Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12713

7 - PROCEDURES

000001

PATIENT: [redacted] ACCT #: [redacted] LOC: [redacted] U #: [redacted]
AGE/SX: 64/F ROOM: [redacted] REG: 11/26/97
REG DR: [redacted] STATUS: [redacted] BED: [redacted] DIS: 12/04/97

********** HEMATOLOGY **********
***** COMPLETE BLOOD COUNT *****

Date	11/27/97	11/26/97			Reference	Units
Time	0600	2055				
>>WBC	6.6	10.6			(4.5-10.8)	K/mm3
>>RBC	4.53 *	4.44 *			(4.70-6.10)	M/mm3
>>HGB	12.8 *	12.6 *			(14.0-18.0)	gm/dL
>>HCT	37.7 *	37.4 *			(42-52)	%
>>MCV	83.3	84.1			(80-105)	fL
>>MCH	28.2	28.3			(26.9-35.1)	pg
>>MCHC	33.9	33.7			(32.0-36.0)	g/dL
>>RDW	14.0	14.8			(10.0-17.9)	%
>>PLT	224	248			(149-451)	K/mm3
>>MPV	9.2	9.4			(7.4-10.4)	fL

***** DIFFERENTIAL *****

Date	11/26/97				Reference	Units
Time	2055					
>>E SEG	74.4 *				(31.0-61.0)	%
>>E LYMPH	16.2 *				(20.4-51.2)	%
>>E MONO	7.32				(1.6-10.4)	%
>>E EOS	1.4				(0.0-7.1)	%
>>E BASO	0.7				(0.0-2.1)	%

[redacted]
AE#12713, Cplt.#NYK-3416
FLA-DO memo 5/11/98 AKR/AKL
EX/ATT: 1 40 146

TEST FLAG KEY: * = ABNORMAL, *H = CRITICAL HIGH, *L = CRITICAL LOW

Patient: [redacted] [redacted] **(Continued)**

********** COAGULATION **********
***** STUDIES *****

Date	11/30/97	--------11/29/97--------		11/28/97		
Time	0455	1800	0440	1850	Reference	Units
>>PT	12.6	12.7	12.2	12.5	(10.9-13.2)	SECONDS
>>INR	1.1	1.2	1.1	1.1	(0.7-1.5)	
>>APTT	29.8	29.0	28.5	29.1	(21.0-36.0)	SECONDS

Date	--------11/28/97--------		--------11/27/97--------			
Time	1230	0615	1815	0600	Reference	Units
>>PT		12.8	12.9	12.5	(10.9-13.2)	SECONDS
>>INR		1.2	1.2	1.1	(0.7-1.5)	
>>APTT	29.1	53.9(A) *H	52.9(B) *H	50.2(C) *H	(21.0-36.0)	SECONDS

(A) Repeated: 11/28/97 0735
PATIENT ON HEPARIN
PATIENT RESULT'S RUNNING ABNORMAL
(B) PATIENT RESULT'S RUNNING ABNORMAL
(C) Repeated: 11/27/97 0720
PATIENT ON HEPARIN

Date	11/26/97					
Time	2055				Reference	Units
>>PT	12.5				(10.9-13.2)	SECONDS
>>INR	1.1				(0.7-1.5)	
>>APTT	28.8				(21.0-36.0)	SECONDS

[redacted]
AE#12713, Cplt.#NYK-3416
FLA-DO memo 5/11/98 AKR/AKL
EX/ATT: 1 41 144

TEST FLAG KEY: * = ABNORMAL, *H = CRITICAL HIGH, *L = CRITICAL LOW

Patient [redacted] **Acc#** [redacted] **Unit** [redacted]

Patient: [redacted] [redacted] (Continued)

********** BLOOD GASES **********

Date	11/26/97				Reference	Units
Time	2105					
>>ABG PH	7.41(@a)				(7.350-7.45	
>>ABG PCO2	40.9(@a)				(35-45)	mmHg
>>ABG PO2	69.6(b) *				(80-100)	mmHg
>>ABG HCO3	26.1(@a) *				(22-26)	MEQ/L
>>BASE EXCESS	2.1(@a) *				(-2-2)	Meq/L
>>O2 SAT	94.1(@a)				(92-100)	%
>>A/a O2 TENSIO	32.8(@a)				(10-50)	mm/HG
>>ALLEN TEST	(F)				(POSITIVE)	

(F) POSITIVE
See also (@a)

>>ABG FIO2	21.0(@a)					%
>>ABG SITE	R RAD(@a)					

Test	Date	Time	Result	Reference	Units
>>RHEUMATOID	11/27/97	0600	NEGATIVE	(NEG)	

NOTES: (@a) SAME
(b) See (c), (@a)
(c) CALCULATED RESULTS ARE BASED ON HGB 15 AND TEMP 98.6 UNLESS OTHERWISE NOTED.

[redacted]
AE#12713, Cpt.#NYK-3416
A-DO memo 5/11/98 AKR/
EX/ATT: 1 11 146

TEST FLAG KEY: * = ABNORMAL, *H = CRITICAL HIGH, *L = CRITICAL LOW

Patient: [redacted] [redacted] (Continued)

********** CHEMISTRY **********
***** GENERAL CHEMISTRY *****

	Date	12/04/97	12/02/97	11/29/97	11/28/97	Reference	Units
	Time	0345	0400	0440	0615		
>>CARDPRO				(D)			
(D)	CK BASE		54			20-233	
	TROP BASE		< 0.35			0.0-1.5	
	TROP 6HR		< 0.35			0.0-1.5	
	CK 6HR		59			20-233	
	TROP 12HR		< 0.35			0.0-1.5	
	CK 12HR		49			20-233	
	CKMB BASE		TEST NOT PERFORMED			0-6	
	CKMB 6HR		TEST NOT PERFORMED			0-6	
	CKMB 12HR		TEST NOT PERFORMED			0-6	
	TSH		< 0.35			0.0-1.5	
>>NA		141	138 *		140	(139-149)	mmol/L
>>K		4.3	4.2		3.8	(3.5-5.3)	mmol/L
>>CL		107	108		108	(99-109)	mmol/L
>>CO2		24	21		19 *	(20-33)	mmol/L
>>GLUCOSE		97	130 *		134 *	(69-111)	mg/dL
>>BUN		14	10		6	(6-19)	mg/dL
>>CREATININE		0.6	0.7		0.7	(0.5-1.4)	mg/dL
>>T4 FREE				1.7		(0.7-2.2)	ng/dl
>>TSH				0.76		(0.38-6.15)	uIU/mL

Date	11/27/97	11/26/97	Reference	Units
Time	0600	2055		
>>NA	143	139	(139-149)	mmol/L
>>K	4.0	4.2	(3.5-5.3)	mmol/L
>>CL	110 *	103	(99-109)	mmol/L
>>CO2	19 *	28	(20-33)	mmol/L
>>GLUCOSE	119 *	115 *	(69-111)	mg/dL
>>BUN	19	26 *	(6-19)	mg/dL
>>CREATININE	0.7	1.0	(0.5-1.4)	mg/dL
>>TOTAL PROTEIN		6.9	(6.3-8.3)	gm/dL
>>ALBUMIN		3.5	(3.3-5.1)	gm/dL
>>CALCIUM		9.4	(8.7-10.6)	mg/dL
>>BILIRUBIN TOT		0.2	(0.0-1.1)	mg/dL
>>SGOT/AST		22	(6-38)	U/L
>>ALK PHOS TOTA		65	(49-150)	U/L
>>CHOLESTEROL	196		(50-201)	mg/dL

[redacted]
AE#12713, Cplt.#NYK-3416
FLA-DO memo 5/11/98 [illegible] Acl
EX/ATT: 1 43 of 146

TEST FLAG KEY: * = ABNORMAL, *H = CRITICAL HIGH, *L = CRITICAL LOW

Patient: [redacted] Acc# [redacted] Unit# [redacted]

[redacted]

CARDIAC ENZYMES

Room No [redacted]

PATIENT NAME: [redacted]

HOSPITAL#: [redacted]

PHYSICIAN: [redacted]

	Baseline	2 hr.	6 hr.	12 hr.
DRAW DATE:	11.29.97		11.29.97	11-29-97
DRAW TIME:	0440		1230	1800
ANALYSIS DATE/ID	11.29.97		11.29.97	11-29-97
ACCESSION #	[redacted]		[redacted]	
CK-TOTAL 21-232 u/l	54	[redacted]	59	49
* CK-MB 0-6 u/l		[redacted]		
** TROPONIN-I 0-1.5 ng/ml	<0.35	[redacted]	<0.35	<0.35
*** MYOGLOBIN < 110 ng/ml			[redacted]	

PATHOLOGIST COMMENT:

Baseline

PG

~~2 hr.~~

No evidence for acute myocardial injury.

PG 11/30/97 08:11

6 hr.

[redacted]

AE#12713, Cpt. [redacted]

DEA-DO memo 5/11/93 [redacted]

12 hr.

EX/ATT. 1 45 1110

* Note A Peak MB greater than 4% of the total CK is considered significant. Normal to slightly elevated total CK values with an apparent CKMB value of 20% or greater of the total CK, or sequential CKMB results not showing the typical rise and fall of activity over a 6-48 hour period are suggestive of atypical CK isoenzymes.

** Note Troponin-I 0-1.5 = Negative for MI, negative for Myocardial Ischemia
Troponin-I 1.6-3.1 = Suggest Myocardial Ischemia Injury
Troponin-I > 3.1 = Strongly suggests Myocardial Injury

***Note Myoglobin values x2 from baseline: 90% probability of impending MI

CHART COPY

Patient: [redacted] [redacted] **(Continued)**

********** CHEMISTRY (continued) **********
***** THERAPEUTIC DRUG MONITORING *****

Date	12/04/97	12/02/97	12/01/97	Reference	Units
Time	0345	0400	0400		
>>DIGOXIN	0.8	0.8	0.9	(0.8-2.1)	ng/mL
>>PROCAINAMIDE	2.5 *	3.4 *		(3.9-10.1)	ug/mL
>>NAPA	1.4(E) *	1.3 *		(3.9-10.1)	ug/ml

(E) REPORT CORRECTED, INPUT ERROR
CALLED TO [redacted]

>>PROCAINAMIDE/	3.9 *	4.7 *		(9-31)	ug/ml

[redacted]
AE#12713, Cplt.#NYK-3416
FDA-DO memo 5/11/98 AKR/AKL
EX/ATT: 1 44 - 146

TEST FLAG KEY: * = ABNORMAL, *H = CRITICAL HIGH, *L = CRITICAL LOW

Patient: [redacted] **Acc#** [redacted] **Unit** [redacted]

MEDICAL RECORDS SPECIMEN REPORT

LOCATION

PATIENT: [redacted] ACCT #: [redacted] LOC: [redacted] U #: [redacted]
AGE/SX: 64/F ROOM: REG: 01/17/98
REG DR: [redacted] STATUS: REG REF BED: DIS:

Specimen: [redacted] COMP Collected: 01/17/98-[redacted] Received: 01/17/98-[redacted]

Test	Result	Flag	Reference
> DIGOXIN	0.6	*	0.8-2.1 ng/mL

Specimen: [redacted] COMP Collected: 01/17/98-[redacted] Received: 01/17/98-[redacted]

Test	Result	Flag	Reference
PT			
> PT	12.3		10.9-13.2 SECONDS
> INR	1.1		0.7-1.5

Specimen: [redacted] COMP Collected: 01/17/98-[redacted] Received: 01/17/98-[redacted]

Test	Result	Flag	Reference
CBC			
> WBC	5.0		4.5-10.8 K/mm3
> RBC	4.85		4.70-6.10 M/mm3
> HGB	13.2	*	14.0-18.0 gm/dL
> HCT	39.9	*	42-52 %
> MCV	82.2		80-105 fL
> MCH	27.2		26.9-35.1 pg
> MCHC	33.0		32.0-36.0 g/dL
> RDW	14.4		10.0-17.9 %
> PLT	98	*	149-451 K/mm3
> MPV	9.8		7.4-10.4 fL

Specimen: [redacted] COMP Collected: 01/17/98[redacted] Received: 01/17/98[redacted]

Test	Result	Flag	Reference
NO REPORTABLE RESULTS			

[redacted]
AE#12713, Cplt.#NYK-3416
DEA-DO memo 5/11/98 AKR/AKR
EX/ATT: 1 pg 39 of 146

Patient: [redacted] [redacted] **(Continued)**

********** URINALYSIS **********
***** BIOCHEMICALS *****

Date	11/26/97						
Time	2229					Reference	Units
>>UA COLOR	YELLOW					(YELLOW)	
>>UA APPEARANCE	CLEAR					(CLEAR)	
>>UA GLUCOSE	NORM					(NORMAL)	mg/dL
>>UA BILIRUBIN	NEG					(NEGATIVE)	mg/dL
>>UA KETONES	NEG					(NEGATIVE)	mg/dL
>>UA SPEC GRAVI	1.020						
>>UA BLOOD	NEG					(NEGATIVE)	/uL
>>UA PH	6.5						
>>UA PROTEIN	30 *					(NEGATIVE)	mg/dL
>>SSA FOR PROTE	TRACE						mg/dL
>>UA UROBILINOG	NORM					(NORMAL)	mg/dL
>>UA NITRITE	NEG					(NEGATIVE)	
>>UA LK ESTERAS	NEG					(NEGATIVE)	/uL

***** MICROSCOPIC *****

Date	11/26/97						
Time	2229					Reference	Units
>>UA WBC	0-2					(NONE SEEN)	wbc/hpf
>>UA RBC	NEGATIVE					(NONE SEEN)	rbc/hpf
>>UA EPITH CELL	0-2						epi/hpf

[redacted]
AE#12713, Cplt.#NYK-3416
FDA-DO memo 5/11/98 AKR/AKR
EX/ATT: 1 42 - 146

TEST FLAG KEY: * = ABNORMAL, *H = CRITICAL HIGH, *L = CRITICAL LOW

Patient: [redacted] **Acc:** [redacted] **Unit:** [redacted]

[redacted]

NAME: [redacted]
PHYS: [redacted]
DOB: [redacted] AGE: 64 SEX: F
ACCT: [redacted] LOCATION: [redacted]
EXAM DATE: 11/26/97 STATUS: [redacted]
RADIOLOGY NO: [redacted]
UNIT NO: [redacted]

[redacted]

EXAMS: [redacted]CHEST AP - 1 VIEW

PORTABLE CHEST
11/26/97
2130 HOURS

COMPARISON: 2/11/97

The exam is significantly limited due to motion artifact. Cardiomegaly and chronic lung changes are again seen. Visualization of the left base is limited due to large heart shadow and overlying soft tissue. Underlying infiltrate at either base cannot be excluded. No pneumothorax is seen. Followup recommended.

REPORTED BY: [redacted]

CC: [redacted] M.D.; [redacted], M.D.

TECHNOLOGIST: [redacted]
TRANSCRIBED DATE/TIME: 11/28/97 (1526)
TRANSCRIPTIONIST: [redacted]
PRINTED DATE/TIME: 11/29/97 (0651) BATCH NO: [redacted]

[redacted]
AE#12713, CP[illegible] /Acl
DA-DO memo [illegible]
EX/ATT: 1 46 of 146

[redacted]

NAME: [redacted]
PHYS: [redacted]
DOB: [redacted] AGE: 64 SEX: F
ACCT: [redacted] LOCATION: [redacted]
EXAM DATE: 11/29/97 STATUS: [redacted]
RADIOLOGY NO: [redacted]
UNIT NO: [redacted]

EXAMS: [redacted] CT HEAD/BRAIN WO CONT

CT SCAN HEAD: 11/28/97

COMPARISON: 11/26/97

HISTORY: Stroke, follow-up.

Noncontrast enhanced sections from the base of the skull to vertex as requested by the ordering physician.

There is a focal area of slight increased CT attenuation in the left temporal region, surrounding white matter edema is seen including mass effect as evidenced by compression of the adjacent ventricular system. The appearance is most consistent with a small area of cerebral infarction and surrounding edema, possibly this is a hemorrhagic infarction although other etiologies not excluded. No interval changes are seen since the prior study.

IMPRESSION:

LEFT TEMPOROPARIETAL INTRACEREBRAL HEMORRHAGE WITH SURROUNDING EDEMA AND MASS EFFECT AS DESCRIBED. FOLLOW-UP RECOMMENDED.

RESULTS WERE CALLED TO THE REFERRING PHYSICIAN IMMEDIATELY UPON COMPLETION OF THE STUDY.

REPORTED BY: [redacted]

CC: [redacted] M.D.

TECHNOLOGIST: [redacted]
TRANSCRIBED DATE/TIME: 11/29/97 [redacted]
TRANSCRIPTIONIST: [redacted]
PRINTED DATE/TIME: 11/30/97 (0953) BATCH NO: [redacted]

[redacted]
AE#12713, CP
FLA-DO memo 5/11/02
EX/ATT: 1 49 of 146

[redacted]

[redacted]

NAME: [redacted]
PHYS: [redacted]
DOB: [redacted] AGE: 64 SEX: F
ACCT: [redacted] LOCATION: [redacted]
EXAM DATE: 11/28/97 STATUS: [redacted]
RADIOLOGY NO: [redacted]
UNIT NO: [redacted]

EXAMS: [redacted] CT HEAD/BRAIN WO CONT

CRANIAL CT
11/29/97

COMPARISON: 11/28/97
HISTORY: FOLLOWUP INTRACRANIAL HEMORRHAGE

Axial CT images were obtained from the foramen magnum to the vertex without the use of IV contrast.

Examination again reveals a focal area of hemorrhage measuring approximately 2 cm in the left basal ganglia. Surrounding edema is also noted. There is mass effect in the area with distortion of the frontal horn of the left lateral ventricle. There is, however no evidence of midline shift. The appearance of the study is unchanged when compared to yesterday's examination. No new areas of intracranial hemorrhage are seen. No extra-axial lesions are identified.

IMPRESSION:

PERSISTENT LEFT BASAL GANGLIA HEMORRHAGE, UNCHANGED FROM 11/28/97. THE FINDINGS ARE MOST LIKELY RELATED TO A HYPERTENSIVE HEMORRHAGE. UNDERLYING VASCULAR MALFORMATION OR NEOPLASM NOT EXCLUDED.

REPORTED BY: [redacted]

CC: [redacted] M.D.

TECHNOLOGIST: [redacted]
TRANSCRIBED DATE/TIME: 12/01/97 (1150)
TRANSCRIPTIONIST: [redacted]
PRINTED DATE/TIME: 12/01/97 (1354) BATCH NO: [redacted]

CHART COPY [redacted]

000012

[redacted]12713, C[illegible]616
[illegible]-DO memo [illegible]R/Ack
EX/ATT: 1 48 of 146

[redacted]

NAME: [redacted]
PHYS: [redacted]
DOB: [redacted] AGE: 64 SEX: F
ACCT: [redacted] LOCATION: [redacted]
EXAM DATE: 11/26/97 STATUS: [redacted]
RADIOLOGY NO: [redacted]
UNIT NO: [redacted]

EXAMS: [redacted] CT HEAD/BRAIN WO CONT

HEAD CT

COMPARISON: 1/1/97

Serial non-contrast axial images of the brain were obtained.

The exam was performed as an emergency after hours study and interpreted/reported by Dr. [redacted] at that time.

There is questionable slight effacement of the left-cortical sulci as well as questionable slight hypodensity of the left basal ganglia. There is no intracranial hemorrhage or midline shift identified.

IMPRESSION:

QUESTIONABLE SLIGHT EFFACEMENT OF LEFT CORTICAL SULCI AND QUESTIONABLE SLIGHT HYPODENSITY OF THE LEFT BASAL GANGLIA. THESE FINDINGS RAISE THE POSSIBILITY OF VERY EARLY INFARCT. A FOLLOWUP CT SCAN WITHIN 24 HOURS IS RECOMMENDED.

REPORTED BY: [redacted]

CC: [redacted]

TECHNOLOGIST: [redacted]
TRANSCRIBED DATE/TIME: 11/28/97 (1524)
TRANSCRIPTIONIST: [redacted]
PRINTED DATE/TIME: 11/29/97 (0651) BATCH NO: [redacted]

CHART COPY [redacted]

000013

#12713, C... KR/ALR
A-DO memo
EX/ATT: 1 47 of 146

[redacted]

26 NOV 1997 21:31:00

[redacted]

000014

64 yrs Female

MISC
09/06/33

PR	161
QRSD	105
	441
	406

(NSR)= Normal sinus rhythm, rate 51 [Remains]
(CLAE)- [Now Absent] Consider left atrial enlargement
(TOAL)- [Now Absent] Nonspecific Anterolateral T abnormalities
- NORMAL ECG

EX/ATT: 1 of 54
FLA-DO memo 5/11/98 AKR/MC
AE#127/13, Cplt.#NXK-3416
[redacted]

Requested by
[redacted]

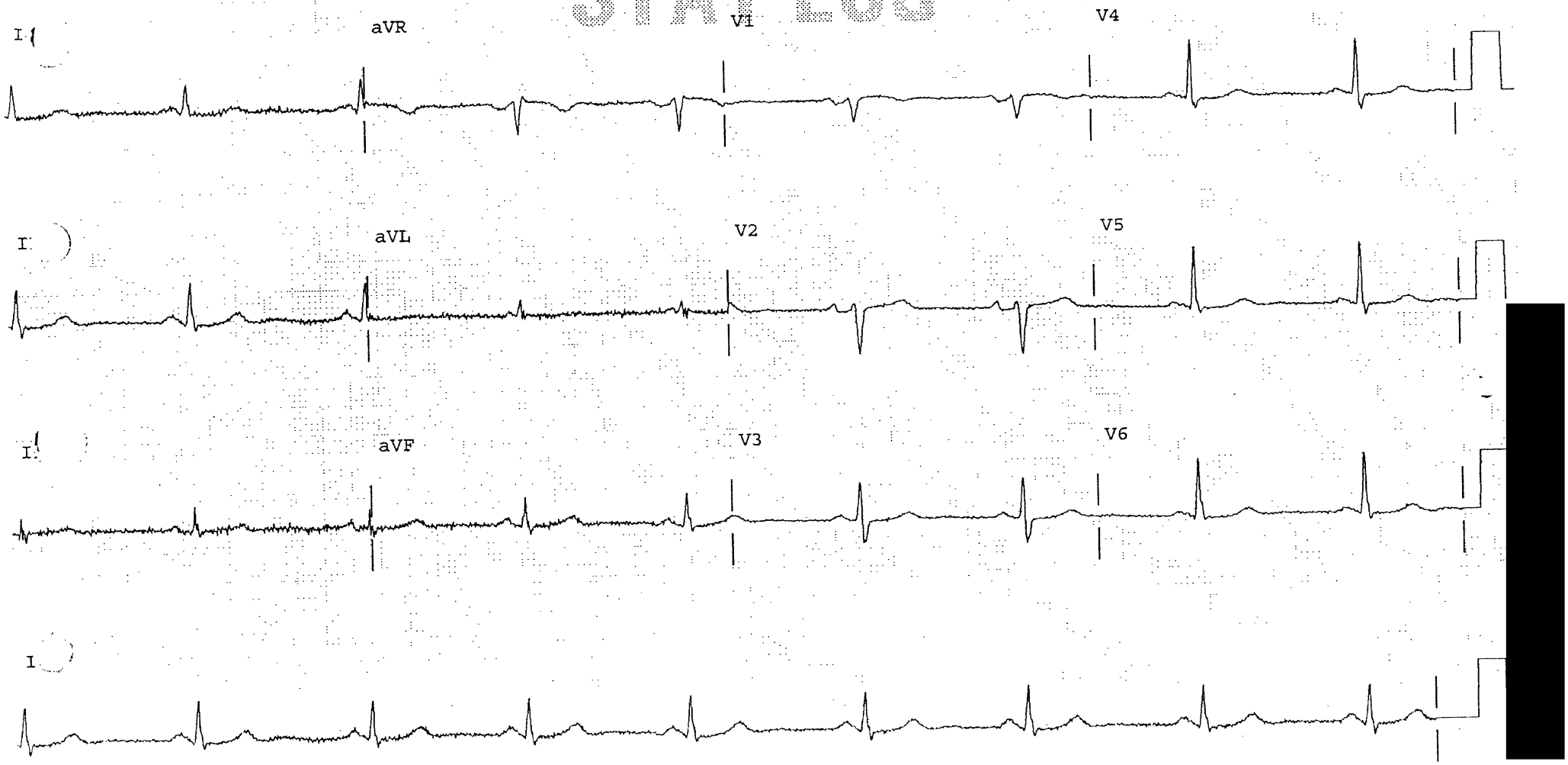
--AXES--

P	74
QRS	27
T	55

COMPARED TO: 31 DEC 1996 23:47:44, CONFIRMED BY [redacted]
[redacted] CARDIOPULMONARY

STAT ECG

Interpreted b [redacted]



[redacted]

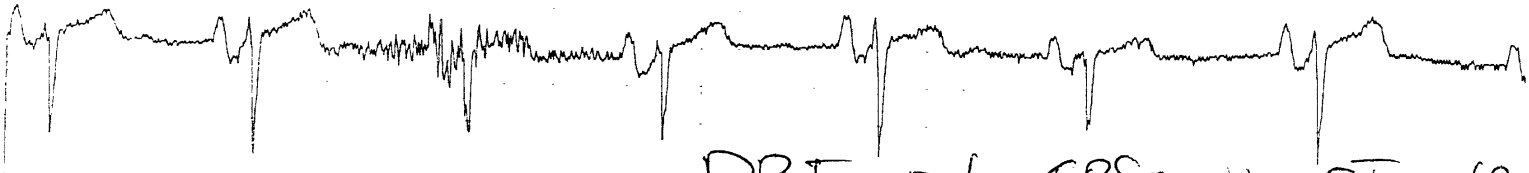
STAT ECG 25 mm/sec 10.0 mm/mV ~ W 0.50-100

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] , [redacted] 27 NOV 97 1:32 ** HR |48 < 50 HR 53 VPB 0 SINUS BRADY PULSE -?- NBP 155/75(100) 25
MCL1

1° AVB

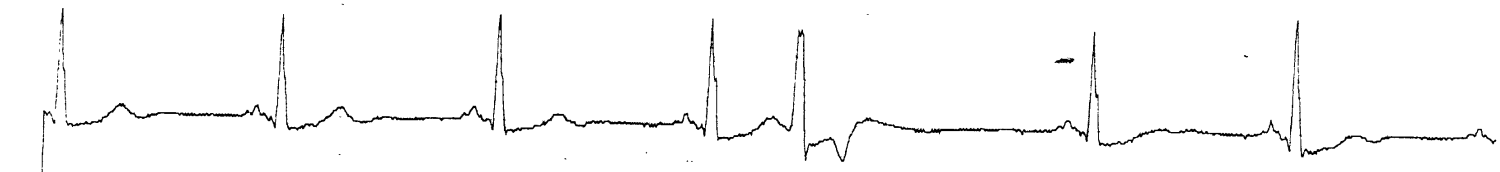
R-R reg



PRI-.24 QRS-.06 QT-.40

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] , [redacted] 27 NOV 97 7:17 HR 52 |VPB 3 SINUS BRADY VPBs 3 PULSE |-?- NBP -?- 2
III



PR 20
QRS .06 QT .36 [redacted] RN

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] , [redacted] 27 NOV 97 19:27 HR 64 | VPB 0 SINUS RHYTHM SVPBs 1 PULSE -?- NBP -?- 25 mm/sec (8AMIA10)
III

[redacted]

AE#12713, Cplt. #NYK-[illegible]5
FLA-DO memo 5/11/98 [illegible]/AKl
EX/ATT: 1 pg 62 of 146

RHYTHM STRIP RECORD

Echo - cardiol
CT head Fri
* PO meds

PATIENT IDENTIFICATION (ADDRESSOGRAPH AREA)

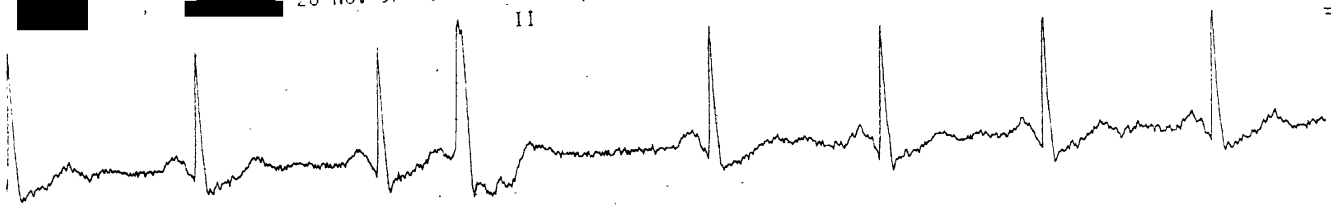
[redacted]

[redacted]

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] [redacted] 28 NOV 97 6:47 HR 64 | VPB 0 SINUS BRADY SVPBs 2 PULSE -?- NBP 196/

II



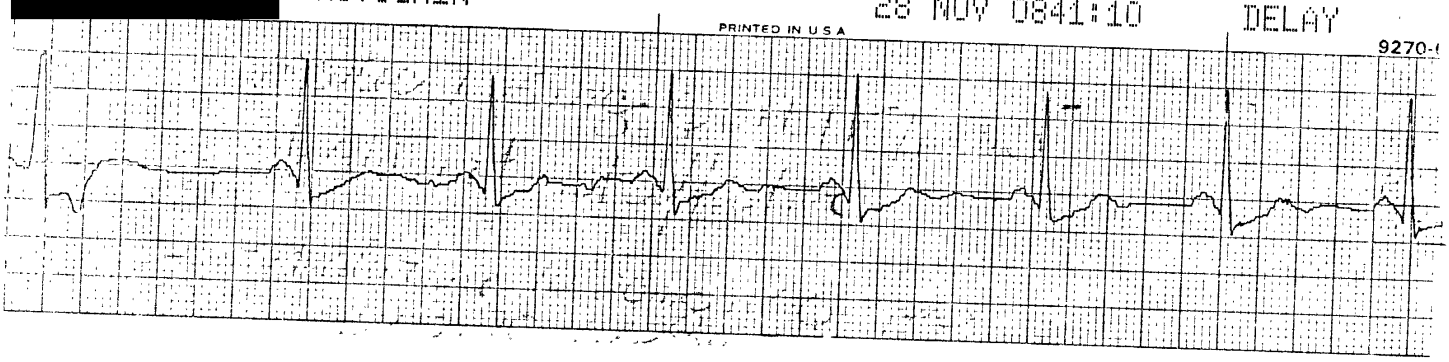
PR 0.20 QRS 0.08 [illegible]

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] LEAD II AUTOGAIN 28 NOV 0841:10 DELAY

PRINTED IN U.S.A.

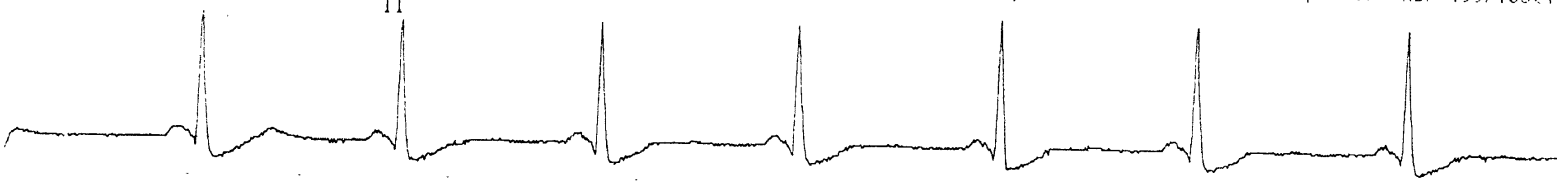
9270-



DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] 28 NOV 97 19:09 ** VPBs > 5/MIN HR 59 VPB 2 SINUS BRADY VPBs | 2 PULSE 50 SpO2 97 NBP 199/105

II



SB PR .16 QRS .08

RHYTHM STRIP RECORD

[redacted]

AE#12713, Cplt.#NYK-3416
ELA-DO memo 5/11/98 AKR/AKR
EX/ATT: 1 pg 63 of 146

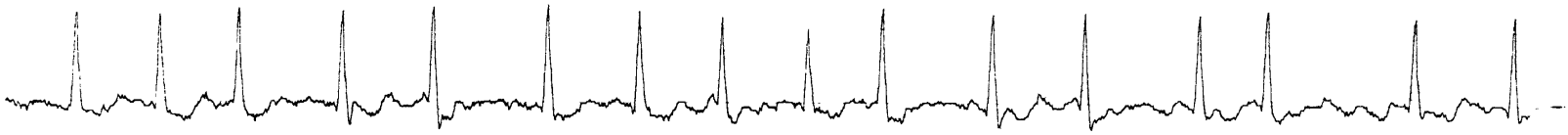
[redacted]

[redacted]

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] , [redacted] 29 NOV 97 2:30 ***TACHY 151 >150 HR 117 VPB 1 IRREGULAR HR VPBs | 1 PULSE 80 Sp02 96 NBP 184/

II



Afib Dig. .5mg IV x 1

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] . [redacted] 29 NOV 97 4:55 ** PAIR VPBs HR 102 VPB 5 IRREGULAR HR VPBs | 5 PULSE 71 Sp02 95 NBP 130/

II

[redacted]

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

29 NOV 1019:00 [redacted] DELAY HR113 [redacted]

PRINTED IN U.S.A.

RHYTHM STRIP RECORD

[redacted]

AE#12713, Cplt.#NYK-3416
PLA-DO memo 5/11/98 AKS/AKR
EX/ATT: 1 pg 64 of 146

PATIENT IDENTIFICATION (ADDRESSOGRAPH AREA)

[redacted]

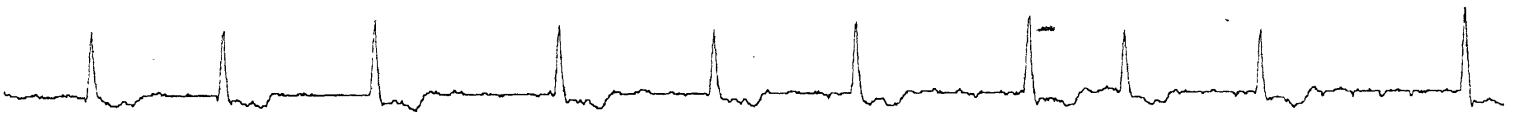
[redacted]

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] , [redacted] 29 NOV 97 12:09 ** MULTIFORM VPBs HR 119 VPB 3 IRREGULAR HR VPBs | 2 PULSE 76 SpO2 96 NB
II

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

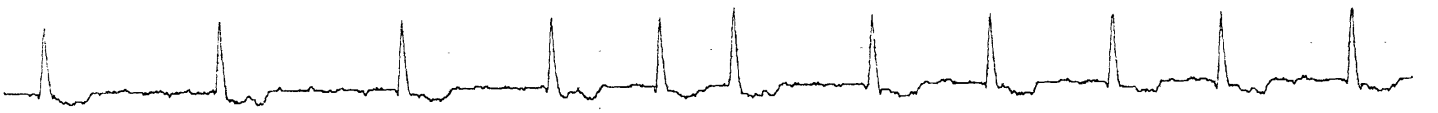
[redacted] , [redacted] 30 NOV 97 0:49 HR 74 | VPB 0 IRREGULAR HR PULSE 71 SpO2 99 NBP 156/81(107) 25 mm/sec (8AM
II



A fib ±74 — QRS .06

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] , [redacted] 30 NOV 97 7:54 HR 85 | VPB 0 IRREGULAR HR PULSE 80 SpO2 98 NBP 131/92(108) 25 mm/sec
II



QRS0.08 AfvD

[redacted]

RHYTHM STRIP RECORD

[redacted]

AE#12713, Cplt.#NYK-3416
FLA-DO memo 5/11/98 AKR/AKR
EX/ATT: 1 pg 65 of 146

PATIENT IDENTIFICATION (ADDRESSOGRAPH AREA)

[redacted]

[redacted]

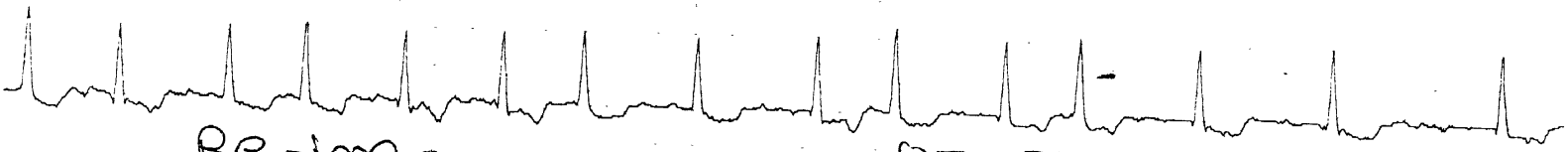
DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] [redacted] 30 NOV 97 19:07 HR 117 | VPB 0 IRREGULAR HR PULSE 108 SpO2 97 NBP |159/73(99) 25 mm/sec (8AMIA10)[G6001
II

R-R Irreg.
PR —
QRS .08
QT .32
A-fib.

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

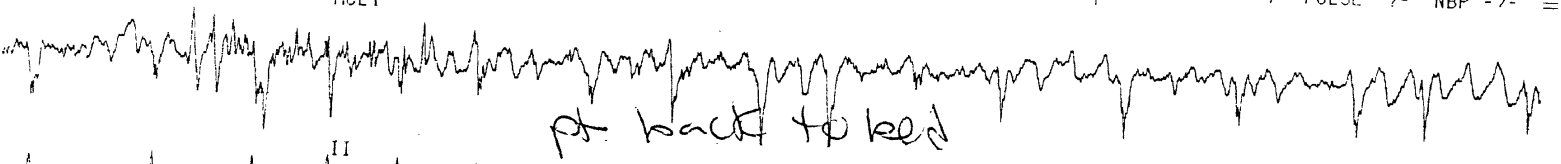
[redacted] [redacted] 01 DEC 97 6:58 HR 116 | VPB 1 IRREGULAR HR VPBs 1 PULSE 78 SpO2 96 NBP 108/48(65) 25 mm
II



RR-irreg
PR Ø
QRS.08
QT-0.32
A-fib
[redacted]

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] [redacted] 01 DEC 97 17:08 ***VENT TACHY HR 152 VPB 36 UNKNOWN ECG RHYTHM RUN VPBs 7 PULSE -?- NBP -?- =
MCL1



pt back to bed

II

Dr [redacted] notified

RHYTHM STRIP RECORD

[redacted]

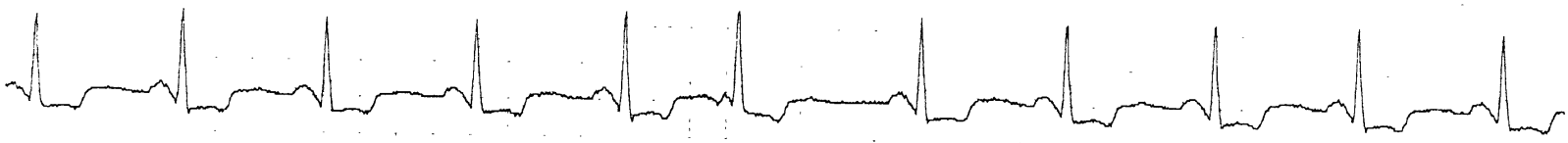
AE#12713, Cplt.#NYK-3416
FDA-DO memo 5/11/98 AKR/AKR
EX/ATT: 1 pg 66 of 146

PATIENT IDENTIFICATION (ADDRESSOGRAPH AREA)

[redacted]

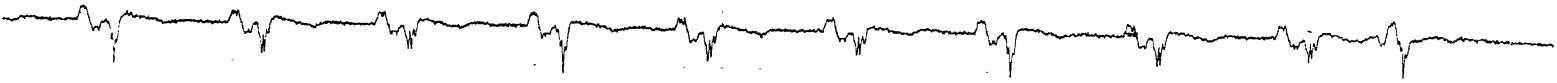
DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] [redacted] 01 DEC 97 18:17 HR 75 | VPB 0 SV RHYTHM PULSE -?- NBP 168/74(102) | 25 mm/sec (8AMIA10)[G8001]
II



DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] [redacted] 01 DEC 97 18:18 HR 80 VPB 0 SV RHYTHM SVPBs 1 PULSE |-?- NBP 168/74(102) 25 mm/sec
MCL1

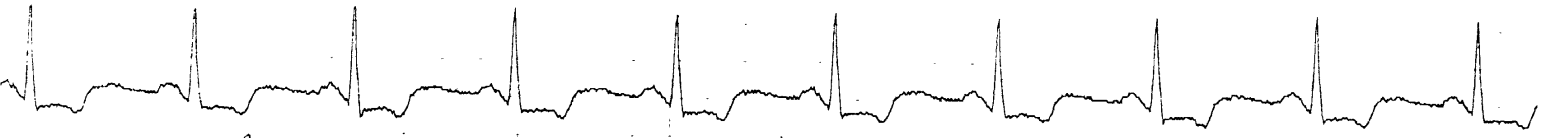


II

Dr. [redacted] notified - Pronestyl bolus started 1745

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] [redacted] 01 DEC 97 20:45 HR 70 | VPB 0 SINUS RHYTHM PULSE -?- NBP 116/57(77) 25 mm/sec (8AMIA10)[G8001]
II



R-R Reg. QRS .08
PR .16 QT .32

Sinus Rhythm

[redacted]

RHYTHM STRIP RECORD

[redacted]

AE#12713, Cplt.#NYK-3416
DLA-DO memo 5/11/98 AKR/AKR
EX/ATT: 1 pg 67 of 146

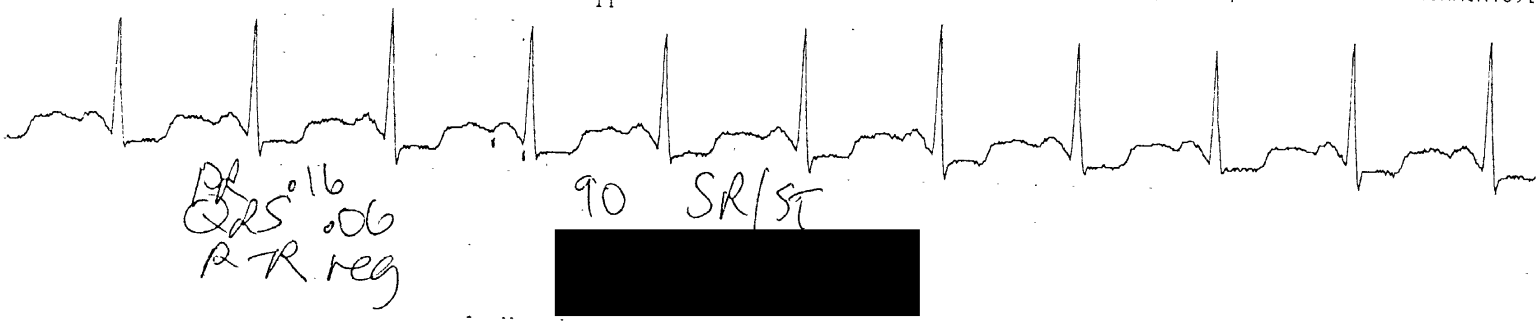
[redacted]

PATIENT IDENTIFICATION (ADDRESSOGRAPH AREA)

[redacted]

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] [redacted] 02 DEC 97 6:46 HR 82 | VPB 0 SINUS RHYTHM PULSE 82 SpO2 93 NBP ?- 25 mm/sec (8AMIA10)[G
II



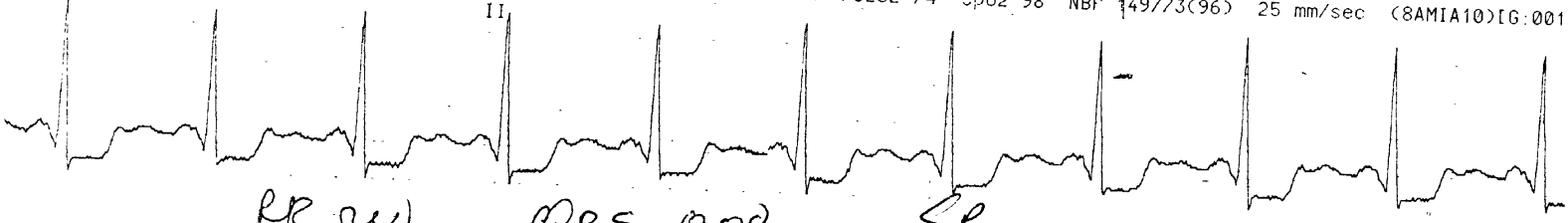
PR .16
QRS .06
RR reg

90 SR/ST

[redacted]

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] [redacted] 02 DEC 97 19:01 HR 75 | VPB 0 SINUS RHYTHM PULSE 74 SpO2 98 NBP 149/73(96) 25 mm/sec (8AMIA10)[G:001
II



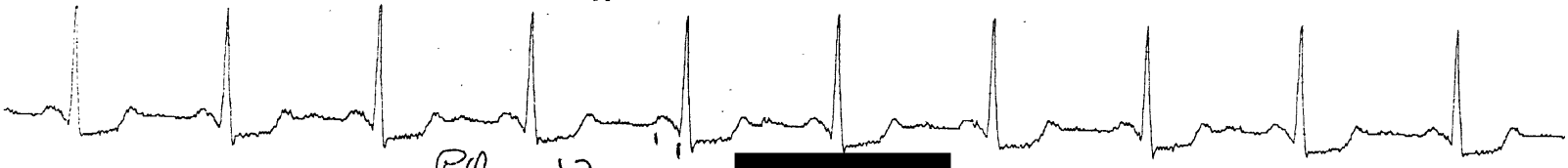
RR reg
RR. 0.16

QRS - 0.08
QT. 0.36.

SR.

[redacted]

[redacted] [redacted] 03 DEC 97 6:46 HR 71 | VPB 0 SINUS RHYTHM PULSE 71 SpO2 98 NBP 138/60(87) 25 mm/sec (8AMIA10
II



PR .12
QRS .08
RR reg

[redacted]

RHYTHM STRIP RECORD

[redacted]

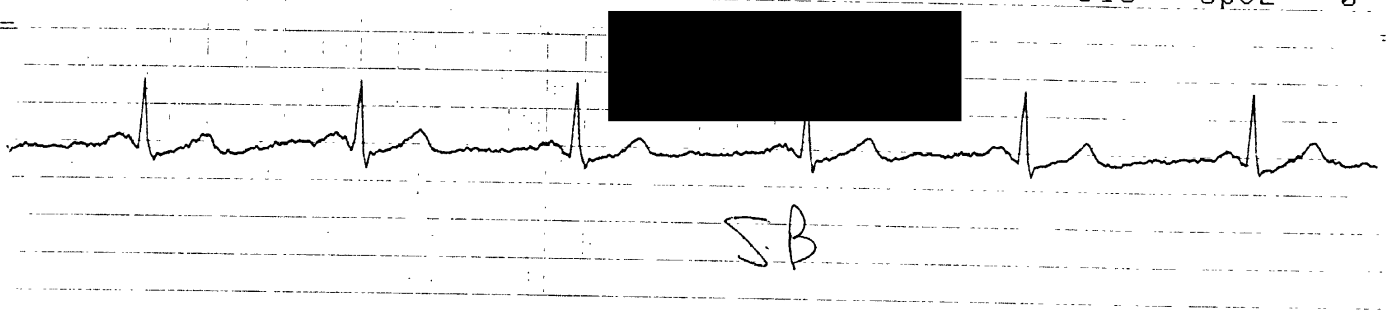
AE#12713, Cplt.#NYK-3416
FDA-DO memo 5/11/98 AKR/AKR
EX/ATT: 1 of 68 of 146

PATIENT IDENTIFICATION (ADDRESSOGRAPH AREA)

[redacted]

[redacted]

DATE	TIM'



DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

DOCUMENT HERE WITH MONITOR STRIP

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

DOCUMENT HERE WITH MONITOR STRIP

RHYTHM STRIP RECORD

[redacted]
AE#12/13, Cplt.#NYK-3416
FLA-DO memo 5/11/98 AKR/AKR
EX/ATT: 1 pg 69 of 146

PATIENT IDENTIFICATION (ADDRESSOGRAPH AREA)

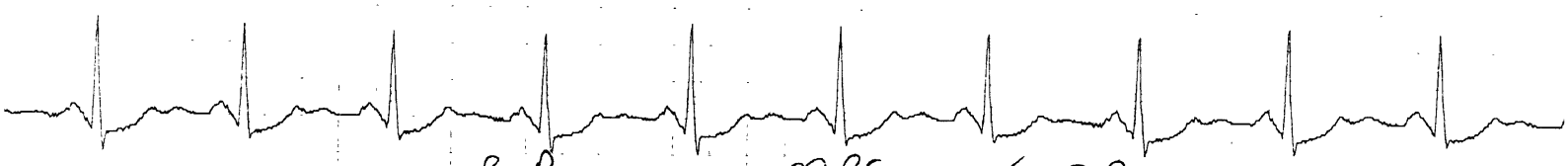
[redacted]

[redacted]

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

[redacted] [redacted] 03 DEC 97 19:08 HR 75 VPB 1 SV RHYTHM VPBs 1 PULSE -?- NBP -?- 25 mm/sec (8AMIA10)[G<06

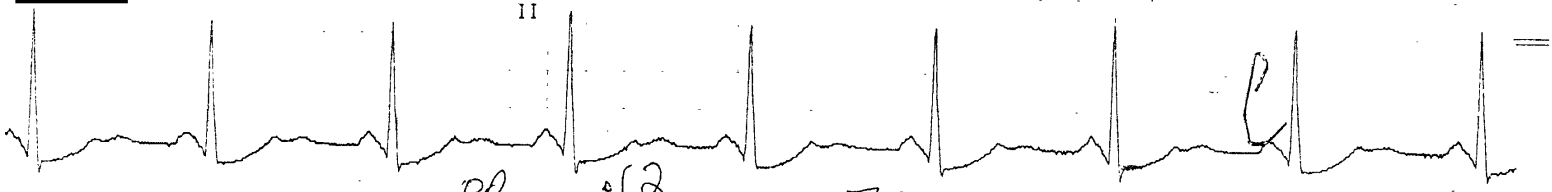
II



R-R-reg. QRS 0.08 SR.
P-R-0.16 QT-0.36 [redacted] RN.

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD
[redacted]	[redacted]	04 DEC 97 6:40 HR 62 VPB 0 SV BRADY SVPBs 1 PULSE -?- NBP -?- 25 mm/sec (8AMIA1			

II



PR .12
QRS .06 SR 70
R-R reg [redacted] RN

DATE	TIME	TYPE OF ARRHYTHMIA	NURSING DIAGNOSIS BY	PR/QRS INTERVAL	LEAD

DOCUMENT HERE WITH MONITOR STRIP

RHYTHM STRIP RECORD

[redacted]

AE#12713, Cplt.#NYK-3415
EEA-DO memo 5/11/98 AKR/AKR
EX/ATT: 1 PG 70 OF 146

[redacted]

PATIENT IDENTIFICATION (ADDRESSOGRAPH AREA)

[redacted]

[redacted]

VASCULAR LABORATORY REPORT [redacted]

Mailbox [redacted]

PATIENT NAME: [redacted]
DATE OF STUDY: 11/27/97
ATTENDING PHYSICIAN: [redacted] M.D. [redacted]
REFERRING PHYSICIAN: [redacted] M.D.
UNIT #: [redacted] ROOM #: [redacted]
ACCOUNT [redacted] DOB: [redacted]

VASCULAR EXAMINATION: Carotid ultrasound.

REASON FOR STUDY:

The right and left extracranial carotid systems were evaluated from the angle of the jaw to the clavicle.

On the right side, the vertebral showed antegrade flow, the common carotid was widely patent, velocities were well maintained. There was no evidence of significant plaquing or ulcerations.

On the left side, again the common carotid was widely patent. The vertebral showed antegrade flow. Again, there was minimal atherosclerotic plaquing at the level of the bulb with no significant velocity changes or diameter reduction.

IMPRESSION:

1. No evidence of significant extracranial carotid stenosis involving the right or the left extracranial carotid system.
2. Antegrade flow bilaterally in the vertebral vessels. Clinical correlation is suggested.

[redacted] M.D.

DD: 11/29/97
DT: 12/01/97
[redacted]

AE#12713, Cpl. NYK-3416
FLA-DO memo 5/11/98 AKR/AKC
EX/ATT: 1 of 50 of 146

[redacted]

ECHOCARDIOGRAPHY REPORT [redacted]

Mailbox [redacted]

PATIENT NAME: [redacted]
DATE OF TEST: 11/28/97
UNIT #: [redacted]
ACCOUNT # [redacted]

ROOM #:
DOB: [redacted]

ECHOCARDIOGRAM WITH DOPPLER:

REASON FOR STUDY:

Please see attached sheet for measurements.

FINDINGS:

This is a technically limited study with limited views particularly in the apical windows.

The aortic valve appears mildly sclerotic with good leaflet excursion and trileaflet. There is no stenosis or insufficiency.

The mitral annulus is calcified particularly posterior annulus. Leaflets appear to move well with only mild thickening. No vegetations are seen. No stenosis. Trace to mild insufficiency.

There is no tricuspid or pulmonic insufficiency. Tricuspid valve leaflets were not well visualized.

Left ventricular chamber size is mildly increased, wall thickness is mildly increased and wall motion is at lower limits of normal with no definite segmental wall motion abnormalities observed. There is no visualized in the left ventricular chamber. Estimated ejection fraction is approximately 55%.

The right ventricular chamber appears mildly increased and wall thickness is increased. Wall motion appears preserved.

The left atrial dimension measures normally. The right atrium was not well visualized.

No thrombus was visualized in the cardiac chambers. There is no pericardial effusion.

[redacted]
AE#12713, Cplt.#NYK-3416
FLA-DO memo 5/11/98 AKR/ACL
EX/ATT: 1 51 of 146

[redacted]

ECHOCARDIOGRAPHY REPORT

Mailbox [redacted]

IMPRESSION:

Technically limited study showing:

1. Mild concentric hypertrophy of the left ventricle with mild enlargement of the ventricle but lower limits of normal systolic function and no segmental abnormalities seen.
2. Mild dilatation and hypertrophy of the right ventricle with normal systolic function.
3. Upper limits of normal left atrial dimension.
4. Mitral annular calcification and mild insufficiency.
5. Mild aortosclerosis with no stenosis or insufficiency.
6. No thrombus visualized in this limited study in the cardiac chambers or associated with the valves.
7. No vegetations seen within the technical limits of the study associated with the cardiac valves.

[redacted] M.D.

DD: 12/01/97
DT: 12/02/97
[redacted]

cc: [redacted]

[redacted]
AE#12713, Cplt.#NYK-3416
FLA-DO memo 5/11/98 AKR/AC
EX/ATT: 1 pg 32 of 146

[redacted]

NAME: [redacted] F [redacted]
ROOM:

HT: 5 FT 7 IN 170 CM WT: 229 LB 15 OZ 104.3 KG

Admit Problem #1:-CVA
Admit Problem #2:-HYPERTENSION
Medication Allergies:NKA
Food/Other Allergies:NKA
Isolation #1:-
IV? O2? DNR:

Physician to read: [redacted]
Does Patient Have History Of Coronary Artery Disease? N
Comments:

DATE: 11/28/97
ROOM: [redacted]
TECH: [redacted]

ECHO M-MODE 2-D (PF) (EMSDP) ROUTINE SER DATE: 11/28/97
TIME: 0800

ORDERED BY: [redacted] ENTERED BY: [redacted] 11/27/97 [redacted]

TUDY [redacted] TAPE [redacted] MONTH 11 YEAR 97 REASON FOR STUDY:

M-MODE AND 2D MEASUREMENTS		Normal Range		DOPPLER MEASUREMENTS		Normal Range	
VIDd	5.9	3.8 - 5.6	cm	MV VEL. (PEAK)	.88	.6-1.3	m/sec
VIDs	3.9	2.2 - 4.0	cm	MV GRADIENT	3-1		mmHg
VSD	1.2	0.7 - 1.1	cm	MV AREA(PH TIME)	2.8	4-6	cm^2
VPWd	1.2	0.7 - 1.1	cm	MV AREA (PLANIM)	—	4-6	cm^2
LVIDd	1.4	0.9 - 2.6	cm	AO VEL (PEAK)	1.0	1-1.7	m/sec
AO ROOT	3.0	2.1 - 4.0	cm	AO GRADIENT(MAX)	4.2		mmHg
AOV EXCURS.	1.6	1.5 - 2.6	cm	AO GRADIENT(MEAN)	2-2		mmHg
LA	3.8	2.0 - 4.0	cm	AO VALVE AREA (CE)	—	3-5	c/m^2
MV D-E EXC.		2.0 - 3.5	cm	PV VEL. (PEAK)	.87	.6-.9	m/sec
MV E-F SLOPE	—	5.9	cm/sec	PV REGURG. VEL.		1.5	m/sec
E-POINT SEPT.	1.2	UP TO 0.6	cm	TV VEL. PEAK)	.45	.3-.7	m/sec
% F.S.	39	25 - 46	%	TV REGURG. VEL.	—	2.5	m/sec
% E.F.	61	50 - 80	%	EST. RVSP	—	18-25	mmHg

[redacted]
AE#12713, Cplt.#NYK-3416
EA-DO memo 5/11/98 AKR/AKR
EX/ATT: 1 pg 53 of 146

Memorandum to ARMS # 12713

COPY

Date: 21Oct98

From: Medical Officer, Clinical Research and Review Staff, Office of Special Nutritionals, HFS-452

Subject: Medical Records Place in Permanent Storage.

The following types and amounts of records (more than 20 pages total) were place in permanent storage on this date because they were not considered essential for interpretation of this adverse event.

Approx Pages	Type of Records
30	Nursing notes
	Dietitian notes
	Respiratory therapy/occupational therapy/physical therapy notes
	Clergy notes
19	Medication records
12	Physician's orders
5	Vital signs, fluids, input/output records
	Ventilator records
9	Hospital administrative records (e.g., insurance information, living will, etc)