

**IMPEDANCE
CARDIOGRAPHY
WITH** ACM
arterial compliance modulation
TECHNOLOGY

THE
6
VITAL SIGN

THE NEW DIMENSION IN
CARDIOVASCULAR
DIAGNOSIS AND MONITORING

OPTIMISED FOR
FLUID MANAGEMENT

medis.

APPLICATIONS

MONITORING AND FLUID MANAGEMENT

Intensive Care Unit
Emergency Department
Heart Failure
Anaesthesiology
Intermediate Care
Paediatrics

- establish baseline hemodynamics
- evaluate and manage the fluid level of a patient
- trend and detect hemodynamic changes for timely intervention
- monitor drug titration to evaluate and optimise treatment
- early identification of the development of oedema by measuring TFC
- possible reduction of catheter use or when the catheter is withdrawn
- when a catheter is too risky, invasive or costly

*"... bioimpedance cardiography has been shown to be accurate and clinically interchangeable with the existing technology of Pulmonary Artery Catheterization." *1*

*"Measurements are highly reproducible on same-day determinations and show device sensitivity to normal hemodynamic changes on inter-day measurements. The availability of expected hemodynamic ranges provides a baseline for objective determination of responses to therapeutic interventions." *2*

HYPERTENSION MANAGEMENT

Hypertension Clinics
Physician's Office

- determine cause of high blood pressure in order to target, optimise, and validate medications
- define most effective antihypertensive drug combination (Beta-blocker, ACE inhibitor, Diuretic and others)
- balance systemic vascular resistance, cardiac output and fluid level (TFC)
- measure aortic pulse wave velocity to evaluate arterial stiffness as an independent predictor of cardiovascular risk and to monitor drugs that can improve it

*"... non-invasive hemodynamic management achieved superior BP levels and control rates, when compared to management by experienced hypertension clinicians. Our results suggest that sequential non-invasive hemodynamics provide effective guidance in drug selection and titration in treatment of resistant hypertensives." *3*

*2007 Guidelines for the Management of Arterial Hypertension. *4*

CARDIOVASCULAR DIAGNOSIS

Rehabilitation
Physician's Office

- evaluate heart performance by different function tests (orthostatic test, Valsalva manoeuvre)
- measure aortic pulse wave velocity to evaluate arterial stiffness for cardiovascular risk stratification
- combine with the measurement of Ankle-Brachial-Index (ABI) to analyse arteriosclerotic changes using the VasoScreen device

*"Because arterial stiffness is an independent predictor of cardiovascular risk, there is now great interest in its use for cardiovascular risk stratification and to monitor drugs that can alter / improve aortic stiffness." *5*

PACEMAKER ADJUSTMENT

Electrophysiology
Physician's Office

- optimise AV-delay and VV-delay in multi-chamber pacemakers
- resynchronisation therapy (CRT)

*"In patients undergoing ventricular resynchronisation therapy, AV delay optimization based on CO determination by impedance cardiography is comparable to that measured by transmitral flow pulsed Doppler. However, ICG seems a more objective and simpler technique." *6*

PHARMACEUTICAL CLINICAL TRIALS

Phase I – III Studies

- facilitate early decision making in drug development and clinical trials

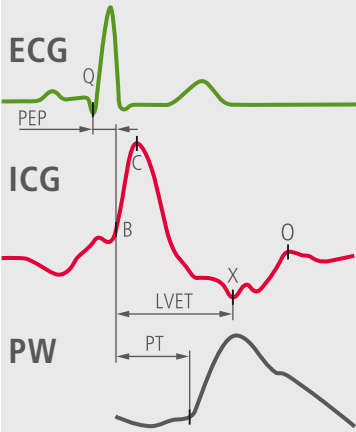
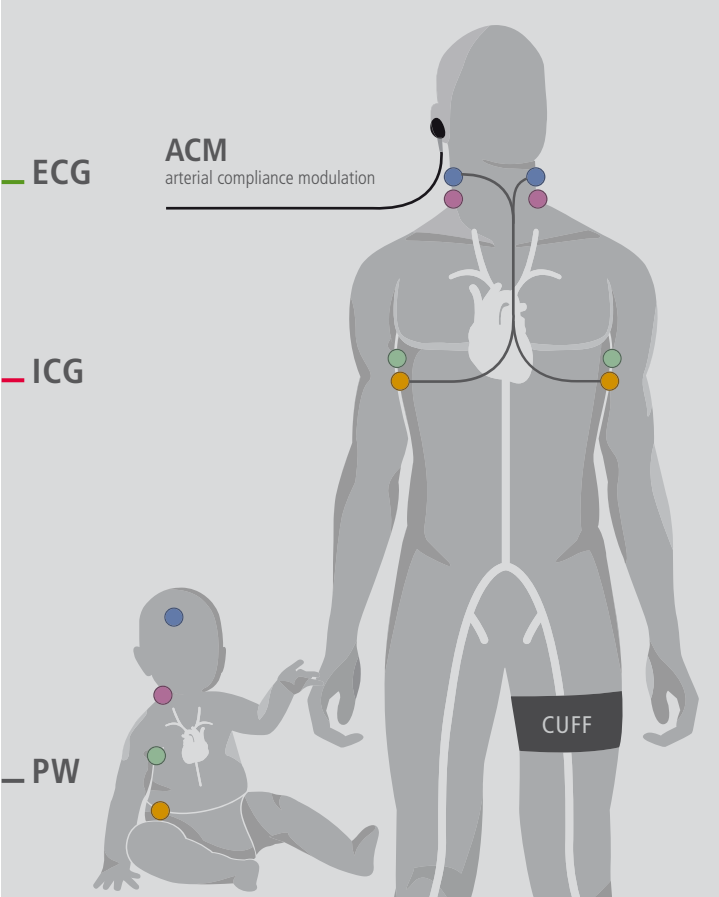
METHODS

IMPEDANCE CARDIOGRAPHY (ICG)

Changes in volume and velocity of blood in the aorta cause variations in the thoracic bio-impedance which is measured and displayed as the ICG waveform. This signal is applied to innovative algorithms to provide key hemodynamic parameters non-invasively and continuously. The accuracy of the method is further improved by the arterial compliance modulation technology (ACM) for which a special ear clip has to be placed.

AORTIC PULSE WAVE VELOCITY (PWVao)

The opening of the aortic valve, when the blood is pumped into the aorta, is defined as the B-point in the ICG signal. On the upper leg a pressure cuff is placed to measure the arrival of the Pulse Wave (PW) and to define its Propagation Time (PT). Taking into consideration the distance between aortic valve and pressure cuff the aortic Pulse Wave Velocity (PWVao) can be calculated to evaluate arterial stiffness for cardiovascular risk stratification.



- Q Beginning of ventricular depolarisation
- PEP Pre-Ejection Period
- B Opening of aortic valve
- C Maximum systolic flow
- X Closing of aortic valve
- O Opening of mitral valve
- LVET Left Ventricular Ejection Time
- PT Propagation Time

PARAMETERS



FLOW

| | | |
|----|----------------|---|
| HR | Heart Rate | Heart beats per minute |
| BP | Blood Pressure | Pressure exerted by the blood on arterial walls |
| SV | Stroke Volume | Amount of blood pumped by the left ventricle with each heart beat |
| SI | Stroke Index | |
| CO | Cardiac Output | Amount of blood pumped by the heart in one minute |
| CI | Cardiac Index | |



CONTRACTILITY

| | | |
|-----|---------------------|---|
| VI | Velocity Index | Reflects the peak velocity of blood flow in the aorta during systole |
| ACI | Acceleration Index | Reflects the maximum acceleration of blood flow in the aorta during systole |
| HI | Heather Index | Contractility indicator |
| PEP | Pre-Ejection Period | Duration of electrical systole equal to isovolumetric contraction phase |
| STR | Systolic Time Ratio | Ratio of electrical systole to mechanical systole |



FLUID

| | | |
|------|------------------------|---------------------------------|
| TFC | Thoracic Fluid Content | Indicator of chest fluid status |
| TFCI | TFC Index | TFC, normalised to body size |

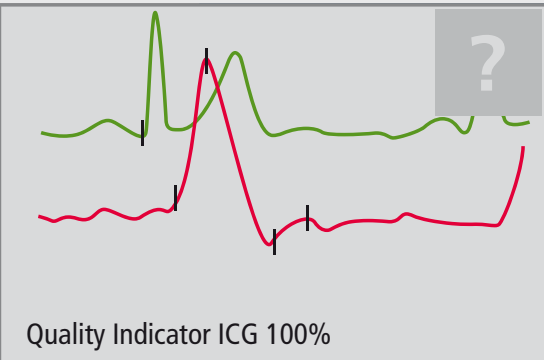


VASCULAR

| | | |
|-------|------------------------------|--|
| PT | Propagation Time | Propagation time of the pulse wave |
| PWVao | Pulse Wave Velocity | Velocity of the aortic pulse wave |
| SVR | Systemic Vascular Resistance | The force the ventricle must overcome to eject blood into the aorta, estimate of "afterload" |
| SVRI | SVR Index | SVR, normalised to body size |
| TAC | Total Arterial Compliance | Indicator of the degree of peripheral arterial stiffness / compliance |
| TACI | TAC Index | TAC, normalised to body size |

SIGNAL QUALITY

Signal Quality Indicator for validation of ICG waveforms shows the quality of the beats used for calculations. Key events of the cardiac cycle are indicated by markers: aortic valve opens (B), peak systolic flow (C) and aortic valve closes (X).

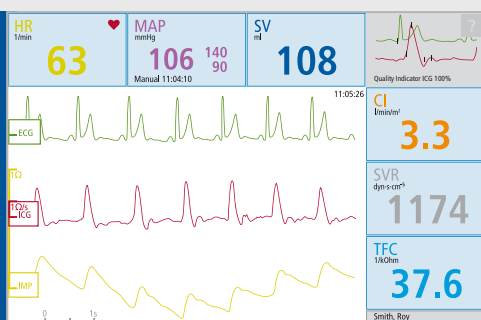


ZOOM

SCREENS

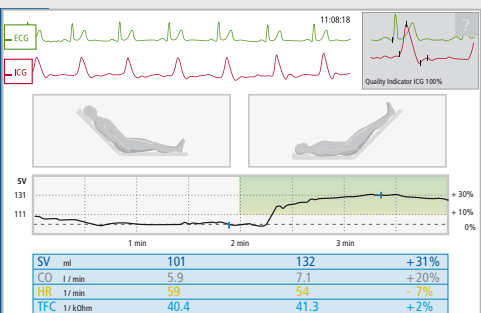
MONITORING

- 6 selectable parameters out of 29
- evaluate and manage the fluid level of a patient
- 3 selectable waveforms



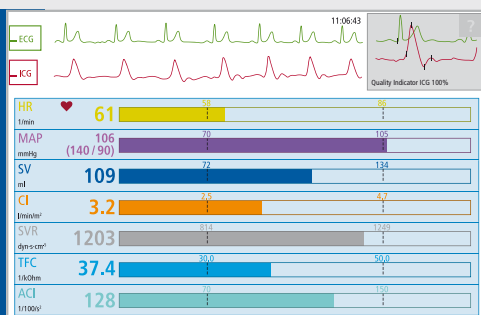
FLUID MANAGEMENT

- Passive Leg Raising (PLR) test
- standardised procedure
- automatic evaluation



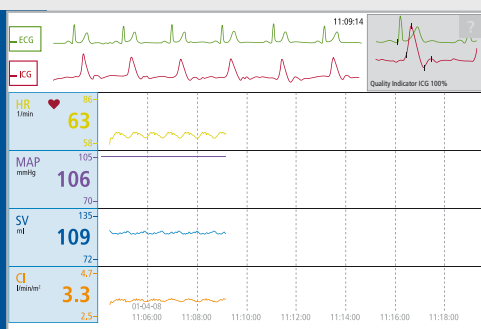
DIAGNOSTIC

- 7 selectable parameter bars with reference ranges
- ICG and ECG waveforms



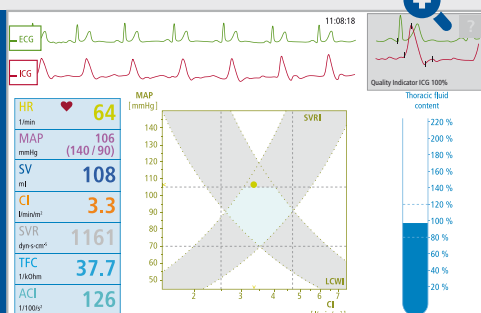
TRENDS

- 4 selectable parameters
- Selectable time scaling
- Event markers
- ICG and ECG waveforms



THERAPEUTIC

- 6 selectable parameters
- Therapeutic graph and TFC scale
- ICG and ECG waveforms



PRODUCTS Non-Invasive · Continuous · Easy

NICCOMO® Non-Invasive Continuous Cardiac Output Monitor

The ideal complement to conventional vital sign monitors



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- Continuous (beat-to-beat) monitoring and recording of curves and 29 parameters
- Continuous signal quality control and adaptive artefact elimination

- Additional modules: NiBP · SpO2 · PWV (aortic Pulse Wave Velocity)

- 10" TFT colour display with touch screen
- Battery available (capacity > 60 min)

NEW STANDARDS

INNOVATIVE

Combination of hemodynamic parameters (ICG) and vascular stiffness (PWVao) to evaluate the complete cardiovascular system.

Simple · Quick · Real-Time

CardioScreen 2000®

The optimal configuration for cardiovascular diagnosis



www.cardioscreen.de

CardioScreen 1000®

Brings ICG technology to your laptop



www.cardioscreen.de



- Display of user selectable waveforms and parameters
- Different screens for optimal data presentation in different clinical settings
- Interface to patient monitors, such as Philips/HP (VueLink)



- USB ports for data export, software updates and external printer connection
- PC software for offline data analysis and data export (e.g. Excel)

- Power supply via USB port

- External computer: Panel PC with touch screen, PC or Notebook
- Combination with VasoScreen and TensoScreen devices possible

FLEXIBLE

Configurable measuring channels and user selectable parameters and screens. Interface to Philips / HP monitoring systems by supporting the VueLink protocol. Different device configurations depending on the needs of the customer.

EASY TO USE

Highly sensitive measuring technology and intuitive operation by touch screen. USB interface for easy data backup and software updates.

TECHNICAL DATA

| | | NICCOMO® | CardioScreen 2000® | CardioScreen 1000® |
|-------------------------------------|---|--|--|--|
| Measurement Principle | | Impedance Cardiography (ICG) Bio-impedance | Impedance Cardiography (ICG) Bio-impedance | Impedance Cardiography (ICG) Bio-impedance |
| Measurement Channels | Standard Configurable | ICG / ECG + ACM ECG · NIBP · SpO2 · PWVao | ICG / ECG + ACM ECG · NIBP · SpO2 · PWVao | ICG / ECG + ACM |
| Impedance Cardiography (ICG) | Meas. current Basic impedance Imp. change Safety | 1.5 mA eff, 85 kHz 0–60 Ohm, 0–1.5 Hz ± 1 Ohm, 0.2–160 Hz defibrillator protected | 1.5 mA eff, 85 kHz 0–60 Ohm, 0–1.5 Hz ± 1 Ohm, 0.2–160 Hz defibrillator protected | 1.5 mA eff, 85 kHz 0–60 Ohm, 0–1.5 Hz ± 1 Ohm, 0.2–160 Hz defibrillator protected |
| ECG | Input voltage Safety | ± 10 mV AC, 0.2–160 Hz defibrillator protected | ± 10 mV AC, 0.2–160 Hz defibrillator protected | ± 10 mV AC, 0.2–160 Hz defibrillator protected |
| Pulse Wave (PW) | Meas. method Frequency range Cuff pressure | Air plethysmography 0.2–30 Hz 60 mmHg | Air plethysmography 0.2–30 Hz 60 mmHg | |
| NIBP | Measuring range Accuracy | 40–260 mmHg ± 3 mmHg | 40–260 mmHg ± 3 mmHg | |
| SpO2 | Measuring range Accuracy | 1–100 % SpO2 ± 2 % (at 70 %–100 % SpO2) | 1–100 % SpO2 ± 2 % (at 70 %–100 % SpO2) | |
| Power Supply | | 100–240 V AC, 50 / 60 Hz max. 60 VA Battery: NiMH, cap. > 60 min | 100–240 V AC, 50 / 60 Hz max. 40 VA | via USB port |
| Dimensions | w × h × d | 290 × 320 × 140 mm | 310 × 260 × 90 mm | 75 × 25 × 130 mm |
| Weight | | Approx. 5 kg (including battery) | Approx. 2 kg | Approx. 300 g |
| Display | | 10.4 " TFT color with touch screen | External computer | External computer |
| Safety | Medical Device Directive Standards | Class II a IEC / EN 601-1 (Class I, Type BF) IEC / EN 601-1-2 CE 0197 | Class II a IEC / EN 601-1 (Class I, Type BF) IEC / EN 601-1-2 CE 0197 | Class II a IEC / EN 601-1 (Class I, Type BF) IEC / EN 601-1-2 CE 0197 |
| PC Requirements | | | Medical PC necessary Operat. system: Windows / Linux RAM: > 512 MB HD: > 40 GB Interface: USB port | Medical PC necessary Operat. system: Windows / Linux RAM: > 512 MB HD: > 40 GB Interface: USB port |

*1 | Sageman W, Riffenburgh H, Spiess BD. Equivalence of bioimpedance and thermodilution in measuring cardiac index after cardiac surgery. J Cardiothorac Vasc Anesth. 2002; 16: 8-14

*2 | Verhoeve PE, Cadwell CA, Tsadok S. Reproducibility of non-invasive bioimpedance measurements of cardiac function. J Cardiac Fail. 1998; 4 (3 Suppl): 53

*3 | Taler SJ, Textor SC, Augustine JE. Resistant Hypertension: Comparing hemodynamic management to specialist care. Hypertension. 2002; 39: 982-988

*4 | The Task Force for the Management of Arterial Hypertension of European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). Journal of Hypertension. 2007; 25: 1105-1187

*5 | Asmar R. Arterial stiffness and pulse wave velocity: Clinical applications. Elsevier, 1999

*6 | Santos JF, Parreira L, Madeira J, Fonseca N, Soares LN, Ines L. Rev Port Cardiol. 2003; 22 (9): 1091-1098

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