ICON®

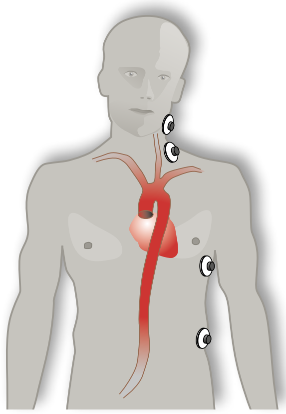
NONINVASIVE HEMODYNAMICS

Electrical Cardiometry™

OSYPKA MEDICAL

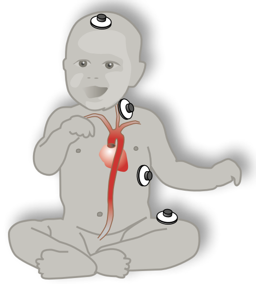
Electrical Cardiometry™ (EC™)

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 Single Patient EC Sensors

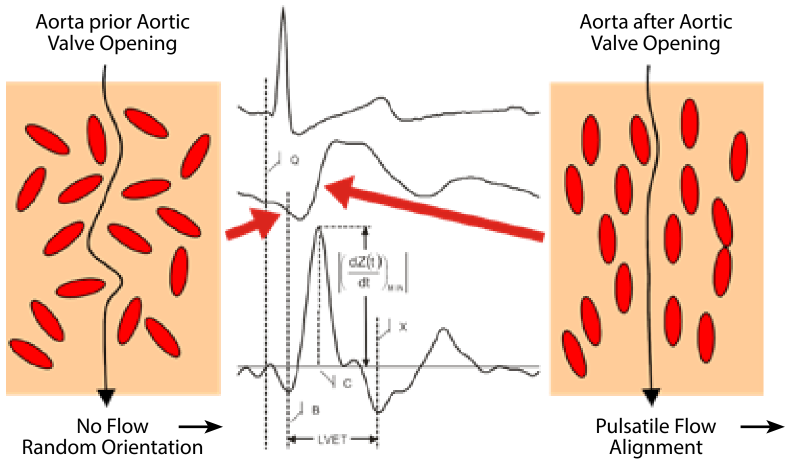


Sensor placement for small children and neonates

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.



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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, non-invasive 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.

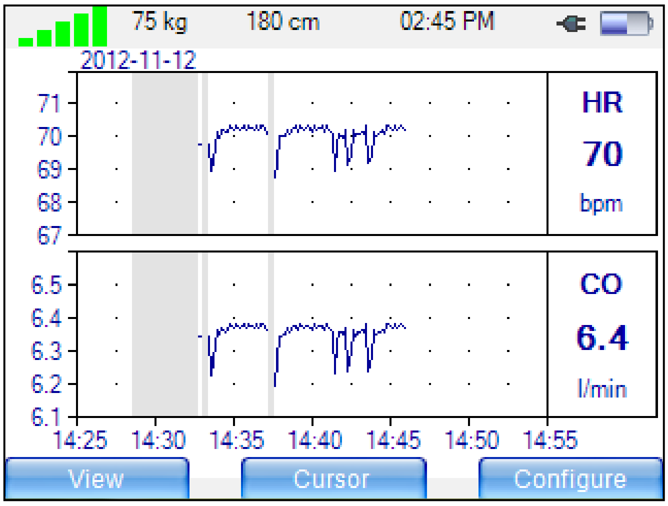
Pacemaker Optimization (Pacemaker Clinic™):

Physicians that perform pacemaker optimization of AV and VV delay can use EC monitors to get quick and immediate data on which settings provide the patient with the best hemodynamics.

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_2I	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 wireless transmission to PC
- iControl™ PC-Software allows data export to Microsoft® Excel™
- Wireless printing with Bluetooth®

Literature

Adult

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Pediatric & Neonate

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