WHY YOU NEED FLOW VERIFICATION DURING ECMO

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A little over a half century ago, the nation was transfixed by a struggle to save the life of Patrick Bouvier Kennedy, the infant son of President John F. and Jacqueline Bouvier Kennedy. Five and a half weeks premature, Patrick, weighing 4 pounds 10 1/2 ounces, was delivered on Aug. 7, 1963. After birth he immediately began having trouble breathing and was transferred from Cape Cod to Boston Children's Hospital where he was placed in a hyperbaric chamber. He died 39 hours later, a victim of hyaline membrane disease which was then the most common cause of death among premature infants (25,000 per year) in the United States.[1] The disease is now known as infant respiratory distress syndrome (IRDS). In those days there were no neonatal intensive care units (NICU), and ventilators had yet to be used for premature babies.

This tragic death of the President's son sparked interest in research on prematurity and, over the following decades, innovations from physicians, nurses and others led to bold and successful treatments for infants which gave rise to a new specialty, neonatology. Had Patrick been born today, his outcome most likely would have been positive due to the groundbreaking work of neonatology pioneers such as Dr. Robert Bartlett of the University of Michigan who adapted extracorporeal membrane oxygenation (ECMO) to treat IRDS.

ECLS Origins

The genesis of Extracorporeal Life Support (ECLS) and the development of the heart-lung machine for arresting the heart during cardiac surgery evolve from a common history. Driven by the death of a patient from a pulmonary embolus, Dr. John H. Gibbon developed a freestanding roller pump device for extracorporeal support which was first used in 1953 during surgery to assist repair of an atrial septal defect in an 18-year-old patient Cecilia Bavolek. The synthesis of silicone rubber in 1957 revolutionized the development of an artificial lung because the silicone was found to be strong enough to withstand hydrostatic pressure, yet still be permeable to gas transfer. The use of this silicone membrane oxygenator led to the use of the term extracorporeal membrane oxygenation (ECMO).


Cardiac case in the OR

ECMO was introduced for the treatment of severe acute respiratory distress syndrome (ARDS) in the 1970s by Dr. Theodore Kolobow who pioneered the artificial membrane lung. In 1971, Dr. Donald Hill reported the survival of a 24-year-old polytrauma patient with ruptured aorta after a motorcycle accident. Even by today's standards the patient would not have been considered a good ECMO candidate. Nevertheless, he was successfully treated on ECMO.

Baby Esperanza & Robert Bartlett

In 1976, interest in ECMO was revived after Dr. Robert H. Bartlett reported the first neonatal ECMO survivor, baby Esperanza. The baby's mother, a poor, illiterate woman from Baja, Mexico crossed the border and headed for Los Angeles, determined that her child would have a better life as a United States citizen. En route, she went into labor and was taken to Orange County Medical Center where her daughter was born. During delivery, the child had aspirated a large quantity of meconium and developed chemical pneumonitis. Even with maximal ventilatory support, the baby was unable to sustain adequate oxygenation.

When the situation was considered so hopeless that there was nothing to lose, Dr. Bartlett, a thoracic surgeon who had been involved in developing the membrane lung, wheeled in a machine from the laboratory. The nurses named the baby Esperanza, meaning hope. After three days of bypass, Esperanza was weaned from bypass and recovered completely. A new era for treating babies with IRDS was born.

Bartlett Used Transonic's First Clamp-on Tubing Flowsensor

In 1987, Transonic launched an innovative breakthrough in the manufacture of Flowsensors with its first C-Series Clamp-on sensors designed for noninvasive sterile tubing. These sensors were the first of their kind to accurately measure flow in tubing.

Shortly after their introduction, Dr. Bartlett, by then director of the University of Michigan's ECMO program, incorporated the Transonic Tubing Flowsensor and its companion HT101DBLZ Flowmeter into his ECMO protocol as an independent safety measure of assuring the correct flow was delivered to the patient. Richard Powers presented his validation of Transonic flow measurement as being independent of temperature & hematocrit at the first Extracorporeal Life Support Organization (ELSO) meeting founded by Dr. Bartlett.[2] Earlier, Dr. Thomas Depner (University of California at Davis) had studied the wear and cavitation of tubing at different pressure pump settings and recommended independent Transonic verification of delivered blood flow versus the pump occlusion setting in long blood pump procedures such as dialysis and ECMO[3]. Also, in 1990 Jeffrey Riley published a paper comparing electromagnetic, Doppler and transit-time flowmeters in vitro for pump occlusion.[4] Other studies that followed offer further validation of the benefits of flow measurement.[5,6]

Product Innovations

In 1993, MC3 contracted for an initial OEM for delivery of a 6X Sterile Tubing Flowsensor and circuit boards for an ECMO pump designed in Dr. Bartlett's lab. This would later become the Avecor pump. The following year, Transonic introduced its first dedicated HT109 Tubing Flowmeter and first four-crystal "X"- sensors for sterile tubing. Designed for clinical use with bubble detection and multiple calibration capabilities for fluid type, temperature and tubing type, it quickly became the standard R&D flowmeter for pump developers and OEMs as well as a standard "must have" on ECMO shopping lists.

HT110 Bypass Flowmeter

Within a couple of years, 30% of all ECMO centers in the USA used Transonic Flowmeters to monitor flow. In 1997, clinical researchers from NYU School of Medicine, and Thomas Jefferson University Hospital published papers in the ASAIO Journal that advised setting roller pump occlusion with the Transonic HT109 flowmeter.[5, 6]

Next Generation Flowmeter and Flowsensors Developed

4-crystal XL Flowsensor

A next generation dedicated HT110 Tubing Flowmeter was released in 1997 with improved measurement stability at low flow and higher frequency Flowsensors. This was particularly important for the low flow volumes (300–500 mL/min) of ECMO circuits. In addition, a full line of 4-crystal XL-series flowsensors was released. By providing an independent measure of delivered blood flow, the Transonic Tubing Flowmeter and its companion Clamp-on Flowsensors became an invaluable safety and quality device. It provides noninvasive, sterile measurements without any contact with the fluid or interruption of the tubing. In addition to its measurement stability at low flows, as used during ECMO, it also has a stable and low zero offset and its calibration can be adjusted on site. It has thus become the standard used by the biomedical industry by which they calibrate and validate other pumps.

These innovations paved the way for another Transonic specialty: Flowsensors to measure oxygen-rich perfluorocarbon solution formulated by Alliance's R&D liquid ventilation project, in Dr. Bartlett's and Dr. Ronald Hirschl's lab at the University of Michigan. A decade later, Spectrum Medical followed suit by incorporating Transonic OEM flow measurement capability in its new ECMO monitor. They continued this practice when they launched their M4 Comprehensive Bypass Monitor in 2011.

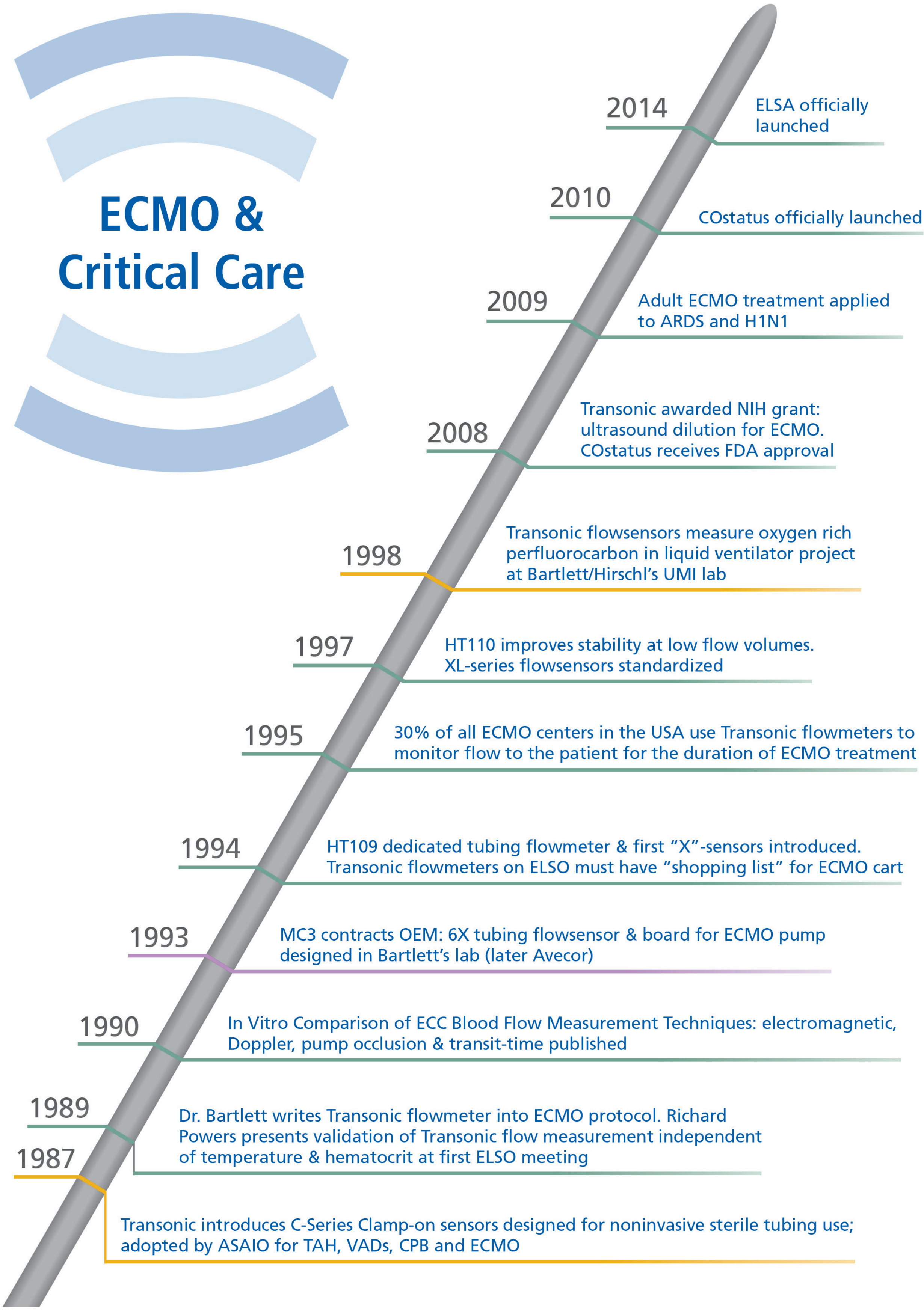

ECMO &
Critical Care
2014
ELSA officially launched
2010
COstatus officially launched
2009
Adult ECMO treatment applied to ARDS and H1N1
2008
Transonic awarded NIH grant: ultrasound dilution for ECMO. COstatus receives FDA approval
1998
Transonic flowsensors measure oxygen rich perfluorocarbon in liquid ventilator project at Bartlett/Hirschl's UMI lab
1997
HT110 improves stability at low flow volumes. XL-series flowsensors standardized
1995
30% of all ECMO centers in the USA use Transonic flowmeters to monitor flow to the patient for the duration of ECMO treatment
1994
HT109 dedicated tubing flowmeter & first "X"-sensors introduced. Transonic flowmeters on ELSO must have "shopping list" for ECMO cart
1993
MC3 contracts OEM: 6X tubing flowsensor & board for ECMO pump designed in Bartlett's lab (later Avecor)
1990
In Vitro Comparison of ECC Blood Flow Measurement Techniques: electromagnetic, Doppler, pump occlusion & transit-time published
1989
Dr. Bartlett writes Transonic flowmeter into ECMO protocol. Richard Powers presents validation of Transonic flow measurement independent of temperature & hematocrit at first ELSO meeting
1987
Transonic introduces C-Series Clamp-on sensors designed for noninvasive sterile tubing use; adopted by ASAIO for TAH, VADs, CPB and ECMO

Figure 1

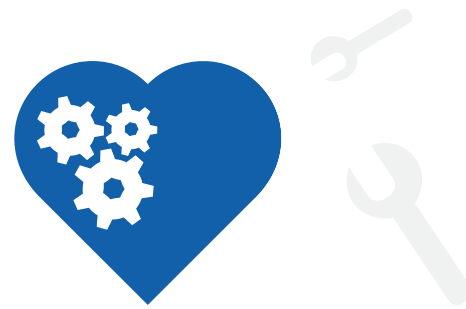
BEST PRACTICES DURING ECMO

ECMO Registry Established 1980

In the interim, back at the University of Michigan, Dr. John Toomasian created the Neonatal ECMO Registry to monitor the ECMO experience. By 1989, the Extracoporeal Life Support Organization (ELSO) was formed with the purpose of stimulating multi-institutional research in the field of acute lung injury and its therapy. Since its inception to support neonates in severe respiratory distress and infants with congenital cardiac defects undergoing surgery, ECMO has since been used to provide temporary (typically days to weeks) support of the pulmonary and/or cardiac circulation to more than 65,000 children and adults. There are currently approximately 160 ECMO centers in the Extracorporeal Life Support Organization (ELSO); 126 are in North America.

Today ECMO is an accepted treatment modality for neonatal, pediatric and adult patients with respiratory and/or cardiac failure, who:

- Fail to respond to maximal medical therapy
- Fail to wean from cardiopulmonary bypass after heart surgery
- Require a bridge to definitive therapy



H1N1 Flu Virus Pandemic Sparks Adult ECMO Surge

The 2009/2010 H1N1 Flu virus pandemic sparked an increase in ECMO to treat adults struck with rapid, progressive acute respiratory distress syndrome (ARDS). ECMO is one of the last resorts for such life-threatening complications. A study published in 2012 in the Journal of the American Medical Association reported that one hospital's mortality rate for the 59 ECMO-referred patients was 24% versus 53% for the 59 non-ECMO-referred patients.[7] In a report from one Oregon hospital, H1N1 patients treated with ECMO had a 67% recovery rate and a 60% survival rate. All survivors were discharged to home.[8]

Extracorporeal Life Support Assurance (ELSA®) Monitor

The H1N1 pandemic created a severe public health challenge for referral centers with ECMO capability.[7-12] Many hospitals adapted their trauma units to handle ECMO patients. Since then ECMO units have proliferated throughout industrialized countries. ECMO setups have become more standardized and streamlined. In many, a Transonic Flowmeter and Tubing Flowsensor are integral to their smooth operation and safety.[13]

Dedicated ELSA Monitor Optimizes ECMO Therapy

In 2004, a Phase I award of $100,000 from the National Institutes of Health (NIH) spurred Transonic's development of a dedicated ECMO monitor. The purpose of the grant was to develop a dedicated ECMO Monitor that used ultrasound dilution technology to derive measurement parameters. An additional $750,000 Phase II NIH grant was awarded to Transonic in 2008 to continue this development of a Pediatric Cardiac Monitor for Extracorporeal Life Support.

The years of development culminated with the launch of the ELSA Monitor in 2014. The Monitor optimizes ECMO therapy in children and adults. In addition to measuring blood flow in the ECMO circuit, the ELSA Monitor, with infusion of a single bolus of room temperature isotonic saline, detects and quantifies recirculation in a VV ECMO patient.[14-23]

ELSA Verifies Delivered Blood Flow

As with the earlier dedicated Tubing Flowmeters and Flowsensors, the ELSA Monitor measures true delivered blood flow through ECMO tubing using "gold standard" transit-time ultrasound technology.

By comparing actual delivered blood flow to the pump's reading, any flow limiting cause such as sub optimal cannulation placement can be identified on the spot and corrected, allowing optimal blood flow delivery.

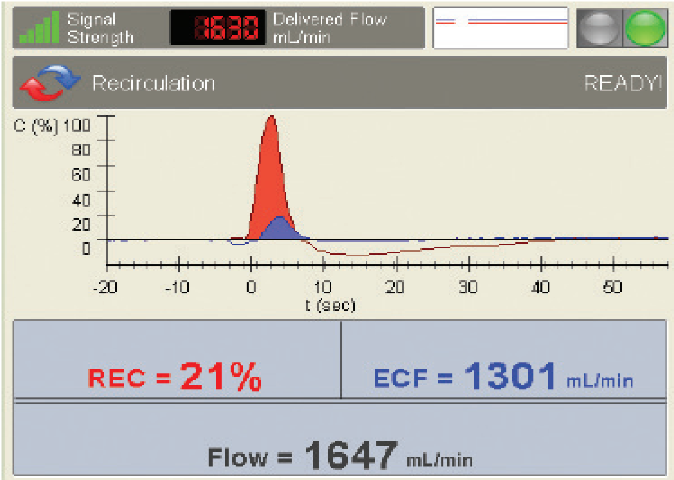


Figure 2
Recirculation measurement results screen. Saline is introduced into the ECMO circuit. The sensors measure the diluted concentration of blood from which recirculation and oxygenator blood volume are calculated.

ELSA Quantifies Recirculation

Recirculation of flow through the cannulas can severely limit the effectiveness of ECMO. With an injection of a small volume of saline into the circuit, the ELSA Monitor can measure the percentage of recirculation that is occurring in the patient.

Oxygenator Blood Volume

Clotting in an ECMO circuit can be catastrophic if not detected early. The challenge for the ECMO team is to maintain blood flow and anticoagulation levels sufficient to minimize clotting in the oxygenator without inducing bleeding in fragile patients.

With an injection of a small volume of saline, the ELSA Monitor measures oxygenator blood volume that will provide tracking of clot development, and expand the window of opportuity to perform an oxygenator change-out.

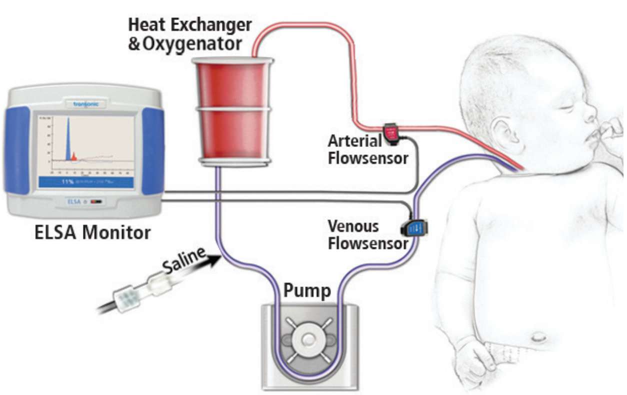


Figure 3
Schematic showing placement of Flow/dilution Sensors and site of saline bolus injection into ECMO circuit.

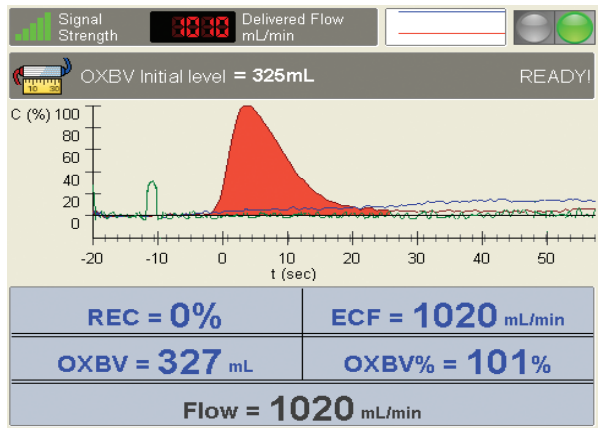


Figure 4
Oxygenator Blood Volume (OXBV) plus Recirculation Results screen during VV ECMO.

HOW THE ELSA MONITOR WORKS

Transit-Time Ultrasound

A clip-on sensor transmits beams of ultrasound through the blood line many times per second. Four transducers 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 blood flow in the tubing. The difference between the upstream and downstream transit-time, multiplied by the area of the lumen provides a measure of volume flow.

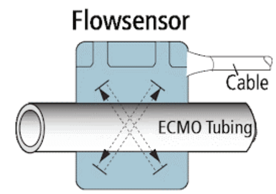


Figure 1
Flow/Dilution Sensor

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 Flow/dilution Sensors measure ultrasound velocity. A bolus of isotonic saline (ultrasound velocity: 1533 m/sec) introduced into the circuit dilutes the blood and reduces the ultrasound velocity. The sensor displays this saline bolus on the monitor as an indicator dilution curve.

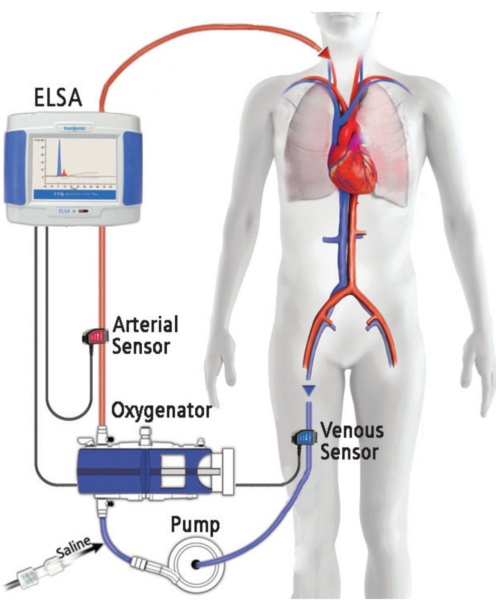


Figure 2
Normal saline is introduced upstream from the oxygenator. The bolus passes the arterial sensor, yielding the volume of clot within the oxygenator. The recirculating portion of the bolus passes through the venous sensor, yielding the percentage of recirculation.

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 indicator concentrations equals recirculation (Fig. 2).

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 directly proportional to the blood volume. 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.

A decrease in oxygenator blood volume over time reflects declining oxygenator performance and the development of clotting within the circuit.

UNIVERSITY OF MICHIGAN EXPERIENCE

The University of Michigan has the largest single cohort of reported ECMO patients. Two thousand patients were managed with ECMO from 1973 to 2010. Of the 2,000 patients, 74% were weaned from ECLS, and 64% survived to hospital discharge.

RESPIRATORY FAILURE PATIENTS (ARDS)

Patients	Survival To Hospital Discharge	
Neonates	n = 799	84%
Children	n = 239	76%
Adults	n = 353	50%

CARDIAC FAILURE PATIENTS

Patients	Survival To Hospital Discharge	
Children	n = 361	45%
Adults	n = 119	38%

Complications

The most common complication during ECMO was bleeding at sites other than the head, with an incidence of 39%. Intracranial bleeding or infarction occurred in 8% of patients, with a 43% survival rate. The least frequent complication was pump malfunction, with a 2% incidence.

Conclusion

The University of Michigan experience concluded that ECLS saves lives of moribund patients with acute pulmonary and cardiac failure in all age groups.

Gray BW, Bartlett RH et al, "Extracorporeal life support: experience with 2,000 patients," ASAIO J. 2015; 61(1): 2-7. (Transonic Reference # 10210AH)

Bartlett RH, Combes A, Peek GJ, "Extracorporeal life support," Ann Am Thorac Soc. 2014; 11(6): 992. (Transonic Reference # 10212AHR)

SUMMARY

The spotlight on the tragic death of Patrick Kennedy, the infant son of President and Mrs. John Kennedy in August 1963, ignited the focus on the care of premature infants. Increased NIH funding for research on the diseases of the newborn resulted in the specialty of neonatology and creation of the modern neonatal intensive care unit, or NICU.

ECMO Pioneer — Dr. Robert Bartlett

Fifty years ago there were few treatment options for infants, children or adults with severe respiratory distress syndrome. Due to the herculean and innovative efforts of pioneers such as Dr. Bartlett, treatment by extracorporeal membrane oxygenation also came into being and has continued to evolve. It remains a last-ditch effort to treat neonatal, pediatric and adult patients who are suffering from severe respiratory distress syndrome and/or cardiac failure who are not responding to other medical treatments. But ECMO eventually reduced infant mortality from 80% to 25% for critically ill infants with acute reversible respiratory and cardiac failure unresponsive to conventional therapy in conditions such as persistent pulmonary hypertension, meconium aspiration, and sepsis.[24]

JANUARY 2015 ESLO REGISTRY STATISTICS[24]

Patients	Total Patients	Survived ECMO	Survived to Discharge or Transfer
Neonatal			
Respiratory	27,728	84%	84%
Cardiac	5,810	62%	62%
Urgent CPR	1,112	64%	64%
Pediatric			
Respiratory	6,569	66%	66%
Cardiac	7,314	66%	66%
Urgent CPR	2,370	56%	56%
Adult			
Respiratory	7,008	65%	65%
Cardiac	5,603	56%	56%
Urgent CPR	1,657	39%	39%
TOTALS	65,171	71%	71%

SUMMARY CONTINUED

Flow Pioneer — Transonic

Hand in hand with the evolution of ECMO has been Transonic's development of Flowsensors that can clamp on and measure the volume flow inside the tubing. The first Transonic Tubing Flowsensors were introduced in 1987. Incremental improvements in the sensors, which now have a 4 "X-style" crystal configuration, have expanded the measurement capability in tubing circuits. The 300–500 mL/min low flows typical to ECMO circuits can now be measured accurately with minimal zero offset with XL-Flowsensors.

Flow Innovations — Dedicated ELSA Monitor

The first dedicated Tubing Flowmeters measured delivered blood flow only and added an independent safety measure to ECMO procedures. Now, the new ELSA Monitor adds additional measurement capability for clinicians. Recirculation in single or dual catheter VV ECMO circuits, and oxygenator blood volume, which has been shown to indicate percent of oxygenator clotting in VV and VA circuits, can be quantified. With measurements from the ELSA Monitor, the 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.

Cannula 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 failure during VV ECMO.

Oxygenator clotting can be detected by tracking the progressive decline of oxygenator blood volumes. Again, through ongoing collaborations with clinicians who bring their measurement needs to Transonic, Transonic's innovative and cumulative engineering know-how generates measurement devices such as the a dedicated Tubing Flowmeter with XL clamp-on Flowsensors that maintain sterility within circuitry and now the ELSA Monitor to offer measurements that help to ensure better patient outcomes.

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

Berube MC, Brink LW, 12th Annual CNMC Symposium 1996.

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www.transonic.com

Americas
Transonic Systems Inc.
34 Dutch Mill Rd
Ithaca, NY 14850
U.S.A.
Tel: +1 607-257-5300
Fax: +1 607-257-7256
support@transonic.com

Europe
Transonic Europe B.V.
Business Park Stein 205
6181 MB Elsloo
The Netherlands
Tel: +31 43-407-7200
Fax: +31 43-407-7201
europe@transonic.com

Asia/Pacific
Transonic Asia Inc.
6F-3 No 5 Hangsiang Rd
Dayuan, Taoyuan County
33747 Taiwan, R.O.C.
Tel: +886 3399-5806
Fax: +886 3399-5805
support@transonicasia.com

Japan
Transonic Japan Inc.
KS Bldg 201, 735-4 Kita-Akitsu
Tokorozawa Saitama
359-0038 Japan
Tel: +81 4-2946-8541
Fax: +81 4-2946-8542
japan@transonic.com