Transonic Systems introduces COstatus®, the first minimally invasive Cardiac Output and Blood Volumes Monitor that's safe for routine use in neonatal to adult ICU patients. With a single bolus of saline, its quick and safe measurements provide key hemodynamic parameters to optimize treatment decisions.
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  - Boston Children’s Hospital, Boston MA 
  - The Hospital for Sick Children (SickKids), Toronto, Canada 
- Europe
  - Skane University Hospital, Lund, Sweden 
  - National Research Center for Surgery, Moscow, Russian Federation 
  - National Center for Hematology, Moscow, Russian Federation 
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- National Defense Medical College, Japan

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### Animal Studies

- USA
  - Cornell University, Ithaca, NY 
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  - State University of NY, Upstate Medical College, Syracuse, NY 
  - University of Florida, Gainesville, FL 
  - Wake Forest University, Winston Salem, NC 
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- Europe
  - Radboud University Nijmegen Medical Center, The Netherlands

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### B. Blood Volume Studies

#### Clinical Studies

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  - Texas Children’s Hospital, Houston, TX 
  - University of Rochester, Rochester, NY 
- Europe
  - National Research Center for Surgery, Moscow, Russian Federation 
  - National Center for Hematology, Moscow, Russian Federation 

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#### Animal Studies

- USA
  - Wake Forest University, Winston Salem, NC 
  - University of Florida, Gainesville, FL

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### C. Shunt Identification

#### Clinical Studies

- USA
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- Europe
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- USA
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Abbreviation List

**Methods**

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<td>TD</td>
<td>Thermodilution</td>
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<tr>
<td>UD</td>
<td>Ultrasound Dilution</td>
</tr>
<tr>
<td>COtd</td>
<td>Thermodilution cardiac output</td>
</tr>
<tr>
<td>COud</td>
<td>Ultrasound Dilution cardiac output</td>
</tr>
<tr>
<td>CO-Fick</td>
<td>Fick method cardiac output</td>
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<tr>
<td>PAC</td>
<td>Pulmonary Artery Catheter</td>
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**COstatus Measurements**

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<th>Abbreviation</th>
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<tr>
<td>CO</td>
<td>Cardiac output</td>
</tr>
<tr>
<td>TEDV</td>
<td>Total End Diastole Volume</td>
</tr>
<tr>
<td>CBV</td>
<td>Central Blood Volume</td>
</tr>
<tr>
<td>ACV</td>
<td>Active Circulation Volume</td>
</tr>
<tr>
<td>TEF</td>
<td>Total Ejection Fraction</td>
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**Clinical Terminology and Applications**

<table>
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<th>Abbreviation</th>
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<tr>
<td>CHS</td>
<td>Congenital Heart Surgery</td>
</tr>
<tr>
<td>CPB</td>
<td>Cardiac pulmonary bypass</td>
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<tr>
<td>CVP</td>
<td>Central Venous Pressure</td>
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<tr>
<td>OR</td>
<td>Operation Room</td>
</tr>
<tr>
<td>ALI</td>
<td>Acute Lung Injury</td>
</tr>
<tr>
<td>ARDS</td>
<td>Acute Respiratory Distress Syndrome</td>
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<tr>
<td>CABG</td>
<td>Coronary Artery Bypass Graft</td>
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Introduction

During the past decade, ultrasound dilution (UD) technology has become the recognized Gold Standard for the measurement of vascular access hemodynamics during hemodialysis. Ultrasound dilution measurements have been validated in over 150 studies published in peer-reviewed journals. Many years of research and refinement of this technology have culminated in COstatus®, a new method to accurately measure cardiac output and blood volumes in ICU patients using existing catheters. In addition to its measurement of advanced hemodynamic parameters, COstatus also identified the presence of shunts in neonatal and pediatric patients.

COstatus goes far beyond a simple cardiac output measurement device. It also provides a group of unique blood volumes that are used to assess preload and afterload hemodynamic conditions. There are also some new areas where COstatus is used, for example, in titrating therapies, demonstrated by the Furosemide clinical study by Ostrowicki R et al of the University of Rochester. This interesting clinical study offers new insights about the effects of Furosemide on intravascular volume changes.

From the first bench study to the present, there have been 60 papers and abstracts published in peer-reviewed journals, including Pediatric Critical Care Medicine (PCCM), Intensive Care Medicine (ICM), and Anesthesiology. Below is a summary of the papers and abstracts organized by:

1. Clinical and Animal Research Studies: 34 clinical publications and 26 animal or bench publications
2. Study Sites
   a. USA and Canada (35 publications from nine sites)
   b. Europe (23 publications from five sites)
   c. Asia (2 publications from one site)
3. COstatus Functionalities
   a. Cardiac output
   b. Blood Volume
   c. Shunt
4. Neonatal Clinical Studies: These are reviewed separately because COstatus is the only available indicator dilution method to measure cardiac output, blood volume, and shunt identification in neonates.

Each grouping includes a brief summary, a list of studies and a brief description of the methods and conclusions of specific studies. The nature of some studies, such as hemorrhage or cardiac arrest models, precludes their clinical feasibility. These two animal studies, in particular, investigate how COstatus volume parameters reflect the true changes in volume during trauma and cardiac arrest cases. Such studies are listed at the end of each category.

Universities and hospitals that use or have used COstatus in their studies include the following:

US and Canada:
- University of Rochester, Rochester, NY
- Cornell University, Ithaca, NY
- Texas Children’s Hospital, Houston, Texas
- Boston Children’s Hospital, Boston, MA
- Crouse Hospital, Syracuse, NY
- The Hospital for Sick Children (SickKids), Toronto, ON, Canada
- SUNY Upstate Medical College, Syracuse, NY
- Wake Forest University, Winston-Salem, NC
- University of Florida, Gainesville, FL
Europe:
- Radboud University Nijmegen Medical Center, The Netherlands
- National Research Center of Surgery, Moscow, Russia Federation
- National Center for Hematology, Moscow, Russia Federation
- Hannover Medical School, Hanover, Germany
- Skane University Hospital, Lund, Sweden

Asia:
- National Defense Medical College, Tokyo, Japan

**COstatus® Theory & Methodology**

The fundamental principle of COstatus is ultrasound dilution. “Blood ultrasound velocity (1560 –1585 m/sec) is a function of total blood protein concentration (sum of proteins in plasma and in red blood cells), temperature, and average ion concentration in plasma. Injection of body temperature isotonic saline (ultrasound velocity of saline is 1533 m/sec) into the AV loop decreases blood ultrasound velocity, producing dilution curves. Then cardiac output (CO) can be calculated based on the classic Stuart-Hamilton principle. Total end-diastole volume (TEDV) is calculated based on the change in shape of the indicator dilution signal as it passes through the heart: “For a bolus traversing the heart and lung vascular beds, the length of the chord drawn upon the dilution curve at half the height of the peak is identified as an efficient, robust predictor of the total blood volume in the heart at end of ventricle diastole.” The spread of the arterial indicator dilution curve from its initial venous shape results largely from indicator mixing in the heart chambers, and the degree to which these chambers empty themselves with each heart beat.

**References:**

4) Krivitski N, Kislukhin V, Thuramalla N, “Identification of Shunts based on the Shape of the Dilution Curve,” 3rd Congress of European Academy of Paediatric Societies (EAPS), Copenhagen, Denmark, Oct. 23-26 2010, Poster Presentation #121 (CO8042)

**A. Cardiac Output Validations**

COstatus Cardiac Output measurements have been validated in various clinical applications against conventional methods. These include Pulmonary Artery Catheter (PAC), Transpulmonary Thermodilution, Fick method and Transit-Time Ultrasound flow measurement. The clinical applications include general surgery, post cardiac surgery, CABG and septic shock.

**Clinical Studies**

**USA and Canada**

**Texas Children’s Hospital, Houston, TX: Heart Transplantation-PAC**

Twenty-eight patients with structurally normal hearts that underwent hemodynamic evaluation in the cardiac catheterization laboratory of a single institution were evaluated (median age: 8 years; median weight: 31 kg). A prograde right heart catheterization was performed and CO was determined using pulmonary artery catheterization (PAC) thermodilution (COtd) technique. Results were compared with CO measurements obtained by using COstatus.
“There is a good agreement in CO measurements determined by ultrasound dilution (UD) versus thermodilution (TD) in pediatric patients. The COstatus system provides a novel, minimally invasive method of determining real time cardiac output in children.”

References:

Boston Children Hospital, Boston, MA: COstatus vs. Fick Method
Nine PICU and CICU patients [ages: 8 days to 17 years] with existing peripheral arterial and central venous catheters were studied using COstatus ultrasound dilution technology and CO-Fick, calculated from oxygen consumption and arterial and systemic venous oxygen saturation levels.

“This pilot study showed acceptable agreement in CO determined by ultrasound dilution and Fick methods in critically ill infants and children. COUD can be used to measure CO in children using existing lines.”

Reference:
1) Rajagopal SK, Costello M, “Validation of an Ultrasound Dilution Cardiac Output Measurement Technique in Critically Ill Children,” Pediatric Critical Care Colloquium, Pittsburgh, PA, May 15-17, 2010 (CO8028V)

The Hospital for Sick Children (SickKids), Toronto, ON, Canada: Congenital Heart Surgery vs. Fick Method
Sixteen congenital heart disease patients [ages: 6 days to 14 years; weights 2.95 - 80 kg] were studied. Cardiac Output was simultaneously measured by respiratory mass spectroscopy and COstatus.

“Ultrasound dilution method appears to be a safe, straightforward and reliable method for measurement of cardiac output in the postoperative neonatal and paediatric congenital heart disease group.”

Reference:
Europe

Skane University Hospital, Lund, Sweden: COstatus® vs. Transit-time Perivascular Flowprobe during and after Cardiac Surgery

Fifteen patients scheduled for congenital heart surgery (CHS) [mean age: 160 (range: 6-1224) days; mean weight 5.2 (3.2 - 14.1) kg]. Measurements (2-4 injections of saline 0.5-1 mL/kg /session) started in the OR, before and immediately after cardiac pulmonary bypass (CPB) which were repeated in the PICU at 2, 3, 4, 5, 6, 12 and 24 hours after weaning. COstatus® accuracy was tested in the operation room (OR) by measuring cardiac output simultaneously with a perivascular flowprobe using transit-time technology (Transonic Systems Inc.). COstatus® offers reproducible measurements in pediatric patients. Two injections are typically adequate for data collection in the absence of shunts. More injections may be required in the presence of shunts.

References:

National Research Center for Surgery, Moscow, Russian Federation: COstatus vs. PAC

Twenty six post cardiac surgery ICU patients were studied. Cardiac output was determined by PA catheterization, and COstatus. A total of 77 ultrasound dilution cardiac output (COUD) and thermodilution cardiac output (COTD) averaged measurement sets were compared.

“We found that cardiac output determined by the new COstatus system based on ultrasound dilution method and the clinical standard pulmonary artery thermodilution method is interchangeable in heterogeneous post cardiac surgery critically ill patients. Being less invasive and safe, COstatus has the potential to be used not only in adults but also in younger age patients.”

References:

National Center for Hematology, Moscow, Russian Federation
COstatus vs. Transpulmonary Thermodilution (PiCCO) Method

Thirty patients were studied: 10 sepsis, ALI/ARDS; 17 septic shock; 2 hemorrhage; 1 pulmonary edema. Cardiac output was determined by PiCCO (Philips Intellivue MP40 with PiCCO-technology module M3012A#10, Netherlands) and COstatus system.

References:
“CO measured by COstatus was found to be equivalent and hence interchangeable with PiCCO in this study population. COstatus blood volumes were found to be within the expected physiological range whilst PiCCO blood volumes were significantly higher, which was also observed in other studies. Future studies using 3D echo/MRI are required to validate these blood volumes.1

References:

Asia

National Defense Medical College, Japan: General Surgery; COstatus vs. PAC

Twenty nine adult patients undergoing general abdominal surgery were evaluated. Cardiac output was determined by PAC (“COtd”) and COstatus (“COud”).

“COud measurements agreed well with COtd. The results of this study indicated that COud might be interchangeable with conventional COtd in perioperative adult patients1.”

Reference:

Animal Studies

USA

Cornell University, Ithaca, NY: COstatus vs. Transit-time Perivascular Flowprobe

Reference:

University of Rochester, Rochester, NY: COstatus vs. Transit-time Perivascular Probe

Reference:
State University of NY, Upstate Medical College, Syracuse, NY:

**COstatus vs. PAC**

**COstatus vs. Transit-time Perivascular Flowprobe**

References:
1) Darling E, Thuramalla N, Searles B, “Validation of Cardiac Output Measurement by Ultrasound Dilution Technique with Pulmonary Artery Thermodilution in a Pediatric Animal Model.”. Accepted for publication in Pediatric Cardiology (CO8120V)

University of Florida, Gainesville, FL: COstatus vs. Lithium Dilution Method

References:

Wake Forest University, Winston-Salem, NC: COstatus vs. Transit-time Perivascular Flowprobe

Reference:

Transonic System Inc., Ithaca, NY

References:
1) Thuramalla NV et al, “First Minimally Invasive Cardiac Output (CO) and Blood Volumes (BV) Monitor for Routine Use in Pediatric ICU Patients,” Crit Care Med 2008; 34(13): A12. Poster presentation at the World Summit on Pediatric and Congenital Heart Surgery Services, Education and Cardiac Care in Children and Adults with Congenital Heart Disease, June 19-21, 2008, Montreal, Canada (CO7643A)
Europe
Radboud University Nijmegen Medical Center, Nijmegen, The Netherlands:
COstatus vs. Transit-time Flowprobe
Nine ~5.8 kg piglets were studied. An arterial catheter was placed in the abdominal aorta via the femoral artery and connected to the arterial limb of the extracorporeal circuit. The central venous catheter was positioned in the top of the right atrium via the femoral vein and connected to the venous limb of the extracorporeal AV loop.

A transit-time ultrasound perivascular flowprobe was positioned around the common pulmonary artery to serve as the standard reference measurement. Hemorrhagic hypotension was induced to manipulate Cardiac Output.

Ultrasound dilution cardiac output measurement is feasible in piglets with the use of a small volume of a nontoxic indicator (isotonic saline) with a clinically acceptable bias and precision. An injection volume of 0.5 ml/kg of isotonic saline is as accurate as a 1.0 ml/kg injection volume.

References:
Papers

Abstracts
B. Blood Volumes Studies

Optimization of fluid status is of paramount importance in critical care. There lacks a routine precise method to determine the blood volume. COstatus provides a group of blood volume parameters to assess preload and afterload. These parameters include Total End Diastole Volume (TEDV), Central Blood Volume (CBV) and Active Circulation Volume (ACV). Clinical studies have shown TEDV and CBV are indicators of preload, while ACV indicator of afterload. These volume parameters may be used to assess fluid loading and drug efficacy.

Clinical Studies

**USA**

**Texas Children’s Hospital, Houston, TX**

Twenty three children (weight: 9.4-74 kg; 1-17 years) with structurally normal hearts were studied.

First study in pediatric patients to show that ACV measured by COstatus strongly correlates with systemic vascular resistance and therefore, could be used as an indicator of afterload in this population¹, while that TEDV and CBV could be used as preload indicators².

Authors advise that further clinical studies in patients with different clinical conditions such as shock and sepsis are necessary to establish the clinical utility of ACV.

**References:**


**University of Rochester, Rochester, NY**

Seven PICU patients (2 weeks to 17 years; 2.8-60 kg) with indwelling arterial and central venous catheters were infused with furosemide (0.5-1 mg/kg. 20 mg maximum). COstatus measurements were performed before diuretic infusion and 30 and 60 minutes after infusion. Urine output was also measured.

Despite brisk urine output, cardiac output and central blood volume did not decrease with furosemide. Cardiac index and central blood volume index seemed to increase with infusion. Cardiac function seemed to improve and central blood volume was preserved after furosemide infusion. Additional studies in more patients are needed to confirm these results¹².

**References:**


Europe

National Research Center of Surgery, Moscow, Russian Federation

Twenty nine adults in post cardiac surgery ICU before and after 30 min infusion of 500 ml of Venofundin (B Braun) or 500 ml of Gelofusine (B Braun) were studied. In this study, loading of Venofundin and Gelofundin produced similar results in initiating CI changes. Venofundin had more pronounced influence on volume changes. Both CBVI and TEDVI act as indicators of cardiac preload.

References:


National Center of Hematology, Moscow, Russian Federation

The study is the first clinical comparison between cardiac output and blood volumes measured by two dilution techniques (COstatus® and PICCO) in an adult ICU. Total thirty patients were studied. 10 sepsis, ALI/ARDS; 17 septic shock; 2 hemorrhage; 1 pulmonary edema. CO measured by COstatus® was found to be equivalent and thus suggest that it can be interchangeable with PICCO. However, PICCO Global End Diastole Volume (GEDV) measurements were 2.5 times higher than COstatus® analogous TEDV measurements. COstatus® blood volumes were found to be within the expected physiological range. Future studies using 3D echo/MRI are necessary to validate the blood volumes.

References:

6) Galstyan G, Bichynin M, Gorodetsky V, "Sources of Discrepancy between Heart End Diastolic Volume Measured by Ultrasound Dilution (UD) and Transpulmonary Thermodilution (TT)," Crit Care Med 2009; 37(Suppl 12): A91 Abstr 211. Poster presentation at the 39th SCCM Critical Care Congress, Jan 9-13, 2010, Miami Beach, FL, USA (CO8031A)
Animal Studies

USA

Wake Forest University, Winston-Salem, NC
Hemorrhage and Resuscitation Study:
Five anesthetized male Sprague-Dawley rats were used in the study. 7-ml/kg per bodyweight was withdrawn from each rat over four steps. After 40 minutes, all the blood was re-infused. The study confirmed that ultrasound dilution is an easy tool to investigate the volume status of rats. The data suggests that CBV and ACV are early predictors of blood loss.

University of Florida, Gainesville, FL
Hemorrhage Shock Study:
CBVI, TEDVI, ACVI, CVP, MAP were measured in 7 healthy ponies (4 - 8 months of age; 80 ± 20 kg) during four different experimental stages:
1) Normovolemia (Baseline phase);
2) After blood withdrawal to 40 mmHg (MAP) (Hemorrhage phase);
3) After norepinephrine infusion to MAP ± 10% of baseline (Norepinephrine phase);
4) After retransfusion of shed blood (Resuscitation phase).
In ponies, TEDVI and ACVI accurately reflected hemorrhage and were good indicators of percentage change of total blood volume. CVP did not. CBVI was inconsistent in reflecting volume status. Norepinephrine infusion induced did not alter TEDVI or ACVI. Norepinephrine infusion induced significant CVP changes, reflecting potentially deceptive fluid status.

Cardiac Arrest Study:
Eight anesthetized ~ 2-month old piglets were resuscitated after 4 minutes of untreated ventricular fibrillation. Animals were maintained in spontaneous circulatory low CO flow state for 120 minutes as CO, TEDV and CBV were measured by ultrasound dilution and compared to intracardiac left ventricle Millar pressure measurements. Measurements were taken at baseline before cardiac arrest and in the low CO flow state. Data was analyzed by Bland Altman and A-nova., p ≤ 0.05 was considered significant.
Six animals survived to the end of the CO low flow state and 96 comparisons were made. Post arrest altered CO, MAP and CBV, but not TEDV. CO and TEDV demonstrated good agreement to MPVS and end diastolic volume (EDV) throughout study.
COstatus® is a viable alternative for measuring cardiac parameters when compared to intracardiac pressure volume catheter measurements in pediatric critical care.

References:


C. Shunt Identification

In addition to quantitative measurements of cardiac output and blood volumes, as a bedside monitor, COstatus identifies the presence of shunts in neonates and pediatrics. This COstatus feature is effective in verifying residual shunts after congenital heart disease repair.

Clinical Studies

USA

University of Rochester, Rochester, NY: Shunt/Fontan Case Report

Ultrasound dilution measurements were performed on a 20 kg patient with a single ventricle after a Fenestrated (4 mm) Extra-Cardiac Fontan operation. COstatus measured an average cardiac index of 2.3 L/min/m². Shunt flow was 1.0 L/min/m². The estimate of a Qp/Qs=0.57 ratio was a value consistent with a child’s low arterial oxygen saturation.

Reference:

Crouse Hospital, Syracuse, NY: Measure CO and BV in Neonates

“This preliminary study in NICU patients presented the first and unique experience of measuring CO and blood volumes in a baby < 1kg. This technique could be used to quantitatively assess the effects of therapies. Further clinical studies in NICU patients with different conditions are required.”

References:
1) Marr B, “Cardiac Output (CO) and Blood Volumes Measurement in Neonatal ICU Using Ultrasound Dilution - First Experience,” Pediatric Critical Care Colloquium, Pittsburgh, PA, May 15-17, 2010 (CO8025A)
3) Marr B, “Can Ultrasound Dilution (UD) Identify and Qualify the Type of Shunt in Neonates with Patent Ductus Arteriosus (PDA)?” Pediatric Critical Care Colloquium, Pittsburgh, PA, May 15-17, 2010 (CO8026A)
Europe

**Hannover Medical School, Hanover, Germany**

Twenty children and adolescents weights (3.5 - 102) kg with cardiac catheterization were studied. Shunts and pulmonary (Qp) versus systemic blood flow (Qs) ratio were determined by routine oximetry. COstatus identified all six of the left-to-right shunts detected by oximetry: sensitivity 100% (6/6); specificity of 92.8% (13/14).

Reference:

**Bakulev Scientific Center for Cardiovascular Surgery, Moscow, Russian Federation**

Reference:
1) G. V. Lobacheva. A.V.Kharkin, E.G. Tkachenko. “Assessment of septal defects (SPD) by ultrasound dilution (UD) technology” Poster Presentation at the Pediatric Cardiac Intensive Care Soc 2010, Dec 8-11, 2010, Miami Beach, FL, USA

Animal Studies

Europe

**Radboud University Nijmegen Medical Center, Nijmegen, The Netherlands**

**Cardiac output Validation in a Shunt Model**: A Gore-Tex® aorto-pulmonary shunt was inserted between the left pulmonary artery and the descending aorta in eight newborn lambs (3.5 to 8.3 kg). Hemorrhagic hypotension was induced during the experiment to manipulate Cardiac Output while the shunt was intermittently opened and closed. Ultrasound dilution cardiac output was measured using 1.0 ml/kg body temperature isotonic saline injections. Direct intraoperative pulmonary blood volume flow was measured by an ultrasound transit-time perivascular flow probe positioned around the main pulmonary artery. A total of 220 measurements were performed and compared. “COstatus® cardiac output measurement with ultrasound dilution technology is reliable and easily applicable in ventilated juvenile lambs, even in the presence of a significant left-to-right shunt.”

References:
2) Vrancken SL, de Boode WP, Hopman JC, Singh SK, Liem KD, “Assessing Cardiac Output and Derived Blood Volumes in a Neonatal Lamb Model with a Left to Right Shunt,” 3rd Congress of European Academy of Paediatric Societies (EAPS), Copenhagen, Denmark, Oct. 23-26 2010, Poster Presentation #1322. (CO8040A)
D. Neonate Clinical Study

There is a lack of methods to measure cardiac output, blood volume in neonates. COstatus provides a safe, accurate, and convenient way to measure these parameters utilizing dilution method.

USA

Crouse Hospital, Syracuse, NY

Measure CO and BV in Neonates

“This preliminary study in NICU patients presented the first and unique experience of measuring CO and blood volumes in a baby < 1kg. This technique could be used to quantitatively assess the effects of therapies. Further clinical studies in NICU patients with different conditions are required.”

References:
1) Marr B, “Cardiac Output (CO) and Blood Volumes Measurement in Neonatal ICU Using Ultrasound Dilution - First Experience,” Pediatric Critical Care Colloquium, Pittsburgh, PA, May 15-17, 2010 (CO8025A)

Shunt Identification

It was the first clinical experience using ultrasound dilution technology to identify and possibly predict the type of shunts in neonates.

Reference:
1) Marr B, “Can Ultrasound Dilution (UD) Identify and Qualify the Type of Shunt in Neonates with Patent Ductus Arteriosus [PDA]?”, Pediatric Critical Care Colloquium, Pittsburgh, PA, May 15-17, 2010 (CO8026A)