1 Introduction

Since the first successful kidney transplantation in 1954, the demand for donor organs has been steadily increasing alongside medical advancement and new treatment methods. However, the increase in demand stands opposite to the worldwide shortage of donor organs. In 2020, 49,000 patients in Europe alone were in need of a donor organ. The number of actual transplantations, however, was about 28,000. For Germany, this means that about 9,200 patients were on the organ transplant waiting list in that same year.

Figure 1: Organ Transport

In addition to the organ shortage, doctors also face a decreasing quality in the organs available for transplantation. People live longer now than they did in the past and with age comes an increased risk of health issues that affect the organs. What is more, not every donor organ is in a condition that is considered fit for transplantation. In fact, 15 to 30 percent of donor organs in Western industrialized nations cannot be transplanted due to preexisting damages.

Another challenge inherent to organ transplantation is the narrow time frame in which a transplantation is possible. Right now, the majority of donor organs are taken out of their circulatory system and placed inside the cooling box in which they are transported. As the lack of circulation, i.e., perfusion, can damage the organs, medical professionals are left with around 12 hours until the organ must be implanted again. Taking into account the time that is needed for the transport and the examination of the organ prior to its transplantation, there is very little time to spare.

This is where machine perfusion systems come in to help alleviate the time pressure and improve the quality of the donor organs.

2 Function and Advantage of Organ Perfusion

Other than with traditional methods, organs placed inside organ perfusion systems remain part of a circulatory system. Here, they are perfused either normothermically or hypothermically and supplied with a blood-like solution and nutrients.

While the specific structure of the system varies with the respective organ, the basic function of organ perfusion systems is the same for all of them: The donor organ is connected to an extracorporeal circulation system consisting of

- a pump,
- an oxygenator,
- a heat exchanger, and
- various sensors that monitor the relevant parameters.

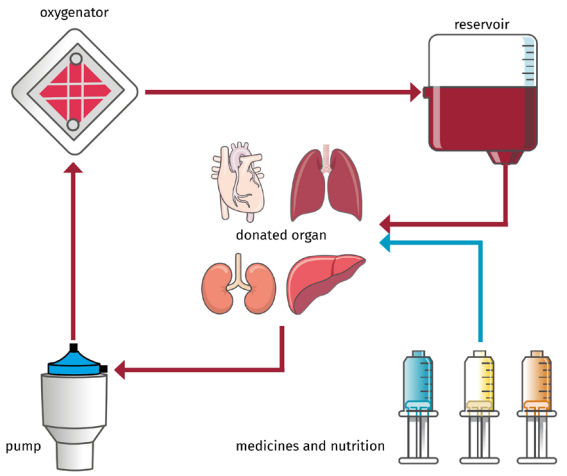

Figure 2: Illustration of an Organ Transport System

Together, all of these components simulate the conditions found in the human body, leading to a much longer survival time of the donor organ of up to 24 hours. Not only does a longer conservation time mean that organs from more distant locations now become available for transplantation and are thus widening the pool of possible donors; it also gives doctors more time to examine the organ and helps to determine whether the organ works as it should prior to its transplantation. Aside from conservation during transport, organ perfusion systems can also help to improve the organ condition, e.g. by allowing fluid accumulations to dry out and by removing unnecessary mucus. Consequently, the organs reach their respective recipients in a much better condition than they would have with the traditional cold storage. Furthermore, even organs that might have been deemed unusable before, can now be transplanted, increasing the number of possible donor organs.

3 em-tec's Contribution

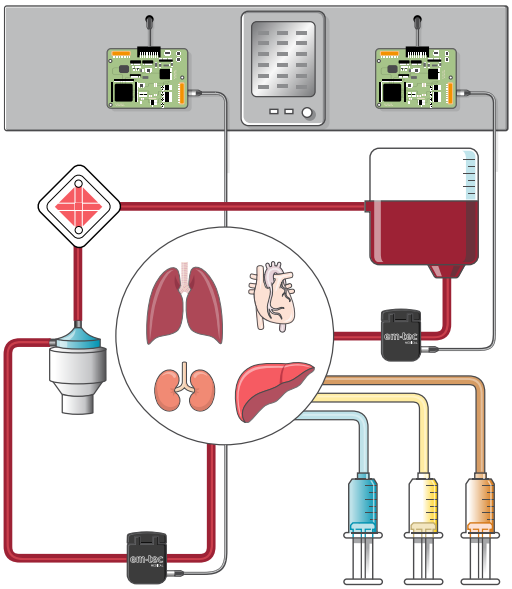

Figure 3: Illustration of an Organ Transport System incl. em-tec

As an OEM supplier and manufacturer with over 30 years of experience in the medical field, em-tec delivers and develops flow measurement solutions for the integration into medical devices. Our established and non-invasive measurement principle has proven itself in heart-lung machines and ECMO devices and is also ideally suited for organ transport systems. Consisting of two components, a flow measurement board of the SonoTT™ SkyLark Series and a compatible sensor, our system can measure the volumetric flow rate and, depending on the board variant, detect air in line.

To ensure the best possible results in regard to the safety and accuracy of and the compatibility to the overall system, we offer several customization options. For the sensors, these options include a customer-specific adjustment and calibration according to the relevant application parameters. For this, also low medium temperatures of ≥4 °C are possible.

Other customization options include the adjustment of cable lengths, cable ducting and/or the lid print. Moreover, the sensors are available with an optional mounting feature, enabling an easy integration into compact devices.

Figure 4: SonoTT™ Clamp-On SL

For the boards, there are several variants with different functions and specifications available, including fast flow output and bubble detection. Moreover, customers can choose which interface to use for the communication with their host system: CAN or RS-232.

All our components are MDR-ready. Additionally, em-tec offers full support from the initial request to the serial production and step-by-step consultation regarding matters of RA and QM. This also includes full documentation.

To learn more about our customization process, check out the leaflet and the video, where everything is explained in more detail.

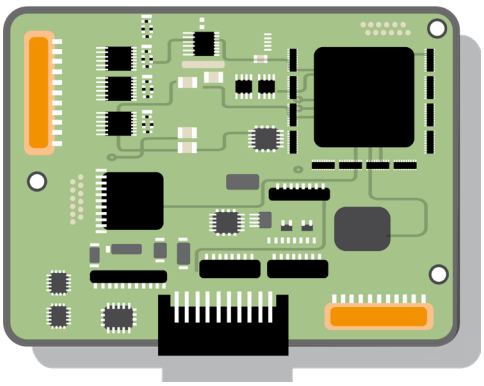

Figure 5: SonoTT™ SkyLark

4 Contact

If there are any questions concerning the information in this document, please do not hesitate to contact us.

You can reach us at:

em-tec GmbH
Lerchenberg 20
86923 Finning
GERMANY

Phone: +49 8806 9236 0
E-Mail: em-tec-info@psgdover.com
Internet: www.em-tec.de

Works Cited:

- Kirste, Günter. (2022, May 2). *„Geschichte der Transplantationsmedizin“*. drze. https://www.drze.de/im-blickpunkt/organtransplantation
- *„Transplantation: Neue Perspektiven durch Organperfusion“* (2022, May 2). MEDICA Magazin. https://www.medica.de/de/News/Archiv/Transplantation_Neue_Perspektiven_durch_Organperfusion
- Uniklinikum Leipzig. (2022, May 2). *Blut, Sauerstoff, Nahrung: Modernes Organperfusionsgeräte bereitet Spenderlebern auf* [Press Rlease]. https://www.uniklinikum-leipzig.de/presse/Seiten/Pressemitteilung_7118.aspx

D126-716 — SonoTT™ TechNote Issue #2:
Organ Perfusion V1.0