# INTRODUCTION OF THE NOVEL CONCEPT OF SIZING FLUID POTTING

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## Background

The treatment of extremely premature infants with immature lung function is a key challenge in neonatal intensive care. Avoiding pulmonary gas ventilation by use of an artificial placenta (AP) is a lung protective alternative treatment concept for this patient group. The AP basically is an oxygenator integrated into the umbilical vascular circulation. Current approaches for oxygenators in the AP context are commercial oxygenators adapted for this purpose and oxygenators with a constant gas exchange surface area or special developed prototypes for this purpose, e.g. the Neonatox. The blood volume and needed gas supply of the extremely premature infant doubles during the treatment process between 24 and 28 weeks of gestation. Current technologies do not fulfil the resulting need for an adjustable system to tackle this growth. The presented approach introduces the novel concept of sizing fluid potting to generate a dual-chambered stacked oxygenator for a volume-adjustable AP.

## Methods

The novel concept is based on using a sizing fluid with a higher density than the potting fluid to create a defined lumen. Therefore, round potting in the acceleration field rotating around its center axis was chosen. The Potting process can be divided into three steps: Potting of the outer sealing of the device following the round potting process, adding the sizing fluid to determine the size of the outer chamber and finally potting the inner wall to divide the two concentric chambers. After defining requirements for usable fluids with either a high density or a changeable aggregate state, the resulting candidate fluids were tested for their applicability with hollow fibre membranes used in conventional oxygenator models and potting materials.

This novel process with the desired sizing fluid was used to generate the targeted dual chamber design. A reproduction test was done to evaluate the defined potting method. The test consists of the corresponding chambers' inner and outer potting diameters and their target parameters.

The dual chamber fiber bundle was further tested in a specially designed prototype for its gas transfer efficiency according to DIN EN ISO 7199 with blood flows between 50 ml/min and 200 ml/min in steps of 25 ml/min. Switching to the additional chamber was performed at 100 ml/min when oxygen saturation dropped below 80 %.

## Results

Perfluorodecaline was chosen as a sizing fluid. The fluid is fully removable from the tested hollow fibre membranes, polypropylene (PP) and polymethylpentene (PMP), and does not interact with the silicone used for potting (Elastosil 620 A/B). A fibre bundle with resulting compartments of 5 ml priming volume each is shown in Figure 1.

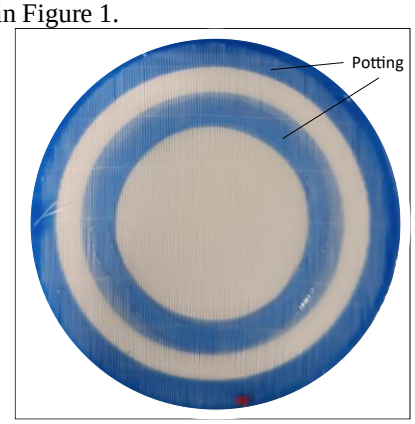


*Figure 1: Dual chambered fibre bundle*

In vitro testing according to ISO7199 showed an increase in transmitted oxygen over time after switching from the inner to both compartments. The resulting oxygen transfer with its corresponding blood flows is shown in Figure 2.

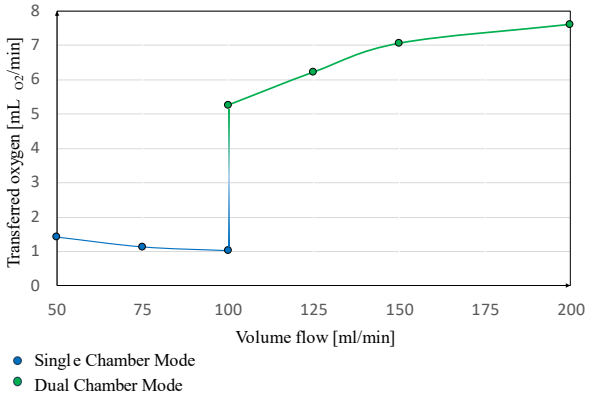


*Figure 2: Transferred oxygen overflow in single (blue) and dual chamber mode (green)*

## Conclusion

This study demonstrates proof-of-concept for a manufacturing process of concentric multi-chamber oxygenators with stacked fiber bundles using a sizing fluid. Reproducibility was demonstrated on hollow fiber bundles with corresponding compartments of 5 ml priming volume each. Sufficient gas transfer results for use as an artificial placenta could be shown.