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

ARMS#

13229

7 - PROCEDURES

[redacted] ID: [redacted] 22-NOV-1998 19:56 [redacted] ROUTINE RECORD

CFS4U 13229

000002

15 yr
Female Caucasian

Loc: [redacted]

| | | |
|---|---|---|
| Vent. rate | 72 | BPM |
| PR interval | 124 | ms |
| QRS duration | 78 | ms |
| QT/QTc | 372/407 | ms |
| P-R-T axes | 57 60 | 19 |

** ** ** ** * Pediatric ECG Analysis * * * * * * *

Normal sinus rhythm

Low voltage T-waves

QT interval has normalized from outside ECG's

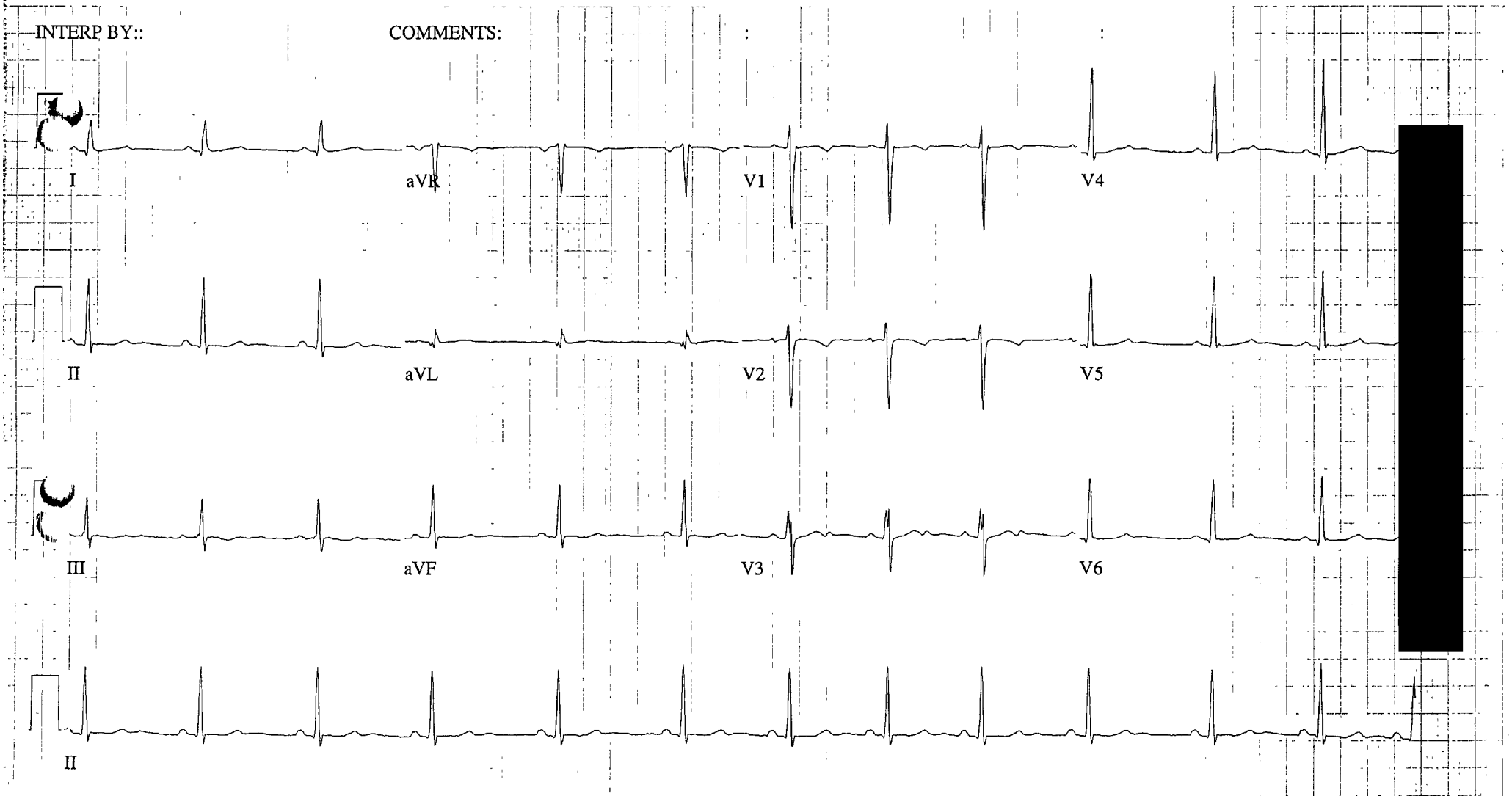
Technician: [redacted]

Referred by:

Confirmed by [redacted]

INTERP BY::

COMMENTS:




[redacted]

25mm/s 10mm/mV 100Hz 004A-004A [redacted]

[redacted] EDT: 13:13 30-NOV-1998 ORDER:

[redacted] ID: [redacted] 23-NOV-1998 09:32 [redacted] ECG ROUTINE RECORD

15 yr
Female

Loc: [redacted]

| | | |
|---|---|---|
| Vent. rate | 52 | BPM |
| PR interval | 132 | ms |
| QRS duration | 78 | ms |
| QT/QTc | 448/416 | ms |
| P-R-T axes | 60 58 | 28 |

** ** ** ** * Pediatric ECG Analysis * ** ** ** **

Sinus bradycardia

Otherwise normal ECG

000003

Technician: [redacted]

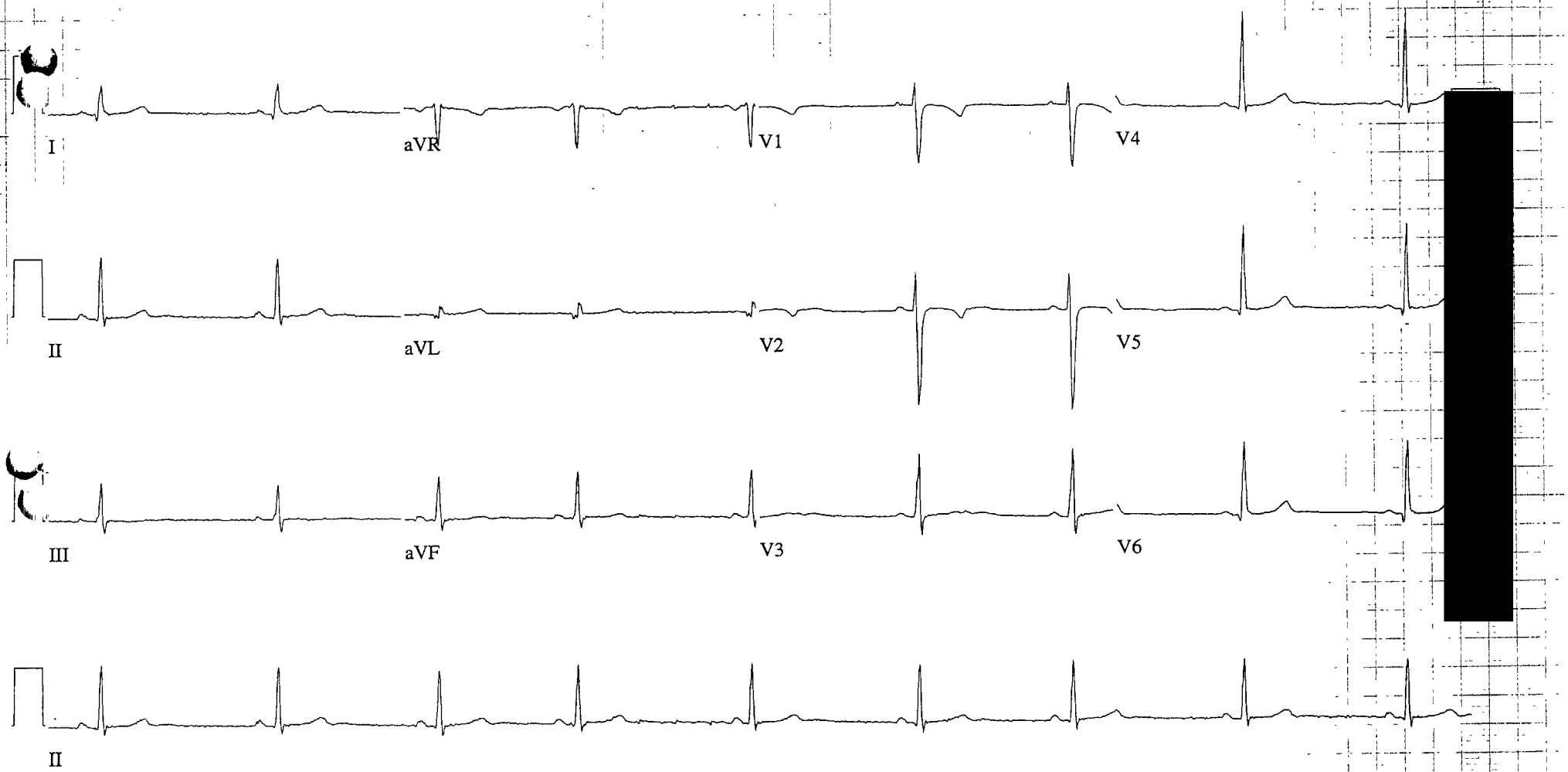
Test ind: CHEST PAIN INDIGESTI

Referred by:

Confirmed by: [redacted] M.D.

INTERP BY::

COMMENTS:




[redacted]

25mm/s 10mm/mV 100Hz 004A-004A [redacted]

[redacted] EDT: 15:47 23-NOV-1998 ORDER:

CFS4N 13229

EXERCISE REPORT

Patient [redacted]

Patient ID [redacted]

FINAL STRESS REPORT

## PATIENT and STUDY INFORMATION

Patient name: [redacted]

Patient ID: [redacted]

DoB/Age: 15 Years

Gender: Female

Study date: 23–Nov–1998

Referring MD:

Technician: [redacted]

## REASON for STUDY

## MEASUREMENTS SUMMARY

Protocol: BRUCE

Max work load: 14.2

Total exer time: 12:34

## MAXIMUM BP

180 / 53

## MAXIMUM HEART RATE

Max achieved HR: 186

Max predicted HR: 205

% of max predicted HR: 90

## INTERPRETATION

Reason for Termination: Fatigue

Comments: Normal HR response to exercise

Normal BP response to exercise

No pathoogical ST segment changes

No arrhythmias induced

Normal AV conduction and repolarization

Normal maximal treadmill exercise test

READING MD: [redacted] M.D.

[redacted] ID: [redacted] 23-NOV-1998 11:48 [redacted]

CFS4U 13229

000005

# GRADED EXERCISE SUMMARY

15 yr | Caucasian | Female | BRUCE | Total Exercise Time: 12:34

Wt: | Ht: | Max HR: 186bpm 90% of Max Predicted 205bpm | 25mm/s

Meds: | Max BP: 180/53 | Maximum Workload: 14.2 METS | 10mm/mV | 100Hz

Reason for Termination: Fatigue

Referred by:

Technician: [redacted]

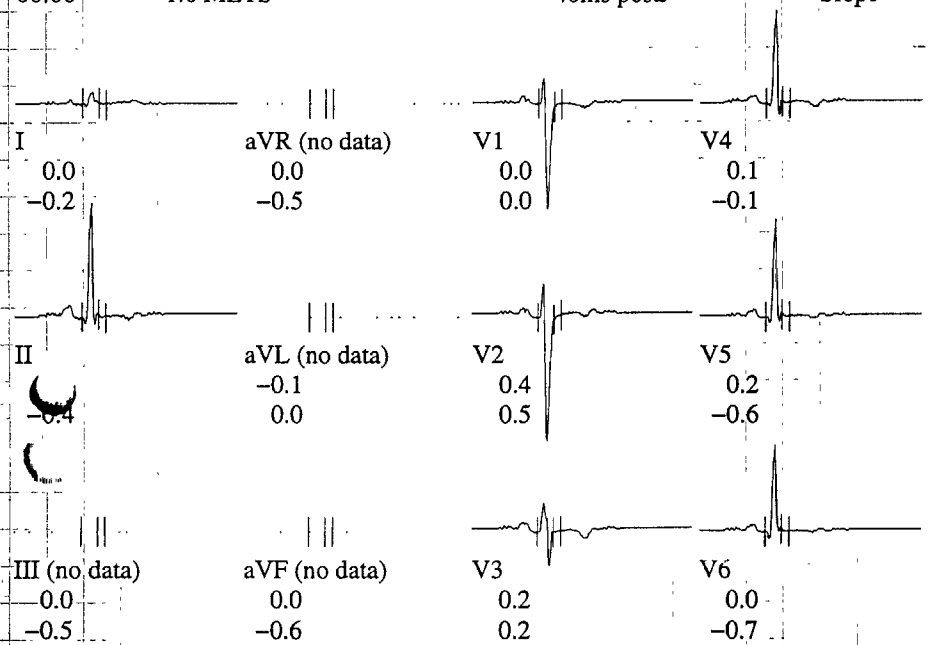
Test Ind.: chest pain ingestion

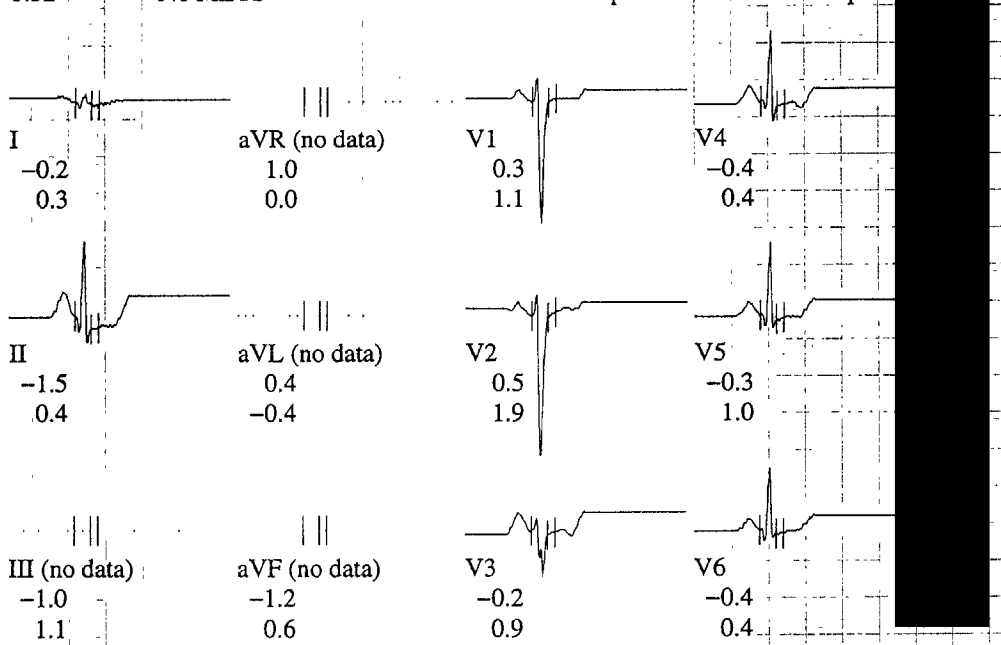
Test type:

Comments: Normal HR response to exercise
Normal BP response to exercise
No pathoogical ST segment changes
No arrhythmias induced
Normal AV conduction and repolarization ...

CPX?:No

ECHO?:No




Confirmed By [redacted] M.D. Date:23-NOV-1998

[redacted] EDT: 15:48 23-NOV-1998 ORDER:

[redacted]

[redacted] ID [redacted] 23-NOV-1998 11:48 [redacted]-ECG ROUTINE RETRIEVAL

CFS4W 13229

# GRADED EXERCISE SUMMARY

000006

15 yr Caucasian Female BRUCE Total Exercise Time: 12:34
Wt: Ht: Max HR: 186bpm 90% of Max Predicted 205bpm
Meds: Max BP: 180/53 Maximum Workload: 14.2 METS

...Normal maximal treadmill exercise test

Referred by:
Technician: [redacted]
Test Ind.: chest pain ingestion
Test type:

CPX?:No
ECHO?:No

[redacted]

Confirmed By: [redacted] M.D. Date:23-NOV-1998

[redacted] EDT: 15:48 23-NOV-1998 ORDER:

[redacted]

[redacted] ID [redacted] 23-NOV-1998 11:48 [redacted] ECG ROUTINE RETRIEVAL

CFSAU 13229

# GRADED EXERCISE SUMMARY

000002

15 yr Caucasian Female BRUCE Total Exercise Time: 12:34
Wt: Ht: Max HR: 186bpm 90% of Max Predicted 205bpm
Meds: Max BP: 180/53 Maximum Workload: 14.2 METS

Reason for Termination: Fatigue
Comments: Normal HR response to exercise
Normal BP response to exercise
No pathoogical ST segment changes
No arrhythmias induced
Normal AV conduction and repolarization ...

Referred by:
Technician: [redacted]
Test Ind.: chest pain ingestion
Test type:

CPX?:No
ECHO?:No

| Phase Name | Stage Name | Time in Stage | Speed mph | Grade % | Work Load METS | Heart Rate bpm | BP mmHg | RPP bpm*mmHg | VE Count ve's/min |
|---|---|---|---|---|---|---|---|---|---|
| PRETEST | SUPINE | 0:00 | 0.0 | 0.0 | 1.0 | 82 | 130/63 | 10700 | 0 |
| | STANDING | 0:00 | 0.0 | 0.0 | 1.0 | 106 | 103/55 | 10900 | 0 |
| | WARMUP | 0:00 | 1.6 | 0.0 | 1.0 | 106 | | | 0 |
| EXERCISE | STAGE 1 | 1:30 | 1.7 | 10.0 | 3.7 | 128 | | | 0 |
| | STAGE 1 | 1:30 | 1.7 | 10.0 | 4.3 | 126 | | | 0 |
| | STAGE 2 | 1:30 | 2.5 | 12.0 | 6.3 | 142 | | | 0 |
| | STAGE 2 | 1:30 | 2.5 | 12.0 | 6.8 | 145 | 180/53 | 26100 | 0 |
| | STAGE 3 | 1:30 | 3.4 | 14.0 | 9.2 | 163 | | | 2 |
| | STAGE 3 | 1:30 | 3.4 | 14.0 | 9.8 | 169 | | | 2 |
| | STAGE 4 | 1:30 | 4.2 | 16.0 | 12.5 | 176 | | | 0 |
| | STAGE 4 | 1:30 | 4.2 | 16.0 | 13.1 | 182 | | | 0 |
| | STAGE 5 | 0:34 | 5.0 | 18.0 | 14.2 | 185 | | | 0 |
| RECOVERY | WALKING | 0:42 | 1.7 | 0.0 | 10.1 | 180 | 180/53 | 32400 | 0 |
| | SUPINE | 12:40 | 0.0 | 0.0 | 1.0 | 83 | | | 0 |

[redacted]

Confirmed By [redacted] M.D. Date:23-NOV-1998

[redacted] EDT: 15:48 23-NOV-1998 ORDER:

[redacted]

[redacted] ID [redacted] 23-NOV-1998 11:48 [redacted] ECG ROUTINE RETRIEVAL

CFSAR 13229

# GRADED EXERCISE SUMMARY

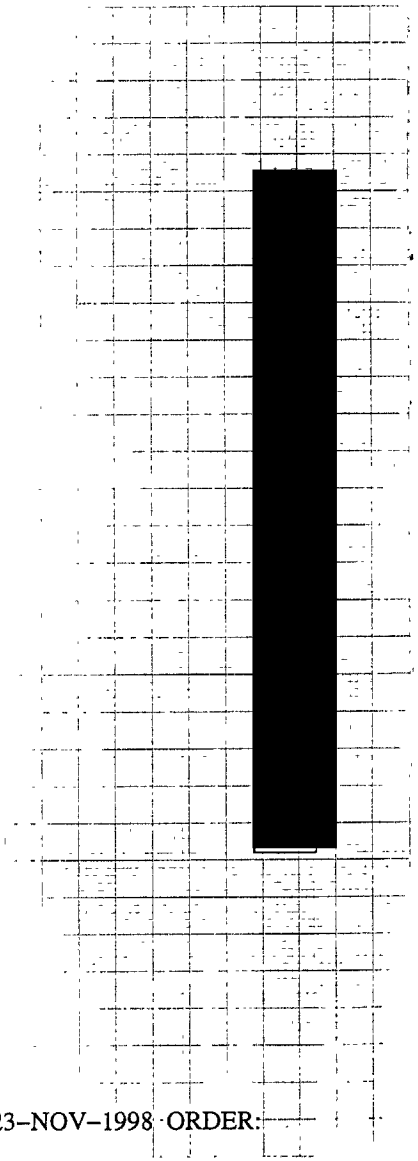
15 yr Caucasian Female BRUCE Total Exercise Time: 12:34
Wt: Ht: Max HR: 186bpm 90% of Max Predicted 205bpm
Meds: Max BP: 180/53 Maximum Workload: 14.2 METS

...Normal maximal treadmill exercise test

000008

Referred by:
Technician: [redacted]
Test Ind.: chest pain ingestion
Test type:

CPX?:No
ECHO?:No



Confirmed By [redacted], M.D. Date:23-NOV-1998

[redacted] EDT: 15:48 23-NOV-1998 ORDER:

[redacted]

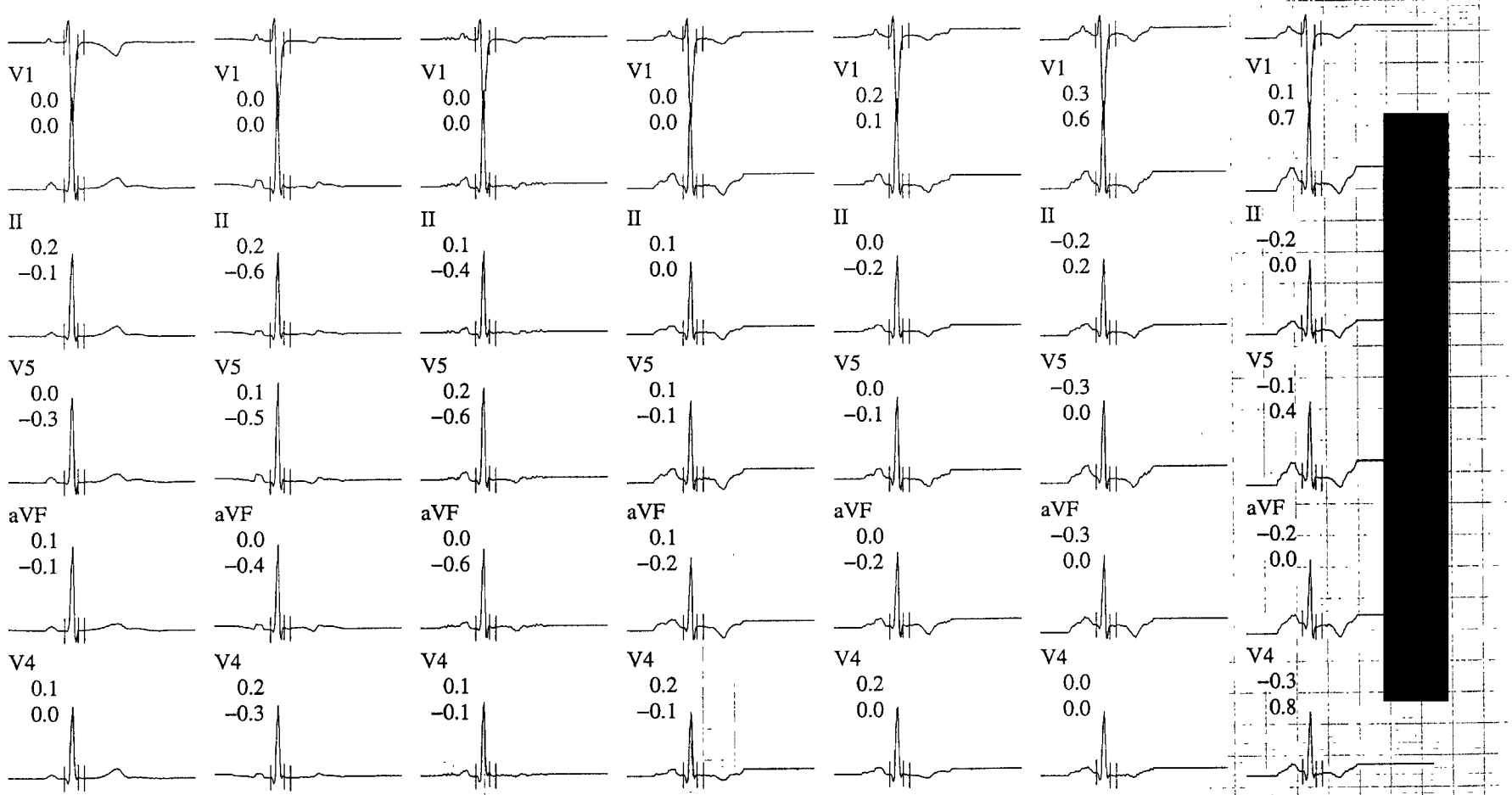
CFSAU 13229

[redacted] ID: [redacted] 23-NOV-1998 11:48 [redacted]-ECG ROUTINE RETRIEVAL

000009

# SAMPLE CARDIAC CYCLES

| | PRETEST SUPINE | PRETEST STANDING | EXERCISE STAGE 1 | EXERCISE STAGE 1 | EXERCISE STAGE 1 | EXERCISE STAGE 2 | EXERCISE STAGE 2 |
|---|---|---|---|---|---|---|---|
| | 24:44 | 1:05 | 0:00 | 1:30 | 3:00 | 4:00 | 4:30 |
| | 71 bpm | 103 bpm | 106 bpm | 128 bpm | 126 bpm | 136 bpm | 142 bpm |
| | 130/63 | 103/55 | | | | | |
| BRUCE | | | | | | | |
| ST @ 10mm/mV | | | | | | | |
| 40ms postJ | | | | | | | |
| 2[illegible]/s | | | | | | | |
| 10[illegible]/mV | | | | | | | |
| 100Hz | | | | | | | |
| Lead | V1 | V1 | V1 | V1 | V1 | V1 | V1 |
| ST | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | 0.3 | 0.1 |
| Slope | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.6 | 0.7 |
| | II | II | II | II | II | II | II |
| | 0.2 | 0.2 | 0.1 | 0.1 | 0.0 | −0.2 | −0.2 |
| | −0.1 | −0.6 | −0.4 | 0.0 | −0.2 | 0.2 | 0.0 |
| | V5 | V5 | V5 | V5 | V5 | V5 | V5 |
| | 0.0 | 0.1 | 0.2 | 0.1 | 0.0 | −0.3 | −0.1 |
| | −0.3 | −0.5 | −0.6 | −0.1 | −0.1 | 0.0 | 0.4 |
| | aVF | aVF | aVF | aVF | aVF | aVF | aVF |
| | 0.1 | 0.0 | 0.0 | 0.1 | 0.0 | −0.3 | −0.2 |
| | −0.1 | −0.4 | −0.6 | −0.2 | −0.2 | 0.0 | 0.0 |
| | V4 | V4 | V4 | V4 | V4 | V4 | V4 |
| | 0.1 | 0.2 | 0.1 | 0.2 | 0.2 | 0.0 | −0.3 |
| | 0.0 | −0.3 | −0.1 | −0.1 | 0.0 | 0.0 | 0.8 |
| | V6 | V6 | V6 | V6 | V6 | V6 | V6 |
| | 0.0 | 0.0 | 0.0 | 0.0 | −0.1 | −0.4 | −0.2 |
| | −0.5 | −0.5 | −0.7 | −0.4 | −0.4 | 0.0 | 0.2 |



BASELINE

[redacted] EDT: 15:48 23-NOV-1998 ORDER:

[redacted]

[redacted] ID: [redacted] 23-NOV-1998 11:48 [redacted] ECG ROUTINE RETRIEVAL

CFSAN 13229

SAMPLE CARDIAC CYCLES

000010

BRUCE

ST @ 10mm/mV
40ms postJ
[redacted]/s
1[redacted]/mV
100Hz

| Lead | EXERCISE STAGE 2 5:30 143 bpm 180/53 | EXERCISE STAGE 2 6:00 145 bpm 180/53 | EXERCISE STAGE 3 7:30 163 bpm | EXERCISE STAGE 3 8:52 169 bpm | EXERCISE STAGE 3 9:00 169 bpm | EXERCISE STAGE 4 10:30 176 bpm | EXERCISE STAGE 4 12:00 182 bpm |
|---|---|---|---|---|---|---|---|
| V1 | 0.2 | 0.1 | 0.1 | 0.3 | 0.2 | 0.0 | 0.3 |
| | 1.0 | 1.1 | 1.2 | 1.1 | 1.1 | 0.9 | 0.9 |
| II | −0.2 | −0.6 | −1.0 | −1.5 | −1.4 | −0.6 | −0.4 |
| | 0.0 | 0.1 | 0.3 | 0.4 | 0.5 | 1.9 | 2.8 |
| V5 | −0.2 | −0.6 | −0.5 | −0.3 | −0.6 | −0.2 | −0.4 |
| | −0.1 | −0.2 | 0.6 | 1.0 | 0.6 | 0.5 | 0.1 |
| aVF | −0.1 | −0.5 | −1.0 | −1.2 | −1.3 | −0.6 | −0.6 |
| | 0.0 | 0.5 | 0.4 | 0.6 | 0.9 | 1.0 | 2.3 |
| V4 | −0.1 | −0.1 | −0.8 | −0.4 | −0.6 | −0.7 | −0.2 |
| | 0.5 | 0.6 | 0.7 | 0.4 | 0.6 | 0.8 | 1.7 |
| V6 | −0.2 | −0.6 | −0.5 | −0.4 | −0.5 | −0.1 | −0.6 |
| ST Slope | 0.1 | −0.1 | −0.5 | 0.4 | 0.5 | 0.1 | 0.4 |

MAX ST

[redacted] EDT: 15:48 23-NOV-1998 ORDER:

[redacted]

[redacted] ID: [redacted] 23–NOV–1998 11:48 [redacted] ECG ROUTINE RETRIEVAL

CF540 1329

000011

# SAMPLE CARDIAC CYCLES

BRUCE

ST @ 10mm/mV
40ms postJ
25 mm/s
10 mm/mV
100Hz

| | EXERCISE STAGE 5 12:34 185 bpm | RECOVERY SUPINE 2:13 115 bpm | RECOVERY SUPINE 3:43 101 bpm | RECOVERY SUPINE 5:13 92 bpm | RECOVERY SUPINE 6:43 87 bpm | RECOVERY SUPINE 8:13 97 bpm 146/64 | RECOVERY SUPINE 9:43 90 bpm |
|---|---|---|---|---|---|---|---|
| V1 | 0.3 | 0.2 | 0.2 | 0.2 | 0.3 | 0.2 | 0.0 |
| | 1.4 | 0.5 | −0.3 | −0.8 | −0.5 | −0.3 | −0.3 |
| II | −0.2 | 0.1 | 0.2 | −0.1 | 0.0 | 0.1 | 0.1 |
| | 3.1 | 1.6 | 0.8 | 0.0 | 0.0 | 0.0 | 0.0 |
| V5 | 0.0 | 0.0 | 0.1 | 0.0 | 0.0 | 0.3 | 0.1 |
| | 1.3 | 1.2 | 0.4 | 0.2 | 0.0 | −0.1 | 0.0 |
| aVF | −0.3 | 0.2 | 0.2 | −0.1 | 0.0 | 0.0 | 0.0 |
| | 2.5 | 1.5 | 0.7 | 0.0 | 0.1 | −0.2 | 0.0 |
| V4 | −0.4 | 0.0 | −0.2 | 0.2 | 0.0 | 0.2 | 0.1 |
| | 1.5 | 1.5 | 0.6 | 0.4 | 0.0 | 0.0 | 0.0 |
| V6 | 0.0 | 0.0 | 0.2 | 0.0 | 0.0 | 0.0 | 0.0 |
| | 1.1 | 0.9 | 0.1 | −0.1 | −0.3 | −0.3 | −0.3 |

Lead
ST
Slope
PEAK

[redacted] EDT: 15:48 23–NOV–1998 ORDER:

[redacted]

[redacted] ID [redacted] 23-NOV-1998 11:48 [redacted]-ECG ROUTINE RETRIEVAL

CFSAU 13229

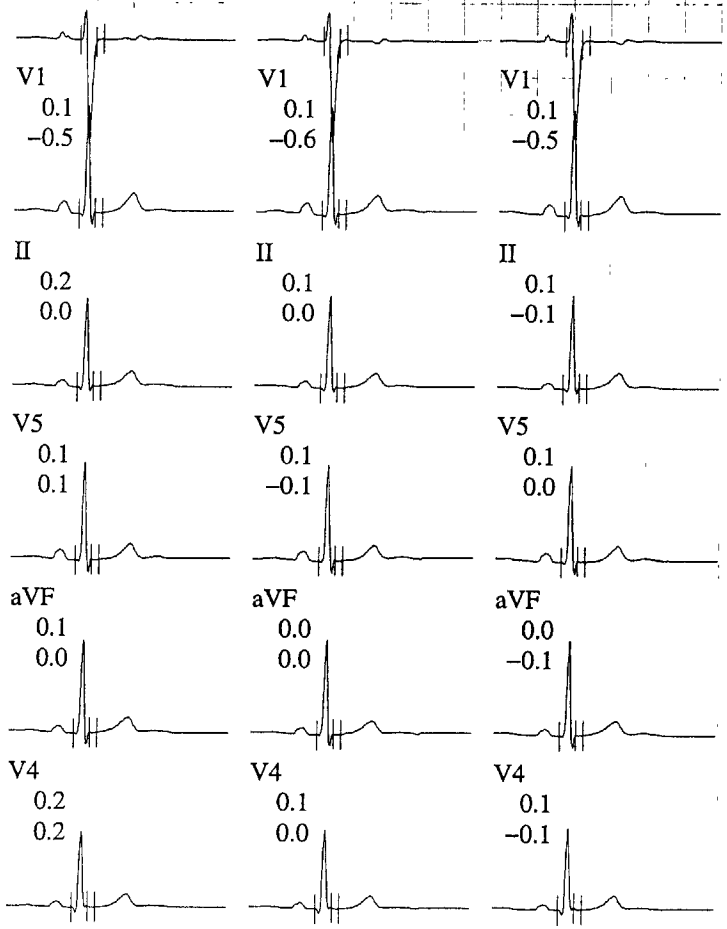
# SAMPLE CARDIAC CYCLES

| RECOVERY | RECOVERY | RECOVERY |
|---|---|---|
| SUPINE | SUPINE | SUPINE |
| 11:13 | 12:43 | 13:23 |
| 89 bpm | 85 bpm | 83 bpm |

000012

BRUCE

ST @ 10mm/mV
40ms postJ
[illegible]mm/s
1[illegible]/mV
100Hz




Lead
ST
Slope

[redacted]

[redacted] EDT: 15:48 23-NOV-1998 ORDER:

[redacted] ID: [redacted] 23-NOV-1998 11:48 [redacted]-ECG ROUTINE RETRIEVAL

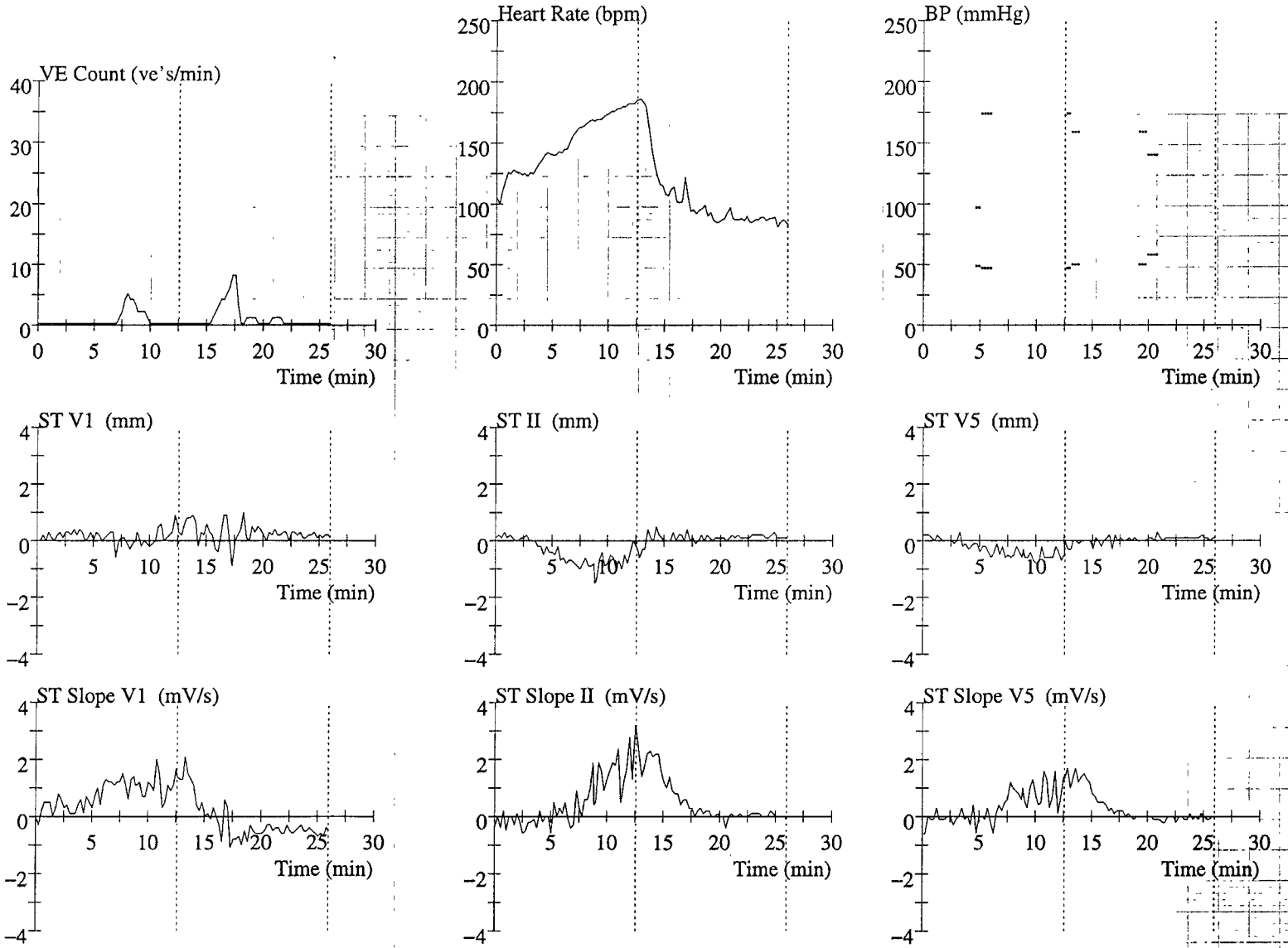
CPSAU 13229

# TREND GRAPHS

BRUCE

000013

ST @ 10mm/mV
40ms postJ




[redacted] EDT: 15:48 23-NOV-1998 ORDER:

[redacted]