Bruce H. Barkalow, Ph.D., PE, CCE,
William E. Grant, M.A., M.L.I.S., and
Farrah J. Curran, B.S.

Biomedical Engineering in Root Cause Analysis Example: Assessing Infant Apnea-Related Deaths

Biomedical/Clinical Information Stored in Medical Devices

- Pacemakers
- Defibrillators
- Nerve stimulators
- Ventilators
- Physiological monitor examples:
  - EKG
  - EEG
  - Respiration
  - Temperature

Introduction/Summary

- Respiration monitors are primarily used to detect infant apnea in the home to prevent sudden infant death syndrome.
- Apnea monitors measure chest wall motion associated with breathing. Apnea is determined by a period of no signal.
- Forensic investigations usually occur when an infant dies or suffers a hypoxic event and the care givers state that no alarm sounded.

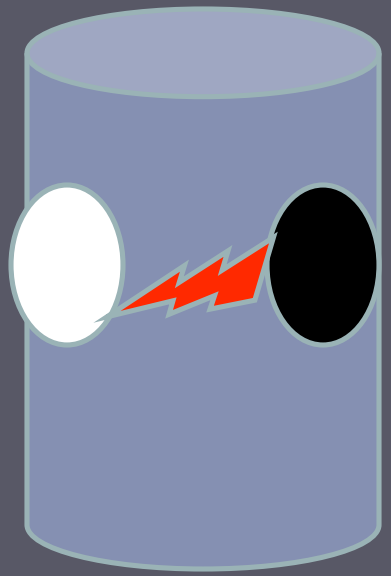
Types of Infant Apnea

- Central Apnea: Lack of breathing due to failure of the central nervous system (absence of breathing effort)
- Obstructive Apnea: Lack of breathing from a blockage or obstruction in airway (presence of breathing effort)
- Mixed Apnea: Combination of central and obstructive apnea

Apnea Monitor

- Detects Transthoracic Impedance
- Uses EKG Electrodes
- Pushes Small AC Current Through Chest
- Measures Change in Impedance with Respiratory Cycle
- ECG is also Monitored

Breathing is detected by constant ac current through chest. As chest expands, impedance rises in a manner consistent with ventilation.



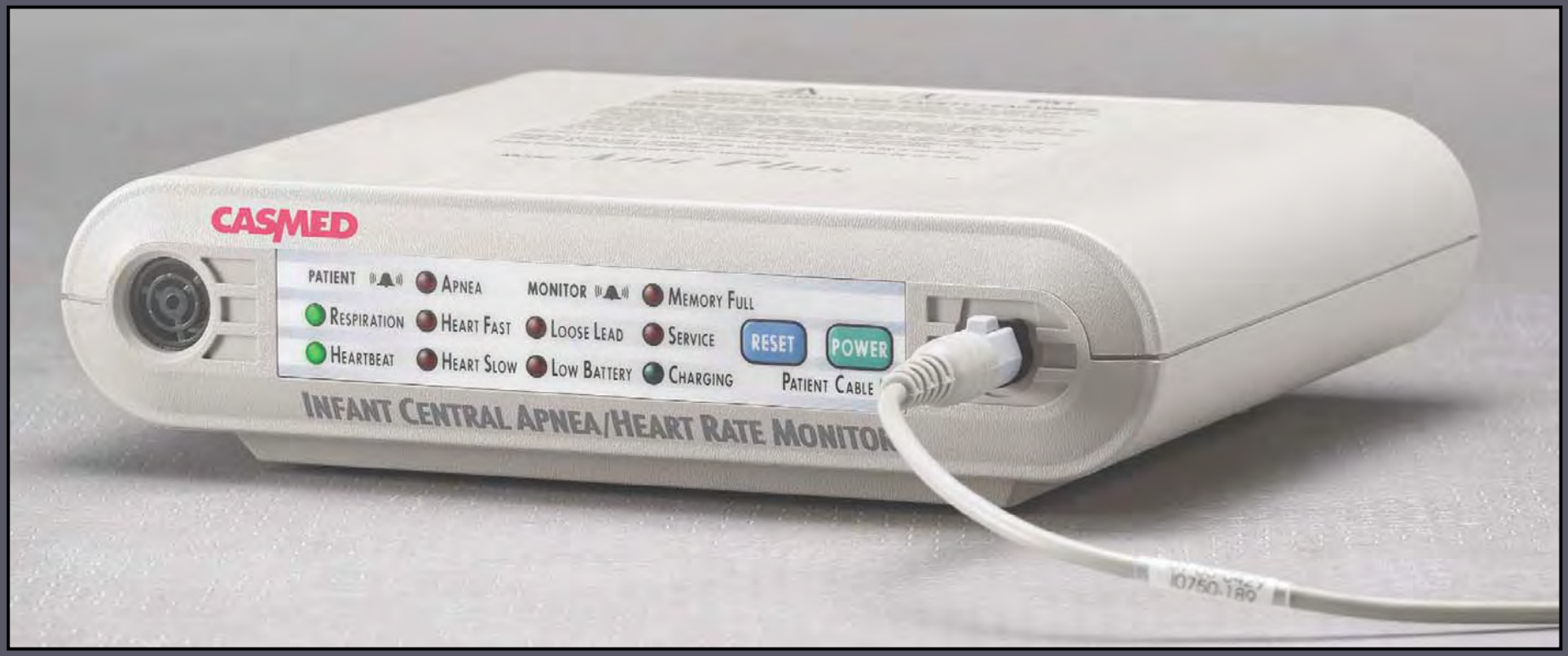
What Central Apnea Monitors Detect

- “Neurological” Apnea - infant “forgets” to breathe
- Alarm set to time a period of no or small changes in transthoracic impedance
- Alarm set for coincidence of QRS and breaths

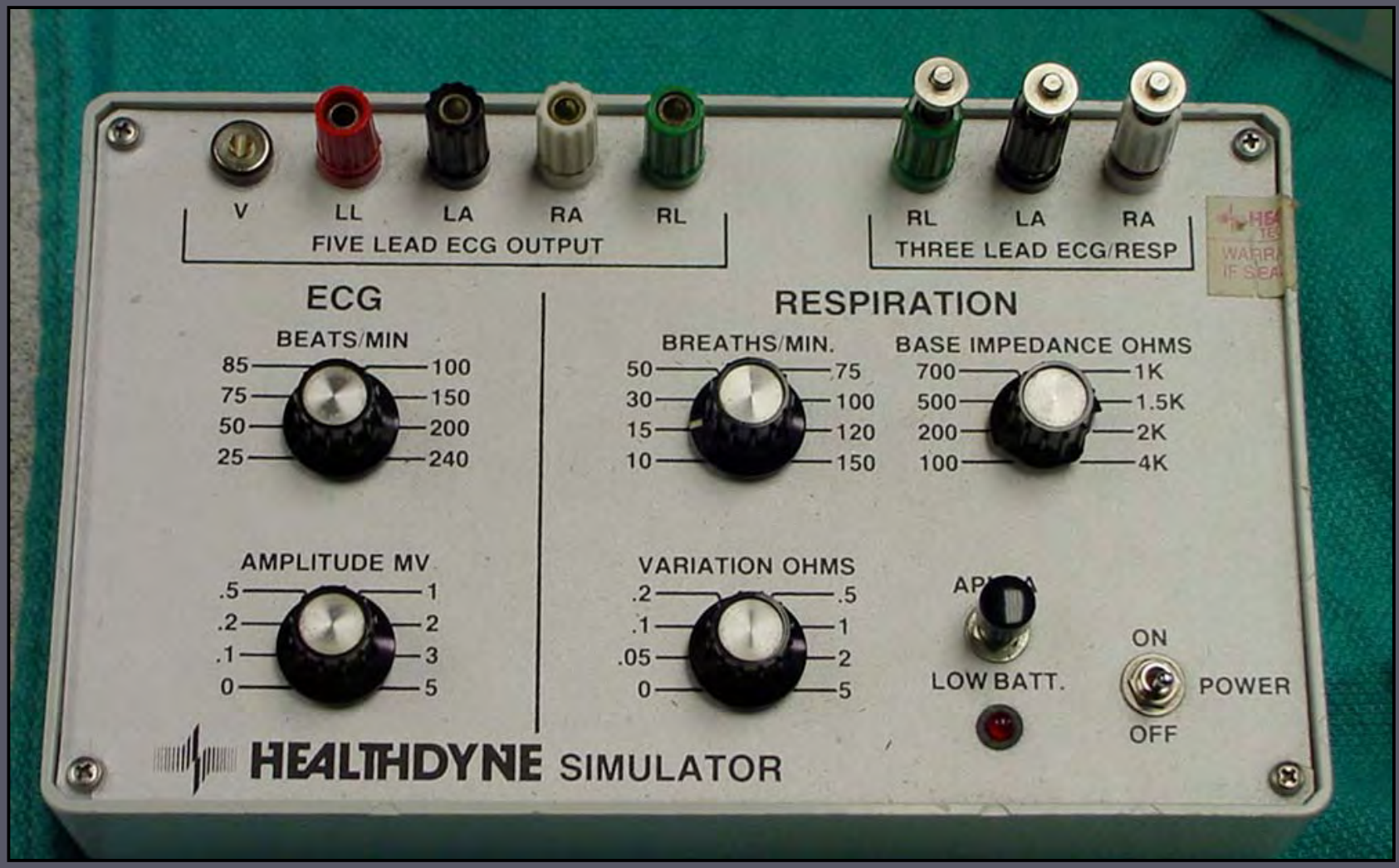
What Central Apnea Monitors Don't Detect

- Obstructive apnea: Chest moves, but airway blocked
- Mixed apnea: Episode contains both obstructive and central apnea
- Apnea masked by artifact:
  - Motion
  - Electromagnetic Interference (EMI)

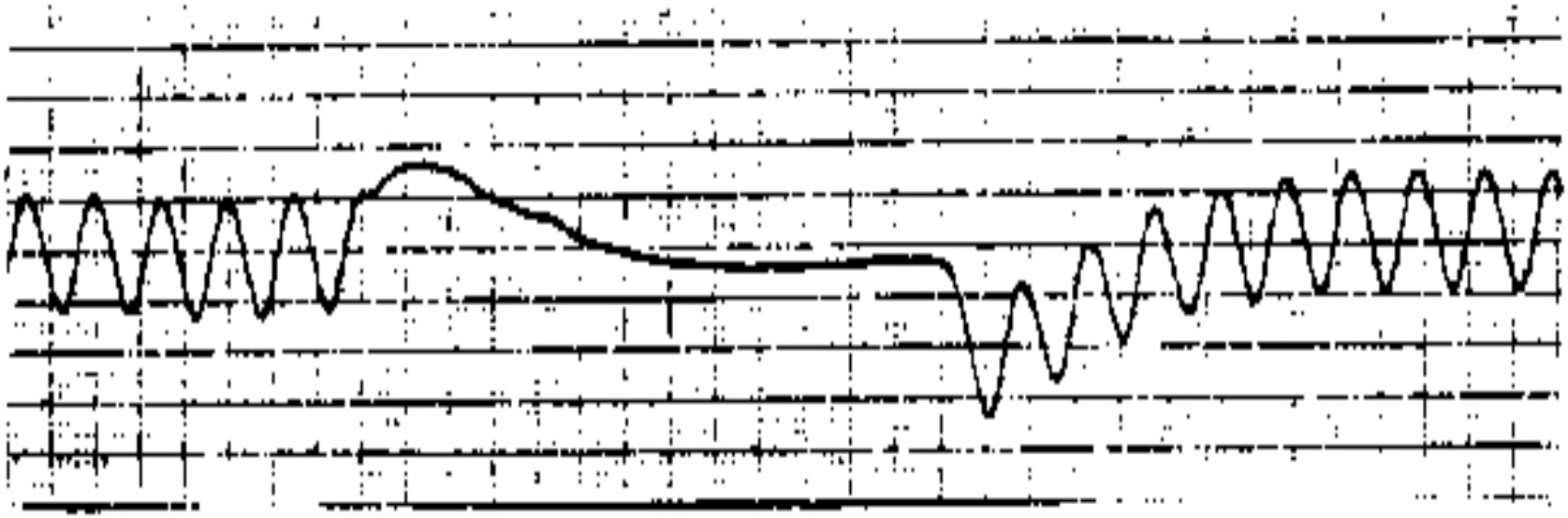
Central Apnea Monitor



Patient Simulator



Example Central Apneic Episode



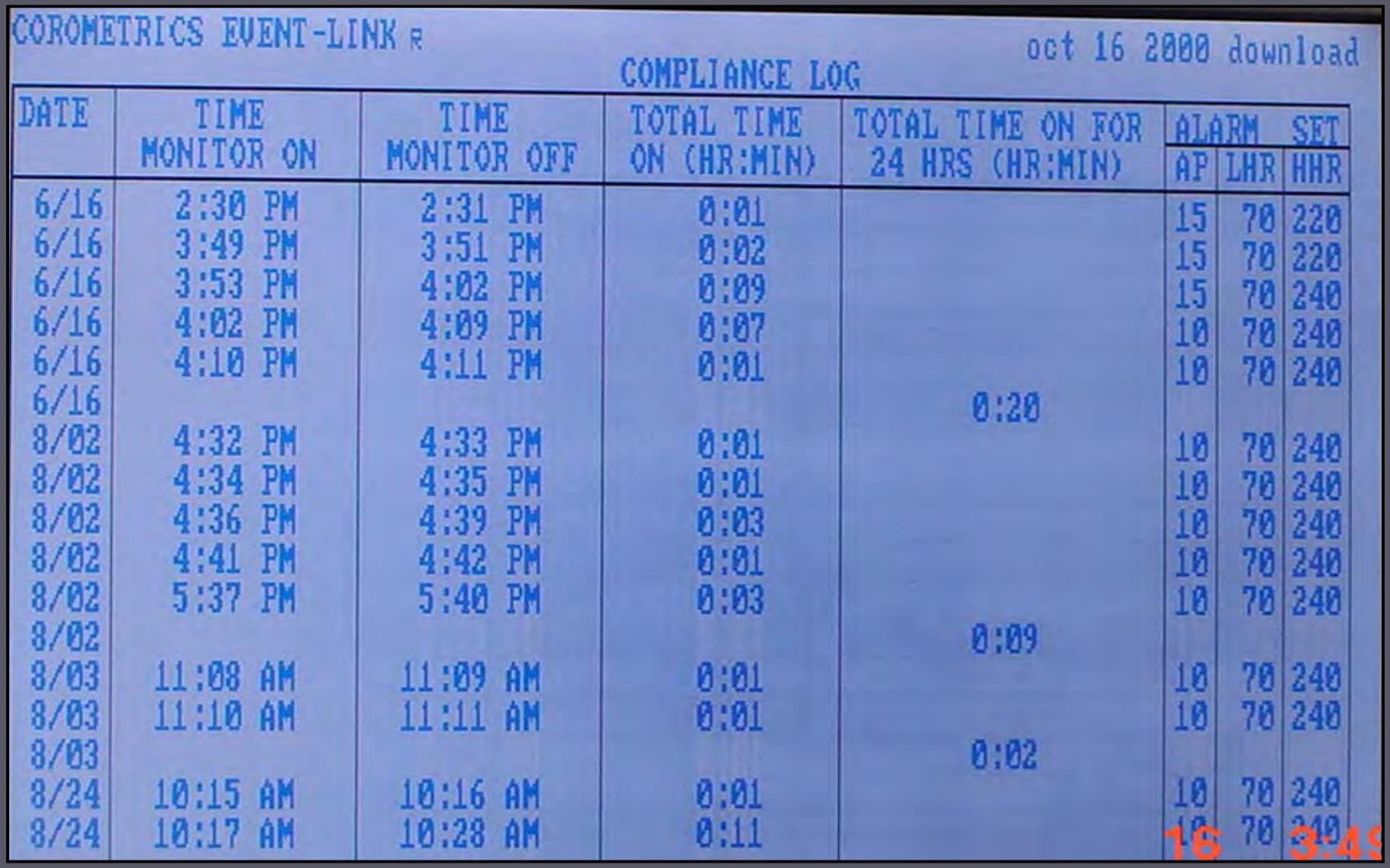
Medical Device Internal Clocks

- Battery operated
- Not synchronized with atomic clock in Boulder, CO
- Often do not compensate for Daylight Savings
- Can be off by minutes or hours

Apnea Monitor Compliance

- Records when electrodes are properly applied and monitor is ON
- Records to device's non-volatile memory
- Data can be downloaded in the form of:
  - Summary Log
  - Real Time Log

Subject Device Compliance Log

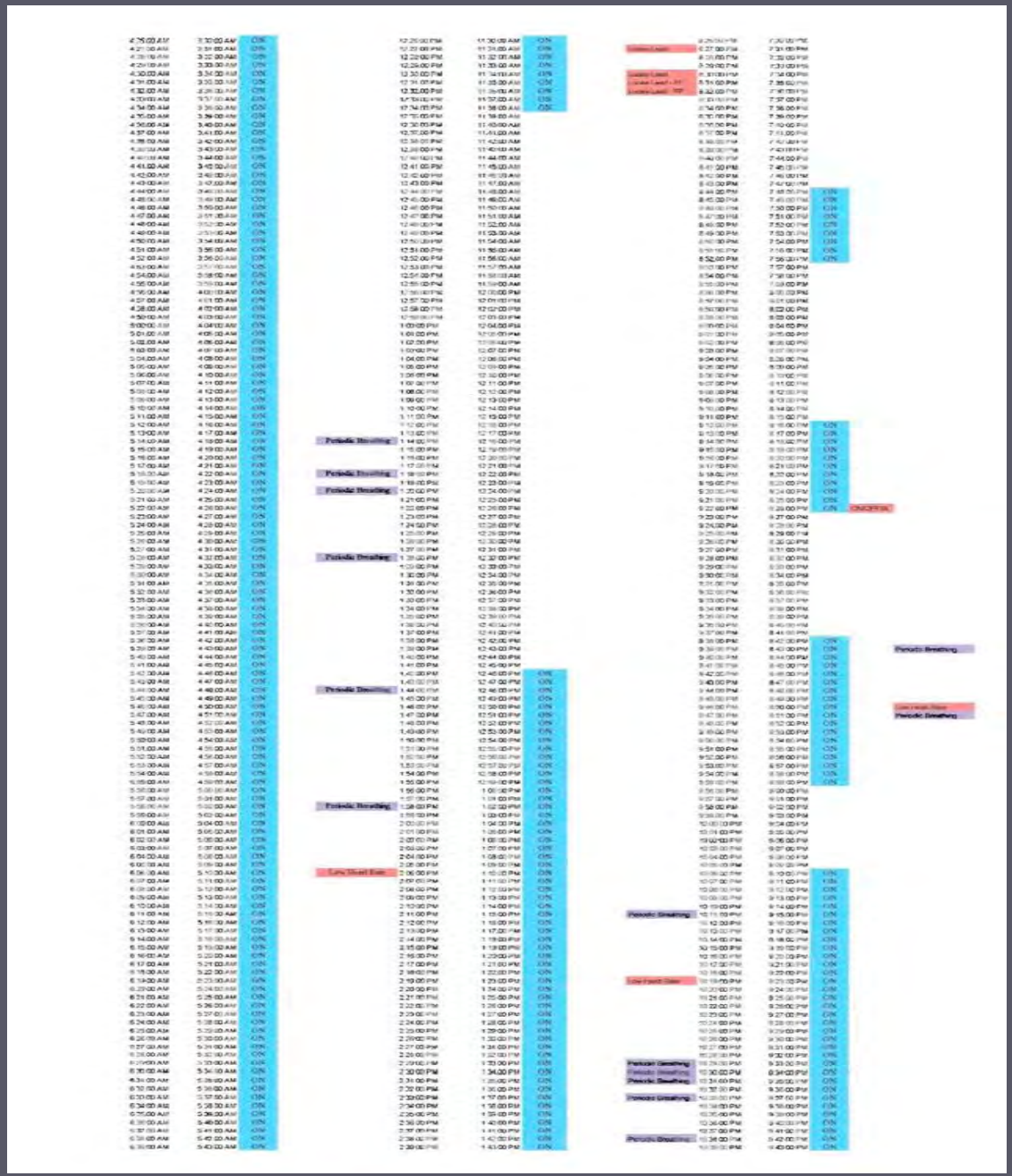


COROMETRICS EVENT-LINK R

oct 16 2000 download

COMPLIANCE LOG

DATE	TIME MONITOR ON	TIME MONITOR OFF	TOTAL TIME ON (HR:MIN)	TOTAL TIME ON FOR 24 HRS (HR:MIN)	ALARM SET		
					AP	LHR	HHR
6/16	2:30 PM	2:31 PM	0:01		15	70	220
6/16	3:49 PM	3:51 PM	0:02		15	70	220
6/16	3:53 PM	4:02 PM	0:09		15	70	240
6/16	4:02 PM	4:09 PM	0:07		10	70	240
6/16	4:10 PM	4:11 PM	0:01		10	70	240
6/16				0:20			
8/02	4:32 PM	4:33 PM	0:01		10	70	240
8/02	4:34 PM	4:35 PM	0:01		10	70	240
8/02	4:36 PM	4:39 PM	0:03		10	70	240
8/02	4:41 PM	4:42 PM	0:01		10	70	240
8/02	5:37 PM	5:40 PM	0:03		10	70	240
8/02				0:09			
8/03	11:08 AM	11:09 AM	0:01		10	70	240
8/03	11:10 AM	11:11 AM	0:01		10	70	240
8/03				0:02			
8/24	10:15 AM	10:16 AM	0:01		10	70	240
8/24	10:17 AM	10:28 AM	0:11		10	70	240



Blue = On

Purple = Periodic breathing

Red = Loose lead

Causes of Alarm Failure

- Faulty audio transducer
- Open conductor on PC board
- Disconnected cable
- Random component failure
- Worn switch
- Intermittent cable connector

Causes of Alarm Failure, Cont.

- Loose connection
- Disconnected ribbon connector
- Faulty solder connection
- Solder short during servicing
- Manufacturing error
- Software “bugs”

Causes of Alarm Failure – No Hardware or Software Fault

- Clinical
  - Infant is choking – chest wall movement is detected as “breathing”
  - Cardiac cycle changes chest impedance in the presence of apnea and is detected as “breathing”
- Environmental
  - Electrical noise is detected
  - Electrode noise is detected

Causes of Alarm Failure – Caregiver Issues

- Monitor is not connected to the infant
- Audible alarm is defeated
- Monitor is connected, but the power is off
- Electrodes are not attached to infant
- Alarm fires but no one hears it
- Infant is in bed with the caregiver and motion artifact is interpreted as “breathing”

Investigation Information Sources

- Download of subject device data
  - Apneic episodes
  - Alarms
  - Monitor On/Off
- Review of device's service records
  - Performance assurance checks
  - Repairs
- Search FDA MAUDE database for model-specific related reports

Investigation Information Sources, Cont.

- Medical records
  - Operative reports
  - Emergency room records
  - EMS records
  - Autopsy report
- Other Documents
  - Depositions
  - Affidavits
  - Police reports

Information/Data Analysis

- Develop event chronology
- Look for specific event correlations—possible cause and effect
- Formulate logical scenarios

Closed Case Background

- Subject Device was manufactured by Corometrics Medical System, Inc. (model 500EAA)
- Device was designed to provide reliable detection of central apnea, bradycardia and tachycardia events
- Device stores monitoring data from infant that can later be reviewed by a physician
- Incident occurred March 31, 1991

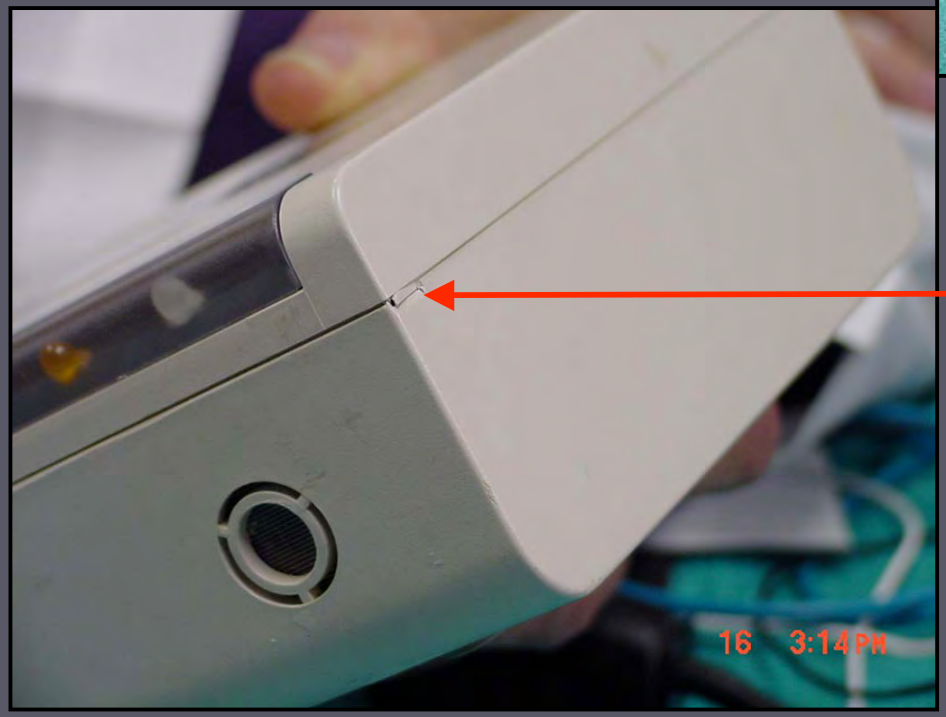
Incident Background

- Infant found by parents - blue and unresponsive
- Parents reported infant had been placed on apnea monitor, but no alarm sounded
- Parents performed CPR; called EMS at 8:57 p.m.
- Monitor was in alarm mode when EMS arrived
- EMS arrived; additional CPR and resuscitation techniques were attempted
- Infant taken to the hospital but did not recover

Incident Background, Cont.

- A recall for the monitor was issued 2 weeks prior to incident
  - Reason: The audio alarm may fail to sound
- Monitor had been dropped prior to use by parents
- Crack in the cover located during inspection
- Loose part found within the monitor case during inspection

Broken calibration seal



Cracked monitor housing

FDA

Enforcement Report

RECALLS AND FIELD CORRECTIONS: DEVICES -- CLASS II

PRODUCT

Corometrics Infant (Apnea) Monitors: Models: 500, 500E, 500EXL, 501, 502, 510, 511. Recall #Z-623/633-9.

MANUFACTURER

Corometrics Medical Systems, Inc., Wallingford, Connecticut.

RECALLED BY

Manufacturer, by telephone on January 18, 1999, and by letter on January 21, 1999. Firm-initiated recall ongoing.

DISTRIBUTION

California, Connecticut, Florida, Georgia, Louisiana, Massachusetts, Maryland, Minnesota, Mississippi, Kansas, Nebraska, New York, Ohio, Tennessee, Texas, Virginia, Washington, international.

QUANTITY

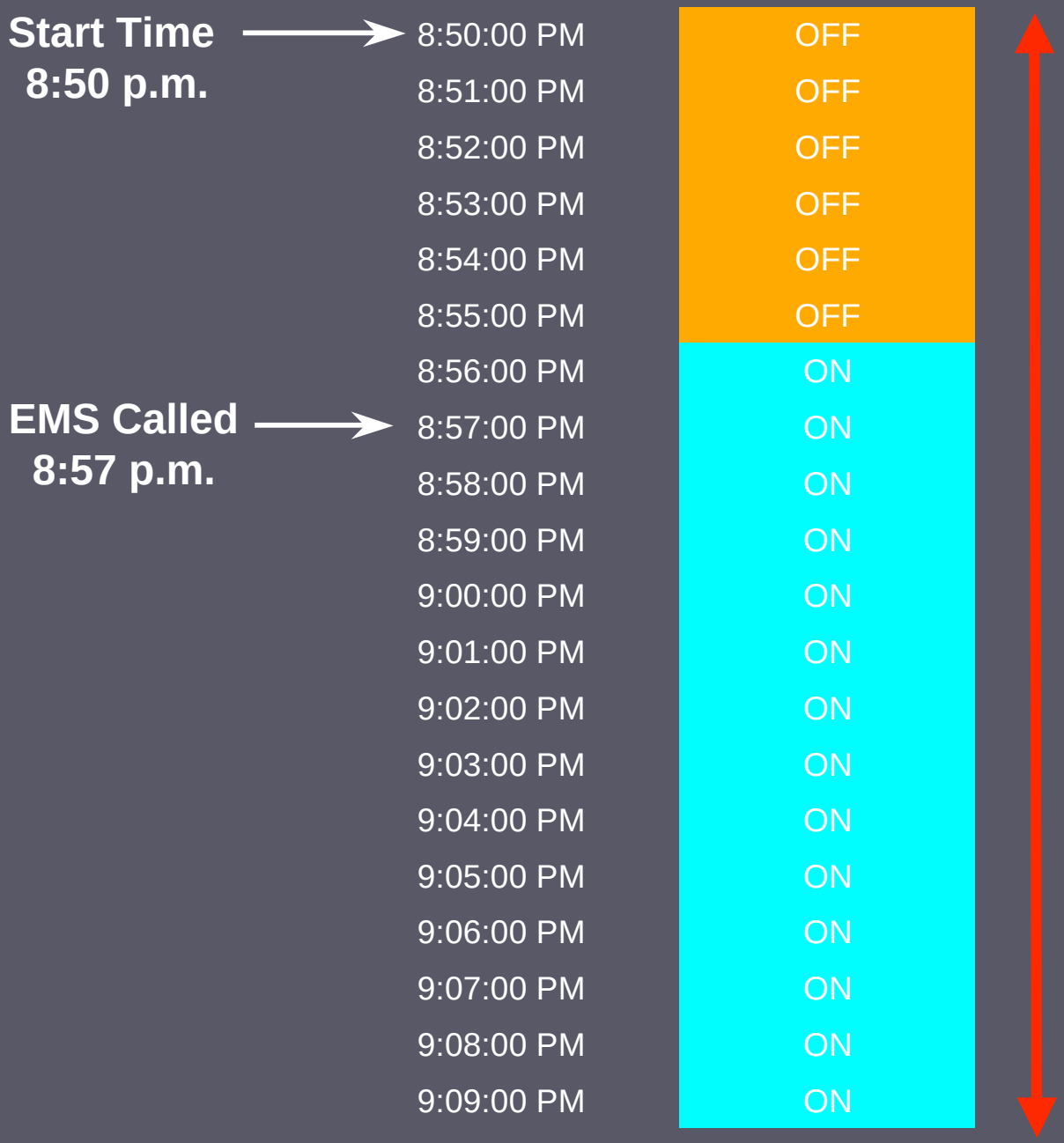
106 units were distributed.

REASON

The audio alarm may fail to sound.

Plaintiff Allegations

- Plaintiff biomedical expert opinions:
  - Monitor was properly used on infant
  - Subject monitor exhibited random failure and did not alarm properly
  - Subject monitor - unreasonably dangerous
    - Defective design
    - Manufacturing error
    - Inappropriately distributed



Plaintiff Biomed expert believes monitor is on - clock slightly off

Subject Device Model - Specific FDA MAUDE Report

Adverse Event Report

COROMETRICS MEDICAL SYS. INC. MODEL 500E INFANT MONITOR INFANT ECG/RESPIRATION MONITOR

back to search results

Model Number 500E

Event Date 06/17/1997

Event Type Malfunction

Event Description

The monitor was returned for svc on 06/24/1997 to repair "alarm won't go off" condition. During initial analysis it was noted that the audio indicator was not functioning.

Manufacturer Narrative

On 07/16/1997 failure analysis of the audio transducer was completed. The condition was due to a broken solder connection between a component lead and an internal circuit board. The unit was repaired and returned to the account.

Subject Device Model - Specific FDA MAUDE Report, Cont.

Adverse Event Report

COROMETRICS MEDICAL SYSTEMS, INC. MODEL 500E INFANT MONITOR

back to search results

Model Number 500E

Event Type Malfunction

Event Description

Monitor was received for servicing with the stated symptom of "does not alarm when unit is first turned on. " the monitor is designed to perform a self test when its first turned on. The audible alarm is sounded as part of this self test.

Manufacturer Narrative

The device was evaluated by the manufacturer for the complaint symptom of "does not alarm when units is first turned on. " the complaint symptom was confirmed and attributed to the failure of the device's audio transducer. The manufacturer is currently conducting recall z-623-9 through z-633-9 to address this product issue.

Subject Device Model - Specific FDA MAUDE Report, Cont.

Adverse Event Report

COROMETRICS MEDICAL SYS. INC. MODEL 500E INFANT MONITOR ECG/RESPIRATION MONITOR

back to search results

Model Number 500E

Event Type Malfunction

Event Description

Prior to unit being sent to caregiver, the respiratory therapist noted that the audio alarm faded out during prolonged alarm conditions.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name MODEL 500E INFANT MONITOR

Subject Device Model - Specific FDA MAUDE Report, Cont.

Adverse Event Report

COROMETRICS MEDICAL SYSTEMS, INC. MODEL 500E INFANT MONITOR INFANT ECG/RESPIRATION MONITOR

back to search results

Model Number 500E

Event Date 07/07/1997

Event Type Malfunction

Event Description

The account returned the monitor on 7/14/97 for repair of "battery won't charge and alarm not functioning conditions.

Manufacturer Narrative

Device failure was analyzed on 7/14/97. The device failure was attributed to a partially lifted interconnecting cable. The cable was reseated and the monitor functioned correctly. The mfr was unable to reliably determine how or under what circumstances the connector became partially disconnected.

Subject Device History

- **4/11/94** - Company requests all Corometric-supplied unprotected lead wires be returned and replaced
- **2/28/95** - Device passes manufacturing tests
- **6/14/95** - Total Home Care Incoming inspection
- **6/15/96** - Device sold to Total Home Care
- **2/22/96** - Failed with cracked case - repaired

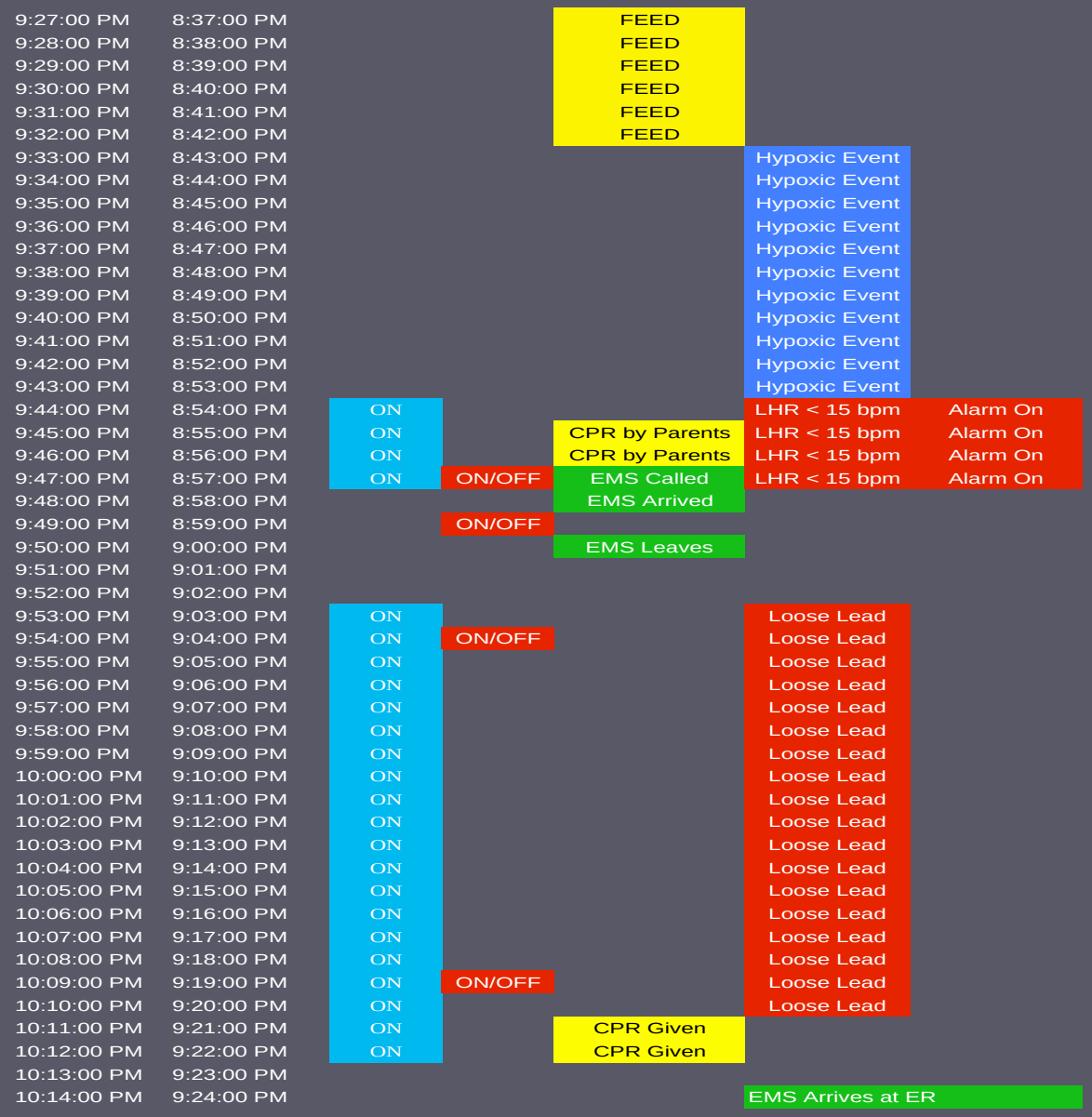
Subject Device History, Cont.

- **11/15/97** - PM Inspection completed
- **3/27/98** - Device sold to Guardian Home Care
- **11/15/98** - Device due for PM inspection, however, this was not done
- **1/18/99** - Recall initiated for device
- **3/10/99** - Subject Incident Occurred

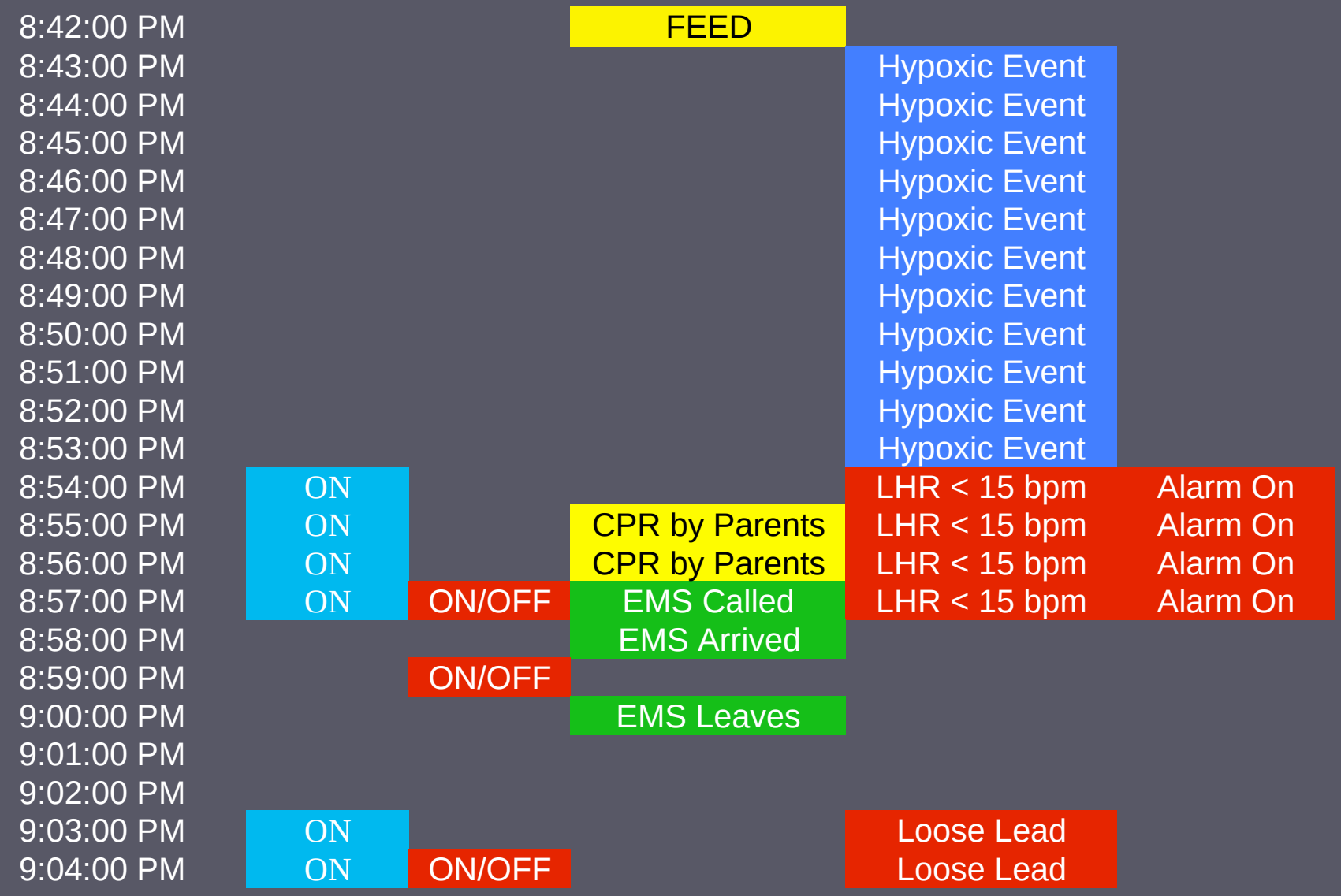
Time Scale Adjustment

Testing subject device using accurate time recordings revealed a difference of 50 minutes when the location of the monitor, clock drift, and Daylight Savings Time were taken into account.

Adjusted Time Chronology



Adjusted Time Chronology, Critical Event



Findings

- Taking all evidence together, subject monitor was not applied to infant after feeding
- Infant suffered a period of hypoxia while not monitored
- No indications of monitor failure in the record; this includes the subsequent monitor testing
- Subject monitor functioned appropriately, but was not attached to the infant at the time of the hypoxic event

Conclusion

Biomedical engineering analyses can add critical pieces of information to identify root cause(s) necessary for forensic determinations of adverse outcomes involving medical technology.

Thank You

Bruce H. Barkalow, Ph.D., PE, CCE
William E. Grant, M.A., M.L.I.S.
and Farrah J. Curran, B.S.

B.H. Barkalow, P.C.
490 Quarterline St.
Newaygo, MI 49337