1. PATIENT

FAILURE MODE
Source of artifacts, poor signal and false alarms.

CAUSES
Movement
Trembling
Obese
Becomes apprehensive/ agitated as alarms are activated/heard in the room.

ROOT CAUSES
HF-C 2, 3, 7 & 13
HF-T 1, 2 & 3
HF-F 1, 2, 3, 6, & 8
E 3, 6, 8, 16, 19, 20, 22
R 13
B 7

SOLUTIONS
Staff must assess and convey the patient's conditions to other shifts and team members. Use a checklist to make sure that the source is under control, at ease and comfortable. (Note: as the nursing population ages, those nurses who are experiencing hot flashes will be more comfortable in a cooler environment but the patient might be trembling). Training by monitoring companies usually cover just their devices and not the patient nor the environment.

2. PATIENT INTERFACES

FAILURE MODE
Loose/intermittant connections
Electrodes falling off resulting in nuisance "Leads off" alarms.
Improper placement of electrodes resulting in poor quality traces.
Transducers are not calibrated/not compatible with the amplifiers.

CAUSES
Poor quality electrodes
Diaphoretic patient
Improper placement
Patient's skin not properly prepped
In a hurry
Not really understanding the idiosyncrasies of the system
Improper calibration of sensors/transducers

ROOT CAUSES
HF-C 14
HF-T 1, 3, 6, 8
HF-F 8
E 6, 7, 8, 15, 16, 20

SOLUTIONS
Must have multidisciplinary input in the selection and procurement of disposable patient interface devices.
Proper training and skills validation of skin preparation, selection of site, proper calibration and application of electrodes, transducers, catheters, sensors to the patient.

3. MONITORING SYSTEMS & PERIPHERAL DEVICES

FAILURE MODE
Too many alarms
False positives
False negatives
Caregiver makes mistakes because too complex for the average caregiver
Alarms are too faint/too loud

CAUSES
Alarms are not configured properly and or misunderstood by the caregiver
Manufacturer of device did not manufacture the other components of the system and/or did not approach the design from systems perspective

ROOT CAUSES
HF-C 14
HF-T 1, 3, 6, 8
HF-F 8
E 6, 7, 8, 15, 16, 20

SOLUTIONS
Must have multidisciplinary input in the selection and procurement of disposable patient interface devices.
Proper training and skills validation of skin preparation, selection of site, proper calibration and application of electrodes, transducers, catheters, sensors to the patient.

4. ENVIRONMENT

FAILURE MODE
Too many alarms
False positives
False negatives
Caregiver makes mistakes because too complex for the average caregiver
Alarms are too faint/too loud

CAUSES
Alarms are not configured properly and or misunderstood by the caregiver
Manufacturer of device did not manufacture the other components of the system and/or did not approach the design from systems perspective

ROOT CAUSES
HF-C 14
HF-T 1, 3, 6, 8
HF-F 8
E 6, 7, 8, 15, 16, 20

SOLUTIONS
Must have multidisciplinary input in the selection and procurement of disposable patient interface devices.
Proper training and skills validation of skin preparation, selection of site, proper calibration and application of electrodes, transducers, catheters, sensors to the patient.

5. STAFFING ISSUES

FAILURE MODE
Loose/intermittant connections
Electrodes falling off resulting in nuisance "Leads off" alarms.
Improper placement of electrodes resulting in poor quality traces.
Transducers are not calibrated/not compatible with the amplifiers.

CAUSES
Poor quality electrodes
Diaphoretic patient
Improper placement
Patient's skin not properly prepped
In a hurry
Not really understanding the idiosyncrasies of the system
Improper calibration of sensors/transducers

ROOT CAUSES
HF-C 14
HF-T 1, 3, 6, 8
HF-F 8
E 6, 7, 8, 15, 16, 20

SOLUTIONS
Must have multidisciplinary input in the selection and procurement of disposable patient interface devices.
Proper training and skills validation of skin preparation, selection of site, proper calibration and application of electrodes, transducers, catheters, sensors to the patient.
1. Is the patient comfortable?
Trembling patient (because the room is cold, or because of apprehension, from a number of things: scared, worried, being sick, actual disease state, constant alarms in the room) will cause artifacts and display on the monitoring screen. Somatic tremor looks like 60 Hertz interference. Will cause false (nuisance) alarms.
Other forms of patient movement (sleeplessness because patient is not used to the bed, pain, other noises on the floor) will cause false alarms. Sometimes patient tries very hard to stay still (to not trigger alarms) and caused his/her vitals to violate alarm thresholds. Are the alarm thresholds appropriately set for the type of patient? Can staff demonstrate that they understand the alarm configurations and appropriately adjust? Are they empowered to do so?

2. This is the most critical part of the system.
Patient electrodes (disposable ECG electrodes), transducers, sensors, lead wires and cables must be carefully chosen with representation from, physicians, nurses, clinical engineers, patient safety managers, and purchasing. Do they meet ANSI standards? These devices must be compatible with the patient and selected for short term vs long term use, they must be compatible with the monitoring systems and the peripheral devices.
1. PATIENT

FAILURE MODE
Source of artifacts, poor signal and false alarms

CAUSES
Movement
Trembling
Obese

Becomes apprehensive/agitated as alarms are activated/heard in the room

ROOT CAUSES
HF- C 2, 3, 7 & 13
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E 3, 6, 8, 16, 19, 20, 22
R 13
B 7

SOLUTIONS
Staff must assess and convey the patient’s conditions to other shifts and team members. Use a checklist to make sure that the source is under control, at ease and comfortable. (Note: as the nursing population ages, those nurses who are experiencing hot flashes will be more comfortable in a cooler environment but the patient might be trembling).
Training by monitoring companies usually cover just their devices and not the patient nor the environment
2. PATIENT INTERFACES
Sensors, electrodes, transducers, lead wires, cables. Proper placement

FAILURE MODE
Loose/intermittant connections
Electrodes falling off resulting in nuisance "Leads off" alarms.
Improper placement of electrodes resulting in poor quality traces.
Transducers are not calibrated/ not compatible with the amplifiers.

CAUSES
Poor quality electrodes
Diaphoretic patient
Improper placement
Patient's skin not properly prepped
In a hurry
Not really understanding the idiosyncrasies of the system
Improper calibration of sensors/transducers

ROOT CAUSES
HF - C 14
HF - T 1, 3, 6, 8
HF - F 8
E 6, 7, 8, 15, 16, 20

SOLUTIONS
Must have multidisciplinary input in the selection and procurement of disposable, patient interface devices.
Proper training and skills validation of skin preparation, selection of site, proper calibration and application of electrodes, transducers, catheters, sensors to the patient.
3. MONITORING SYSTEMS & PERIPHERAL DEVICES

Initial setup
Upgrades

FAILURE MODE

Too many alarms
False positives
False negatives

Caregiver makes mistakes because the monitoring system has become too complex for the average caregiver
Alarms are too faint/too loud

CAUSES

Alarms are not configured properly and or misunderstood by the caregiver
Manufacturer of device did not manufacture the other components of the system and/or did not approach the design from systems perspective
4. ENVIRONMENT
   Noise level of area
   Room layout
5. STAFFING ISSUES
Patient to Nurse Ratio
Logistics
Training
False Norms