Integration of Flow Measurement in Cardiac Support Systems

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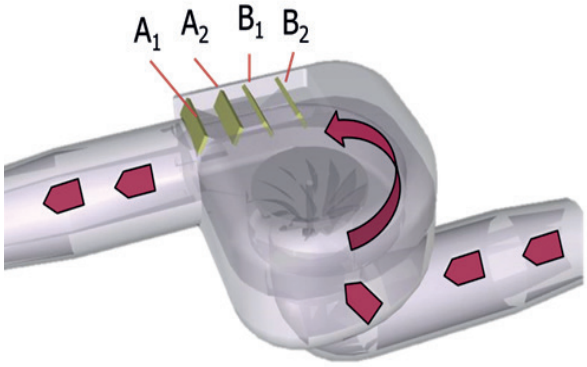
Experts in Flow Measurement

- em-tec GmbH has been offering end-products, components and development services for medical and non-medical use for 30 years.
- Our métier is the non-invasive flow measurement using the ultrasonic transit-time principle TTFM which, in contrast to Doppler, does not require any particles.
- All medical products comply with corresponding regulations (e.g. ISO 13485) and can be used for flow measurement in cardiac and vascular surgery or any extracorporeal therapies.

Challenges in Flow Measurement for VAD

- Cardiac support systems ventricular assist devices (VAD) use implantable axial, diagonal or radial pumps with an electrical driven impeller and implanted cannulas as connection to the vascular system.
- The controller of these pumps often calculates the resulting constant or pulsatile blood flow in the circuit indirectly - based on the hydraulic load resulting in a back force on the impeller which can be measured electrically.
- This indirect flow measurement does not satisfy all needs regarding pump management and control. Only additional direct flow measurement can rapidly detect dynamic flow changes e.g. due to viscosity and pressure changes, a flow compromising kinking of a cannula or partially or fully deployed obstructions in the liquid path to improve patient safety.

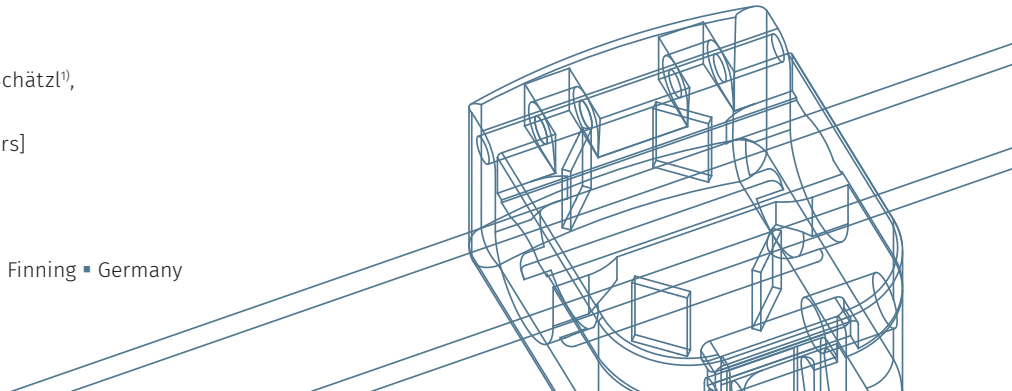
Principle of Ultrasonic TTFM in a VAD system



Sensor section at outlet of the radial VAD pump.
Several piezo crystal positions are verified to identify the most reliable and stable flow and signal conditions.

1. The piezo ceramics transmitter A1 is stimulated by a high frequency burst and sends out an ultrasonic downstream signal, running through the liquid in the channel and reflected to receiver B1.
2. A1 and B1 change their function for ultrasonic upstream signal.
3. The time difference of both signals is related to the real flow inside the liquid path, which has a temporal flow resolution up to 1 kHz to indicate dynamic flow changes caused by patient physiology, position or stress.

References: Dr.-Ing. E. Huber[1)], Dr. O. Lange[1)], S. Schätzl[1)], M. Bober[1)], B. Reszel[2)], Dr. rer. nat. T. Lebold[2)],
[1)Research and Development; 2)Regulatory Affairs]



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Method and framework

- The existing pump design, especially the liquid path, the hemodynamic and housing structure, is analyzed in detail to identify the optimal position at pump inlet or outlet (e.g. “Rotaflow”) to ensure a stable and reliable flow measurement and ultrasonic piezo crystal placement.
- Ideally, the sensor elements are fully integrated in the pump housing structure without changes of the liquid path as this avoids an external sensor on the grafts with all its disadvantages.
- Regulatory conditions for medical device development and relevant specific technical standards for implantable circulatory support devices, e.g. ISO 14708-5 have to be considered to ensure compliance with market approval requirements for the device, especially regarding patient safety and reliability.
- The well-known technical challenges from available cardiac assist devices need to be addressed with respect to hydro-dynamic, mechanical and electrical distortions of the ultrasonic signals.
- The proprietary em-tec electronics with adaptive full signal correlation analysis of the entire signal and a high sampling rate is used to measure and calculate flow even under compromised and changing signal conditions.
- Standard industrial electronics can not be used, as e.g. instable zero crossing points in the received ultrasonic signals will lead to an instable flow measurement.

Solutions for Cardiac Systems

- A little over 15 years ago: first experience with integration of ultrasonic transit-time flow measurement TTFM in the pump head of the “Rotaflow” centrifugal pump system (Maquet, Getinge Group) and still manufactured by em-tec.
- 2005: direct integration of the TTFM in the housing of extracorporeal and implantable impeller pumps made of titanium alloys, e.g. “Circulite Synergy System”. Pump calibration and in-vitro testing can be performed with a special developed blood mimicking fluid which mimics viscosity and ultrasonic properties of blood in test circuits.
- In-vivo trials demonstrated long-term reliability of the flow measurement in implanted systems in large animals.
- Successful demonstrating of TTFM integration inside housing structures in existing implantable and extra-corporeal pump systems which drive the impeller with constant and also pulsatile speed.
- Preclinical trials demonstrated the reliability of the patented flow measurement technique in-vitro and in-vivo on several types of implantable ventricular assist devices. The current clinical application of “Rotaflow” demonstrates that also this flow measurement technique fulfills the needs in cardiac support systems, generally in hypo- and normotherm conditions with blood.
- em-tec’s proven TTFM technology platform is adapted by hardware & software modifications to special VAD requirements
- For a successful integration of ultrasonic flow measurement, an experienced team familiar with the relevant standards and an ample knowledge of the best available techniques in risk and development management is essential. In addition, a safe and stable manufacturing process for successful device approval has to be established.

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