure a ble to do to keep you	Never over the past 2 weeks s a are you that you Completely sure sure sure	u know what to	o do or

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シールじ	TON	See a	nnotation p.6 c	of Baseline	9	12-M
			Patient Number:	 site #	patient #	Patient's Initials:
nsas City C	ardiomyop	athy Questi	onnaire (K	CCQ) (cor	ntinued)	
Over the <u>past 2 w</u>	veeks, how much h	has your heart fai	lure limited your	enjoyment o	f life?	
has extremely limited my njoyment of life	It has limited my enjoyment of life quite a bit	It has moderately limited my enjoyment of life	t has slightly limited my enjoyment of life	It has not my enjoyr life at	ment of	
f you had to sper	nd the rest of your	life with your hea	rt failure the way	y it is <u>right n</u>	<u>ow</u> , how wou	ld you feel about this
Not at all	Mostly	Somewhat	Mostly	Comple	etely	
satisfied	dissatisfied	satisfied	satisfied	satisfi	**	
Over the <u>past 2 w</u>	<u>veeks</u> , how often h	nave you felt discou	•			or heart failure?
I felt that way	I felt that way	occasionally	l rarely felt	neve		
all of the time	most of the time	felt that way	that way	that w	ay s	
all of the time	most of the time	,	that way	that w	ay s	may have Does Not Apply or Did Not Do for Other Reasons
all of the time	most of the time 	e affect your lifesty owing activities ove Limited Quite	that way 	that w	beart failure Did Not Limit at	Does Not Apply or Did Not Do for
all of the time	most of the time 	e affect your lifesty owing activities ove Limited Quite a Bit	that way a le? Please indicate or the <u>past 2 week</u> Moderately Limited	that w	beart failure Did Not Limit at	Does Not Apply or Did Not Do for
all of the time	most of the time	e affect your lifesty owing activities ove Limited Quite a Bit	that way 4 le? Please indicate the past 2 week Moderately Limited 3	that w	beart failure Did Not Limit at	Does Not Apply or Did Not Do for

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12-Month

Patient Number: ____ site # Potient's Initials: _________

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.

patient #

 Sadness: o 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. Pessimism: o 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. 	 7 Self-Dislike: 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: 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.
 3 I feel my future is hopeless and will only get worse. 3 Past Failure: 0 1 do not feel like a failure. 1 1 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 1 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. 	 Suicidal Thoughts or Wishes: 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. Crying: I cry more than I used to. I cry over every little thing. I feel like crying, but I can't.
 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 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. 3 I feel I am being punished. 	 11 Agitation: a m no more restless or wound up than usual. 1 feel more restless or wound up than usual. 1 feel more restless or agitated that it's hard to stay still. 1 am so restless or agitated that I have to keep moving or doing something. 12 Loss of Interest: 0 have not lost interest in other people or activities. 1 am less interested in other people or things than before. 2 have lost most of my interest in other people or things. 3 It's hard to get interested in anything.

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See annotation p.8 of Baseline

12-Month

	Potient Number: potient # Potient's Initials:
eck Depression Inventory (BDI) (contin	ued)
3 Indecisiveness:	18 Changes in Appetite (check only one):
o I make decisions about as well as ever.	I have not experienced any change in my appetite.
I find it more difficult to make decisions than usual.	My annetite is computed loss than usual
2 I have much greater difficulty in making decisions	1 _a My appetite is somewhat less than usual.
than I used to.	here a somewhat greater than usual.
3 I have trouble making any decisions.	2a My appetite is much less than before.
	_{2b} My appetite is much greater than usual.
4 Worthlessness:	3α I have no appetite at all.
o I do not feel I am worthless.	_{3b} I crave food all the time.
1 I don't consider myself as worthwhile and useful as I used	i to.
I feel more worthless as compared to other people.	19 Concentration Difficulty:
3 I feel utterly worthless.	o I can concentrate as well as ever.
	I can't concentrate as well as usual.
5 Loss of Energy:	It's hard to keep my mind on anything for very long.
o I have as much energy as ever.	I find I can't concentrate on anything.
1 I have less energy than I used to have.	
2 I don't have enough energy to do very much.	20 Tiredness or Fatigue:
3 I don't have enough energy to do anything.	I am no more tired or fatigued than usual.
	I get more tired or fatigued more easily than usual.
6 Changes in Sleeping Pattern (check only one):	2 I am too tired or fatigued to do a lot of the things
🔄 I have not experienced any change in my sleeping patter	
_	a I am too tired or fatigued to do most of the things I
1a I sleep somewhat more than usual.	used to do.
1b I sleep somewhat less than usual.	_
2a I sleep a lot more than usual.	21 Loss of Interest in Sex:
26 I sleep a lot less than usual.	o I have not noticed any recent change in my
₃₄ I sleep most of the day.	interest in sex.
□ _{3b} I wake up 1–2 hours early and can't get back to sleep.	1 am less interested in sex than I used to be.
	2 I am much less interested in sex now.
7 Irritability:	I have lost interest in sex completely.
o I am no more irritable than usual.	
1 am more irritable than usual.	
2 I am much more irritable than usual.	
3 I am irritable all the time.	OUTPUT 2 (TYPE 3)
	0011012(11120)
roductivity Assessment	
LOSTWK <f:9:3></f:9:3>	ual activities in the past 30 days due to problems with your health?
How many days have you lost from work and/or your usu LOSTWK <f:9:3> days</f:9:3>	EMPLOYST <i:3><acemp></acemp></i:3>
How many days have you lost from work and/or your use LOSTWK <f:9:3> days Check one of the following to indicate your current employed</f:9:3>	EMPLOYST <i:3><acemp></acemp></i:3>
How many days have you lost from work and/or your use LOSTWK <f:9:3> days Check one of the following to indicate your current employed 1 Employed/self-employed full-time (> 30 hours week)</f:9:3>	EMPLOYST <i:3><acemp></acemp></i:3>

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12-Month

Potient Number: ______

patient # Patient's Initials:

fiols: ______

TIENT 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.	🗌 o No	1 Yes
3	I currently engage in regular physical activity.	o No	□ ₁ Yes
4	I have been regularly physically active for the past 6 months.	o 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:	slightly confident	a Moderately confident	4 Very confident	5 Extremely confident
2	When I am in a bad mood: \Box_1 Not at all confident \Box_2	2 Slightly confident	3 Moderately confident	4 Very confident	5 Extremely confident
3	When I feel I don't have timeNot at all confident		3 Moderately confident	4 Very confident	5 Extremely confident
4	When I am on vacation:	2 Slightly confident	a Moderately confident	4 Very confident	□ ₅ Extremely confident
5	When it is raining or snowin	-	a Moderately confident	4 Very confident	5 Extremely confident



See annotaion p.11 of Baseline



-	T V	~				Patient Number:	patis	at #	_ P	atient's	Initials:	first midd
D	ecisiona	l Balan	ce									
to l	be physically	active. In e		about <u>how</u>		our decision of whether f <u>eel right now</u> , not how	Not at All Image	Slightly Indiana	Mod ^{eratelv 1}	Very Important	Extremely Import	fub
1	I would have	ve more ene	rgy for my fan	nily and frie	nds if	I exercised regularly.						
2	Regular ex	ercise would	l help me reliev	e tension.								
3	I think I wo	uld be too ti	red to do my d	laily work o	fter e	xercising.						
4	I would fee	l more confi	dent if I exercis	ed regular	у.							
5	I would sle	ep more sou	ndly if I exerci	sed regular	ly.							
6	I would fee	l good abou	ıt myself if I ke	pt my comn	itmer	t to exercise regularly.						
7		d it difficult t bad weath		ise activity	that I	enjoy that is not						
8	I would like	e my body b	etter if I exerci	sed regular	y.							
9	It would be	easier for n	ne to perform r	outine phys	ical to	asks if I exercised regularly	. 🗆					
10	I would fee	l less stresse	d if I exercised	regularly.								
11	I feel uncor heart beats		nen I exercise b	ecause I ge	et out	of breath and my						
12	I would fee	I more comf	ortable with m	y body if I o	exerci	sed regularly.						
13	Regular ex	ercise would	take too much	n of my time								
14	Regular ex	ercise would	l help me have	a more pos	sitive o	outlook on life.						
15	I would have	ve less time	for my family c	ind friends i	flex	ercised regularly.						_
16	At the end	of the day, I	am too exhau	sted to exe	cise.							
	· · · · · ·											
	arrier So											
Ple	ase indicate	the extent to Not at All	which you anti Somewhat	cipate that t A Lot	he foll	owing might interfere with y	our contin Not at Al		particij omew		in this : A Lo	-
1	Finances:	NOT OF AIL	somewhar	ALOT	6	Boredom:		1 3	omew	nar		ſ
2	Child care:				7	Fatigue:						
3	Weather:				8	Transportation:						
4	Vacation:				9	Work:						
5	Pain:				10	Household responsibilities	:					

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Potient Number: site H Patient's Initials:

12-Month

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

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.

During the last 7 days, on how many days did you do 1 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.

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

___ minutes per day

OR Don't know/not sure

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.

patient #

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 <u>last 7 days</u>, 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 guestion 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 <u>last 7 days</u>, how much time did you spend sitting on a weekday?

____ hours per day

OR Don't know/not sure

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میں کا ک		atient's Initials:
edical Hist		
		4 of 2 Month
	eart failure class (check only one):	
Current Canadia	n Cardiovascular Society (CCS) angina class (check only one): No angina	
rrent Med	cations	
eck "No" or "Yes	for each medication and provide the total daily dose, if applicable.	notation p.13 of Bas
ACE inhibitor:		
$\square_0 \text{ No} \rightarrow \text{Reasons}$	n for not using (check only one): \Box_1 Contraindicated \Box_2 Intolerance \Box_3 MD preference	4 Patient preference
	Check only one and provide the TOTAL DAILY DOSE:	
	Benazepril: mg Quinapril: mg	
	□_2 Captopril: mg □_7 Ramipril: mg	
	□ ₃ Enalapril: mg □ ₈ Trandolapril: mg	
		mg
	□ _s Lisinopril: mg	
Angiotensin rece	ptor blocker:	
No		
	Check all that apply: Valsartan Losartan Irbesartan Candesartan	
Beta blocker:		
	n for not using (check only one): 1 Contraindicated 2 Intolerance 3 MD preference	Detient performance
	Check only one and provide the <u>TOTAL DAILY DOSE</u> :	
	A Atenolol: mg A Metoprolol immediate release: gisoprolol: mg s Metoprolol XL:	
Aspirin:		
	n for not using (check only one): 1 Contraindicated 2 Intolerance 3 MD preference	4 Patient preterence
\square_1 Yes \rightarrow If Yes	Dose: mg	
Loop diuretic:		
No No		
Yes → If Yes	Check only one and provide the TOTAL DAILY DOSE:	
-	Furosemide: mg Torsemide: mg	
	Burnetanide: mg Other (specify):	mg
A standard star	-	
Antiarrhythmic:		
\square_1 Yes \rightarrow If Yes	Check all that apply: Amiodarone Sotalol Dofetilide Other (specify):	
Lipid-lowering a	jent:	
□ ₀ No		
$1 \text{ Yes} \rightarrow \text{If Yes}$	Check only one: \square_1 HMG-CoA reductase inhibitor \rightarrow Check all that apply: \square Atorva: \square_2 Other lipid-lowering agent \square Simvas	
Selective serotor	in reuptake inhibitor:	
□ _o No	-	
	all that apply: Sertraline Citalopram Paroxetine Fluoxetine Oth	her
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See annotation p.14 for Baseline

12-Month

	Patie	ent Number: _		patient #	Patient's Initi	als:
Current Medications						
Check "No" or "Yes" for each medication.						
9 Tricyclic antidepressant:	o No	1 Yes				
10 Other antidepressant (excluding SSRIs and TCAs):	o No	1 Yes				
11 Antipsychotic:	□ ₀ No	1 Yes				
12 Clopidogrel:	o No	1 Yes				
13 Coumadin:	🗌 o No	1 Yes				
14 Digoxin:	□ ₀ No	□ ₁ Yes				
15 Nitrate:	o No	1 Yes				
16 Calcium channel blocker:	□ ₀ No	1 Yes				
17 Spironolactone:	□ ₀ No	1 Yes				
18 Eplerenone:	o No	1 Yes				
19 Non-loop diuretic (excluding aldosterone antagonist):	o No	1 Yes				
20 Potassium:	□ ₀ No	1 Yes				
21 Insulin:	o No	1 Yes				
22 Glitazone:	□ ₀ No	1 Yes				
23 Other oral diabetic agent:	□ ₀ No	1 Yes				
24 Thyroid replacement:	o No	1 Yes				
25 NSAID:	o No	1 Yes				
26 COX-2 inhibitor:	□ ₀ No	1 Yes				
27 Sildenafil:	o No	1 Yes				
Reserved for potential new drugs. Do not complete u	nless ins	tructed by t	he Duke Cli	nical Resear	ch Institute	e (DCRI).
28 Other:					□ ₀ No	Yes
29 Other:					O No	Yes

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See annotation p.17 of Baseline except PATINS, SIG 12-Month

Patient's Initials: Ant middle lost

Potient Number: _______ - ____ patient #

Q	uality of Life	e—Reason for Missing Data	
		forms complete? $\square_0 \text{ No} \rightarrow \text{ If No:}$ $\square_1 \text{ Patient died}$ $\square_2 \text{ Patient refused}$ $\square_3 \text{ Patient withdrew consent}$ $\square_4 \text{ Patient missed visit}$ $\square_5 \text{ Patient sick}$ $\square_{98} \text{ Other}$	
6	-Minute Wa	ılk Test	
1	Did the patient at	tempt the 6-minute walk at this visit?	
-	□ _o 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 missed visit	
		Start walk time:::	
		Total distance walked: Feet 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:	
2	Were the QOL ins	struments completed before or after the 6-minute walk? Check only one:Before 2 < 30 mins after 3 30-60 mins after 4 > 60 mins after	

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See annotation p.26 of 3-Month

12–Month

		See annotat	see annotation p.26 of 3-Month	Patient Number:	site # patient #	Potient's Initials: for add but
õ	Outpatient Log					
÷	tas the patient had any non-urgent) outpatient visits sir	Has the patient had any non-urgent outpatient visits since the last study visit? (Do not include protocol-specified follow-up visits) 🔤 No 🔤 Yes 🕂 Complete the table below.	col-specified follow-up visi	#±) □0 No □1 Yes → Complete the	table below.
	Provider Type		Number of Office/ Clinic Visits	isits	Number of Home Visits	
Ξ	Cardiologist:					
1.2	Orthopedic surgeon:					
1.3	Other specialist:					
1.4	Primary care physician:					
1.5	Physician extenders (includes NPs, PAs, etc.);	As, etc.)t				
1.6	OT or PT:					
1.7	Mental health provider:					
1.8	Nurse (includes RNs, LPNs, nurse's aides or ather equivalent);	: or other equivalent);				
1.9	Other (specify):					
4	Has the patient had any outpatient cardiac pro _₀ N₀	ca rdiac procedure: sble below.	Has the patient had any outpatient cardiac procedures/tests {including KD lining) or orthopedic procedures/tests since the last study visit? □0 No □1 Yes → Compete the table below.	orocedures/tests sin	ce the last study visit?	
	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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e annotation p.27 of 3-Month

12–Month

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Initials
Patient's
patient #
Patient Number:

Outpatient Log

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 Complete the table below.
¥es ₹
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visit?
st study
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i outpatient b
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		Number of Visits Due to	Number of Visits Due to Cardiovascular Disease*	Number of Visits Due to Non-Cardiovascular	Number of Visits Due to Unknown	Number of Visits Due to a Cardiovascular Event Occurring During	
	Outpatient Service Type	Heart Failure*	(other than heart failure)		Cause*	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 1 st ER visit (for any reason since randomization);	ince randomization);	day - / yeer	OR1No ER visit to date 2 Previously recorded	le ded		
3.5	Date of 1 st urgent clinic visit due to heart failure exacerbation (since randomization); $\frac{1}{4w}$	to heart failure	exacerbation (since randomizati		per OR _ No	$\{\rm 3}$ No urgent clinic visit for HF to date $\{\rm 2}$ Previously recorded	
e H	Other Types of Resource Utilizatic	Utilization	-				
z	Number of days on home IV infusion for heart failure since the last study visit:	n for heart failur	e since the last study visit: _	days			
7	Since the last study visit, how many days did the patient live in each of the following	days did the pati	ient live in each of the follo	wing			
	Their home: days						
	Caregiver's home (e.g. family and friends):		_ days				
	Assisted living: days						
	Skilled nursing facility:	- days					
	Acute care hospital: do	days					
	Rehabilitation center:	days					
	Other (specify):		days				

* Primary diagnosis

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notation p.28 of 3-Month

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ide # Potient # Potient's Initials: first adde tar

12–Month

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.)

No No Yes → If Yes: How many hospitalizations?

			Primary Cardiac	Secondary Cardiac	
		Driment Descon	rrocedure (and doministratis	Procedure	Discharge
	Ho spitalization:	for Hospitalization*	Record a zero if patient did not have cardiac procedures.	ot have cardiac procedures.	Destination*
1 Hospitalization: Admission date:/	Planned Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? $\square_0 \land 0$					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ No \ \square_1 \ \forall es \rightarrow If Yes: Complete the Cardiovascular Event forms.$					
2 Hospitalization: Admission date:/	Planned Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? \square_0 No \square_1 Yes					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ No \ \square_1 \ Yes \rightarrow If Yes$: Complete the Cardiovascular Event forms.					
3 Hospitalization: Admission date:/	Planned Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? $\square_0 \land 0 \circ \square_1 \forall e_5$					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ N_0 \ \square_1 \ \forall es \rightarrow If Yes: Complete the Cardiovascular Event forms.$					

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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HF-ACTION_12.MO_1.2_16JUN2003

CRF, page 70
This is a repeating page n)GIIOK First page should have page rep 0 12-Month See annotation p.29 of 3-Month Patient's Initials: patient # site ff Telephone Log 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 divretics: Diuretic dose increases: Diuretic dose decreases: Exercise Training Group: Is patient performing the training as prescribed? No → If No: Indicate primary reason code*: _____ , Yes Usual Care Group: Is patient performing physical activity (formal or non-formal)? 2 Date of call: ____/____/ 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 divretics: Diuretic dose increases: Diuretic dose decreases: Exercise Training Group: Is patient performing the training as prescribed? o → If No: Indicate primary reason code*: _____ , Yes Usual Care Group: Is patient performing physical activity (formal or nonformal)? 3 Date of call: ____/_____ 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 divretics: Diuretic dose increases: Diuretic dose decreases: _____ Exercise Training Group: Is patient performing the training as prescribed? No → If No: Indicate primary reason code*: _____ , Yes Usual Care Group: Is patient performing physical activity (formal or non-formal)?

*See choices on opposite page.

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

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	= DATA_FORMS	15-Montl
VISITDT P	SUBJNO	INITIALS
	site # patient #	And middle los
te of visit:/		
edical History		
Current NYHA heart failure class (check only one):	See annotation p.24	of 3-Month
Current Canadian Cardiovascular Society (CCS) angina cla		
urrent Medications		
eck "No" or "Yes"; if "Yes", provide the total daily dose.		
Loop diuretic: O No		
Yes → If Yes: Check only one and provide:		
2 Bumetanide:		mg
eck "No" or "Yes" for each medication.		
Spironolactone: 0 No 1 Yes	16 Calcium channel blocker:	0 No 1 Yes
Eplerenone: D ₀ No 1 Yes	17 Insulin:	0 No 1 Yes
Non-loop diuretic:	18 Glitazone:	o No _ 1 Yes
(excluding aldosterone antaganist)	19 Other oral diabetic agent:	No Yes
Potassium: 0 No 1 Yes	_	
ACE inhibitor:	20 Thyroid replacement:	0 No 1 Yes
	21 Selective serotonin	
Angiotensin receptor blocker: No _ 1 Yes	reuptake inhibitor:	0 No 1 Yes
Beta blocker: D ₀ No D ₁ Yes	22 Tricyclic antidepressant:	o No a Yes
Aspirin: O No 1 Yes	23 Other antidepressant:	0 No 1 Yes
Antiarrhythmic:	(excluding SSRIs and TCAs)	
	24 Antipsychotic:	0 No 1 Yes
Lipid-lowering agent:	25 NSAID:	o No 🔄 Yes
Clopidogrel: O No 1 Yes	26 COX-2 inhibitor:	
Coumadin: Do No 1 Yes		
Digoxin: Do No 1 Yes	27 Sildenafil:	0 No 1 Yes
Nitrate: 0 No 1 Yes		
erved for potential new drugs. Do not complete unless i	nstructed by the Duke Clinical Research	Institute (DCRI).
Other:	-	No 1 Yes
Other:		No Yes
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s,	NGHON		See annotation p.26 of 3-Month			-	15–Month
V	e l			Patient Number:	site # patient #		Potient's Initials: first widds last
õ	Outpatient Log						
-	tas the patient had any non-urge s	nt outpatient visits si	1 Has the patient had any non-urgent outpatient visits since the last study visit? (Do not include protocol-specified follow-up visits) 🔤 No	col-specified follow-up visi		\Box_1 Yes \rightarrow Complete the table below.	able below.
	Provider Type		Number of Office/ Clinic Visits	isits	Numb	Number of Home Visits	
11	Cardiologist:						
1.2	Orthopedic surgeon:						
1.3	Other specialist:						
1.4	Primary care physician:						
1.5	Physician extenders (includes NPs, PAs, etc.):	, PAs, etc.):					
1.6	OT or PT:						
1.7	Mental health provider:						
1.8	Nurse (includes RNs, LPNs, nurse's aides or other equivalent);	les or other equivalent);					
1.9	Other (specify):						
2 1	the patient had any outpatient cardiac pro 0, No 0, Yes → Compete the table below.	t cardiac procedure table below.	Has the patient had any outpatient cardiac procedures/tests {including KD fining} or orthopedic procedures/tests since the last study visit? □_0 No □_1 Yes → Compete the table below.	srocedures/tests sin	ce the last study visit	Q.	
	Procedure Code*	Number	Procedure Code*	Number	Procedure Code*	ode*	Number
*See	choices on opposite page. Recor	rd one per row. If a I	*See choices on opposite page. Record one per row. If a procedure/test is not listed, please record it in the table above.	d it in the table abo	ve.		
	St	ubmit WHITE and YE	Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.	Institute. • Retain I	VINK page at site.		

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HF-ACTION_15MO_1.2_16JUN2003

CRF, page 73 (1 of 2)

s,	A REFIER	See anr	See annotation p.27 of 3-Month			15–Month	
				Partier	Patient Number:	- Patient's Initials for eads but	
õ	Outpatient Log						
τ m	Has the parient required any urgent/emergency care on an outpatient basis since the last study visit? $\Box_0 N \circ \Box_1 Yes \rightarrow Complete the table below.$	/emergency car	e on an outpatient basis sin	tce the last study visit?	₀ No □, Yes ↓ C	mplete the table below.	
		Number of	Number of Visits Due to	Number of Visits Due	Number of Visits	Number of Visits Due to a	
		Visits Due to	Cardiovascular Disease*	to Non-Cardiovascular	Due to Unknown	Cardiovascular Event Occurring During	
	Outpatient Service Type	Heart Failure*	(other than heart failure)	Disease*	Cause*	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):	nce randomization);		 OR1No ER visit to date 2 Previously recorded 	te ded		
3.5	Date of 1st urgent clinic visit due to heart failure exacerbation (since randomization); $\frac{1}{4y}$	to heart failure	exacerbation (since randomizat	-/- <u></u>	year OR I No	$\hfill 1$ No urgent clinic visit for HF to date $\hfill 2$ Previously recorded	
ō	Other Types of Resource Utilization	Utilizatior	-				
-	1 Number of days on home IV infusion for heart failure since the last study visit:	n for heart failur	e since the last study visit: .	days			
2	Since the last study visit, how many days did the patient live in each of the following	days did the pat	iient live in each of the follo	wing			
	Their home: days						
	Caregiver's home (e.g. family and friends):		_ days				
	Assisted living: doys						
	Skilled nursing facility:	. days					
	Acute care hospital: da	days					

* Primary diagnosis

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days

days

Rehabilitation center:

Other (specify):

CRF, page 74 (2 of 2)

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15–Month

Pertient's Initials: for ends for

Patient Number: ________ - _________

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.}	ed study visit? mation if the patient is	currently hospitalized.)			
No ☐ ₁ Yes → If Yes: How many hospitalizations?					
			Primary Cardiac Procedure*	Secondary Cardiac Procedure*	
	Hospitalization:	Primary Reason for Hospitalization*	(code/d escription)* (code/d escription)* Record a zero if patient did not have cardiac procedures.	(code/d excription)* hient did not have cardiac procedures.	Discharge Destination*
1 Hospitalization: Admission date:	Planned Unplanned				
ccur during or v					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \operatorname{No} \square_1 \operatorname{Yes} \to$ If Yes: Complete the Cardiovascular Event forms.					
2 Hospitalization: Admission date:	Planned Unplanned				
cur during or v					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 No = \square_1 Yes \rightarrow If Yes: Complete the Cardiovascular Event forms.$					
3 Hospitalization: Admission date:	Planned Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? \square_0 No \square_1 Yes					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ No \ \square_1 \ Yes \rightarrow$ If Yes: Complete the Cardiovascular Event forms.					
*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.	ination is not list alization form.	ed, please record it in t	he table above.		

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First page should have page rep 0	5-Month
See annotation p.29 of 3-Month	
Potient Number: Potient # Potient's In	finitials:
Telephone Log	
1 Date of call:/	
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 \rightarrow If \geq 1: How many of the contacts resulted in:	
Changes to medications other than divretics:	
Diuretic dose increases:	
Diuretic dose decreases:	
Evention Testation Overally antiont conforming the training or according 12	
Exercise Training Group: Is patient performing the training as prescribed? 	
\square_0 (13 \rightarrow 11 No. Indicate primary reason code :	
Usual Care Group: Is patient performing physical activity (formal or non-formal)?	
2 Date of call://	
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 \rightarrow If \geq 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 \rightarrow If No: Indicate primary reason code*:	
1 Yes	
Usual Care Group: Is patient performing physical activity (formal or non-formal)?	
3 Date of call://	
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 \ge 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?	
No → If No: Indicate primary reason code*:	
Yes	

*See choices on opposite page.

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

CRF ANNOTATION VERSION 6.0_11May2004

Usual Care Group: Is patient performing physical activity (formal or non-formal)?

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s views s	PROTOCOL = HFACTION STUDYBOOK = DATA_FOR FORM = 18MONTH Patient Number:		18-Mont nt's Initiols: NITIAL
Date of visit:/			
Medical History			
Current NYHA heart failure class (check	only one):	annotation p. 24 of 3	-Month
Current Canadian Cardiovascular Socie	ety (CCS) angina class (check only one): No	o angina 📃 I 📃 II	
Current Medications			
1 Fu	only one and provide the total daily dose rosemide: mg3 Torsemide		
Check "No" or "Yes" for each medication.			
Spironolactone:		el blocker:	
Eplerenone:	₀ No 17 Insulin:		₀ No 1 Yes
Non-loop diuretic:		betic agent:	
Potassium:	No Yes	ement:	
ACE inhibitor:	No 1 Yes		
Angiotensin receptor blocker:	21 Selective serot No _1 Yes reuptake inhib	onin bitor:	No 1 Yes
Beta blocker:	No _1 Yes 22 Tricyclic antide	pressant:	No 1 Yes
Aspirin:	No 1 Yes 23 Other antidep	ressant:	0 No 🔄 Yes
0 Antiarrhythmic:	No 1 Yes		No. Ver
Lipid-lowering agent:	No 1 Yes		
2 Clopidogrel:	No 1 Yes		
3 Coumadin:	No 1 Yes)r:	
4 Digoxin:	27 Sildenafil:		o No 🔄 Yes
5 Nitrate:	No 1 Yes		
	complete unless instructed by the Duk		
			No 1 Yes
	W — Duke Clinical Research Institute • 1		No 1Yes

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	2			Patient Number:	site # potient #	Patient's Initials for eads for
0	Outpatient Log					
-	Has the patient had any non-urgen	nt outpatient visits sir	Has the patient had any non-urgent outpatient visits since the last study visit? (Do not include protocol-specified follow-up visits) on No in Yes -+ Complete the table below.	col-specified follow-up visit	¹ ±} □0 No □1 Yes → Complete the	able below.
	Provider Type		Number of Office/ Clinic Visits	isits	Number of Home Visits	
7	Cardiologist:					
1.2	Orthopedic surgeon:					
1.3	Other specialist:					
1.4	Primary care physician:					
1.5	Physician extenders (indudes NPs, PAs, etc.);	PAs, etc.):				
1.6	OT or PT:					
1.7	Mental health provider:					
1.8	Nurse (includes RNs, LPNs, nurse's aides or ather equivalen);	es or other equivalent);				
1.9	Other (specify):					
2	Has the patient had any outpatient cardiac pro N₀ Yes → Compete the table below.	table below.	Has the patient had any outpatient cardiac procedures/tests (including <i>JCD</i> living) or orthopedic procedures/tests since the last study visit? $\square_0 \text{ No} = \square_1 \text{ Yes} \rightarrow \text{Compete the table below.}$	rrocedures/tests sin	ce the last study visit?	
	Procedure Code*	Number	Procedure Code*	Number	Procedure Code*	Number
*See	s choices on opposite page. Record	d one per row. If a p	*See choices on opposite page. Record one per row. If a procedure/test is not listed, please record it in the table above.	d it in the table abo	ve.	

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CRF, page 78 (1 of 2)

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See annotation p.27 of 3-Month

18–Month Patient's Initials: <u>for wide</u> for

N.			See annotation p.27 of 3-Month		Patient Number:		
õ	Outpatient Log						
3	Has the patient required any urgent/emergency 	i∕ emergency car	tare on an outpatient basis since the last study visit? $\square_0 N \circ = \square_1 Ye_5 o Complete the table below.$	ce the last study visit?	No 7 Yes 4 C	mplete the table below.	
		Number of Visits Due to	Number of Visits Due to Cardiovascular Disease*	Number of Visits Due to Non-Cardiovascular	Number of Visits Due to Unknown	Number of Visits Due to a Cardiovascular Event Occurring During	
3.1	Emergency room, hospital < 24 hours, or observation unit:		famme anna anna	0 0 0 0	0000		
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)	nce randomization)t -	day	OR, No ER visit to date 2 Previously recorded	e Jed		
3.5	Date of 1 st urgent clinic visit due to heart failure exacerbation (since randomization): $\frac{1}{4y}$	to heart failure (exacerbation (since randomizati		year OR D No	No urgent clinic visit for HF to date Previously recorded	
ō	Other Types of Resource Utilization	Utilization					
-	Number of days on home IV infusion for heart failure since the last study visit:	n for heart failur	e since the last study visit: .	days			
2	Since the last study visit, how many days did the patient live in each of the following	days did the pati	ient live in each of the follor	wing			
	Their home: days						
	Caregiver's home (e.g., family and friends):		days				
	Assisted living: days						
	Skilled nursing facility:	, days					
	Acute care hospital: do	days					
	Rehabilitation center:	days					
	Other (specify):		days				

* Primary diagnosis

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CRF, page 79 (2 of 2)

	This is First pa	This is a repeating page First page should have page rep 0	le rep 0	18	18–Month
See annotation p.28 of 3-Month		Potient	Potient Number:	patient # Patient's Init	Portient's Initials: <u>inst_edde bar</u>
Hospitalization Record only hospitalizations for ≥ 24 hours.					
Has the parient 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 parient is currently hospitalized.) $\Box_0 \text{ No } = 1$ Yes: \rightarrow 1f Yes: How many hospitalizations?	ted study visit? emation if the patient is	currently hospitalized.)			
			Primary Cardiac Procedure*	Secondary Cardiac Procedure*	
	Hospitalization:	Primary Reason for Hospitalization*	(code/description)* Record a zero if patient did not have cardiac procedures.	(code/description)* tient did not have cardiac procedures.	Discharge Destination*
Admission date:	Planned Unplanned				
ccur during or v					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \text{ No} = \square_1 \text{ Yes} \rightarrow If \text{ Yes}$: Complete the Cardiovascular Event forms.					
2 Hospitalization: Admission date:/	Planned Unplanned				
ccur during or v					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ No \ \square_1 \ Yes \rightarrow If Yes: Complete the Cardiovascular Event forms.$					
3 Hospitalization: Admission date:/	Planned Diplanned				
ccur during or v					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ No \ \square_1 \ Yes \rightarrow If Yes: Complete the Cardiovascular Event forms.$					
* 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 hostinalizations occurred, complete an Additional Hostinalization form.	tination is not liste talization form.	od, please record it in	the table above.		
Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.	s to Duke Clinical	Research Institute.	Retain PINK page at site	đ	
HF-ACTION_18MO_1.2_16JUN2003	2003 DCRI — Confidential	Confidential			CRF, page 80

This is a repeating page (110N) First page should have page rep 0 18-Month See annotation p.29 of 3-Month Potient Number: Potient's Initials: ________ patient # Telephone Log 1 Date of call: ____/_______ 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 divretics: Diuretic dose increases: _ Diuretic dose decreases: _____ Exercise Training Group: Is patient performing the training as prescribed? No → If No: Indicate primary reason code*: _____ , Yes Usual Care Group: Is patient performing physical activity (formal or non-formal)? 2 Date of call: ____/____/_____ 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*: _____ , Yes

Usual Care Group: Is patient performing physical activity (formal or non-formal)?

3 Date of call://
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 \rightarrow If \geq 1: How many of the contacts resulted in:
Changes to medications other than divretics:

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 nonformal)?

*See choices on opposite page.

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

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1			I = 21M	Patient Number:				
		, i		Ponent Nomber:	site #	patient #	Folient's Init	fort middle
a	te of visit:/ //	унат						
Ν	edical History							
	Current NYHA heart failure cla	ISS (check only or	ne): 🗌 I 🛛		IV	See ani	notation p.2	4 of 3-Mor
2	Current Canadian Cardiovascu	lar Society (C	CS) angina	class (check only on	∞): 🗌 No anç			
l	urrent Medications							
h	eck "No" or "Yes"; if "Yes", pro	wide the total	daily dose.					
	Loop diuretic:₀ No	: Check only	one and pro	ovide the total d	ailv dose:			
		1 Furosemi	de:	mg 🛛 🖂 🛛	Torsemide:			
		2 Bumetan	ide:	mg	_B Other, (specify):		m
h	eck "No" or "Yes" for each mea	dication.						
	Spironolactone:	🗌 🛛 No	1 Yes	16 Calci	um channel b	locker:	🗌 0 No	Yes
	Eplerenone:	🗌 0 No	1 Yes	17 Insuli	n:		🗌 0 No	🔄 1 Yes
	Non-loop diuretic:	🗆 No	1 Yes	18 Glita	zone:		🗆 0 No	Yes
	(excluding aldosterone antagonist)			19 Othe	r oral diabeti	c agent:	🗆 No	, Yes
	Potassium:	🗌 0 No	1 Yes	20 Thyro	oid replaceme	nt:	No.	, Yes
	ACE inhibitor:	🗌 🛛 No	1 Yes	-	tive serotonin			
	Angiotensin receptor blocker: .	🗌 🛛 No	1 Yes				🗌 0 No	Yes
	Beta blocker:	🗆 No	1 Yes	22 Tricyc	lic antidepres	sant:	🗌 0 No	Yes
1	Aspirin:	🗌 🛛 No	1 Yes	23 Othe	r antidepress	ant:	🗌 0 No	Yes
0	Antiarrhythmic:		, Yes	(exclud	ding SSRIs and TC	'As)		
	Lipid-lowering agent:			24 Antip	sychotic:		🗌 0 No	Yes
		_		25 NSAI	D:		🗆 No	Yes
	Clopidogrel:			26 cox-	2 inhibitor:		🗌 🛛 No	1 Yes
3	Coumadin:	🔄 🛛 No	1 Yes	27 Silde	nafil:		🗖 a No	, Yes
4	Digoxin:	🗌 0 No	1 Yes					
5	Nitrate:	🗌 0 No	1 Yes					
e	served for potential new drugs.	Do not com	olete unles	s instructed by	the Duke C	linical Resea	rch Institute	e (DCRI).
	Other:	-		-			□ ₀ No	
	Other:						o No	Yes

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Patient's Initials Patient Number: ________ - _________

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-	Has the patient had any non-urge i	int outpatient visits si	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.	col-specified follow-up vis	#s.} □_0 No □_1 Yes → Complete the i	table below.
	Provider Type		Number of Office/ Clinic Visits	lisits	Number of Home Visits	
2	Cardiologist:					
1.2	Orthopedic surgeon:					
1.3	Other specialist:					
1.4	Primary care physician:					
1.5	Physician extenders (includes NPs, PAs, etc.):	t, PAs, ekc.)‡				
1.6	OT or PT:					
1.7	Mental health provider:					
1.8	${\sf Nurse}$ (includes RNs, LPNs, nurse's aides or ather equivalent);	des or other equivalent);				
1.9	Other (specify):					
4	Has the patient had any outpatient cardiac pro 0 No1 Yes → Compete the table below.	nt cardiac procedure table below.	Has the patient had any outpatient cardiac procedures/tests {including KD fining} or orthopedic procedures/tests since the last study visit? □0 No □1 Yes → Compete the table below.	srocedures/tests sin	ice the last study visit?	
	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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HF-ACTION_21 MO_1.2_16JUN2003

	NOLLON X					21 – Month	hth
		ŭ	See annotation p.27 of 3-Month		Patient Number:		nidfe for
õ	Outpatient Log						
n	Has the patient required any urgent/emergency care on an outpatient basis since the last study visit? $\Box_0 N_0$ $\Box_1 Y_{es} \rightarrow Complete the table below.$	l∕ emergency car	e on an outpatient basis sin	ice the last study visit?	o No	mplete the table below.	
	Outnotitent Service Type	Number of Visits Due to Heart Failure*	Number of Visits Due to Cardiovascular Disease* (other theor board foilure)	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	uring
3.1							
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):	nce randomization);	day / year	ORNO ER visit to date Previously recorded	ed		
3.5	Date of 1 st urgent clinic visit due to heart failure exacerbation (since randomization): $\frac{1}{4y}$	to heart failure	ex acerbation (since randomizati	ion‡/	OR	No urgent clinic visit for HF to date Previously recorded	
ō	Other Types of Resource Utilization	Utilizatior					
-	Number of days on home IV infusion for heart failure since the last study visit:	n for heart failur	e since the last study visit: .	days			
n	Since the last study visit, how many days did the patient live in each of the following	days did the pat	ient live in each of the follor	wing			
	Their home: days						
	Caregiver's home (e.g. family and friends):		days				
	Assisted living: days						
	Skilled nursing facility:	- days					
	Acute care hospital: do	days					
	Rehabilitation center:	days					
	Other (specify):		— days				
* Prin	* Primary diagnosis						
		mit WHITE and	Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site.	nical Research Institute.	Retain PINK page a		,
HF-AC	HF-ACTION_21 MO_1.2_16JUN2003		2003 DCR	2003 DCRI — Confidential		CRF, page 84 (2 of 2)	‡ (2 of 2)

CRF, page 84 (2 of 2)

		This is a repeating page First page should have page rep 0	age ive page rep 0	21	21 – Month
	See annotation p.28 of 3-Month	Patient	Patient Number:	Patient # Patient's Initials:	ical s: instant and instant
Hospitalization Record only hospitalizations for ≥ 24 hours.	l 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.)	t completed study visit? cospital information if the patient is	s currently hospitalized.)			
O No 0, Yes → If Yes: How many hospitalizations?					
			Primary Cardiac Procedure*	Secondary Cardiac Procedure*	
	Hospitalization:	Primary Reason for Hospitalization*	{code/description}* Record a zero if patient did not have cardiac procedures.	(code/description)* tient did not have cardiac procedures.	Discharge Destination*
1 Hospitalization: Admission date:					
Discharge date:/	Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? $\square_0 \ No$	ithin				
Did a cardiovascular event cause or occur during this hospitalization? □ No □ Yes → If Yes: Complete the Cardiovascular Event forms.	zation? t forms.				
2 Hospitalization: Admission date:/	Planned				
Did the event leading to this hospitalization occur during or within 3 hours offer eventions No.					
Did a cardiovascular event sause or occur during this hospitalization?	zetion?				
Dud d cardiovascural even cause or occur duning mus mosphranzamon: □₀ N₀ □₁ Yes → If Yes: Complete the Cardiovascular Event forms.	t forms.				
3 Hospitalization: Admission date:/	Planned Diplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? \square_0 No \square_1 Yes	ithin				
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ No \ \square_1 \ Yes \rightarrow If Yes: Complete the Cardiovascular Event forms.$	zation? t forms.				
* See choices on opposite page. If a diagnosis/ procedure/discharge destination is not listed, please record it in the table above.	arge destination is not list	ed, please record it in t	he table above.		
If more than 3 hospitalizations occurred, complete an Additional Hospitalization form.	al Hospitalization form.				
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	This is a repeating page First page should have page rep 0	01 44 41
		21-Month
	Potient Number: patient #	Patient's Initials:
Telephone Log		
1 Date of call:/	year	
	es has the patient's provider been contacted due to changes in th	e patient's
	initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)	
contacts → If ≥ 1: How	w many of the contacts resulted in:	
Cho	inges to medications other than diuretics:	
Diu	retic dose increases:	
Diu	retic dose decreases:	
Exercise Training Group: Is patie	ent performing the training as prescribed?	
	→ If No: Indicate primary reason code*:	
1 Ye	ŝ	
Usual Care Group: Is patient per	forming physical activity (formal or non-formal)? 🔲 No 🛛 🔲 Yes	
2 Date of call:/		
	es has the patient's provider been contacted due to changes in th	e patient's
	initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)	
	w many of the contacts resulted in:	
	inges to medications other than diuretics:	
	retic dose increases:	
	retic dose decreases:	
Evergice Training Group: Is patie	ent performing the training as prescribed?	
	→ If No: Indicate primary reason code*:	
, Ye:		
Usual Care Group: Is patient per	forming physical activity (formal or non-formal)?	
3 Date of call:/	year	
Since the last call, how many time	es has the patient's provider been contacted due to changes in th	e patient's
	initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)	
contacts → If ≥ 1: Hor	w many of the contacts resulted in:	
Cho	inges to medications other than diuretics:	
Diu	retic dose increases:	
Diu	retic dose decreases:	
Exercise Training Group: Is patie	ent performing the training as prescribed?	
	→ If No: Indicate primary reason code*:	
	5	
Usual Care Group: Is patient per	forming physical activity (formal or non-formal)? 🔲 No 🔲 1 Yes	
See choices on opposite page.		
f more than 3 telephone calls were c	ompleted, complete an Additional Telephone Log form.	

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Study Book = DATA_FORMS NODATA-2YES: 24-MONT Notice: 24-MONT Notic
VISITOT Potient Number:
iste # patent # p
And you wast your your processed. placing a checkmark in one box in each group below, please indicate it statement best describes your own health state today. See annotation p.3 of Baseline Mobility: I have no problems in walking about. I have no problems in walking about. I have no problems in walking or dessing myself. I have no problems with self-care. I have no problems with self-care. I have no problems with self-care. I have no problems with performing my usual activities. I an unable to wash or dress myself. I have no problems with performing my usual activities. I have no problems with performing my usual activities. I have no problems with performing my usual activities. I have no problems with performing my usual activities. I have no problems or discomfort. I have moderate pain or discomfort. I have moderate pain or discomfort. I am unable to anal or depressed. I am not anxious or depressed. I am moderately anxious or depressed. I am moderately anxious or depressed. I am extremely anxiou
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Pain/discomfort: 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
 ☐ I have no pain or discomfort. ☐ I have moderate pain or discomfort. ☐ I have extreme pain or discomfort. Anxiety/depression: ☐ I am not anxious or depressed. ☐ I am moderately anxious or depressed. ☐ I am extremely anxious or depressed. ☐ I am extremely anxious or depressed. ☐ Please let your study coordinator know that you are ready for the EuroQoL Thermometer worksheet.
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□ ₃ I am extremely anxious or depressed. → Please let your study coordinator know that you are ready for the EuroQoL Thermometer worksheet. ain Assessment
→ Please let your study coordinator know that you are ready for the EuroQoL Thermometer worksheet.
ain Assessment
How much hadily pain have you had during the past 4 weeks (sheet ask as ??
□ None □ Very mild □ Mild □ Moderate □ Severe □ Very severe
Bud and a set of a large stability of the first of the second second second second second second second second
During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? \square_1 Not at all \square_2 A little bit \square_3 Moderately \square_4 Quite a bit \square_5 Extremely
roQol Thermometer Response
sponse to the EuroQoL thermometer:
, ,
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Patient Number: site #

patient #

Patient's Initials: _______

24-Month

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.

Heart failure affects different people in different ways. Some feel shortness of breath while others feel fatigue. 1 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 your	self:		2	3	4	5	6
Showering/bo	athing:		2	3	4	5	6
Walking 1 blo	ck on level ground:		2	3	4	5	6
Doing yard w or carrying gr	ork, housework oceries:			\square_3	4	5	6
Climbing a flig stairs without	*		2	3		5	6
Hurrying or jo (as if to catch a bu			2	\square_3	4	5	6
-	<u>th 2 weeks ago</u> , hav of heart failure hav Slightly			art failure (shor Slightly	tness of breath, : Much		a swelling) changed? Id no symptoms
worse	worse	chang 3	ed	better 4	better	over th	he last 2 weeks
	2 weeks, how many when you woke up			elling in your f	eet,		
Every morning	3 or more times a w but not every morn			Less than once a week	Never ove past 2 we		
Over the <u>past</u>	2 weeks, how much	has swellin	g in your f	eet, ankles or le	gs bothered	you? It has	been
Extremely		Somew		Slightly	Not at		I've had
bothersome	bothersome	botherso	ome	bothersome	botherso s	me no	swelling

		See anno	otation p.5 of Base	eline		
⇒-/Ւն	TON					24-Mo
			Patient Number:	site# P	atient # Pa	tient's Initials:
nsas City (Cardiomyop	athy Ques	stionnaire (K	CCQ) (continue	d)	
Over the <u>past 2 v</u>	weeks, on average,	how many time	es has fatigue limite	d your ability to d	lo what you w	anted?
All of	Several	At	3 or more	1-2	Less than	Never
the	times	least once	times per week	times	once	over the
time	per day	a day	but not every day	a week	a week	past 2 weeks
	2	3	4	5	6	7
Over the <u>past 2 v</u>	weeks, how much h	as your fatigu	e bothered you? It he	as been		
Extremely	Quite a bit	Moderately	Slightly	Not at all	l've ho	bd
bothersome	bothersome	bothersome	bothersome	bothersome	no fatig	gue
\Box_1	2	3	4	5	6	-
Over the <u>past 2 v</u>	<u>veeks</u> , on average, l	now many times	has shortness of br	eath limited your	ability to do wl	hat you wanted?
All of	Several	At	3 or more	1-2	Less than	Never
the	times	least once	times per week	times	once	over the
time	per day	a day	but not every day	a week	a week	past 2 weeks
		□_3 Î		5	6	
Juar the nast 2 .	weeks how much h	ar your chorin	ess of breath both	arad you? It has h		
Extremely	Quite a bit	Moderately		Not at all	l've had	no
bothersome	bothersome	bothersome	bothersome	bothersome	shortness of	
						bream
Over the nast 2	weeks on average	how many time	es have you been for	red to sleep sittin	a un in a chair	or with
	to prop you up be		•	ced to sleep sinni	g op in a chai	or with
	3 or more times	1-2	Less than	Never		
Every	a week, but	times	once	over the		
night	not every night	a week	a week	past 2 weeks		
	2	3	4	5		
leart failure sy	ymptoms can worse	en for a number	of reasons. How sur	re are you that yo	u know what t	o do or
vho to call, if yo	ur heart failure g	ets worse?				
Not at all	Not very	Somewhat	Mostly	Completely		
sure	sure	sure	sure	sure		
	2	3	4	5		
			ble to do to keep yo	or heart failure	symptoms fro	m getting
vorse (for example,	weighing yourself, eating	g a low-salt diet etc.)!	?			
o not understand	Do not understand	Somewhat	Mostly	Completely		
Do not understand at all		Somewhat understand	Mostly understand	Completely understand		

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≫5-AN(9	LION VION	See a				24-Mo
محكما الم			Patient Number:		patient #	Patient's Initials:
nsas City C	ardiomyop	oathy Questi	ionnaire (K	CCQ) (cor	ntinued)	
Over the <u>past 2 w</u>	eeks, how much l	has your heart fai	lure limited your o	enjoyment o	f life?	
t 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 my enjoyr life at	ment of all	
f you had to sper	d the rest of your	r life with your hea	rt failure the way	y it is <u>right n</u>	<u>ow</u> , how wou	ld you feel about this?
Not at all	Mostly	Somewhat	Mostly	Comple	etely	
satisfied	dissatisfied	satisfied	satisfied	satisfi		
Querthe next 2 u	eeks how often l	have you felt discou	uraged or down in	the dumps	because of yo	ur heart failure?
over me pasi z w	eeks, now onen i					
I felt that way	I felt that way	occasionally	I rarely felt	l neve	r felt	
I felt that way all of the time	I felt that way most of the time	felt that way	that way	that w	vay s	
I felt that way all of the time In How much does y	I felt that way most of the time 2 our heart failur cipation in the foll	occasionally	that way	that w	vay s	may have Does Not Apply or Did Not Do for Other Reasons
I felt that way all of the time 1 How much does y imited your partie Check only one bax of	I felt that way most of the time 	Limited Quite	that way a de? Please indicate ar the <u>past 2 week</u> Moderately	that w how your l s. Slightly	heart failure Did Not Limit at	Does Not Apply or Did Not Do for
I felt that way all of the time inited your partie Check only one bax of Activity	I felt that way most of the time	Limited Quite a Bit	that way a de? Please indicate er the <u>past 2 week</u> Moderately Limited	that w how your l s. Slightly	heart failure Did Not Limit at All	Does Not Apply or Did Not Do for
I felt that way all of the time inited your partie Check only one bax of Activity Hobbies, recreation activities:	I felt that way most of the time our heart failur cipation in the foll r each line.) Severely Limited onal nips friends	Limited Quite a Bit	that way a de? Please indicate er the <u>past 2 week</u> Moderately Limited 3	that w how your l s. Slightly	heart failure Did Not Limit at All	Does Not Apply or Did Not Do for

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HF-ACTION_24MO_1.2_16JUN2003 CRF ANNOTATION VERSION 6.0_11May2004



Sodness:

2 Pessimism:

3 Past Failure:

4 Loss of Pleasure:

5 Guilty Feelings:

6 Punishment Feelings:

a I do not feel sad.

I feel sad much of the time.

I am sad all of the time.

l do not feel like a failure.



Patient Number: site H

Patient's Initials:

Beck Depression Inventory (BDI)

I am so sad or unhappy that I can't stand it.

1 I feel more discouraged about my future than I used to be.

I get as much pleasure as I ever did from the things I enjoy.

, I get very little pleasure from the things I used to enjoy.

a I can't get any pleasure from the things I used to enjoy.

1 feel guilty over many things I have done or should have done.

CRF ANNOTATION VERSION 6.0 11May2004

I feel my future is hopeless and will only get worse.

o I am not discouraged about my future.

1 I have failed more than I should have.

As I look back, I see a lot of failures.

a I feel I am a total failure as a person.

I don't enjoy things as much as I used to.

I don't feel particularly guilty.

1 feel quite guilty most of the time. a I feel guilty all of the time.

I don't feel I am being punished.

, I feel I may be punished.

I expect to be punished.

a I feel I am being punished.

I do not expect things to work out for me.

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.

patient #

7 Self-Dislike:

- ____a I feel the same about myself as ever.
- , I have lost confidence in myself.
- , I am disappointed in myself.
- 3 I dislike myself.

8 Self-Criticalness:

- I don't criticize or blame myself more than usual.
- 3 I blame myself for everything that happens.

9 Suicidal Thoughts or Wishes:

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

10 Crying:

- 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:

- 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.
- a I am so restless or agitated that I have to keep moving or doing something.

12 Loss of Interest:

- 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.

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ATIENT SELF-REPORT FORM

- 1 am more critical of myself than I used to be. I criticize myself for all of my faults.

carry them out.

	ige 8 of Baseline 24-Month
	nt Number: Patient's Initials:
Beck Depression Inventory (BDI) (continued)	site# potient# Aut midde loot
 13 Indecisiveness: I make decisions about as well as ever. I find it more difficult to make decisions than usual. I have much greater difficulty in making decisions than I used to. I have trouble making any decisions. 14 Worthlessness: 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: I have as much energy as ever. I have less energy than I used to have. 	 18 Changes in Appetite (check only one): 0 I have not experienced any change in my appetite. 1 My appetite is somewhat less than usual. 1 My appetite is much less than before. 2 My appetite is much greater than usual. 3 My appetite is much greater than usual. 3 Have no appetite at all. 3 I have no appetite at all. 3 I crave food all the time.
 1 Indiveress energy individual to have. 1 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. 1 a I sleep somewhat more than usual. 1 sleep somewhat less than usual. 	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.
2 ₂₀ I sleep a lot more than usual. 2 _{2b} I sleep a lot less than usual. 3 ₃₀ I sleep most of the day. 3 _{3b} I wake up 1-2 hours early and can't get back to sleep. 17 Irritability: 0 1 am no more irritable than usual.	21 Loss of Interest in Sex: □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ <td< td=""></td<>
1 am more irritable than usual. 2 1 am much more irritable than usual. 3 1 am irritable all the time. Productivity Assessment	See annotation p.61
 How many days have you lost from work and/or your usual ac days Check one of the following to indicate your current employment 	
1 Employed/self-employed full-time (> 30 hours week)3 Stud	

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 patient # Patient's Initials:

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 <u>last 7 days</u>. Please answer each question

Think about all the **vigorous physical activities** that you did in the <u>last 7 days</u>. 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.

 During the <u>last 7 days</u>, 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 <u>last 7 days</u>. 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 <u>last 7 days</u>, 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 \rightarrow 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

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 the time you spent **walking** in the <u>last 7</u> <u>days</u>. 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 <u>last 7 days</u>, 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 <u>last 7 days</u>. 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 <u>last 7 days</u>, how much time did you spend sitting on a weekday?

____ hours per day

or Don't know/not sure

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J		N.	See annotation p.24 of 3-Month	24-Month
4			Patient Number:	Patient's Initials:
N	ledical History			
1	Current NYHA heart failure cla	ISS (check only one):	V	
2		lar Society (CCS) ang	gina class (check only one): No angina I	
	urrent Medications			
Ch 1	<pre>neck "No" or "Yes"; if "Yes", pro Loop diuretic:0 No</pre>	vide the total daily d	lose.	
		1 Furosemide:	d provide the total daily dose: mg Torsemide: mg	
		2 Bumetanide:	mg Other, (specify):	mg
Ch	eck "No" or "Yes" for each mea			
2	Spironolactone:	No1	Yes 16 Calcium channel blocker:	0 No 1 Yes
3	Eplerenone:	🗋 No 📃 1	Yes 17 Insulin:	No Yes
4	Non-loop divretic:	🗋 No 📃 1	Yes 18 Glitazone:	No Yes
_	* *		19 Other oral diabetic agent:	🗆 0 No 🖳 1 Yes
5	Potassium:		20 Thyroid replacement:	🗌 0 No 🔄 1 Yes
0	ACE inhibitor:		21 Selective serotonin	
7	Angiotensin receptor blocker: .			No Yes
8	Beta blocker:	🗆 No 🔲 1	Yes 22 Tricyclic antidepressant:	🗋 ₀ No 🔄 1 Yes
9	Aspirin:	🔄 No 🔄 1	Yes 23 Other antidepressant: (excluding SSRIs and TCAs)	No Yes
10	Antiarrhythmic:	🗋 No 📃 1	Yes 24 Antipsychotic:	
11	Lipid-lowering agent:	🗋 No 📃 1	Yes	
12	Clopidogrel:	🗆 No 📃 1		
13	Coumadin:	🗆 No 🖂 1		
14	Digoxin:	🗋 No 📃 1	27 Sildenafil: Yes	No Yes
15	Nitrate:	🗋 No 📃 1	Yes	
		-	nless instructed by the Duke Clinical Resea	
29	• Other:			No 1 Yes

$\sum_{i=1}^{n}$	a - AC	FLON	See annota	ation p.17 of Baseline	e except PATINS, S	sig 24-Month
Ļ	صمكر المستع			Patient Number:	te # patient #	Patient's Initials:
G	uality of Lif	e—Reason	for Missing	Data		
	e all quality-of-life	-	No → If No:	1 Patient died 2 Patient refused 3 Patient withdrew con 4 Patient missed visit 5 Patient sick 98 Other	sent	
_	-Minute Wo					
	□ _o No → If No:	Specify primary Patient was too Patient cannot Not done due Patient refused Patient died Patient withdre Patient withdre Date of 6-minute Start walk time:	e critically ill walk for technical re to oversight w consent visit walk:/	easons (e.g., a patient who is i	an amputee)	
		None A		the following symptoms eadedness Syncope (RPE) Scale: (6-20)	? (check all that apply)	
2	Were the QOL in	struments complet	ted before or after	r the 6-minute walk? Che	□ ₂ < 3 □ ₃ 30	ore :0 mins after -60 mins after :0 mins after

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See annotation p.26 of 3-Month	site # Patient's	
		Fortent's Innous:
Has the patient had any non-urgent outpatient visits since the last study visit? (Do not include protocol-specified follow-up visits) 📃 No	No ☐1 Yes → Complete the table below.	table below.
Number of Office/ Clinic Visits	Number of Home Visits	
Has the patient had any outpatient cardiac procedures/tests (including \mathbb{KD} limited or orthopedic procedures/tests since the last study visit? $\square_0 \mathbb{N}_0 = \square_1 \mathbb{Y}$ for $\square_1 \mathbb{Y}$ so $\square_1 \mathbb{Y}$ and $\square_1 \mathbb{Y}$ and $\square_0 \mathbb{Y}$ is a formula of the last study visit?	e last study visit?	
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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t study visit? (Do not include protocol-specified follo Number of Office/Clinic Visits Number of Office/Clinic Visits		the last study visit? K page at site.

HF-ACTION_24MO_1.2_16JUN2003

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Outpatient Log

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Potient's Initials: for add int

24–Month

patient # Potient Number: ______ - ___ - ____

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Vot II Complete the table helen:	
Chick where we are a discriminated in the second	
antions having since	

н С	Has the patient required any urgent/emergency care on an outpatient basis since the last study visit? 0 No 0. Yes → Complete the table below.	/emergency car	e on an outpatient basis sin	ce the last study visit?	₀No 🛛 Yes 🕇 🤇	mplete the table below.	
		Number of	Number of Visits Due to	Number of Visits Due	Number of Visits	Number of Visits Due to a	
		Visits Due to	Cardiovascular Disease*	to Non-Cardiovascular	Due to Unknown	Cardiovascular Event Occurring During	
	Outpatient Service Type	Heart Failure*	(other than heart failure)	Disease*	Cause*	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):	nce randomization): .		OR1No ER visit to date 2 Previously recorded	e ded		
3.5	Date of 1st urgent clinic visit due to heart failure exacerbation (since randomization); $\frac{1}{4y}$	to heart failure (exacerbation (since randomizati	-/	yeer OR No	$\hfill \hfill No urgent clinic visit for HF to date \hfill 2 Previously recorded \hfill \hfill No urgent value \h$	
ġ	Other Types of Resource Utilization	Utilization					
-	1 Number of days on home IV infusion for heart failure since the last study visit:	n for heart failur	e since the last study visit: _	days			
7	Since the last study visit, how many days did the patient live in each of the following	days did the pati	ient live in each of the follov	wing			
	Their home: days						
	Caregiver's home (e.g., family and friends):		days				
	Assisted living: days						
	Skilled nursing facility:	, days					
	Acute care hospital: da	days					
	Rehabilitation center:	days					
	Other (specify):		— days				

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See annotation p.28 of 3-Month

24–Month

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Initials:
Patient's
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patient #
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site B
Patient Number:

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.)

No ☐, Yes → If Yes: How many hospitalizations? _

			Primary Cardiac Procedure*	Secondary Cardiac Procedure*	
		Primary Reason	(code/description)	cription)*	Discharge
	Hospitalization:	for Hospitalization*	Record a zero il patient did not have cardiac procedures	ot have cardiac procedures.	Destination*
1 Hospitalization: Admission date:/	Planned Unplanned				
ccur during or w					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ No \ \square_1 \ Yes \rightarrow If Yes: Complete the Cardiovascular Event forms.$					
2 Hospitalization: Admission date:/	Planned Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? \square_0 No \square_1 Yes					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ No$ $\square_1 \ \gamma_{es} \rightarrow If Yes$: Complete the Cardiovascular Event forms.					
3 Hospitalization: Admission date:/	Planned Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? $\Box_0 No \Box_1 Yes$					
Did a cardiovascular event cause or occur during this hospitalization? $\Box_0 N \circ \Box_1 \gamma_{es} \rightarrow$ If Yes: Complete the Cardiovascular Event forms.					
		-			

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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24-Month

ľ		Potient Number: Potient # Potient's Initials:
Т	Telephone Log	
•	Date of call:/	year
	Since the last call, how n	nany times has the patient's provider been contacted due to changes in the patient's
		ig 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 pa	tient performing physical activity (formal or non-formal)?
-		
2	2 Date of call:/	/
	Since the last call, how n	nany times has the patient's provider been contacted due to changes in the patient's
		ig 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?
	, · · · · · · · · · · · · · · · · ·	□ _o No → If No: Indicate primary reason code*:
		1 Yes
	Usual Care Group: Is pa	tient performing physical activity (formal or non-formal)?
3	3 Date of call:/	/
		nany times has the patient's provider been contacted due to changes in the patient's
		ing contacts initiated by patient, patient's family/friend, study personnel, and/or exercise trainer)?
		≥ 1: How many of the contacts resulted in:
	condets	Changes to medications other than diuretics:
		Diuretic dose increases:
		Diuretic dose decreases:
	Everyice Training Group	: Is patient performing the training as prescribed?
	Exercise fraining oroup	$\square_0 \text{ No} \rightarrow If No: Indicate primary reason code*:$
	Usual Care Group: Is pa	tient performing physical activity (formal or non-formal)?
*Se	ee choices on opposite pag	je.

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

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	PROTOCOL = HFACT	ION	NODATA <z< th=""><th>YES></th></z<>	YES>
	STUDYBOOK = DATA	FORMS	S	CONTEXT Final Vis
	FORM = FINAL VISIT		UBJNO	
VISITDT	Patient Numbe	r:	patient #	Potient's Initials: Initials:
te of visit:///////				
day month y	107			
roQoL Questionnaire				
placing a checkmark in one box in				
ich statement best describes your o	wn health state <u>today</u> .		See annotation	p. 3 of Baseline
Mobility:	and the second se			
I have no problems in walking at 1 have some problems in walking				
\square_2 I am confined to bed.				
Self-care:				
1 have no problems with self-care				
2 I have some problems washing o				E
3 I am unable to wash or dress my	self.			
Usual activities (e.g. work, study, housev	vork, family or leisure activities):			·
1 I have no problems with performi	ing my usual activities.			
2 I have some problems with perfo				U
3 I am unable to perform my usual	activities.			
Pain/discomfort:				
1 l have no pain or discomfort.				2
2 I have moderate pain or discomf				-
3 I have extreme pain or discomfor	t.			
Anxiety/depression:				2
1 am not anxious or depressed.				
2 I am moderately anxious or depr				
3 I am extremely anxious or depres	ised.			
\rightarrow Please let your study co	oordinator know that you are re	ady for the l	EuroQoL Thermo	meter worksheet.
-				
ain Assessment				
How much bodily pain have you h	ad during the past 4 weeks (check or	ly one)?		
1 None 2 Very mild 3 N	tild 4 Moderate 5 Severe	6 Very seve	re	
During the past 4 weeks, how mu	ch did pain interfere with your norm	al work (includ	ding both work outside t	he home and housework)?
1 Not at all 2 A little bit	3 Moderately 4 Quite a bit	5 Extremely		
roQol Thermometer R	lesponse			
ponse to the EuroQoL thermomete	r			
	(0-100)			
WHITE and YE	LLOW — Duke Clinical Research In	stitute • Pl	NK — retain at sit	e
TION_FinalVisit_1.2_16JUN2003	2003 DCRI — Confider	tial		CRF, page 1



See annotation p. 4 of Baseline

Final Visit

Potient Number: _______

patient

Patient's Initials:

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 your	self:		2	3	4	5	6
Showering/bo	ıthing:		2	3	4	5	6
Walking 1 blo	ck on level ground:		2	3	4	5	6
Doing yard w or carrying gr	ork, housework oceries:			3		5	6
Climbing a flig stairs without	r			3	4	5	6
Hurrying or jo (as if to catch a bu			2	3	4	5	6
	th 2 weeks ago, have of heart failure have Stated		oms of hec		ness of breath, Much		
worse	Slightly worse	change	ed	Slightly better 4	better		d no symptoms ne last 2 weeks
	<u>2 weeks</u> , how many when you woke up	-		elling in your fe	et,		
Every morning	3 or more times a we but not every morni	,		Less than once a week	Never ove past 2 we		
Over the <u>past</u>	2 weeks, how much	has swellin g	j in your fe	et, ankles or leg	gs bothered	you? It has	been
Extremely	Moderately	Somew		Slightly	Not at		I've had
bothersome	bothersome	bothersc 3	me	bothersome	botherso	me no	swelling

			See an	notation p. 5 of Ba	seline		
Z	≫-/i\(9	TON					Final V
-	- كمرا المستقل			Patient Number:		nient# Pat	ient's Initials:
7	ancas City C	ardiamyon	the Ouer	tionnaire (K			101 114
Ň							
5	Over the <u>past 2 w</u>	eeks, on average,	how many time	s has fatigue limited	d your ability to d	o what you w	anted?
	All of	Several	At	3 or more	1-2	Less than	Never
	the	times	least once	times per week	times	once	over the
	time	per day	a day	but not every day	a week	a week	past 2 weeks
		2	3	4	5	6	7
	Over the <u>past 2 w</u>	eeks, how much h	as your fatigue	bothered you? It ha	as been		
	Extremely	Quite a bit	Moderately	Slightly	Not at all	l've ha	d
	bothersome	bothersome	bothersome	bothersome	bothersome	no fatig	jue
		2	3	4	5	6	
	Over the past 2 we	<u>eeks</u> , on average, h	ow many times	has shortness of br e	eath limited your o	ability to do wł	nat you wanted?
	All of	Several	At	3 or more	1-2	Less than	Never
	the	times	least once	times per week	times	once	over the
	time	per day	a day	but not every day	a week	a week	past 2 weeks
		2		4	5	6	7
	-			ess of breath bothe			
	Extremely	Quite a bit	Moderately	• •	Not at all	l've had	
	bothersome	bothersome	bothersome	bothersome	bothersome	shortness of	breath
		2	3	4	5	6	
	Over the <u>past 2 w</u>	eeks, on average,	how many time	s have you been for	ced to sleep sitting	g up in a chair	or with
	at least 3 pillows t	to prop you up bed	ause of shortn	ess of breath?			
		3 or more times	1-2	Less than	Never		
	Every	a week, but	times	once	over the		
	night	not every night	a week	a week	past 2 weeks		
		2	3	4	5		
0	Heart failure svi	mptoms can worse	n for a number	of reasons. How sur	e are vou that vo	u know what t	o do or
		r heart failure ge			,,.		
	Not at all	Not very	Somewhat	Mostly	Completely		
	sure	sure	sure	sure	sure		
		2	3	4	5		
		understand what t	hings you are a	ble to do to keep yo	ur heart failure	symptoms from	n getting
1	How well do you	*					
1		weighing yourself, eating	a low-salt diet etc.)?	•			
1		veighing yourself, eating	a low-salt diet etc.)? Somewhat	Mostly	Completely		
1	worse (for example, v	veighing yourself, eating			Completely understand		

シールじ	TON	See annota				Final V
			Patient Number:		patient #	Patient's Initials:
nsas City C	ardiomyop	athy Quest	ionnaire (K	CCQ) (co	ntinued)	
Over the <u>past 2 w</u>	veeks, how much h	nas your heart fai	lure limited your	enjoyment o	of life?	
t has extremely limited my	It has limited my enjoyment of life	It has moderately limited my	 It has slightly limited my 	lt has not my enjoy		
enjoyment of life	quite a bit	enjoyment of life	enjoyment of life	life at	4	
f you had to sper	nd the rest of your	life with your hea	rt failure the wa	y it is <u>right n</u>	10w, how wou	ld you feel about this
Not at all	Mostly	Somewhat	Mostly	Compl	etely	
satisfied	dissatisfied	satisfied	satisfied	satisf		
L_1	2	3	4		5	
Over the <u>past 2 w</u>	<u>veeks</u> , how often h	nave you felt discou	uraged or down in	the dumps	because of yo	ur heart failure?
I felt that way	I felt that way	occasionally	l rarely felt	Ineve	r felt	
I felt that way	I felt that way most of the time		l rarely felt that way	l neve that v		
I felt that way	,				vay	
I felt that way all of the time I How much does y imited your partie Check only one box of	most of the time 	e affect your lifesty owing activities over Limited Quite	that way 	that v e how your <u>(s</u> . Slightly	heart failure Did Not Limit at	Does Not Apply or Did Not Do for
I felt that way all of the time In How much does y imited your partie Check only one bax of Activity	most of the time 	felt that way a ffect your lifesty owing activities over Limited	that way	that v	heart failure Did Not	Does Not Apply
I felt that way all of the time I How much does y imited your partie Check only one box of	most of the time 	e affect your lifesty owing activities over Limited Quite	that way 	that v e how your <u>(s</u> . Slightly	heart failure Did Not Limit at	Does Not Apply or Did Not Do for
I felt that way all of the time inited your partie Check only one box of Activity Hobbies, recreated activities: ntimate relations	most of the time 	e affect your lifesty owing activities over Limited Quite	that way a de? Please indicate er the <u>past 2 week</u> Moderately Limited	that v e how your <u>(s</u> . Slightly	heart failure Did Not Limit at	Does Not Apply or Did Not Do for
I felt that way all of the time inted your partie Check only one box of Activity	most of the time	e affect your lifesty owing activities over Limited Quite	that way a the? Please indicate ar the <u>past 2 week</u> Moderately Limited 3	that v e how your <u>(s</u> . Slightly	heart failure Did Not Limit at	Does Not Apply or Did Not Do for



See annotation p. 7 of Baseline

Final Visit

Patient Number: _ site fi

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.

Sadness:	7 Self-Dislike:
o I do not feel sad.	o I feel the same about myself as ever.
1 feel sad much of the time.	1 have lost confidence in myself.
2 I am sad all of the time.	2 I am disappointed in myself.
3 I am so sad or unhappy that I can't stand it.	3 I dislike myself.
2 Pessimism:	8 Self-Criticalness:
o I am not discouraged about my future.	o I don't criticize or blame myself more than usual.
1 I feel more discouraged about my future than I used to be.	1 am more critical of myself than I used to be.
2 I do not expect things to work out for me.	2 I criticize myself for all of my faults.
a I feel my future is hopeless and will only get worse.	I blame myself for everything that happens.
3 Past Failure:	9 Suicidal Thoughts or Wishes:
o I do not feel like a failure.	I don't have any thoughts of killing myself.
1 I have failed more than I should have.	1 l have thoughts of killing myself, but I would not
2 As I look back, I see a lot of failures.	carry them out.
a l feel I am a total failure as a person.	2 I would like to kill myself.
	3 I would kill myself if I had the chance.
4 Loss of Pleasure:	10 Crying:
🔲 o 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.	. o I don't cry any more than I used to.
2 I get very little pleasure from the things I used to enjoy.	\square_1 Cry more than 1 used to. \square_2 I cry over every little thing.
3 I can't get any pleasure from the things I used to enjoy.	3 I feel like crying, but I can't.
5 Guilty Feelings:	11 Agitation:
o I don't feel particularly guilty.	o I am no more restless or wound up than usual.
1 I feel guilty over many things I have done or should have done	e. I feel more restless or wound up than usual.
2 I feel quite guilty most of the time.	2 I am so restless or agitated that it's hard to stay still.
3 I feel guilty all of the time.	3 I am so restless or agitated that I have to keep
	moving or doing something.
5 Punishment Feelings:	12 Loss of Interest:
o I don't feel I am being punished.	Loss of merest.
1 feel I may be punished.	\square_{0} have not os interested in other people or dotvines.
2 I expect to be punished.	than before.
□ ₃ I feel I am being punished.	
	It's hard to get interested in anything.

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See annotation p. 8 of Baseline

Final Visit

	Patient Number: patient # Patient's Initials:
Beck Depression Inventory (BDI) (continue	ued)
 13 Indecisiveness: I make decisions about as well as ever. I find it more difficult to make decisions than usual. I have much greater difficulty in making decisions than I used to. I have trouble making any decisions. 	 18 Changes in Appetite (check only one): I have not experienced any change in my appetite. My appetite is somewhat less than usual. My appetite is somewhat greater than usual. My appetite is much less than before. My appetite is much greater than usual.
 Worthlessness: I do not feel I am worthless. I don't consider myself as worthwhile and useful as I used I feel more worthless as compared to other people. I feel utterly worthless. 	a I have no appetite at all. ab I crave food all the time. ito. 19 Concentration Difficulty: ab I can concentrate as well as ever. 1 I can't concentrate as well as usual.
 15 Loss of Energy: 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. 	 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 get more tired or fatigued more easily than usual.
16 Changes in Sleeping Pattern (check only one):o I have not experienced any change in my sleeping patter	$\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfill\hfi$
2° I sleep a lot more than usual. 2° I sleep a lot less than usual. 3° I sleep most of the day. 3° I wake up 1–2 hours early and can't get back to sleep.	 21 Loss of Interest in Sex: 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.
 17 Irritability: 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.	See annotation p.61 for OUTPUT2
Productivity Assessment	
	ual activities in the past 30 days due to problems with your health?
Check one of the following to indicate your current empl Employed/self-employed full-time /> 30 bours week!	loyment status:

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2 Employed part-time (specify hours per week):

4 Homemaker

6 Disabled

a Retired

CHOMORY CARLON

See annotation p. 9 of Baseline

Final Visit

			Patient Number:	ber:	potient #		Patient's Initials: for edde for	in la
Perceived Social Support Scale (PSSS)								
We are interested in how you feel about the following statements. Read each statement carefully. Please check the box that most dosely corresponds to how you feel about each statement, from very strongly disagree to very strongly agree.	ach statement it each statem	carefully. ient, from very	y strongly dis	agree to very	strongly agre	ú		
	Very Strongly Disagree	Strongly Disagree	Mildly Disogree	Neutral	Mildly Agree	Strongly Agree	Very Strongly Agree	ΡA
There is a special person who is around when I am in need:				"	د ا	°	_	TIE
2 There is a special person with whom I can share joys and sorrows:		2	–	"	2		_	ΝT
3 My family really tries to help me:			"	4	5	°	_	SE
4 I get the emotional help and support I need from my family:				4	2	°	7	LF
5 I have a special person who is a real source of comfort to me:			_	4	5	°	7	- R I
6 My friends really try to help me:				–	\$	¢	7	ΡO
7 I can count on my friends when things go wrong:			_	4	5	°	_	RT
8 I can talk about my problems with my family:			_	4	5	°	_ ,	FC
9 I have friends with whom I can share my joys and sorrows:				4	5	°	Π,) R /
10 There is a special person in my life who cares about my feelings:	Ľ			,	s	°	Π,	N
11 My family is willing to help me make decisions:	Ĺ		_	1	s	°	Π,	
12 I can talk about my problems with my friends:		2		,	ی ا	•	_	
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Final Visit

Patient Number: _____ - ____ patient #

Potient's Initials: _______

Physical	Activity	Quest	ionnaire	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 <u>last 7 days</u>. 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 <u>last 7 days</u>. 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.

 During the <u>last 7 days</u>, 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 <u>last 7 days</u>. 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 <u>last 7 days</u>, 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 <u>last 7</u> <u>days</u>. 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 <u>last 7 days</u>, on how many days did you walk for at least 10 minutes at a time?

____ days → Continue to question 6.

- or \square No walking \rightarrow Skip to question 7.
- 6 How much time did you usually spend walking on one of those days?



or Don't know/not sure

The last question is about the time you spent **sitting on weekdays** during the <u>last 7 days</u>. 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 <u>last 7 days</u>, how much time did you spend sitting on a weekday?

_ ___ hours per day

or Don't know/not sure

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J		See ann	notation p. 2	24 of 3-Month	Fir	nal Visit
L			Po	tient Number: potient #	Patient's Initi	ols:
N	ledical History					
1	Current NYHA heart failure clas	ss (check only one)	: 🛛 I 🖂 I	□ III □ IV		
2	Current Canadian Cardiovascul	ar Society (CC	S) angina cla	is (check only one): No angina I		IV
C	urrent Medications					
Cł	neck "No" or "Yes"; if "Yes", prov	vide the total d	aily dose.			
1	Loop divretic: $\square_0 \text{ No}$ $\square_1 \text{ Yes} \rightarrow \text{ If Yes}$:		в:	e the total daily dose: mg Torsemide: mg mg ₉₈ Other, (specify):		mg
Cł	neck "No" or "Yes" for each med		_			
2	Spironolactone:	No	1 Yes	16 Calcium channel blocker:	0 No	1 Yes
3	Eplerenone:	🗌 0 No	1 Yes	17 Insulin:		Yes
4	Non-loop diuretic:	🗌 0 No	1 Yes	18 Glitazone:		
5	Potassium:	🗌 0 No	1 Yes	 Other oral diabetic agent: Thyroid replacement: 	-	-
6 -	ACE inhibitor:	-	-	21 Selective serotonin		
7	Angiotensin receptor blocker:			reuptake inhibitor:	_	
8	Beta blocker:	-	-	22 Tricyclic antidepressant:		
	Aspirin:			23 Other antidepressant:	🔄 ₀ No	Yes
	Lipid-lowering agent:			24 Antipsychotic:	-	
12	Clopidogrel:	🗆 No	Yes	25 NSAID:		
13	Coumadin:	🗌 0 No	Yes	26 COX-2 inhibitor:		
14	Digoxin:	🗌 0 No	1 Yes	27 Sildenafil:		1 res
15	Nitrate:	🗌 0 No	Yes			
		-		structed by the Duke Clinical Res		
	8 Other:				No	
29	• Other:				No	1 Yes

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See annotation p. 17 of Baseline except PATINS, SIG

	Patient Number: patient t	Potient's Initials:
Quality of Life—Reason for Missing	y Data	
Are all quality-of-life forms complete? $\square_0 \text{ No} \rightarrow \text{ If No:}$ $\square_1 \text{ Yes}$	 Patient died Patient refused Patient withdrew consent Patient missed visit Patient sick 98 Other 	
6–Minute Walk Test		
1 Did the patient attempt the 6-minute walk at this visi	it?	
 Not done due to oversight Patient refused Patient died Patient withdrew consent Patient missed visit Total distance walked: 	reasons (e.g., a patient who is an amputee)	
	eadedness Syncope	
Borg Rating of Perceived Exertion	(RPE) Scale:(6-20)	
2 Were the QOL instruments completed before or after		Before 2 < 30 mins after 3 30-60 mins after 4 > 60 mins after

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Final Visit

2

See annotation p. 26 of 3-Month

Final Visit

Patient's Initials: for made int

Patient Number: ______ = _____ _____

	patient Log	
	5	
ľ	0	

-	1 Has the patient had any non-urgent outpatient	If outpatient visits si	visits since the last study visit? (Do not include protocol-specified follow-up visits) \Box_0 No \Box_1 Yes \rightarrow Complete the table below.	col-specified follow-up visi	4s) _0 No _1 Yes → Complete the	table below.
	Provider Type		Number of Office/ Clinic Visits	risits	Number of Home Visits	
7	Cardiologist:					
1.2	Orthopedic surgeon:					
1.3	Other specialist:					
1.4	Primary care physician:					
1.5	Physician extenders (indudes NPs, PAs, etc.):	PAs, etc.):				
1.6	OT or PT:					
1.7	Mental health provider:					
1.8	${\sf Nurse}$ (includes RNs, LPNs, nurse's aides ar other equivalent);	es ar ather equivalent);				
1.9	Other (specify):					
я 1	Has the patient had any outpatient cardiac pro $\square_0 N_0 = \square_1 Y_{es} \rightarrow Compete the table below.$. cardiac procedure table below.	Has the patient had any outpatient cardiac procedures/tests (including ICD lining) or orthopedic procedures/tests since the last study visit? $\square_0 \ No \ \square_1 \ \forall es \rightarrow Compete the table below.$	orocedures/tests sin	ce the last study visit?	
	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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Ŋ			See annotation	See annotation p. 27 of 3-Month	Portient Number:	Potient # Potient's Initials
õ	Outpatient Log					
e	Has the patient required any urgent/emergency care on an outpatient basis since the last study visit?o No Yes → Complete the table below.	emergency car	e on an outpatient basis sin	ce the last study visit?	No 🗌 Yes 🕇 🤉	mplete the table below.
		Number of Visits Due to	Number of Visits Due to Cardiovascular Disease*	Number of Visits Due to Non-Cardiovascular	Number of Visits Due to Unknown	Number of Visits Due to a Cardiovascular Event Occurring During
	Outpatient Service Type	Heart Failure*	(other than heart failure)	Disease*	Cause*	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):	ce randomization);	day //	or,No ER visit to date	he ded	
3.5	Date of 1 st urgent clinic visit due to heart failure exacerbation (since randomization): $\frac{1}{4a_{y}}$	o heart failure	ex acerbation (since randomizati	-/	year OR No	$_{\rm 1}$ No urgent clinic visit for HF to date $_{\rm 2}$ Previously recorded
ō	Other Types of Resource Utilizat	Utilization				
-	1 Number of days on home IV infusion for heart failure since the last study visit:	for heart failur	e since the last study visit: _	days		
2	Since the last study visit, how many days did the patient live in each of the following	lays did the pat	ient live in each of the follo	wing		
	Their home: days					
	Caregiver's home (e.g. family and friends):		days			
	Assisted living: days					
	Skilled nursing facility:	days				
	Acute care hospital: da	days				
	Rehabilitation center:	days				
	Other (specify):		— days			
• Prin	* Primary diagnosis					

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This is a repeating page First page should have page rep 0	rep 0			ï	Final Visit
See	See annotation p. 28 of 3-Month		Patient Number: =	patient # Patient's Ini	Patient's Initials for made for
Hospitalization Record only hospitalizations for ≥ 24 hours.					
Has the patient been hospitalized for any reason since the last completed study visit?	ed study visit?				
			Primary Cardiac Procedure*	Secondary Cardiac Procedure*	
	Hospitalization:	Primary Reason for Hospitalization*	(code/description)* Record a zero if patient did not have cardiac procedures.	code/description)* lient did not have cardiac procedures.	Discharge Destination*
	Planned				
	Unplanned				
ccur during or v					
Did a cardiovascular event cause or occur during this hospitalization? \square_0 No \square_1 Yes \rightarrow If Yes: Complete the Cardiovascular Event forms.					
2 Hospitalization: Admission date:/	Planned Unplanned				
ccur during or v					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ No \ \square_1 \ \forall es \rightarrow If Yes: Complete the Cardiovascular Event forms.$					
3 Hospitalization: Admission date:/	Planned Unplanned				
œur during or v					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ No \ \square_1 \ \forall es \rightarrow If Yes$: Complete the Cardiovascular Event forms.					

* 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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*See choices on opposite page.

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

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VISITDT	Patient Number:	SUBJNO	Patient's Initials:	IAL
		site# patient#	Sut e	niddle
ate of visit:///				
uroQoL Questionnaire				
y placing a checkmark in one box ir hich statement best describes your «	n each group below, please indicate own bealth state today	See ennet	tation p. 3 of Baseline	
-	in near state <u>reary</u> .	See annot	ation p. 5 of baseline	
Mobility:	have			
1 have no problems in walking a 2 have some problems in walking				
1 am confined to bed.	g abour.			
Self-care:				
1 I have no problems with self-care	е.			F
2 I have some problems washing a				E
3 I am unable to wash or dress my				F
				ŀ
Usual activities (e.g. work, study, house				E
1 have no problems with perform				
2 I have some problems with perfo				
3 I am unable to perform my usua	l activities.			t
Pain/discomfort:				F
1 l have no pain or discomfort.				E
2 I have moderate pain or discom	fort.			
3 I have extreme pain or discomfo				5
Anviete/descession				
Anxiety/depression:				Ľ
1 am moderately anxious or depressed.	rorred			
2 I am initiateralely anxious or depre				
3 r am exitemely anxiets of depre				
→ Please let your study c	oordinator know that you are ready f	or the EuroQoL The	ermometer worksheet.	
ain Assessment				
am Assessment				
	had during the past 4 weeks (check only one)			
1 None 2 Very mild 3 A	Mild 🔄 4 Moderate 🔤 5 Severe 🔤 6 V	ery severe		
	ch did pain interfere with your normal wa	· +	utside the home and housework)	?
1 Not at all 2 A little bit	3 Moderately 4 Quite a bit 5 Extre	mely		
uroQol Thermometer I	Response			
esponse to the EuroQoL thermomete	-			
sponse to me corococ mermomere	(0-100)			
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Potient Number: ______ - .

Patient's Initials:

patient #

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 <u>past 2 weeks</u>.

(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 you	rself:		2	3	4	5	6
Showering/b	athing:		2	3	4	5	6
Walking 1 bl	ock on level ground:		2	3	4	5	6
Doing yard w or carrying g	vork, housework roceries:		 2	_ 3		5	6
Climbing a fli stairs without	•		2	_ 3	4	5	6
Hurrying or j (as if to catch a b			2	3	4	5	6
	<u>ith 2 weeks ago</u> , have s of heart failure have		oms of hea	rt failure (shart)	ness of breath,	fatigue, or ankle	swelling) changed?
Much worse	Slightly worse	Not change 3	d	Slightly better 4	Much better □_s		d no symptoms ne last 2 weeks
-	<u>t 2 weeks</u> , how many s when you woke up			lling in your fe	et,		
Every morning	3 or more times a we but not every mornin 2			Less than once a week	Never ove past 2 we		
Over the <u>pas</u>	t 2 weeks, how much	has swelling	in your fe	et, ankles or leg	s bothered	you? It has	been
Extremely bothersome	,	Somew botherso		Slightly bothersome	Not at botherso		I've had swelling

ansas City Ca Over the <u>past 2 we</u> All of the time 	eks, on average, Several times per day		Patient Number: Stionnaire (Ko as has fatigue limited 3 or more times per week but not every day	CCQ) (continue	d) lo what you wa Less than once	ient's Initials:
Over the <u>past 2 we</u> All of the time	eks, on average, Several times per day	how many time At least once	s has fatigue limited 3 or more times per week	d your ability to d 1-2 times	lo what you we Less than once	
Over the <u>past 2 we</u> All of the time	eks, on average, Several times per day	how many time At least once	s has fatigue limited 3 or more times per week	d your ability to d 1-2 times	lo what you we Less than once	
the time	times per day 2	least once	times per week	times	once	Never
	per day					
		a day	but not every day	a week	m	over th
	□_2	3		u week	a week	past 2 we
Over the past 2 we			4	5	6	7
-	eks, how much h	as your fatigue	bothered you? It ha	ıs been		
Extremely	Quite a bit	Moderately	Slightly	Not at all	l've ha	d
bothersome	bothersome	bothersome	bothersome	bothersome	no fatig	ue
	2	3	4	5	6	
Over the past 2 wee	<u>ks</u> , on average, h	ow many times	has shortness of br e	eath limited your	ability to do wh	at you wante
All of	Several	At	3 or more	1-2	Less than	Never
the	times	least once	times per week	times	once	over th
time	per day	a day	but not every day	a week	a week	past 2 we
	2		4	5	6	7
Over the <u>past 2 we</u>	<u>eks</u> , how much h	as your shortn e	ess of breath bothe	red you? It has b	een	
Extremely	Quite a bit	Moderately	Slightly	Not at all	l've had	no
bothersome	bothersome	bothersome	bothersome	bothersome	shortness of	breath
	2	3	4	5	6	
-	-	-	s have you been for	ced to sleep sitting	g up in a chair	or with
at least 3 pillows to	prop you up bed	ause of shortn	ess of breath?			
	3 or more times	1-2	Less than	Never		
Every	a week, but	times	once	over the		
night	not every night	a week	a week	past 2 weeks		
	2	3	4	5		
Heart failure sym who to call, if your			of reasons. How sur	e are you that yo	u know what to	o do or
Not at all	Not very	Somewhat	Mostly	Completely		
sure	sure	sure	sure	sure		
	2			5		
How well do you u	nderstand what t	hings you are a		-	symptoms from	n gettir
Do not understand D		Somewhat	Mostly	Completely		

understand

4

understand

5

at all

 \Box_1

very well

understand

_____3

Year 3

first middle last

PATIENT SELF-REPORT FORM

ショルレ	TON	See annot	tation p. 6 of Ba	seline		Ye
			Patient Number:		patient #	Patient's Initials:
nsas City C	ardiomyop	athy Quest	ionnaire (K	CCQ) (cont	inued)	
Over the <u>past 2 w</u>	veeks, how much h	nas your heart fai	lure 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 li my enjoym life at c s	ent of	
If you had to spe	nd the rest of your	life with your hea	rt failure the wa	y it is <u>right no</u>	w, how wou	ld you feel about this
Not at all	Mostly	Somewhat	Mostly	Complet	tely	
satisfied	dissatisfied	satisfied	satisfied	satisfie	d	
Over the <u>past 2 v</u>	<u>veeks</u> , how often h		•	the dumps b		or heart failure?
I felt that way	I falt that way	loccasionally	rarely tell			
I felt that way	I felt that way	l occasionally	I rarely felt			
all of the time	most of the time	felt that way	that way	that wa	у	
all of the time	most of the time 		that way	that wa s e how your h	у	e may have Does Not Apply or Did Not Do for Other Reasons
all of the time	most of the time 	felt that way a affect your lifesty owing activities over Limited Quite	that way 	that wa s e how your he <u>ss</u> . Slightly	eart failure Did Not Limit at	Does Not Apply or Did Not Do for
all of the time	most of the time	felt that way a affect your lifesty owing activities over Limited Quite a Bit	that way 	that wa s e how your he <u>ss</u> . Slightly	eart failure Did Not Limit at	Does Not Apply or Did Not Do for
all of the time	most of the time	felt that way a affect your lifesty owing activities over Limited Quite a Bit	that way 	that wa s e how your he <u>ss</u> . Slightly	eart failure Did Not Limit at	Does Not Apply or Did Not Do for

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Patient Number: _______ - ____

Potient's Initials:

Beck Depression Inventory (BDI)

This questionnaire consists of 21 groups of statements. Please h read each group of statements carefully, and then pick out a the **one statement** in each group that best describes the way you have been feeling during the **past one week**, m **including today**. Check the box beside the statement you **1** Sadness:

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.

patient #

 Sadness: o 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. Pessimism: o I am not discouraged about my future. 	 7 Self-Dislike: o I feel the same about myself as ever. 1 have lost confidence in myself. 2 I am disappointed in myself. 3 I dislike myself. 8 Self-Criticalness: o I don't criticize or blame myself more than usual.
 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. 	 1 am more critical of myself than I used to be. 1 criticize myself for all of my faults. 1 blame myself for everything that happens.
 Past Failure: O 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. 	 Suicidal Thoughts or Wishes: 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.
Loss of Pleasure:	10 Crying:
 Guilty Feelings: I don't feel particularly guilty. I feel guilty over many things I have done or should have done. I feel guilty most of the time. I feel guilty all of the time. 	11 Agitation: I am no more restless or wound up than usual. I leel 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.
 Punishment Feelings: 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. 	 Loss of Interest: 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. I have lost most of my interest in other people or things.

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See annotation p.8 of Baseline



Patient Number: ______

Potient's Initials: Aut middle lost

patient #

eck Depression Inventory (BDI) (continued)	
3 Indecisiveness:	18 Changes in Appetite (check only one):
o I make decisions about as well as ever.	I have not experienced any change in my appetite.
1 I find it more difficult to make decisions than usual.	
2 I have much greater difficulty in making decisions	_{1a} My appetite is somewhat less than usual.
than I used to.	1b My appetite is somewhat greater than usual.
3 I have trouble making any decisions.	2a My appetite is much less than before.
	_{2b} My appetite is much greater than usual.
4 Worthlessness:	3 _a I have no appetite at all.
o I do not feel I am worthless.	_{ab} I crave food all the time.
I don't consider myself as worthwhile and useful as I used to.	
2 I feel more worthless as compared to other people.	19 Concentration Difficulty:
3 I feel utterly worthless.	o I can concentrate as well as ever.
	I can't concentrate as well as usual.
5 Loss of Energy:	It's hard to keep my mind on anything for very long.
o I have as much energy as ever.	I find I can't concentrate on anything.
1 I have less energy than I used to have.	
2 I don't have enough energy to do very much.	20 Tiredness or Fatigue:
I don't have enough energy to do anything.	I am no more tired or fatigued than usual.
	I get more tired or fatigued more easily than usual.
6 Changes in Sleeping Pattern (check only one):	1 am too tired or fatigued to do a lot of the things
I have not experienced any change in my sleeping pattern.	I used to do.
a l sleep somewhat more than usual.	a I am too tired or fatigued to do most of the things I
□ _{1b} I sleep somewhat less than usual.	used to do.
$_{1b}$, even of the manufacture share the state $_{1b}$, even $_{2a}$ is share the state $_{2a}$ i	
2_{a} i sleep a lot less than usual.	21 Loss of Interest in Sex:
	o I have not noticed any recent change in my
3 _{3a} I sleep most of the day.	interest in sex.
_{ab} I wake up 1–2 hours early and can't get back to sleep.	1 am less interested in sex than I used to be.
-	2 I am much less interested in sex now.
7 Irritability:	3 I have lost interest in sex completely.
o I am no more irritable than usual.	
1 am more irritable than usual.	
2 I am much more irritable than usual.	
3 I am irritable all the time.	
	See annotation p.61 for OUTPUT2
Productivity Assessment	
How many days have you lost from work and/or your usual act	ivities in the past 30 days due to problems with your health?
days	
Check one of the following to indicate your current employme	

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s Volunteer

, Disabled

, Unemployed

, Retired

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2 Employed part-time (specify hours per week); _

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□₃ Student

, Homemaker





Year 3

Patient Number: _____ - ____ patient #

Patient's Initials: _______

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 <u>last 7 days</u>. Please answer each question

Think about all the **vigorous physical activities** that you did in the <u>last 7 days</u>. 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.

 During the <u>last 7 days</u>, 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 <u>last 7 days</u>. 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 <u>last 7 days</u>, 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

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 the time you spent **walking** in the <u>last 7</u> <u>days</u>. 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 <u>last 7 days</u>, on how many days did you walk for at least 10 minutes at a time?
 - ____ days → Continue to question 6.

OR \square No walking \rightarrow 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 <u>last 7 days</u>. 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 <u>last 7 days</u>, how much time did you spend sitting on a weekday?

____ hours per day

OR Don't know/not sure

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See annotation p.24 of 3-Month



Year 3

Ę			Patient Number: patient #	_ Patient's Initials:
N	Aedical History			
1	Current NYHA heart failure	class (check only one):		
2	Current Canadian Cardiova	scular Society (CCS) angina	class (check only one): No angina	
С	urrent Medications	5		
Ch	heck "No" or "Yes"; if "Yes", p	provide the total daily dose.		
1	Loop diuretic: $\square_0 \text{ No}$	Yes: Check only one and pro	wide the total daily doce:	
		Furosemide:	mg Toremide: mg	
		2 Bumetanide:	mg Other, (specify):	mg
Ch	heck "No" or "Yes" for each n	nedication.		
2	Spironolactone:	ONO 1 Yes	16 Calcium-channel blocker:	0 No 1 Yes
3	Eplerenone:	0 No 1 Yes	17 Insulin:	
4	Non-loop diuretic:		18 Glitazone:	
	(excluding aldosterone antagonist)		19 Other oral diabetic agent:	🗆 No 🔄 1 Yes
5	Potassium:	0 No 1 Yes	20 Thyroid replacement:	
6	ACE inhibitor:	No Yes	21 Selective serotonin	
7	Angiotensin receptor blocke	r:	reuptake inhibitor:	
8	Beta blocker:		22 Tricyclic antidepressant:	0 No 1 Yes
9	Aspirin:	No Yes	23 Other antidepressant:	No Yes
10	O Antiarrhythmic:		(excluding SSRIs and TCAs)	
11	Lipid-lowering agent:	No Yes	24 Antipsychotic:	0 No 1 Yes
	2 Clopidogrel:		25 NSAID:	No Yes
			26 COX-2 inhibitor:	No Yes
	3 Coumadin:		27 Sildenafil:	
14	4 Digoxin:	0 No 1 Yes		
15	5 Nitrate:	0 No 1 Yes		
1			s instructed by the Duke Clinical Reso	
	8 Other:			No Yes
29	9 Other:			No Yes

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	See annotation p.17 of Baseline excep	ot PATINS, SIG	Year 3
	Potient Number:	Patient #Pati	ient's Initials: det midde last
Quality of Life—Reason fo	r Missing Data		
	o No → If No: Patient died Patient refused Patient withdrew consent Patient missed visit S Patient sick Pgg Other Yes		
6–Minute Walk Test			
1 Did the patient attempt the 6-minute w	alk at this visit?		
 Not done due to a Patient refused Patient died Patient withdrew a Patient missed visit 1 Yes → If Yes: Date of 6-minute was Start walk time: Total distance walke 	itically ill Ik for technical reasons (e.g., a patient who is an amputee, oversight consent t alk:/		
None Angir	erience any of the following symptoms? (check all na Light-headedness Syncope eived Exertion (RPE) Scale: (6-20)	that apply)	
2 Were the QOL instruments completed	before or after the 6-minute walk? Check only a	one:1Before 2 < 30 mins 3 30-60 mi 4 > 60 mins	ins after

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See annotation p.26 of 3-Month

Patient Number: _______ - _____ Patient # Patient's Initials ______

Year 3

Outpatient Log

-	Has the patient had any non-urge n	nt outpatient visits si	Has the patient had any non-urgent outpatient visits since the last study visit? (Do not include protocol/specified followup visits) \Box_0 No \Box_1 Yes \rightarrow Complete the table below.	col-specified follow-up vis	^{±±}} □ No □, Yes → Complete the	table below.
	Provider Type		Number of Office/ Clinic Visits	risits	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.);	, PAs, etc.)t				
1.6	OT or PT:					
1.7	Mental health provider:					
1.8	 Nurse (includes RNs, LPNs, nurse's aides or other equivalent); 	les ar ather equivalent):				
1.9	Other (specify):					
2	Has the patient had any outpatient cardiac pro □_ ₀ No □_1 Yes → Compete the table below.	t cardiac procedure table below.	Has the patient had any outpatient cardiac procedures/tests {including KD fining} or orthopedic procedures/tests since the last study visit? □_0 No □_1 Yes → Compete the table below.	procedures/tests sin	ce the last study visit?	
	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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s and a second s	A AMON		See annota	See annotation p.27 of 3-Month		Year 3	3
				Potien	Portient Number:		1
õ	Outpatient Log						
т Ю	Has the parient required any urgent/emergency cure on an outpatient basis since the last study visit?o No1 Yes → Complete the table below.	i/emergency car	e on an outpatient basis sin	ce the last study visit?	₀ No □1 Yes ↓ C	mplete the table below.	
		Number of Visits Due to	Number of Visits Due to Cardiovascular Disease*	Number of Visits Due to Non-Cardiovascular	Number of Visits Due to Unknown	Number of Visits Due to a Cardiovascular Event Occurring During	
	Outpatient Service Type	Heart Failure*	(other than heart failure)	Disease*	Cause*	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):	nce randomization);		or, No ER visit to date	e		
3.5	Date of 1 st urgent clinic visit due to heart failure exacerbation (since randomization): $\frac{1}{4\eta}$	to heart failure (exacerbation (since randomizati	_/	year OR No	 No urgent clinic visit for HF to date Previously recorded 	
ð	Other Types of Resource Utilization	Utilization					
z	Number of days on home IV infusion for heart failure since the last study visit:	n for heart failur	e since the last study visit: .	days			
2	Since the last study visit, how many days did the patient live in each of the following	days did the pati	ient live in each of the follo	wing			
	Their home: days						
	Caregiver's home (e.g. family and friends):		days				
	Assisted living: days						
	Skilled nursing facility:	- days					
	Acute care hospital: do	days					
	Rehabilitation center:	days					
	Other (specify):		— days				
* Prima	* Primary diagnosis						

CRF, page 1 10 (2 of 2)

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See annotation p.28 of 3-Month

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Year 3

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.)

No Yes → If Yes: How many hospitalizations?

			Primary Cardiac Procedure*	Secondary Cardiac Procedure*	
		Primary Reason	(code/dea	code (description) *	Discharge
	Hospitalization:	for Hospitalization*	Record a zero if patient did not have cardiac procedures.	ot have cardiac procedures.	Destination*
1 Hospitalization: Admission date:/	Dlanned Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? $\square_0 \land o$					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \text{ No} \square_1 \text{ Yes} \rightarrow \text{ If Yes: Complete the Cardiovascular Event forms.}$					
2 Hospitalization: Admission date: <u>day / mark</u> / <u>mark</u> / <u>mar</u>	Planned Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? \square_0 No \square_1 Yes					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 N \circ \square_1 \forall es \rightarrow If Yes$: Complete the Cardiovascular Event forms.					
3 Hospitalization: Admission date:/	Planned Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? $\square_0 \ \begin{tabular}{ c c c c c c c c c c c c c c c c c c c$					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 N_0 = \square_1 Y_{es} \rightarrow If Yes$: Complete the Cardiovascular Event forms.					
'See choices on opposite page. If a diagnosis/procedure/discharge destination is not listed, please record it in the table above.	tination is not liste	sd, please record it in t	he table above.		

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

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*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

Usual Care Group: Is patient performing physical activity (formal or non-formal)?

	CONTEXT
	ODATA <zyes></zyes>
	fudy Completion/Death
	SUBJNO INITIALS
site #	Patient's Initials: And middle lost
Study Completion	
Did the patient complete the study? COMPLETE <zyesno></zyesno>	STUDCOMP (TYPE 1)
No → If No: Reason (check only one): NOCMPREA <i:3><accomp> 1 Patient lost to follow-up</accomp></i:3>	DCRI MedDRA
2 Patient withdrew consent	MEDRCODE <v:8>,CONFLVL<v:2></v:2></v:8>
Patient died → Complete section below and submit the disch and/or brief summary describing the out-of-t	arge summar MEDIOTEXTED (100>,MATCHE6 <v:4> WORKFLOW<v:5></v:5></v:4>
and/or brief summary describing the out-ot-t	CODER <v:20></v:20>
2 Did the patient have a permanent disability related to study intervention PERMD	DIS <i:3><acdis></acdis></i:3>
\square_0 No \square_1 NA, patient in the Usual Care group \square_1 Yes \rightarrow If Yes: Check all the	at apply: Musculoskeletal
	Stroke PERMSTRO <zye\$></zye\$>
PERMOTH <z< th=""><th>YES> Other, (specify): Little V. 1007</th></z<>	YES> Other, (specify): Little V. 1007
Death	
	DEATH (TYPE 1)
2 Date of death:/ / DEATHDT	DCRI MedDRA MEDRCODE <v:8>,CONFLVL<v:2></v:2></v:8>
DEATHCAU<	MEDRTEXT <v:100>,MATCHES<v:4></v:4></v:100>
1, Cardiovascular death → Check only one: DEACARD <i:3><accrea></accrea></i:3>	WORKFLOW <v:5> CODETM</v:5>
DCRI MedDRA Sudden death MEDRCQD2 <v:8>,CONFLVL2<v:2> Pump failure</v:2></v:8>	CODER <v:20></v:20>
MEDRTXT2 <v:100>.MATCHES2<v:4< th=""><th></th></v:4<></v:100>	
> 3 Fatal myocardial infarction WORKFLW2 <v:5> 4 CVA</v:5>	VPROCSP <v:100></v:100>
CODETM2 _ Cardiovascular procedure-related death → Specific	
	VSP <v:100></v:100>
2 Non-cardiovascular death → Specify: NONCVSP <v:100></v:100>	DCRI MedDRA
3 Juknown	MEDRCOD3 <v:8>,CONFLVL3<v:2></v:2></v:8>
4 Was an autopsy performed? No Yes AUTOPSY <zyesno></zyesno>	MEDRTXT3 <v:100>,MATCHES3<v:4> WORKFLW3<v:5></v:5></v:4></v:100>
5 Was death the direct result of exercise training (during or within three hours after training)?	CODETM3 CODER3 <v:20></v:20>
DEATHEX <i:3><acdth></acdth></i:3>	
1_1 Yes \rightarrow If Yes: Please fax this page within 5 days of knowledge of the patient	-
at (919) 668-7138 and provide a brief narrative of the event.	DEATHSM1 <v:200>no verification</v:200>
	DEATHSM2 <v:200>no verification</v:200>
	DEATHSM3 <v:100>no verification</v:100>
2 Unable to determine	DEATHSING V. TOO/TO Verification
Investigator's Signature	
I have reviewed and found all the case report form data pertaining to this patient to	
Principal Investigator's signature:	See annotation p.17 of Baseline
· · · · · · · · · · · · · · · · · · ·	Date://
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		PROTOCOL	= HFACTIO	N	NODATA <z< th=""><th>YES></th><th>CONTEX</th></z<>	YES>	CONTEX
		FORM= CAR	DIOEVI			ar Ever	
Visit: 1 3-Mont 6 18-Mon	nth 7 21-Month	3 9-Month 4 1 8 24-Month 9 Y	/ear 3 10 Fir	-Month al	CAR	DVIST (1	TYPE 4)
-	rst item of EACH se	-	nts.				
Congestive	e Heart Failure	e (CHF)					
	nt experience a worse ₁ Yes → If Yes: Date de YESNO>				Cr		T (TYPE 4
2 What eviden VFATIGU⋤orsening VDYSPN⋤∳spnea	ce was there of worse /increasing fatigue [WRALES	WGASSJiRGtinal dis	tress Periphe /D Ascites/	ral edema W hepatomegal			WOTHER Other
3 Was the patie	ent treated with intrav	enous diuretics?		Yes	TREDIUR<2	ZYESNO>	
4 Was the patie	ent treated with intrav	enous inotropic age	nts?	Yes	TREINO <z< th=""><th>ESNO></th><th></th></z<>	ESNO>	
5 Was the patie	ent treated with an int	ravenous vasodilato	r? 🗌 N	Yes	TREVASO<	ZYESNO>	
6 Was there sig	nificant augmentation	n (50% increase) of oral	therapy? N	Yes	TREORAL<	ZYESNO>	
		Send copy of the I	lospital Discharge	Summary.			
Myocardia	I Infarction (N	AI)					
 Did the patie 	nt experience a myoco	ardial infarction?					1 (1186 4
2 Was the clinic	1 Yes → If Yes: Date de SNO> cal presentation consis	ocumented:}	No 1 Yes	CLNCALMI	<zyesno></zyesno>		T (TYPE 4
MIEVNT <zye 2 Was the clinic</zye 	1 Yes → If Yes: Date de SNO>	ocumented: $\{day}$ stent with an MI? \square_1 Yes \rightarrow If Yes: Se	No Tres	CLNCALMI surrounding	<zyesno></zyesno>		1 (11764
MIEVNT <zye 2 Was the clinic</zye 	1 Yes → If Yes: Date de SNO> cal presentation consis	ocumented:}	No Tres	CLNCALMI surrounding	<zyesno> the event. ECGS<z< td=""><td></td><td></td></z<></zyesno>		
No MIEVNT <zye 2 Was the clinic 3 Were there E</zye 	1 Yes → If Yes: Date de SNO> cal presentation consis CGs done? □ ₀ No	stent with an MI? → If Yes: Se Send copy of the I → PFAKCKD → month	NO TYPES	Surrounding Summary. OCKTM 00:00 to 23:59	<zyesno> the event. ECGS<z< th=""><th>YESNO> IoneCKND<z< th=""><th>YES></th></z<></th></z<></zyesno>	YESNO> IoneCKND <z< th=""><th>YES></th></z<>	YES>
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This is a repeating page First page should have page rep 0 Patient Number:	Cardiovascular Event Form
Unstable Angina	site # patient # Patient s mindels. That middle loa
Did unstable angina occur? UANG <zyesno> □_0 No □_1 Yes → If Yes: Date documented: UANGDT </zyesno>	UNSTANG (TYPE 4)
Serious Adverse Arrhythmias/Cardiac Arrest	
Did the patient have any serious adverse arrhythmias, including cardiac arrest $\square_0 \text{ NoSAA}$ $\square_1 \text{ Yes} \rightarrow \text{ If Yes: Date documented: } \/\$	est? SAARRH (TYPE 4)
Check "No" or "Yes" for each:	
VENTTACH <zyesnstained tachycardia="" ventricular=""> 30 seconds:</zyesnstained>	
VENTFIB <zyesn@#ricular fibrillation:<="" th=""><th></th></zyesn@#ricular>	
SUPTACH <zyesno> Supraventricular tachycardia with rapid ventricular respor CARREST<zyesno arrest:<="" cardiac="" th=""><th></th></zyesno></zyesno>	
BRADYCRD <zyesno>Bradycardia (heart rate < 50, symptomatic and not felt to be related to</zyesno>	medication):
Stroke	
Did a stroke occur? STROKE <zyesno> $\square_0 \text{ No}$ $\square_1 \text{ Yes} \rightarrow \text{ If Yes: Date documented: } \underline{STROKEDT}_{\text{rearth}} / _{\text{rearth}} / _{\text{rearth}}$</zyesno>	OTHEVENT (TYPE 4)
STRKTYPE <i:3><acstk> Classification (check only one): 1 Ischemic 2 Hemorrhagi</acstk></i:3>	ic 99, Unknown
Send copy of the Hospital Discharge Summary, reports of any CT an	nd MRI scans and neurological consults done.
Transient Ischemic Attack (TIA)	
Did a transient ischemic attack occur? TIA <zyesno> $\square_0 \text{ No}$ $\square_1 \text{ Yes} \rightarrow \text{ If Yes: Date documented: }{day} /{rearth} /{year}$</zyesno>	

		This is a repeating page First page should have	e NO	DATA <yes></yes>	CONTEXT Training Worksheet
i			OL= HFACHON OOK = DATA_FORMS TRAIN WKSHEF	, For Cardi	ac Rehabilitation Programs INITIALS
TRAI	IVIS	S <i:3><actran> Visit: 1 6-Month 2 9-Month 2 27-Month 930-Mont (Protocol requires supervised exerc ADDSESS<zyes></zyes></actran></i:3>	h 10 33-Month 11 Year 3 ise training sessions to be held once every t	1239-Month 13	WKSHEET (TYPE 4) 21-Month 724-Month 42-Month 145-Month 15Final month 6.)
	Vis	it date and time:		AINTM	
	1 2	Weight: <u>TWEIG</u> HT<∰9:8₽ Training heart rate range (assigned b	2 kg TWTUNIT <zwgtu> THRMIN<1:3> ny CPX Core Lab): to</zwgtu>	THRMAX <i:3></i:3>	/IN <i:3> TRPEMAX<i:3></i:3></i:3>
	3 4 5	Resting heart rate: Resting BP: TBPSYS <i:3> TBPSYS ryutofic </i:3>	:3> PDIA <i:3></i:3>		
	6	Exercise(s) performed (check all that a	ւթելծ)։		FREEWALK <zyes></zyes>
		ZY Freedmill exercise Total exercise duration: DUR <f:9:3> </f:9:3>	Bicycle exercise [†] B Total exercise duration: min ^{**} BIKEDUR<	IKE <zyes> <f:9:3></f:9:3></zyes>	Total exercise duration:
SPEED <i:3>A(1=mph 2=km/h</i:3>		Speed:mph SPEED <f: INCLINE<f:9:3> Heart rate:TREADHR@1:3> Borg RPE:TREADRE<1:3></f:9:3></f: 	9:3> BIKEWWATTS<&&> BIK Heart rate: _BIKEHR<& Borg RPE: _BIKERPE&1:3		Heart rate: <u>WALKHR</u> ≴biậ> Borg RPE: <u>WALKRPE</u> <i:3></i:3>
		* For special ** 1	circumstances making measurement of targ fotal exercise duration does not include time umbent bike allowed only during 1st 2 wee "Heart rate should be obtained using Po	for warm up and cool dow ks of training unless prescri	vn.
	7 8	Cool down: O Yes I No Did patient achieve and maintain t			
TDY	TAN SP	Did patient achieve exercise duration ZYES> If patient did not achieve and main NGIMAgina ICD distribute Dyspnea PresyTics by Sympo- Arrhythmia Claudication TCLAUD	ntain training heart rate or exercise Leg fatigue TLEGF ncope Fatigue TFATIGUE Musculoskeletal comp	se duration, check all AT Lack of m Exercise-re plaint Hypoglyc	SETTRDUR <zyesno> that apply to indicate the reason(s): Divation TMOTIV elated fall or injury TINJURY emia THYPOGLY ase specify): - TRAINSP<v:100></v:100></zyesno>
	Ca	rdiac Rehab Staff Signature:	REHABSIG <zyes></zyes>	Facility Name:	FACILNAM <v:50></v:50>
	Ва	atch in sets of 3 and forward or fax con	Cardiac Rehab S	Study Coordinator	
J	HF-AC	TION_SET_1.2_16JUN2003	ordinator: Submit a copy of each co 2003 DCRI - Confid		he DCRI with the CRFs. Supervised Exercise Training Worksheet CRF, page 133

CRF ANNOTATION VERSION 6.0_11May2004

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This is a repeating page Additional Hospitalization

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Patient's Initials
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Patient Numbe
See annotation p. 28 OF 3-Month for HOSPITAL

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			Primary Cardiac Procedure*	Secondary Cardiac Procedure*	
		Primary Reason	(code/description)*	cription)*	Discharge
	Hospitalization:	for Hospitalization*	Record a zero il patient did not have cardiac procedures.	ot have cardiac procedures.	Destination*
1 Hospitalization: Admission date:/	Planned				
Discharge date:/	Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? $\square_0 \land o$					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 No \square_1 \forall es \rightarrow If Yes: Complete the Cardiovascular Event forms.$					
2 Hospitalization: Admission date:/	Planned				
-///	Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? \square_0 No \square_1 Yes					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 No \square_1 Yes \rightarrow$ If Yes: Complete the Cardiovascular Event forms.					
3 Hospitalization: Admission date:/	Planned Unplanned				
cor during or v					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 N_0 = \square_1 Yes \rightarrow If Yes$: Complete the Cardiovascular Event forms.					
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See choices on opposite page. It 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.

C.R.F. page_

HF-ACTION_AH_1.2_16JUN2003

This is a repeating page

	Additional Telephone Log
Т	elephone Log
ı	Date of call://
	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 \rightarrow If \geq 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?
	_ No → If No: Indicate primary reason code*:
	1 Yes
	Usual Care Group: Is patient performing physical activity (formal or non-formal)?
2	Date of call:///
	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 \rightarrow If \geq 1: How many of the contacts resulted in:
	Changes to medications other than divretics:
	Diuretic dose increases:
	Diuretic dose decreases:
	Exercise Training Group: Is patient performing the training as prescribed? □ _o No → If No: Indicate primary reason code*: □ ₁ Yes
	Usual Care Group: Is patient performing physical activity (formal or non-formal)?
3	Date of call:///
	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)?

*See choices on opposite page.

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

CRF ANNOTATION VERSION 6.0_11May2004

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

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			PROTOCOL = HFACTION	HFACTIC	NODATA <zyes></zyes>	<zyes></zyes>	CONTEXT	
Collon			STUDYBOOK = DATA_FORMS FORM= COMPLIANCE	= DATA_F	SUB	xercise	Exercise Compliance	
		This is a repeating page			site #		Partient's Initials: INITIALS for made bar	
Visit: 3-Month 6-Month	9-Month	12-Month 15-Month	onth 18-Month	21-Month	th 🗌 24-Month 📃 Year 3	Final	Same as CARDVIST p.128	0.128
Home Exercise Compliance Complete for exercise training group only.	ompliance _{Complete}	tor exercise trainin	g group only.					_
Date Interval	Primary Target Training Intensity	Total Number of Days of Exercise During Interval	Average Heart Rate (bpm) OR RPE*	Average Exercise Dur chion (minutes)	Compliance Comments (choose one compliance code letter per item)	Patient- Reported Symptom Frequency	HOME COM (TYPE 4) Primary Mode of Exercise During this Time Period	ГҮРЕ 4)
	IHRMIN<		EXERDAY <i:3> AVGHR<f:9:3></f:9:3></i:3>	NGDUR <f:9:3></f:9:3>	COMPFREQ <v:3> Frequency (a or b): 9:3></v:3>	SZMFREQA <i:3>1 Trea</i:3>	SYMFREQA <i:3>1 Treadmill Shurpeopul:3>2 Bike</i:3>	-
ţ	OR		OR		Intensity (c. d. or a): SYMEREQC(1:3>[3] Free walk	SYMFREQC	<1:3>3 Free walk	
dy	RPE* range (6-20): TRPEMIN463> TRPEMAX <i:3></i:3>	JAX <i:3></i:3>	Average RPE *: AVGRPE <f:93></f:93>	3	COMPDUR <v:3>S MIFREQD<i:3> 98 Other buration (f, g, h, or i):S YMFREQE<i:3> SYMFREQE<i:3> Exercise mode (f or k): COMPMODE<v:3> Exercise mode (f or k): COMPMODE<</v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></v:3></i:3></i:3></i:3></v:3>	SMITREOD<1:3> SYMFREQE<1:3> 10DE <v:3> E</v:3>	d:3> [980ther d:3> EQUIP<1:3> <acequi></acequi>	QUI>
Supervised Exercise Training	ise Training							
Did the patient have additional supervised training sessions since the last complete study visit? □_o No □_1 Yes → If Yes: Submit a copy of each Supervised Exercise Training Worksheet.	d the patient have additional supervised training sessions since the last comple ₀ No ₁ Yes → If Yes: Submit a copy of each Supervised Exercise Training Worksheet.	ssions since the last xercise Training Wor	complete study visi A ksheet.	sir? ADDSUPEX <zyesno></zyesno>	ZYESNO>			
* Use RPE only for special circumstances making measurement of the target heart rate invalid	umstances making measu	rement of the target	heart rate invalid.					

Submit WHITE and YELLOW pages to Duke Clinical Research Institute. • Retain PINK page at site. 2003 DCRI – confidential

HF-ACTION_EC_1.2_16JUN2003

Home Compliance, page 132

This	is a repeating page				
	ATION ST	ROTOCOL = HFA IUDYBOOK = DA DRM= MISSED V	TA_FORMS	< ^{ZYES>} COM Missed Visi	NTEXT t Form
		Patient Nur	mber: SUBJNC	Potient's Initials	INITIALS
		the patient missed an entire	e study visit but is continuir	a in the trial. M	/ISITFM (TYPE 4)
	m per missed visit.				
Missed visit (check	only one): MISSVIS <i< th=""><th>:3><acmiss></acmiss></th><th></th><th></th><th></th></i<>	:3> <acmiss></acmiss>			
1 3-Month	3. 9-Month	5 15-Month	7 21-Month	9 Year 3	
2 6-Month	4 12-Month	6 18-Month	8 24-Month		
					
		it the original of each form inder in place of the month		batch of CRF pages.	
maintain a			iy visii pagasi		
					

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.



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://year
2	PRHRMIN <i:3> PRHRMAX<i:3> Prior training intensity:tobpm</i:3></i:3>
	PRRPEMIN <i:3> PRRPEMAX<i:3></i:3></i:3>
2	RVHRMIN <i:3> RVHRMAX<i:3></i:3></i:3>
3	Revised training intensity: to bpm
	OR DVDDEMINALOS RV/RPEMAXALOS
	RVRPEMIN <i:3> RVRPEMAX<i:3></i:3></i:3>
4	Reason for modification: MODREAS <i:3><acmodr></acmodr></i:3>
	(cheak only one)
	1 Change in beta blocker
	2 Other medication change
	3 Atrial fibrillation
	4 Atrial/ventricular ectopy
	98 Other (specify): MODREASP <v:200></v:200>

Instruction s:

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.

Exercise Training Prescription Form Follow-up Prescription

This is a repeating page	PROTOCOL=HF	ACTION	FORM=HO	SPFORM		
First page should have a page rep 1	STUDYBOOK=C	EC				
		lpoint	Classific SUB		Hospitaliz	zation INITIALS
REVTYPE <i:3><acrevu></acrevu></i:3>	Enter this page	Patient N umb	 	parient#	Patient's Initials:	ikt nätie int
Review type: 🛄, Committee member		rdinator 🛛	4 Committee me	eting <mark>5</mark> , Fu	II committee	
6_, QA	7, Re-review				REVIEW1(
Review codes: # <u>CECO</u> DE# <u>R1<</u>	2>CECODER2 <i:2></i:2>	Releas	ed code£≣CC)DER3 *I :2>	. CECOD	ER4 <i:2></i:2>
Endpoint Classification Ho	spitalization Form					
Date of hospitalization:/	CECHSPDT			C	ECHOSP (TYPE 4)
Primary cause of hospitalization 1 , Warsening heart failur CECH 2 , Unstable angina 3 , Myocardial infarction 4 , Cardiovascular procedure 5 , Resuscitated cardiac arrest 6 , Arrhythmia (check only one): Atrial: ARRHTYPE 1 Suproventricular tachycardia 2 Atrial fibrillation/atrial Ventricular: 3 Ventricular tachycardia 4 Ventricular fibrillation Conduction disorder: 5 Brachycardia 6 Heart black 7 Sick sinus node syndra 7 , Other cardiovascular (check ont) 1 , CVA (stroke) OTHCX 2 , Transient ischemic attack 3 , Vascular: Peripheral vas 4 , Presy ncope 5 , Sy ncope 6 , Chest pain 7 , Hypotension 8 , Hype rtension 9 , CV drugs 10 , CV procedure related a 98 , Other 8 , Non-Cardiovascular Additional data needed or rationale	ISPCA <i:3><accau DNUMBHOS<i:6> E<i:3><acatyp> cordia Rutter /TYP<i:3><acotyp color disease</acotyp </i:3></acatyp></i:3></i:6></accau </i:3>	^{\$} > 3.1]] 3.2] 3.3	hospitalization? \bigcirc No \bigcirc Yes \rightarrow IF Yes Did a myocardi \bigcirc No CEC \bigcirc Yes \rightarrow IF Yes Did a constant of Yes	es Date occurre der Date occurre der CECHSP as Date occurre der CECI der CECI der CECI der est cur <u>during</u> the h ISPST <zye es Date occurre</zye 	eart failure occur d HF <zyesno: DNUMBCH HEDT HEDT ESNO> MIDT MIDT SNOP</zyesno: 	> IF <i:6> Italization? BMI<i:6></i:6></i:6>
Additional data needed or rationale		entered				
Reviewer (signature):HS	PREVSG <zyes></zyes>			Donte:	HSPREVDT CRF pa	age 2
HF_ACTION_CEC V2.0 26FEB2004			ENDPO	NT CLASSIFICA	TON-Hospitaliza	tion, page 2
C	RF ANNOTATION V	ERSION	6.0_11May2	2004		

	PROTOCO	_=HFACTION	CONTEXT NODATA <zyes< th=""></zyes<>
	STUDYBOO FORM= DE	DK=CEC ATHFORM Endpoint	Classification–Death
	Enter this page	SUBJ 	NO INITIALS
		J U	
CECODER1< Review codes: # #	I:2> CECODER2< 	I:2> CECODE Released codes: #	ER3 <l:2> CECODER4<l:2></l:2></l:2>
Death Form CECDTHDT			
Dote of death:/	_/	DNUMBDTH <i:6></i:6>	CECDEATH(TYPE4)
2 Cause of death (check anly one): 1, Cardiovascular Death (check arly one): 1, Sudden death 2, Pump failure 3, Fatal myocardial info 4, Fatal myocardial info	CECCVDTH <i:< th=""><th></th><th></th></i:<>		
CVA Gardiovascular proc	edure-related death → Sp	ecify:	CECPRCSP <v:100></v:100>
2, Non-Cardiovascula	r death → Specity:		CECOTHSP <v:100> CECNONSP<v:100></v:100></v:100>
8 Unknown			
Additional data needed or rational	e:This	is not entered	
Reviewer (signature):	DEAREVSG <zyes:< td=""><td>> I</td><td>DEAREVDT Dote:/</td></zyes:<>	> I	DEAREVDT Dote:/

CRF	page	1

HF_ACTION_CEC V2.0 26FEB2004

ENDPOINT CLASSIFICATION-Death, page 1

	COL = HFACTIO		ATING PAGE		Missed V
	SOOK = CPX	PAGEID = 999	Patient Number:	SUBJNO	Patient's Initials:
M	issed Visit				
Ple	ase fill out this form f 07, according to the • If the patient was • If the patient was	to capture the primary reason of or any patient who did not following instructions: randomized on or after 01Dec randomized on or after 01Ma	t complete a protoco cember 2006 and misse arch 2006 and missed t	ol-specified CPX de ed the 3-Month and/ the 12-Month CPX	ue on or after O1 Marc 'or 12-Month CPX
	It the patient was	randomized on or after 01Ma	irch 2005 and missed f	he 24-Month CPX	CPXMISSV(TYPE4)
1	Date form complete	de			
2	Benchmark CPX visit	SMS<1:3> <acpxms> tmissed (dreck only one): 3.1 3-m 4.2 12- 5.3 24-</acpxms>	-month		
2	NOCPXREA <i:3></i:3>				
2	Patient was too cr	id not occur (check only one): itically ill			
	2 Patient could not	walk/bike for technical reasons (e	e.g., a patient who is an ampi	utee, has physical limitations	s due to stroke, etc.)
	3 Not done due to	oversight			
	4 Patient refused				
	5 8 Patient died				
	6 Patient withdrew o	and a second s			
	7 Patient missed visit				
	28 Patient only being	followed by phone (e.g., patient w		nger come to study visits; po	stient refuses to come in
		for office visits,	efc.)		
	9 Patient currently lo				
	10 Physician/physio	logist decision			

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 Number:

CONTEXT NODATA<ZYES> Post Final Visit Contact Form

SUBJNO

Subject's Initials:

Post Final Visit Contact

PAGEID = 999

TION

INSTRUCTIONS: Complete this form if additional primary endpoint data is discovered for for any subject who had not reached 4 years of trial participation at th	
NOTE: This form is expected for any HF-ACTION subject whose final visit was in Decem the time of that final visit, had not reached 4 years of trial participation. Please co later than March 31, 2008.	-
 1 BEENHOSP<i:3><xynunk> Has the subject been hospitalized for any reason since the last completed study visit</xynunk></i:3> □ No → If No: As of (date):FOLLOWDT	orms Management.
CAUDEATH <i:3><acdeat 2, Outpatient CAUDEATH<i:3><acdeat death (check only one): 1, Cardiovascular death → Check only one: DCRI MEDRA</acdeat </i:3></acdeat </i:3>	DCRI MEDRA MEDRCODE <v:8>,CONFLVL<v:2> MEDRTEXT<v:100>,MATCHES<v:4> WORKFLOW<v:5> CODETM CODER<v:20></v:20></v:5></v:4></v:100></v:2></v:8>
MEDRCOD2 <v:8>, CONFLVL2<v:2> MEDRTXT2<v:100>, MATCHES2<v:4< td=""> 2 Pump failure WORKFLW2<v:5> CODETM2 CODER2<v:20> 3 Fatal myocardial infarction 2 2 Condition 2 2 Condition Condition 2 <t< th=""><th>h (specify): CVPRODSP V:100> OTHCVDSP<v:100></v:100></th></t<></v:20></v:5></v:4<></v:100></v:2></v:8>	h (specify): CVPRODSP V:100> OTHCVDSP <v:100></v:100>
$ \begin{array}{c} \boxed{3}_{99} \text{ Unknown} \\ \boxed{1}_{1} \text{ Yes} \rightarrow \text{ If Yes: Last date known alive: } \\ \boxed{2}_{day} / \underbrace{\frac{\text{LSTALVDT}}{\text{menth}} / \underbrace{\frac{1}{year}}{\frac{1}{year}} \end{array} $	DCRI MEDRA MEDRCOD3 <v:8>,CONFLVL3<v:2> MEDRTXT3<v:100>,MATCHES3<v:4> WORKFLW3<v:5> CODETM3 CODER3<v:20></v:20></v:5></v:4></v:100></v:2></v:8>

Please fax completed form to DCRI Forms Management at 1-919-668-7100

HF-ACTION Post Final Visit Contact_V1.0_13 NOV 2007

2007 DCRI - Confidential

Post Final Visit Contact Form

CRF ANNOTATION VERSION 7.0_06Dec2007

MODOW	Firs	First page should have page rep 1		Additional Hospitalization	alization
See annotation p. 28 OF 3-Month for HOSPITAL	DF 3-Month for I		Patient Number:	patient # Patient's In	Patient's Initials: Set welle by
Hospitalization Record only hospitalizations for ≥ 24 hours.					
			Primary Cardiac Procedure*	Secondary Cardiac Procedure*	
	Hospitalization:	Primary Reason for Hospitalization*	(code/d Record a zero if patient did	(code/description)* Record a zero if patient did not have cardiac procedures.	Discharge Destination*
1 Hespitalization: Admission date:	Inplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? $\square_0 \ N_0 \ \square_1 \ \gamma_{es}$					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ N_0 \ \square_1 \ Ves \rightarrow$ If Yes: Complete the Cardiovascular Event forms.					
2 Hespitalization: Admission date:/	Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? \square_0 No \square_1 Yes					
Did a cardiovascular event cause or occur during this hospitalization? $\square_0 \ No \ \square_1 \ Ves \rightarrow$ If Yes: Complete the Cardiovascular Event forms.					
3 Hospitalization: Admission date:	Unplanned				
Did the event leading to this hospitalization occur during or within 3 hours after exercise? $\square_0 \text{ No} = \square_1 \text{ Yes}$					
Did a cardiovascular event cause or occur during this hospitalization? $\Box_0 \ No \Box_1 \ Yes \rightarrow If \ Yes: Complete the Cardiovascular Event forms.$					
* 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.	fination is not list alization form.	ed, please record it in t	he table above.		

CRF ANNOTATION VERSION 7.0_06Dec2007

This is a repeating page

PAGEID = 999

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