ELSA Extracorporeal Life Support Assurance

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





Critical Care

Maximizing ECMO Efficiency

Optimize ECMO Delivery with Delivered Pump Flow Verification, Recirculation Percentage and Oxygenator Clot Detection

VERIFY DELIVERED BLOOD FLOW

Pump (delivered blood) flow errors and recirculation can compromise ECMO delivery of oxygenated blood. The Transonic 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 incorrect cannulation placement can be identified and corrected.

Delivered Flow is used to:

- Verify circuit flows;
- Determine flows with bridges or shunts;
- Determine the optimal pump flow setting with any cannula or configuration;
- Identify tubing flow restrictions that might cause hemolysis or over pressure within the circuit.

MEASURE OXYGENATOR CLOTTING

Clotting in the oxygenator is one of the major complications of ECMO. The challenge is to minimize oxygenator clotting while preventing bleeding in fragile patients.

With an injection of a small volume of saline the ELSA Monitor measures oxygenator blood volume to quantify early clot formation in the ECMO circuit oxygenator. Early detection and trending of clot formation in ECMO circuits allows a wider window of opportuity to perform oxygenator change-outs when needed.

OPTIMIZE ECMO THERAPY

With a single bolus of saline, the Transonic ELSA Monitor detects and quantifies recirculation. Measuring recirculation with the Transonic ELSA Monitor provides an intensivist with vital information about a patient. High recirculation during VV ECMO may indicate:

- Cannula misplacement;
- Hypo- or hypervolemia;
- Cardiac failure.

Knowing the amount of recirculation helps an intensivist establish the optimal pump setting to minimize the length of ECMO runs, optimize cannula position, and identify restricted flow due to hypo-volemia and/or cardiac failure.



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

Transonic Systems Inc., global manufacturer of biomedical flow measurement equipment, sells "gold standard" ultrasound transit-time flowmeters, hemodialysis, endovascular and laser Doppler perfusion monitors worldwide to surgeons, nephrologists, interventional radiologists, researchers and original equipment manufacturers (OEMs).

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VV ECMO Recirculation Measurements Help Detect Cannula Misplacement, Hyper- & Hypovolemia or Cardiac Failure

Until now recirculation has been an unquantifiable problem for patients on VV ECMO. Cannulas often under-deliver oxygenated blood due to the presence of recirculation. With a single bolus of saline, the Transonic ELSA Monitor detects and quantifies recirculation in any single or dual-lumen circuit. By having known values for flow and recirculation, cannula migration can be detected and corrected, volume status can be identified and cardiac failure foreshadowed.

The ECMO pump is set to deliver a certain rate of blood flow. The ELSA Monitor will confirm that the rate of flow set by the intensivist is being delivered to the patient, or will indicate by the presence of recirculation that the set delivery is not being achieved and oxygenated blood is recirculating back into the ECMO circuit before it traverses the body's circulatory system. For instance, a 50% recirculation measurement shows that half of the intended oxygenated blood is not being circulated through the patient. The pump flow will be misleadingly high.

There are several potential causes of recirculation. The cannula or cannulas could be positioned badly. The venous cannula could be stuck up against the wall of the IVC (restricting flow traveling out). The arterial cannula might be directing flow toward the venous cannula rather than through the tricuspid valve.

What if the cannula positioning is good? What does recirculation indicate here? At this point, recirculation becomes an indicator of either a patient's blood volume or heart function. Blood volume is the total amount of blood in the circulatory system. There has to be enough blood volume in a patient for the heart to do its work. Preload is the filling up of the heart before it contracts. If there is low preload, or low blood volume, the patient is said to be hypovolemic and there is just not adequate fluid/blood to allow the heart to deliver enough blood to and back from the organs. In VV ECMO, the patient is deliberately kept 'dry' so not much fluid is added to the



Recirculation calculation procedure by the ELSA unit. The flow curve is plotted in red, and whatever is returned immediately through the return line to the venous cannula is plotted in blue. The two are compared, and the recirculation and effective cardiac flow are reported. The important number is the ECF, and there is no other technology or calculation that can accurately provide it.



All recirculation measurements are recorded, and displayed together as a trend. Here you can see where recirculation climbed to a level that was harmful, the cannula was repositioned, and the recirculation returned to baseline.



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ELSA Recirculation Measurements Help Optimize Cannula Placement

patient. Why is this?

If too much fluid is introduced, the interstitial space of tissues can be overloaded with fluid which can cause a host of undesirable problems. However, enough fluid still needs to be available to allow the heart to have adequate preload for the heart to pump sufficient amounts of blood throughout the body. This balance is a struggle to maintain.

If the cannula positioning is good and the patient is being kept dry, low volumes (aka low preload or hypovolemia) could be the culprit for recirculation.

A third possibility exists, if cannula positioning is good and blood volumes are adequate, the right heart is failing and is the cause of recirculation. For instance, 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. The Intensivist may decide to perform an echocardiogram to check the status of the heart – in some cases recirculation may indicate that VA ECMO should be considered to help assist the heart as well as the lungs.

When visiting an ECMO unit, work with the nurse, as they know if anything was recently changed or added, such as patient position or medications. Recirculated flow will raise SvO_2 level which could falsely indicate a better patient condition.

Some physicians will also order a Doppler ultrasound study, but the results are difficult to interpret and impossible to accurately quantify.

In conclusion, high recirculation during ECMO may indicate:

- Cannula misplacement;
- Hyper- or Hypovolemia;
- Cardiac failure.

Measuring recirculation with the Transonic ELSA Monitor provides an intensivist and ECMO team vital information about a patient.



Single Lumen x 2

Dual lumen

Single-lumen cannulation on the left, Avalon dual-lumen on the right. Red arrows show delivered blood, blue arrows show returning venous blood.



Two primary companies make dual-lumen cannulas,OriGen & Avalon. 6 OriGen sizes, 7 Avalon sizes, but an infinite amount of pt sizes.



Detecting Oxygenator Clotting with the ELSA Monitor

Among the many problems facing ECMO team members, persistent clotting is among the most frustrating.

Clots within the ECMO circuit can have catastrophic consequences. Consequently, all circuits are run with low levels of Heparin to reduce the potential for clot formation while keeping bleeding at a minimum. Clot formation is traded for lower stroke risk. Full anticoagulation requires an Activated Clotting Time (ACT) of 400 to 480 seconds, but in ECMO cases ACT levels are maintained at 180 to 200 seconds, virtually assuring clot formation.

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.

The most common method of measuring clot formation is monitoring the pressure proximal and distal to the oxygenator. The concept is that a clot resists the flow linearly with clot growth, and upstream pressure will increase. When 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.



The arterial sensor senses the increase in flow during the injection, and marks the time. When the saline bolus passes the sensor, the saline bolus is plotted in red. The flow from the injection point to the center of the flow curve represents the total volume between the injection site and the sensor.



Shown is a Maquet Quadrox oxygenator in use. It is by far the most common type of ECMO oxygenator. Whatever the model, oxygenators all share the same tendency to clot. During a case, it is impossible to see through the flowing blood to identify the underlying amount of clot that has formed. Physicians and perfusionists are not taught about variance in clot formation and clots can differ.



Shown in this oxygenator is a thin, soft layer of clot over most of the fibers with some fibers exposed so there is no pressure gradient change. Mixed density, some hard formations growing.

As a clot increases in volume, 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.



Non-flaking soft clots evenly spread across the fibers shown here cause a high pressure gradient. This would tempt some teams to change out the oxygenator, even though it is still functioning well. That would not be a good move, as changing an oxygenator is risky (zero flow for a couple of minutes, and potential air embolism) as well as detrimental loss of RBCs, clotting factors, proteins, etc., in the oxygenator.



This pattern of clotting formation is the nightmare. There will be no pressure change upstream, since there are large open portions of fibers showing on the periphery. In the center a hard, well developed clot has formed which will continue to grow and shed thrombolic emboli. The team will have no indication since pressure and oxygenation are fine. These hard clot formations will grow and slough off, and eventually cause a stroke in VA patients, or pulmonary emboli in VV patients.



Detecting Oxygenator Clotting with the ELSA Monitor cont.

Trending is available in 4 hours, 24 hours, or totalcase-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 for device change outs, before clotting becomes a serious clinical risk.



Each injection is plotted. Here you can see where the volume decreased (as clot volume increased), and returns to baseline when the oxygenator is changed out.



Volume is also plotted as a percentage, if preferred.



ECMO

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ELSAReferences(ELS-1-ref)RevD2018USltr

ECMO/CP Bypass

ELSA -HCE101 The Extracorporeal Life Support Assurance Monitor

Optimize ECMO Therapy by Ensuring Optimal Perfusion

The Transonic ELSA Monitor is used to optimize ECMO therapy in children and adults. It uses established transit-time ultrasound technology to measure blood flow in ECMO circuits, and gold standard ultrasound flow/dilution technology to quantify recirculation and detect oxygenator clotting with an infusion of a single bolus of room temperature saline into the circuit.

The ELSA Monitor helps guide optimal cannula placement and ECMO delivery by:

- Helping establish a maximum flow setting with minimum recirculation;
- Utilizing known values for flow and recirculation to shorten the duration of ECMO runs;
- Recognizing cannula positioning problems by identifying elevated rates of recirculation.
- Quantifying clot development in oxygenators to allow a wider window of opportuity to perform change-outs.
- Identifying reduction in cardiac output during VV ECMO.

Flow/Dilution Sensors

ELSA Flow/Dilution Sensors use ultrasonic transit time technology to measure delivered volume flow with highest accuracy. Most fluids can be measured including saline, cardioplegia, and blood. With a single bolus of saline using flow/dilution technology, the Transonic ELSA Monitor detects and quantifies recirculation with VV ECMO single- and dualcannula configurations. It also quantifies oxygenator clotting. No physical contact is made with the fluid media so sterility is maintained within the circuit. The size of the Flow/Dilution Sensors is determined by outside diameter of the tubing.

ELSA HFX FLOW/DILUTION SENSORS			
FLOW/ DILUTION SENSOR #	TUBING		Flow Range
	ID (inches)	OD (inches)	(L/min)
H6FX	1/4	3/8	0 - 5
H7FX	1/4	7/16	0 - 10
H9FX	3/8	9/16	0 - 10



HCE101 ELSA Monitor



H7FX Flowsensors

Choosing Your Sensor

Size

Three sizes of Flow/dilution sensor pairs are available. Sensors are scaled in 1/16 inch increments to clamp around standard tubing diameters.

Tubing

Flexible medical grade and laboratory tubings (PVC, silicon, polyurethane) are generally compatible for use with -XL Sensors. A 30 - 60 cm tubing sample is required to calibrate the Sensor pair.

Optional

Sensors are calibrated for specific tubing densities and temperature.



ELSADatasheet (ELSA-101-ds) RevC 2019 USltr

ECMO

ELSA Principle of Operation: Ultrasound Dilution Technology

Transonic ELSA Monitor Uses Ultrasound Indicator Dilution Technology to Measure:

- Delivered Blood Flow (flow in the ECMO tubing, pump flow): Ultrasound sensors clipped onto ECMO tubing blood lines transmit minute levels of ultrasound through the tubing wall into the blood stream.
 Sensitive electronics derive flow via transittime ultrasound principles.
- Recirculation: Using indicator dilution principles, the same sensors quantify recirculation in the VV patient. Cannulas deliver less flow due to the presence of recirculation.
- Oxygenator Blood Volume: The ELSA Monitor also uses dilution technique to measure Oxygenator Blood Volume. As clots form within the oxygenator, the circulating blood volume decreases. This quantitative assessment of oxygenator blood volume thereby foreshadows diminished oxygenator performance and potential clotting within the circuit. Accurate trending helps to predict when an oxygenator will need to be changed out.



Fig. 1: Schematic showing placement of Flow/dilution Sensors and site of saline bolus injection into the VV ECMO circuit.

System Components

- Transonic ELSA Monitor
- Arterial & Venous Flow/Dilution Sensors
- Room temperature isotonic saline (0.9% NaCl) injected into the circuit.

Principle I: Differential Transit-Time Ultrasound Delivered Blood Flow

The clip-on sensor transmits beams of ultrasound through the blood line many times per second. Two 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 transducer to the other ("transit time") resulting from the flow of blood in the vessel. The difference between the upstream and downstream transit times and the area of the tubing provide a measure of volume flow.

During ECMO, two matched flow/dilution sensors are clipped onto the arterial and venous lines (Fig. 1). The monitor continuously displays both blood flows. Comparison of the readings with the pump flow setting (i.e., the flow the pump is assumed to deliver) provides an opportunity to identify and correct flow delivery problems.

Principle II: Ultrasound Indicator Dilution Patient Blood Flows, Recirculation, Oxygenator Blood Volume

The velocity of ultrasound in blood (1560-1590 m/sec) is determined primarily by its blood protein concentration. The Transonic ELSA Monitor and matched Flow/dilution Sensors measure ultrasound velocity. A bolus of isotonic saline (ultrasound velocity: 1533 m/sec) introduced into the blood stream dilutes the blood and reduces the ultrasound velocity. The Sensor records this saline bolus as a conventional indicator dilution curve. When a bolus of saline indicator is introduced into the blood line, the arterial and venous sensors each register an indicator dilution curve.

Protected under USA patents # 5,453,576; 5,595,182; 5,685,989. International patent #EP 0 781 161 B1



ELSAUltrasoundDilutionPrinciple(ELS-10-tnRevC2019USltr