Transonic®
Flow Measurement in Tubing

transonic
THE MEASURE OF BETTER RESULTS.

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Tubing Flow(Clinical) Handbook
EC-1-hb, Rev A, 2017

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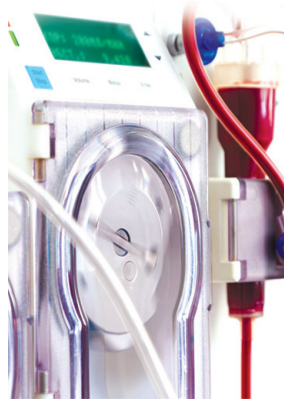
I. Introduction

A. Why Measure Blood Flow in Tubing?

"A rotary blood pump inherently provides only one noninvasive "observable" parameter (motor current) and allows for only one "controllable" parameter (pump speed.)" *Konishi H, Artif Organs. 1996 Jun;20(6):618-20.*



Whether a pump is being used as a mechanical circulatory assist device such as a heart bypass pump during cardiac surgery, in ventricular assist devices, extracorporeal membrane oxygenation (ECMO) circuits, or for hemodialysis, it is propelling life saving or sustaining fluids through a flexible plastic tubing circuit and patient. The amount of flow must be accurate and precise.

Transonic's unmatched tubing measurements allow the true flow through a circuit to be known at all times. By comparing actual delivered blood flow to the flow reading on the pump, flow limiting conditions can be detected and corrected on the spot. Kinks and circuit blockages can be detected and corrected before catastrophic circuit failures with dire consequences occur.

Transonic Tubing Sensors measure true delivered blood flow through tubing circuits with "gold standard" transit-time ultrasound technology. An external clamp-on Flowsensor clips onto the tubing to continuously monitor actual flow delivery to the patient. Measurements are non-invasive, continuous and bi-directional.

Transonic Tubing Sensors

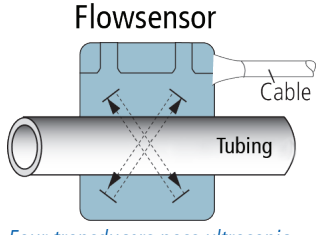
- Measure volume flow in mL or L/min in tubing non-invasively;
- Maintain sterility of liquids;
- Are specifically calibrated for the tubing on which they are used;
- Are reusable and EtO sterilizable;
- Can be custom calibrated for different fluid & temperature combinations

B. Gold Standard Methodologies

Two gold standard Transonic technologies are used to measure flow through flexible plastic tubing with unmatched accuracy and zero outset drift. They are transit-time ultrasound technology and flow/dilution technology.

Transit-time Ultrasound (TTU) Technology

Transit-time ultrasound technology was developed more than 35 years ago at the New York State Veterinary College at Cornell University by Transonic founder Cornelis Drost. Under the guideance of his mentor Physiology Professor Dr. Alan Dobson, Cor invented a way to measure the amount of blood flowing through vessels, such that the measurement would not influence the flow inside the vessel itself.



Four transducers pass ultrasonic signals, alternately intersecting the vessel in upstream and downstream directions. The Transonic® Flowmeter or Monitor derives an accurate measure of the changes in the time it takes for the wave of ultrasound to travel from one transducer to the other ("transit time") resulting from the flow of blood in the vessel. The difference between the upstream and downstream transit times is a measure of volume flow.

A decade later, a heart bypass pump manufacturer asked for a sensor that could measure flow within tubing that would serve as an independent measure of the pump's flow. In 1987, Transonic introduced its first Clamp-on Tubing Flowsensors specifically designed for noninvasive use on sterile tubing. Soon after, University of Michigan's extracorporeal membrane oxygenation (ECMO) pioneer Dr. Robert Bartlett began using a Transonic Flowmeter and Tubing Sensor as a safeguard and independent measure of flow delivered to his critically ill ECMO patients. These first applications sparked a plethora of applications in which Transonic Tubing Sensors are used to verify the flow within the circuit.

Transit-time ultrasound technology has clear advantages over other flow measurement technologies.

TTU Directly Measures Volume Flow, Not Velocity

Wide beam ultrasonic illumination of transit-time ultrasound Flowsensors measure the velocity of fluid across the entire vessel lumen and derive VOLUME FLOW in mL/min or L/min. Doppler derives flow from separate estimates of average VELOCITY in cm/sec of particles in a field. Doppler measures speed. Transit time ultrasound measures speed times cross section to arrive at volume flow.

B. Gold Standard Methodologies cont.

Transit-time Ultrasound Measures Flow in All Fluids

Transit-time ultrasound measurements are not dependent on particulate matter in the fluid in order to measure flow. Fluids such as saline, water and physiological buffers can be measured with transit-time ultrasound unlike Doppler measurements which requires signals to bounce off moving particles within a fluid in order to measure flow.

Checksum Safety Feature

For volume flow measurements in tubing, Tubing Flowsensors are specifically calibrated for the mechanical properties of a specific tubing including a tubing's composition, its wall thickness and inside and outside diameters. A calibration factor (called a checksum) is stored in an Tubing Flowsensor's EEPROM memory. As a safety precaution, Transonic's Tubing Flowmodules are programmed to read the checksum of a specific Flowsensor and lock out any sensors that do not meet the right calibration specifications. Similarly, the checksum allows ease of interchangeability between sensors that do have the same calibration factor programmed in their EEPROM.

Unmatched Zero-Flow Stability

The acid test of any transit-time flowmeter design is its zero-flow stability in regards to time and temperature. A flowmeter's noisy oscillator drives its transmitting circuitry and functions as the phase reference signal for its sensitive receiver amplifiers and detectors. Direct pickup of an oscillator's signal into the received signal exhibits itself as a zero-flow offset.

If the phase relationship between the transmit and received signal fluctuates due to variations in acoustic transit-times as a result of temperature or other liquid property changes, this pick-up signal manifests in a varying zero flow offset which is indistinguishable from a change in true flow unless the flow is stopped and a meter is re-zero'ed.

Transonic's hallmark high stability and low, stable zero offset demonstrates the sophisticated engineering of Transonic Flowmeters that has been honed, time-tested and proven over more than thirty-five years.

B. Gold Standard Methodologies

Ultrasound Dilution Technology

The second Transonic technology used to measure flow in tubing is ultrasound dilution devloped by Biomedical Engineer Nikolai Krivistki.

In 1991, Nikolai Krivistki, Ph.D., D.Sc., emigrated from Russia and joined Transonic Systems. He spent his first several months at Transonic familiarizing himself with Transonic products, especially its proprietary Clamp-on Tubing Flowsensors and its dedicated HT110 Tubing Flowmeter.

Then, in an "Aha" moment, he envisioned how existing transit-time ultrasound technology could be combined with classical indicator dilution technology to provide an advanced flow measurement, specifically for hemodialysis. He termed this innovative marriage of technologies "ultrasound indicator dilution." An integral component of this new technology was direct measurements of delivered blood flow in tubing using transit-time ultrasound technology.

Ultrasound dilution technology is predicated on the fact that the velocity of ultrasound in blood (1560-1590 m/sec) is determined primarily by its blood protein concentration. Ultrasound dilution technology measures this ultrasound velocity. When a bolus of isotonic saline (ultrasound velocity: 1533 m/sec) is introduced into the blood stream, it dilutes the blood. A matched pair of arterial and venous sensors register indicator dilution curves to arrive at measures of recirculation, access flow and cardiac output.

II. Tubing Flow Applications

A. Mechanical Circulatory Support

The fist-sized human heart is an incredibly precise pump. To be exact it is two pumps separated by a wall down the middle and encased in a single sheath of muscle. Each side has two chambers, a receiving tank atrium and a ventricle pump. The right side sends blood gently to the lungs, while the left side pump propels five quarts of oxygen-rich blood per minute throughout the body. Although the two pumps are required to exert significantly different forces, their synchronous beat ensures that blood flow is smooth and continuous. When it no longer is, heart failure ensues and the heart's action must be augmented. Mechanical circulatory support is one strategy used to help the heart pump.

The need for mechanical circulatory support for heart failure is daunting. There are an estimated 5.7 million Americans with heart failure. That number is expected to increase to over eight million by 2030[1]. Of these, nearly one million have end-stage heart failure and are no longer responsive to maximal medical therapy.

The ultimate and ideal goal for these patients is to receive a heart transplant, but in actuality only 2-4% will receive a new heart. Many will die waiting for a transplant. In the interim, many of these patients depend on a variety of mechanical circulatory support devices to improve their cardiac outflow, hemodynamics, and tissue perfusion.

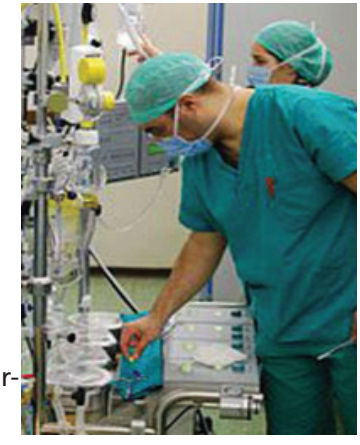
A host of mechanical circulatory support devices are now available. Temporary devices include the intraarotic balloon pump and the bypass pump, both used during cardiothoracic surgery, ECMO systems for more extended heart and/or pulmonary bypass, and percutaneous ventricular assist devices (pVADs). Longer term solutions for heart failure include implantable VADs and total artificial hearts.

All these devices try to augment, replace or restore the function of the body's most essential pump, the heart. Their flows need to verified. Transonic® tubing flow measurements fill this need.

[1]Ergle K *et al*, Ochsner J 2016; 16: 243-249.

1. Temporary Mechanical Circulatory Support Devices cont.

a. Cardiopulmonary Bypass Pumps



A Cardiopulmonary Bypass (CPB) pump, often referred to as a heart lung machine or simply as "the pump," mimics the function of the heart and lungs by temporarily taking over the heart's and lung's function during surgery. This enables the surgeon to operate in a bloodless surgical field.

The CPB pump was first used by Dr. John H. Gibbon, its developer, in 1953 during successful open heart surgery. Now used during coronary artery bypass (CABG) and other cardiothoracic surgeries as well as heart and lung transplantation, the heart-lung machine has become a fixture in any modern cardiac surgery operating room.

As with any pump, flow may change and problems can develop. Verification of true pump flow is advised. That is why one sees so many Transonic Tubing Flowsensors applied to CPB circuits within operating room suites.

Clamp-on Tubing Flowsensors connect to a Transonic® HT110 Tubing Flowmeter to provide an independent measure of actual flow. The system provides noninvasive, sterile measurements without any contact with the fluid or interruption of tubing. It has a stable and low zero offset and calibration can be adjusted on site. The Transonic® HT110 Tubing Flowsensor/Flowmeter system is the "Gold Standard" used throughout the biomedical and surgical community in order to calibrate & validate heart/lung pumps.

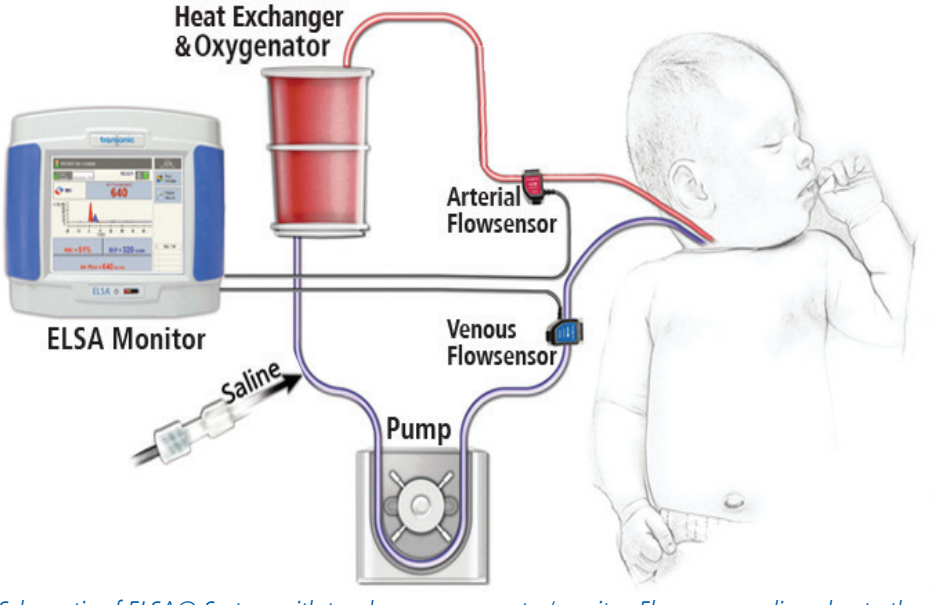
The system

- Maintains tubing integrity;
- Sensor clips onto existing tubing;
- Exhibits unmatched accuracy ± 10%

1. Temporary Mechanical Circulatory Support Devices cont.

b. Extracorporeal Membrane Oxygenation.(ECMO)

"Use of the Transonic Flowmeter allows the ECMO specialist to monitor actual patient blood flow and hemofilter shunt enhancing patient care management" *Berube, MC*



Schematic of ELSA® System with touch screen computer/monitor, Flowsensors clipped onto the tubing lines on either side of the oxygenator.

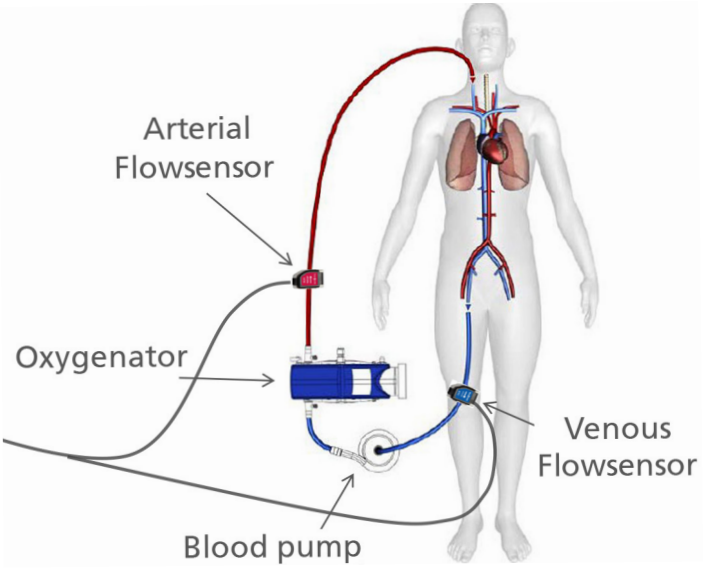
Extracorporeal membrane oxygenation (ECMO) is the use of prolonged extracorporeal cardiopulmonary bypass (CPB) in patients with acute, reversible cardiac or respiratory failure. The two most common of which are the veno-arterial (VA) and veno-venous (VV). In both, blood drained from the venous system is oxygenated outside of the body by an oxygenator. In VA ECMO, this blood is returned to the arterial system. In VV ECMO the blood is returned to the right heart and no cardiac support is provided.

1. Temporary Mechanical Circulatory Support Devices cont.

b. Extracorporeal Membrane Oxygenation.(ECMO) cont.

Adult
ECMO

ELSA Monitor



Schematic of ELSA® System connected to an adult patient showing placement of arterial and venous sensors, and cannulas in the femoral artery and vena cava.

The use of ECMO in adults increased during the 2009/2010 H1N1 influenza pandemic. Within a day of the flu's onset, a small percentage of adults were struck with rapid, progressive Adult Respiratory Disease Syndrome (ARDS). New ECMO centers were created to serve as a last resort for such life threatening complications. The Extracorproeal Life Support Organization (ELSO) provided guidelines for use of ECMO in adults with cardiac failure that included:

- Inadequate tissue perfusion (hypotension and low cardiac output;• Shock persisting despite volume adminstration, inotropes and vasoconstrictors, and intra-aotic balloon counter-pulsation, if appropriate;
- Typical causes: acute myocardial infarction, myocarditis, peripartum cardiomyopathy, decompesated chronic heart failure, post-cardiotomy shock;
- Septic shock (indication in some centers).

1. Temporary Mechanical Circulatory Support Devices cont.

b. Extracorporeal Membrane Oxygenation (ECMO) cont.

Pump or delivered blood flow errors and recirculation compromise the delivery of oxygenated blood to fragile ECMO patients. When actual delivered blood flow is compared to the flow reading on the pump, flow limiting causes such as incorrect cannula placement can be identified and corrected on the spot.

Therefore, Transonic Extracorporeal Tubing Flow systems serve as critical safety and quality devices in ECMO by providing an independent measure of delivered blood flow. Used throughout medicine to calibrate and validate pumps for many uses, Transonic's gold standard technology measures blood, water and other non-aerated aqueous solutions with unmatched accuracy to provide an independent measure of actual delivered flow over wide dynamic ranges that also include very low ECMO flows.

When Transonic Tubing Flowsensors measure flow through the ECMO circuit, catastrophic circuit failures with dire consequences can be averted. Actual blood flow is known at all times and kinks and circuit blockages can be immediately identified and corrected. Moreover, the time that the patient has to be on ECMO is shortened when known values for flow and recirculation are used to achieve optimal placement of cannulas.

Sterility within the ECMO circuit is maintained by the noninvasive sensor that clips onto the outside of the tubing precluding contact with the fluid. It provides noninvasive, sterile measurements without any contact with the fluid or interruption of tubing. The measurement is stable at low ECMO flows.

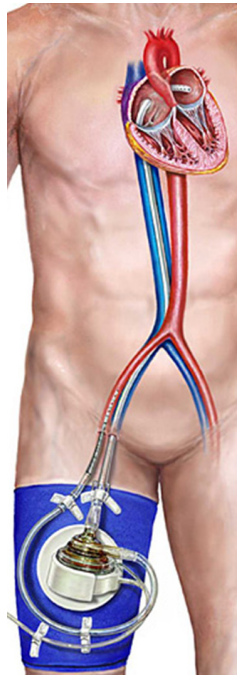
Two systems are available to verify Delivered Blood Flow in ECMO circuits:

- HT110 Bypass Flowmeter and H_XL Clamp-on Flowsensors (page 18
- ELSA Monitor with H_FX Flow Dilution Sensors (page 26)

1. Temporary Mechanical Circulatory Support Devices cont.

c. Percutaneous VADs (pVADs)

Cardiogenic shock is a hemodynamic problem characterized by impaired cardiac output leading to reduced systemic perfusion, increased residual volumes in both ventricles and increased cardiac filling pressures. A primary treatment for cardiogenic shock is circulatory support that increases mean arterial pressure and microvascular perfusion, ventricular unloading and myocardial perfusion.



Tandem Heart

In patients who have developed heart failure as a result of heart surgery or a heart attack, percutaneous ventricular-assist devices (pVADs) are one strategy to achieve this cardiogenic shock treatment goal in the acute setting from a few hours up to 14 days. Because they offer more hemodynamic support than the 40-year-old gold standard of intra-aortic balloon pumps (IABPs), the use of pVADs has increased over the past several years. During the first critical weeks post-op, a pVAD gives a patient's heart time to heal and strengthen, and potentially regain its former function. Percutaneous VADs are also now being used as a bridge to a definitive long-term therapy.

Percutaneous VADs feature a continuous flow pump in an extracorporeal circuit with various deployment configurations customized to support either the left or right heart. The TandemHeart (Cardiac Assist Inc., Pittburgh, PA) uses a centrifugal pump to draw blood from the left or right atrium into an extracorporeal circuit that returns blood into the femoral artery to increase mean arterial pressure and microvascular perfusion. The Impella (AbioMed Europe, Aachen, Germany) uses an axial pump that is inserted retrograde across the aortic valve via the femoral artery.

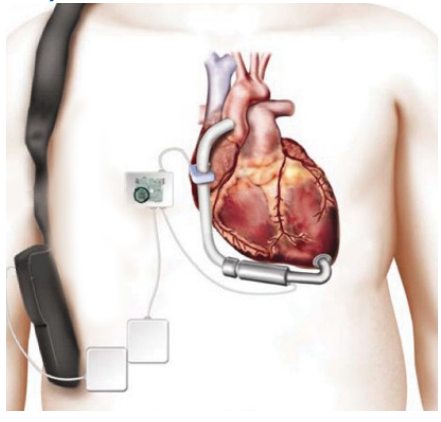
During the development and testing phases of pVADs, simulated flow models that depend on Transonic tubing measurements, test the devices at each stage of their development.

2. Permanent Mechanical Circulatory Support Devices

a. Ventrciular Assist Devices (VADs)

Patients with non-reversible, progressive, chronic heart failure may be placed on long-term implantable heart ventricular assist devices (VADs) as a bridge to destination or heart transplant.

During the development of VADs over the past quarter century, flow measurements have been used to test virtually all devices in mock circulatory models on the bench and *in vivo.* One VAD, Reliant's HeartAssist5®, has taken flow measurement one step further and has incorporated true flow measurement in its final clinical product.



HeartAssist5 VAD implant showing customized Flowprobe on its outflow cannula.

Innovative Development

Development of the heartAssist5 began as the DeBakey axial-flow VAD in 1988 through a collaboration with Drs. Michael E. DeBakey, George P. Noon, NASA engineers, and Baylor College of Medicine.

MicroMed was formed in 1996 to continue the VAD development with *in vitro* and *in vivo* animal testing, before proceeding to clinical trials. Titanium pumps the size of a cigarette lighter, were devised for adults and children. Their flow rates reached 10L/min with revolutions per minute (rpm) ranging from 7,500 to 12,500. From the outset, A Transonic flowboard was incorporated into the VAD for continuous realtime flow measurements. The first human implant of the MicroMed DeBakey Noon VAD in November 1998 was in Berlin, Germany, and then in the United States in 2002.

Although originally meant to be used as bridges to transplants, some VADs are now considered implanted for life or as "Destination therapy." After being tested in Europe and the Middle East, Reliant's HeartAssist5® VAD, with its Transonic True Flow feature, is now seeking FDA clearance for use in the United States.

2. Permanent Mechanical Circulatory Support Devices

b. Artificial Hearts

Javik 2000 Total Artificial heart

The 1980s was a milestone decade in the development of artificial hearts for permanent use in cardiac failure patients. In 1982, retired dentist Barney Clark received an artificial heart at the University of Utah and survived for 112 days. By 1985, five more implantations of the Jarvik 7 artificial heart had been performed. William Schroeder was the longest survivor, living for 620 days with the Javik 7 heart. By the end of the decade, surgeons at 16 centers had used the Jarvik 7 as a bridge to heart transplantation in more than 70 patients. In 1988, Jarvik Heart, Inc. and the Texas Heart Institute began developing the second generation Jarvik 2000 Heart.

Cardiovascular explorer George Pantalos

From the outset, cardiac pioneers such as Dr. Michael DeBakey recognized the need to measure and verify flow in these innovative artificial heart devices and incorporated Transonic flow measurement in the first MicroMed artificial hearts developed with NASA. The current version ReliantHeart5 still boasts this competitive advantage of offering True Flow.

Cardiovascular Explorer George Pantalos

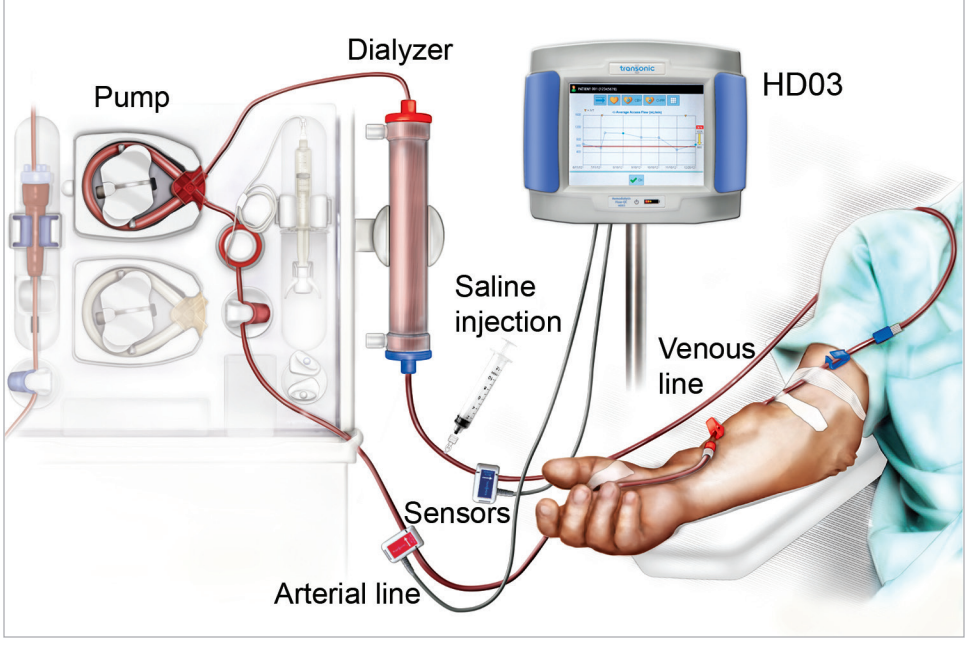
The painstaking development of artificial hearts to replace failed human hearts coincides with development of robust mock circulatory systems that mimic human circulation. Transonic's longtime collaborator and cardiovascular explorer George M. Pantalos, Ph.D. has been instrumental in developing such circulatory systems, first at the University of Utah and now as Professor of Cardiovascular, Thoracic Surgery and Bioengineering at the University of Louisville, KY.

Throughout his career, which has included flying 27 research missions on the NASA Zero-G airplane, Dr. Pantalos has tried to understand cardiovascular function by treating heart failure with mechanical devices including artificial hearts and ventricular assist devices, which he has helped develop, test and implement clinically in patients.

He and other artificial heart developers have depended on Transonic's highly accurate tubing measurements to verify flow every step of the way in mock tubing circuits, including an artificial heart which has flown twice on the Space Shuttle Discovery.

B. Delivered Blood Flow during Hemodialysis

More than twenty-five years ago, renown nephrologist Dr. Thomas Depner studied the wear and cavitation of tubing at different pressure pump settings and recognized that actual pump flow can differ from a pump's setting during hemodialysis. He requested a way to independently measure delivered blood flow to verify the flow set by the pump during prolonged blood pump procedures such as dialysis and ECMO. Not only did his observation spur development of the Transonic Hemodialysis Monitor that measures delivered pump flow directly with transit-time ultrasound Flowsensors applied to the outside of dialysis lines, but also to the incorporation of Transonic Flowboards and Flowsensors into various dialysis machines.

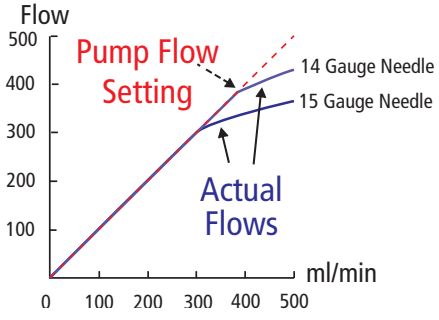


Schematic of Transonic HD03 Hemodialysis System with its touch screen computer/monitor and Flow/dilution Flowsensors clipped onto the arterial and venous tubing lines.

B. Delivered Blood Flow during Hemodialysis cont.

Delivered blood flow is measured because a sufficient access flow rate is necessary for dialysis to occur and to maintain the patency of the access. Delivery of the prescribed dose of dialysis closely correlates to the amount of blood cycled through the dialyzer and therefore, to the rate of delivered blood flow

Delivered blood flow is expected to be within 10% of the dialysis pump setting so that the fluid's mechanical shear force will delay stenosis and subsequent thrombosis by working against the body's clotting mechanisms.



Discrepancy between delivered blood flow and the pump setting can be caused by: negative pressure effects of the roller pump; access condition; needle size and placement; kinked or occluded tubing; calibration of dialysis machine or sensors.

Delivered blood flow (the blood flow in the dialysis lines) can be different than the pump setting due to:

- negative pressure effects of the roller pump;
- condition of access;
- needle size;
- site of needle placement in the access;
- kinked or occluded tubing;
- calibration of dialysis machine;
- change in type of dialysis tubing;
- calibration of flow/dilution sensor.

Large delivered blood flow discrepanies between the pump and the monitor can be diagnosed by turning the pump speed to 200 mL/min. At this speed, the Monitor's delivered blood flow reading should correspond to the dialysis pump setting

At high pump settings, it is not uncommon to see a difference between the two due to the size of the access needle, for larger diameter needles (15G) deliver flow more efficiently than smaller diameter needles (16G).

B. Delivered Blood Flow during Hemodialysis cont.

Underdelivery of prescribed blood flow may also be caused by the site of needle placement in the access. The tip of the arterial needle may be too close to the vessel wall.

If the arterial needle is not directed toward incoming access flow, it may also be difficult to achieve high delivered blood flow.

Transonic Flow-QC® and Catheter Hemodialysis Dose Delivery

Even though central venous catheters carry a considerable risk of thrombosing and harboring infection, 75% of hemodialysis patients receive catheters at some point in their treatment, either to initiate hemodialysis or for permanent hemodialysis delivery. The National Kidney Foundation's Kidney Dialysis Outcomes Quality Initiative (KDOQI) Guidelines define central venous catheter dysfunction as failure to attain and maintain blood flow sufficient to perform hemodialysis without significantly lengthening hemodialysis treatment. Guidelines recommend catheter blood flow be maintained at more than 300 mL/min to ensure adequate hemodialysis.

One potential pitfall of using central venous catheters is that a tissue flap and/or fibrin sheath can block the lumen of the catheter's arterial entry port, and impede flow thereby causing a severe drop in dialysis dose delivery. This can be identified and corrected via the Flow-QC® Delivered Blood Flow Test.

Flow-QC® Delivered Blood Flow Test with Catheters

During hemodialysis, Transonic Delivered Flow is conpared with the dialysis pump setting. If the disparity is more than 10%, kinked tubing, a tissue flap and/or fibrin sheath may be causing possible inflow obstruction and reduced dose delivery. Check the tubing for kinks and/or reverse the dialysis lines

Again compare Transonic Delivered Flow with the machine pump setting. If the two are now within 10%, dialysis may be continued with the lines in this configuration. If a large discrepancy between the two readings persists, central venous catheter failure may be indicated and the nephrologist should be alerted.

C. "Transonic Inside" in OEM Devices

Transonic began partnering with outside companies as an original equipment manufacturer (OEM) shortly after the company's inception in 1983. Such robust Transonic/customer synergy is part of Transonic's DNA and is at the heart of the development of all Transonic products.

Transonic's transit-time ultrasound technology demonstrates clear advantages over other technologies. Transonic's Tubing Flowsensors, developed in 1987, measure volume flow of water, saline and blood analogs like glycerin & water solutions used to mimic the viscosity of blood and best assess pump designs on the bench. Transonic offers its OEM customers: capability, functionality, confidentiality, know-how and a proven track record of successful OEM projects.

For extracorporeal devices, the Clamp-on Tubing Flowsensors have no contact with the fluid and keep circulating blood sterile. Transonic's OEM applications range from the use of standard Transonic products straight off the shelf to customized novel devices that wouldn't usually be recognized as a Transonic device.

Products that use Transonic customized OEM Flowsensors and Flowboards include the following:

- Heart Lung Machines
- Organ Preservation Apparatuses
- Artificial Organs
- Infusion/Transfusion/Perfusion Systems
- Ventricular Assist Devices
- Dialysis Systems
- CP Bypass Pumps/ECMO
- Ophthalmic Microsurgery Systems.

IV. Transonic Tubing Measurement Systems

Depending upon the application in which flow measurement through tubing is intended, there are several Transonic flow system combinations including Flowmeters, Monitors and Flowsensors that offer the capability to measure true volume flow through sterile tubing.

Both the HT110 Bypass Tubing Flowmeter and Surgical Optima Flowmeters use Clamp-on Tubing Flowsensors to measure flow within sterile tubing with gold standard transit-time ultrasound technology.

The needs of Original Equipment Manufacturers are met with customized transit-time ultrasound Flowboard and Flowsensor systems.

In the dialysis unit, the HD03 Monitor and H4FX Flow/dilution sensors measure delivered blood flow through dialysis tubing as well vascular access recirculation, vascular access flow and cardiac output after a saline injection. Similarly, in critical care units, the ELSA Monitor with its FX Sensors measure true volume flow through ECMO circuits in addition to recirculation and oxygenator clotting after a bolus of saline has been introduced.

In this chapter each of these flow measurement systems will be described along with their specifications.

HT110 Bypass Flowmeter

Single-channel Optima® Flowmeter

HD03 Hemodialysis Monitort

HC101 ELSA Monitor

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A Transit-time Ultrasound Systems

1. HT110 Bypass Flowmeter

The Transonic HT110 Bypass Flowmeter is the flowmeter of choice to measure volume flow rates of blood or perfusate in extracorporeal circuits. It provides non-invasive volume flow measurement over a wide dynamic range. Measurement accuracy and resolution are unmatched.

HT110 Flowmeter

An external H_XL Clamp-on Flowsensor clips onto the tubing to continuously monitor actual flow delivery to the patient.
Measurements are non-invasive, continuous and bi-directional.

The Flowmeter/Flowsensor system

- Displays actual volume flow in mL or L/min
- Measures blood, saline, and cardioplegia
- Maintains sterility of liquids
- Custom sensor calibration is available for different fluids and temperature combinations
- Easily customized for specialized applications

Optional

Sensors are calibrated for specific tubing densities and temperature. The HT110s have the capability to specify, when ordering, up to four tubing, fluid, temperature, and flow rate combinations. Fluid samples and MSDS information are required for custom calibration requests.

A Transit-time Ultrasound Technology Systems cont.

2. Optima Flowmeters (HT350-360 Series)

Although used primarily with Perivascular Flowprobes for flow measurements in vessels or grafts during surgery, Optima Flowmeters can also be used to provide non-invasive volume flow measurement in tubing. They accommodate HQ-XL Tubing Sensors to measure flow of blood or perfusate in extracorporeal circuits such as with the CP Bypass.

An external Clamp-on Flowsensor clips onto the tubing to continuously monitor actual flow delivery to the patient. Measurements are non-invasive, continuous and bi-directional. Transonic Optima® Flowmeters provide immediate, quantitative flow measurements to ensure vessel and graft patency with unsurpassed accuracy and resolution.

HT353 Single-channel Optima® Flowmeter

HT364 Dual-channel Optima® Flowmeter permits simultaneous measurements with two Flowprobes or Flowsensors.

Key-activated and Keyless Systems

- Universal System: HT353 single-channel and HT363 dual-channel Flowmeters for purchase. No keys required for use.
- Key-activated HT354 single-channel and HT364 dual-channel Flowmeters for US and Canada placement. An Optima Key is required for each use.

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A Transit-time Ultrasound Technology Systems cont.

3. H_XL & HQ_XL Clamp-on Tubing Flowsensors

HQ_XL-Series Clamp-on Tubing Flowsensor

Innovative transit-time ultrasound technology revolutionized blood flow measurements in medical tubing with Clamp-on Tubing Flowsensors that clip onto the outside of flexible tubing to measure the true volume flow within. By providing non-invasive measurement with high accuracy and stability, they have become the standard for extracorporeal flow verification in challenging clinical environments where sterility must be maintained.

The Flowsensors do not break circuit sterility and can measure most fluids including saline, cardioplegia, and blood. No physical contact is made with the fluid media. HXL-Series Flowsensors can be calibrated and programmed for any fluid / temperature / tubing combinations.

Sensors are scaled in 1/16 inch increments to clamp around standard tubing diameters. Transmitting the ultrasound signal through the tubing wall requires a snug, compressive fit, so the Sensor size is determined by outside diameter of the tubing.

Tubing

Flexible medical grade tubings (PVC, silicon, polyurethane) are generally compatible for use with -XL Sensors. A 50 cm tubing sample is required to calibrate the Sensor(s).

Fluid/Temperature Calibration

Fluid temperature and density alter the transit time of an ultrasound signal and can affect the acoustic properties of tubing. Therefore, H_XL Tubing Sensors are calibrated specifically for these parameters. Operational fluid temperature should be within ±2 degrees Celsius of the specified calibration temperature.

Transonic issues a Calibration Certification for Transonic XL-Series Tubing Sensors certifying that the Sensors are calibrated to within ± 10% absolute accuracy (true flow) and have a specified relative accuracy (linearity) of ± 4% of flow reading after the zero offset is nulled. If ordering Tubing Sensors for use with the HT110 Bypass Flowmeter, up to four tubing, fluid, temperature and flow rate combinations can be ordered.

3. HQ_XL Clamp-on Tubing Flowsensors cont.

HQD - XL Sensors (Inches)			
Catalog #	Tubing		
	ID inches	Wall Thickness inches	OD inches
HQD2XL	In sizes 2XL-5XL ratio of tubing wall thickness to OD must not exceed 1.5 for PVC; 1:3 for silicone		1/8
HQD3XL			3/16
HQD4XL			1/4
HQD5XL			5/16
HQD6XL	1/4	1/16	3/8
HQD7XL	1/4	3/32	7/16
HQD8XL	3/8	1/16	1/2
HQD9XL	3/8	3/32	9/16
HQD10XL	1/2	1/16	5/8
HQD11XL	1/2	3/32	11/16
HQD12XL	1/2	1/8	3/4

HQD - XL Sensors (metric)	
Catalog #	OD mm
HQD2XL-M2	2 mm
HQD2XL-M3	4 mm
HQD3XL-M5	5 mm
HQD4XL-M6	6 mm
HQD5XL-M7	7 mm
HQD6XL-M8	8 mm
HQD7XL-M9	9 mm
HQD8XL-M10	10 mm
HQD9XL-M12	12 mm
HQD10XL-M14	14 mm
HQD11XL-M16	16 mm
HQD12XL-M20	20 mm

STOCK TUBING			
Procedure	Cat #	TUBING (inches) Inner Diameter Wall Thickness	Tygon Stock Tubing: If using tubing of different diameter or type, please discuss tubing with a customer service representative.
CAROTID SHUNTS	HQD 2XL	3/32 x 1/32	Tygon ND 100-65; Tygon E-3603
	HQD 3XL	1/8 x 3/32	Tygon E-3603
	HQD 4XL	1/8 x 1/16	Tygon ND 100-65; Tygon E-3603
	HQD 5XL	3/8 x 1/16	Tygon ND 100-65; Tygon E-3603
PED CPB, ECMO	HQD 6XL	1/4 x 1/16	Tygon ND 100-65; Tygon E-3603
	HQD 7XL	1/4 x 3/32	Tygon ND 100-65; Tygon E-3603
	HQD 8XL	3/8 x 1/16	Tygon ND 100-65; Tygon E-3603
ADULT CPB	HQD 9XL	3/8 x 3/32	Tygon ND 100-65; Tygon E-3603
	HQD 10XL	1/2 x 1/16	Tygon ND 100-65; Tygon E-3603
	HQD 11XL	1/2 x 3/32	Tygon ND 100-65; Tygon E-3603

3. H_XL Clamp-on Tubing Flowsensors

Accuracy Specifications

Sensor Size	Bidirectional flow outputs		System Accuracy Specifications		ultrasound frequency
	resolution[1]	max flow	max zero offset	Absolute Accuracy	
	mL/min	5V output in L/min	mL/min	% of reading	MHz
H2XL	0.5	1	± 5.0	± 10	3.6
H3XL	1.0	2	± 10.0	± 10	3.6
H4XL	1.0	2	± 10.0	± 10	2.4
H5XL	1.0	2	± 10.0	± 10	2.4
H6XL	2.5	5	± 30	± 10	2.4
H7XL	5	10	± 60	± 10	1.8
H8XL	5	10	± 60	± 10	1.8
H9XL	5	10	± 60	± 10	1.8
H10XL	10	20	± 120	± 10	1.2
H11XL	10	20	± 120	± 10	1.2
H12XL	10	20	± 120	± 10	1.2
H14XL	25	50	± 300	± 10	1.2
H16XL	25	50	± 300	± 10	1.2
H20XL	50	100	± 600	± 10	0.9

Calibration is dependent on tubing material, wall thickness, ultrasound velocity of liquid flowing through the tube & temperature.

1. Resolution represents the smallest detectable flow change at 0.1 Hz filter (average flow output).
2. Absolute accuracy is comprised of zero stability, resolution and zero-offset effects. Stated values apply when flow rate is greater than 5% of maximum range and zero offset is nulled.

Cleaning and Sterilization

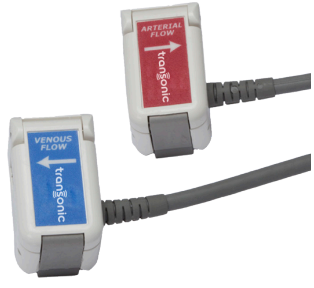
Care should be taken to avoid scratching the Flowsensor. Tubing Flowsensors may be cleaned with a solution of mild soap and warm water (<55° C). Do not use harsh abrasives. H–XL Tubing Sensors may be sterilized with EtO gas.

B Transonic Flow/Dilution Monitoring Systems

1. HD03 Hemodialysis Monitor

The HD03 Hemodialysis Monitor is used to optimize dialysis delivery by measuring delivered pump blood flow and recirculation, each of which can compromise delivery of a KT/V prescription. The Monitor is also used to optimize dialysis through central venous catheters by helping to establish a maximum dialysis pump setting before recirculation occurs.

HD03 Hemodialysis Monitor



H4FX PairedFlow/Dilution Sensors

True Delivered Blood Flow Verified by Transit-Time Ultrasound

Underdialysis is often caused by poor delivered blood flow. When Flow/Dilution Sensors are clipped onto the arterial and venous bloodlines during hemodialysis, the HD03 Monitoring System measures Delivered Flow with gold standard transit-time ultrasound technology. The measurement immediately displays on the Monitor's screen. By comparing the flow reading of Transonic actual delivered blood flow with the dialysis pump's setting, dialysis delivery problems can be quickly identified and resolved.

1. HD03 Hemodialysis Monitor cont.

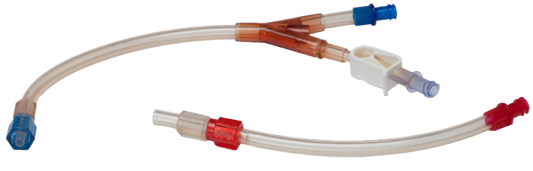
Tubing Selection

Tubing sensors are sensitive to differences in tubing brands and the accuracy decreases if the sensor is not calibrated for the specific tubing being used. In general, the accuracy of the Transonic® Delivered Blood Flow reading is ± 6%. Other possible causes for pump and hemodialysis monitor blood flow discrepancies could be:

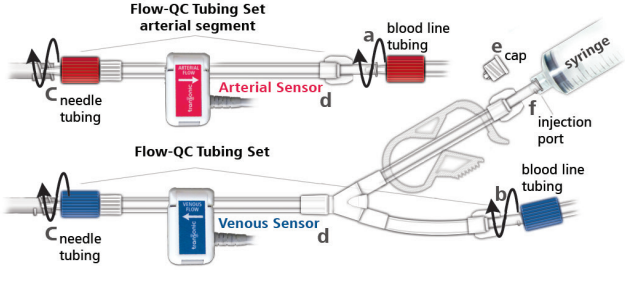
- the dialysis machine is not in calibration
- the arterial needle tip is too close to the vessel wall.

If the HD03 Monitor's and HD pump's delivered blood flow readings do not agree at the 200 mL/min pump setting, check the tubing selection on the monitor to make sure it matches the dialysis tubing being used.

Cardiac Output measurements with the HD03 Hemodialysis Monitor require the use of proprietary Flow-QC® Clear Advantage tubing segments on which the arterial and venous Flow/Dilution Sensors are applied. By standardizing this tubing for the sensors' application, the highest accuracy for the fluid measurement within the tubing is ensured. Saline injection is made into the Flow-QC® tubing injection port.



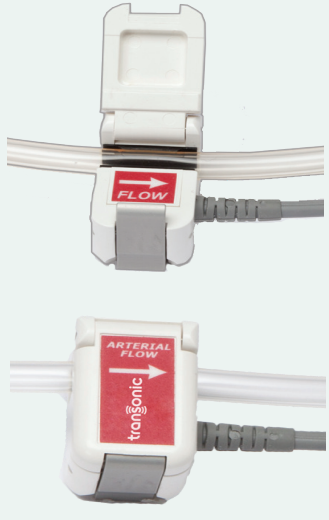
Flow-QC Clear Advantage Tubing segments



1. HD03 Hemodialysis Monitor cont.

Flow/Dilution Sensor Set-up

1. Open the door of the first paired Flow/dilution Sensor.
2. Place the tubing segment to be inserted next to the Flow/dilution Sensor. The arrow on the Sensor must point in the direction of flow.
3. Open a 70% isopropyl alcohol wipe (prep pad).
4. Wipe the entire circumference of the tubing segment which will be inserted into the Flow/dilution Sensor.
5. Immediately insert this tubing segment into the Flow/dilution Sensor
6. Close the Tubing Sensor door.
7. Repeat the same sequence [Wipe, Insert, Close Door] for the second paired Flow/dilution Sensor and tubing segment.
8. Verify Signal Strength indicator on the upper left of the Hemodialysis Monitor screen is green when the Monitor has been turned on. This means that the paired Flow/dilution Sensors have adequate contact with the tubing. If the Signal Strength indicator is not green, repeat the sequence [Wipe-Insert-Close door] to achieve proper contact.



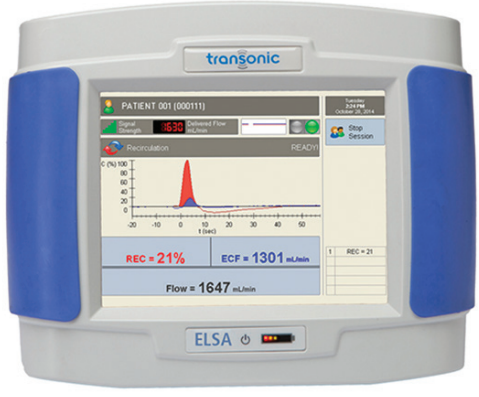
Open and closed arterial Flow/dilution Sensor on tubing.

Note: If you are using Flow-QC® tubing, place the arterial sensor in the center of the arterial Flow-QC segment and the venous sensor in the center of the venous Flow-QC segment.

B Transonic Flow/Dilution Monitoring Systems

2. HC101 ELSA® ECMO Monitor

The HC101 Extracorporeal Life Support Assurance (ELSA) Monitor system consists of a touch screen Monitor with an integrated computer, a pair of Flow/Dilution Sensors and a Data Transfer Module that stores patient data. The ELSA system provides clinically relevant data to healthcare providers treating neonatal, pediatric, and adult patients with arterial and venous sensors.



HC101 ELSA® Monitor

When Flowsensors are clipped onto the arterial and venous bloodlines, the system measures Delivered Blood Flow with gold standard transit-time ultrasound technology to compare against the pump flow setting. Pump flow is immediately displayed at the bottom of the Monitor.

Paired ELSA H_FX Flow/dilution Sensors

2. HC101 ELSA® ECMO Monitor cont.

Paired Transonic HnFX Flowsensors use an X configuration, four-crystal design to pass ultrasound waves through the tubing to measure blood flow and recirculation. These Flowsensors are available in three sizes:

- H6FX Flowsensors for use with ID x OD = 1/4" x 3/8" tubing;
- H7FX Flowsensors for use with ID x OD = 1/4" x 7/16" tubing;
- H9FX Flowsensors for use with ID x OD = 3/8" x 9/16" tubing.

The Flowsensors are calibrated to Tygon ND 100-65 tubing as a standard, but could be calibrated to different tubing materials per user request.

Flowsensor	Tubing Size (Inches)		Flow Range (L/min)
	ID	OD	
H6FX	1/4	3/8	0-5
H7FX	1/4	7/16	0-10
H9FX	3/8	9/16	0-10

Measurement	Delivered Flow
Range	-2 to +2 L/min
Accuracy	± 6% of the flow reading ± the zero offset
Maximum zero flow offset:	± 10 ml/min

Flowsensor	Max Zero Offset	Absolute Accuracy*	Relative Accuracy	Ultrasound Frequency
H6FX	± 30 mL/min	10%	± 4%	2.4 MHz
H7FX	± 60 mL/min	10% or ± 50 mL/min whichever is larger	± 4%	1.8 MHz
H9FX	± 120 mL/min	10%	± 4%	1.8 MHz

** Absolute Accuracy consists of zero stability, sensitivity and linearity errors. Stated values apply when zero offset is nulled.*

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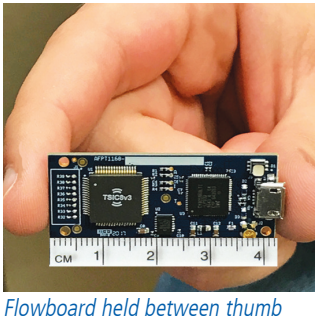
C. Transonic OEM Flow Systems

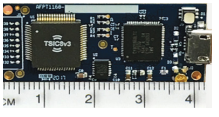
OEM Custom Flowboards

Customized Transonic® Flowboards mount inside an OEM's device, drawing power from the device's power supply and connecting to standard or customized Transonic Flowsensors.



Flowboard held between thumb and forefinger.

Transonic offers several choices for baseline boards which can be further customized. Transonic also designs custom boards may be to meet specific form or function requirements.



4 cm long Flow chip

OEM Flowmeter boards are usually derivatives of standard Transonic Flowmeters which can provide the following:

- Any standard Transonic Flowmeter feature, including volume flow sensing, bubble detection, liquid properties measurement, sensor diagnostics, etc.
- Customer specified "CHECKSUM" assignment to accept only the customized Flowsensor selected by the OEM.
- Analog or digital functionality and data output.
- Communication protocols to fit the OEM's needs.
- Board-to-board interconnects which can be modified to meet the OEM's needs.

All Transonic OEM Flowmetering modules and Flowsensors are manufactured under FDA's Good Manufacturing Practices (GMP) and ISO13485:2003 guidelines.

C Transonic OEM Flow Systems

Custom H_XL Tubing Flowsensors

Transonic® Tubing Flowsensors clip on to the outside of flexible tubing to measure the volume flow of blood, water, and most non-aerated liquids including saline and buffer solutions. The reusable Flowsensor has no contact with liquid, thereby preserving the flow dynamics and sterility of the fluid. Flowsensors use advanced ultrasonic flow illumination designs to provide reliable, stable measurements even under turbulent and non-steady flow conditions.

Clamp-on Tubing Sensor without label so that OEM customer can have private label

Customized Transonic® Flowsensors typically derive from a standard Transonic Flowsensor to minimize re-engineering costs. The sensors are:

- Labeled and numbered as products of the customer (to assure that service and re-ordering proceeds via the customer);
- Customized with connector and cable for the customer;
- Calibrated for customer use conditions;
- Programmed to be compatible only with the customer's Flowboard or a standard Transonic Flowmeter for test and quality control purposes. This prevents cross connection and use with any other Transonic customer's OEM Flowsensor which might be physically compatible, but may be calibrated for different tubing-fluid-temperature situations.

XL Style Flowsensors

- Reusable clamp-on sensor with no fluid contact
- Calibrated for specific tubing size, material, fluid and temperature
- Available for flexible plastic tubing from 1/8" to 1 1/4" OD (inch or metric sizes)

Keyed, custom connectors can also be specified which would further assure no other Flowsensors could connect in place of the desired Flowsensors.

- Precision measurements in any flow condition;
- Stable low zero offset & increased accuracy under conditions of turbulent flow;
- Excellent frequency response for pulsatile flow analysis.

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Appendix: Fluid Dynamics

Tubing flow is governed by laws of conservation including the conservation of mass, conservation of linear momentum or Newton's Second Law of Motion, and conservation of energy or the First Law of Thermodynamics.

Pressure and Volume

Pressure equals the product of a fluid's density, gravitational force and height of the fluid column. It is the force exerted by a fluid against any unit area of a tube's wall as expressed in millimeters of mercury (mmHg). Volume is the quantity of fluid that passes a given point in a given period of time as expressed in ml/min or L/min.

Poiseuille's Law

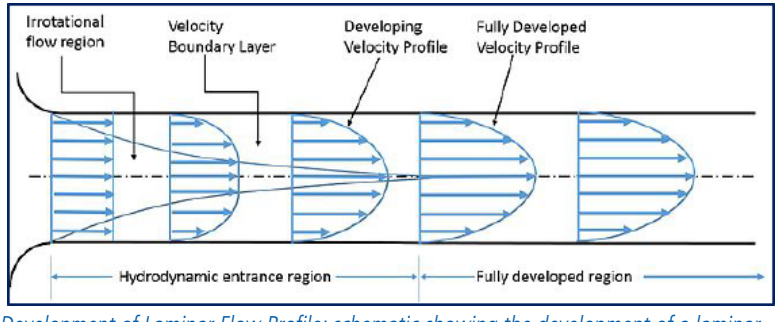
In the 1840s, Poiseuille predicted that the pressure gradient across a vessel varies directly with a fluid's flow, its viscosity and the length of the tube, and varies inversely with the radius of the vessel.

$$Q = \frac{\pi \mathrm{Pr}^4}{8\eta l}$$

Q = flow
P = Pressure
r = radius
n = fluid viscosity
l = length of tubing

Laminar Flow and Friction

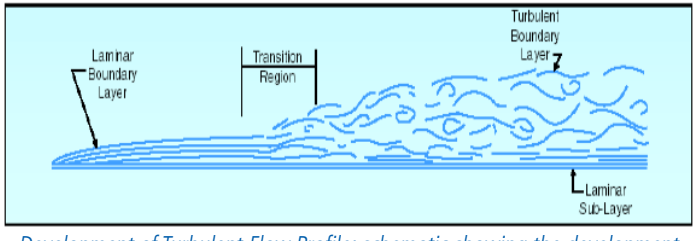
When blood flows at a steady rate through a long smooth tube, it flows in layers or concentric laminae, with each layer of fluid remaining the same distance from the wall of the tube. The velocity of the flow laminae at the center of the tube is much greater than those at the outer edges where wall friction causes fluid molecules to touch and adhere to the tube's wall.



Development of Laminar Flow Profile: schematic showing the development of a laminar velocity flow profile with the laminae at the center of the tube or vessel moving quicker at higher velocities than the laminae near the walls of the tube where friction causes the flow molecules to touch and adhere.

Inertia and Viscous Forces

When a pump propels fluid forward in a tube, its momentum is its inertial force. The denser a fluid and the higher its velocity, the more momentum or inertia it has. A force that counteracts this inertial force is a viscous force caused by the friction from closely packed fluid particles between a fluid's concentric laminae layers. The ratio of the a fluid's inertial force to its viscous force is known as the Reynolds number (Re). In straight, smooth tubes and vessels, flow will be laminar at Re <2,000, turbulent at Re > 4,000 and in transition between laminar and turbulent between these values (see figure below).



Development of Turbulent Flow Profile: schematic showing the development of a turbulent velocity flow profile with, at high velocities, the laminae change from parallel layers to whirls and eddy currents when the flow passes an obstruction of bend in the tubing.

Turbulent Flow

When the flow passes an obstruction or makes a sharp turn at high velocities, it may become turbulent and start moving across the vessel in whirls or eddy currents rather than in concentric laminae.

Stenoses

At low velocities laminar flow can be maintained if there is a blockage in the flow. However, at higher velocities turbulent flow will result as the flow moves past a stenosis. Transonic's four-crystal sensors are specifically designed to measure flow under turbulent flow conditions as well as laminar flows (see next page).

Appendix: Glossary of Terms

ACCURACY: the quality of adhering closely to a standard of correctness.

ABSOLUTE ACCURACY: the accuracy of an instrument's measurement at most physiological flows; offset error is insignificant compared to slope error. The term absolute accuracy has therefore evolved as a synonym for the range of error resulting from an incorrect slope.

RELATIVE ACCURACY: the accuracy of the instrument: often a linear correction with a slope and offset. Relative accuracy is often known as linearity.

ACOUSTIC WINDOW/ FIELD: the area defined by the pathway of the ultrasound beam between the transducers in the Flowprobe body and the acoustic reflector.

ANALOG OUTPUT SIGNAL: voltage output corresponding to the parameter measured by a device. The signal generated is calibrated by a scaling factor. The voltage range of Transonic ultrasound Flowmeters is -5 to +5 volts DC with 1 volt equivalent to full scale of the Flowsensor used.

APPLICATIONS: documented uses for Transonic Flowmeters.

BI-DIRECTIONAL FLOW: flow measured in positive and negative directions.

BI-DIRECTIONAL ILLUMINATION: with ultrasonic transit-time, Transonic Flowprobes, a tube or vessel is positioned between transducers which generate wide beams of ultrasound to fully illuminate the vessel or tube. The ultrasound beams alternately intersect the flowing liquid in upstream and downstream directions. The Flowmeter derives an accurate measure of the changes in "transit time" (time it takes for the wave of ultrasound to travel from one transducer to the other) influenced by the motion of the liquid.

CALIBRATION: *(often misused as a synonym for validation)*
In Situ: adjustment or correction made to a measurement device for errors produced under actual conditions of use by comparing the measurement with a known standard.
In Vivo: adjustment or correction made to a measurement device during use in a living body.

CHECKSUM: A calibration factor stored in a Flowsensor's EPROM memory.

CLAMP-ON TUBING FLOWSENSOR: A sensor that is applied to the outside of flexible plastic tubing that measures the flow moving through the tubing.

ECMO: Extracorporeal Membrane Oxygenation mechanical circulatory support.

ELSA MONITOR: Extracorporeal Life Support Assurance Monitor that measures delivered flow, recirculation and oxygenation clotting with ultrasound dilution technology during ECMO.

ELECTRICAL ISOLATION: grounding of the Flowmeter's circuitry to prevent accidental electrical conductance between the Flowmeter and the subject.

EPROM: (Acronym for "electrically erasable programmable read only memory") programmed component that contains the identification and calibration information specific to each Flowsensor.

EXTRACORPOREAL: measurements outside a body.

FILTERS: in electronics, a circuit that only passes certain signals. For blood flow measurement, a low pass filter is often used to

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strip out high frequency noise, leaving only the biological components of interest.

FLOW: volume or velocity movement of a liquid (blood, saline, isotonic solutions) passing a given point in a given time (measured in L/min or ml/min).

FLOW/DILUTION SENSOR: a paired sensor that measures volume flow by transit-time ultrasound technology and concentration of the blood by standard dilution technique. Technology used by Transonic Hemodialysis, COstatus and ELSA Monitors.

FLOW-QC® CLEAR ADVANTAGE TUBING
Custom tubing upon which Flow/Dilution Sensors are applied for Cardiac Output measurements during hemodialysis.

FLOW VELOCITY PROFILE: the distribution of velocity across the vessel.

FLOWMETER: a device for measuring velocity or volume of flow of liquids or gases passing a given point per unit of time. For Transonic Flowmeters, the box which houses the power supply and signal processing circuitry for a digital readout of flow.

FLOWMETRY: the study of flow parameters.

FLOWPROBE/SENSOR: a sensor which measures flow. Ultrasonic transducers within Transonic ultrasound Flowprobes/sensors insonate vessels or tubing to measure volume flow of blood, buffers & other liquids;

FLOWSENSOR: a device which measures the volume of a liquid passing through tubing by transit-time ultrasound technology.

GAIN: a linear factor in electronic circuitry used in a device as a multiplier after calibration. The sensitivity of a Sensor is adjusted by changing the gain.

HEMODIALYSIS MONITOR: Measures delivered flow, recirculation vascular access flow and cardiac output during hemodialysis using flow/dilution technology

HZ: a cycle or repetition per second. In ultrasound: Transonic specification for the frequency of the ultrasound from the sensor crystals is listed in Megahertz (MHz).

INERTIA: In fluid dynamics, inertia is the momentum that propels fluid forward in a tube.

INTRA-AORTIC BALLOON PUMP: A pump connected to a balloon device that is inserted into the aorta to provide temporary assistance to the heart in the management of left ventricular failure.

LAMINAR FLOW: Concentric layers (laminae) of fluid that stay at the same distance from the wall of the tube. The velocity of the flow laminae at the center of the tube is much greater than those at the outer edges where wall friction causes fluid molecules to touch and adhere to the tube's wall.

MECHANICAL CIRCULATORY SUPPORT: Devices or therapies used to augment circulation due to heart failure.

MICROPROCESSOR: miniaturized integrated circuit capable of processing a high volume of signals to report results or control functions of instruments or machines.

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OEM SYSTEMS: Original Equipment Manufacturer (OEM) systems: Transonic custom engineered systems to be embedded within clinical OEM products such as bypass pumps, ECMO apparatus, infusion/transfusion/perfusion systems, dialysis apparatus and organ preservation apparatus.

POISEUILLE'S LAW: a pressure gradient across a vessel varies directly with a fluid's flow, its viscosity and the length of the tube, and varies inversely with the radius of the vessel.

PRECISION: the quality of repeatable recognition of minute changes in measurements. An instrument may be precise but inaccurate or vice versa.

PRESSURE: the product of a fluid's density, gravitational force and height of the fluid column. It is the force exerted by a fluid against any unit area of a tube's wall as expressed in millimeters of mercury (mmHg)

PUMP: Rotary: a pump for transferring water or other fluids by the rotating action of its components.
Axial: a pump with a propeller inside of a tube. It consists of a screw type impeller that spins pushing fluid through the tube.
Centrifugal: a pump having vanes that rotate in a casing and whirl the fluid around so that it acquires sufficient momentum to discharge the fluid.

pVAD: (percutaneous ventricular assist device) a temporary mechanical circulatory support device to bolster a failing heart's performance.

RANGE: the set of numbers between the limits of the maximum and minimum values measurable.

RESOLUTION: the smallest detectable change in flow. Probe resolutions are generally specified at 0.1Hz filtering.

REYNOLD'S NUMBER: The ratio of the a fluid's inertial force to its viscous force. In straight, smooth tubes and vessels, flow will be laminar at Re <2,000, turbulent at Re > 4,000 and in transition between laminar and turbulent between these values.

SAMPLING RATE: number of samples taken per unit of time. In digital signal processing (Nyquist theory), it is necessary to sample twice as fast as the highest frequency component.

SENSITIVITY: amount of voltage output per unit of parameter measured.

SENSITIVITY ERROR: error resulting from incorrect gain. Total error is the sum of sensitivity error and the offset error.

SIGNAL-TO-NOISE RATIO: the ratio of desired signal to undesired noise; often expressed in decibels, a logarithmic scale commonly used by engineers.

TRANSDUCER: a device that transforms a physical parameter into an electrical signal. In a Transonic ultrasound Flowsensor, ultrasound signals generated by piezoelectric crystals are transformed and converted into electrical signals proportional to volume flow.

TRANSIT-TIME: time it takes for a pulse of ultrasound to travel from one transducer to another in a Flowsensor.

TURBULENT FLOW: flow moving in whirls or eddy currents rather than in concentric laminae. Occurs when flow passes a blockage or makes a sharp turn at high velocities,

ULTRASONIC: relating to energy waves similar to those of audible sound but of higher frequency (above 30,000 Hz)

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ULTRASONIC COUPLANT: a material that propagates acoustical waves; for blood flow measurement, a material is chosen that mimics the acoustic characteristics of biological tissue.

ULTRASONIC SIGNAL COUPLING: a term used to describe sound propagation between a transducer and tissue; degraded by air bubbles and materials that do not conduct sound.

ULTRASONIC TRANSIT TIME: a technology to measure volume flow of liquids by using wide-beam illumination; transducers pass ultrasonic signals back and forth, alternately intersecting a flowing liquid in upstream and downstream directions. The Transonic® Flowmeter derives an accurate measure of the "transit time" it took for the wave of ultrasound to travel from one transducer to the other. The difference between the upstream and downstream integrated transit times is a measure of volume flow.

ULTRASOUND DILUTION: a technology which unites dilution and ultrasonic transit time to measure the changes that occur in the velocity of a liquid when diluted with isotonic saline; measures recirculation, access flow and cardiac output during hemodialysis.

VAD: (ventricular assist device) a mechanical circulatory support device to bolster a failing heart's performance as a bridge to transplant or as a "destination therapy."

VALIDATION: test to confirm calibration and accuracy of a measurement, usually by comparing to a known standard such as timed collection.

VISCOUS: A force caused by the friction from closely packed fluid particles between a fluid's concentric laminae layers that counteracts an inertial force.

CROSS BEAM (X) ILLUMINATION: Ultrasonic illumination of a vessel or tube positioned between four transducers that generate wide beams of ultrasound that alternately intersect the flowing liquid in upstream and downstream directions. The Flowmeter derives an accurate measure of the changes in "transit time" of the wave resulting from the motion of the liquid. The integrated difference between the upstream and downstream transit times is a measure of volume flow.

WIDE-BEAM ILLUMINATION: the use of an ultrasonic beam wider than the vessel of interest. Wide-beam illumination is fundamental for volume flow measurement with ultrasonic transit-time technology.

ZERO OFFSET: the measurement registered by the instrument under conditions of zero input. In blood flow, this is the Flowmeter reading when flow is known to be zero due to occlusion of the vessel or other means. A two point calibration can be performed by combining a zero offset determination with a timed collection.

ZERO OFFSET DRIFT: the change in zero offset over time. Caused by fluctuations in a flowmeter's oscillations due to variations in acoustic transit-times as a result of temperature or other liquid property changes that are picked up by a Flowmeter's sensitive receiver amplifiers and detectors.

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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. Transonic® also provides pressure and pressure volume systems, laser Doppler Flowmeters and telemetry systems.

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