

This PDF contains SOLVD Registry forms in alphabetical order as below:

HSR Holter ECG Report

RBF Registry Baseline Form

RDD Registry Designation of Death Form

REC Registry Echo Substudy

RFF Registry Follow-Up Form

RHF Registry Hospitalization Form

RNH Registry Neurohumoral

RSA Registry Pulmonary Edema Discharge Summary Abstract

RSB Registry Substudy Baseline Form

SNC SOLVD Nosological Coding Form

THE METHODIST HOSPITAL

CARDIOLOGY SERVICES

HOLTER ECG REPORT

Form HSR

PATIENT INFORMATION

NAME: [REDACTED]
ID #: [REDACTED]
AGE: 08/ [REDACTED] /21
SEX: M

DATE RECORDED: 07/[REDACTED]/88
PHYSICIAN: UNKNOWN
SOLVD/REGISTRY

LOG NUMBER: [REDACTED]

INDICATIONS:

- 1: DRUG STUDY
- 2: VISIT #01

PROCESSING INFORMATION

RECORDER #:
CABLE #:
BATTERY:
TAPE QUALITY: FAIR

RECORDER TYPE: Reel-to-reel
HOOKUP TECH.:

DATE PROCESSED: 06/[REDACTED]/91
ANALYST: LGM
EDITOR TECH.: LGM

IMPRESSIONS

H, RSMA10081 was monitored for a total of 1:16.2 hours. The long-term electrocardiogram exhibited sinus rhythm. There were transient episodes of atrial fibrillation.

The average heart rate was 67. The minimum rate, 38, occurred during the interval ending at 4:00.0P1. The maximum rate, 107, occurred during the interval ending at 4:00.0P1.

This patient had an average of 78 VPBs per hour with the maximum of 88 occurring during the interval ending 4:00.0P1. There were multiform VPB morphologies. There was 1 SVPB.

PHYSICIAN'S SIGNATURE _____

SUMMARY OF FINDINGS

* TIME: START: 3:14.5P1 END: 4:30.7P1 TOTAL: 1:16.2

* HEART RATE: LOW: 38 MEAN: 67 HIGH: 107

* ECTOPIC ACTIVITY:

	<u>TOTAL</u>	<u>HIGH IN ANY INTERVAL</u>	<u>MEAN</u>	<u>MEAN PER 1000 HB</u>
SVPB	1	1	.87	.22
VPB	89	88	77.62	19.19

* TABLE OF EXAMPLES:

<u>EXAMPLE</u>	<u>STRIP TIME</u>				
----------------	-------------------	-------------------	-------------------	-------------------	-------------------

No examples documented.

This table documents our analyst's findings and should not be construed as an interpretation or diagnosis.

* DIARY CORRELATION:

<u>DIARY TIME REPORTED SYMPTOM</u>	<u>FINDINGS</u>	<u>STRIP TIME</u>
------------------------------------	-----------------	-------------------

No diary entries.

GENERAL PROFILE

TIME ENDING	HEART RATE			TOTAL BEATS	RHYTHM	SVPB TOTAL	SVPB PER 1000 HB	VPB TOTAL	VPB PER 1000 HB	TIME ANALYZED
	LO	MEAN	HI							
4:00.0P1	38	58	107	2717	Sinus, A. Fib.	1	.37	88	32.39	0:39.3
4:30.7P1	48	62	92	1921	Sinus, A. Fib.	0	0.0	1	.52	0:29.5
SUMMARY:	38	67	107	4638		1	.22	89	19.19	1:08.8

ECTOPY PROFILE

TIME ENDING	SUPRAVENTRICULAR					VENTRICULAR						
	TOTAL	SINGLE	PAIRED	RUNS	of BEATS	TOTAL	SINGLE	PAIRED	RUNS	of BEATS	RonT	MFORM
4:00.0P1	1	1	0	0	0	88	88	0	0	0	0	Y
4:30.7P1	0	0	0	0	0	1	1	0	0	0	0	N
SUMMARY:	1	1	0	0	0	89	89	0	0	0	0	Y

VENTRICULAR RUN LENGTH TABLE

TIME ENDING	HEART RATE < 100					HEART RATE >= 100					TOTALS				
	3	4	5	6-9	10+	3	4	5	6-9	10+	3	4	5	6-9	10+
4:00.0P1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4:30.7P1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUMMARY:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

The longest run was - beats, beginning at -, with a maximum rate of -.
 The run of maximum rate was - beats, beginning at -, with a rate of -.

SUPRAVENTRICULAR RUN LENGTH TABLE

TIME ENDING	HEART RATE < 120					HEART RATE >= 120					TOTALS				
	3	4	5	6-9	10+	3	4	5	6-9	10+	3	4	5	6-9	10+
4:00.0P1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4:30.7P1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUMMARY:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

The longest run was - beats, beginning at -, with a maximum rate of -.
 The run of maximum rate was - beats, beginning at -, with a rate of -.

SEEMS TO BE PART OF
HOLTER ECG REPORT (FORM HSR)

Deb.

JOB NAME: General Profile
 JOB NO: _____
 DATE: 20-APR-84
 BY: V. Valvo

FUNCTION
 Alpha A
 Numeric N
 Time T

JOB NAME:
 JOB NO:
 DATE:
 BY:

PAGE 11

FIELD NO.	RECORD FIELD DESCRIPTION	COLUMNS FROM	FIELD THRU	LENGTH	FIELD TYPE	REMARKS	FIELD NO.	RF
	Record #	1	3	3	N		1012	R
1001	Time Ending - Interval	4	12	9	T	Form: HH:MM.T [A] [P]		
1002	Low H.R. - Interval	13	15	3	N			
1003	Mean H.R. - Interval	16	18	3	N			
1004	High H.R. - Interval	19	21	3	N			
1005	Total Beats - Interval	22	26	5	N			
1006	Rhythm - Interval	27	42	16*	N	Bit Mapping		
1007	Total SVPB - Interval	43	47	5	N			
1008	SVPB/1000 HB - Interval	48	54	7	A	Form: 9999.99 or -		
1009	VPB Total - Interval	55	59	5	N			
1010	VPBs/1000 HB - Interval	60	66	7	A	Form: 9999.99 or -		
1011	Time Analyzed - Interval	67	73	7	T	Form: HH:MM.T		

* Rhythm is provided as a 0/1 character mapping. Every character position represents a rhythm with a value 0 meaning that particular rhythm absent or a value 1 meaning that particular rhythm present. Character positions progress right to left.

- | | |
|-----------------------------|----------------------------------|
| Character Position 1: Sinus | Character Position 2: A. Flutter |
| 3: A. Fib. | 4: 1st Degree Block |
| 5: 2nd Degree Block | 6: 3rd Degree Block |
| 7: Paced | 8: Other |
| 9: Nodal | 10: Idioventricular |
| 11: Accelerated Ventricular | 12: Junctional |
| 13-16: Unused | |

e.g. 000000010001000 represents: 1st Degree Block and Other Rhythms

m.g. vs k 5 10 100 11
ns t 5 10 100 11

HSR15

10.5 Zip Code/Canadian or European Postal Code:

11. Participant Telephone Number (Home):
 - -

HOSPITAL INFORMATION

12.1 Hospital Name:

12.2 Hospital Street Address:

12.3 City:

12.4 State/Province:

12.5 Country:

12.6 Zip Code/Canadian or European Postal Code:

13. Patient Hospital ID Number:

PRIVATE PHYSICIAN INFORMATION

14.1 Last Name:

(Private physician continued)

14.2 First Name:

15.1 Street Address:

15.2 City:

15.3 State/Province:

15.4 Country:

15.5 Zip Code/Canadian or European Postal Code:

16. Telephone Number:
 - -

NEAREST RELATIVE OR FRIEND NOT RESIDING WITH PARTICIPANT

17.1 Last Name:

17.2 First Name:

18. Relationship:

19.1 Street Address:

19.2 City:

19.3 State/Province:

19.4 Country:

(Nearest relative/friend continued)

19.5 Zip Code/Canadian or European Postal Code:

20. Telephone number:
 - -

D. X-RAY FINDINGS Yes No

21.1 Is chest X-ray available? Y N
 (If NO, skip to Section E)

21.2 Date of most recent chest X-ray (should be 7 or more days after MI, cardiac surgery, PTCA, or balloon valvuloplasty):

// //
 Month Day Year

Yes No Unrecorded

21.3 Is this X-ray the qualifying X-ray? Y N

22. Pulmonary congestion:

22.1 Is there evidence of pulmonary congestion? Y N U
 (If NO or UNRECORDED, skip to Section E)

22.2 Is there evidence of basal or perihilar vascular blurring? ... Y N U

22.3 Is there evidence of Kerley B lines? Y N U

(continued on next screen)

Yes No Unrecorded

22.4 Alveolar or pulmonary edema? ... Y N U

22.5 Pleural effusion secondary to CHF? Y N U

E. ETIOLOGY OF DISEASE

23.1 What is the primary etiology of participant's heart disease (choose only one of the following):

- Ischemic heart disease (IHD) 1
- Hypertensive heart disease (HHD) 2
- Active myocarditis 3
- Valvular heart disease - aortic 4
- Valvular heart disease - mitral 5
- Idiopathic cardiomyopathy 6
 (specifics unknown)
- Specific cardiomyopathy 7
 (ex: viral, toxic, ETOH, postpartum, history of cocaine use)
 (If no specific cardiomyopathy skip to Q. 24)

Yes No Unrecorded

23.2 Specify: _____

24. Indicate all of the following that occur concurrently (including etiology specified above):

24.1 Ischemic heart disease (IHD) Y N U

24.2 Hypertensive heart disease (HHD) Y N U

(continued on next screen)

	Yes	No	Unrecorded
24.3 Active myocarditis	Y	N	U
24.4 Idiopathic cardiomyopathy	Y	N	U
24.5 Specific cardiomyopathy	Y	N	U
(ex: viral, toxic, ETOH, post-partum, history of cocaine use)			
(If NO or UNRECORDED, skip to Q. 24.7)			
24.6 Specify: _____			
24.7 Valvular heart disease - aortic	Y	N	U
24.8 Valvular heart disease - mitral	Y	N	U

	Yes	No	Unrecorded										
F. RELATIONSHIP TO SOLVD TRIALS													
25.0 Is the participant's EF > 35? (If YES, skip to Section G)	Y	N	U										
25.1 If participant is being considered for the SOLVD trials, copy Eligibility (temporary) ID:	<table border="1" style="width: 100%; height: 20px;"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table>												
25.2 Has the participant been randomized into the SOLVD trials?	Y	N	U										
(If NO or UNRECORDED, skip to Q. 26)													
25.3 Randomization ID:	<table border="1" style="width: 100%; height: 20px;"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table>												

	Yes	No	Unrecorded
26.0 Was the participant considered for but excluded from the SOLVD trials? (If NO or UNRECORDED, skip to Q. 27)	Y	N	U
Please identify the reason(s) for exclusion:			
26.1 Hemodynamically significant valvular or outflow tract obstruction	Y	N	U
26.2 Constrictive pericarditis	Y	N	U
26.3 Complex congenital heart disease	Y	N	U

	Yes	No	Unrecorded
26.4 Myocardial infarction within 30 days of expected randomization	Y	N	U
26.5 History of intolerance to enalapril	Y	N	U
26.6 Currently taking ACE inhibitor and unwilling/unable to discontinue	Y	N	U
26.7 Renal failure	Y	N	U
26.8 Uncontrolled hypertension	Y	N	U

	Yes	No	Unrecorded		Yes	No	Unrecorded
26.9 Cor Pulmonale	Y	N	U	26.16 Cancer	Y	N	U
26.10 Advanced pulmonary disease	Y	N	U	26.17 Immunosuppressive therapy	Y	N	U
26.11 Major neurological disease	Y	N	U	26.18 Active myocarditis	Y	N	U
26.12 Cerebrovascular disease	Y	N	U	26.19 Significant primary liver disease	Y	N	U
26.13 Collagen vascular disease	Y	N	U	26.20 Likely to be nonadherent (alcoholism, drug addiction, lack of a fixed address, etc.)	Y	N	U
26.14 Any major cardiac surgery likely ..	Y	N	U	26.21 Syncopal episodes presumed to be due to life-threatening arrhythmias	Y	N	U
26.15 Unstable angina pectoris	Y	N	U				

	Yes	No	Unrecorded		Yes	No	Unrecorded
26.22 Other life-threatening disease or not realistically expected to be discharged alive	Y	N	U	26.26 Failure to give consent for the SOLVD trials	Y	N	U
26.23 Suspected significant renal artery stenosis	Y	N	U	26.27 Lack of adherence or tolerance to medication	Y	N	U
26.24 Woman likely to bear children	Y	N	U	26.28 Lack of adherence to placebo run-in	Y	N	U
26.25 Other investigational drug protocols (except compassionate use)	Y	N	U	27. For which trial is/was the participant being considered or is/was randomized?			
				Prevention			P
				Treatment			T
				Not considered/randomized			N

G. CLINICAL HISTORY Yes No Unrecorded

28.1 Date history taken (within 3 months of enrollment)

		//			//		
Month			Day			Year	

Is there history of:

- | | | | |
|--------------------------------------------------|---|---|---|
| 28.2 Diabetes mellitus | Y | N | U |
| 28.3 Chronic obstructive pulmonary disease | Y | N | U |
| 28.4 Cerebrovascular accident | Y | N | U |
| 28.5 Angina pectoris | Y | N | U |

Yes No Unrecorded

- | | | | | | |
|--------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|---|--|-------|
| 28.6 Peripheral embolism | Y | N | U | | |
| 28.7 Pulmonary embolism | Y | N | U | | |
| 28.8 Syncope | Y | N | U | | |
| 28.9 Hypertension | Y | N | U | | |
| 28.10 Peripheral vascular disease | Y | N | U | | |
| 28.11 Edema | Y | N | U | | |
| 28.12 Breathlessness on exertion ... | Y | N | U | | |
| 28.13 Asthma | Y | N | U | | |
| (If NO or UNRECORDED, skip to Q 28.15) | | | | | |
| 28.14 Approximate duration of asthma (in years): | <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table> | | | | years |
| | | | | | |

Yes No Unrecorded

- | | | | | | | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|------|---|--|--|--|--|
| 28.15 Pulmonary edema | Y | N | U | | | | |
| 29.1 Previous myocardial infarction? | Y | N | U | | | | |
| (If NO or UNRECORDED, skip to Q. 30) | | | | | | | |
| 29.2 Enter date of most recent myocardial infarction: | | | | | | | |
| <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table> // <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table> | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Month | | Year | | | | | |
| 29.3 Was the MI complicated by pulmonary edema, shock, or heart failure? | Y | N | U | | | | |

Yes No Unrecorded

- | | | | |
|-----------------------------------------------------------------|---|---|---|
| 30. Smoking history (cigarettes only) | | | |
| 30.1 Has the participant ever been a smoker (tobacco)? | Y | N | U |
| (If NO or UNRECORDED, skip to Q. 31) | | | |
| 30.2 Does the participant currently smoke? | Y | N | U |
| 31. Alcohol consumption history | | | |
| 31.1 Has the participant ever regularly consumed alcohol? | Y | N | U |
| (If NO, skip to Q. 32) | | | |
| 31.2 Is there a history of alcohol abuse? | Y | N | U |
| 31.3 Does the participant currently consume alcohol? | Y | N | U |

(See the Manual of Operations for amplitude calculations)

48. Amplitude of R wave in V5 or V6 (whichever is larger): mm

49. Amplitude of R wave in AVL: mm

50. Amplitude of R wave in II, III, or AVF (whichever is larger): mm

51. Amplitude of S wave in V1: mm

52. Amplitude of S wave in V3: mm

53. ST segment depression in inferior leads or V5 or V6: mm

	Yes	No
54. Is Q-wave MI present? (If NO, skip to Section K)	Y	N
55. Location of MI:		
Anterior		A
Inferior		I
Both		B
Unknown		U

K. LABORATORY RESULTS (Use most recent results; use only if recorded within 6 months of enrollment)

56. Date of laboratory tests:

/ /

Month Day Year

57. Sodium (Na): meq/l

58. Potassium (K): meq/l

59. Blood urea nitrogen (BUN): mg/dl

60. Creatinine: mg/dl

L. CORONARY ARTERIOGRAPHY (Use only if taken within 12 months of enrollment)

	Yes	No
61. Does the participant have a coronary arteriogram? (If NO, skip to Section M)	Y	N

62. Date of coronary arteriogram:

/ /

Month Day Year

63. The arteriogram shows (select ONE):

Normal coronary arteries	N
Insignificant coronary artery disease (less than 50% stenosis of all major arteries)	I
Significant coronary artery disease (significant stenosis of at least one major artery)	S
Unknown or unrecorded	U

M. SOURCE OF REGISTRY PATIENT

64. Hospitalized (In-patient)	H
Outpatient	O

N. SELECTION FOR REGISTRY SUBSTUDY

	Yes	No
65. Data Entry System has identified this participant for the Registry Substudy	Y	N
66. Participant consents to Registry Substudy	Y	N

— SOLVD REGISTRY —

DESIGNATION OF DEATH FORM

REG ID:

FORM: R D D
 VERSION: A
 VISIT: 0 1

INSTRUCTIONS: This form should be completed when all clinical information has been collected following a Registry participant's death to determine the cause of death as cardiovascular or noncardiovascular. Print clearly when entering a response in the appropriate boxes. For multiple choice questions, circle the one appropriate letter or number corresponding to the response chosen. Specific instructions for various questions are enclosed in boxes directly below the question. See the SOLVD Registry General Instructions for Completing Forms for details.

REGISTRY DESIGNATION OF DEATH FORM (screen 1 of 4) (RDD page 1 of 3)

A. IDENTIFYING INFORMATION

1. Today's Date: / /
 Month Day Year

2.1 Date of Death: / /
 Month Day Year

2.2a Time of Death: :
 Hours Minutes

2.2b a.m. A
 p.m. P

3.1. Last Name:

3.2. First Name:

3.3. Middle Name:

B. TYPE OF DEATH

Condition of Death: Yes No

4.1. During a hospital admission..... Y N

If Yes, complete the REGISTRY HOSPITALIZATION FORM.

4.2. Observed Y N

4.3. Traumatic Y N

4.4. Suicide Y N

Condition of Death:	Yes	No
4.5. Within 7 days of a myocardial infarction.....	Y	N
4.6. Within 7 days of cardiac surgery.....	Y	N
4.7. Within 7 days of non-cardiac surgery.....	Y	N

C. CAUSE OF DEATH

5. Cause of Death Cardiovascular C
 Noncardiovascular N

If Noncardiovascular (N), go to Question 7.1. on page 3.

6.1. If Cardiovascular (C), indicate one type

Cardiac	C
Stroke	S
Pulmonary embolism	V
Other vascular or unknown	O

If Stroke (S) or Pulmonary embolism (V) or Other vascular or unknown (O), go to Section D. INITIALS OF PERSON COMPLETING THIS FORM, Question 8, on page 3.

(Cardiac Death)

6.2. Choose the one most likely terminal event.....

Circle one number.

Probable <u>arrhythmia without</u> preceding worsening symptoms of CHF.....	1
Probable <u>arrhythmia with</u> some preceding worsening symptoms of CHF.....	2
Primarily related to pump failure (even if terminal event was an arrhythmia)....	3
Other.....	4

If the number circled was 1, 2 or 3, go to section D. INITIALS OF PERSON COMPLETING THIS FORM, Question 8. on page 3.

6.3. If Other (O), specify:

PLEASE PRINT CLEARLY.

Go to section D. INITIALS OF PERSON COMPLETING THIS FORM, Question 8. on page 3.

7.1. If Noncardiovascular (N),
 indicate the type of death.....

Circle one number.

A secondary complication of
 heart failure (e.g., pneumonia,
 hepatic or renal dysfunction,
 etc.)..... 1

A primary event (independent
 of heart failure)..... 2

Neither 1 or 2..... 3

If a secondary complication (1),
 go to Question 8.

If neither 1 or 2 (3),
 go to Question 7.4.

7.2. If a primary event,
 was death due to cancer?.....Yes Y

No N

If No, go to Question 8.

7.3. If Yes (cancer), specify primary site:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Go to Question 8.

7.4. If Neither 1 or 2 (3), specify:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

D. INITIALS OF PERSON
 COMPLETING THIS FORM

8. Initials.....

--	--

FORM REC

REGISTRY ECHO SUBSTUDY

Quality

Patient Name _____ BP _____
 Registry No R 1003 ~~Center~~ _____ good
 Date 8-1-88 Wt _____ Ht _____

2-D ECHO

LV dias dim 76
 LV sys dim 59
 Sep dias thick 6
 LVPW dias thick 8
 LA dimension 40
 Aorta diam 32
 LV dias vol 250
 LV sys vol 183
 LV EF 27
 LV long axis 99

DOPPLER

LVOT diam 19
 LVOT peak Vel 83
 LVOT eject time 330
 LVOT TVI 164
 Heart Rate 55
 MA E 65
 MA A 18
 MA dec time 100 — 2 or 3 digits
 MA atrial FF 7 — 1 or 2 digits
 MR 1 AR 1 TR _____ PAP _____

Could be 3 digits

Wall motion

It could be 3 digits (Example, 110)

	BAS	MID	APICAL
ant septum	1	2	3
anterior	1	2	3
lateral	1	2	3
inferior	2	2	3
inf septum	1	2	3

- 1 = normal
- 2 = hypokinetic
- 3 = akinetic
- 4 = dyskinetic
- 5 = aneurysm

RV RA AV MV MA PM Clot PE

N	N						
N							

REGISTRY ECHO SUBSTUDY

Patient Name _____ BP _____
 Registry No _____ Center _____
 Date _____ Wt _____ Ht _____

2-D ECHO

LV dias dim ETD 4
 LV sys dim ETD 5
 Sep dias thick ETD 3
 LYPH dias thick ETD 9
 LA dimension ETD 10
 Aorta diam ETD 2
 LY dias vol. ETD 37
 LY sys vol ETD 38
 EF ETD 36
 LV long axis This is new

DOPPLER

LVOT diam This is new
 LVOT peak Vel EDP 41
 LVOT eject time EDP 67
 LVOT TVI This is new
 Heart Rate EDP 4
 HA E EDP 33
 HA A EDP 34
 HA dec time EDP 38
 HA atrial FF EDP 39
 MR AR TR PAP
 IVRT EDP 73

Wall motion score

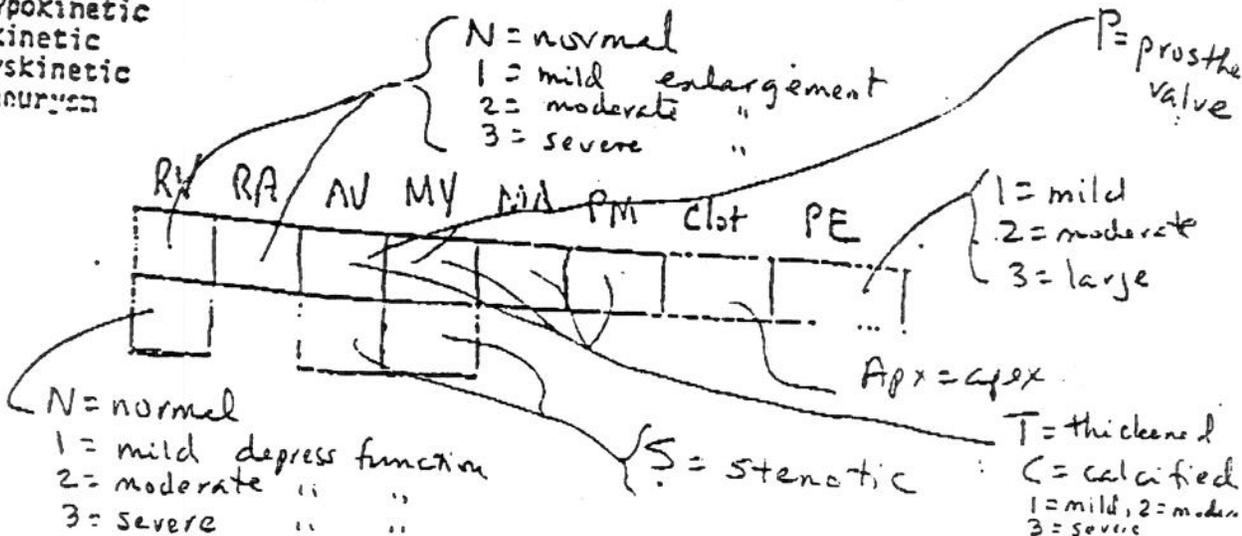
ant septum
 anterior
 lateral
 inferior
 inf septum

BAS	MID	APICAL
ERW 1	ERW 6	ERW 11
ERW 2	" 7	" 12
ERW 3	" 8	" 13
ERW 4	" 9	" 14
ERW 5	" 10	This one is new

SCORE:

- 1 = normal
- 2 = hypokinetic
- 3 = akinetic
- 4 = dyskinetic
- 5 = aneurysm

RV = right ventricle
 RA = right atrium
 AV = aortic valve
 MV = mitral valve
 PM = papillary muscle
 Clot = clot
 PE = pericardial effusion



SOLVD REGISTRY

FOLLOW-UP FORM

12/7/88

REGISTRY
ID:

FORM: R F F VERSION: A VISIT: 0 2

INSTRUCTIONS: This form is to be completed on the basis of the follow-up contact letter or telephone interview. It should be completed within 60 days of the one-year anniversary of enrollment. Consult the SOLVD Registry Instructions for Completing Forms and Registry follow-up protocol for details.

SOLVD REGISTRY FOLLOW-UP FORM (screen 1 of 3) (RFF page 1 of 2)

A. IDENTIFYING INFORMATION

1.1 Today's date: // //
Month Day Year

1.2 Initials of person completing form:

2.1 Participant's Last Name:

2.2 Participant's First Name:

2.3 Participant's Middle Initial:

B. CONTACT INFORMATION

3.1 Follow-up period covers from (beginning date):
 // //
Month Day Year

3.2 to (ending date):
 // //
Month Day Year

3.3 Date of contact (if in SOLVD, date of visit):
 // //
Month Day Year

3.4 Number of attempts before contact successfully made:

— SOLVD REGISTRY —

HOSPITALIZATION FORM

REG ID:

FORM: R H F

VERSION: A

SEQUENCE NUMBER:

INSTRUCTIONS: This form is to be used each time a participant has been hospitalized. The sequence number is needed to indicate the number of times this form has been used. Sequence number should start with 01 the first time the form is used for the participant. Print clearly when entering a response in the appropriate boxes. For multiple choice questions, circle the one appropriate letter corresponding to the response chosen. Specific instructions for various questions are enclosed in boxes directly below the question. See the SOLVD Registry General Instructions for Completing Forms for details.

HOSPITALIZATION FORM (screen 1 of 6) (RHF page 1 of 4)

A. IDENTIFYING INFORMATION

1. Today's Date: // //

Month Day Year

2.1 Last Name:

2.2 First Name:

2.4 Middle Name:

3. Hospital Name:

4.1 Date of Admission: // //

Month Day Year

4.2. Date of Discharge: // //

Month Day Year

B. PRIMARY REASON FOR HOSPITALIZATION

5. Hospitalization.....

Noncardiovascular N

Cardiovascular C

If Cardiovascular (C), go to Question 7. on page 2.

6. If Noncardiovascular (N), specify:

6.1. HICDA coding:

Go to section C. SECONDARY REASONS FOR HOSPITALIZATION, Question 11. on page 3.

7. If Cardiovascular, enter the code for PRIMARY REASON.....

- CODE REASON
- A - Worsening CHF
 - B - New CHF
 - C - Worsening or new angina
 - D - Myocardial infarction
 - E - Nonfatal cardiac arrest or ventricular tachycardia that required defibrillation
 - F - Supraventricular tachycardia or fibrillation that required DC conversion or pacing
 - G - Uncertain tachycardia that required DC conversion or pacing

- CODE REASON
- H - Other arrhythmias
 - I - Stroke
 - J - Cardiac surgery
 - K - Pulmonary embolism
 - L - Peripheral embolism
 - M - Hypotension
 - N - Azotemia
 - O - Any other major event
 - P - Digitalis toxicity

Note: If PRIMARY REASON = Myocardial infarction (D) go to Question 8.1a,
 If PRIMARY REASON = Cardiac surgery (J) go to Question 9.1.
 If PRIMARY REASON = Any other major event (O) go to Question 10.
 Otherwise, go to section C. SECONDARY REASONS FOR HOSPITALIZATION, Question 11. on page 3.

HOSPITALIZATION FORM (screen 3 of 6) (RHF page 2 of 4)

Myocardial Infarction

If Yes, indicate the following:

8.a. Date of MI: / /
 Month Date Year

8.b. Time of MI (rounded to the nearest hour):

Hour

8.c. a.m. A
 p.m. P

Indicate the presence of the following:

	Yes	No	Unrecorded
8.1. Pain.....	Y	N	U
8.2. Elevated enzymes....	Y	N	U
8.3. Changes in ECG.....	Y	N	U

Go to section C. SECONDARY REASONS FOR HOSPITALIZATION, Question 11. on page 3.

Cardiac Surgery

- 9.1. If Yes, indicate surgery.....Graft (CABG) G
 Valve V
 Transplantation T
 Graft & Valve B
 Other O

If Graft (G), Valve (V) or Transplantation (T) or Graft & Transplant (B), go to Question 11, page 3.

9.2. If Other (O), specify:

Go to Question 11. on page 3.

Any Other Major Event

10. If Yes, specify other major event:

10.1. HICDA coding:

C. SECONDARY REASONS FOR HOSPITALIZATION

11. Hospitalization.....

Noncardiovascular N
 Cardiovascular C
 None O

If Cardiovascular (C), go to Question 13.
 If None (O), go to Question 28. on page. 4.

12.1. If Noncardiovascular (N), specify:

12.2. HICDA coding:

Go to Question 28. on page 4

Indicate SECONDARY REASONS:

13. Worsening CHF Yes No
 Y N

14. New CHF Yes No
 Y N
 15. Worsening or new angina Y N
 16.1. Myocardial Infarction (MI) Y N

If NO, go to Question 17.

16.1a Date of MI: // //
 Month Day Year

16.1b Time of MI (round to nearest hour):

16.1c a.m. A
 p.m. P

Indicate the presence of the following:

16.2. Pain Yes No Unrecorde
 Y N U
 16.3. Elevated enzymes Y N U

HOSPITALIZATION FORM (screen 5 of 6) (RHF page 3 of 4)

16.4. Changes in ECG Yes No Unrecorded
 Y N U
 17. Nonfatal cardiac arrest or ventricular tachycardia that required defibrillation Y N U
 18. Supraventricular tachycardia or fibrillation that required DC conversion or pacing ... Y N U
 19. Uncertain tachycardia that required DC conversion or pacing Y N U
 20. Other arrhythmias Y N U
 21. Stroke Y N U
 22.1. Cardiac surgery Y N U

If NO or UNRECORDED (Cardiac Surgery), go to Question 23.

22.2. If Yes (cardiac surgery), indicate the type.....Graft G
 Valve V
 Transplantation T
 Graft & Valve B
 Other O

If Graft (G), Valve (V), Transplantation (T), or Graft & Valve (B), go to Question 23.

22.3. Specify other (0):

23. Pulmonary embolism Yes No
 Y N
 24. Peripheral embolism Y N
 25. Hypotension Y N

Yes No

26. Azotemia..... Y N

27.1. Any other major event..... Y N

If No, go to Question 28.

27.2. If Yes, specify other major event:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

27.3. HICDA coding :

--	--	--	--	--

 .

--

D. INITIALS OF PERSON
COMPLETING THIS FORM

28. Initials.....

--	--

DATE: 31-MAY-90
TIME: 14:15:10

VIKING FORMS MANAGER 2.44
SVRNHA V 1.00

RECORD FORM ID: 5

FLD #	REC LOC	SCREEN SIZE	COLOR LIN COL	ATTR FG/BG	F IUBR	CHAR SET D	FLD NUFSLR78	SKIP 12345678	PARAMETERS JZBECRFPVNTD	SAV DUP	GET A DUP.P
33	162	1	15 80	...	RP.....	0	55
34	163	3	17 64	I...	-	N.....	8	JZB.....	0	0
35	166	2	17 68	I...	-	N.....	8	.ZB..R.....	0	0
36	168	1	17 80	...	RP.....	0	55

DATA_AREA LENGTH = 168 NEXT RECORD ID: 1 ASSOCIATED MENU ID: 9

SCREEN CLEARED FROM (2, 1)
LINE(S) CLEARED AT (1, 21)

QNH

1 2 3 4 5 6 7 8
1234567890123456789012345678901234567890123456789012345678901234567890

SVRNHA V 1.00 AUTO J/F

ID: _____ %% FORM: _____ VERSION: _____ %%VISIT: _____ %% UPDATE: _____

SOLVD Registry Substudy Neurohumoral coding screen (1 of 1)

ADMINISTRATIVE INFORMATION

- 561 1. Date Analyzed: ___/___/___ %
mo dy yr
- 562 2.1. Last Name: _____ %
- 563 2.2. First Name: _____ %
- 564 2.3. Middle Name: _____ %
- 565 3. Initials of person keying form: ___ %

B. SAMPLE DETERMINATION

- 4. PNE: SB6 _____ pg/ml
- 5. PRA: SB7 _____ ng/ml/hr
- 6. AVP: SB8 _____ pg/ml
- 7. ANP: SB9 _____ pg/ml

6. Previous hospital admission for CHF: (Circle 1, 2, or 3)

1 - Yes

2 - No

3 - Unknown

[If "no" or "unknown,"
skip to Question 8]

7. Was there a prior admission to your hospital for CHF? (Circle 1, 2, or 3)

1 - Yes

2 - No

3 - Unknown

E. Discharge Summary Information:

8. Precipitating event for this episode of "pulmonary edema":
(Circle one or more as needed)

1 - Worsening CHF

2 - Noncompliance with meds or diet

3 - New or recurrent ischemia

4 - Arrhythmia

5 - Unknown

6 - Non Q-wave MI

a. If yes, give peak CPK: _____

7 - Other reason

a. Give reason: _____

9.1 Admission date:
mo day year

9.2 Discharge date:
mo day year

9.3 Was patient discharged from hospital alive? (Circle 1 or 2)

1 - Yes 2 - No

10.1 Did acute symptoms of pulmonary edema begin outside the hospital?
(Circle 1, 2, or 3)

1 - Yes

2 - No

3 - Unknown

[If "no" or "unknown,"
skip to Question 11.1]

10.2 If yes, duration of rest dyspnea prior to arrival: (Circle 1, 2, or 3)

- 1 - <1 hr
 2 - 1-4 hrs
 3 - >4 hrs

F. Appearance of Patient on Arrival to Hospital:

11.1 Blood Pressure /

11.2 Heart Rate

11.3 Respirations

12.1 Hyperventilating	1 - Y	<input checked="" type="radio"/> 2 - N	<input type="radio"/> 3 - U	} Circle 1, 2, or 3
12.2 Diaphoretic	1 - Y	<input checked="" type="radio"/> 2 - N	<input type="radio"/> 3 - U	
12.3 Dyspneic	1 - Y	<input checked="" type="radio"/> 2 - N	<input type="radio"/> 3 - U	
12.4 Anxious	1 - Y	<input checked="" type="radio"/> 2 - N	<input type="radio"/> 3 - U	
12.5 Pale	1 - Y	<input checked="" type="radio"/> 2 - N	<input type="radio"/> 3 - U	

13.1 Were there rales present on admission? (Circle 1, 2, or 3)

- 1 - Yes
 2 - No [If "no" or "unknown," skip to Question 14]
 3 - Unknown

13.2 If yes, circle 1, 2, or 3:

- 1 - Basilar only
 2 - To mid chest
 3 - To apices

G. Chest X-ray Information: (use CXR showing pulmonary edema only)

14. Date of CXR used to document pulmonary edema:

mo day year

15. Is there evidence of pulmonary congestion? (Circle 1, 2, or 3)

- 1 - Yes
 2 - No
 3 - Unknown

16. Is there evidence of basal or peripheral vascular blurring?
 (Circle 1, 2, or 3)

- 1 - Yes
 2 - No
 3 - Unknown

17. Is there evidence of Kerley B lines? (Circle 1, 2, or 3)

- 1 - Yes
- 2 - No
- 3 - Unknown



R 10108

H. Ejection Fraction:

18.1 Was an ejection fraction measured?

- 1 - Yes
- 2 - No [If "no," skip to Question 19.1]

P.4

18.2 %

18.3 Source: (Circle 1, 2, or 3) 1 - RVG 2 - Cath 3 - Echo

18.4 Date of EF: mo day year

I. Admission Laboratory Values:

19.1 NA+ (meq/l)

19.2 K+ (meq/l)

19.3 BUN (mg/dl)

19.4 Creatinine (mg/dl)

J. Overall Clinical Impression: (Circle only one number)

- 1 - No CHF, patient's information originally entered wrong
- 2 - No overt symptoms, found by exam or CXR only
- 3 - CHF not severe
- 4 - Severe CHF
- 5 - Cardiogenic Shock
- 6 - Unable to determine from information provided

*Please double-check Registry ID# on Page 1.

— SOLVD REGISTRY —

SUBSTUDY BASELINE FORM

REG. ID:

FORM: R S B

VERSION: A

VISIT: 0 1

INSTRUCTIONS: This form is to be completed on Registry subjects selected and included in the Registry Substudy. The information is to be obtained from the subject at a clinic visit by a physician, nurse practitioner, or physician's assistant. The clinic visit should take place no later than 90 days after the Registry Baseline Form has been completed. Please print clearly. See the SOLVD Registry General Instructions for Completing Forms for details.

A. IDENTIFYING INFORMATION

1.1 Today's date: / /
Month Day Year

1.2 Initials of person completing form:

2.1 Participant's Last Name:

2.2 Participant's First Name:

2.3 Participant's Middle Initial

B. ECHOCARDIOGRAPHY ELIGIBILITY Yes No

3.1 Date 2D and M-mode echos done:
 / /
Month Day Year

3.2 Were these echocardiograms of good quality? (See protocol for criteria) (If NO, exit form) Y N

3.3 Was Doppler echo done? (only for those participants in the Echo Substudy) ... (If NO, skip to Section C) Y N

3.4 Date Doppler done:
 / /
Month Day Year

C. ETIOLOGY OF DISEASE AND NYHA CLASS

4.1 Indicate the primary etiology of the patient's heart disease (choose only ONE of the following):

- Ischemic heart disease (IHD) 1
 - Hypertensive heart disease (HHD) 2
 - Active myocarditis 3
 - Valvular heart disease - aortic 4
 - Valvular heart disease - mitral 5
 - Idiopathic cardiomyopathy (specifics unknown) 6
 - Specific cardiomyopathy (ex: viral, toxic, ETOH, postpartum, history of cocaine use) 7
- (If no specific cardiomyopathy, skip to Q. 5)

4.2 Specify: _____

Yes No

5. Indicate all of the following etiologies that have occurred (including the etiology specified above):

- 5.1 Ischemic heart disease (IHD) Y N
- 5.2 Hypertensive heart disease (HHD) Y N
- 5.3 Active myocarditis Y N
- 5.4 Valvular heart disease - aortic Y N
- 5.5 Valvular heart disease - mitral Y N

(continued)

- 5.6 Idiopathic cardiomyopathy Y N
(specifics unknown)

5.7 Specific cardiomyopathy (ex: viral, toxic, ETOH, postpartum, history of cocaine use) Y N
(If NO, skip to Q. 6)

5.8 Specify: _____

- 6. New York Heart Association CHF Class: 1
(Choose only one) 2
3
4

D. PAST CLINICAL HISTORY (up to completion of the Registry Baseline Form) Yes No

7. Does the participant have a history of:
- 7.1 Pulmonary edema Y N
 - 7.2 Diabetes mellitus Y N
 - 7.3 Chronic obstructive pulmonary disease Y N
 - 7.4 Cerebrovascular accident Y N
 - 7.5 Angina pectoris Y N

(continued)

	Yes	No		Yes	No	
7.6 Peripheral embolism	Y	N	7.14 Approximate duration of asthma:	<input type="text"/>	<input type="text"/>	years
7.7 Pulmonary embolism	Y	N	8. Cigarette smoking (ignore any other tobacco use)			
7.8 Syncope	Y	N	8.1 Has the participant ever smoked cigarettes regularly?	Y	N	(If NO, skip to Q. 9)
7.9 Hypertension	Y	N	8.2 At what age did the participant first begin to smoke cigarettes regularly?	<input type="text"/>	<input type="text"/>	years of age
7.10 Peripheral vascular disease	Y	N	8.3 For how many years in total has the participant smoked regularly?	<input type="text"/>	<input type="text"/>	years
7.11 Edema	Y	N				
7.12 Breathlessness on exertion	Y	N				
7.13 Asthma	Y	N				
(If NO, skip to Q. 8)						

8.4 For how many of those years did the participant smoke filter-tipped cigarettes?	<input type="text"/>	<input type="text"/>	years	8.8 - During last 6 months	<input type="text"/>	<input type="text"/>	<input type="text"/>	cigts/week
What (approximately) was the largest number of cigarettes the participant generally used to smoke in a week? (Count 1 oz of handrolled tobacco as 28 cigarettes) -				8.9 Did the participant smoke any cigarettes in the past week?	Y	N		
8.5 - Before 20 years of age	<input type="text"/>	<input type="text"/>	<input type="text"/>	9. Alcohol consumption history				
			cigts/week	9.1 Has the participant ever consumed alcohol regularly?	Y	N		(If NO, skip to Q. 10.1)
8.6 - From 20-24 years of age	<input type="text"/>	<input type="text"/>	<input type="text"/>	9.2 Does the participant currently consume alcohol regularly?	Y	N		(If NO, skip to Q. 9.5)
			cigts/week					
8.7 - After 24 years of age	<input type="text"/>	<input type="text"/>	<input type="text"/>					
			cigts/week					

9.3 Last week, how many drinks did the participant have? (1 drink = 12 oz beer = 4-5 oz wine = 1.5 oz spirits)

drinks

9.4A Specify drinking pattern:

Heavy	H
Regularly	R
Socially	S
Rarely	X
Unknown	U

9.4B Number of days a week the participant currently drinks:

days

GO TO Q. 10.1.

9.5 Number of days a week the participant used to drink:

days

9.6 Number of drinks the participant used to consume per week (1 drink = 12 oz beer = 4-5 oz wine = 1.5 oz spirits):

drinks/week

9.7 Specify former drinking pattern:

Heavy	H
Regularly	R
Socially	S
Rarely	X
Unknown	U

	Yes	No
10.1 Previous myocardial infarction? (If NO, skip to Q. 11.)	Y	N

10.2 Date of most recent myocardial infarction:

/
Month Year

10.3 Was the MI complicated by pulmonary edema, shock, or heart failure? Y N U

11. Permanent pacemaker? Y N

12. Use of automatic implantable defibrillator? Y N

	Yes	No	Unknown
13.1 Previous cardiac surgery, PTCA, or balloon valvuloplasty? (If NO, skip to Section E)	Y	N	

13.2 Date of most recent cardiac surgery, PTCA, or balloon valvuloplasty:

/
Month Year

14. Type of cardiac surgery:

	Yes	No	U
14.1 Coronary artery bypass graft ..	Y	N	U

SOLVD REGISTRY SUBSTUDY BASELINE (screen 8 of 15) (RSB page 5 of 8)

	Yes	No	Unknown	E.	MEDICATIONS CURRENTLY USED	Yes	No
14.2 Valve replacement - aortic	Y	N	U				
14.3 Valve replacement - mitral	Y	N	U	15.1	Digitalis	Y	N
14.4 Percutaneous transluminal coronary angioplasty (PTCA)	Y	N	U	15.2	Other inotropic agent	Y	N
14.5 Balloon valvuloplasty	Y	N	U	15.3	Potassium-losing diuretic	Y	N
14.6 Other	Y	N		15.4	Potassium-sparing diuretic	Y	N
(If NO, skip to Section E)				15.5	Antiarrhythmic drug other than beta-blocker or calcium antagonist ..	Y	N
14.7 Specify: _____				15.6	Regular use of antiplatelet	Y	N

(continued)

SOLVD REGISTRY SUBSTUDY BASELINE FORM (screen 9 of 15) (RSB page 5 of 8)

	Yes	No			Yes	No	
15.7 Beta-blocker	Y	N					
15.8 Long-acting oral nitrate and paste	Y	N		15.14	Anticoagulant	Y	N
15.9 Hydralazine	Y	N		15.15	Insulin	Y	N
15.10 Open-label ACE inhibitor	Y	N	S	15.16	Steroids	Y	N
(Select "S" if in SOLVD trial)				15.17	Beta-2 agonist inhalers	Y	N
15.11 Calcium antagonist	Y	N		15.18	Potassium supplements	Y	N
15.12 Other vasodilator	Y	N					
15.13 Antihypertensive (other than above) ...	Y	N					

F. PHYSICAL EXAMINATION

16. Weight (enter lbs or kg)
 16.1 lbs OR 16.2 kg
17. Height (enter inches or cm)
 17.1 in OR 17.2 cm
18. Heart rate: beats/min

19. Systolic blood pressure: mmHg
20. Diastolic blood pressure: mmHg
21. Are any of the following present? Yes No
- 21.1 Rales Y N
- 21.2 Edema Y N
- 21.3 Elevated jugular venous pressure Y N
- 21.4 S3 gallop Y N
- 21.5 Mitral regurgitation murmur Y N

G. ECG FINDINGS (Should be 72 or more hours after an MI)

22. Date ECG taken: / /
 Month Day Year
23. Atrial fibrillation/flutter? Yes No
 (If YES, skip to Q. 25)
24. P wave terminal force in V1: mm
25. QRS delay <=120 ms? Yes No
 (If NO, skip to Q. 32)
26. Amplitude of R wave in V5 or V6
 (whichever is larger):

27. Amplitude of R wave in AVL: mm
28. Amplitude of R wave in II, III,
 or AVF (whichever is larger): mm
29. Amplitude of S wave in V1: mm
30. Amplitude of S wave in V3: mm
31. ST segment depression in
 inferior leads or V5 or V6: mm
32. Is Q-wave MI present? Yes No
 (If NO, skip to Section H)

TO BE COMPLETED LATER	
40.7 PNE:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> pg/ml
40.8 PRA:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> ng/ml/hr

41. Were the procedures done on the same day the echocardiograms were taken? Y N
(If YES, skip to Section J)
42. Did any major events occur in the interim? Y N
(If YES, complete Registry Hospitalization Form for EACH hospitalization)

- | | Yes | No |
|------------------------------------------------------------------------|-----|----|
| J. SIX-MINUTE WALKING TEST | | |
| 43. Did the participant finish the six-minute walking test? | Y | N |
| 44. Time completed: | | |
| <input type="text"/> min <input type="text"/> <input type="text"/> sec | | |
| 45. Were there any breaks in continuity? .. | Y | N |
| 46. Indicate any of the following symptoms present: | | |
| 46.1 Angina | Y | N |
| 46.2 Dyspnea | Y | N |

- | | Yes | No |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|----|
| 46.3 Fatigue | Y | N |
| 46.4 Dizziness | Y | N |
| 46.5 Syncope | Y | N |
| 47. Total distance travelled (enter feet <u>or</u> meters) | | |
| 47.1 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> ft <u>OR</u> 47.2 <input type="text"/> <input type="text"/> <input type="text"/> m | | |

- K. LADDER OF LIFE
48. On which step does the participant feel he/she is standing at the PRESENT time?
-
49. On which step does the participant feel he/she was standing FIVE YEARS AGO?
-
50. On which step does the participant feel he/she will be standing FIVE YEARS FROM NOW?
-

