Embedded Systems
INSTITUTE

ArtistDesign Workshop on Embedded Systems in Healthcare 2009

André Stollenwerk

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, I^2C 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.

artist

Embedded Contributions to an Intensive Care Safety Concept

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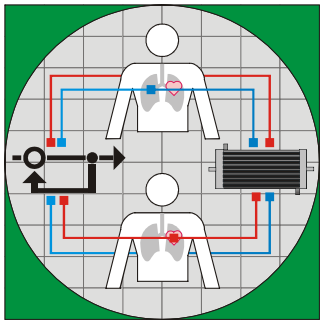
Embedded Software Laboratory, RWTH Aachen University



Workshop on Embedded Systems in Healthcare 2009
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Outline

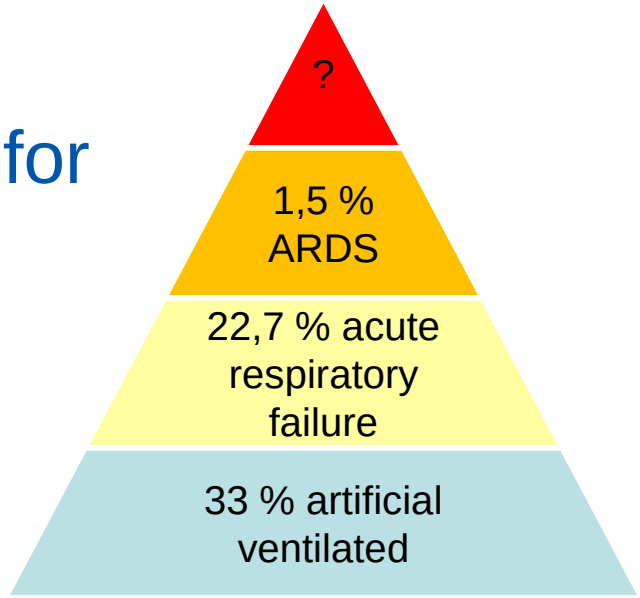
- Motivation
- The SmartECLA Project
- Safety Concept
  - Analysis
  - Goals
  - Methods
- Conclusions

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

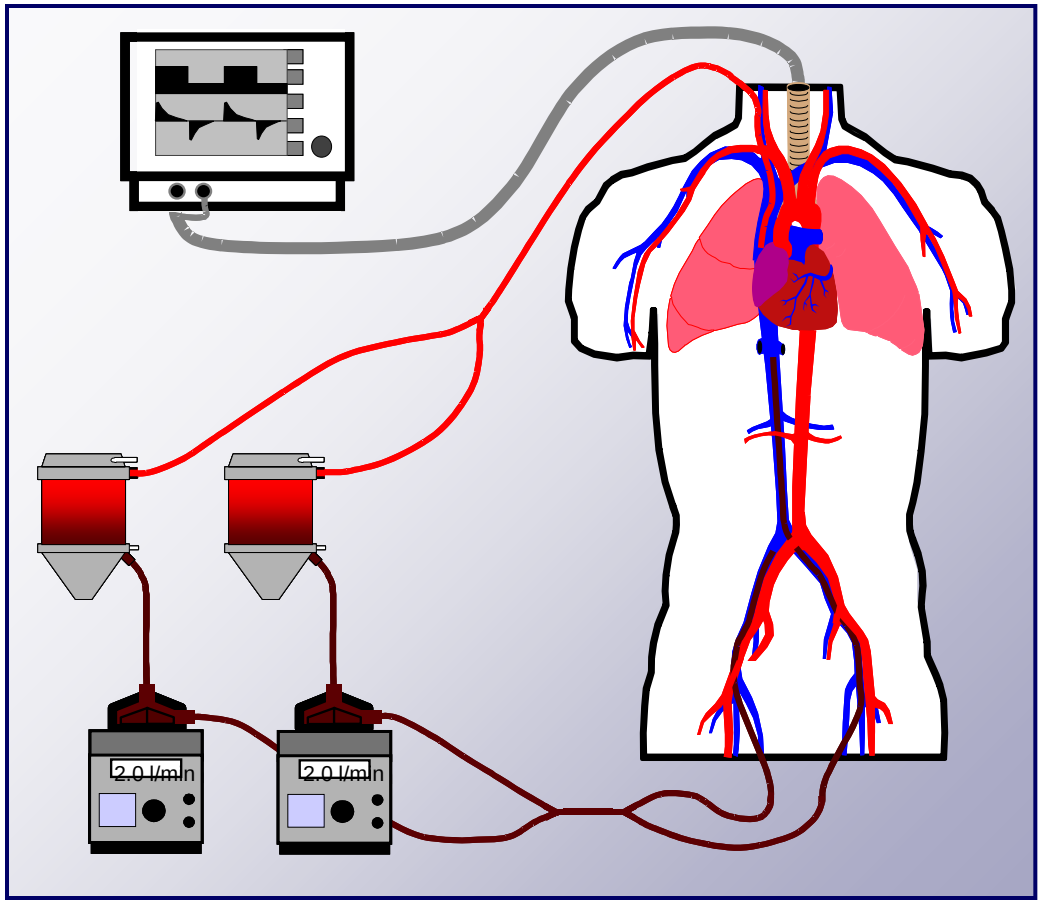


Source: Esteban et al., JAMA. 2002;287(3):345-355

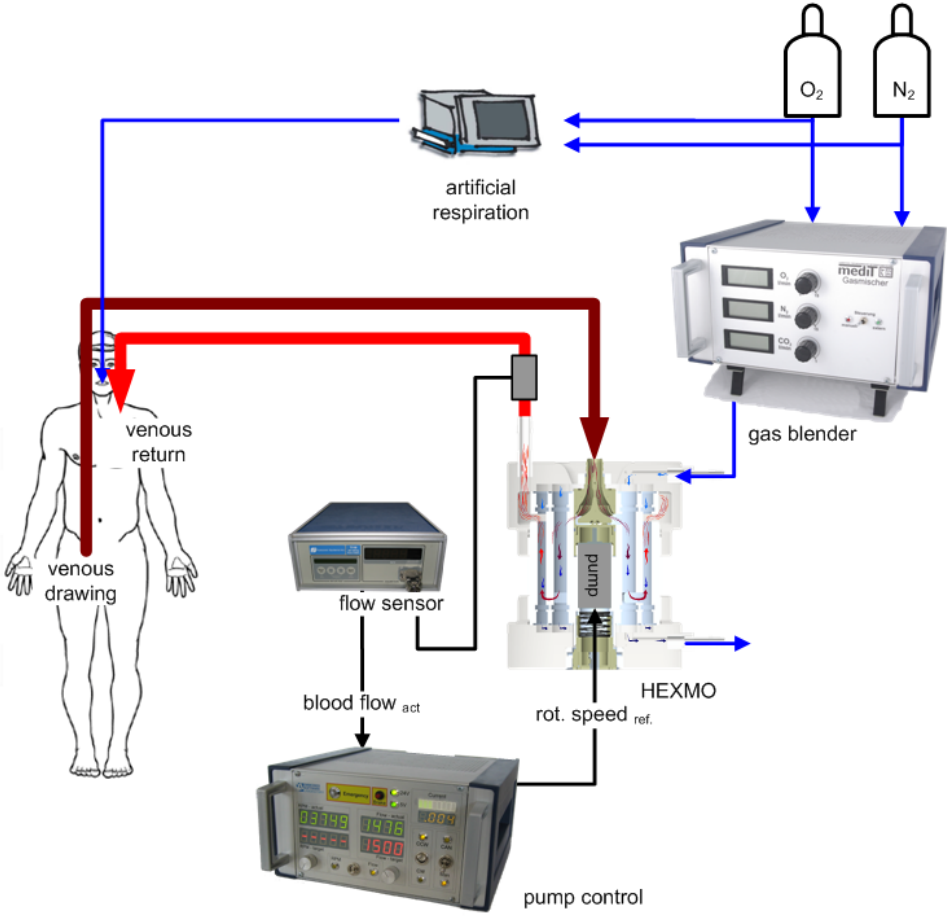
ECMO

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

ECMO

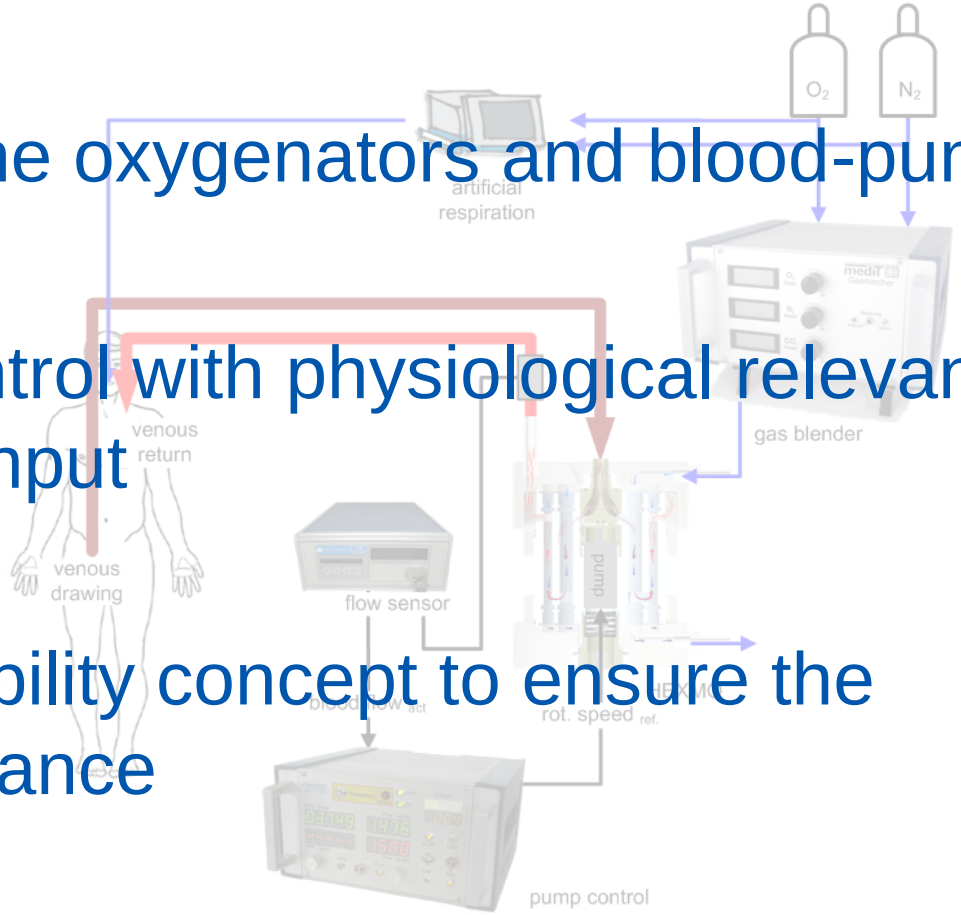


ECMO

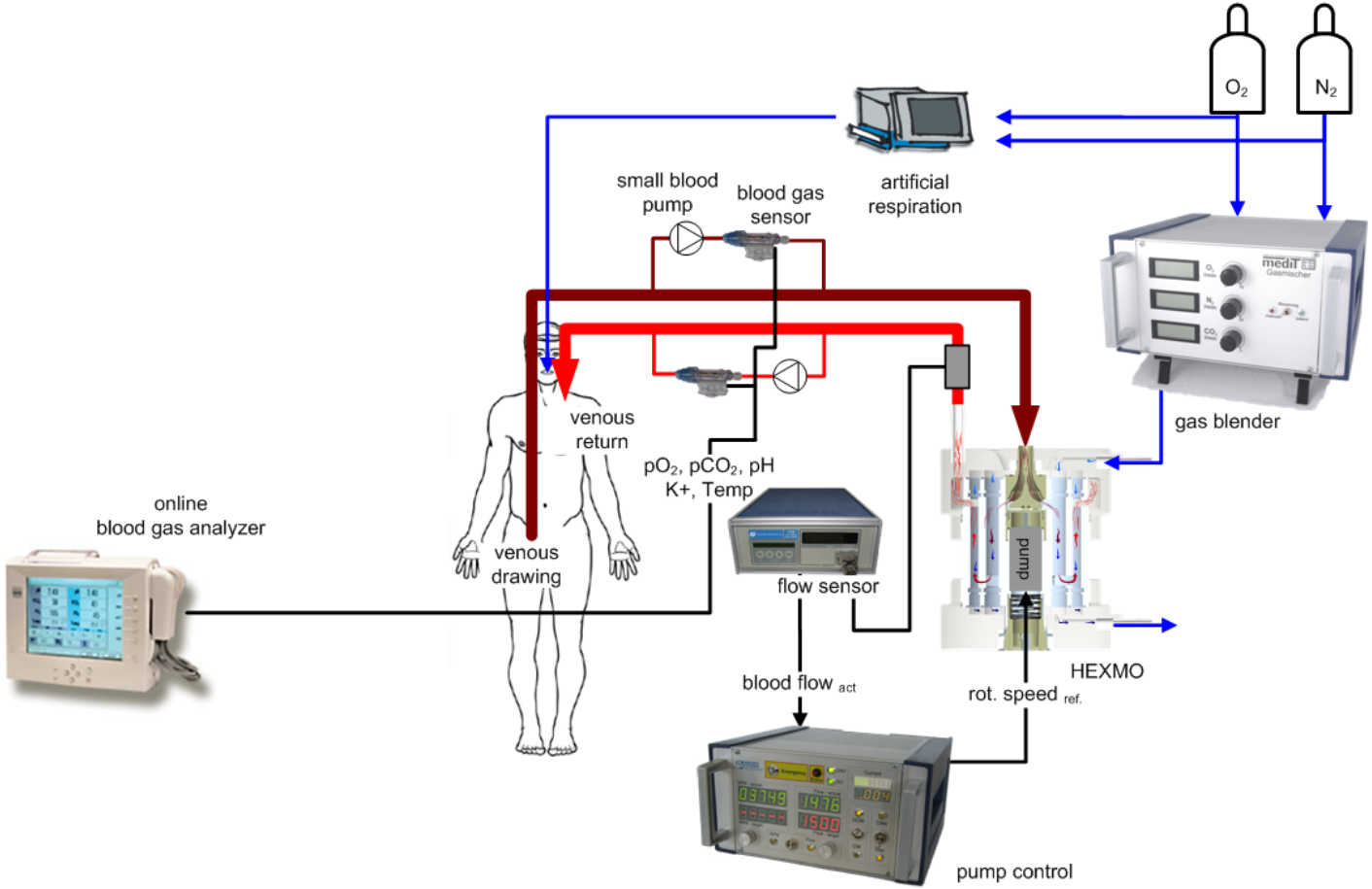

O_2
N_2
artificial respiration
gas blender
venous return
venous drawing
flow sensor
pump
HEXMO
blood flow act
rot. speed ref.
pump control

SmartECLA

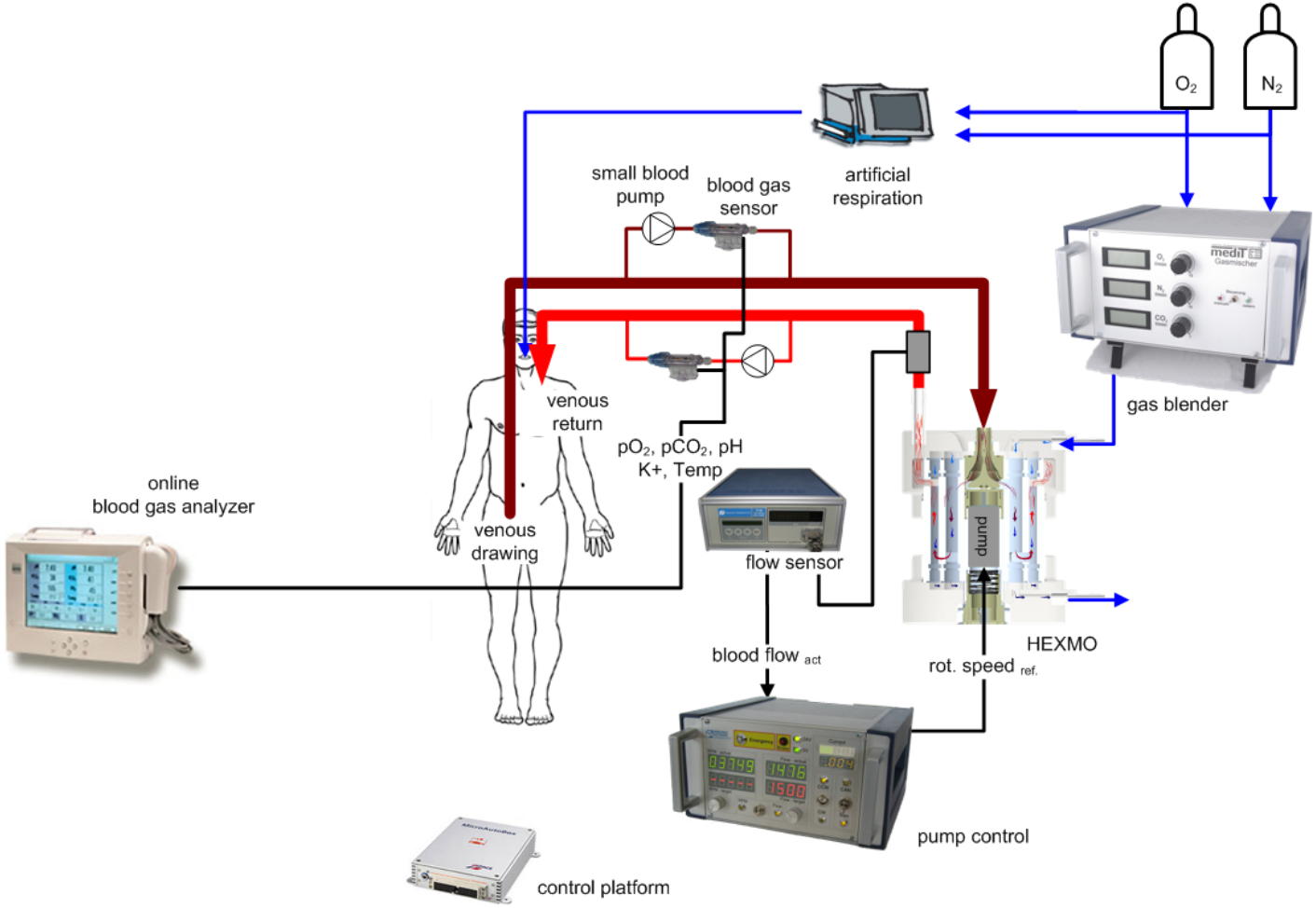
- Optimazing of the oxygenators and blood-pumps
- Closed-loop control with physiological relevant parameters as input
- Safety and reliability concept to ensure the needed performance



SmartECLA


O_2
N_2
artificial respiration
small blood pump
blood gas sensor
gas blender
venous return
pO_2, pCO_2, pH
K+, Temp
online blood gas analyzer
venous drawing
flow sensor
pump
HEXMO
blood flow act
rot. speed ref.
pump control

SmartECLA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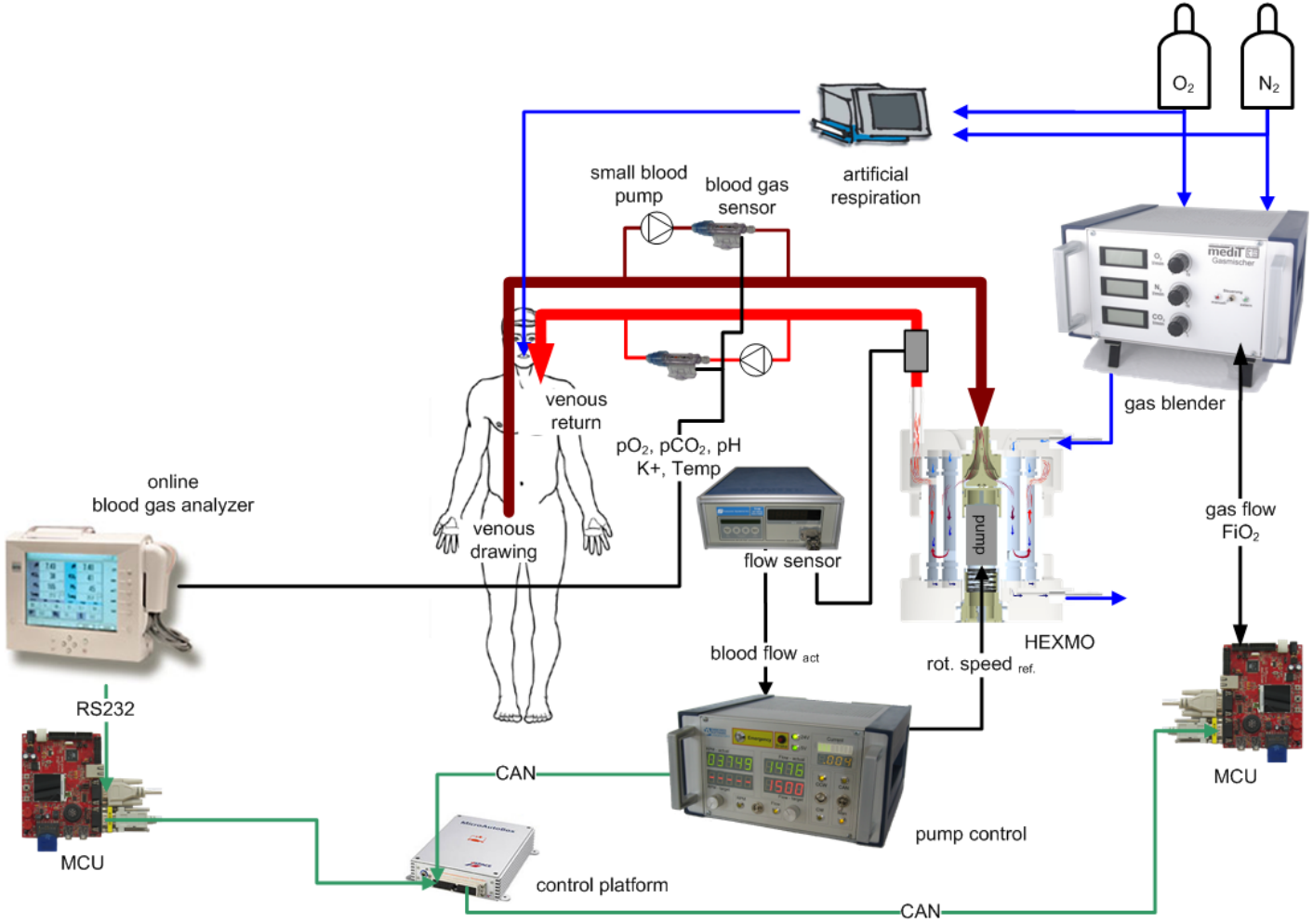
flow sensor
pump
HEXMO
blood flow act
rot. speed ref.
pump control
control platform

SmartECLA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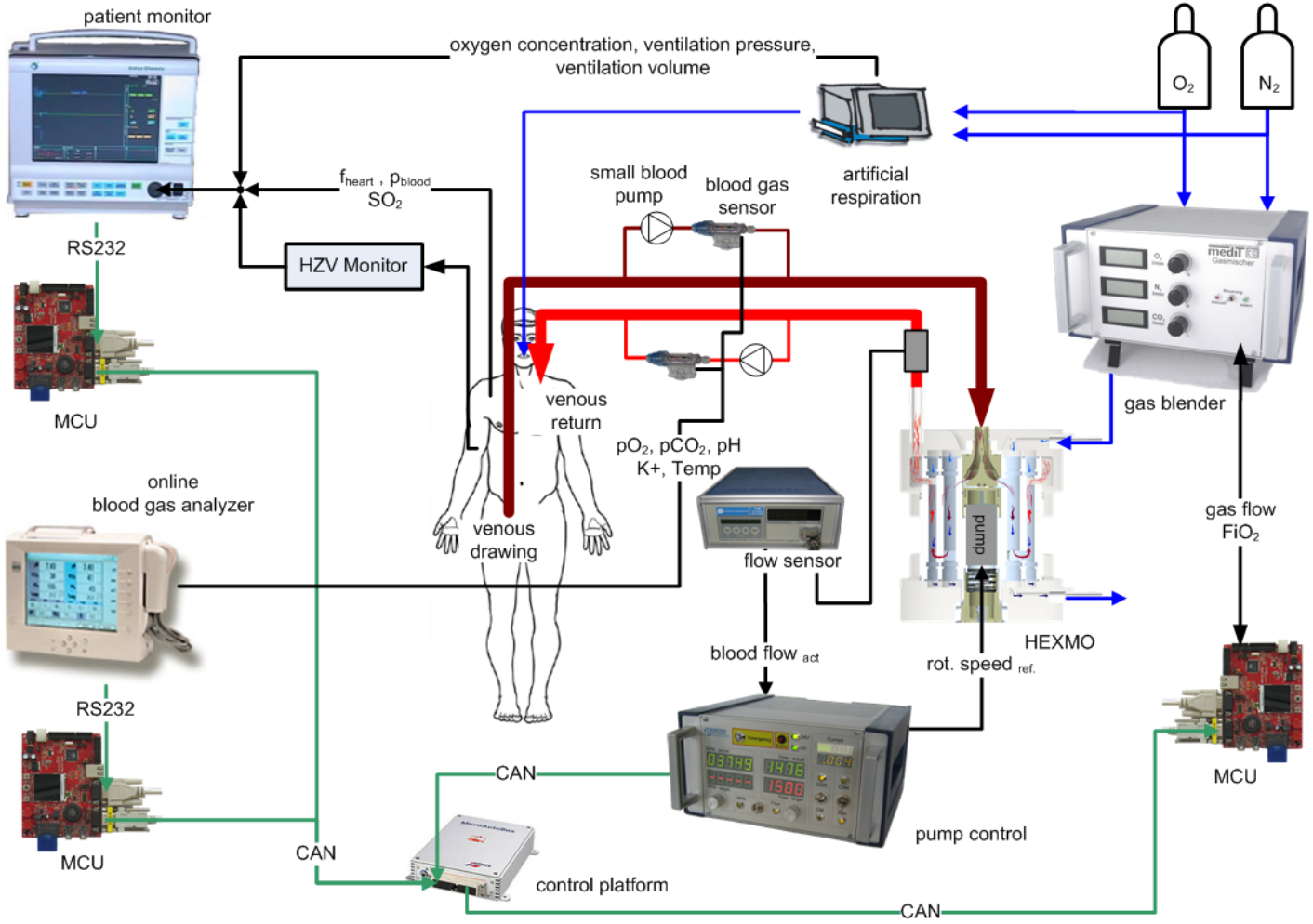
HEXMO
gas flow FiO2
blood flow act
rot. speed ref.
RS232
MCU
CAN
pump control
MCU
control platform
CAN

SmartECLA

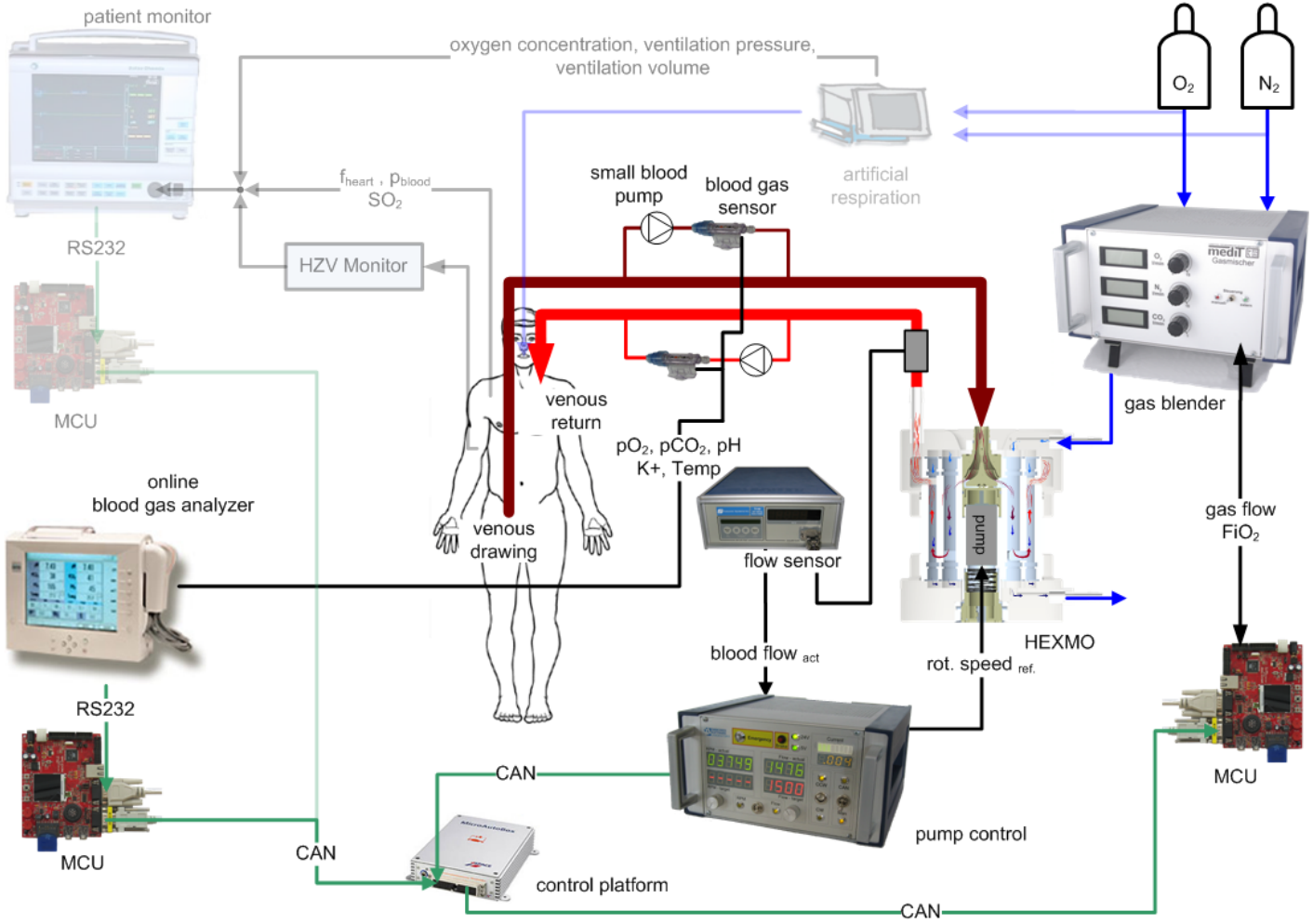

patient monitor
oxygen concentration, ventilation pressure, ventilation volume
O_2
N_2
artificial respiration
f_{heart}, p_{blood}
SO_2
small blood pump
blood gas sensor
RS232
HZV Monitor
MCU
venous return
gas blender
pO_2, pCO_2, pH
K+, Temp
online blood gas analyzer
venous drawing
flow sensor
pump
gas flow
FiO_2
HEXMO
blood flow act
rot. speed ref.
RS232
MCU
CAN
pump control
MCU
CAN
control platform
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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MCU
CAN
control platform
pump control
MCU
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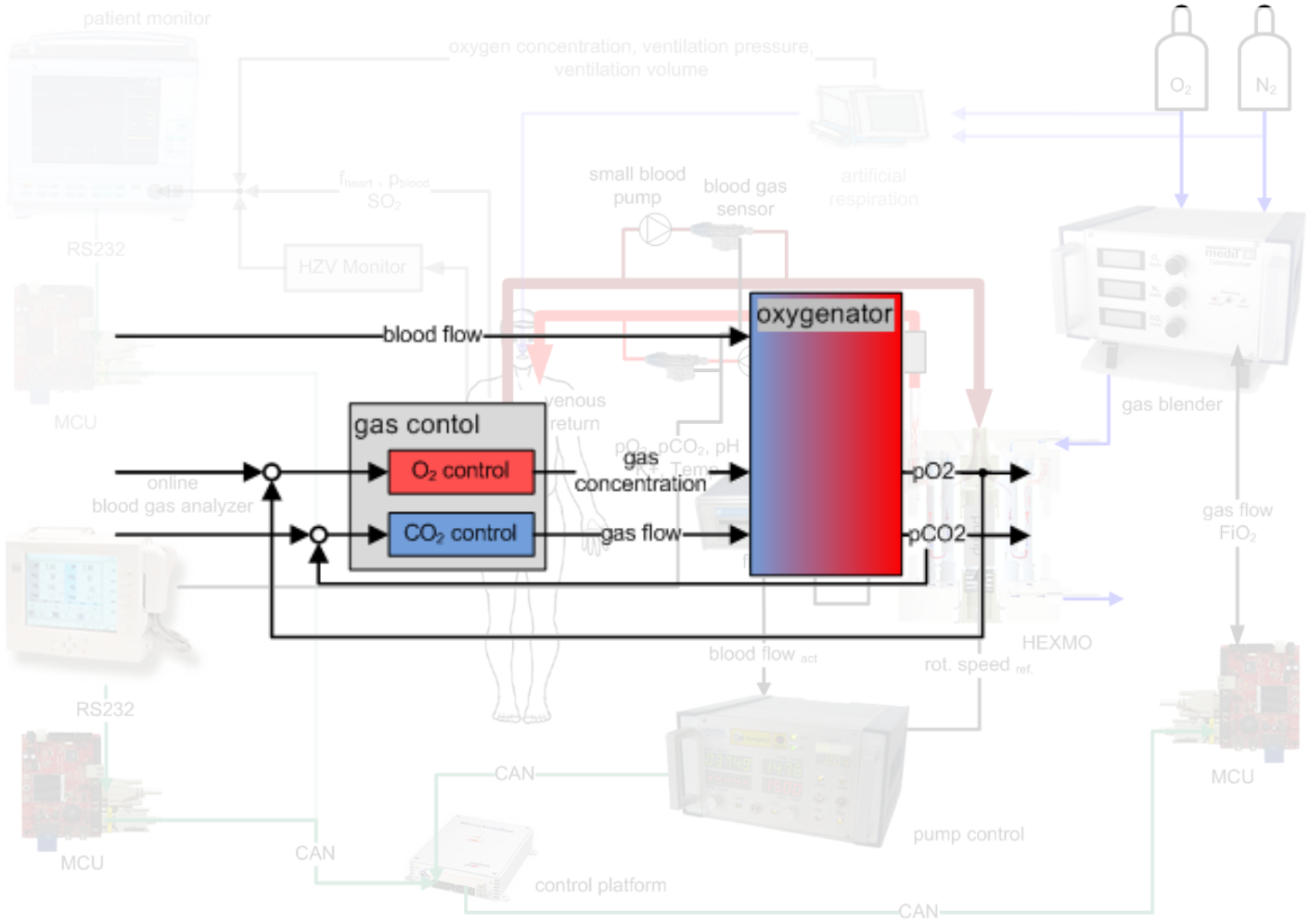
patient monitor
oxygen concentration, ventilation pressure, ventilation volume
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RS232
HZV Monitor
blood flow
oxygenator
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gas contol
O_2 control
CO_2 control
gas concentration
gas flow
online blood gas analyzer
venous return
gas blender
pO2
pCO2
gas flow FiO_2
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pump control
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MCU
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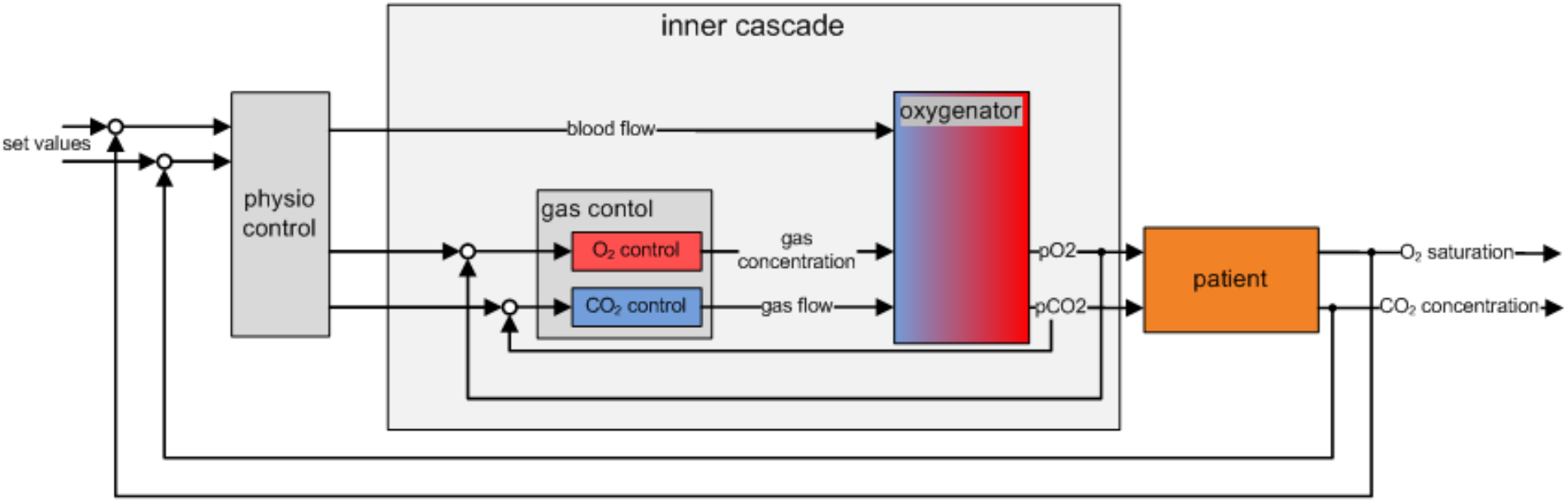
SmartECLA


inner cascade
set values
physio control
blood flow
oxygenator
gas contol
O_2 control
CO_2 control
gas concentration
gas flow
pO2
pCO2
patient
O_2 saturation
CO_2 concentration

Safety Concept

- Life-sustaining system
- No continuous supervision
- Healthcare personnel not into technical details

→Minimizing patients‘ risk during operation of ECMO

Safety Analysis

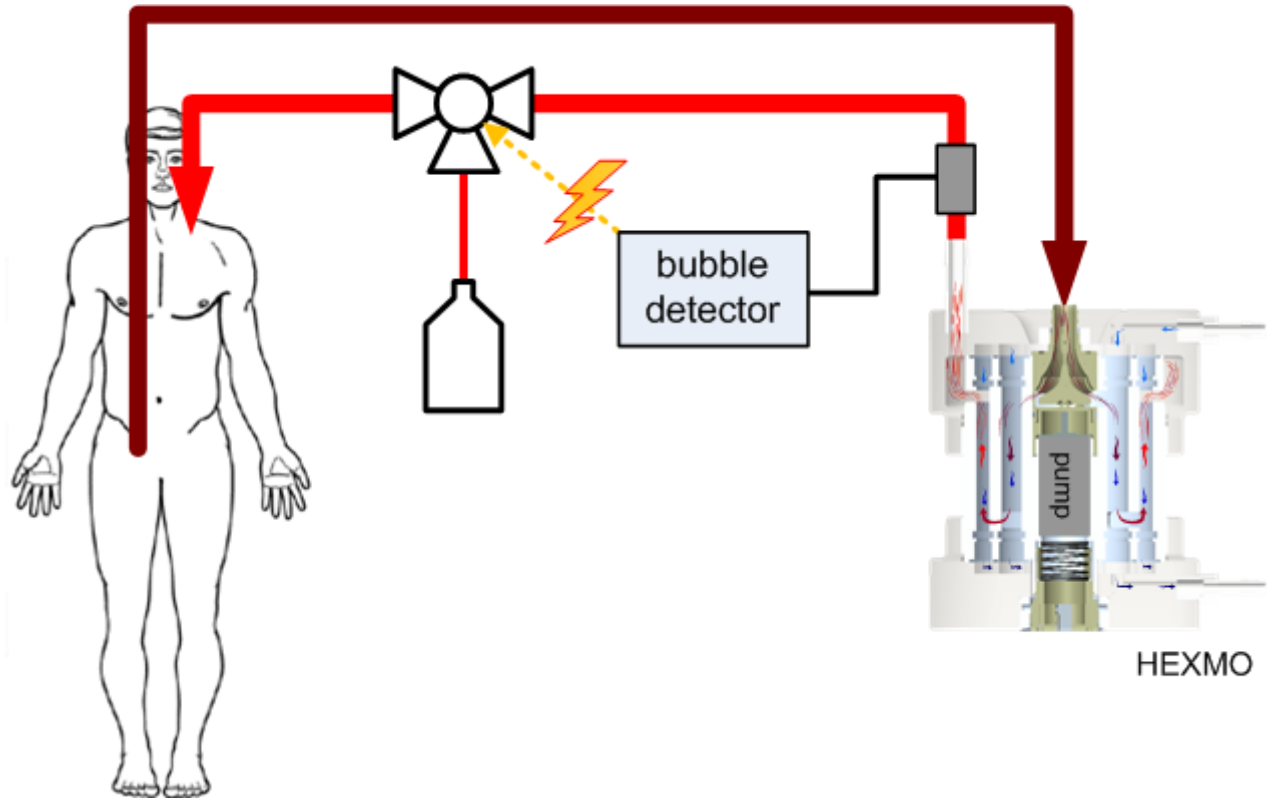
- FMEA of the system (SmartECLA setup)
- Derivation of safety goals
  - Technical facts out of FMEA
  - Physiological facts identified with medical partners
- FTA for identification and classification of technical risks

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

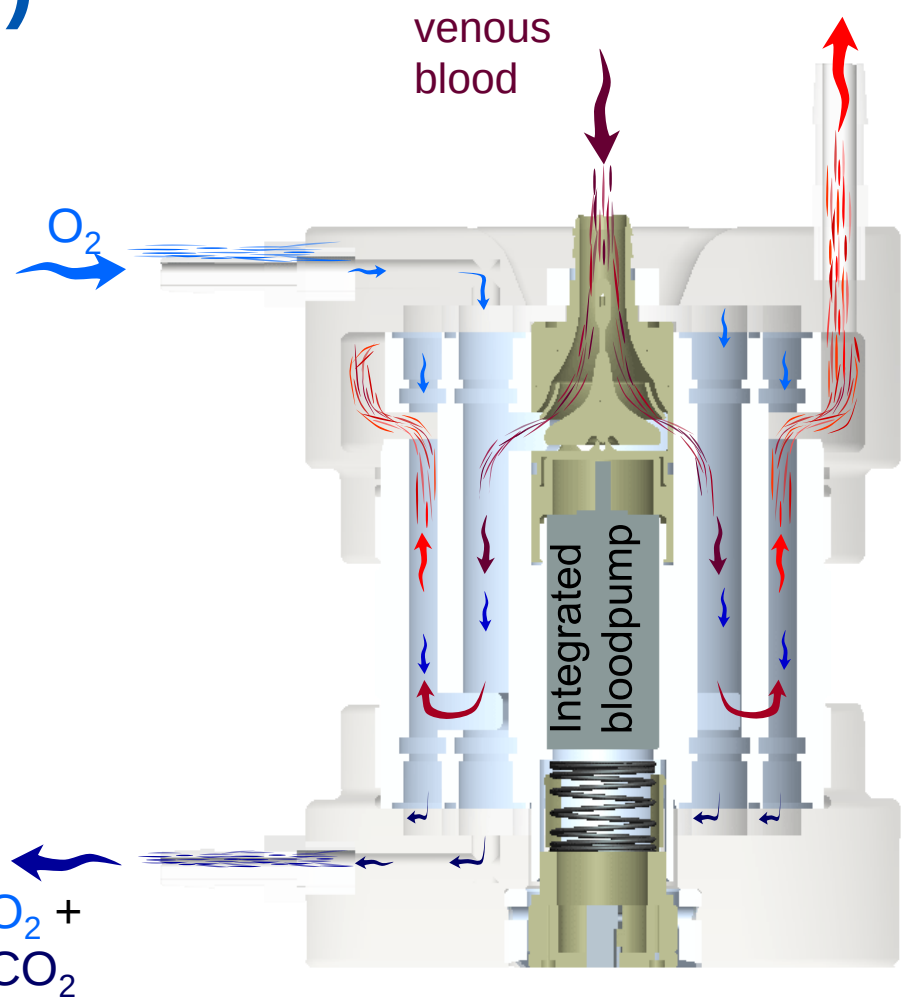
Constructive Redesign – Bubble Detection

- Gas-bubbles in bloodstream are an indefensible risk → embolism



Oxygenator (HEXMO)

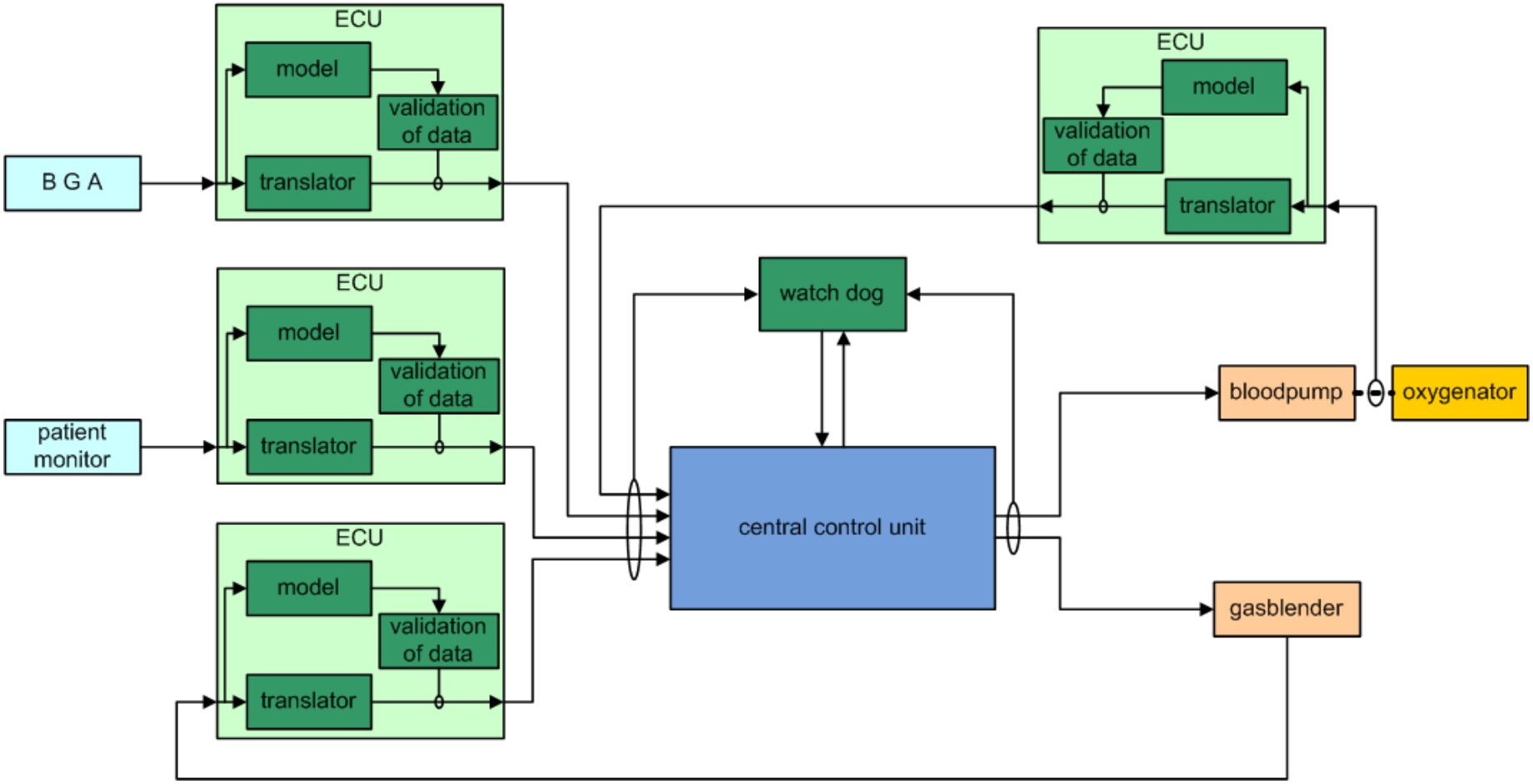
- Integrated blood-pump
- Membrane surface of ca. 1 m²
- Small priming volume



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

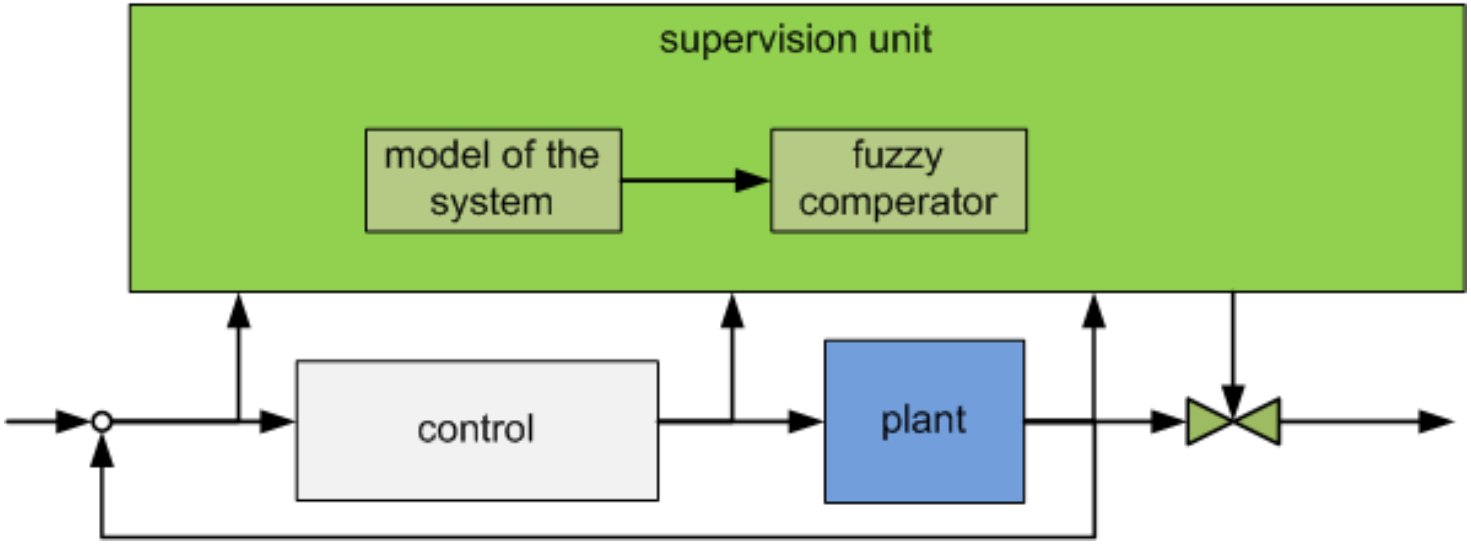
Distributed translation nodes



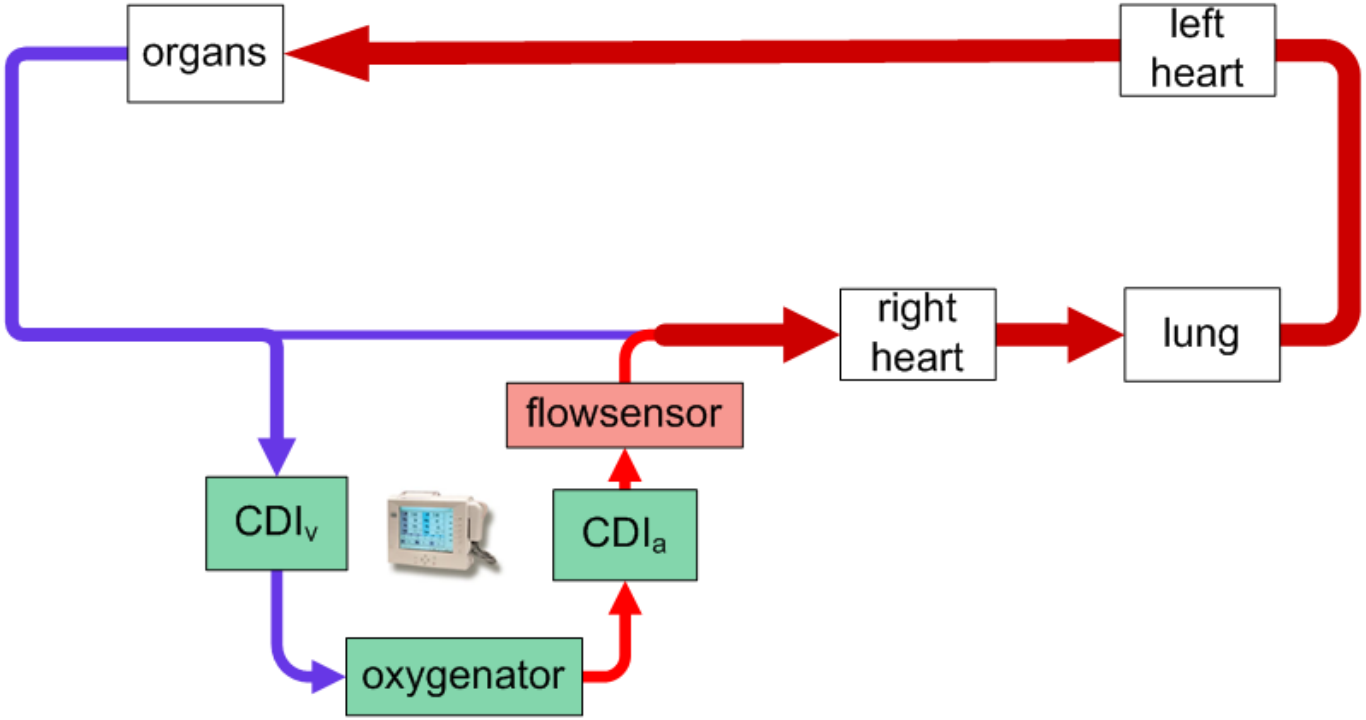
Basic Safety Measures

- 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

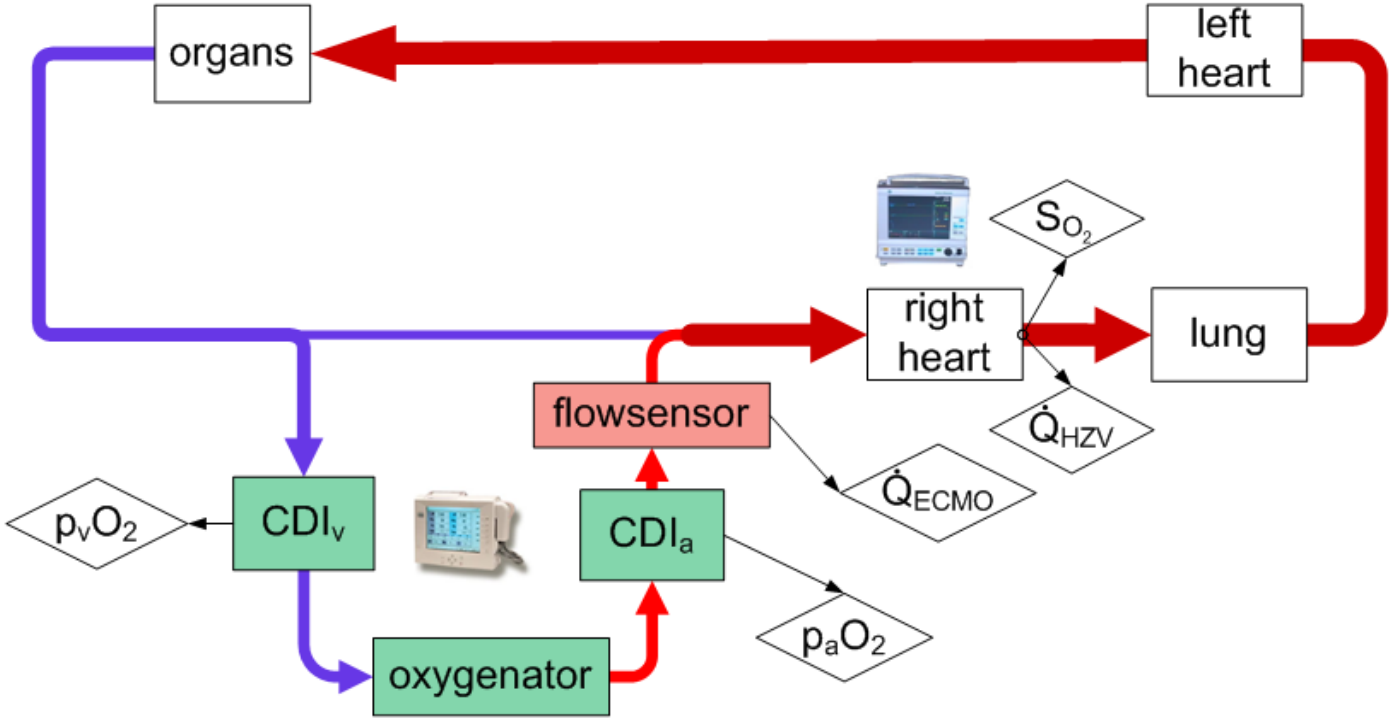
Extended Safety Measures – Model Based



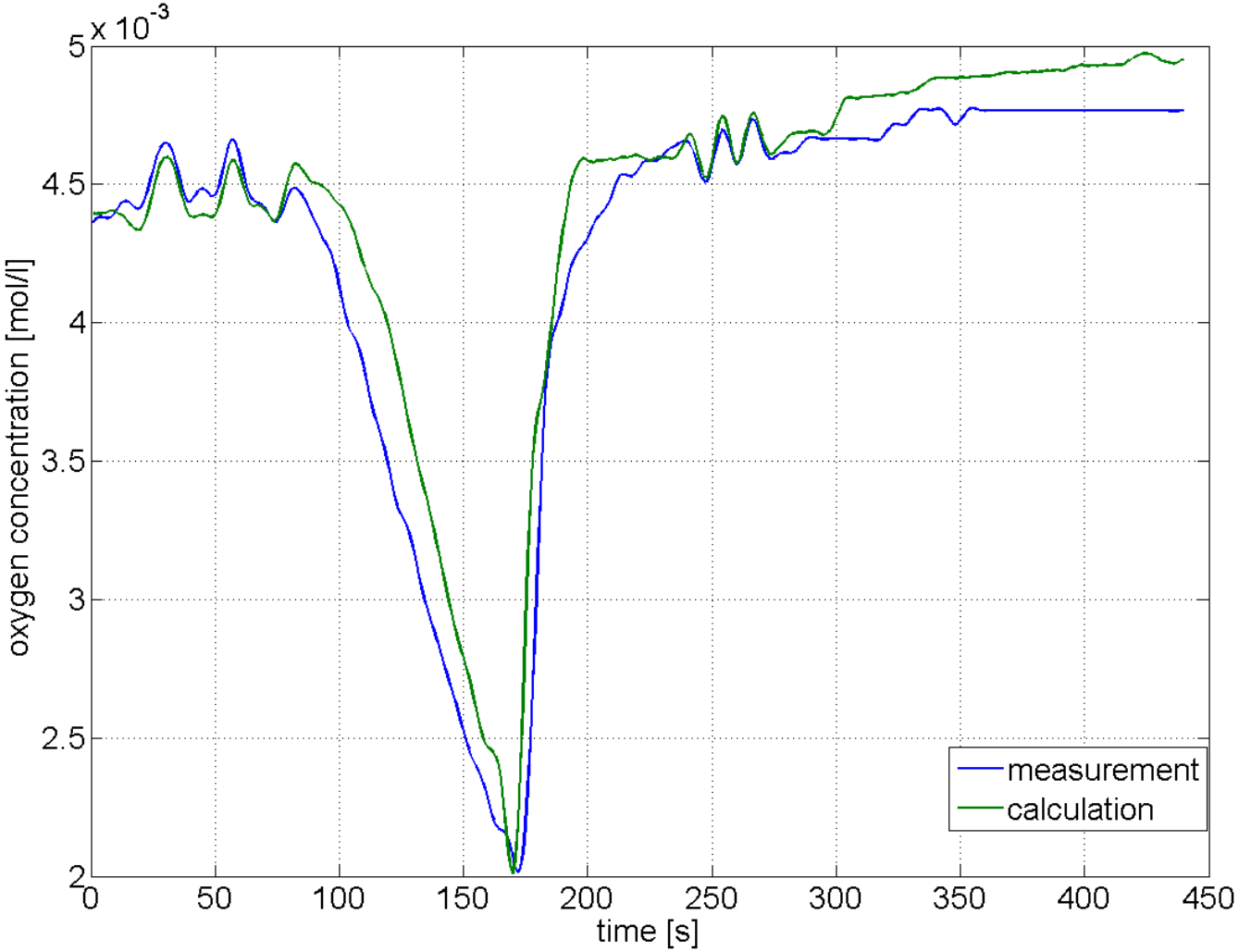
Measurement Validation - Blood Gas Sensor



Measurement Validation - Blood Gas Sensor



Measurement Validation - Evaluation



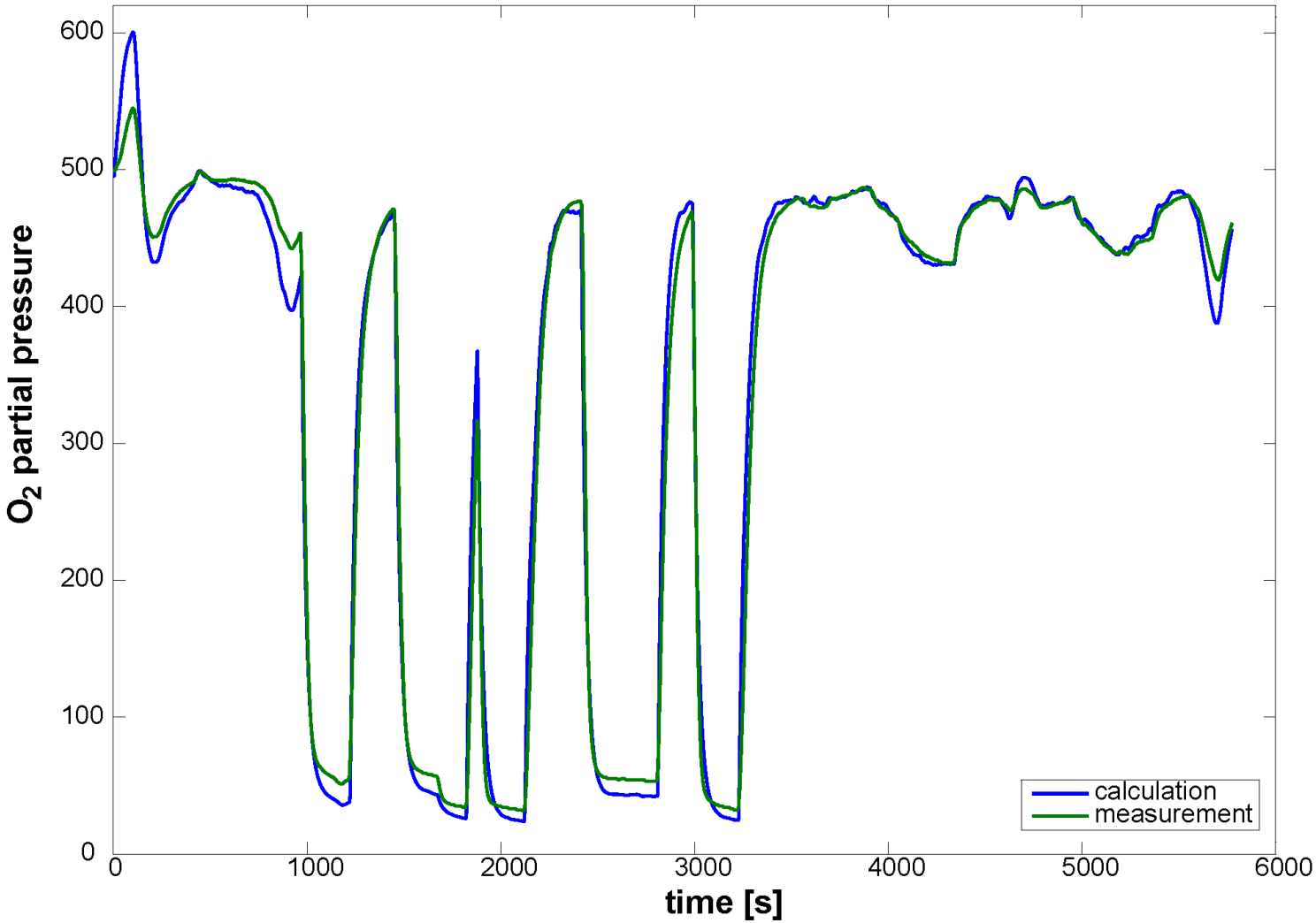
Diffusion Capacity of the Oxygenator

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

- Periodic replacement needed

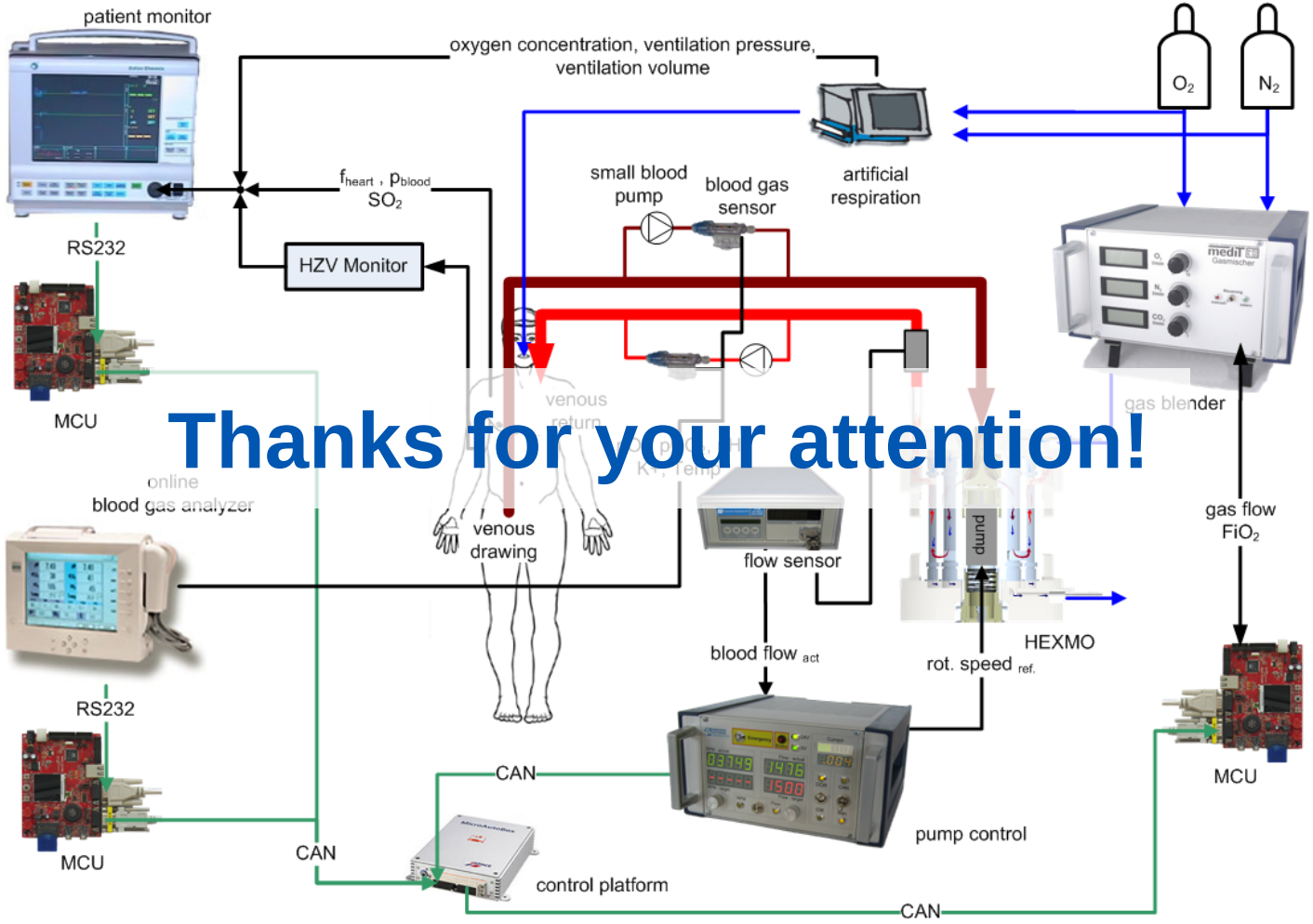
- Prediction of replacement-time by modeling the oxygenator
  → Increased reliability

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!