OR.NET – Approaches for Risk Analysis and Measures of Dynamically Interconnected Medical Devices

Franziska Kühn[1,2], Martin Leucker[1], and Alexander Mildner[3]

1 **Institute for Software Engineering and Programming Languages, University of Lübeck, Germany**
{kuehn,leucker}@isp.uni-luebeck.de
2 **Graduate School for Computing in Medicine and Life Science, University of Lübeck, Germany**
3 **UniTransferKlinik Lübeck, Germany**
a.mildner@unitransferklinik.de

Abstract

Nowadays, it lacks an open, standardized and dynamic interconnection of medical devices. All existing combinations of medical devices consist of isolated solutions with proprietary interfaces, as no common standards for networking and the exchange of data of medical devices exist. This situation leads to confusing operating rooms and inefficient operations. Thus, new strategies need to be developed for the authorization of dynamically interconnected medical devices. Primarily, those concern of an acquisition and methodical adaption of new requirements and risks resulting from this way of interconnection. The approach is to develop a method for a risk analysis for interconnected medical devices, which is structured modular and consists of a risk assessment of the standalone device and a risk analysis for the interconnection considering the risks involved in the transfer of functions. When interconnecting the medical devices the risk analysis of each of the devices is taken and they are compared by a gap analysis. Through this strategy it will be possible to realize a standard-compliant dynamic interconnection of medical products, which would be advantageous both for clinic operators and producers. This paper presents the current situation of the authorization of combined medical devices and proposes a strategy for the risk management of dynamically interconnected medical devices as a substantial part of the authorization.

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1 Introduction

At present, the dynamic interconnection of medical devices poses as well legal as technical challenges, especially for clinic operators. On the one hand most medical devices the clinic operators would like to interconnect are not interoperable, on the other hand the connection of medical devices (which have not been authorized together) leads to a self-production by the clinic operator [3]. The clinic operators can choose all-in-one operating room solutions from certain manufacturers, but often expensive and elaborate custom integration projects are necessary. All of the possible combinations today consist of isolated solutions with proprietary interfaces and have a limited flexibility and interchangeability, as no common

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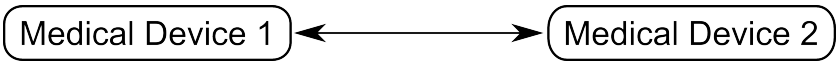

Figure 1 Risk analysis and conformity statement today.

standards for networking and the exchange of data of medical devices to each other and to adjacent IT-systems exist. This situation leads to confusing operating rooms and inefficient operations.

The OR.NET-project[1], funded by the federal ministry of education and research (BMBF), focuses on the safe, secure and dynamic interconnection of medical devices in the operating room and clinic. The project includes almost 50 project partners ranging over medical device manufacturers, clinic operators, standardisation organisations and research institutes. Besides the safe and secure interconnection of medical devices, the main goals are a standardised solution for the interoperability of all medical devices and the possibility of interconnecting arbitrary medical devices for clinic operators without taking responsibility for the resulting system.

This paper shows the authorization of combined medical devices nowadays, which is illustrated in Section 2. The content of Section 3 deals with our general idea of the authorization of dynamically interconnected medical devices. The strategy for the risk management of such systems as a substantial part of the authorization is approached in Section 4. Conclusively the paper discusses the advantages of a dynamic interconnection of medical devices.

2 Today's Situation of Authorisation

Figure 1 shows the idea of the procedure for obtaining an authorization of today's systems and combinations.

The procedure is generally based on the assumption that the whole system is known and the individual components have been developed for an interaction of each other. Either the person establishing the interconnection declares conformity and is responsible for the entire system or both producers of the medical devices allow the application with the other, precisely specified device and document this option in the intended use of their own medical device [4]. Approving all combinations of interest in advance is not possible because of the enormous number of possible combinations. Another problem is that once a component is replaced, a new conformity assessment procedure of the entire system must be worked through. These obstacles for a dynamic interconnection of medical devices, especially from different producers, lead to a large amount of not connected medical devices and thereby to a confusing amount of control elements and monitors in the operating room as shown in Figure 2.

3 Futures Authorization

A dynamic, open interconnection of medical devices with their hardware and software components is not yet implemented in today's authorisation processes. Thus, new strategies need to be developed for the authorization of such systems. Primarily, those concern of an acquisition and methodological adaption of new requirements and risks resulting from

[1] http://www.ornet.org

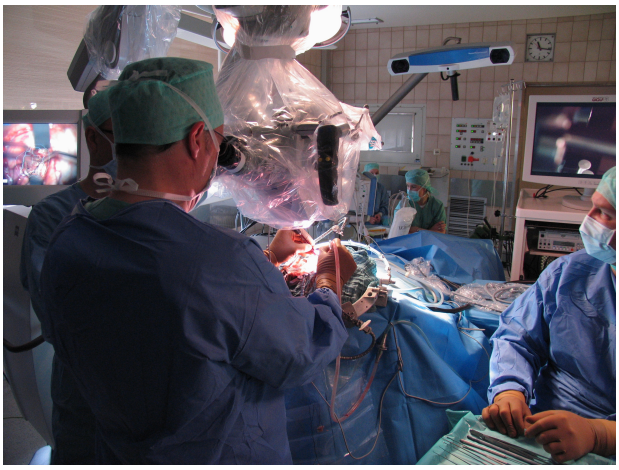

Figure 2 Operating room today.

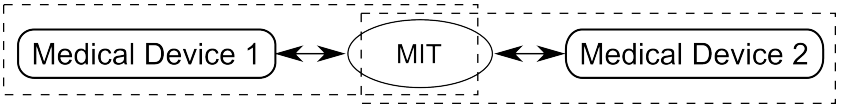

Figure 3 Authorization of dynamically interconnected systems.

this way of interconnection [2]. Figure 3 shows the idea of the procedure for obtaining an authorization of futures, dynamically interconnected medical device combinations. The devices are authorized without knowledge of each other but with a defined interface. They are connected by a safe medical IT-network (MIT), constructed and controled according to EN 80001 [1].

4 Approaches for Risk Analysis and Measures

The aim is to develop a method to consider risks of a dynamic interconnection without defining a specified connection partner. This method must be able to assess, evaluate, control and document the risks additionally occurring by an interconnection. The structure of the risk management is shown in Figure 4.

Risk analysis, -evaluation and -control is to be made separately for every medical device in the combination. The producers do not longer allow the interconnection with only one other, precisely specified medical product, but comply with a precisely defined interface. For this reason it is necessary to precisely define the interfaces of the medical devices and certify the respective medical devices including the interface specifications. The risk analysis of each device is structured modular and consists of a risk assessment of the standalone device (in accordance with today's practices) and a risk analysis for the interconnection. The risk analysis of the interconnection is developed by considering the risks involved in the transfer of functions of the medical device to another one or the takeover of functions of another medical device. These risks are transferred to a Failure Mode and Effects Analysis (FMEA) [5] and risk control measures are applied. The clinic operator is only responsible for a safe and reliable network conforming to EN IEC 80001 [1] and for meeting the producers demands on the network e.g. like a minimum bit rate and, if required, implement risk measures for the interonnection defined in the FMEA of a certain medical device. When interconnecting the

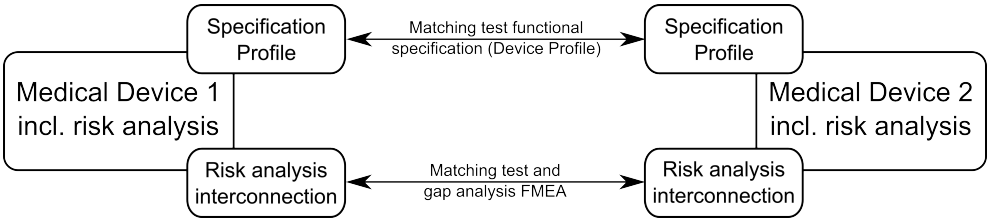

Figure 4 Risk management for dynamic interconnections.

medical devices the FMEAs of each of the devices are taken and they are compared by a gap analysis. In that gap analysis the risks considered in the FMEAs for the interconnection are compared by the clinic operator. If there are risks considered only in one of the FMEAs it has to be checked if those mean additional risks also for the interconnected device. Only if this is the case additional risk measures have to be taken to enable a safe and secure interconnection.

5 Discussion

It lacks an open, standardized and dynamic interconnection of medical devices. This interconnection would be advantageous both for clinic operators and producers. The clinic operators could put together their ideal device combinations that would support their operation flow best. An expected simplification of work processes would also lead to monetary savings. In large medical technology companies the loss of proprietary interfaces would lead to savings potentials, enabled by a simplified authorization and less needed expert know-how. For small and medium businesses a standardized interconnection would open up new business areas and they could have a better chance in the market if their devices could interact with those of large producers. Simplified procedures and a reduced number of control elements would relieve the operating room staff and increase patient safety. Merging data sets from multiple devices would increase the quality of diagnoses and reduce the number of required monitors.

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