Assistive Control of Extracorporeal Oxygenation Systems

M. Walter¹, C. Brendle¹, J. Kühn², T. Janisch³, R. Kopp¹, A. Stollenwerk¹, S. Leonhardt¹

¹. Chair for Medical Information Technology, RWTH Aachen University, D-52074 Aachen, Germany
². Informatik 11 - Embedded Software, RWTH Aachen University, D-52074 Aachen, Germany
³. Department of Intensive Care and Intermediate Care, RWTH Aachen University Hospital, D- 52074 Aachen, Germany

Motivation:
In cases of severe lung failure and lung injury conventional artificial ventilation may not be sufficient in maintaining gas transfer. Even when applying modern therapy guidelines in protective lung ventilation required pressure levels may lead to even increased lung damage and subsequent loss of lung areas [1, 2]. One option to break this vicious circle and to maintain sufficient gas transfer is to support gas transfer by extracorporeal circulation. As a consequence it is now possible to relieve ventilation to healthier pressure levels [3]. In the past this treatment option was limited to emergency cases as complication rate was rather high and the required technical, medical and operational skill to operate such devices challenging. With the advent of improved oxygenator and pump technology many of the mentioned problems are relieved. However, the scenario of operating such complicated life saving machines 24/7 remains critical. In the operating theatre supervision and optimal setting of an extracorporeal circulation requires permanent attention of a specially trained cardiovascular perfusionist/technician. When transferred to the intensive care unit (ICU) the operating scenario (see Fig. 1 left) changes significantly and machine operation is reduced to intermittent/alarm driven supervision and control. In order to provide similar levels of control performance, reliability and safety, ICU devices should provide advanced autonomous functions. In our interdisciplinary project “ECLA-VENT” we developed patient oriented control strategies to address this issue.

Methods:
We developed a full electronic extracorporeal gas exchange system based on standard components enhanced with extended patient monitoring (see Fig. 1 right). Our proposed extracorporeal lung assistance (ECLA) consists of two femoral venous cannulae where venous blood is collected, a centrifugal blood pump (DP3; Medos Medizintechnik AG; Heilbronn; Germany), an oxygenator (Hilite® LT 7000; Medos Medizintechnik AG) as well as a jugular vein cannula for blood reinfusion. A MicroAutoBox (dSPACE GmbH; Paderborn; Germany) is used for central processing and control prototyping. Actuators are a self designed electronic gas blender and a self designed pump control unit. Sensor components are pressure sensors (at pump inlet, pre oxygenator and return cannula), online blood gas measuring system (CDI® Blood Parameter Monitoring System 500, pre and post oxygenator; Terumo Cardiovascular Systems Corporation; Ann Arbor; Michigan; USA), a blood flow meter in the external circuit (HT110 flow meter and H9XL flow probe, Transonic Systems Inc., Ithaca, USA), patient gas monitors (Dräger Medical GmbH, Lübeck; Germany) for gas analysis pre- and post- oxygenator, as well as a fully equipped patient monitor (A/S3 Datex Ohmeda Inc.; Madison; Wisconsin; USA) including ventilator gas monitoring and continuous cardiac output monitor. Additionally, we use a Ventilator (Servo Ventilator 300; Siemens-Elema AB; Solna; Sweden) which is modified so we can set user input settings (e.g. pressures, tidal volume, respiratory rate or FIO2) electronically. Each actuator and sensor component is connected to the CAN based data bus via microcontroller based network nodes [111 et al.], which implement data protocol translation.
From a technical viewpoint both ventilation and extracorporeal gas exchange act on the same target value (blood gas concentrations) inside the patient body. Thus, from a treatment point of view the control strategy has to solve a MIMO control problem with constraints regarding actuators. In consequence, the following list provides the main goals of the automation system:

- Provide sufficient amount of gas exchange of O$_2$
- Control of arterial oxygen levels within physiological limits
- Provide sufficient amount of gas exchange of CO$_2$
- Control of venous CO$_2$ levels
- Operate ventilation at least invasive levels
- Operate extracorporeal circulation at least invasive levels maintaining optimal operating conditions

This can be achieved by a cascaded control structure as shown in Fig. 2:

![Fig. 2 Cascaded control scheme of an automation system for control of extracorporeal circulation and artificial ventilation. Adapted from [4]](image)

An inner loop controls gas exchange in the oxygenator independently for O$_2$ and CO$_2$. This enables a decoupling of the control quantities and independent control. It also compensates for changes in gas exchange capacity of the oxygenator over time. Ventilation parameters are set in an independent feed forward concept. Here we implemented an automatic maximum compliance search strategy to optimize the point of ventilation. All other parameters were set according to the protective ventilation scheme of the ARDS-Net protocol [2]. Physiological target values of peripheral oxygen saturation $S_{pO_2}$ and venous CO$_2$ partial pressure $P_vCO_2$ are controlled using the outer control loop manipulating oxygenator gas transfer as well as ventilator oxygen fraction (see Fig. 2). One safety feature is included for oxygen transfer. In case of a sudden life threatening hypoxic crisis the control is reconfigured to create maximum O$_2$ gas transfer until a safe oxygen saturation is reached. Subsequently, the autonomous system switches back to the optimal control maintaining the new safe state.

**Results:**

To validate the designed control structure, we performed a series of animal experiments (55-75 kg domestic pigs, approved by LANUV NRW; Recklinghausen; Germany 84-02.04.2014.A113;). After instrumentation and connection to the extracorporeal circuit, varying degrees of lung failure were introduced by lung lavage with saline solution. In all cases moderate to severe ARDS could be created ($P_aO_2$ / $F^2O_2$ < 200 mmHg). After steady state at the initial operating point, control was activated and several setpoints for $S_{pO_2}$ and $P_vCO_2$ were selected. Intermittent identification of lung parameters and operating point search optimized ventilation. Figure 3 shows results for both $S_pO_2$ and $P_vCO_2$ control during a section of the trial. As can be seen, target values could be established and maintained as required. Under normal operating conditions the controller was able to reach the desired physiological target concentrations within 20 Minutes for CO$_2$ and 3-5 Minutes for O$_2$. Even with extreme disturbances hypoxic episodes with $S_pO_2$<85 could be prevented. Only in cases where venous wall suction at the inlet cannulae prevented further increase of blood flow control targets could not be met (not shown).
Fig. 3 Target control of $S_p$O$_2$ and P$_v$CO$_2$ during an animal trial, adapted from [4]

Conclusions:
Our experiments could prove efficacy and performance of the designed control system. Combined with advanced safety functions (not presented here) we show the feasibility of next generation ECLA devices enabling routine application in demanding hospital situations.