Tamer Abdulbaki Alshirbaji*, Nour Aldeen Jalal, Knut Moeller

Data Recording Framework for Physiological and Surgical Data in Operating Theatres

Abstract: Integrated operating rooms typically connect medical devices providing the clinical user a complete control over environment, device setting and digital management of intervention-related data. Consequently, the opportunity to analyse and present data from different perspectives and with different objectives has arisen. The available integrated ORs are so far designed as closed systems, thus connecting co-existing systems from different manufactures e.g. anaesthesia machines and surgical devices is demanding. The purpose of this project is to facilitate data collection from anaesthesiology, patient monitoring and surgical devices. The study is performed on laparoscopic procedures, and the data are going to be recorded at the Schwarzwald-Baar Klinikum (SBK) in Villingen-Schwenningen (Germany). Therefore, this part of the project focuses on the overall architecture for collecting data in the operating theatre at the SBK. In this work, (i) the system architecture (i.e. hardware components), (ii) software architecture and (iii) required protocols for synchronous recording of data in the OR are described. The proposed framework demonstrates that signal recording is possible with variety of devices at different sampling rates during surgical procedure.

Keywords: Data fusion, operating room, system architecture, medical devices, surgical data.

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***Corresponding author: Tamer Abdulbaki Alshirbaji:** Institute of Technical Medicine, Furtwangen University, Jakob-Kienzle-Straße 17, Villingen-Schwenningen, Germany, e-mail: abd@hs-furtwangen.de
Nour Aldeen Jalal (ja@hs-furtwangen.de)**, Knut Möller** (moe@hs-furtwangen.de)**:** Institute of Technical Medicine, Furtwangen University, Villingen-Schwenningen, Germany

1 Introduction

1.1 Background

The surgical department is one of the major units for medical treatment in hospitals. It is the most cost-intensive department because it requires an accurate collaboration with other departments in different medical disciplines. Therefore, current operating theatres are equipped with advanced medical devices and technologies. This, in turn, led to increase the complexity of the workflow inside the OR. For some time, the trend has led to integrated operating rooms in which medical devices are technically interconnected, which gives the clinical user a complete control over environment, devices settings, display content and digital management of intervention-related data. Furthermore, the opportunity to analyse and present data from different perspectives and with different objectives has arisen. The available integrated ORs are so far designed as closed systems, thus connecting co-existing systems from different manufactures, e.g. anaesthesia machines and OR-infrastructure, is difficult to achieve. The purpose of data fusion inside ORs is to support clinicians in making decisions and generate a comprehensive image of the individual patient from various perspectives.
In this project, the patient data from anaesthesiology and patient monitor (patient view) is included and combined with device data from the surgical side (instrument view) (e.g. electrosurgical unit, laparoscopic camera and Insufflator). The aim is to find out if surgical actions affect the physiological situation of patients and how to employ this knowledge for assisting the surgical team and improve patient safety. The study is performed on laparoscopic procedures, and the data is going to be recorded at the Schwarzwald-Baar Klinikum (SBK) in Villingen-Schwenningen (Germany). Therefore, this part of the project, described in this paper, focuses on the overall architecture for collecting data at the operating theatre in the SBK. In this work, (i) the system architecture (i.e. hardware components), (ii) software architecture and (iii) required protocols for synchronous recording of data in the OR are described.

1.2 State of the art

Nowadays operating rooms (ORs) are already networked systems that can continuously supply and deliver large amounts of data, including vital signs, biosignals, images and videos and devices technical and usage data. KARL STORZ SE & Co. KG developed the OR1 ™ system which is a platform for controlling endoscopic and ambient equipment to visualize, document and control information from videos or other data sources. The basis for this system is the interconnectivity of devices via the Storz Communication Bus (SCB) [1]. Furthermore, anaesthesia machines and patient monitors can be coupled to a data logger via available interfaces (e.g. RS232 or LAN interfaces). However, data from surgical devices [2] and anaesthesiology [3] were recorded and analysed separately, e.g. for detecting surgical phases [4-6] or predicting the remaining time of the procedure [7], or for investigating patient status using the anaesthesia data [8].

In several third-party funded projects, e.g. SmartOR [9] (BMWi, Autonomik, 2009-12), TeKoMed [10] (ZPW Schl. Holstein, 2009-11) and OR.NET [11] (2012-2016), several concepts for networking medical devices were developed and evaluated. The IEEE 11073 service-oriented device connectivity (SDC) standard [12], which aims to enable medical device-to-device interoperability, has been developed.

2 Materials and Methods

2.1 System requirements

Special requirements and different technical challenges have to be considered when developing a system for data recording in ORs: (1) the system should enable users to record data without affecting the workflow of the intervention. (2) It does not add any additional risk to the patient or the surgical team. (3) Assure synchronous recording of data from all different devices and no data loss.

2.2 Description of data sources

In this work, physiological data from the Anaesthesia machine and Patient monitor and data from surgical devices (in particular laparoscopic camera, light source, insufflator, pump, motor system and electrosurgical unit) are synchronously recorded.

The anaesthesia machine is a “LeonPlus neo” provided by Heinen Löwenstein GmbH. This device has a RS232 interface for data transmission and the data is transmitted via a specific protocol called HULBUS.

The patient monitor is “Philips monitor Mx800”. Data from the Philips monitor are transferred to an external device via a Local Area Network (LAN) interface.
The laparoscopic camera, light source, insufflator, pump and motor system are from KARL STORZ. These devices are interconnected via the Storz Communication Bus (SCB). Device data is collected by connecting one of these devices to the data logger using a SCB interface control.

The electrosurgical unit is a “VIO 300 D” from ERBE GmbH. This device can be connected to the SCB via the Erbe Communication Bus (ECB) using an ECB-SCB adapter. Hence, data is transferred from the electrosurgical unit via the SCB.

2.3 System and software architectures

The data recording system was designed to fulfil the aforementioned requirements. A system architecture, software architecture and required protocols for synchronously recording data in an integrated operating room (Karl Storz OR1) at the SBK were developed. The system architecture (Figure 1) shows available medical devices inside the operating room (OR), connected to a central data logger, required hardware components (connectors, signal converters and cables) and their specifications.

The data is recorded during surgical procedures using a computer installed in a technical room (i.e. outside the operating room). Data is transferred through an Ethernet connection between the OR and the technical room. Therefore, the workflow of the intervention is not affected.

A SCB Connector Application writes data streams of available surgical device data into a database. In addition, an Image Connector Application captures the laparoscopic videos into mp4 files and writes a corresponding frame number into the database so that device data can be synchronized with an endoscopic image.

A Löwenstein Connector Software writes data from the anaesthesia machine, including current values of devices state, ventilation state, device and ventilation settings and real-time data streams for pressure, flow, CO2, O2, N2O and agent. The sample rate of real time data is 20 ms.

Philips monitor uses the Universal Datagram Protocol/ Internet Protocol (UDP/IP) to collect alarm, waveform and numerical data through its LAN interface. The software for recording data from the anaesthesia machine and patient monitor were developed in C++. The recorded data is saved into PostgreSQL database.

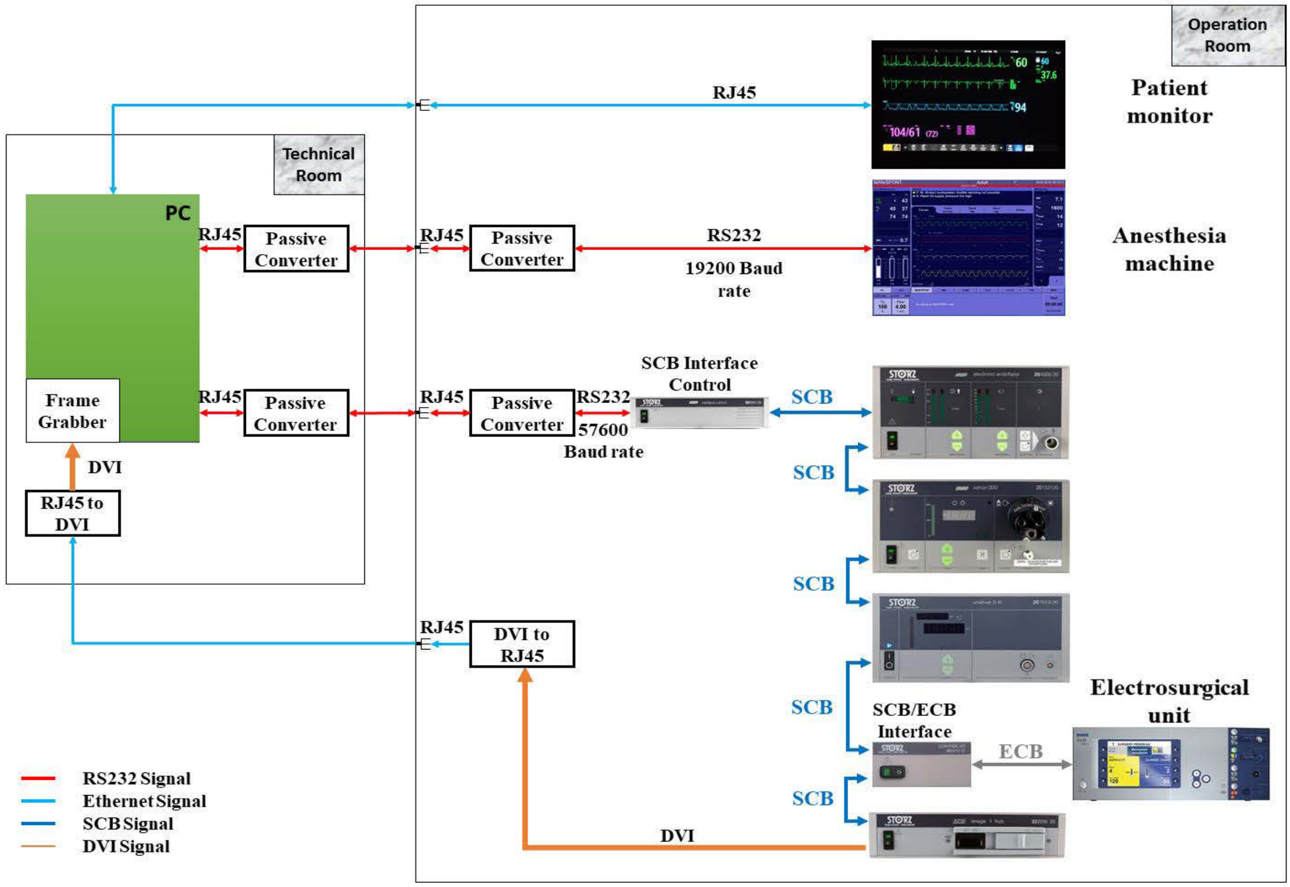

Figure 1: The system architecture for data recording in an integrated OR at the SBK. All available medical devices and hardware components are presented. Different signals are represented by different colours.

3 Results

This study aims to create a database of physiological data and data from surgical devices from patients undergoing laparoscopic procedure. The data streams are stored into a PostgreSQL database in a format that can be readily accessed without the need for other software. Moreover, all data are stored with a unified time stamp into tables, ensuring synchronous data recording from different sources.

Figure 2 shows collected signals of complete procedure recorded at the SBK. These signals were recorded with different sampling frequencies. Numeric data from Philips monitor (e.g. mean blood pressure, temperature and heart rate) was sampled at a rate of 1 Hz, and continuous waves at 500, 250, 125, or 62.5 Hz. Wave data from anaesthesia machine was sampled at 50 Hz.

4 Discussion

The present data recording system is utilized to collect data from different medical devices inside the operating room at SBK where patients undergo laparoscopic procedure. Ethic approval was obtained to record data and perform the study.

The system architecture shows that two passive adapters from RS232 to RJ45 are used to transfer the data from the anaesthesia and STORZ devices through Ethernet connection to the computer in the technical room. Since the distance between the technical room and the operating room is considered long for RS232 signals, those two adapters were tested several times and proved to work properly without any signal distortion. The SCB interface control and ECB/SCB interface control are medical devices class IIB according to their instruction manual. Moreover, all these adapters and interfaces are located outside the sterile area and have no impact on the workflow of the operation.

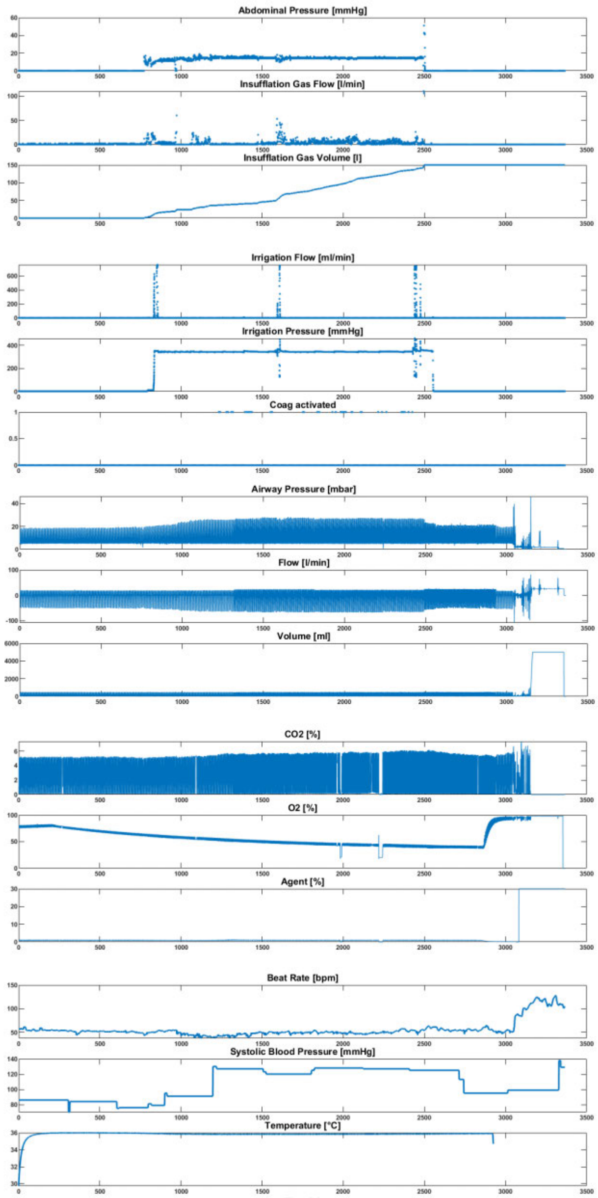

Figure 2: Visualization of recorded signals: abdominal pressure, Insufflations gas flow and volume, Irrigation pressure and flow, HF device activity, anaesthesiology signals and physiological data from patient monitor.

5 Conclusion

Clinical data recording inside operating rooms is a challenging task due to the special requirements that need to be considered and the manufacture-dependent communication protocols used by medical devices. In this work, system architecture and software architecture for recording data from multiple medical devices inside the OR at the SBK were presented. The System is ready to use and allows synchronous recording of almost all data available in the OR.

Author Statement

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