

# T400-Series Technical Note

## Flow Measurement in Ventricular Assist Devices (VADs): Progression from Laboratory Research to Medical Use

### Introduction

A VAD is a Ventricular Assist Device which temporarily or permanently supplements or replaces heart function. There are both external pVADs (percutaneous) and implanted iVADs in which the “i” is commonly dropped and are designated by Left (LVAD), Right (RVAD) or both Left and Right (biVADs).

In the 1970s, VADs were the size of commercial clothes washers. Some external VADs still have heavy cart-based controller units. Implantable VADs with medium percutaneous cables appeared next. With these, the patient has to wear or carry a battery or two as well as a controller for a total weight of about 10-15 pounds. Early pulsatile VADs were large, noisy and short-lived because they severely restricted the patient.

Newer second and third generation VADs now use non-pulsatile rotary or axial pumps with magnetic drives and some magnetic levitation of the impeller. These pumps are quieter, smaller, have a longer life and can be used with smaller patients. They permit the user to enjoy a better quality of life. Jarvik 2000 FlowMaker®, MicroMed HeartAssist 5®, and Thoratec HeartMate II® all weigh significantly less than 10 pounds for the entire package: pump, controller and battery.

VADs are quickly becoming a viable alternative for heart failure patients, rather than merely a device of research interest. The potential for VADs is staggering, and in view of the new devices, may finally begin to research some of its potential. VADs can be used as a “bridge to recovery” wherein the patient’s heart rests and then is later able to take on its former function. As a “bridge to transplant,” the device buys time until a heart transplant is available. As a “destination therapy,” the VAD is intended to stay with the patient for life.

### Flow Measurement During Implantation

Dr. Jarvik’s protocol for implant of the Jarvik 2000 FlowMaker® calls for use of the Transonic® Flowmeter with an AU- Flowprobe on the outflow graft to be used intraoperatively during the implant procedure. In this way, the surgeon can assure good flow (or find out if it isn’t producing good flow) right away. Also when surgeons delay closure of the chest to assure a well-functioning LVAD implant, flow measurement can be extended for more than the initial few minutes to final closure.

### Grafts for Implantable VADs

Grafts can be made of two or more materials:

- pTFE – (GoreTex)
- Polyester (Dacron)

and of many types of construction:

- Sealed - generally some type of gelatin sealant
- Unsealed with or without various plastic or metal reinforcements

and by several different manufacturers:

- Vascutek (a Terumo company)
- Gore

iVADs use many different sizes and types of grafts

- MicroMed HeartAssist 5® uses a custom 12 mm Probe on it’s graft
- Thoratec HeartMate II® uses a ~18 mm OD graft.

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## Progression from Laboratory Research to Medical Use Cont.

### Ordering Flowprobes for iVADs Grafts

To order a AU-Series COncidence Flowprobe® with Ultrafit Liner (HQx16AU, 16PAU), indicate the following:

1. Name of Device?
2. Name of Graft?
3. Material of Graft?
4. Size of Graft? ID? OD?
5. Anything about reinforcement (if any) removal?
6. Special requirements for calibration documentation?

## From Bench Testing to Implantable Clinical Devices

Transonic's versatile implementation of ultrasonic transit time technology provides the biomedical engineer with a set of reliable volume flow measurement tools that are used at every stage in the development of heart assist devices and blood pumps. The Flowsensors and Flowprobes meet these changing requirements as a project develops.

### Bench Testing

Pumps are first conceived and tested on the bench in tubing models that reproduce physiologic pressures and flow rates of the human circulatory system. Pulsatile and mean volume flow are important measurement parameters in determining the validity of the bench set up as well as the performance of the device in the circuit. Transonic® Inline Flowsensors are spliced into the tubing circuit for an accurate flow measurement.

The characteristics of the test fluid also impact the dynamics of the circuit and performance of the device. Therefore, various recipes, such as water and glycerine mixes are used to mimic the viscosity and density of blood. These are known as blood analogs. Transonic® Inline and Clamp-on Flowsensors can be calibrated for multiple specific blood analogs at various temperatures for the greatest accuracy and convenience to the engineer.

### In Vivo Testing (RL-42-sp)

Transonic® implantable Perivascular Flowprobes are also important in the preclinical stage of the device testing. Several different types of pump devices have been designed including total artificial heart replacements, implantable ventricular and biventricular assist devices, and extracorporeal assist devices. The efficacy of all of these must be tested in animal models that share the size and volume flow capacity of the human for which they are designed. Long term implant studies are performed in calves and sheep; often with multiple Transonic® Perivascular Flowprobes implanted on the pump outlet graft, the pulmonary artery, the ascending aorta, and various peripheral vessels or a coronary artery to determine the effectiveness of the pump in maintaining whole body circulation. These studies can run from 3 months to a year and rely on the continued accuracy and performance of Transonic® Flowprobes. Custom calibration and programming of Probes may apply to increase performance under specialized conditions.

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## From Bench Testing to Implantable Clinical Devices Cont.

### "Transonic® Inside" - OEM

The marriage between Transonic® flow technology and pump devices does not end in the final stage of a clinical device. Transonic® flow measurement technology has become an integral part of several clinical blood pumps that verify the volume flow delivered to the patient. Visit our website [www.transonic.com](http://www.transonic.com) or contact our OEM Product Manager at [OEM@transonic.com](mailto:OEM@transonic.com) to learn more about integrating Transonic® flow measurement technology into your device.



Transonic Systems Inc. is a global manufacturer of innovative biomedical measurement equipment. Founded in 1983, Transonic sells "gold standard" transit-time ultrasound flowmeters and monitors for surgical, hemodialysis, pediatric critical care, perfusion, interventional radiology and research applications. In addition, Transonic provides pressure and pressure volume systems, laser Doppler flowmeters and telemetry systems.

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