IV. PACEMAKER ADJUSTMENT

In patients undergoing ventricular resynchronisation therapy, A V delay determination based on CO determination by impedance cardiography is recommended. A V delay is used to align left and right ventricular contractions to ensure optimal cardiac function. This delay also determines the patient's need for a pacemaker.

Medis recommends that physicians determine CO through impedance cardiography, which is considered a more objective technique compared to other methods. CO determination is crucial for adjusting pacemaker settings to achieve optimal cardiac performance.
**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- possible reduction of catheter use or when the catheter is withdrawn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

IMPEDEANCE 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.

PARAMETERS

**FLOW**

- **HR** Heart Rate
- **BP** Blood Pressure
- **SV** Stroke Volume
- **SI** Stroke Index
- **CO** Cardiac Output
- **CI** Cardiac Index

**CONTRACTILITY**

- **VI** Velocity Index
- **ACI** Acceleration Index
- **HI** Heather Index
- **PEP** Pre-Ejection Period
- **LVET** Left Ventricular Ejection Time
- **STR** Systolic Time Ratio
- **FTc** Corrected Flow Time

**FLUID**

- **TFC** Thoracic Fluid Content
- **TFCI** TFC Index

**WORK**

- **LCWI** Left Cardiac Work Index
- **LSWI** Left Stroke Work Index
- **CPO** Cardiac Power Output
- **CPI** Cardiac Power Index

**VASCULAR**

- **PT** Propagation Time
- **PWVao** Pulse Wave Velocity
- **SVR** Systemic Vascular Resistance
- **SVRI** SVR Index
- **TAC** Total Arterial Compliance
- **TACI** TAC Index

**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).
IMPEDANCE CARDIOGRAPHY (ICG) can be used to evaluate arterial stiffness for cardiovascular risk stratification. On the upper leg, a pressure cuff is applied, and the aortic Pulse Wave Velocity (PWVao) can be calculated. This signal is then used by innovative algorithms to provide key hemodynamic parameters.

### METHODS
- **Aortic Pulse Wave Velocity (PWVao)**: This parameter is improved by arterial compliance modulation.
- **ACM (Arterial Compliance Modulation)**: This parameter shows the quality of the beats used for calculations.
- **Signal Quality Indicator**: This parameter is used for validation of ICG waveforms and ACM signal.
- **Parameters**:
  - Propagation Time (PT)
  - LVET (Left Ventricular Ejection Time)
  - Opening of mitral valve (O)
  - Maximum systolic flow (C)
  - Pre-Ejection Period (PEP)
  - Beginning of ventricular contraction (Q)
  - Duration of mechanical systole; time interval between opening (B-point) and closing of aortic valve (X)

### SIGNAL QUALITY
- **Quality Indicator**: ICG 100%

### 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
- Therapeutic graph for hemodynamic evaluation
- ICG and ECG waveforms

### SCREENS
- Non-Invasive · Continuous · Easy

### PRODUCTS
- NICCOMO® Non-Invasive Continuous Cardiac Output Monitor

**The ideal complement to conventional vital sign monitors**

- Battery available (capacity > 60 min)
- 10" TFT colour display with touch screen
- USB ports for data export, software updates and external printer connection

### NEW STANDARDS
- Combination of hemodynamic parameters (ICG) and vascular stiffness (PWVao) to evaluate the complete cardiovascular system.
IMPEDANCE CARDIOGRAPHY (ICG)

and pressure cuff the aortic Pulse Wave Velocity (PWVao) can be calculated to
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This signal is applied to innovative algorithms to provide key hemodynamic
thoracic bio-impedance which is measured and displayed as the ICG waveform.
Changes in volume and velocity of blood in the aorta cause variations in the

ACM: 90%  ICG: 89%

Quality Indicator ICG 100%

Quality Indicator ICG 100%

Quality Indicator ICG 100%

Quality Indicator ICG 100%

Quality Indicator ICG 100%

Non-Invasive Continuous Cardiac Output Monitor

Brings ICG technology
to your laptop

· Continuous signal quality control and adaptive artefact elimination
· Combination with VasoScreen devices for vascular diagnosis possible
· External computer: Panel PC with touch screen, PC or Notebook
· Different screens for optimal data presentation in different clinical settings
· Display of user selectable waveforms and parameters
· Interface to patient monitors, such as Philips/HP (VueLink)
· Configuration 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.

CardioScreen 2000®
The optimal configuration for cardiovascular diagnosis

CardioScreen 1000®
Brings ICG technology
to your laptop

· 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

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

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.
**TECHNICAL DATA**

<table>
<thead>
<tr>
<th>Measurement Principle</th>
<th>NICCOMO®</th>
<th>CardioScreen 2000®</th>
<th>CardioScreen 1000®</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Measurement Channels</strong></td>
<td>Standard</td>
<td>ICG / ECG + ACM</td>
<td>ICG / ECG + ACM</td>
</tr>
<tr>
<td></td>
<td>Configurable</td>
<td>ECG · NIBP · SpO2 · PWVao</td>
<td>ICG / ECG + ACM</td>
</tr>
<tr>
<td><strong>Impedance Cardiography (ICG)</strong></td>
<td>Meas. current</td>
<td>1.5 mA eff, 85 kHz</td>
<td>1.5 mA eff, 85 kHz</td>
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<tr>
<td></td>
<td>Basic impedance</td>
<td>0–60 Ohm, 0–1.5 Hz</td>
<td>0–60 Ohm, 0–1.5 Hz</td>
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<tr>
<td></td>
<td>Imp. change</td>
<td>± 1 Ohm, 0.2–160 Hz</td>
<td>± 1 Ohm, 0.2–160 Hz</td>
</tr>
<tr>
<td></td>
<td>Safety</td>
<td>defibrillator protected</td>
<td>defibrillator protected</td>
</tr>
<tr>
<td>ECG</td>
<td>Input voltage</td>
<td>± 10 mV AC, 0.2–160 Hz</td>
<td>± 10 mV AC, 0.2–160 Hz</td>
</tr>
<tr>
<td></td>
<td>Safety</td>
<td>defibrillator protected</td>
<td>defibrillator protected</td>
</tr>
<tr>
<td><strong>Pulse Wave (PW)</strong></td>
<td>Meas. method</td>
<td>Air plethysmography</td>
<td>Air plethysmography</td>
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<tr>
<td></td>
<td>Frequency range</td>
<td>0.2–30 Hz</td>
<td>0.2–30 Hz</td>
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<tr>
<td></td>
<td>Cuff pressure</td>
<td>60 mmHg</td>
<td>60 mmHg</td>
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<tr>
<td><strong>NIBP</strong></td>
<td>Measuring range</td>
<td>40–260 mmHg</td>
<td>40–260 mmHg</td>
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<tr>
<td></td>
<td>Accuracy</td>
<td>± 3 mmHg</td>
<td>± 3 mmHg</td>
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<tr>
<td><strong>SpO2</strong></td>
<td>Measuring range</td>
<td>1–100 % SpO2</td>
<td>1–100 % SpO2</td>
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<tr>
<td></td>
<td>Accuracy</td>
<td>± 2 % (at 70 %–100 % SpO2)</td>
<td>± 2 % (at 70 %–100 % SpO2)</td>
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<tr>
<td><strong>Power Supply</strong></td>
<td>Battery: NIMH, cap. &gt; 60 min</td>
<td></td>
<td>via USB port</td>
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<tr>
<td><strong>Dimensions</strong></td>
<td>w × h × d</td>
<td>290 × 320 × 140 mm</td>
<td>310 × 260 × 90 mm</td>
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<tr>
<td><strong>Weight</strong></td>
<td>Approx. 5 kg (including battery)</td>
<td>Approx. 2 kg</td>
<td>Approx. 300 g</td>
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<tr>
<td><strong>Display</strong></td>
<td>10.4” TFT color with touch screen</td>
<td>External computer</td>
<td>External computer</td>
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<td><strong>Safety</strong></td>
<td>Medical Device Directive</td>
<td>Class IIa</td>
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<td>Insulation Standards</td>
<td>Class I, Type BF, 4 kV</td>
<td>Class I, Type BF, 4 kV</td>
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<td>EN 60601-1</td>
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<td>CE 0197</td>
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<td><strong>PC Requirements</strong></td>
<td>Computer</td>
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<td>Operating system</td>
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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