Adventist HealthCare, Inc.
Clinical Policy Manual
AHC Clinical Alarm/Medical Device Safety

Effective Date: 02/14 | **Policy No**: AHC CP 11.0
Cross Referenced: TJC: NPSG.06.01.1 | **Origin**: Patient Safety/Risk Management
Reviewed: 04/16, 02/17, 2/18, 1/20, 1/21, 1/22, 12/22, 1/24 | **Authority**: CSB
Revised: 1/19, 3/15/22 | **Page:** 1 of 8

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SCOPE:
All Adventist HealthCare (AHC) Entities that utilize Clinical Alarms/Medical Devices

POLICY
AHC will ensure that all clinical alarms and medical equipment alarm systems utilized for patient care will be operational and set to clinically appropriate levels.

All AHC Entities will ensure that alarms on patient care equipment are evaluated prior to use based on function, physical risks associated with clinical use, maintenance requirements and equipment incidents. All AHC Entities will develop risk-based alarm parameters based on the evaluation criteria. An inventory of equipment included in the program and equipment maintenance records documenting all maintenance on equipment is kept in the Clinical Engineering Department.

PROCEDURE GUIDELINES:
CLINICAL ALARMS:

Patient Care Units/Departments:

- Patient care teams members will verify clinical alarms prior to use of medical equipment/devices on the patient population:
    - Confirm that audible and visual alarms function during the equipment power on self-test.
        - An environmental assessment of the alarm will be performed to assure the alarm can be heard within an appropriate distance and with competing noise in the unit where the medical device/equipment is being used. The environmental assessment will include assurance that any visual aspects of the alarm system are working properly when activated.
- Patient care team members will verify and reset, if necessary, the alarm parameters at the beginning of each shift, when the nurse returns from breaks, when the patient is turned or moved, or after patients are transferred.
    - Ensure that dysrhythmia detection functions are available and appropriately activated, and that the alarm volume is high enough to be heard outside the patient's room.
    - Alarm parameters are patient specific. Parameters should be set at 5-10% above and below expected rate.

- Patient care team members will assure that direct observation of the patient is routinely conducted to avoid singular dependence on alarm systems.

- Patient care team members will **not** suspend alarms.

- Be sure to correctly discharge patients from their monitors on transfer or discharge from the bed, unit or hospital.

- Never rely solely on pagers, mobile phones and other secondary alarm enhancements for alarm communication.

- Immediately report any device malfunctions or concerns to the Engineering/ Biomedical team. Remove the device from operation according to the hospital's policies and procedures until it has been evaluated.

- Staffing on all patient care units will consider the amount and complexity of medical equipment/devices utilized for patient care to assure sufficient team members available to assess, operate, hear and respond appropriately to clinical alarms at all times. The staffing ratio will be appropriate to the complexity of the medical equipment/devices in use and the acuity of the patient.

Team members Education:

- All team members that utilize or maintain medical equipment/devices with clinical alarm systems will be properly oriented to the equipment/device and the alarm and trained on its use within the scope of their role.

    - Patient care team members must demonstrate both physical knowledge of the operational aspects of the equipment/device and alarm, and the physiological aspects as to why alarms become activated related to the specific equipment/ device in use for the patient.

        - Patient care team members must be familiar with all monitor functions, especially dysrhythmia detection, alarms and icons on the screen, and the meanings of various alarm sounds.

    - Engineering/Biomedical team members must demonstrate functional and technical knowledge of the equipment/device alarm systems.

- All team members using medical equipment/devices with related alarm systems must be assessed and proven competent to operate the equipment/device and manage its associated alarm mechanism prior to use of that equipment/device.
    - For all equipment/devices with clinical alarms, team members competency assessment will be conducted prior to initial use of the equipment/ device and per needs assessment thereafter.

- Patient care unit/department Nurse Manager will ensure that team members, including travel and float nurses, are adequately trained on the unit's monitors before they care for monitored patients.

- All patient care team members will receive education at orientation and per needs assessment thereafter about the hospital's backup plan if monitors become dysfunctional, per written policy and procedure.

Alarm Testing:

- Engineering and Clinical Engineering Departments will perform functional testing of clinical alarms and alarm systems associated with medical equipment as part of routine preventive maintenance and in accordance with risk appropriate maintenance strategies:
- Testing is designed to ensure the alarming mechanism (audible, visual, both) is functioning according to the manufacturer's specifications.
    - Nursing and Clinical Departments will conduct periodic operational testing and functional (human factor) testing.
        - Functional testing will be performed by periodic activation of the alarm on the device/equipment in a patient care area for equipment on the inventory list.
        - The functional test will be conducted on a piece of equipment/device that is not in use on a patient.
        - The device/equipment will be brought to the patient care unit for evaluation of the team's member response to the alarm.
            - A corrective action plan will be developed by an interdisciplinary team (Team members from the specific patient care unit, Engineering/Biomedical team members, Patient Safety Committee representative) upon identification of any environmental noise, staffing or other issues that prevent team members from hearing and responding to the alarm.
        - A corrective action plan will be developed collaboratively by administration, Engineering/Biomedical Department and the Patient Safety Committee (or representative thereof) and a representative (as appropriate) from the patient care unit for any identified malfunction of safety/security alarm systems (i.e., infant abduction alarms).
- Clinical Engineering Department will maintain an inventory of all equipment included in the medical equipment management program. The inventory will include the equipment risk category, equipment management number and preventive maintenance interval.
- All incoming equipment will be compared to an included device list.

- Equipment evaluation results will be reviewed by the Safety/Environment of Care Committee. Any changes to the medical equipment management program must be coordinated and approved with the Safety/Environment of Care Committee.

EXHIBIT A
SAMPLE: CLINICAL ALARMS SURVEY

Instructions: Please read the following statements about clinical alarms in our facility and rank by circling the response that best reflects your perception/experience. This survey is anonymous and honest responses are encouraged.

1 = Strongly Agree
2 = Agree
3 = Neutral
4 = Disagree
5 = Strongly Disagree

Clinical alarms are a nuisance on my unit.	1	2	3	4	5
Nuisance alarms occur frequently on my unit.	1	2	3	4	5
I am distracted from patient care activities by nuisance alarms.	1	2	3	4	5
I can differentiate the various clinical alarms.	1	2	3	4	5
I can determine the priority of an alarm based on its sound.	1	2	3	4	5
The alarms used on my unit adequately alert me to changes in a patient's condition.	1	2	3	4	5
There have been instances when I have not heard an alarm.	1	2	3	4	5
I always respond to alarms immediately.	1	2	3	4	5
It can be confusing when a number of devices are used with a patient to determine if a sound is an alarm or a function of normal operations.	1	2	3	4	5
I am aware of and understand this organization's clinical alarms policy.	1	2	3	4	5

Standard practice on my unit is to document that the alarms are set and parameters are appropriate for each patient.	1	2	3	4	5
I have experienced difficulty setting a clinical alarm.	1	2	3	4	5
I have experienced difficulty understanding a clinical alarm's priority.	1	2	3	4	5
Frequent false alarms reduce my attention to alarms.	1	2	3	4	5
I have been adequately trained on every device with a clinical alarm on my unit.	1	2	3	4	5

EXHIBIT B

RISK	FUNCTION
LIFSUP	Life Support
1	High Level Therapeutic / Life Support
2	Diagnostic / Monitoring / Mid Level Therapeutic
3	Analytical / Low Level Diag / Monitor / Therap
4	Miscellaneous

DEPARTMENT	MANUFACTURER - TYPE	COUNT	RISK	ATTENDED		SYSTEM ALARMS			PATIENT ALARMS		
						AUDIO	VISUAL		AUDIO	VISUAL	ADJUSTABLE

SAMPLE: ALARM EQUIPMENT GRID

REFERENCES:

U.S. Food and Drug Administration (FDA), Medical Devices, Products and Medical Procedures, *Device Approvals and Clearances Databases*, page last updated 3/26/2018 https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-denials-and-clearances
Content current as of 03/26/2018

The Joint Commission (TJC), **National Patient Safety Goal (NPSG) 2022** NPSG.06.01.01
http://www.jointcommission.org

Circulation. *Update to Practice Standards for Electrocardiographic Monitoring in Hospital Settings: A Scientific Statement from the American Heart Association.* Volume 136, Issue 19, 7 November 2017; Pages e273-e344. **Refer to: Table 7. Recommended Electrocardiographic Monitoring of Hospitalized Adult Patients by Population** https://www.ahajournals.org/doi/10.1161/CIR.0000000000000527