Optimize Treatments for Your Pediatric Patients

Extracorporeal ELSA Monitor

- Provides VV ECMO Recirculation
- Verifies Delivered Blood Flow
- Quantifies Oxygenator Clotting

Intra-op & Post-op Volume Flows

- Directly Measures Qp/Qs
- Verifies VAD Performance

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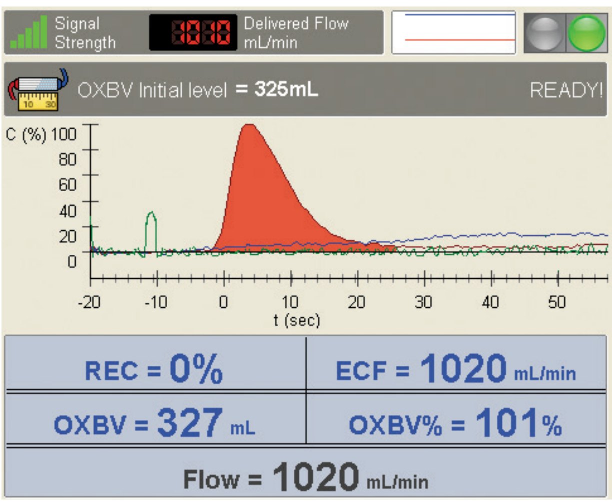
Complementary Measurement Technologies Optimize Pediatric Treatment and Care

Dedicated ELSA Monitor

The new ELSA Monitor uses ultrasound dilution technology to measure Delivered Blood Flow, Recirculation, Oxygenator Blood Volume to indicator oxygenator clotting. With ELSA measurements, a clinician can optimize ECMO delivery by verifying delivered pump blood flow, and identifying and diagnosing any flow limiting causes that might contribute to poor patient outcomes.

Catheter performance can be enhanced by establishing a maximum pump setting before recirculation occurs; using known values for flow and recirculation to minimize the length of ECMO runs; identifying cannula migration through high recirculation rates and possible cardiac output failure during VV ECMO.

Oxygenator clotting can be detected by tracking the progressive decline of oxygenator blood volumes.



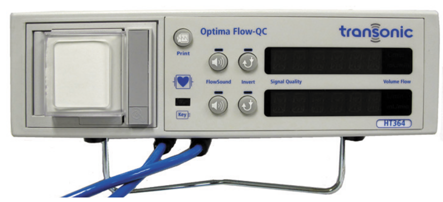
VV ECMO Oxygenator Blood Volume & Recirculation results screen.

COnfidence Flowprobes with Optima/ AureFlo Systems

Transonic's miniature 4 mm and 6 mm COnfidence Flowprobes offer unprecedented flow measurement capability during congenital heart defect (CHD) repairs in young children. The cables are specially oriented to allow for extended measurements in difficult CHD anatomical sites. They work with HT350 and HT360-Series Optima Flowmeters using gold standard transit time ultrasound technology to measure volume blood flow directly within these small blood vessels.

Now surgeons have a quantitative tool with which they can objectively assess the outcome of their surgery intraoperatively and post-operatively. No longer will a pediatric cardiac surgeon have to rely solely on clinical impressions to assess the quality of the surgery during the procedure. This on-the-spot volume flow technology produces flow information quickly, accurately, and non-intrusively. The ability to immediately know flow provides the pediatric heart surgeon with a unique opportunity to determine Qp/Qs during surgery and achieve positive patient outcomes for his or her patient.

6 mm, left, and 4 mm COnfidence Flowprobe are 8 times use.



HT364 Optima single-channel Flowmeter

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Pediatric Cover sheet (CV-800-fly) Rev. A 10/2018 USltr

ELSA Monitor to Optimize Pediatric ECMO Therapy

- Quantify VV Recirculation
- Measure Oxygenator Clotting
- Verify Delivered Blood Flow

Life Saving ECMO

Extracorporeal Membrane Oxygenation (ECMO) is a last ditch therapy to save the "sickest of the sick." Preemies with underdeveloped lungs are placed on ECMO circuits to allow time for their lungs to finish developing. So too are neonates with congenital heart defects who are recovering from corrective cardiac surgery. For these fragile patients, being supported by ECMO will mean the difference between life and death.

This makes it all the more incumbent to use and follow the best practices available with unwavering determination and vigilance during an ECMO run that could last for several weeks.

The Transonic Extracorporeal Life Assurance (ELSA) Monitor offers intensivists a valuable tool with which to monitor ECMO performance, optimize its benefits, and maximize its success in pediatric patients.

ELSA Verifies Delivered Blood Flow

The ELSA Monitor measures true delivered blood flow through the ECMO circuit using "gold standard" transit-time ultrasound technology.

The clip-on sensors transmit beams of ultrasound through the tubing many times per second. Four transducers in each sensor pass ultrasonic signals back and forth, alternately intersecting the flowing blood in upstream and downstream directions.

The ELSA Monitor derives an accurate measure of the changes in the time it takes for the wave of ultrasound to travel from one pair of transducers to the other ("transit time") resulting from the flow of blood in the vessel. The difference between the upstream and downstream transit times within the area of the tubing provide a measure of volume flow. By comparing actual delivered blood flow to the pump's reading, any flow limiting cause such as incorrect cannula placement can be identified on the spot and corrected, allowing optimal blood flow delivery.

ELSAPediatric White Paper (EC-800-wp), Rev B 2018 USltr

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Optimizing Pediatr

Measure Recirculation to Optimize VV ECMO Therapy

Recirculation is a chronic problem for patients on VV ECMO. Cannulas often under-deliver oxygenated blood due to the presence of recirculation.

The Transonic® ELSA Monitor detects and quantifies recirculation in any single or dual-lumen circuit. When a saline bolus is injected upstream from the arterial Flowsensor, the ELSA Monitor identifies the saline bolus at both Flowsensors. This ratio of indicator concentrations equals recirculation. All recirculation measurements are recorded, and can be displayed as a trend.

By having known values for flow and recirculation, cannula migration can be detected and optimized to help avoid extending runs due to correctable recirculation. If cannula positioning is good and therefore not the cause of recirculation, and the patient is being kept dry, low volumes (aka low preload or hypovolemia) could also be the culprit for recirculation.

A third possibility exists when cannula positioning is good and blood volumes are adequate. A failing left heart could cause elevated recirculation. If the ECMO pump is set to deliver 5 liters of oxygenated blood, but the left ventricle is only strong enough to pump 3 liters of blood, the remaining 2 liters will not be taken up by the heart and will be recirculated back to the ECMO circuit. In some cases recirculation may indicate that VA cannulation should be considered to help assist the heart as well as the lungs.

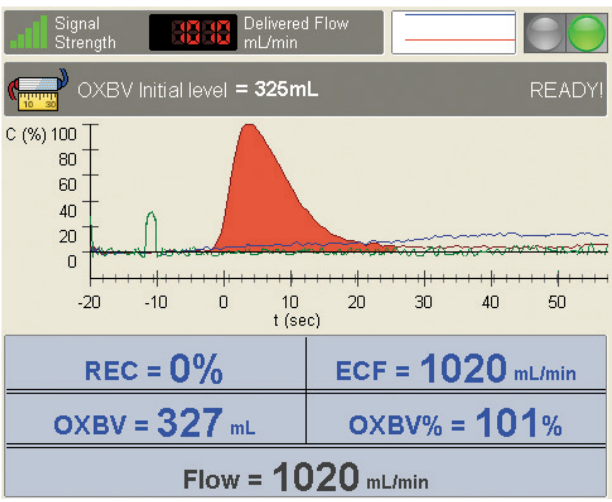


Fig. 1: Oxygenator Blood Volume (OXBV) plus Recirculation Results screen during VV ECMO.

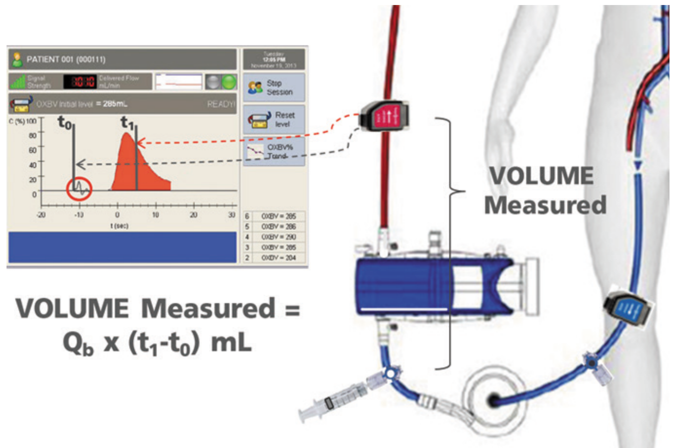
Measure Oxygenator Blood Volume to Detect Clot Formation

Among the many problems facing ECMO team members, persistent clotting is among the most frustrating. Clots within the ECMO circuit can have catastrophic consequences. Circuits are run with low levels of Heparin to reduce the potential for bleeding, but this promotes coagulation. Clot formation is traded for lower stroke risk.

Each ECMO patient is different, requiring different flows, different circuit sizes/branches, and different patient blood chemistry. In some patients, a clot can begin forming within hours. In others, it might take days.

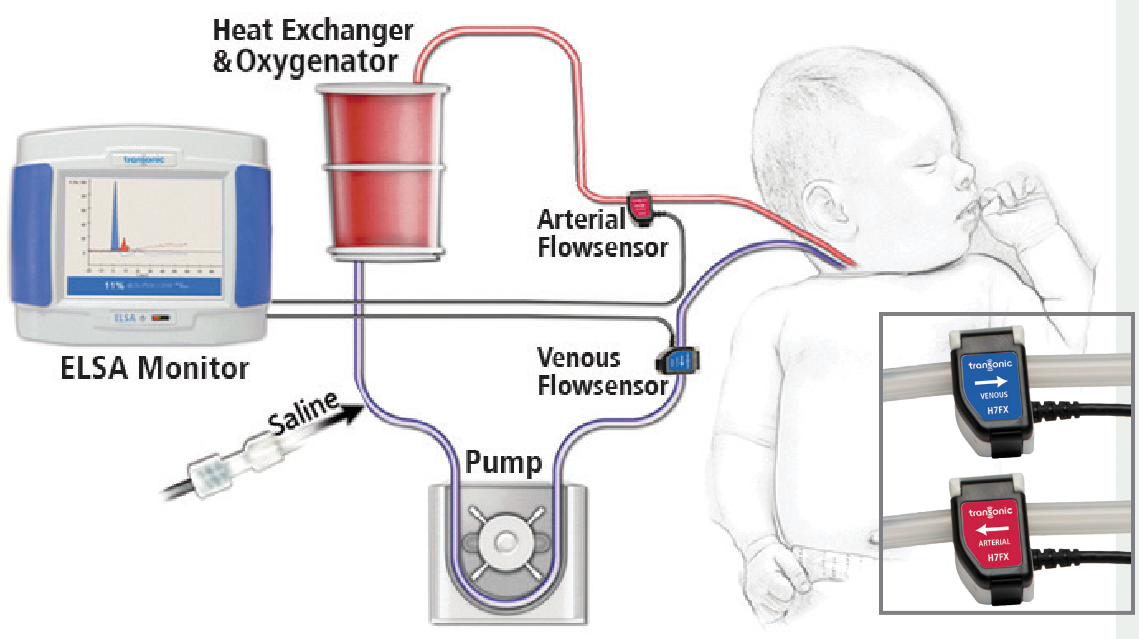
When a bolus of room temp saline; (1 mL/kg from 5mL up to 20 mL), is injected near the inlet of the oxygenator, the ELSA Monitor measures oxygenator blood volume (OXBV) between the injection site and the arterial sensor and displays the result for each injection on a timeline. OXBV decreases as clot volume increases.

Trending is available on 4 hour, 24 hour, or total-case-time screens. The trended curves will help predict when an oxygenator change-out will be necessary. Such foreshadowing of clot formation in ECMO circuits can allow more time for device change outs, before clotting becomes an emergent situation.



The arterial sensor identifies the increase in flow during the injection, and marks the time. When the saline bolus passes the sensor, the difference in wavelength is plotted in red. The flow from the injection to the center of the flow curve represents the total volume between the injection site and the sensor. As a clot increases in size, the blood volume decreases. To make oxygenator volume measurements (slightly) more accurate, an ELSA screen asks for the volume within the tubing between the injection site and the arterial sensor. ELSA will deduct the tubing volume from the total volume, isolating the volume of the oxygenator.

HOW THE ELSA MONITOR WORKS



DIFFERENTIAL TRANSIT-TIME ULTRASOUND MEASURES DELIVERED BLOOD FLOW

Paired clip-on sensors transmit ultrasound through the ECMO circuit many times per second. The transducers within each sensor pass the signals back and forth, alternately intersecting the flowing blood in upstream and downstream directions. The ELSA derives an accurate measure of the changes in the time it takes for the wave of ultrasound to travel from one pair of transducers to the other ("transit time") resulting from the flow of blood in the tubing. The difference between the upstream and downstream transit times and the area of the tubing provide a measure of volume flow.

ULTRASOUND INDICATOR DILUTION

The velocity of ultrasound in blood (1560-1590 m/sec) is determined primarily by its blood protein concentration. The Transonic® ELSA Monitor and its complementary Flow/dilution Sensors measure ultrasound velocity. A bolus of saline (ultrasound velocity: 1533 m/sec) introduced into the circuit dilutes the blood and reduces its ultrasound velocity. The Sensor records this saline bolus as an indicator dilution curve from which the following are derived:

RECIRCULATION

When a saline bolus is injected upstream from the arterial Flowsensor, the ELSA Monitor identifies the saline concentrations at both Flowsensors. The ratio of saline concentrations equals recirculation).

Rec= Sv/Sa*100%; where Sa and Sv are areas under arterial and venous dilution curves respectively.

OXYGENATOR BLOOD VOLUME MEASUREMENT

When a saline bolus is injected upstream from the oxygenator, the time that the indicator takes to travel through the oxygenator is proportional to its blood volume. As a clot forms and grows, volume decreases, and the amount of a clot is identified.

OXBV = Qb * MTT; where Qb is blood flow through oxygenator and MTT is mean transit time of indicator travel through the oxygenator. Percent change of OXBV% in time can be expressed: OXBV% = OXBVt / OXBVi*100%; where OXBVt is the value of OXBV measured at any moment in the ECMO process. OXBVi – initial OXBV measured at the beginning of ECMO process when oxygenator is free of clots.

References

Krivitski N, Galyanov G, Cooper D, Said MM, Rivera O, Mikesell GT, Rais-Bahrami K, **"In vitro and in vivo assessment of oxygenator blood volume for the prediction of clot formation in an ECMO circuit (theory and validation).,"** Perfusion 2018; 33(IS): 51-56. (Transonic Reference # ELS11317)

Said MM, Rivera O, Mikesell GT, Rais-Bahrami K, **"Influence of central hemodynamics on VV ECMO oxygen delivery in neonatal animal model,"** J Neonatal Perinatal Med. 2017 Apr 8. (Transonic Reference # ELS11180AH)

Palmér O, Palmér K, Hultman J, Broman M, **"Cannula Design and Recirculation During Venovenous Extracorporeal Membrane Oxygenation,"** ASAIO J. 2016; 62(6): 737-742. (Transonic Reference # EC11034AH)

Körver EP, Ganushchak YM, Simons AP, Donker DW, Maessen JG, Weerwind PW, **"Quantification of recirculation as an adjuvant to transthoracic echocardiography for optimization of dual-lumen extracorporeal life support,"** Intensive Care Med. 2012 38(5): 906-909. (Transonic Reference # ELS9679AH)

Said MM, Mikesell GT, Rivera O, Khodayar Rais-Bahrami K, **"Precision and Accuracy of the New Transonic ELSA Monitor to Quantify Oxygenator Blood Volume (*in-vivo* and *in-vitro* studies),"** 2015 PAS Annual Meeting and Eastern SPR Annual Meeting. (Transonic Reference # ELS10230V)

Said MM, Mikesell GT, Rivera O, Khodayar Rais-Bahrami K, **"Influence of central hemodynamics and dual-lumen catheter positioning on recirculation in neonatal veno-venous ECMO,"** 2015 PAS Annual Meeting and Eastern SPR Annual Meeting. (Transonic Reference # ELS10231V)

Dalton HJ, Garcia-Filion P, Holubkov R, Moler FW, Shanley T, Heidemann S, Meert K, Berg RA, Berger J, Carcillo J, Newth C, Harrison R, Doctor A, Rycus P, Dean JM, Jenkins T, Nicholson C, Eunice Kennedy Shriver National Institute of Child Health and Human Development Collaborative Pediatric Critical Care Research Network, **"Association of bleeding and thrombosis with outcome in extracorporeal life support,"** Pediatr Crit Care Med. 2015;16(2):167-74. (Transonic Reference # EC10243AHR)

Walker J, Primmer J, Searles BE, Darling EM, **"The potential of accurate SvO2 monitoring during venovenous extracorporeal membrane oxygenation: an *in vitro* model using ultrasound dilution,"** Perfusion 2007; 22(4): 239-44. (Transonic Reference # 7594A)

Walker JL, Gelfond J, Zarzabal LA, Darling E, **"Calculating mixed venous saturation during veno-venous extracorporeal membrane oxygenation,"** Perfusion. 2009; 24(5): 333-9. (Transonic Reference # 7904A)

Melchior R, Darling E, Terry B, Gunst G, Searles B, **"A novel method of measuring cardiac output in infants following extracorporeal procedures: preliminary validation in a swine model,"** Perfusion 2005; 20(6): 323-7. (Transonic Reference # 10234A)

Darling EM, Crowell T, Searles BE, **"Use of dilutional ultrasound monitoring to detect changes in recirculation during venovenous extracorporeal membrane oxygenation in swine,"** ASAIO J 2006; 52(5): 522-4. (Transonic Reference # 7309A)

van Heijst AF, van der Staak FH, de Haan AF, Liem KD, Festen C, Geven WB, van de Bor M, **"Recirculation in double lumen catheter veno-venous extracorporeal membrane oxygenation measured by an ultrasound dilution technique,"** ASAIO J, 2001; 47(4): 372-6. (Transonic Reference # HD49V)

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Volume Flow with 4 & 6 mm COnfidence Probes

A Direct Measure of Volume Flow through the Aorta & Pulmonary Artery to Determine Qp/Qs

Blood Flow - the Heart of the Matter

Whatever the nature of a defect, the primary goal of pediatric surgery is to create or restore blood flow to traverse its normal circulatory route through the lungs and heart and into the systemic circulation so that a child can grow and thrive.

After surgery, waiting for symptomatic acknowledgement of surgical success is anxiety-provoking, time-consuming and subjective. When blood flow is measured directly during the surgery to determine single flows or Qp/Qs, surgeons have the opportunity to make immediate, necessary revisions before closing the patient.

Transonic's intraoperative measurements may either confirm a surgeon's clinical impression during the course of the surgery, or they can alert the surgeon to a potential problem when it can be most easily addressed.

To Measure Is to Know

The size and fragility of pediatric patients make their surgeries among the most challenging to perform. Topping the list of challenging pediatric surgeries is repair of hearts of children born with congenital defects (CHD). Extending open-chest periods and staged surgeries add to the importance of knowing how much blood is flowing through re-directed pathways.

Since 1988, Transonic flow measurements have been used by flow innovators such as Dr. Constantine Mavroudis to develop procedures such as the fenestrated Fontan for pediatric heart repair.

Now Transonic's four-crystal AU Confidence Flowprobes that measure turbulent flow through great vessels have been sized for pediatric hearts. The small 4 & 6 mm Flowprobes offer immediate and highly accurate measurements of volume flow through the tiniest vessels.

AU Probe Pediatric White Paper (CV-800-wp), Rev A 2018 USltr

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Continuous Measurem

Determining QP/QS during Pediatric Surgery with Flow-Assisted Surgical Technique (F•A•S•T)

Measuring Flow

Select Correct COnfidence Flowprobe Size

↓

Measure and Record Baseline Flows
on vessels of interest (Aorta, PA)

↓

Assess surgical strategy informed by flow data

Measure flows during the course of the surgery

↓

Record flow values

↓

Evaluate surgical progress informed by flow values

Measure and record flows at completion of surgery

F•A•S•T Medical Notes are intended to assist in surgical decision-making and are not diagnostic tools. Surgical interpretation is required.

1. Expose & identify vessels to be measured

2. Select correct COnfidence Flowprobe size

   Measure the diameters of the vessels to be measured with a gauge before opening the Flowprobe package. Select a Flowprobe size so that the vessel will fill between 75% - 100% of the Flowprobe's ultrasonic sensing window.

6 & 4 mm Flowprobes

3. Prepare Vessel for Flowprobe

   Determine the optimal position for applying the Flowprobe by selecting a site wide enough to accommodate the Flowprobe's body. Clear approximately 1 cm of the vessel to be measured of extraneous tissue (i.e. fascia, fat). Fat could interfere with acoustic transmission.

4. Add Couplant to Flowprobe

   Apply ultrasonic gel to the inside of the liner. Then apply gel to the inside of the probe shell.

5. Apply Flowprobe

   Position the liner on the vessel. Place the probe shell over the liner. Position the Flowprobe on the vessel so that the entire vessel lies within the ultrasonic sensing window of the Flowprobe.

6. Check Signal Strength

   Check the Flowprobe's signal strength on the Flowmeter's Signal Quality Indicator. If acoustic contact falls below an acceptable value, an acoustic error message will be displayed. Apply more gel, if needed.

7. Multi-stage Flow Measurements

   a. Measure Flows *In Situ*
      Measure baseline flows.
   b. Measure Flows, as needed, throughout the course of surgery
   c. Final Flow Measurement
      Measure flows at completion of surgery

   Note: Probes can be left on the vessel for up to 24 hours.

5. Document Multi-stage Flows for Case Record

   Document flow values from the multi-stage flow assessments. If the Flowmeter displays a negative flow, press the INVERT button to change the polarity before printing the waveform.

nents in Great Vessels

Optima Flowmeters & the AureFlo® System

Why rely on guesswork and intuition, or wait until postoperative conditions determine surgical success? Transonic Optima® Flowmeters provide immediate, quantitative flow measurements with unsurpassed accuracy and resolution. Make intraoperative flow measurements with a Transonic Flowmeter part of your routine to verify establishment of adequate blood flow before closing your patient.

The Optima Flowmeter complements a full line of Perivascular Flowprobes for vessels from 0.5 mm to 36 mm in diameter and Tubing Flowsensors for any size tubing.

HT354 Optima single-channel Flowmeter

HT364 Optima dual-channel Flowmeter for simultaneously measurements of aortic and pulmonary artery flows.

AureFlo System with Optima dual-channel Flowmeter

- Versatile Display
- Intuitive Operation
- Archive & Retrieve
- Convenient, Portable
- Case Portfolios: Record & Display

References

1 Kotani Y, Van Arsdell GS *et al,* "Is Indexed Preoperative Superior Vena Cava Blood Flow a Risk Factor in Patients Undergoing Bidirectional Cavopulmonary Shunt?," Ann Thorac Surg. 2012. (Transonic Reference # 9735AH) *A new indicator-low SVC flow, may be a marker for BCPS failure or death, suggesting that the SVC flow vs size is more important in predicting successful BCPS.*

2. Kotani Y, Van Arsdell GS et al, "The Utility of Aortic Blood Flow Measurements in the Prediction of Pulmonary Artery Banding Outcome," Ann Thorac Surg. 2015 Apr 15. (Transonic Reference: 10278AH) *Study identifies the change in the aortic blood flow as a new, physiologically based parameter to help predict pulmonary artery banding outcome.*

3. Dean DA *et al,* "Validation Study of a New Transit Time Ultrasonic FlowProbe for Continuous Great Vessel Measurements," ASAIO Journal 1996; 42: M671-676. (Transonic Reference # 29V) *Aortic Flowprobes showed a highly linear correlation with respiaiton. During laminar flow states, Aortic Flowprobes are accurate regardless to position on the great vessels.*

4. Mavroudis C *et al,* "Fenestrated Fontan with Delayed Catheter Closure, Effects of Volume Loading and Baffle Fenestration on Cardiac Index and Oxygen Delivery," Circulation 1992; 86 II: 85-92. (Transonic Reference # 261A) *Intraoperative hemodynamic measurements (n = 8) included cardiac index (by aortic flow probe)*

5. Mavroudis C *et al,*"Bidirectional Glenn Shunt in Association with Congenital Heart Repairs: The 1-1/2 Hour Ventricular Repair, "Ann Thoracic Surg 1999; 68: 976-982. (Transonic Reference # 1305AH) *Intraoperative hemodynamic assessment was done in 2 patients in group A by selective use of inflow occlusion and flow probes.*

6. Sharp MK *et al,* "Aortic Input Impedance in Infants and Children," J Appl Physiol. 2000; 88(6): 2227-39. (Transonic Reference # 2590AH) *Flow and pressure measurements were performed in the ascending aortas of six pediatric patients ranging in age from 1 to 4 yr and in weighing from 7.2 to 16.4 kg*

7. Pantalos GM *et al,* "Estimation of Timing Errors for Intraaortic Balloon Pump Use in Pediatric Patients," ASAIO Journal, 1999; 45(3): 166-171. (Aortic, pediatric, A probes) (Transonic Reference # 1073AH) *Aortic root flow waveforms were used to estimate timing errors with intraaortic balloon pump use in pediatric patients.*

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