Medical Device Alarms – The Clinician

M. Imhoff

Abteilung für Medizinische Informatik, Biometrie und Epidemiologie, Ruhr-Universität, Bochum, Germany

Abstract—**The alarms of medical devices are a matter of concern in critical and perioperative care. The high rate of false alarms is not only a nuisance for patients and caregivers, but can also compromise patient safety and effectiveness of care. The development of alarm systems has lagged behind the technological advances of medical devices over the last 20 years. From a clinical perspective, major improvements of alarm algorithms are urgently needed. This requires not only methodological rigor and a good understanding of the clinical problems to be solved, but also adequate matching of statistical and computer science methods to clinical applications. It is important to see the broad picture of requirements for monitoring and therapy devices in general patient populations. This can only be achieved in close cooperation between clinicians, statisticians, and engineers. The Collaborative Research Centre SFB475 with its clinical and industrial partners can serve as an example for the successful cooperation to provide solutions to the challenges of biomedical technology. As part of the joint work new alarm algorithms have been developed and validated against large annotated clinical data sets.**

Keywords— **Device alarms, alarm systems, alarm algorithms, false alarms, statistical time series analysis.**

I. INTRODUCTION

Patients in the ICU and OR are surrounded by a multitude of medical devices that have alarm capabilities and generate optic and acoustic alarms to alert the staff to either a change in the patient's condition or a malfunction of the equipment. From a clinical viewpoint, an alarm is an automatic warning that results from a measurement or any other acquisition of descriptors of a state, and shall indicate a relevant deviation from a normal state. In this context alarms shall be triggered early when any relevant abnormality of vital organ function or essential device function occurs [1]. Different goals for device alarms can be distinguished: detection of life-threatening situations, detection of life-threatening device malfunction, detection of imminent danger, detection of imminent device malfunction, diagnostic alarms.

II. CLINICAL PROBLEMS OF MEDICAL DEVICE ALARMS

Clinical studies show that up to 90% of all alarms in critical care monitoring are false positives. In many cases they result from measurement and movement artefacts. The vast majority of all threshold alarms in the intensive care unit do not have real clinical impact on the care of the critically ill [2, 3, 4, 5]. In one study, 72% of all alarms did not result in any medical action [1]. The study showed that the positive predictive value was only 27%, the specificity only 58%. The negative predictive value and the sensitivity were 99% and 97%, respectively. These results are supported by earlier studies that report a rate of relevant alarms as low as 10% [4] or 5% [3]. While 27% were induced alarms—i.e., caused by nursing procedures—68% were truly false alarms [3]. The positive predictive value ranged from 5% to 16% depending on the monitored variable. From a medical perspective, false alarms fall into three categories: technically false alarms, clinically false alarms, false alarm through interventions.

The huge incidence of false alarms leads to a dangerous desensitization of the intensive care staff toward true alarms [6]. Moreover, alarm limits may be set dangerously wide or are even completely disabled to reduce the nuisance from false alarms [7]. Also, clinical studies show that critical care nurses can identify only the minority of all audible alarms correctly [8, 9].

III. DEVELOPMENT OF NEW ALARM ALGORITHMS

Clinical experience and scientific studies show that the quality of medical device alarms is unsatisfactory to the degree that the poor quality not only annoys caregivers and hampers their work, but also affects quality of care and patient safety. While these problems are multifaceted, one root cause is the poor quality of alarm generating algorithms.

Addressing the challenges of new alarm algorithms requires several steps:

- Deep understanding of the clinical problem to be solved.
- Deep understanding of alarm algorithms.
- Clear identification of algorithmic problems and goals.
- Capabilities and expertise to develop new algorithms.
- Acquisition and annotation of clinical data that is sufficient to support development and validation of new algorithms.

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- Ability to implement new algorithms in a medical device setting.

IV. RESULTS FROM INTERDISCIPLINARY COOPERATION

The multitude of resulting requirements cannot be met by one profession alone but only in a multidisciplinary team of methodologists and clinicians, eventually also bringing together academia and industry. Such an interdisciplinary team was formed in a Collaborative Research Center (Sonderforschungsbereich 475, Deutsche Forschungsgemeinschaft) at the Technical University Dortmund where in two projects clinicians from one community hospital (Klinikum Dortmund)) and one university hospital (University Hospital Regensburg), statisticians from the Technical University Dortmund, and later also engineers from industry (Dräger Medical) worked together for nearly 12 years to accomplish the following goals:

- Development of new alarm algorithms that are robust against artefacts and missing values, can be applied online and in real-time, have a predictable behaviour, and follow methodological rigor (overview in [10]).
- Acquisition and comprehensive clinical annotation of a large dataset of monitoring alarms from an unselected group of critically ill patients [11].
- Development of an algorithmic prototype for a new alarm system and validation of these alarm algorithms against the clinical dataset [12].

These accomplishments exemplify the successful cooperation between statisticians, engineers and clinicians.

V. CONCLUSIONS

The development of alarm systems has lagged behind the technological advances of medical devices over the last 20 years. From a clinical perspective, major improvements of alarm algorithms are urgently needed.

This requires not only methodological rigor and a good understanding of the clinical problems to be solved, but also adequate matching of statistical and computer science methods to clinical applications. It is important to see the broad picture of requirements for monitoring and therapy devices in general patient populations.

This can only be achieved in close cooperation between clinicians, statisticians, and engineers. The Collaborative Research Center SFB475 with its clinical and industrial partners can serve as an example for the successful cooperation to provide solution to the challenges of biomedical technology.

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Use macro [author address] to enter the address of the corresponding author:

Author: PD Dr. med. Michael Imhoff
Institute: Ruhr-Universtität Bochum
Street: Postfach
City: D-44780
Country: Germany
Email: mike@imhoff.de