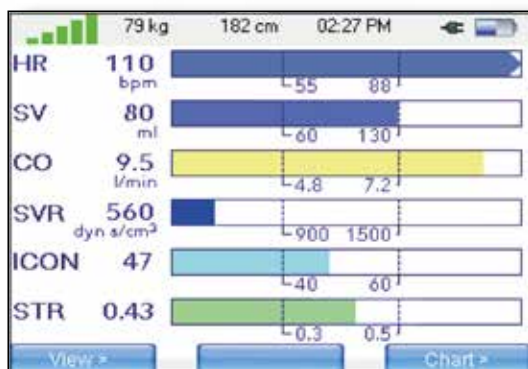


ICON[®]

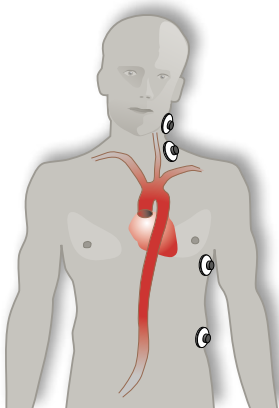
NONINVASIVE HEMODYNAMICS

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.

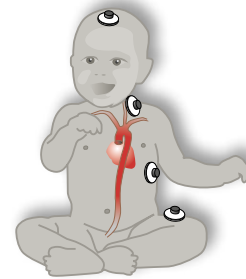


Sensor located at the left side of neck and thorax

iSense
ELECTRICAL CARDIOMETRY
Single patient use EC Sensors



iSense Single Patient EC Sensors

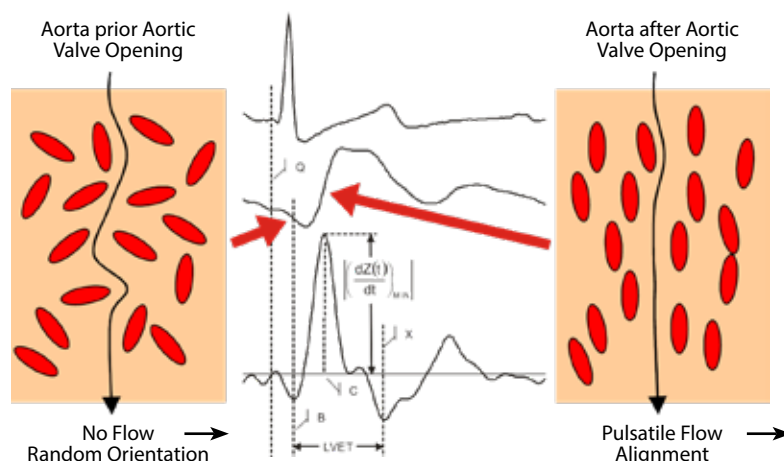


Sensor placement for small children and neonates

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. The EC™-cardiometer makes 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. The EC™-cardiometer es ideal for these patients and for Early Goal Directed Therapy (EGDT) protocol for shock patients.

Pediatrics and Neonates:

The EC™-monitor and cardiometers are the ONLY FDA cleared easy to use, non-invasive devices for pediatrics and neonates. Invasive monitors like pulmonary artery catheters are typically too dangerous or impossible to use these patients. The EC™-devices 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™-devices 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.

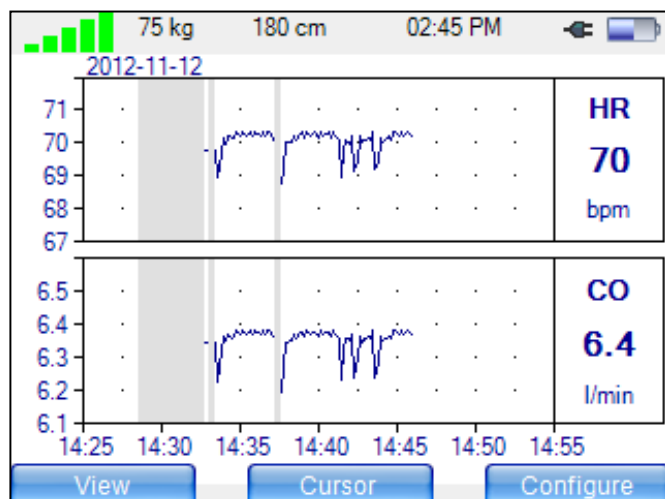
Heart Failure and Hypertension Management:

The EC™-cardiometer is 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

ICON® Parameters

Blood Flow

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

Vascular System

SVR /SVRI	Systemic Vascular Resistance/ SVR-Index based on input of MAP and CVP
-----------	---

Contractility

ICON™	Index of Contractility
VIC™	Variation of Index of Contractility
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

DO ₂ / DO ₂ l	Oxygen Delivery / DO ₂ -Index based on input of Hemoglobin and SpO ₂
-------------------------------------	--

ICON® Features

- 3.5" high resolution color display
- Rechargeable battery backup for 120 min. of operation
- Connectivity to Philips monitoring systems by supporting the VueLink and IntelliBridge interface protocol
- Internal data storage and transmission to PC

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.
- Mejjaddam 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.

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 non-invasive 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.

Osypka Medical GmbH

Albert-Einstein-Strasse 3
12489 Berlin, Germany
Phone: +49 (30) 6392 8300
Fax: +49 (30) 6392 8301
E-Mail: mail@osypkamed.com
www.osypkamed.com

United States of America:
Osypka Medical, Inc.

dba. Cardiotronic
La Jolla, CA 92037, USA
Phone: +1 (858) 454 0600
Fax: +1 (858) 454 0640
E-Mail: mail@cardiotronic.net
www.cardiotronic.net

U.S. Patent Nr. 6,511,438. Other patents pending.

AESCLON, Cardiotronic, Electrical Cardiometry, Electrical Velocimetry, EV, ICON, Window to the Heart, Window to the Circulation and logos are trademarks of Osypka Medical.
MASIMO, SET SpHb and PVI are trademarks of Masimo Corporation.
Microsoft and Excel are Trademarks of Microsoft.

Copyright © 2022 Osypka Medical

