

#### **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- · possible reduction of catheter use or when the catheter is withdrawn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
- · diagnosis of pre-eclampsia

"... 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

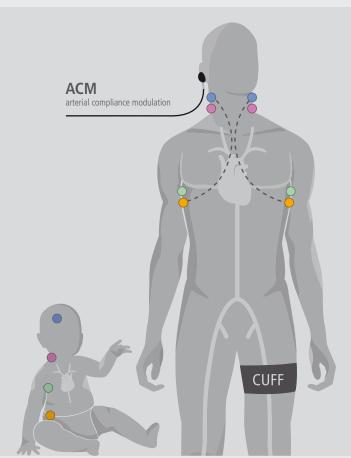
### **METHODS**

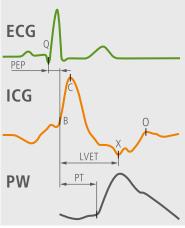
#### IMPEDANCE CARDIOGRAPHY (ICG)

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
- Pre-Ejection Period PEP
- В Opening of aortic valve
- C Maximum systolic flow
- Χ Closing of aortic valve
- 0 Opening of mitral valve
- LVET Left Ventricular Ejection Time
- **Propagation Time**

### **PARAMETERS**



ACI

#### **FLOW**

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

## CONTRACTILITY

Velocity Index

Acceleration Index

Corrected Flow Time

		flow in the aorta during systole			
HI	Heather Index	Contractility indicator			
PEP	Pre-Ejection Period	Duration of electrical systole equal to isovolu metric contraction phase			
LVET	Left Ventricular Ejection Time	Duration of mechanical systole; time interval between opening (B-point) and closing (X-point) of aortic valve			
STR	Systolic Time Ratio	Ratio of electrical systole to mechanical systole			

LVET related to Heart Rate

aorta during systole

Reflects the peak velocity of blood flow in the

Reflects the maximum acceleration of blood

## **FLUID**

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

# WORK

<b>*</b>	WORK				
LCWI	Left Cardiac Work Index	Work the heart must perform to pump blood each minute, normalised to body size			
LSWI	Left Stroke Work Index	Work the heart must perform to pump blood each heart beat, normalised to body size			
СРО	Cardiac Power Output	Combination of Mean Arterial Pressure and Cardiac Output; parameter describes myocardial oxygen requirements			

#### CPI Cardiac Power Combination of Mean Arterial Pressure and Index Cardiac Index; parameter describes myocardial oxygen requirements

## **VASCULAR**

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

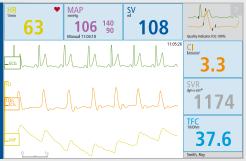
## SIGNAL QUALITY

Signal Quality Indicator for validation of ICG waveforms and ACM signal show 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).

### **SCREENS**

#### **MONITORING**

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



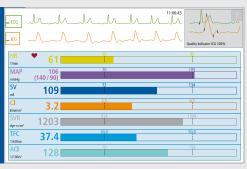
#### **FLUID MANAGEMENT**

- · Passive Leg Raising (PLR) test
- $\cdot$ standardised procedure
- · automatic evaluation

ECG	]\_\ ]\_\_	h_h 	_h_h 	11:08:18	builty Indicator ICG 100%	
	1					
SV 131					+ 30%	
111	_		~		+ 10%	
					0%	
		1 min	2 min	3 min		
	SV ml	101		132	+31%	
	CO 1/min	5.9		7.1	+20%	
	HR 1/min				- 7%	
	TFC 1/k0hm	40.4		41.3	+2%	

#### **DIAGNOSTIC**

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



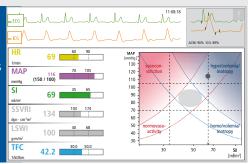
#### **TRENDS**

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



#### **THERAPEUTIC**

- · Therapeutic graph for heamodynamic evaluation
- ·ICG and ECG waveforms



# **PRODUCTS** Non-Invasive · Continuous · Easy

NICCOMO® Non-Invasive Continuous Cardiac Output Monitor







- · 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)
- $\cdot$  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®



#### CardioScreen 1000®









- · 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 devices for vascular diagnosis 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. 100 VA Battery: NiMH, cap. > 60 min	100-240 V AC, 50 / 60 Hz max. 40 VA	via USB port
Dimensions	$W \times h \times d$	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 Insulation Standards Notified Body	Class II a Class I, Type BF, 4 kV EN 60 601-1 EN 55011 Class B CE 0197	Class II a Class I, Type BF, 4 kV EN 60 601-1 EN 55011 Class B CE 0197	Class II a Class II, Type BF, 4 kV EN 60 601-1 EN 55011 Class B CE 0197
PC Requirements	Computer Operating system RAM HDD Interface		medical standard MS Windows > 1 GB > 60 GB USB 2.0	medical standard MS Windows > 1 GB > 60 GB USB 2.0

NICCOMO®

CardioScreen 2000® CardioScreen 1000®

- \*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
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- \*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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