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Embedded Contributions to an Intensive Care Safety Concept

Abstract
In nowadays intensive medical care ARDS (acute respiratory distress syndrome) became one of the most problematic disease patterns. Mortality rate for ARDS is still between 40 and 60 percent.

A newer treatment option for this illness is the extracorporeal oxygenation. Here the patient is connected to an oxygenator. This device realizes a high percentage of the needed gas exchange with the blood outside the human body. The lung is disencumbered during this procedure in order to have a chance to regenerate faster.

The project SmartECLA emphasizes on enhancing the extracorporeal membrane oxygenation (ECMO). Therefore researchers out of four different faculties started improving the existing and clinically used setup. The overall aim is to optimize the used devices for the extracorporeal oxygenation according to the medical requirements and to develop a safety driven closed-loop control for this system. As a result the medical scientist shall no longer be forced to understand the internal details of the technical system in order to work with it; in fact the system shall present the important technical facts in combination with their medical impact to the medical.

The proposed system needs a high level of safety and reliability in order to be applicable to the intensive care routine. One keystone to this goal is the embedded safety concept. Each sensor and each actuator in the system is connected to a microcontroller. All these microcontrollers are connected through a CAN network. The basic need for these nodes arises from the varying structure of the interfaces to all devices in the system (e.g. RS232, I²C or just analog voltages). The microcontrollers act as translation units between the CAN network and the connected device.

Our proposed concept benefits of these distributed nodes which have all information available. This enables us to perform a diagnosis on selected parts of the systems by modeling the physical and chemical behavior which leads to a better fault prediction and an increased reliability of the overall system. Each node can evaluate the acquired information before transmitting it to the network and the other way round we are able to perform a more accurate sanity check for each control value set to an actuator with this setup. In addition to the small nodes we have one central node (dSpace micro auto box) — mainly in charge of performing the control algorithms and driving the human-computer-interface — which is performing a model-based diagnosis of more complex system components.
Embedded Contributions to an Intensive Care Safety Concept

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Outline

• Motivation

• The SmartECLA Project

• Safety Concept
  – Analysis
  – Goals
  – Methods

• Conclusions
Acute Respiratory Distress Syndrome

• Serious reaction of the lung to injury / inflammation
• Caused by
  – Inhalation of toxic gases
  – Aspiration of water
  – Shock
  – Burning
• Conventional therapies
  – Artificial ventilation with special Parameters
  – Prone positioning
  – Extracorporeal membrane oxygenation (ECMO)
Status Quo on ARDS

- ARDS reached by low percentage of patients
- Conventional methods do fail for some patients
- ECMO as „ultima ratio“ on ARDS

Source: Esteban et al., JAMA. 2002;287(3):345-355
ECMO

- Extracorporeal membrane oxygenation
- Gas exchange performed outside the body
- Blood is pumped in a bypass
- State-of-the-art: manually controlled system
ECMO
ECMO
SmartECLA

• Optimazing of the oxygenators and blood-pumps

• Closed-loop control with physiological relevant parameters as input

• Safety and reliability concept to ensure the needed performance
SmartECLA

Smart Life Support

Lang, Stollenwerk; WESH09, Eindhoven
SmartECLA

- Smart Life Support

- Online blood gas analyzer
- Venous return
- Venous drawing
- Small blood pump
- Blood gas sensor
- Artificial respiration
- Flow sensor
- Blood flow act
- Rot. speed ref.
- Pump control
- HEXMO
- Gas blender

Lang, Stollenwerk; WESH09, Eindhoven
SmartECLA
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Patient monitor

Oxygen concentration, ventilation pressure, ventilation volume

Small blood pump

Blood gas sensor

Artificial respiration

Gas blender

Gas flow

pO₂, pCO₂, pH
K⁺, Temp

Blood flow

Rot. speed

Pump control

Control platform

RS232

MCU

Online blood gas analyzer

Venous return

Venous drawing

CAN

CAN
Control Concept

• Cascaded control structure

• Inner cascade for technical operating parameters

• Control of physiological parameters in surrounding cascade

→ no need for a physician to fully understand technical parameters
SmartECLA

SmartECLA is a life support system designed to monitor and manage various physiological parameters. It includes a patient monitor, a small blood pump, oxygen concentration, ventilation pressure, and ventilation volume monitoring. The system also incorporates artificial respiration, a blood gas sensor, a gas blender, and a flow sensor. Additionally, it features online blood gas analyzers and venous return monitoring. The system is controlled through a MCU and a control platform, ensuring precise management of blood flow and other critical functions.
SmartECLA
SmartECLA
Safety Concept

• Life-sustaining system

• No continuous supervision

• Healthcare personnel not into technical details

→ Minimizing patients‘ risk during operation of ECMO
Safety Analysis

• FMEA of the system (SmartECLA setup)

• Derivation of safety goals
  – Technical facts out of FMEA
  – Physiological facts identified with medical partners

• FTA for identification and classification of technical risks
Safety Goals (technical)

• Minimum gas exchange

• Minimum extracorporeal blood flow

• No blood leakage

• Minimizing hemolysis (e.g. temp < 41°C)

• No bubbles in blood return tube
Constructive Redesign – Bubble Detection

- Gas-bubbles in bloodstream are an indefensible risk → embolism
Oxygenator (HEXMO)

- Integrated blood-pump
- Membrane surface of ca. 1 m²
- Small priming volume
Distributed translation nodes

- Variety monitoring devices with diverse interfaces and protocols
- Different query intervals
- Some datasets are available from more than one device
- Based on ARM architecture
Distributed translation nodes

- ECU
  - model
  - validation of data
  - translator

- ECU
  - model
  - validation of data
  - translator

- Patient monitor
  - ECU
    - model
    - validation of data
    - translator

- Watch dog
  - Central control unit
  - Blood pump
  - Oxygenator
  - Gas blender

Lang, Stollenwerk; WESH09, Eindhoven
Basic Safety Measures

• Limitation of control values
  – Extracorporeal blood flow < 4 l / min
  – Gas flow < 8 l / min

• Supervision of measurements
  – Blood temperature < 40 °C
  – Extracorporeal oxygenated blood \( pO_2 > 100 \) mmHg

• Basic validation of measurements
  – Comparing temp-sensors date to each other
Extended Safety Measures – Model Based

- Measurement validation
  - Blood gas sensor
  - Pressure measurement
- Device supervision
  - Oxygenator (diffusion capacity)
  - Blood pump

Diagram:
- Supervision unit
  - Model of the system
  - Fuzzy comparator
- Control
- Plant
Measurement Validation - Blood Gas Sensor
Measurement Validation - Blood Gas Sensor

Diagram showing the flow of blood through the body, from organs to the left heart, through the right heart to the lung, and back to the organs.

Key components include:
- Oxygenator
- Flowsensor
- CDI\textsubscript{v}
- CDI\textsubscript{a}
- p\textsubscript{v}O\textsubscript{2}
- p\textsubscript{a}O\textsubscript{2}
- SO\textsubscript{2}
- Q\textsubscript{HZV}
- Q\textsubscript{ECMO}
Measurement Validation - Evaluation

![Graph showing oxygen concentration over time](image-url)

- **x 10^-3**
- **2 x 10^-3**
- **3 x 10^-3**
- **4 x 10^-3**
- **5 x 10^-3**

**Axis:**
- **Time [s]:** 0 to 450
- **Oxygen concentration [mol/l]:** 0 to 5 x 10^-3

**Legend:**
- Measurement
- Calculation

Lang, Stollenwerk; WESH09, Eindhoven
Diffusion Capacity of the Oxygenator

- Pores of oxygenator get chocked over time
  → Lowered diffusion capacity

- Periodic replacement needed

- Prediction of replacement-time by modeling the oxygenator
  → Increased reliability
Evaluation of the Oxygenator Model
Conclusion

• ECMO is last resort therapy with ARDS

• Automation and safety improvements enable wider use

• More powerful MCUs enable model based observation
  → Measurement Validation
  → Device Supervision
Thanks for your attention!