Noninvasive Cardiac Output

Electrical Cardiometry™

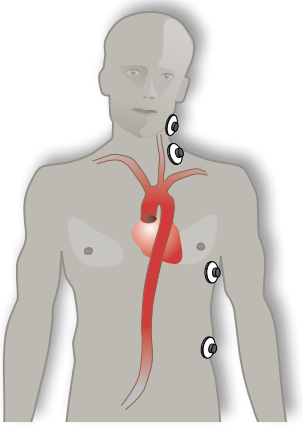
AESCULON®
Window to the Circulation®

ICON®
Window to the Heart®

OSYPKA MEDICAL
Berlin, Germany · San Diego, California, USA

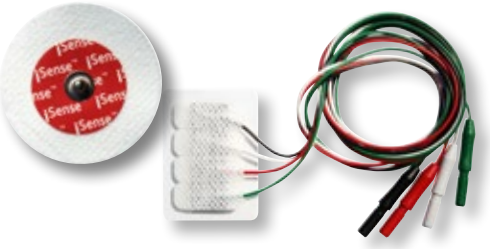
Electrical Cardiometry™ (EC™)

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.

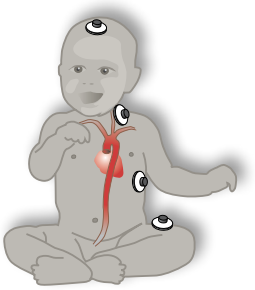


Sensor located at the left side of neck and thorax

iSense
ELECTRICAL CARDIOMETRY



iSense Single Patient EC Sensors

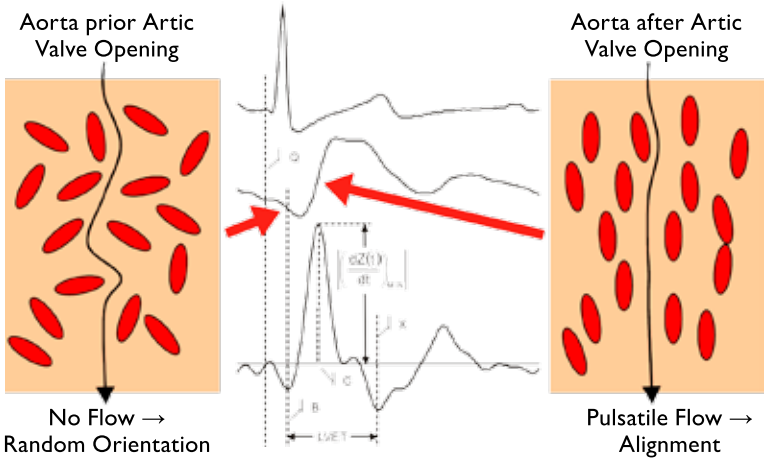


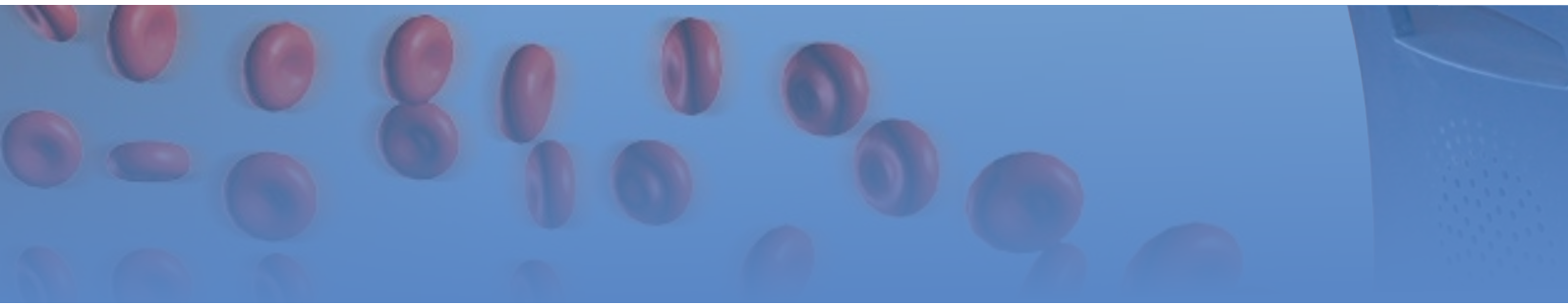
Sensor placement for small children and neonates

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, 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.

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. The AESCULON can even integrate with Osypka Medical's PACE 203 / PACE 300 external chamber pacemakers using Pacemaker Clinic to automate the optimization process.

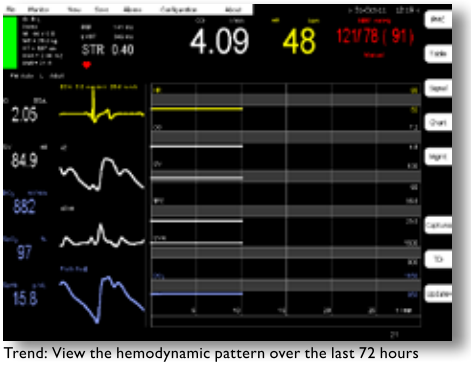
Predictive Parameters: Complexity Analysis:

EC monitors offer the parameter HRC which has been shown helping to predict the need for life saving intervention in trauma patients.

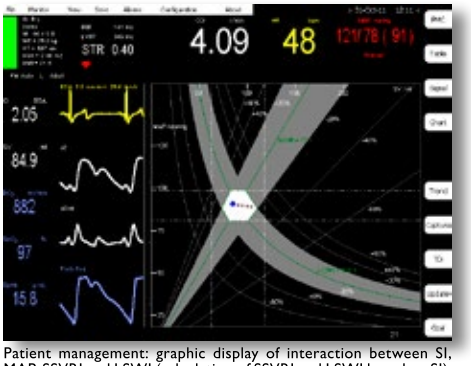
Window to the Circulation®

Waveforms: Sophisticated signal processing: Measured waveforms and calculated parameters at a glance

Bar Screen: 10 selectable parameter bars with normal ranges and variance



Trend: View the hemodynamic pattern over the last 72 hours



Patient management: graphic display of interaction between SI, MAP, SSVRI and LSWI (calculation of SSVRI and LSWI based on SI).

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 Central Venous Pressure (CVP)
SSVR / SSVRI	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 (Pulse Oximetry) MASIMO SET® Rainbow (optional)

SpO_2	Oxygen Saturation
SpHb™	Levels of Total Hemoglobin
SpMet	Level of Methemoglobin Concentration
SpCO	Level of Carbon Monoxide Concentration
PI / PI Change	Perfusion Index / PI Percent Change
Desat Idx	Desaturation Index
DO_2 / DO_2I	Oxygen Delivery / DO_2-Index

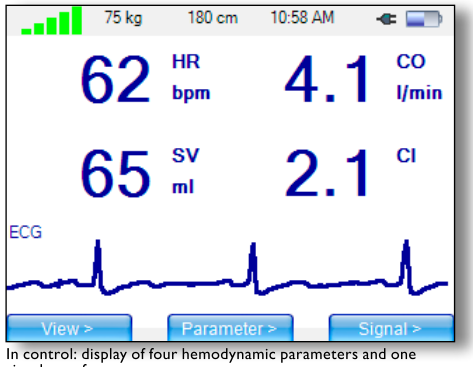
AESCULON® Features

- Pacemaker Clinic™ optimization of cardiac pacing and resynchronization therapy (CRT).
- 12″ high resolution color display
- Rechargeable battery backup for 20 min. of operation
- Connectivity to Philips monitoring systems by supporting the VueLink and IntelliBridge interface protocol
- USB Interface for convenient backup of patient data and printing
- Waveform Explorer™ PC-Software allows data export to Microsoft® Excel™

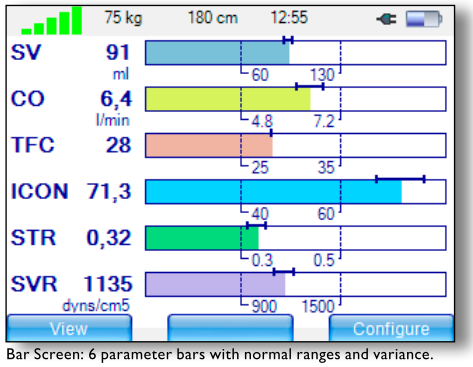
AESCULON®

Window to the Circulation®

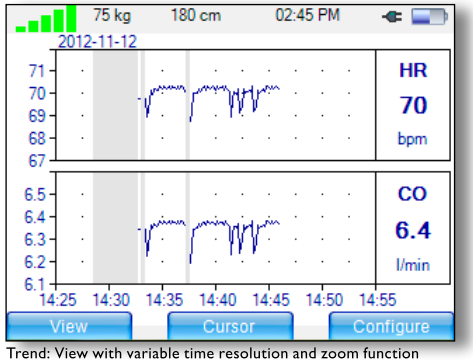
Window to the Heart®



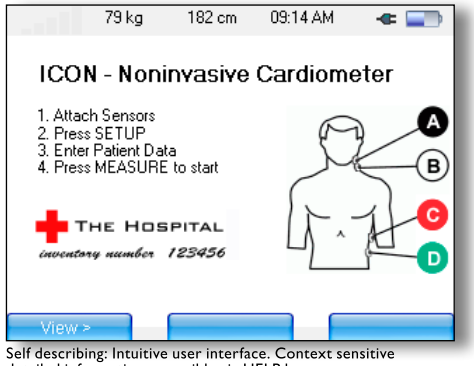
In control: display of four hemodynamic parameters and one signal waveform.



Bar Screen: 6 parameter bars with normal ranges and variance.



Trend: View with variable time resolution and zoom function



Self describing: Intuitive user interface. Context sensitive detailed information accessible via HELP key

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 Blood Pressure (BP) and Central Venous Pressure (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®

ICON®
Window to the Heart®

Technical Data

AESCULON®

ICON®

		AESCULON®	ICON®
Measurement Method		Electrical Cardiometry (EC) Electrical Velocimetry (Advanced Bio-Impedance)	Electrical Cardiometry (EC) Electrical Velocimetry (Advanced Bio-Impedance)
Measurement Current		<=2.0 mA RMS/50kHz	<=2.0 mA RMS/50kHz
EKG		30 ... 300 bpm	30 ... 300 bpm
Non-invasive Blood Pressure (NIBP)		Oscillatoric systolic: 40 mm Hg ... 260 mm Hg diastolic: 25 mm Hg ... 200 mm Hg	Can be entered manually
Oxygen Saturation (SpO_2) optional		1 % ... 100 %	Can be entered manually
AC Input		100 ... 240 VAC 47 ... 63 Hz	100 ... 240 VAC 47 ... 63 Hz
Power Consumtion		max. 100 VA	max. 15 VA
Internal Battery		NiMH, cap. > 20 min	Lithium Ion, cap. > 2 hours
Display		12“ color TFT	3,5“ color TFT
Enclosure Dimensions: height x width x depth		293 mm X 310 mm X 185 mm	205 mm x 110 mm x 38 mm
Weight		6 kg	750 g
Classification	According to EC-Directive	Class IIa	Class IIa
	US. Regulatory Class	Class II	Class II
	Protection Type	Class 1 equipment (Typ BF)	Class 11 equipment (Typ BF)
	Standard Compliance	IEC 60601-1, IEC 60601-1-2 and more	IEC 60601-1, IEC 60601-1-2 and more

Literature: Adult

- Rajput R, Das S, Chauhan S, Bisoi A, Vasdev S. 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, Subramanian A, Chauhan S, Hote M. Correlation of Electric Cardio-metry 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, King D, et al. Real-time heart rate entropy predicts the need for lifesaving interventions in trauma activation patients. J Trauma Acute Care Surg. 2013.
- Flinck et al. Cardiac output measured by electrical velocimetry in the CT suite correlates with coronary artery enhancement: a feasibility study. Acta Radiol. 2010.
- Zoremba et al. Comparison of electrical velocimetry and thermodilution techniques for the measurement of cardiac output. Acta Anaesthesiol Scandinavia. 2007.
- Schmidt et al. Comparison of electrical velocimetry and transoesophageal Doppler echocardiography for measuring stroke volume and cardaic output. British Journal of Anaesthesia. 2005.

Literature: Pediatric & Neonate

- Lien R, Hsu KH, Chu J, Chang Y. Hemodynamic alterations recorded by electrical cardiometry during ligation of ductus arteriosus in preterm infants. European Journal of Pediatrics. 2014. 1-8.
- 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, Viswanathan S, Chambers A, Stumper O. Non-invasive cardiac output monitoring during catheter interventions in patients with cavopulmonary circulations. Cardiol Young. 2014.
- Grollmuss O, Demontoux S, Capderou A, Serraf A, Belli E. Electrical velocimetry as a tool for measuring cardiac output in small infants after heart surgery. Intensive Care Med. 2012.
- Rauch R, Wlisch E, Lansdell N, 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.
- Noori S, Drabu B, Soleymani S, Seri I. Continuous Non-invasive cardiac output measurements in the neonate by electrical velocimetry: a comparison with echocardiography. Arch Dis Child Fetal Neonatoloy Ed 2012.
- Norozi K et al. Electrical velocimetry for measuring cardiac output in children with congenital heart disease. Br J Anaesth. 2007.
- Osthaus et al. Comparison of electrical velocimetry and transpulmonary thermodilution for measuring cardiac output in piglets. Pediatric Anesthesia. 2007.

OSYPKA

Osypka Medical GmbH

Albert-Einstein-Strasse 3
D-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.

7463 Draper Avenue
La Jolla, CA 92037, USA
Phone: +1 (858) 454 0600
Fax: +1 (858) 454 0640
E-Mail: mail@osypkamed.com
www.osypkamed.com

OAIE141103