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# Technical Information Report



## AAMI TIR71: 2017

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Guidance for logging of  
alarm system data

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Approved 11 August 2017 by  
**AAMI**

**Abstract:** Provides guidance to manufacturers of medical devices that generate alarm signals to meet the requirements for logging of alarm system data and support investigative activities performed by manufacturers and responsible organizations.

**Keywords:** medical device alarms, device logs, logs, data

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Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

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## Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

[www.aami.org/standards/glossary.pdf](http://www.aami.org/standards/glossary.pdf)



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## Committee representation

### Association for the Advancement of Medical Instrumentation

#### Medical Device Alarms Committee

This AAMI Technical Information Report was developed by the **Medical Device Alarms Committee**.

Committee approval of this document does not necessarily imply that all committee members voted for its approval. At the time this document was published, the committee had the following members.

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Dave Osborn

*Members:* Pat Anglin-Regal, Massachusetts General Hospital  
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## Foreword

As used within the context of this document, "should" indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. "May" is used to indicate that a course of action is permissible within the limits of the TIR. "Can" is used as a statement of possibility and capability. Finally, "must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

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NOTE—This foreword does not contain provisions of the AAMI TIR71, *Guidance for logging of alarm system data* (AAMI TIR71:2017), but it does provide important information about the development and intended use of the document.

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## Introduction

RESPONSIBLE ORGANIZATION ALARM SYSTEM LOG data has been demonstrated to be valuable for both MANUFACTURERS and RESPONSIBLE ORGANIZATIONS to support investigations related to ALARM CONDITIONS. The following are example use cases that can benefit from the information contained in the log data:

- investigate PATIENT adverse events;
- identify causes of PATIENT or OPERATOR HARM or potential HAZARDOUS SITUATIONS;
- assess PATIENT care protocol(s) adherence;
- identify failure modes;
- compile ALARM SYSTEM statistics;
- assess policy adherence; and
- conduct post-market surveillance.

In addition to the RESPONSIBLE ORGANIZATION ALARM SYSTEM LOG data, MEE and MES may provide OPERATOR ALARM SYSTEM LOG data (i.e. full disclosure and trends) that may assist in the investigation of specific ALARM CONDITIONS related to a PATIENT or PATIENTS. The scope of this document does not include the contents of OPERATOR ALARM SYSTEM LOG data.

MANUFACTURERS should consider ease of access as a design goal for RESPONSIBLE ORGANIZATIONS to access LOG files through a common service process. ALARM SYSTEM LOGS should be integrated into other LOGS in an MEE or MES.

Terms defined in Clause 3 of this document and in ANSI/AAMI ES60601-1 and ANSI/AAMI/IEC 60601-1-8 are noted in SMALL CAPITALS.

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# Guidance for logging of alarm system data

## 1 Scope

This document provides guidance to MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT (MEE) and MEDICAL ELECTRICAL SYSTEMS (MES) that generate ALARM CONDITIONS and/or ALARM SIGNALS to meet the requirements for logging of ALARM SYSTEM data and support investigative activities performed by MANUFACTURERS and RESPONSIBLE ORGANIZATIONS.

This document is not intended to provide guidance for a product feature used by clinicians while caring for a PATIENT that stores physiological PATIENT data (waveform and numeric parameter data) or ALARM CONDITIONS. While this type of data is important, it is not considered RESPONSIBLE ORGANIZATION ALARM SYSTEM LOG data and is outside the scope of this document.

## 2 Normative references

ANSI/AAMI/IEC 60601-1-8, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

## 3 Terms and definitions

For the purpose of this document, the terms and definitions given in ANSI/AAMI ES 60601-1<sup>[1]</sup>, ANSI/AAMI/IEC 60601-1-8, ANSI/AAMI/IEC 62366-1<sup>[2]</sup> and the following apply.

### 3.1

#### ALARM SYSTEM LOG

LOG containing events related to the ALARM SYSTEM

### 3.2

#### MEDICAL EQUIPMENT ACCESS LOG

LOG containing events related to remote access to a MEE/MES

### 3.3

#### OPERATOR-SETTINGS LOG

LOG containing events related to changes to the OPERATOR SETTINGS of a MEE/MES

### 3.4

#### CONFIGURATION LOG

LOG containing events related to changes in the hardware or software configuration of a MEE/MES

### 3.5

#### DATA LOGGER

equipment that can be used to store LOG data

### 3.6

#### DATA STORE

data repository of a set of integrated objects; these objects are modelled using classes defined in database schemas

NOTE DATA STORE includes not only data repositories like databases; it is a more general concept that includes also flat files that can store data.

### 3.7

#### COMMUNICATOR

#### COM

function of the ALARM SYSTEM that generates ALARM SIGNALS to notify an OPERATOR

NOTE 1 A COM can receive an OPERATOR response.

NOTE 2 An OPERATOR response is not limited to direct OPERATOR action.