# Hemodynamic Monitoring with an Implantable Sensor Enables Automated Pharmacological Heart Failure Management

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## Introduction

Management of the patient's fluid state is the cornerstone of heart failure (HF) management. HF patients suffer from fluid overload and congestion caused by mal-adapted compensatory mechanisms. Besides treatment with beta blockers and RAAS inhibitors (only in patients with HF with reduced ejection fraction) volume is managed symptomatically with diuretics. Invasive measurement of left-sided filling pressures and management of fluid status has been demonstrated to reduce HF hospitalizations due to acute decompensation.

## Methods

Left sided cardiac filling pressures can be inferred from measurement of the pulmonary artery (PA) diastolic pressure. A leadless pressure sensor has been designed to be permanently implanted in the PA. The sensor implant comprises a titanium capsule which is anchored in the PA by NiTi wire loops. The capsule contains active electronics including a capacitive pressure transducer, an RF communication transceiver and an accelerometer. An integrated battery supplies the electronics with power. The system automatically samples and processes both PA pressure and the patient's posture and activity and transmits the data to a bedside RF communication unit which relays the data via mobile network to the BIOTRONIK data base. No patient action is needed for data acquisition and transfer. The system has been evaluated in bench tests and chronic animal experiments using 7 Merino sheep with a follow-up time of 1 year.

## Results

The sensor implant has a projected longevity of 5 years when pressure data are transmitted every night. Longevity might be prolonged to 10 years for stable patients where data are required less frequently. The sensor has a drift rate of typically < 1 mmHg per year. It was demonstrated that the sensor could be safely implanted in the left and right PA as well as in segment arteries which have a size of 12±2 mm. There were no adverse events. High fidelity pressure readings were reliably transmitted to receivers installed on the pasture.

## Conclusion

A fully automatic implantable PA pressure sensor system without mandatory patient interference proved to be feasible. Reliable and consistent PA pressure measurements enable the elaboration of a standard operating procedure (SOP) which shall be used by physicians and study nurses to control the patient's fluid state. This SOP might be translated into an algorithm running on the patient's smart phone which directly informs the patient on the medication doses and reduces workload in the hospitals which follow HF out-patients.

# Real World Experience with an Optimized Control Scheme for a Ventricular Assist Device

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## Introduction

Berlin Heart EXCOR® is a paracorporeal ventricular assist device for pediatric and adult patients in need of single-ventricular or bi-ventricular support. The new EXCOR® Active driving unit is small and mobile. Optimizing the closed-loop control for the driver involved balancing goals for usability, durability, pump wash out, blood stress and power consumption. We present the resulting new control scheme and the first device performance data.

## Methods

The characteristics of the driving unit, blood pumps and the cardiovascular system were determined experimentally and from literature. A detailed Simulink model and a mock loop for control development were built. The resulting controller moves the piston of a pneumatic cylinder on an optimized trajectory to operate the pump's diaphragm reproducibly and fast while keeping wear and current consumption low. Friction estimation and a nonlinear current control model are part of this loop. Different pressure targets for the opening of an air mass regulating valve ensure easy adjustability by the user and a good rejection of disturbances. Changes in atmospheric pressure and the pump pressure amplitude are captured with multiple sensors and compensated directly. An adapting valve model keeps power consumption low and prevents slow control behavior. Verification was done using state of the art tests: Mock loop in vitro tests, endurance tests and flow visualization. Device data was captured with the logging mechanism of the driver.

## Results

In vitro tests show: a) The control software meets its functional requirements. b) All Berlin Heart EXCOR® pumps together with the wide range of cannulas can be operated (0.6 to 5.7 lpm). c) The battery runtime is up to 7 hours. Endurance tests prove: A maintenance interval of 34 million pump cycles can be supported. PIV measurements confirm that fluid dynamics with EXCOR® Active are equivalent to those with the stationary Ikus driving unit. Device data from the first cases shows that the blood flow stays stable with power reserves.

## Conclusion

The new control scheme supports all Berlin Heart EXCOR® pumps and cannulas with a set of optimized piston trajectories. Robust control targets for air mass regulation ensure usability and constant blood flow in the clinical practice.

# Robust predictive control for respiratory $CO_2$ gas removal in closed-loop mechanical ventilation: An in-silico study

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## Introduction

In this simulation study a physiological closed-loop system for the control of arterial $CO_2$ partial pressure was designed and comprehensively tested using a set of models of the respiratory $CO_2$ gas exchange.

## Methods

The underlying preclinical data were collected from 12 pigs in presence of severe changes in hemodynamic and pulmonary condition. A minimally complex nonlinear state space models of $CO_2$ gas exchange was identified post hoc in different lung conditions. The control variable was measured noninvasively using the end-tidal $CO_2$ partial pressure. For the simulation study the controller output signal was defined as the alveolar minute volume set value of an underlying adaptive lung protective ventilation mode. A linearization of the two-compartment $CO_2$ gas exchange model was used for the design of a model predictive controller (MPC). It was augmented by a tube-based controller suppressing prediction errors due to model uncertainties. The entire controller was subject to comparative testing in interaction with each of the $CO_2$ gas exchange models previously identified on the preclinical study data. The performance was evaluated for the system response towards the following five tests in comparison to a PID controller: recruitment maneuver, PEEP titration man oeuvre, stepwise change in the $CO_2$ production, breath-hold maneuver and a step in the reference signal.

## Results

A root mean square error of 2.69 mmHg between arterial $CO_2$ partial pressure and the reference signal was achieved throughout the trial. The reference-variable response of the model predictive controller was superior regarding overshoot and settling time.

## Conclusion

The results demonstrated robust performance of the proposed closed-loop systems for a variety of changes in the physiological state, which in parts represent extreme versions of clinically occurring situations.

# A novel approach for increasing the traceability of 3D printed medical products

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## Introduction

According to the European Medical Device Directive (MDR (EU) 2017/745), medical products of all risk classes are obliged to be labeled with Unique Device Identification Codes (UDI). In order to meet the requirements of the MDR, a novel method of identification for additively manufactured metallic products was developed at Fraunhofer IWU. The method provides a product traceability within its production process and during the whole product lifespan, and functions also as a counterfeit protection.

## Methods

Additive manufacturing methods based on laser-beam melting of metallic powder enable product labelings during the production process. This technology is particularly interesting for products of risk class III such as implants, which have to be clearly identified even in the implanted state. The proposed method to identify additively manufactured medical products consists of three stages. The first stage is the preliminary CAD design of the product with an integrated identifier and the building process. The second stage involves the adjustments of the chosen non-destructive methods to the embedded identifiers' type, dimensions and position, with its subsequent readout. On the third stage the obtained signal processing and decoding are performed.

## Results

The integration of a unique identification during an additive manufacturing process was demonstrated for a titanium specimen. The readout of the integrated indetification was executed using ultrasonic and eddy current methods, as well as computer tomography. The obtained results are discussed in the paper.

## Conclusion

In various medical branches the numbers of initial implantations and implant revisions are continuously rising. At the same time, the identification of medical products isn't always possible due to the deficiency of the acces to the specific implant-patient data and absence of an appropriate identification method with a non invasive in vitro verification.

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# The evaluation of synthetic datasets on training AlexNet for surgical tool detection

**Abstract:** Surgical tool recognition is a key task to analyze surgical workflow, in order to improve the efficiency and safety of laparoscopic surgeries. The laparoscopic videos are important sources to conduct this task, However, there are some challenges to analyze these videos. Focus on the imbalanced dataset problem, data augmentation method based on generate different synthetic datasets and evaluate their performance training on a convolutional neural network model are investigated in this research. The results show the effect on the model with different background patterns. A better performance was achieved when the model was trained by a structure background dataset. Further research will be needed to understand why the original background patterns support the correct classification. It is assumed that this is an overlearning effect, that will not hold if other procedures were included into the test set.

# Automatic Detection and Classification of Cough Events Based on Deep Learning

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## Introduction

A deep learning approach for classification of cough sounds is presented. The architecture of the network is based on a pre-trained network wherein three recording channels are used. Two classification models are presented.

## Methods

Data acquisition has been performed by using the LEOSound Lung-Sound-Monitor. The spectrogram images are extracted by applying Fourier transform on windowed, zero-padded signals with 50% overlap. We have used a CNN-based pre-trained network for transfer learning. The classification in our approach is a twofold classification problem. Firstly, a binary classification wherein a sequence to sequence labelling will be performed is presented. The second classification type is a 3-label classification model.

## Results

The achieved accuracy for the 2-label (class) model is lower-bounded by 92% while it is 81% for the 3-label model. The precision and F1-measure score for the 2-label classification are 88% and 92%. Similar measures for the 3-label classification are 77%, 74%, 92% and 74%, 77%, 90% respectively. The AUC for the ROC curves is 0.97 and 0.92 respectively.

## Conclusion

A machine learning approach for cough sound detection has been presented. The proposed solution is based on a deep learning architecture wherein the elaborate feature selection process is performed automatically. In future, we will utilize deep learning with localization through CNN/LSTM fed by raw signal data with short time steps.