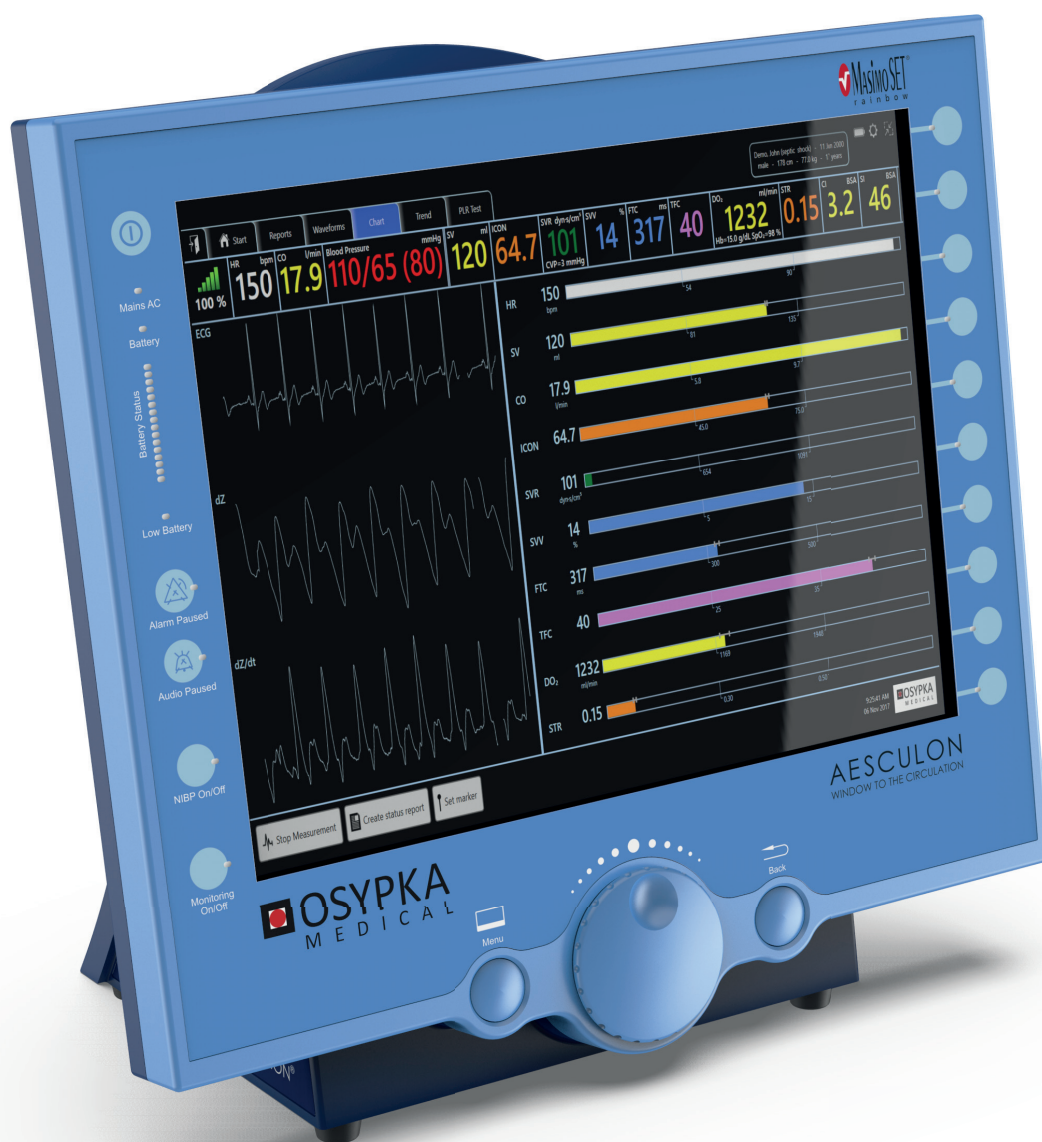


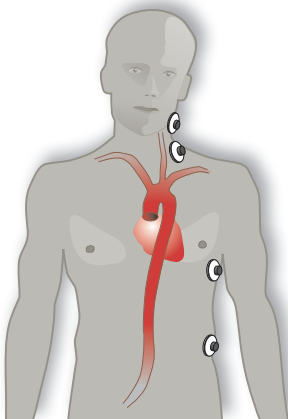
AESCULON®

HEMODYNAMIC MANAGEMENT Electrical Cardiometry™



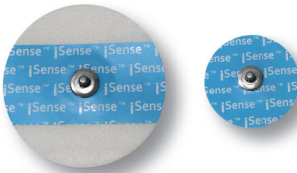
Electrical Cardiometry™ (EC™)

Electrical Cardiometry™ is a method for the non-invasive determination of stroke volume (SV), cardiac output (CO), and other hemodynamic parameters in adults, children, and neonates. Electrical Cardiometry has been validated against “gold standard” methods such as thermodilution and is a proprietary method patented by Osypka Medical.

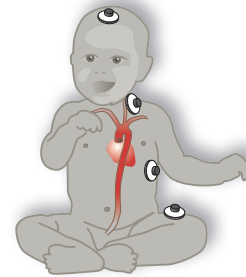


Sensor located at the left side of neck and thorax

iSense
ELECTRICAL CARDIOMETRY
Single patient use EC Sensors



iSense Single Patient EC Sensors

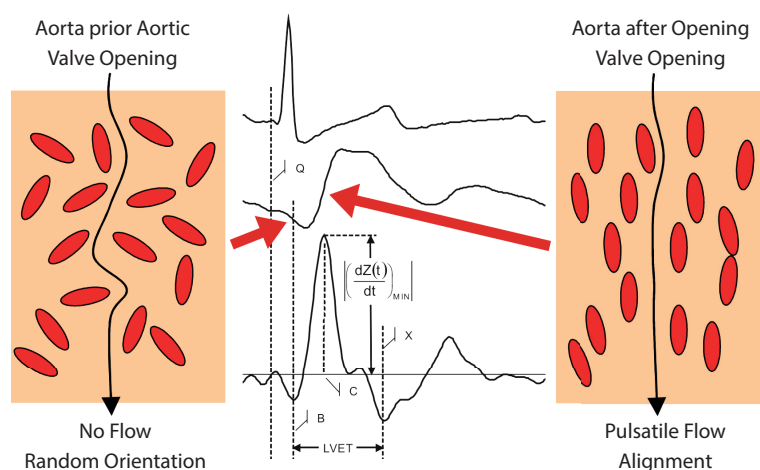


Sensor placement for small children and neonates

How it works

The placement of four skin sensors on the neck and left side of the thorax allow for the continuous measurement of the changes of electrical conductivity within the thorax. By sending a low amplitude, high frequency electrical current through the thorax, the resistance that the current faces (due to several factors) is measured. Through advanced filtering techniques, Electrical Cardiometry™ (EC™) is able to isolate the changes in conductivity created by the circulatory system. One significant phenomenon, which is picked up, is associated with the blood in the aorta and its change in conductivity when subjected to pulsatile blood flow. This occurrence is due to the change in orientation of the erythrocytes (RBCs).

During diastole, the RBCs in the aorta assume a random orientation, which causes the electrical current to meet more resistance, resulting in a lower measure of conductivity. During systole, pulsatile flow causes the RBCs to align parallel to both the blood flow and electrical current, resulting in a higher conductivity state. By analyzing the rate of change in conductivity before and after aortic valve opening, or in other words, how fast the RBCs are aligning, EC technology derives the peak aortic acceleration of blood and the left ventricular ejection time (flow time). The velocity of the blood flow is derived from the peak aortic acceleration and used within our patented algorithm to derive stroke volume.



Applications

Advanced, Non-Invasive Hemodynamic Monitoring:

Blood pressure, heart rate and other vital signs typically available to clinicians do not give a complete picture of a patient's hemodynamics. Guiding therapy by traditional parameters makes it very difficult to decide whether volume, inotropes, or vasopressors would be best for the patient.

With the ICON and AESCULON, the user gets a complete picture of the patient hemodynamics using a method that is quick, easy, safe, non Invasive and accurate. The parameters provided by EC fill in the blanks of traditional monitoring, helping physicians guide fluid resuscitation and drug therapy in a targeted, continuous manner. In addition to providing parameters such as Cardiac Output and Stroke Volume measurements, there are several parameters unique to EC that provide enhanced indications of preload, contractility, afterload and delivered oxygen.

Goal-Directed Therapy and Fluid Management in the OR, ICU and ED:

Goal-directed therapy is a technique to guide administration of fluid and drugs to achieve certain hemodynamic goals. Protocols based on goal-directed therapy have been proven to reduce morbidity and mortality rates for critical patients specially who are suffering from severe sepsis, septic shock and patients undergoing high to medium risk surgeries. EC monitors make it easy and safe to use these protocols into routine practice.

Shock Differential Diagnosis:

Differential diagnosis and treatment of shock can be extremely challenging with traditional parameters like blood pressure and heart rate. Clinicians need a complete picture of the patient's hemodynamics (flow, preload, contractility and afterload) to identify the type of shock (cardiogenic vs. hypovolemic for instance) and continuous monitoring to guide therapy and assess the patient's response. EC monitors are ideal for these patients and for Early Goal Directed Therapy (EGDT) protocol for shock patients.

Pediatrics and Neonates:

EC monitors are the ONLY FDA cleared easy to use, noninvasive monitors for pediatrics and neonates. Invasive monitors like pulmonary artery catheters are typically too dangerous or impossible to use these patients. EC monitors are ideal because they are safe and easy to use. The sensors are small and gentle enough to use on even the tiniest and most fragile neonate. The data provided by EC monitors can help clinicians distinguish warm vs. cold shock, guide therapy, titrate medications and potentially provide an early warning of adverse events, and most important is a perfect fluid management tool.

Heart Failure and Hypertension Management:

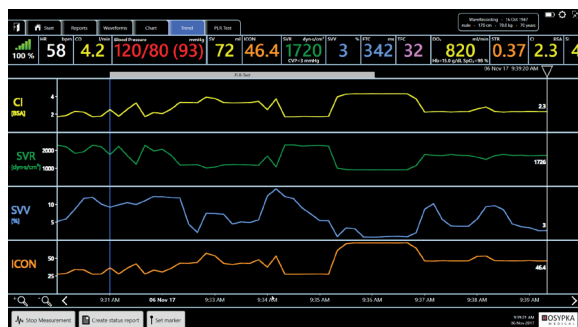
EC monitors are ideal for the management of heart failure and hypertension, especially in an outpatient and even in home care setting. In less than 3 minutes, physicians have access to advanced hemodynamic data that can be used to optimize treatment and even predict future events in HF patients. This practice can potentially reduce hospitalization and ER visits and improve the patient's quality of life.

Advanced Statistics:

Nonlinear statistics applied to the measured heart rate (HRC; or Sample Entropy) have the potential of predicting life-saving interventions (Peev M, King D et al. Journal of Critical Care 2013)



Window to the Circulation®



Various screens available including Trend View

AESCULON® Parameters

Blood Flow

SV/SI	Stroke Volume / Stroke Index
HR	Heart Rate
CO/CI	Cardiac Output /Cardiac Index

Vascular System

NIBP	Non-invasive Blood Pressure
SVR /SVRI	Systemic Vascular Resistance/
SVR-	Index based on input of MAP and CVP
SSVR / SVRI	Stroke System Vascular Resistance/SSVR Index

Contractility

ICON™	Index of Contractility
VIC™	Variation of Index of Contractility
LCW / LCWI	Left Cardiac Work based on input of
	Wedge Pressure (PAOP)
LSW / LSWI	Left Stroke Work
STR	Systolic Time Ratio (PEP/LVET)
CPI	Cardiac Performance Index

Fluid Status

TFC	Thoracic Fluid Content
SVV	Stroke Volume Variation
FTC	Corrected Flow Time

Oxygen Status MASIMO SET®

Rainbow® (Optional)

SpO ₂	Oxygen Saturation
SpHb™	Levels of Total Hemoglobin
SpCO	Level of Carbon Monoxide Concentration
PI / PI Change	Perfusion Index / PI Percent Change
Desat Idx	Desaturation Index
DO ₂ / DO ₂ I	Oxygen Delivery / DO ₂ -Index based on
	input of Hemoglobin and SpO ₂



AESCULON® Features

- 12" high resolution color display with touch operation
- integrated iControl™ software
- Rechargeable battery backup for 20 min. of operation
- Patient data are recorded beat to beat for review and data export
- Passive Leg Raise test procedure integrated (Optional)
- HL7 communication protocol for connectivity to Patient Data Management Systems (PDMS)
- Interface to Philips IntelliVue and Dräger Infinity Gateway
- USB Interface for convenient backup of patient data and printing
- PDF status reports can be saved and printed

Literature: Adult

- Narula J, et al. Assessment of Changes in Hemodynamics and Intrathoracic Fluid Using Electrical Cardiometry During Autologous Blood Harvest Journal of Cardiothoracic and Vascular Anesthesia. 2017.
- Liu Y H, et al. Continuous non-invasive cardiac output monitoring during exercise: validation of electrical cardiometry with Fick and thermodilution methods, British Journal of Anaesthesia. 2016.
- Mahmoud K H, et al. Non invasive adjustment of fluid status in critically ill patients on renal replacement therapy. Role of Electrical Cardiometry. The Egyptian Journal of Crit Care Med. 2016
- Soliman R, et al. Bedside Assessment of Preload in Acute Circulatory Failure Using Cardiac Velocimetry. J Med Diagn Meth. 2016
- Rajput R, et al. Comparison of Cardiac Output Measurement by Noninvasive Method with Electrical Cardiometry and Invasive Method with Thermodilution Technique in Patients Undergoing Coronary Artery Bypass Grafting. World Journal of Cardiovascular Surgery. 2014.
- Malik V, et al. Correlation of Electric Cardiometry and Continuous Thermodilution Cardiac Output Monitoring Systems World Journal of Cardiovascular Surgery. 2014.
- Peev M, et al. Real-time sample entropy predicts life-saving interventions after the Boston Marathon bombing. Journal of Critical Care. 2013.
- Mejaddam A Y, et al. Real-time heart rate entropy predicts the need for lifesaving interventions in trauma activation patients. J Trauma Acute Care Surg. 2013.
- Flinck M, et al. Cardiac output measured by electrical velocimetry in the CT suite correlates with coronary artery enhancement: a feasibility study. Acta Radiol. 2010.
- Zoremba N, et al. Comparison of electrical velocimetry and thermodilution techniques for the measurement of cardiac output. Acta Anaesthesiol Scandinavia. 2007.
- Schmidt C, et al. Comparison of electrical velocimetry and transoesophageal Doppler echocardiography for measuring stroke volume and cardiac output. British Journal of Anaesthesia. 2005

Literature: Pediatric & Neonate

- Narula J, et al. Electrical Cardiometry: A Reliable Solution to Cardiac Output Estimation in Children With Structural Heart Disease. Journal of Cardiothoracic and Vascular Anesthesia. 2017.
- Freidl T, et al. Haemodynamic Transition after Birth: A New Tool for Non-Invasive Cardiac Output Monitoring. Neonatology 2017.
- Hsu K-H, et al. Hemodynamic reference for neonates of different age and weight: a pilot study with electrical cardiometry Journal of Perinatology. 2016.
- Neurinda P, et al. Electric velocimetry and transthoracic echocardiography for noninvasive cardiac output monitoring in children after cardiac surgery. Crit Care & Shock. 2015.
- Katheria A C, et al. Measuring cardiac changes using electrical impedance during delayed cord clamping: a feasibility trial. Maternal Health, Neonatology, and Perinatology 2015.
- Lien R, et al. Hemodynamic alterations recorded by electrical cardiometry during ligation of ductus arteriosus in preterm infants. European Journal of Pediatrics. 2014.
- Coté CJ, et al. Continuous noninvasive cardiac output in children: is this the next generation of operating room monitors? Initial experience in 402 pediatric patients. Paediatr Anaesth. 2014.
- Grollmuss O, et al. Non-invasive cardiac output measurement in low and very low birth weight infants: a method comparison. Front Pediatr. 2014.
- Noonan P, et al. Non-invasive cardiac output monitoring during catheter interventions in patients with cavopulmonary circulations. Cardiol Young. 2014.
- Noori S, et al. Continuous Non-invasive cardiac output measurements in the neonate by electrical velocimetry: a comparison with echocardiography. Arch Dis Child Fetal Neonatol Ed. 2012.
- Rauch R, et al. Non-invasive measurement of cardiac output in obese children and adolescents: comparison of electrical cardiometry and transthoracic Doppler echocardiography. J Clin Monit Comput. 2012.
- Grollmuss O, et al. Electrical velocimetry as a tool for measuring cardiac output in small infants after heart surgery. Intensive Care Med. 2012.
- Norozi K, et al. Electrical velocimetry for measuring cardiac output in children with congenital heart disease. Br J Anaesth. 2007.
- Osthaus W A, et al. Comparison of electrical velocimetry and transpulmonary thermodilution for measuring cardiac output in piglets. Pediatric Anesthesia. 2007.

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