A Dutch roundtable discussion on safe medical alarm management towards silent intensive care units.

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**Introduction**

Medical alarms are used to notify the caregiver that a patient requires help. This can be an alarm from a physiological monitor, alerting on a deterioration of the patient, or an alarm from a therapeutic device (like the ventilator or an infusion pump), or a patient calling the nurse. In the Intensive Care Unit (ICU), patients are critically ill and require support and monitoring from many (life supporting) devices, leading to a lot of alarms and potentially critical situations if alarms are missed (1-3). The Joint commission announced 2014 the year focused on alarm safety (4,5). In 2011, the Association for the Advancement of Medical Instrumentation (AAMI) presented the results of a roundtable discussion on alarm safety (6). The motivation for the discussion was that alarms in clinical practice were missed because of the desensitization of nurses to alarms due to so-called alarm fatigue. The AAMI addressed the topic of alarm fatigue but also the standardization of alarms and the integration between devices (6), for which they concluded that another approach from manufactures and regulatory bodies (like FDA) is needed to allow for changes in standards and legislation (6).

In addition, a trend is observed in Intensive Care Units and lately also in Neonatal Intensive Care Units (NICU) towards single room intensive care and silent ICUs (7-12). Noise in Intensive Care Units is considered to have negative effects on the recovery and development of the patients and is associated with sleep disturbances and delirium (13-15) (16). Single room care can reduce the noise, it adds privacy for the patient and is for sure a better environment to prevent infections (10), however this situation poses challenges for the alarm management. In single room care, the caregiver is not always in the proximity of the alarm generating machine.

To discuss the possibilities but also the limitations of these trends, an initiative from the Dutch “Joint association of medical technology” has resulted in a Taskforce on Safe and Silent Alarming. Three brainstorm sessions have been organized. Not only representatives of the main medical technology societies in the Netherlands were involved, but also the representatives of a large group of manufactures and vendors. One of the sessions was joined by a representative of the Dutch Health Authority and by an expert involved in the developments of standards. At a congress for users, both physicians and nurses have given their opinion on safe and silent alarming. In addition, the medical staff of our hospitals have contributed to the risk assessment.

**Purpose of the Taskforce on Safe and Silent Alarming** is to address and discuss the main problems encountered upon implementation of medical alarm management systems in clinical practice, in particular in a single room intensive care situation. During the brainstorm sessions, the Taskforce realized that the challenges were still too high to be able to develop a directive. Therefore, this paper will give an advice on safe implementation of alarm management in clinical practice, and address the issues of silent alarming, i.e. without alarms sounding in the room of the patient. We will present the main topics and challenges addressed in the brainstorm sessions and they will be discussed in the following sections. The summary of these challenges are defined as a set of requirements, meant as a cry for help to the manufacturers and norm bodies, in order to develop safer systems that allow for more silent ICUs. One of the main goals is that the cooperation between vendors is stimulated to help hospitals answering in a safe way to this trend in society.

**Alarms and alarm management systems**

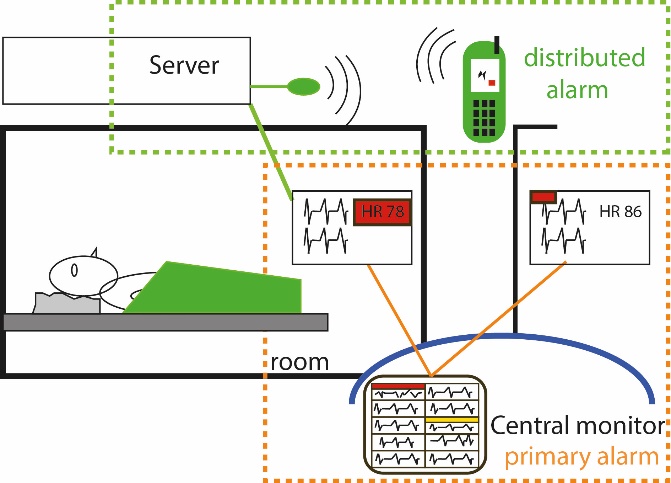


Figure 1. Alarm in the room is distributed to the central monitor (primary alarm chain) and via a server to a handheld (distributed system)

An alarm is implemented in medical devices to alert caregiver on a possibly critical situation of the patient. Nowadays, devices are used in a network, usually connected to a central monitor, sometimes to other monitors or to handheld devices via a distribution system. We call this the alarm management system, as illustrated in Figure 1. The primary alarm chain consists of the patient monitor, the central monitor and the connection to the other patient monitors (interbed communication). In this chain, an alarm is guaranteed to be visualized within a specified brief period of time at the central monitor and at the interbed communication. If components in this alarm chain malfunction, a notification is given.

In case of a distributed system, the alarm is sent over the hospital infrastructure (network, wifi) to other more distant components, like a handheld. The timing accuracy of the alarm chain is not at all times guaranteed and also the robustness of the system is not subject to the very strict specifications like in primary alarming.

**Standards and norms**

The main legislation for medical devices is defined in the Medical Device Direction (MDD). In addition, standards are meant for manufacturers, as a guideline for designing systems. This will ensure that the presentation to end-users will be standardized for some main safety aspects. Several important standards with respect to alarm management systems are the IEC 60601 series, including the 60601-1-8 addressing alarms and distributing systems. In addition, the ISO 80001 on the application of risk management for IT-networks incorporating medical devices has a substandard 80001-2-5 on alarms in networks. In addition, an IHE group focuses on alarms, the IHE-PCD specification which defines a “standard” protocol to communicate clinical alarms from patient care devices to an alarm management system.

The Dutch Taskforce observes that the legislation with respect to life support machines is strict, based on the assumption that alarms require immediate action, expecting a caregiver to be in the direct neighborhood of the patient. From that point of view, generating alarms without sound is inappropriate. However, in clinical practice nowadays in single room care, with privacy for patient and family, caregivers are nearby but not in the room itself. The alerting sound should be at the position of the caregiver and not of the patient, requiring new designs but also new standards that are adjusted to these trends.

One of the main problems in connecting medical systems is that not all devices speak a vendor-independent language, thus complicating connecting different systems. Though there are standards, manufacturers still often use vendor-specific communications protocols and the connection is then considered to be the hospitals responsibility. Like in the medical imaging field, a better compliance with IHE-like protocols is needed.

**Risks of alarm management**

**1. what is the responsibility of the manufacturer?**

* set a clear definition of intended use.
* make a safe and well-functioning device for the intended use, evaluated with a risk-assessment
* provide clear instructions on how to use the device safely, within intended use.
* comply with standards
* perform a post-market surveillance and notify users if errors in device occur
* describe the integration possibilities to other systems: interoperability might not be a part of the standard but it is considered the responsibility of the manufacturer to inform the users.

**Quick win**: Add a summary of risks of device use in red and yellow bullets in the instructions for use. This could then be used for a local risk analysis.

One of the major risks of using alarms is that it may lead to alarm fatigue due to the large number of false alarms caused by the implementation according to the better safe than sorry methodology (17-19). This will be discussed in more detail in the next paragraph. Other risks include the failures of alarm distributing systems, unclear alarm handling protocols without clear definition of responsibilities and unclear definitions in hospitals of how to choose/set alarm limits (20).

The Dutch Taskforce considers a critical assessment of medical alarm management necessary upon implementation of new patient monitoring systems in hospitals, in particular if distributed medical alarm systems are used (as described in IEC-60601-1-8 (21)). Figure 1 displays primary and distributed alarm system. Both alarm handling by the users and by the distributed systems need to be addressed. It is important to define the responsibility of the users but also the responsibility of the manufacturer when installing such a system in a hospital. The results of the brainstorms on these two aspects are shown in the “insertion boxes 1 and 2”.

**2. what is the responsibility of the hospital?**

* adequate and safe implementation of alarm systems in close collaboration with vendor.
* provide an adequate infrastructure that complies with the requirements specified by the vendor.
* inform users on intended use and take care that non-intended use does not occur.
* perform risk analysis before first use, evaluating the complete alarm handling process as used in clinical practice.
* ensure that all users are well trained.
* inform vendor if inexplicable errors or unsafe situations occur

***Quick win:*** Users need to be informed of the limitations of the alarm management system and of their own responsibility. Be aware that emergency protocols are in place if the system fails.

A multi-disciplinary user group (consisting of nurses, physicians, technicians/engineers, supported by advisers from the manufacturer of the system) is needed to make the right choices about alarm limits, alarm urgency and alarm distributed systems. In particular the protocol used by the nurses and physicians with respect to adjusting alarm limits for individual patients needs to be discussed, since there is a major risk in adjusting alarm limits without informing co-workers. It might be possible to standardize the basic set of alarm limits for typical groups of patients, however the local choices for the alarm limits are influenced by the local situation and the team structure. Some teams use the “buddy method” (9,22) in which the first responsible nurse always works with a buddy who will take care of the patient if the first responsible nurse is not available. Other methods are to use the whole team as a backup if the first responsible nurse is not available to react to an alarm, or to send an alarm to all nurses.

Upon implementation of patient monitoring systems using an alarm management system, a local risk analysis is very important to find the main risks in the system and to determine measures to reduce risks (see insertion box 3). Manufacturers perform a risk analysis before bringing a product into the market, evaluating device safety based on intended use (in international setting). This information is usually not freely available, but by including the vendor/manufacturer in the local hospital risk assessment this information can be included in the local risk assessment performed by the hospital. A local risk analysis improves the safety of the implementation of alarm management systems (9) and improves the “safety thinking” of the users, however note that a risk analysis is never a complete guarantee for safe implementation.

**Alarm fatigue**

Alarm fatigue is recognized by the experts as the largest risk. According to users in our hospitals, safe alarming is a topic discussed in the teams, not only since adequate alarms will increase patient safety by a more adequate reaction to critical situations, but also because the noise of alarms induces stress in both patient and the caregiver (13). The large number of false alarms is known to inhibit the response of the caregivers (2,19). To improve alarm safety, only alarms that are relevant to changes in the patient’s condition should be used to alert the caregiver.

Though the users recognize the risk of alarm fatigue, they don’t know where to start to decrease it: there is no clear guideline on which alarm limits to use: how do we know which alarms are relevant and which ones are not? Focus on making alarms more specific and more clinically relevant should be one of the first topics of investigation and is not only applicable to alarm management in distributing alarm systems but is applicable to all alarms in critical care units. Most hospitals even have no clue about the number of alarms in their units, except that it is assumed to be “a lot” or “(too) many”. Only recently the first alarm dashboards have become available, displaying the number of alarms generated per unit or per patient. Giving insight into numbers of alarms, sources of alarms and also the timing of alarm handling would be a good start to investigate the possibilities for improvement (9).

What we need are clinically relevant alarms by using for example smart algorithms (23,24) to filter the irrelevant alarms out of the alarm chain, or by combining alarms from various sensors into one alarm related to a clinically significant deterioration. This requires methods to determine whether alarms were relevant. Preferably critical situations are detected in an earlier phase before the situation becomes really critical. This still requires a lot of research.

**3. Overview checklist for implementation of safe alarm systems for hospitals**

* Check the certificate of the system and the separate components with respect to the MDD. IN particular when several systems are connected, a good description of responsibilities for this connection is necessary.
* Acquire a system according to the procurement procedure in the hospital.
* According to the standards 80.001, the hospital is responsible of the risk assessment, performed in the acquisition phase. If “in house” knowledge on risk assessment is insufficient, this service should be acquired.
* The team for risk assessment in the hospital should contain the users group (nurse, physician) but also experts from medical technology/clinical physics, ICT experts. Consider also to include the manufacturer/vendor.
* Define the complete alarm handling process, the main failures modes, the accompanying risks and the measure to reduce them. It would help if one general template as a basis could be used.
* Standardizing the procedures of using the system is important.
* One of the most important steps is to define the alarm limits used in the unit, in the multidisciplinary user group.
* Before release for use, all users of the system should be trained in the use of the system and the limitations of the system and emergency protocols.
* Before release for use, acceptance testing is performed to check all components and possible handling of alarms in the system.

***Quick win:*** involve manufacturer/vendor in the risk analysis, e.g. by planning with manufacturer a risk assessment workshop within the tender.

**The need for silent ICU’s**

The noise level in intensive care units is high, ranging from 50 to 75 dBA, with peak level up to 103 dBA (14,16,25), this is much higher than the maximum background noise level defined by the World Health Organization (WHO) of 30 dBA with peaks not higher than 40 dB during night to prevent from sleep disturbance (26). Speaking and medical equipment are causing the peak sound levels exceeding 80 dBa (25) (27) and the sound of monitor alarms is considered one of the main disturbing noise sources (28).

Intensive care units could first be made more silent by adequate design of the environment (10,29). A first step to reduce alarm sound levels is to reduce the number of false alarms. Since less than 20% of all alarms are considered clinically relevant (2,30,31), a significant reduction of noise is then achievable. A second step is to silence medical alarms in the rooms: a general observation is that if no caregiver is available in the patient room to react to the alarm, why do we bother patients with alarms they cannot attend themselves? A passenger in an airplane does not need to hear the alarms from the cockpit. In general, the clinical need for silent ICU’s is recognized by the industry. However, several critical remarks can be given:

* Nurses are tuned to alarms. To take away sound as an alert, the nurse might not be triggered sufficiently. This requires a new way of working.
* If alarms in the rooms are silenced, the requirements for the central monitoring system and potentially the alarm distributing systems become even higher.
* There is a major legal aspect to this topic, as already addressed by the AAMI (6) and also discussed in this Taskforce: manufactures are not allowed to change the alarm sounds since the standards prescribe the alarm sounds (21). Even if new standards are developed which will allow for setting sound levels of alarms to zero, it takes years to implement this on devices before available on the market.

In conclusion, the road to the silent ICU without medical equipment sounding alarms is still considered long. However, hospitals require further developments in this direction and we ask the manufacturers but also the norm committees to further investigate the possibilities, e.g. technically but also with respect to norms.

A better collaboration between manufacturer and user is needed, to create a market-pull instead of market-push in order to really develop what users need in their clinical practice. For manufacturers, the pre-market surveillance is becoming more important in order to develop with the end-users before bringing the device into the market, in order to make the product suit better to the clinical needs.

**Reaction of the health authority representative**

Device safety of all equipment legally to be classified as a medical device (including clinical monitoring systems with alarm functionality) should be assured by the manufacturer and includes fulfillment on compliance with MDD by notified body. E.g. on intended use & output of the types of alarms.

Hospital safety should be investigated by a local risk assessment. The Dutch health authority (IGZ) warns to be careful with distributed systems, when subsystems are incorporated which are not classified as a medical device (like telecom systems, regular IT-networks or nurse calling systems). If a subsystem is not a medical device it complies to less safe standards and is not subject to the Medical Device Directive. The manufacturer involved is not subject to the supervision of the IGZ. In that case supervision of the IGZ is limited to the health care institution and/or individual health care provider, which both have to comply on organizing and delivering adequate care. Requirements for that are in the Netherlands laid down in the ‘Kwaliteitswet zorginstellingen’ and ‘Wet BIG.’

Post market surveillance by manufacturers is a crucial element in the European regulatory system for medical devices to control the safety of products put on the market. Manufacturers should pro-actively evaluate the use of their devices and use this information in the continuous process of verifying and possibly adapting the initial risk assessment. In case of clinical incidents relating to their products they have to inform the competent authority involved.

The role of the health authority is to supervise the compliance of both manufacturers (product safety) as well as caregivers (adequate care) to abiding laws. Starting this year the IGZ has an active policy on the supervision on software which has to be classified as a medical device (for more information: <http://www.igz.nl/onderwerpen/medische_technologie/ict_in_de_zorg/software_als_medisch_hulpmiddel/>)

**Set of requirements: Technical challenges and possible solutions**

Based on the discussions in the Taskforce sessions, we can outline the main requirements to the field:

1. Hospitals require a safe alarm management system, with a reduction in false alarms. Developments focusing on improving the clinical relevance of alarms are necessary. A small step forward would be to use alarm dashboards to help the unit to investigate the alarm pressure and to reduce it. This has recently technically become available but is not yet frequently used in hospitals. A common standard or “best practices guidance” is needed quickly. Manufacturers point out that they are forced to treat each new customer engagement as a complete “fresh-start” solution, relying on that site’s clinical resources to re-invent appropriate alarm management workflow.
2. Medical alarm systems should have a high availability. The redundancy of these critical systems concerning IT network and hardware components should be adequately addressed. Chain /network monitoring is to be implemented to guarantee that the system is functioning. This is technically already feasible, however it requires overview of the different components, usually of different vendors, which complicates the implementation.
3. Medical alarm systems should use standards and use a vendor-independent language. Hospitals ask the manufacturers to follow the standards and to work together in connecting systems. In general, hospitals experience problems between vendors / manufacturers to take responsibility for the connection and the handshake instead of working together. The adoption of the IHE-PCD specification without vendor-specific “improvisations” to the protocol is necessary.
4. For the development of standards on alarm management, the requirements and developments in clinical practice should be included. Single room intensive care asks for a new approach of alarm management and these developments should not be hindered by old-fashioned standards limiting the vendors/manufacturers in their progression.

In conclusion, the brainstorm has led to a practical advice for hospitals on how to proceed towards safer alarm management. The possibilities for silent ICU’s are explored and topics are outlined that need to be addressed before this path can be followed. The next step is for the manufacturers: to develop methodologies for safer (and certified, affordable) alarm management in distributed systems. At the same time, hospitals should investigate local alarm pressure and develop methodologies to improve alarm safety and reduce alarm fatigue.

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