Presenter Disclosure Information

Barbara Drew has received research funding or honoraria from:

GE Healthcare

Philips Healthcare

(None in the past 12 months; none planned in the future 12 months)

FDA Public Workshop on Study Methodology for Diagnostics in the Post-Market Setting

May 12, 2011, Silver Spring, MD

Cardiac Monitoring Devices *Clinical Alarm Fatigue*

Barbara J. Drew, PhD, RN, FAAN, FAHA University of California, San Francisco barbara.drew@ucsf.edu

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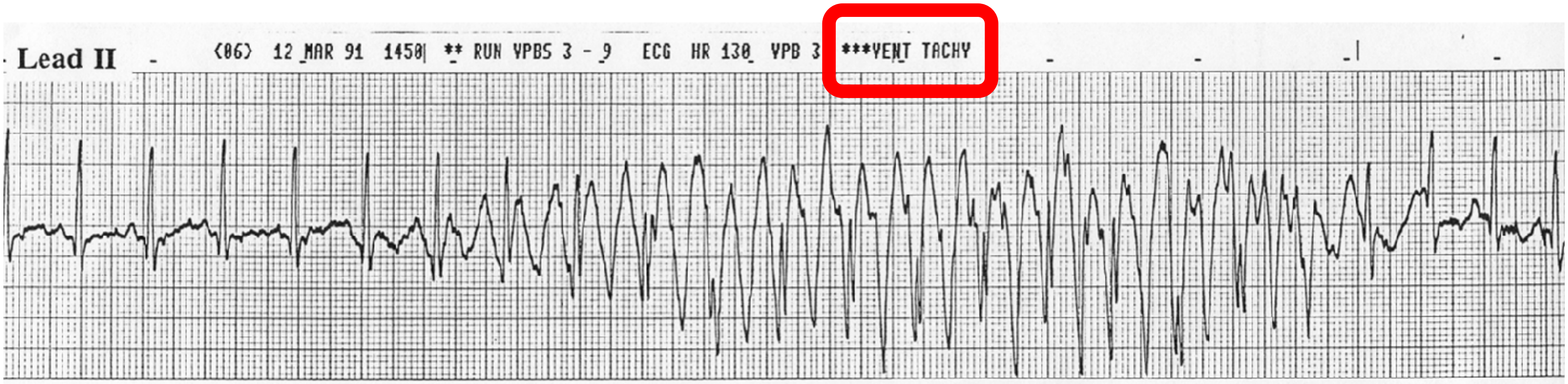
Perfect Cardiac Monitor Alarm System

1. **Never miss a clinically important ("actionable") event (100% sensitivity)**

2. **Never trigger an alarm when there is no cardiac event (100% specificity)**

Current devices have nearly 100% sensitivity at the expense of specificity (~99% of monitor alarms are false)

False monitor alarm due to noisy signal mimicking VT



Drew BJ. Pitfalls and artifacts in electrocardiography. *Cardiol Clin* 2006;24:309-315.

Clinical Consequences of Misdiagnosis

Diagnostic cardiac catheterization was performed in three patients solely because of the incorrect diagnosis of ventricular tachycardia. Unnecessary medical therapies included intravenous lidocaine in seven patients, intravenous nitroglycerin in one patient, and sublingual nitroglycerin in one patient. Two patients were given a precordial thump that was interpreted as a successful cardioversion. One patient in whom torsade de pointes was incorrectly diagnosed underwent implantation of a permanent pacemaker to prevent a recurrence by keeping bradycardia, which typically precedes polymorphic ventricular tachycardia, from occurring. One patient underwent placement of an implantable cardioverter–defibrillator after an episode of artifact was misdiagnosed as polymorphic ventricular tachycardia. Another patient was given a blood transfusion because it was thought that his ventricular tachycardia had been caused by anemia.

The misdiagnosis of artifact increased the use of health care resources. Two patients were transferred

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Analysis of "full disclosure" cardiac monitor alarm data on all patients treated during a 2-month period in 6 adult critical care units (154 beds) at Stanford University Medical Center

Average, 883 alarms/unit/day

(all units had ST-segment monitoring alarms disabled; 5 of 6 units had QT interval monitoring alarms disabled)

Rationale: too many false alarms

Not counting alarms from ventilators, IV infusion pumps, ventricular assist devices, feeding pumps, bed/chair alarms, wound vacuum devices, sequential compression devices, etc.

Fidler R, Helfenbein E, Pickham D, Drew BJ. Quantification of hospital cardiac monitoring alarms. *J Electrocardiol* 2011 (in press).

Most common cardiac monitor alarms

Alarm Type	Number	%
PVCs (paired, multiform, R-on-T, bigeminy, trigeminy, >5/min, etc.)	120,732	38.0
Other non-critical (HR, respiratory rate ↑↓ pre-set limits, etc.)	136,908	43.0
Desaturation / Low SpO_2	43,447	13.8
Invasive/noninvasive BP; CVP, PA pressures ↑↓pre-set limits	3,631	1.1
Nurse call (wireless telemetry units)	1,724	0.5
Apnea	4,761	1.5
VT or VFib	4,557	1.4
Asystole	2,249	0.7
Total:	**318,009**	100%

11,567 critical alarms

“Code Blue”
Events, n=19
Patients, n=17

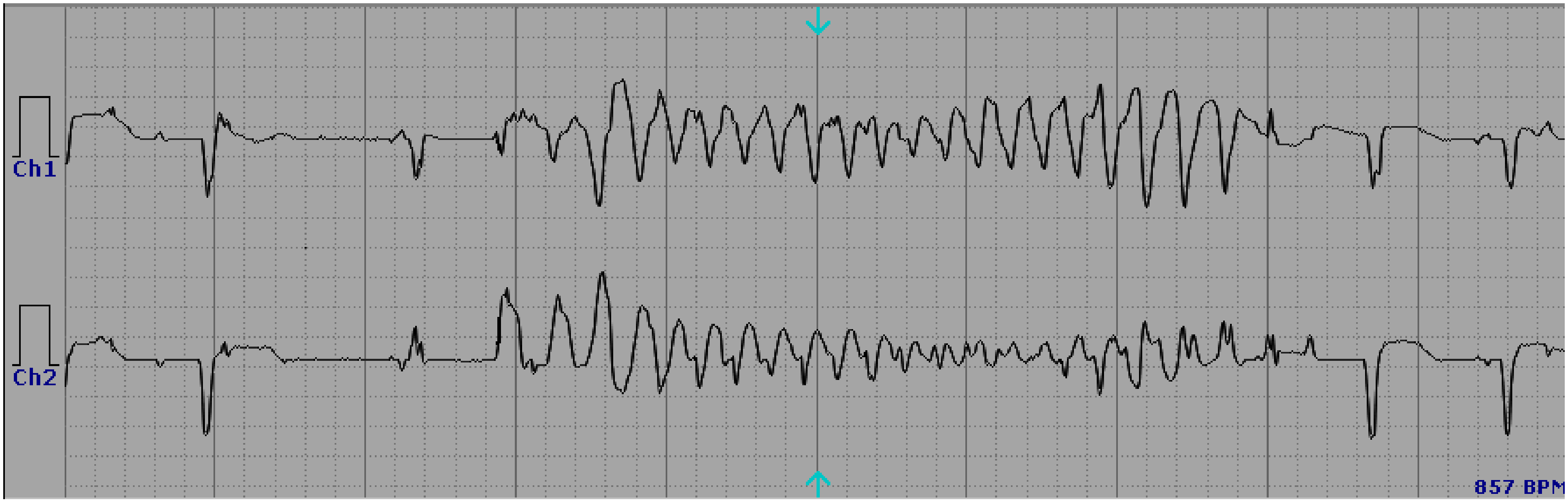
Deaths (n=7)

Fidler R, Pickham D, Drew BJ. Quantification of hospital cardiac monitoring alarms. *J Electrocardiol* 2011 (in press).

69 y/o Female with 2 Code Blue events requiring defibrillation X 2

- CHF, EF 24%
- QTc 403-691 ms (mean,510±53 ms) ***QT monitoring alarms disabled***
- K+ 3.0 (hypokalemia); administered QT-prolonging drugs

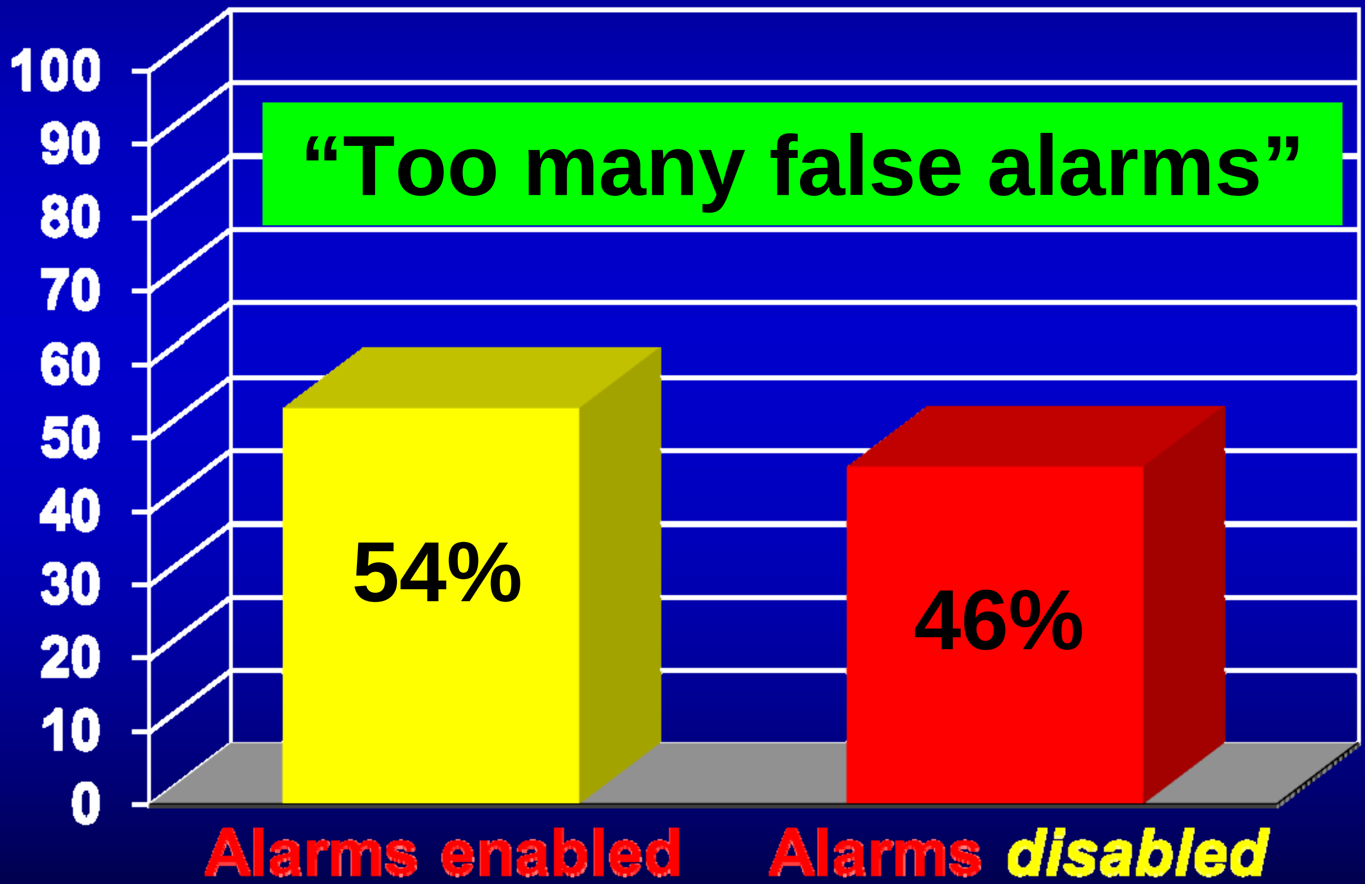
- Arrhythmia mechanism stated in medical record = ventricular fibrillation



Unrecognized Torsade de Pointes !

ST-segment monitoring alarms are usually disabled in hospital units

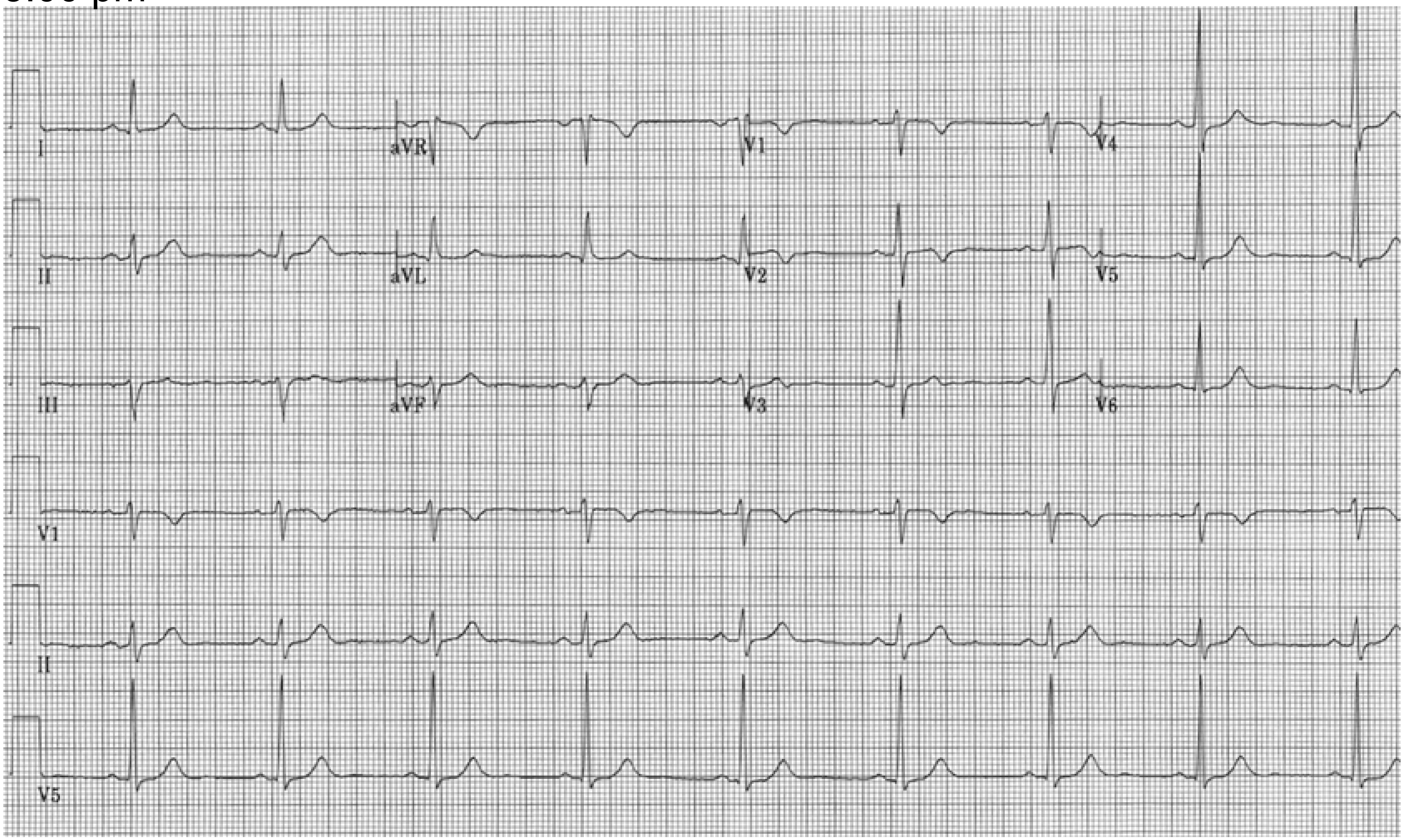
Random survey of 192 hospital CV unit nurse managers



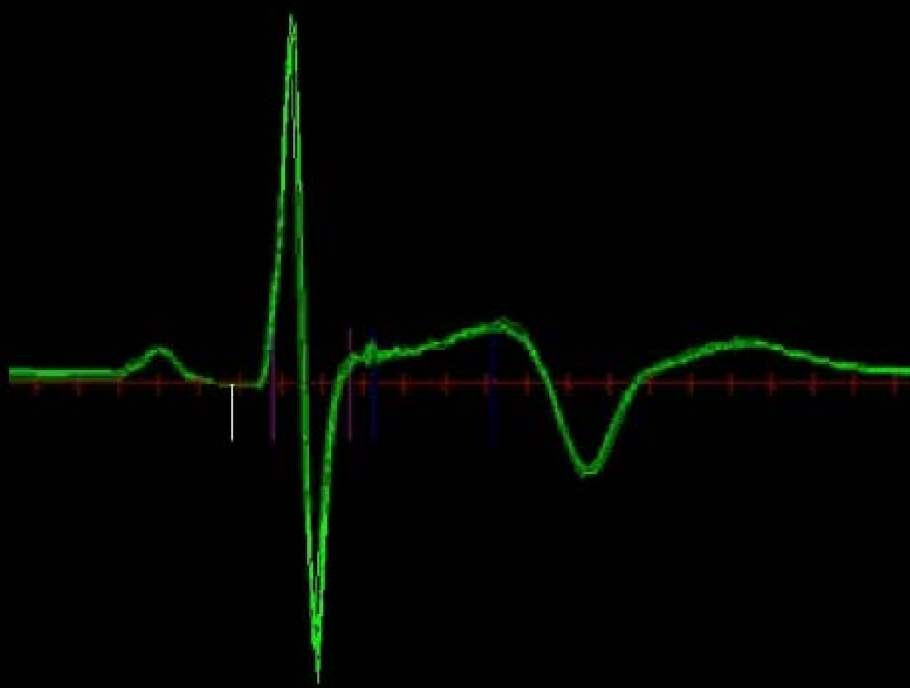
Patton & Funk, *Am J Crit Care* 2001;10:23-34

Initial ECG in 40 y/o male presenting to the ED with increasing chest pain episodes; Troponins negative

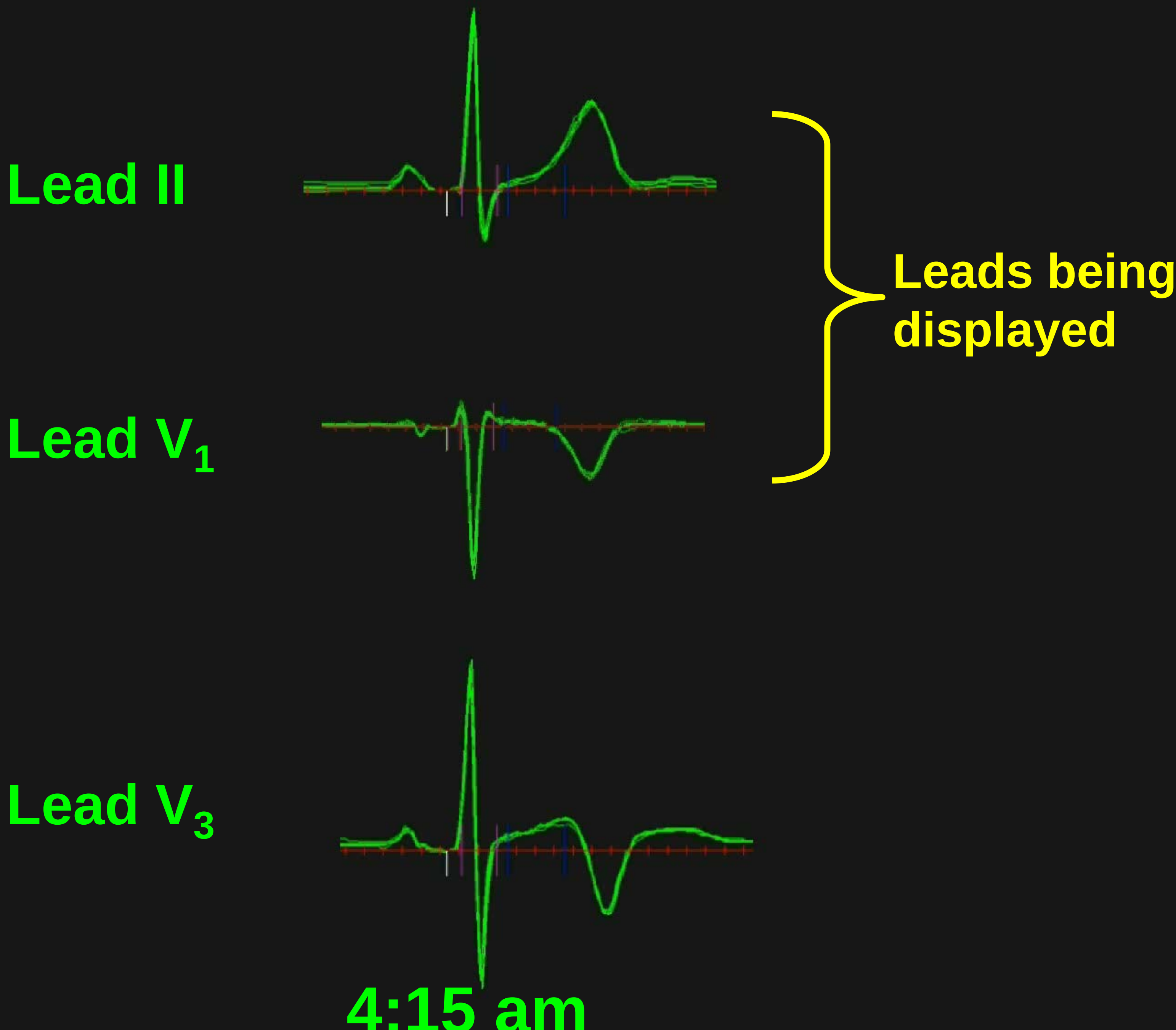
5:00 pm



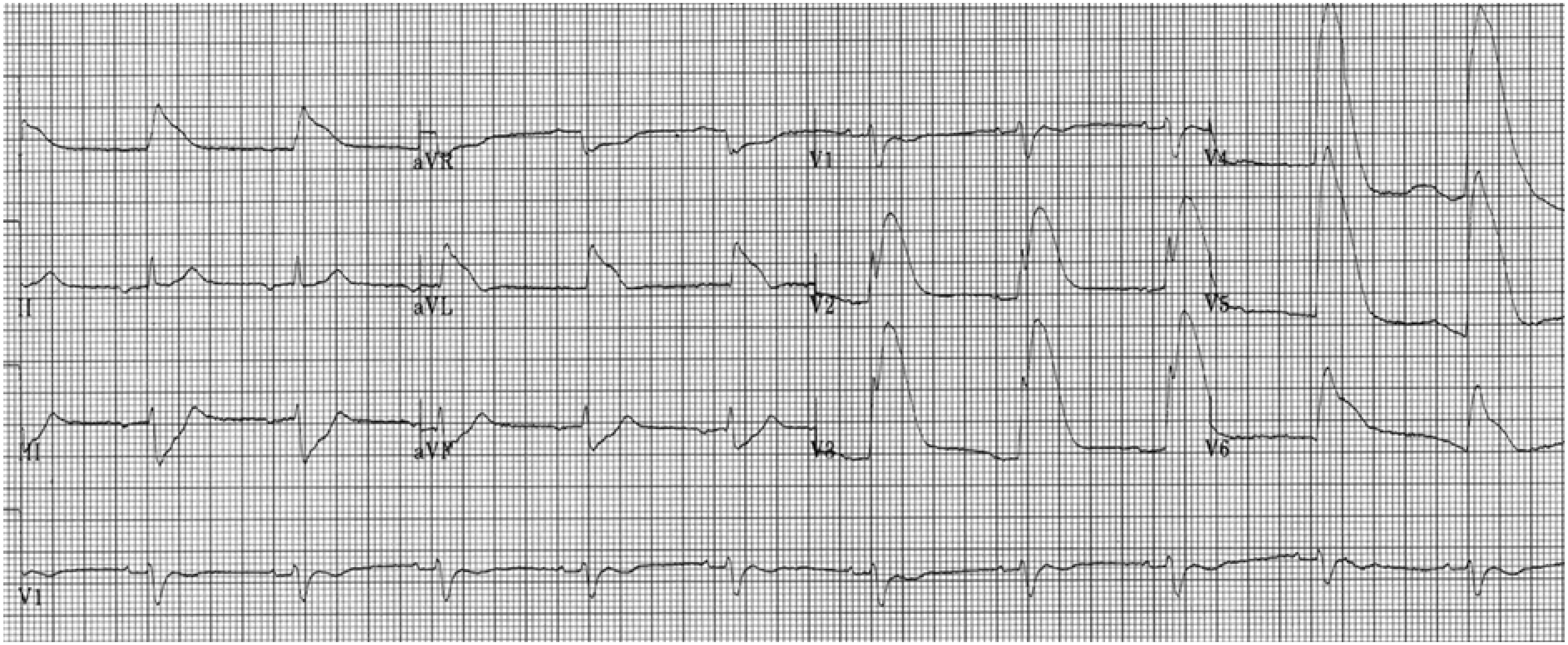
Lead V_3



2:00 - 5:00 am


Lead II
Lead V_1
Lead V_3
Leads being displayed
4:15 am

6 days following hospital discharge, patient was brought to ED after witnessed collapse on golf course



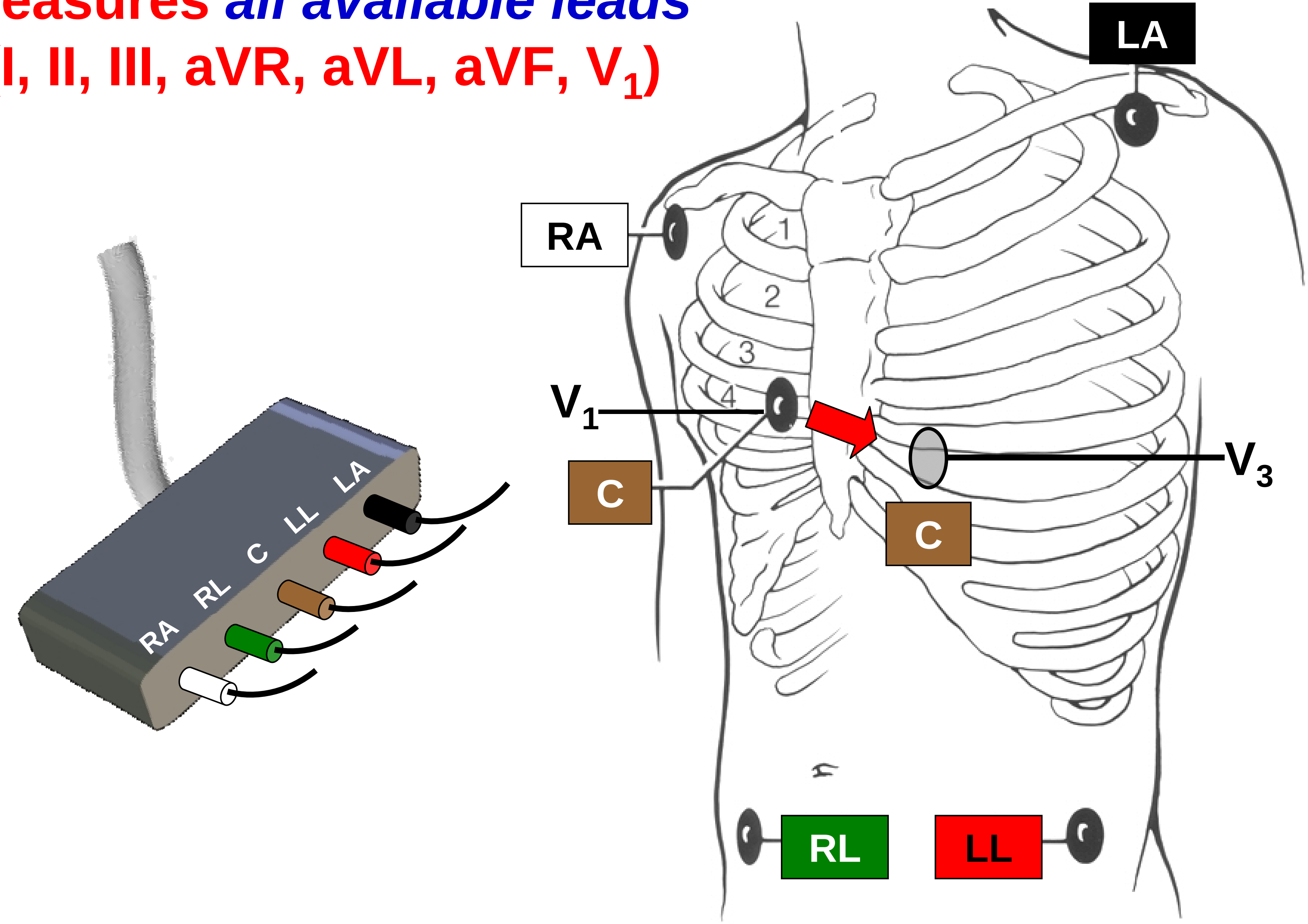
Rapidly developed profound shock, could not be resuscitated, and died

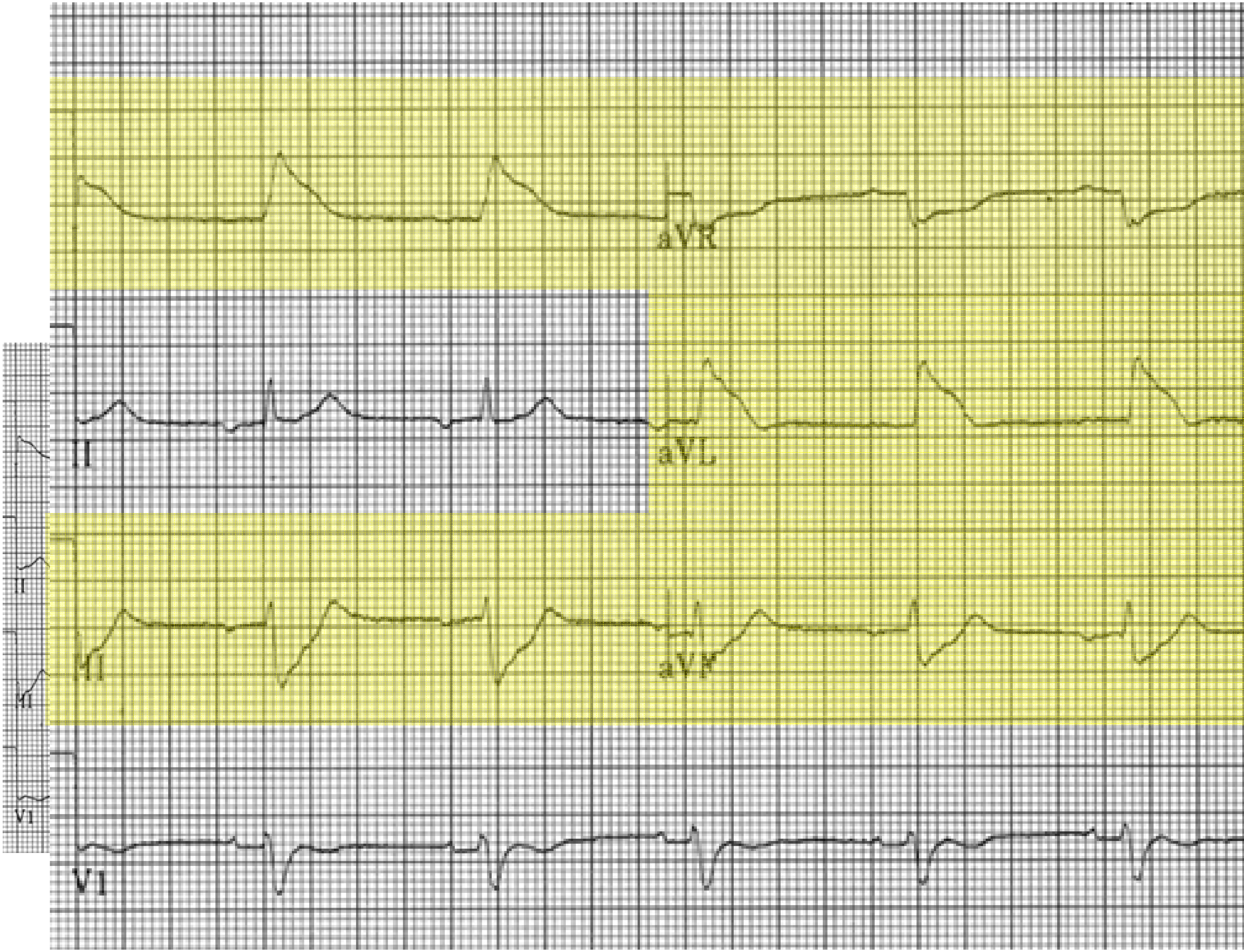
Why was this event missed?

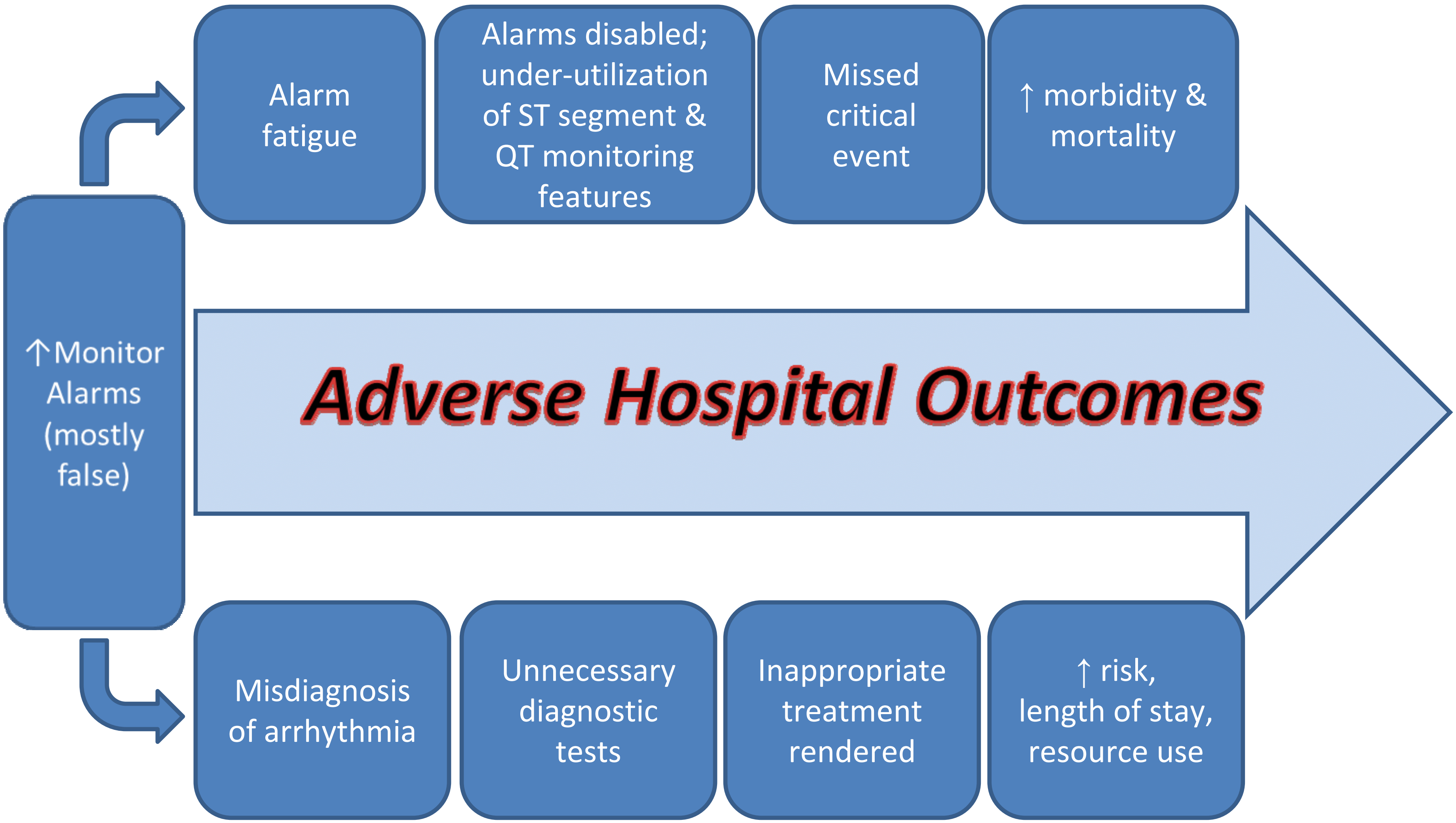
1. Leads selected for visual display on the monitor (Lead II & V_1) didn't show ST changes

2. ST-segment monitoring alarms were not enabled

ST monitoring feature measures *all available leads* (I, II, III, aVR, aVL, aVF, V_1)




aVR
II
aVL
III
aVF
V1



↑Monitor Alarms (mostly false)
Alarm fatigue
Alarms disabled; under-utilization of ST segment & QT monitoring features
Missed critical event
↑ morbidity & mortality
Adverse Hospital Outcomes
Misdiagnosis of arrhythmia
Unnecessary diagnostic tests
Inappropriate treatment rendered
↑ risk, length of stay, resource use

Causes of False Cardiac Monitor Alarms & Alarm Fatigue

1. **Patient factors: agitation, diaphoresis, morbid obesity (skin folds)**
2. **Nurse factors:**
   - **Lack of education re: how to tailor alarms to individual patient/unit; how to determine false vs true alarm**
   - **Lack of policies re: when it is OK to disable alarms**
3. **Device factors:**
   - **Outdated algorithms**
   - **Lack of "smart" alarms that combine measurements to detect *clinically important* events (e.g., alarm for PVCs *only* if QTc is ↑)**
   - **Additional sensors to detect muscle artifact & changes in body position (?)**

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Thank You

Questions?

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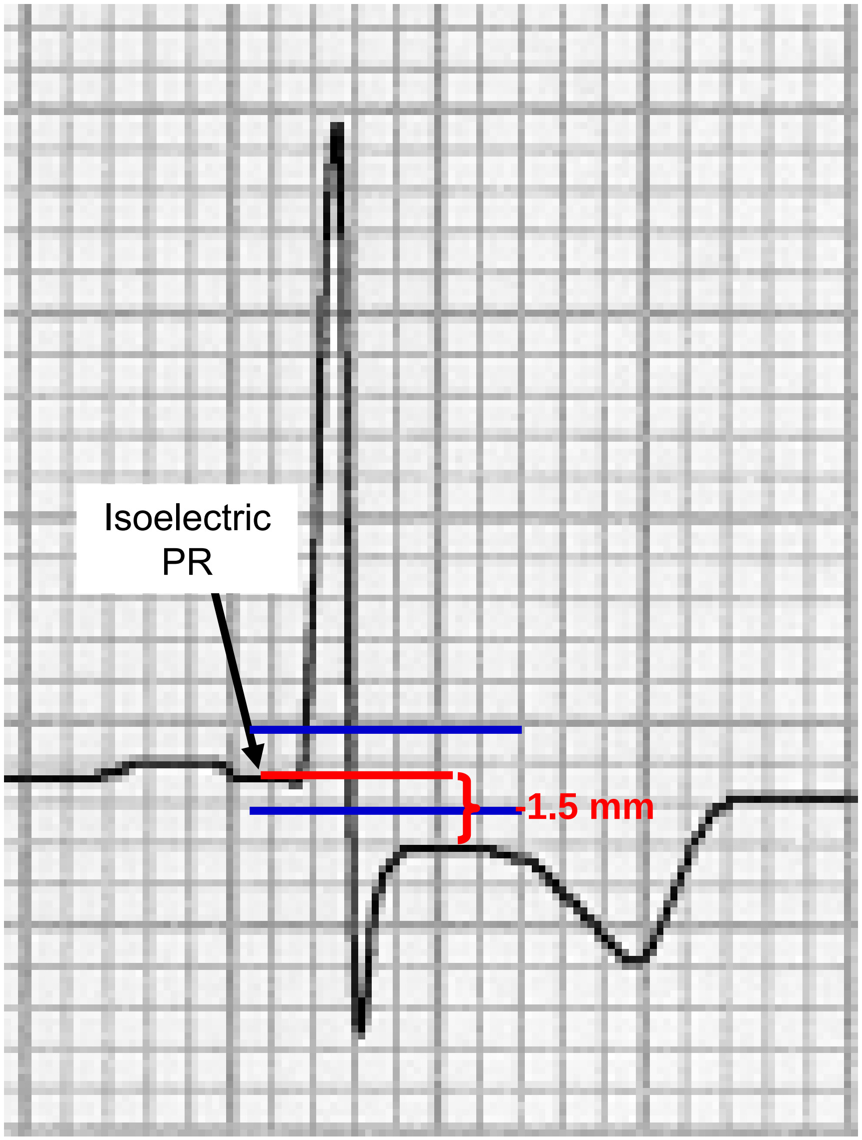
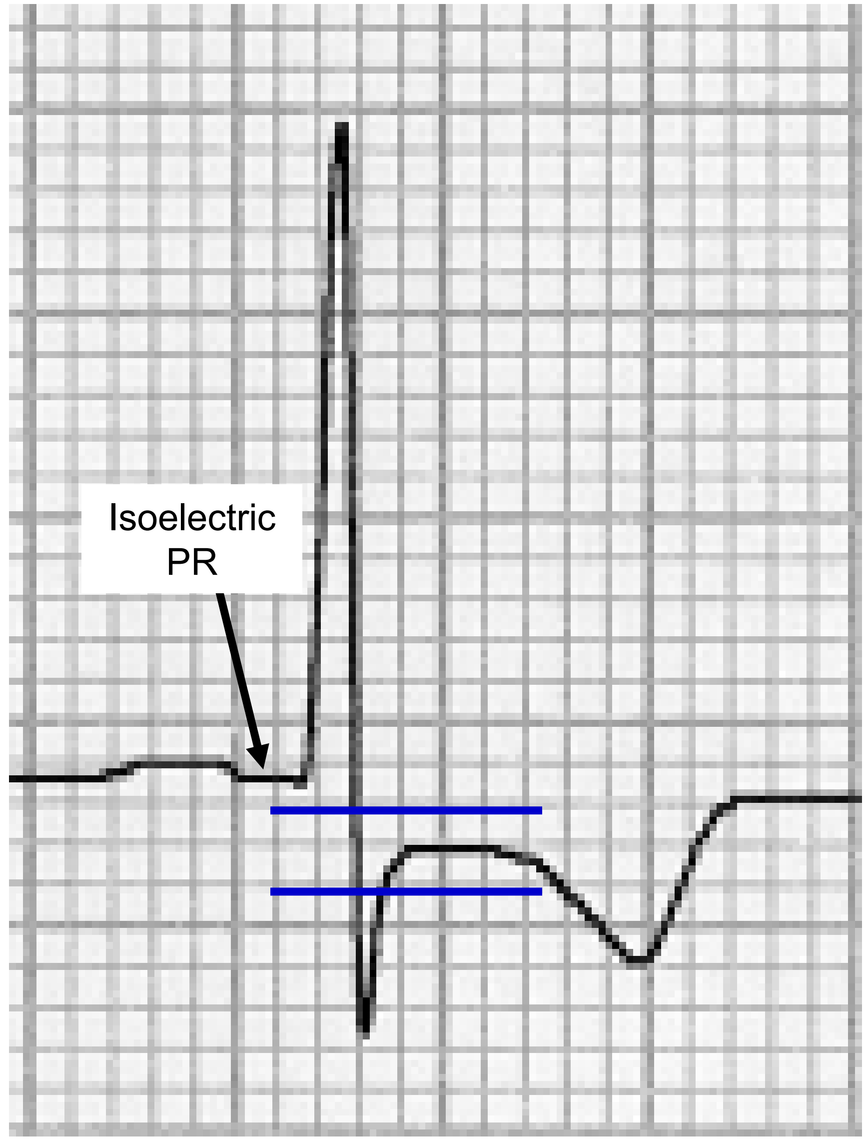
False ST-segment monitoring alarms due to non-ischemic causes

Patient with chronic ST depression due to LVH

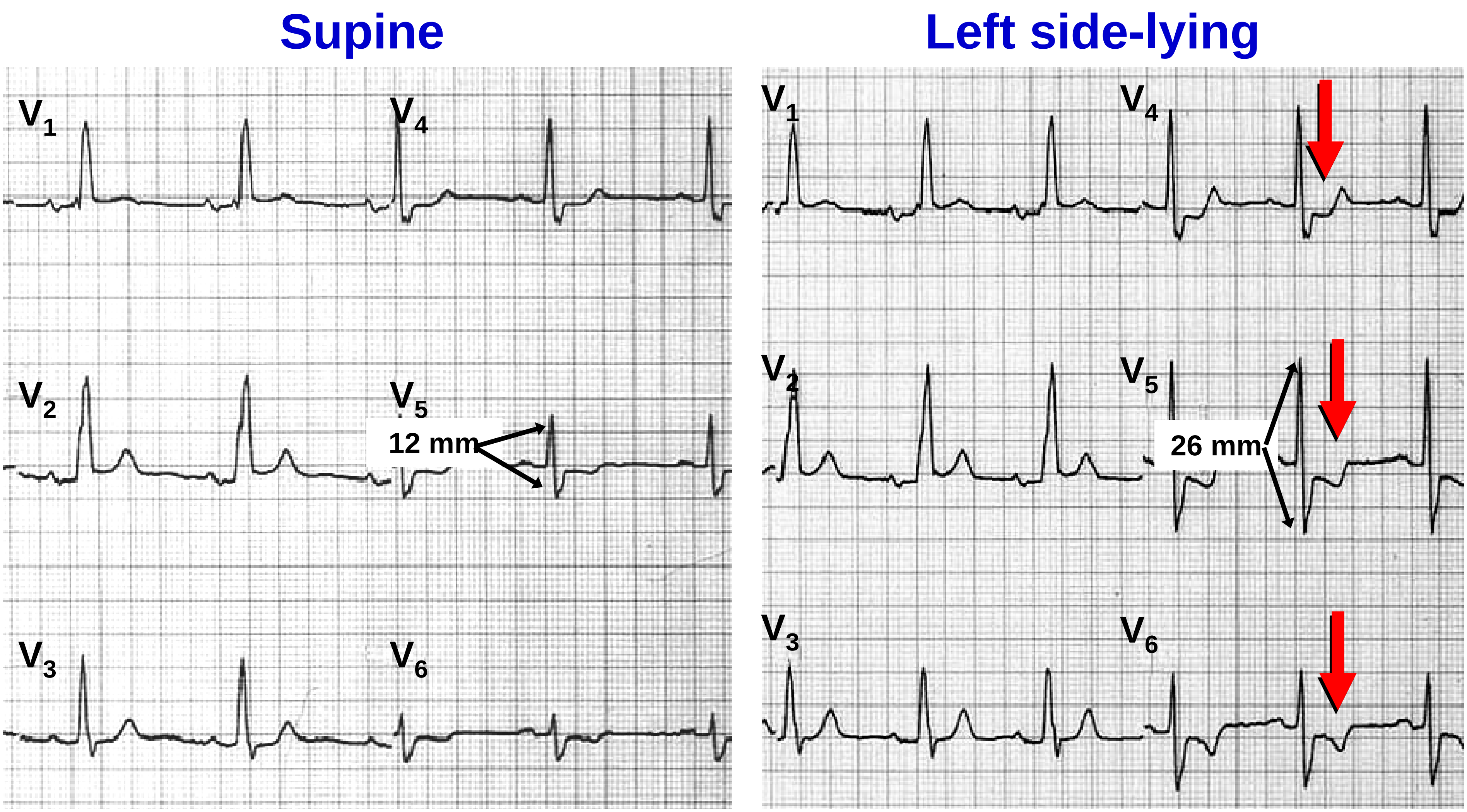


Tailoring ST alarm limits around patient's baseline

Patient with chronic ST depression due to LVH



False ST-segment monitoring alarms due to body position change



Drew BJ, Adams MG. Clinical consequences of ST segment changes due to body position mimicking transient myocardial ischemia: Hazards of ST segment monitoring? *J Electrocardiol* 2001;34:261-64.

ST-Segment Monitoring Protocol

ST alarm

Is there a noisy signal?

Yes → **False ST alarm** Check electrodes

No

Is there a change in rhythm that alters the ST segment?
(new BBB, ventricular pacing, coarse atrial fib/flutter)

Yes → **False ST alarm** Due to rhythm change

No

Are *either* of the following present?
1. ST changes accompanied by major change in size or shape of QRS?
2. ST changes resolve when patient changed from side-lying to supine?

Yes → **False ST alarm** Due to position change (ST monitoring may need to be discontinued)

No

True ST alarm!
Does the patient have new symptoms?
(chest pain, SOB, altered vital signs)

1. Document ST alarm rhythm strip
2. Notify physician (anticipate STAT 12-lead ECG)
3. Change ST alarm parameters from ± 2 to ± 1 mm around patient's current ST level for next 12 hrs

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