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AST Guidelines for Best Practices in Alarm Management in the Operating Room

Introduction

The following Guidelines for Best Practices were researched and authored by the AST Education and Professional Standards Committee, and are AST approved.

AST developed the following Guidelines to support healthcare delivery organizations (HDO) reinforce best practices in alarm management as related to the role and duties of the Certified Surgical Technologist (CST®), the credential conferred by the National Board of Surgical Technology and Surgical Assisting (NBSTSA). The purpose of the Guidelines is to provide information OR supervisors, risk management, and surgical team members can use in the development and implementation of policies and procedures for alarm management in the surgery department. The Guidelines are presented with the understanding that it is the responsibility of the HDO to develop, approve, and establish policies and procedures for the surgery department regarding alarm management practices according to HDO protocols.

Rationale

The following are guidelines in alarm management in the surgery department. As a working definition, an alarm is an automatic warning that results from a measurement indicating a deviation from the normal parameters.¹⁸ *Medical device alarms* perform an essential patient safety function providing a warning alert system to the surgical team that there is a potential problem with the physiology of the patient or the medical device itself, but if not properly managed patient care may be compromised.^{1,26} The large number of devices with alarms, such as during surgical procedures, has become identified as a major issue with negative results including healthcare personnel (HCP) becoming overwhelmed responding to several alarms in short spans of time; becoming desensitized, called “*alarm fatigue*”, leading to ignoring and/or missing alarms; delayed responses placing patients at risk; *false or nuisance alarms*; or even turning off alarms.^{1,26} In the *Standards for Basic Anesthetic Monitoring* published by the American Society of Anesthesiologists, it states that alarms should only be turned off for short interruptions in “rare and unusual circumstances.”¹³ Other issues associated with alarm management include default settings of alarms that are not at an *actionable level* and alarm limits that are too narrow.²⁰

In its April 2013 edition of *Sentinel Event Alert*, The Joint Commission (TJC) reported that a search of the U.S. Food and Drug’s Manufacturer and User Facility Device Experience (MAUDE) database, January 2005 – June 2010 there were 566 patient deaths related to alarm-related device events.¹⁹ In regard to false alarms, Schmid, et al.¹⁷ studied 25 consecutive cardiac surgical procedures reporting the patient monitor and anesthesia workstation generated alarms at 1.2 alarms per minute and 80% of the alarms had no therapeutic consequences leading to what he calls the “crying wolf” phenomenon where alarm fatigue occurs leading to ignoring critical alarms

that do have critical consequences. This has led to the ECRI listing alarm hazards in its list of top ten health technology hazards multiple years including being the number one hazard in 2015.¹⁰

The majority of research conducted in the operating room has been focused on anesthesia providers since they are responsible for managing most of the devices that have alarms. However, even this research has been limited. Therefore, the following are broad-based guidelines. But it must be emphasized that the CST serves as another “pair of eyes” in the OR and can best serve the patient through her/his knowledge of alarms.

Evidence-based Research and Key Terms

The research of articles, letters, nonrandomized trials, and randomized prospective studies is conducted using the Cochrane Database of Systematic Reviews and MEDLINE®, the U.S. National Library of Medicine® database of indexed citations and abstracts to medical and healthcare journal articles.

The key terms used for the research of the guidelines include: actionable level; alarm fatigue; artifacts; buzzing; electrosurgical alarm; false alarms; medical device alarms; nuisance alarms; smart alarms. Key terms used in the guidelines are italicized and included in the glossary.

Guideline I

The surgery department should develop a systematic, coordinated approach to the safe management of alarms that involves the surgical team, information technology experts, healthcare technology management technicians (biomedical technicians), risk management and HDO administration.

1. TJC recommends the following broad actions that also reflect the recommendations of the Association for the Advancement of Medical Instrumentation (AAMI) and ECRI.^{1,2} These can be translated into actions that the surgery department should implement.
 - A. Ensure that there is a process for safe alarm management and response with measurable results.
 - 1) The leadership goals for establishing an alarm safety management program in the surgery department should be based upon the following goals:²
 - a) Enhance patient care and patient safety
 - b) Decrease nuisance alarms and alarm fatigue
 - c) Ensure staff accountability and responsiveness to alarm signals and ensure they know their responsibility
 - d) Improve productivity and work flow
 - e) Increase patient and staff satisfaction
 - f) Optimize technology
 - g) Align with TJC National Patient Safety Goal on alarm management
 - h) Make the HDO an environment of healing, where there is a decrease in the noise
 - B. An inventory of alarm-equipped medical devices should be completed identifying the default alarm settings and the limits appropriate for each care area.
 - 1) It is recommended to complete a failure mode and effects analysis (FMEA) on alarms. FMEA is an approach for identifying the possible failures that can occur with an alarm and the actions to take to eliminate

or reduce the failures, starting the highest priorities.²¹ “Failure modes” means the way in which the alarm can fail and affect the patient; “effects analysis” refers to studying the consequences of the failures.²¹ Failures are prioritized according to the seriousness of the consequences and actions to address the failures are completed.²¹

- 2) Evidence-based indications should be considered for the appropriate initiation, maintenance and discontinuation of medical devices that have an alarm.²
- C. Establish policies and procedures (P&P) for alarm settings on alarm-equipped medical devices, including identification of situations when alarm signals are not clinically necessary. This can prevent false alarms, also called nuisance alarms, from occurring that are a source of noise and distraction that can disrupt patient care.¹² If an alarm has been silenced/turned off, it should be recorded who turned off the alarm; when the alarm was turned off; and the reason why.
- 1) To prevent nuisance alarms it is recommended to customize alarm settings according to individual surgical patients and use *smart alarms* when available.¹² Smart alarms can reduce the number of nuisance alarms through technology that takes into account multiple parameters, rate of change and signal quality and the alarms are based on physiologic trends sensed over a period of time.²⁶
 - 2) Protocols, based upon evidence-based practices, should be established for proper skin preparation and placement of electrodes to prevent false alarms.¹¹ Additionally, *artifacts* (e.g. patient movement or manipulation of sensors) should be taken into consideration for the cause of false alarms.¹⁷
 - 3) Evidence-based practice has also confirmed that single-use pulse oximeter sensors are less prone to false alarms versus recycled sensors.¹¹
 - 4) Electrical cords and cables from alarm equipped devices such as the electrodes and pulse oximeter should be regularly inspected for damage to prevent false alarms.¹¹
- D. Establish P&Ps for situations in which alarm settings and limits may be modified to minimize alarm signals and the extent to which alarms may be modified.
- E. Based upon a study by F. R. Man et al. (2013) the number of alarms significantly increase during induction and emergence of anesthesia as opposed to maintenance; however, a large percentage of the alarms are clinically irrelevant.⁸ The increase in the number of alarms can be expected due to hemodynamic and respiratory changes, in particular during emergence.⁸ The surgical team should maintain awareness of the clinical alarms while taking into consideration the work activities that are occurring during the care of the patient during induction and emergence.
- F. Based upon manufacturers’ recommendations and instructions-for-use (IFU), the surgery department should establish a schedule with the input of the healthcare technology management technicians for the inspection and maintenance of alarm-equipped devices to ensure proper operation of the devices as well as accurate and appropriate alarm settings.

Guideline II

The CST is responsible for the control of the active electrode (also called electrosurgical or electrocautery pencil or Bovie) when not in use to prevent inadvertent activation to avoid burns to the patient and surgical team, and ignition or puncture of the drapes.

1. The “*buzzing*” noise that the electrosurgical unit (ESU) emits indicates when the active electrode is in use. However, it becomes an alarm for the CST to be aware of if the buzzing noise occurs and the surgeon is not using the active electrode. The CST should immediately bring it to the attention of the sterile team in the event that someone is leaning on an active electrode that was left on the drapes.
 - A. The active electrode should always be placed in a dry, well-insulated safety holster when not in use to prevent inadvertent activation or contamination by falling down by the side of the OR table.^{4,9,14,16,25}
 - B. The safety holster should be attached to the sterile field using an atraumatic clamp, preferably non-metal.^{3,4,16}
 - 1) The safety holster should be placed in a location on the sterile field according to the surgical procedure that facilitates easy retrieval by the surgeon.
 - 2) Endoscopic active electrodes are longer than normal and usually do not fit inside the safety holster. In this instance, the active electrode should be placed on the Mayo stand.^{4,7,9,16} If the surgeon maintains that the active electrode be placed on the drapes, this should be recorded in the operative record.^{3,4}
 - 3) For details regarding electrosurgery refer to the *AST Guidelines for Best Practices in the Use of Electrosurgery*.

Guideline III

The surgery department should complete a thorough review of an adverse event involving harm or potential harm to a patient and improper management of an alarm(s).

1. The review should be conducted as a root-cause analysis with a focus on what lead to the occurrence of the adverse event, what P&Ps were not possibly followed/enforced, and how it can be prevented in the future.
 - A. The P&Ps that were not followed should be reviewed for clarity and if they are in-line with current safety trends, and if necessary, revised.
 - B. The surgical team members that were involved in the adverse event should complete continuing education that includes review of the incident and how it could have been prevented.
 - 1) The individuals should provide feedback if they are of the opinion that P&Ps are not clearly stated or other situations are occurring such as alarm fatigue in order for the surgery department to make further improvements in its alarm safety management program.
 - C. The adverse event should be shared with the surgery department staff as a tool for learning without sharing the details of who was involved in the incident.

Guideline IV

The surgery department should review the policies and procedures (P&P) regarding safe alarm management on an annual basis.

1. Universal solutions and standardization contribute to safe alarm management, but have yet to be established with the recognition that solutions may have to be customized and a “one-size-fits-all” approach will not work even within the various departments of a HDO due to differences in the environment of patient care, patient needs, and staff readiness.² However, the surgery department should develop a systematic, coordinated approach to alarm management that is practiced on a uniform basis by the surgery department staff.²⁰
2. The surgery department should include members of the surgical team and administration when reviewing the P&Ps, including CSTs, surgeons, anesthesia providers, RNs, risk management, information technology, and healthcare management technicians.
 - A. It is recommended that the surgery department create an alarm safety management committee that is responsible for the review and revision of P&Ps, review of adverse events and providing continuing education.¹⁵ This would eliminate the uncertainty of who is responsible for creating and managing alarm system P&Ps.²
 - B. The review and revision process of P&Ps should include administering staff surveys to gather their feedback regarding alarm management including identifying their perceptions and concerns.²
 - C. It is recommended to review the P&Ps from other HDOs to consider adopting or adopting with revisions to meet the needs of the surgery department, i.e. don’t reinvent the wheel.²
3. The surgery department should confirm the elements of performance (EP) from the *National Patient Safety Goal on Alarm Management* issued by TJC are incorporated in the P&Ps.²⁰
 - A. As of July 1, 2014, HDOs should have established alarm system safety as a hospital priority.
 - B. Additionally, during 2014, the HDOs should have identified the most important alarm signals to manage based on the following:
 - 1) Input from the medical staff and clinical departments.
 - 2) Risk to patients if the alarm signal is not attended to or if it malfunctions.
 - 3) Whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue.
 - 4) Potential for patient harm based on internal incident history.
 - 5) Published best practices and guidelines.
 - C. As of January 1, 2016, HDOs should have established P&Ps for managing alarms that, at a minimum, address the following:
 - 1) Clinically appropriate settings for alarm signals.
 - 2) When alarm signals can be disabled.
 - 3) When alarm parameters can be changed.
 - 4) Who in the organization has the authority to set alarm parameters.
 - 5) Who in the organization has the authority to change alarm parameters.
 - 6) Who in the organization has the authority to set alarm parameters to “off”.
 - 7) Monitoring and responding to alarm signals.
 - 8) Checking individual alarm signals for accurate settings, proper operation, and detectability.

- 4) As of January 1, 2016, HDOs should be educating staff and licensed independent practitioners about the purpose and proper operation of alarm systems for which they are responsible.
4. The process should include review of reports published by healthcare agencies and HDOs to identify trends and safety practices that can be used as opportunities for improving the P&Ps.¹
5. The P&Ps should establish protocols for when monitoring is suspended or on standby such as when transporting a patient from preoperative holding to the OR and vice-versa, and when electrodes are being manipulated such as after a patient has been positioned on the OR table.²²
6. It is recommended the P&Ps include a process for completing a checklist when a new piece of equipment is set up to confirm that the alarm(s) are functioning, and the parameters are properly chosen and set.²³
7. A recommendation for strengthening the P&Ps is to assign a stakeholder to monitoring one or more P&Ps for compliance, such as a CST, RN or healthcare technology management technician.²

Guideline V

CSTs should complete continuing education to remain current in their knowledge of alarm management.⁵

1. Education of all surgical department staff is critical to establishing and maintaining a culture of patient safety.^{5,22,24} The P&Ps of the HDO should be used as a basis for designing the education and training.²
2. The continuing education should be based upon the concepts of adult learning referred to as andragogy. Adults learn best when the information is relevant to their work experience; the information is practical, rather than academic; and the learner is actively involved in the learning process.²⁷
3. It is recommended surgery departments use various methods of instruction to facilitate the learning process of CSTs.
 - A. If the education is primarily lecture, methods to engage learners include presentation of case studies for discussion, and audience discussion providing suggestions for reinforcing alarm management.
 - B. Other proven educational methods include interactive training videos, and computerized training modules and teleconferences.
 - C. The continuing education should be delivered over short periods of time such as in modules, and not in a one-time lengthy educational session.
4. Continuing education programs should be periodically evaluated for effectiveness including receiving feedback from surgery department personnel.
5. The surgery department should maintain education records for a minimum of three years that include dates of education; names and job titles of employees that completed the continuing education; synopsis of each continuing education session provided; names, credentials, and experience of instructors.

6. CSTs should be familiar with and have basic knowledge of the types of alarm-equipped devices that are used in the operating room including devices that are specific to surgical specialties, e.g. cardiovascular surgery.
 - A. The CST should be familiar with the purpose of the devices as well as the sound of the alarms for each device.
 - B. The CST should complete annual continuing education in safe alarm management as well as complete continuing education about new devices that have been acquired by the surgery department.⁵
 - 1) Surgical staff should be educated about new equipment since the alarms may differ from the old equipment.
 - C. If poor compliance with a P&P is identified, the surgery department alarm safety management committee should examine the issue to determine if the P&P is necessary or if the poor compliance can be addressed through education and training.²

Competency Statements

Competency Statements	Measurable Criteria
<ol style="list-style-type: none"> 1. CSTs have the knowledge and skills, and teamwork approach, to work with surgical team members in promoting a safe and caring surgical environment through the development and implementation of alarm-safety management policies and procedures. 2. CSTs can serve on as well as participate in the work of an HDO Alarm Safety Management Committee and/or Surgery Department sub-committee. 3. CSTs have the knowledge and skills to contribute to the teamwork in the OR regarding awareness of alarms and communicating to the correct team member there is a potential problem with a patient or with the medical device itself. 4. CSTs have in-depth knowledge of the ESU, in particular the active electrode and the skills to be aware of when the active electrode is in use and when not in use. 	<ol style="list-style-type: none"> 1. Educational standards as established by the <i>Core Curriculum for Surgical Technology</i>.⁶ 2. The didactic subject of the types of medical equipment used in the OR is included in a CAAHEP accredited surgical technology program.⁶ 3. Students demonstrate knowledge of medical equipment in the lab/mock OR and during clinical rotation. 4. CSTs work with the surgical team members in implementing the alarm safety management policies and procedures of the HDO. 5. CSTs participate on the HDO's Alarm Safety Management Committee and/or Surgery Department sub-committee. 6. CSTs complete continuing education to remain current in their knowledge of alarm safety management practices for the OR.

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Glossary

Actionable level: The alarm of a medical device is activated when a clinical intervention is required.

Alarm fatigue: Occurs when healthcare worker is exposed to a large number of frequent alarms and becomes desensitized to hearing them leading to longer response times or clinically important alarms.

Artifacts: Patient movement, movement of sensors or other clinically unnecessary event that causes a false alarm.

Electrosurgical alarm/buzzing: The sound the electrosurgical unit (ESU) emits when the active electrode is activated; due to the unique sound it is referred to as “buzzing”.

False or nuisance alarms: An alarm that occurs for a clinically unnecessary event, such as a patient moving.

Medical device alarms: Tones or sound a medical device that is connected to a patient emits when a clinical or physiological event causes the alarm to be activated.

Smart alarms: Alarms on medical devices that can monitor multiple parameters and the alarms are based on the patient’s physiologic trends over a period of time.

References

1. American College of Surgeons. Medical device alarms pose safety issues for hospitals. 2013. <http://bulletin.facs.org/2013/07/medical-device-alarms-pose-safety-issues-for-hospitals/>. Accessed September 22, 2016.
2. Association for the Advancement of Medical Instrumentation. Clinical alarm management compendium. 2015. http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/HTSI/Alarms/Alarm_Compendum_2015.pdf. Accessed September 22, 2016.
3. Association of Surgical Technologists. AST standards of practice for creating the sterile field. 2009. http://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Standard_Creating_Sterile_Field.pdf. Accessed September 24, 2016.
4. Association of Surgical Technologists. AST standards of practice for electrosurgery. 2012. http://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Standard%20Electrosurgery.pdf. Accessed September 21, 2016.
5. Association of Surgical Technologists. AST continuing education policies for the CST and CSFA. 2005. <http://www.ast.org/webdocuments/CEpolicies/>. Accessed July 28, 2016.

6. Association of Surgical Technologists. Core curriculum for surgical technology. 2011.
http://www.ast.org/uploadedFiles/Main_Site/Content/Educators/Core%20Curriculum%20v2.pdf. Accessed July 28, 2016.
7. Caruthers B. Electrosurgery. *The Surgical Technologist*. 2005. 37(2): 18-23.
8. de Man FR, Greuters S, Boer C, Veerman DP, Loer SA. Intra-operative monitoring – many alarms with minor impact. *Anaesthesia*. 2013. 68(8): 804-810.
9. ECRI. Burns and fires from electrosurgical active electrodes. 2011.
http://www.mdsr.ecri.org/summary/detail.aspx?doc_id=8203. Accessed September 19, 2016.
10. ECRI. Top 10 health technology hazards for 2015. November 2014.
https://www.ecri.org/Documents/White_papers/Top_10_2015.pdf. Accessed September 23, 2016.
11. Edworthy J. Alarms are still a problem! *Anaesthesia*. 2013. 68(8): 791-794.
12. Feil M. Distractions in the operating room. 2014.
http://patientsafetyauthority.org/ADVISORIES/Advisory/Library/Documents/2014_p_repub_distractions.pdf. Accessed September 23, 2016.
13. Katz JD. Noise in the operating room. *Anesthesiology*. 2014. 121(4): 894-898.
14. Mattuci KF, Militana CJ. The prevention of fire during oropharyngeal electrosurgery. *Ear, Nose, and Throat Journal*. 2003. 82(2): 107-109.
15. Miller T. Alarm fatigue: understanding and solving a complicated problem. 2013.
<http://www.24x7mag.com/2013/07/alarm-fatigue-understanding-and-solving-a-complicated-problem/>. Accessed July 28, 2016.
16. PA-PSRS. Electrosurgery safety issues. 2006.
[http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2006/Mar3\(1\)/Pages/30.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2006/Mar3(1)/Pages/30.aspx). Accessed August 5, 2016.
17. Schmid F, Goepfert M, Kuhn D, Eichhorn V, Diedrichs S, Reichensperner H, Goetz AE, Reuter DA. The wolf is crying in the operating room: patient monitor and anesthesia workstation alarming patterns during cardiac surgery. *Anesthesia and Analgesia*. 2011. 112(1): 78-83.
18. Schmid F, Goepfert MS, Reuter DA. Patient monitoring alarms in the ICU and in the operating room. *Critical Care*. 2013. 17(216): 1-7.
19. The Joint Commission. Medical device alarm safety in hospitals. April 2013.
http://www.jointcommission.org/assets/1/18/SEA_50_alarms_4_5_13_FINAL1.PDF. Accessed September 26, 2016.
20. The Joint Commission. The Joint Commission announces 2014 national patient safety goal. *Joint Commission Perspectives*. 2013. 33(7): 1-4.
21. Tague NR. *The quality toolbox*. 2nd ed. Milwaukee, WI: ASQ Quality Press; 2004.
22. The Truax Group Healthcare Consulting Patient Safety Solutions. Alarm issues in the news again. February 2010.
http://www.patientsafetysolutions.com/docs/February_23_2010_Alarm_Issues_in_the_News_Again.htm. Accessed July 28, 2016.
23. The Truax Group Healthcare Consulting Patient Safety Solutions. Joint commission sentinel event alert: alarm safety. May 2013.
http://www.patientsafetysolutions.com/docs/May_2013_Joint_Commission_Sentinel_Event_Alert_Alarm_Safety.htm. Accessed July 28, 2016.

24. The Truax Group Healthcare Consulting Patient Safety Solutions. Issues in alarm management. July 2013.
[http://www.patientsafetysolutions.com/docs/July 2 2013 Issues in Alarm Management](http://www.patientsafetysolutions.com/docs/July_2_2013_Issues_in_Alarm_Management). Accessed July 28, 2016.
25. US Food & Drug Administration. MAUDE adverse report: 3M healthcare universal electrosurgical dispersive electrode.
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Search.cfm>. Accessed July 28, 2016.
26. Wong M. Four technology recommendations to reduce alarm fatigue. 2012.
<http://www.psqh.com/news/four-technology-recommendations-to-reduce-alarm-fatigue/>. Accessed August 24, 2016.
27. Pappas C. The adult learning theory-andragogy-of Malcolm Knowles. May 2013.
<https://www.elearningindustry.com/the-adult-learning-theory-andragogy-of-malcolm-knowles>. Accessed June 12, 2016.