

Innocor[®]

Cardiopulmonary Exercise Testing with Non-Invasive Measurement of Cardiac Output



- Hemodynamic measurements by inert gas rebreathing
- True breath-by-breath metabolic gas exchange analysis
- Spirometry and SpO₂

innovision

Unique non-invasive solutions
for hemodynamic exercise testing

Complete CPET

Innocor® combines direct, non-invasive hemodynamic measurements with traditional metabolic measurements using true breath-by-breath gas exchange analysis for determination of VO_2 , VCO_2 and V_E plus a large number of derived variables such as peak VO_2 , AT, and V_E/VCO_2 .

Innocor® gives the complete metabolic and hemodynamic profile comprising a conventional cardiopulmonary exercise test (CPET) together with non-invasive measurement of cardiac output. This unique combination enables the possibility to distinguish between ventilatory, central circulatory or peripheral causes of exercise intolerance.

By using inert gas rebreathing for the hemodynamic measurements the hazards and costs of using PA-catheters are eliminated and inaccuracies of other non-invasive methods avoided.

All in all, Innocor® represents a significant contribution to enhanced patient care, safety and reduced health care costs.

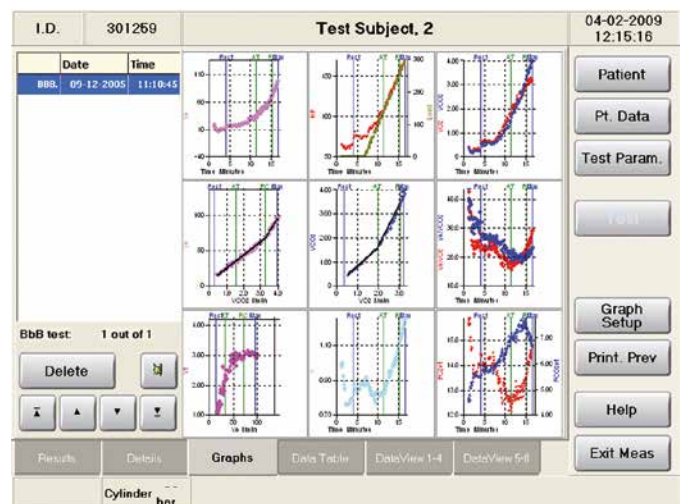
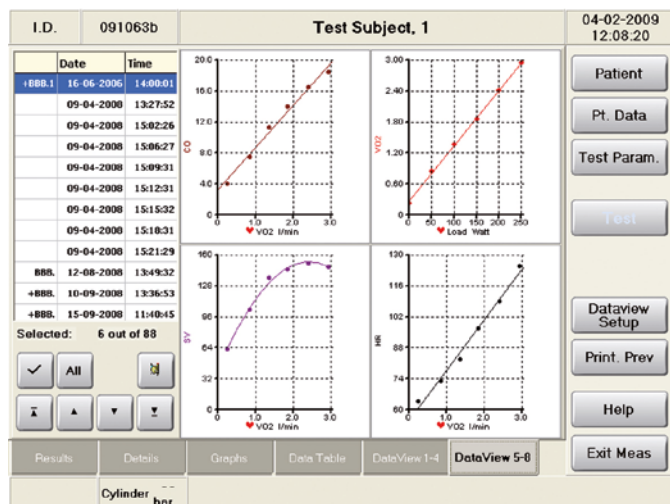
Objective Functional Assessment of Patients with Cardiovascular Disorders

Innocor® provides the most comprehensive system available for evaluation of CHF patients or use in all other cases where cardiovascular disorders are suspected or being treated.

- Innocor® is used to assess and monitor cardiovascular disorders
- Innocor® provides important additional information for prognostic evaluation of HF patients
- Innocor® is ideal for monitoring during rehabilitation and recovery of HF patients
- Innocor® provides objective treatment evaluation
- Innocor® is suitable for accurate performance testing

Hemodynamic (cardiac output and stroke volume) response to graded exercise.

9-plots Wasserman screen from breath-by-breath test to maximum exertion.



The Exclusive Solution to Non-invasive Hemodynamic Exercise Testing

Innocor® is the only instrument on the market utilising the physiologically sound and well-tested principle referred to as Inert Gas Rebreathing for hemodynamic measurements. This principle is 100% analytical and has no empirical base.

During a rebreathing test the subject rebreathes an oxygen enriched mixture containing very small amounts of two physiologically inert gases - one blood soluble and one insoluble component - from a closed rebreathing system. The test lasts about 5 breaths or 15 seconds. During this time the blood soluble gas is dissolved in the blood perfusing the ventilated parts of the lungs. Innocor® measures the concentration curve of the blood soluble gas and calculates the wash-out rate, which is proportional to the Cardiac Output. In patients with a significant intra-pulmonary shunt, the shunt flow is calculated by using the well proven Fick principle for oxygen. The blood insoluble gas is measured to determine the lung volume and to account for other factors that affect the distribution of the blood soluble gas.

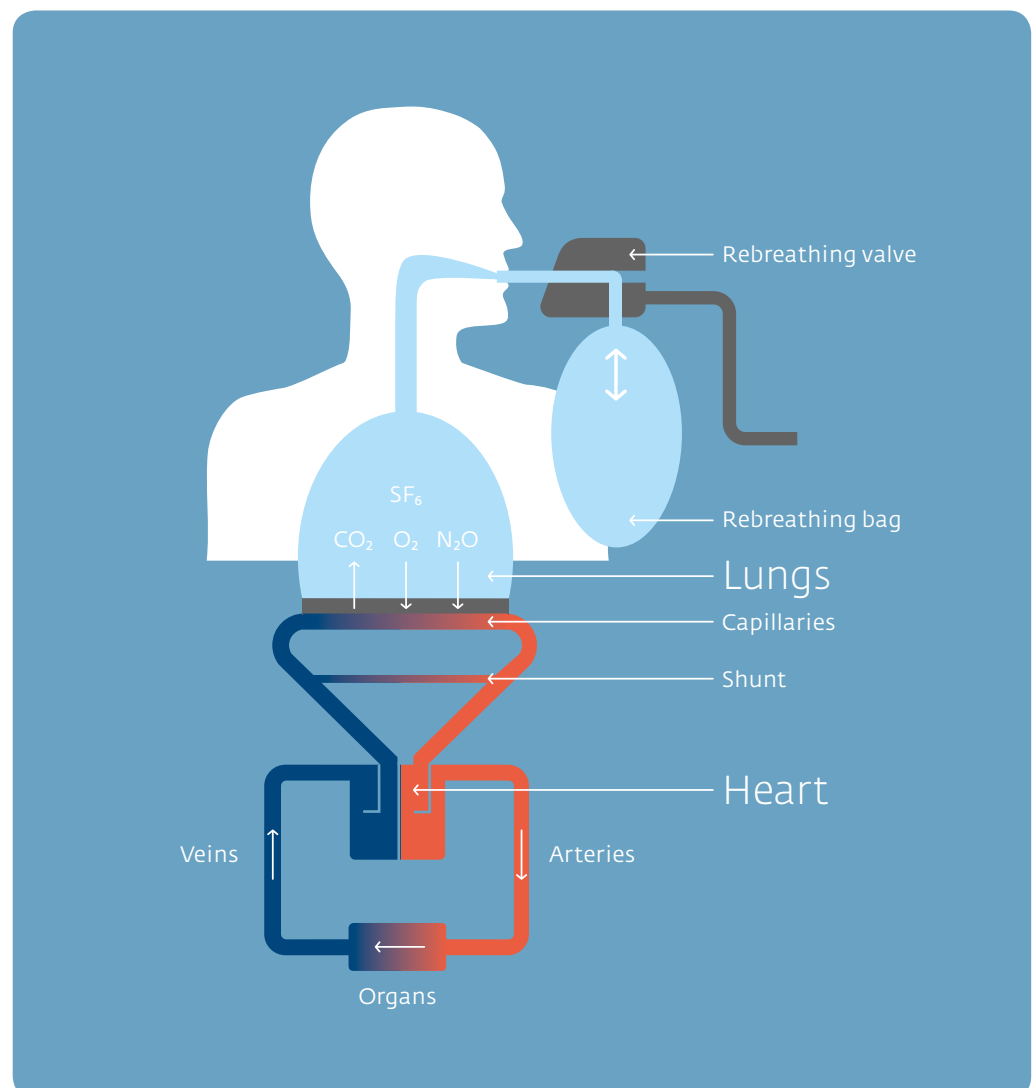
It is reassuring for the Innocor® users to know that the validity of Inert Gas Rebreathing is documented in an impressive number of peer reviewed scientific papers. This documentation applies to diverse conditions in both health and disease and is conclusively far better than for any other non-invasive method. As opposed to other non-invasive techniques, Innocor® can be used equally well in patients at rest and during exercise.

Innocor® Technologies

Innocor® utilises Innovision's proprietary gas analyser technology for measuring nitrous oxide (N_2O , blood soluble), sulphur hexafluoride (SF_6 , insoluble) and CO_2 continuously and simultaneously. The advanced analyser is a photoacoustic infrared type which combines a fast response with unsurpassed sensitivity and accuracy and inherent stability. No tedious calibrations are required - all you

need is a yearly calibration check. This technology replaces a medical mass spectrometer for inert gas analysis and offers superior performance, compactness and reduced cost.

The oxygen sensor uses laser diode absorption spectroscopy, meaning no limited life parts. A Nafion sampling tube ensures optimal humidity removal.



Features

- Proven analytical methodology
- Compact and portable
- No daily calibration of gas analyser

Innocor® is easy to use

Innocor® is small and portable. Switch it on and you are ready to go. No tedious gas calibrations to distract you from the full attention to your patient. The rebreathing test takes less than 1 minute and can be repeated within short intervals. Training in the use of Innocor® takes short time. The software is intuitive with only one interface for the operator: a bright and colourful 12-inch LCD touch screen.

Innocor® is cost effective

Compared to other methods of assessment Innocor® is competitive both in cost of the device, maintenance and daily use. Therefore, Innocor® is a realistic option not only in specialised hospital departments but also in most other segments of the health care system including out-patients departments dealing with cardiovascular diseases.

Innocor® connects to other systems

The built-in Ethernet and USB interfaces allow data exchange between Innocor® and other data storage and analysis systems, including other medical devices (e.g. ECGs) and the offline Viewer version of Innocor®. All major treadmills and bicycle ergometers can be controlled by Innocor® during an exercise protocol.



Space efficient and portable with integrated lifting slot, allowing free movement.



Pneumatic rebreathing valve with replaceable insert for maximum hygiene.

Miniature gas cylinder with self-dispensing valve for rebreathing gas mixture. Test capacity is expanded typically tenfold by automatic dilution with air, thereby avoiding a bulky external cylinder.

Connectors for networking, printing and PC interface.

Quick connector panel for rebreathing valve, SpO₂ and optional NIBP interfaces.



LCD colour display with high resolution and wide viewing angle.

Intuitive Windows software and touch screen for effortless operation.



Product Line Innocor®

Test parameters \ product models	INN00010 CPET	INN00050* CO	INN00100 CO	INN00200* CO + NIBP	INN00300* CO + NIBP	INN00400 CPET + CO	INN00500* CPET + CO + NIBP
Hemodynamic parameters (Inert Gas Rebreathing) CO, CI, SV, SI, PBF, V _L , HR, SpO ₂		•	•	•	•	•	•
Derived hemodynamic parameters I SvO ₂ , A-V O ₂ diff., VO ₂ , VO ₂ /kg, Shunt			•		•	•	•
Derived hemodynamic parameters II SYS, DIA, MAP, SVR, SVRI, CPO, CPI				•	•		•
Metabolic parameters (Breath-by-breath technique) VO ₂ , VO ₂ /kg, VO ₂ /HR, VCO ₂ , R, V _E , V _A , V _D , V _T , f _B , F _{ET} O ₂ , F _{ET} CO ₂ , V _E /VO ₂ , V _E /VCO ₂ , V _E /VCO ₂ slope, AT, RC, BR	•					•	•
Spirometry parameters FEV ₁ , FVC, FEV ₁ %, PEF, MEF 75, MEF 50, MEF 25, FET, MVV	•					•	•

* Restricted availability in certain markets

Parameters

Hemodynamic

CO	Cardiac output
CI	Cardiac index
SV	Stroke volume
SI	Stroke index
PBF	Pulmonary blood flow
V _L	Lung volume (or FRC)
HR	Heart rate
SpO ₂	Arterial oxygen saturation

Derived hemodynamic

SvO ₂	Mixed venous oxygen saturation
A-V O ₂ diff.	Arterio-venous O ₂ saturation difference
VO ₂	Oxygen uptake (by rebreathing)
VO ₂ /kg	Oxygen uptake per kg (by rebreathing)
Shunt	Intrapulmonary shunt fraction
SYS	Systolic blood pressure
DIA	Diastolic blood pressure
MAP	Mean arterial blood pressure
SVR	Systemic vascular resistance
SVRI	Systemic vascular resistance index
CPO	Cardiac power output
CPI	Cardiac power index

Metabolic

VO ₂	Oxygen uptake
VO ₂ /kg	Oxygen uptake per kg

VO ₂ /HR	Oxygen pulse
VCO ₂	Carbon dioxide excretion
R	Respiratory exchange ratio
V _E	Expiratory minute ventilation
V _A	Alveolar ventilation
V _D	Anatomical dead space
V _T	Tidal volume
f _B	Respiratory rate
F _{ET} O ₂	End-tidal concentration of oxygen
F _{ET} CO ₂	End-tidal concentration of carbon dioxide
V _E /VO ₂	Ventilatory equivalent for oxygen
V _E /VCO ₂	Ventilatory equivalent for carbon dioxide
V _E /VCO ₂ slope	Slope of V _E versus VCO ₂
AT	Anaerobic threshold (V-slope method)
RC	Respiratory compensation (V-slope)
BR	Breathing reserve

Spirometric

FEV ₁	Forced expiratory volume in 1 second
FVC	Forced vital capacity
FEV ₁ %	FEV ₁ /FVC
PEF	Peak expiratory flow
MEF 75,	Max. instantaneous forced expiratory flow
MEF 50,	(75%, 50% and 25% of FVC remaining,
MEF 25	respectively)
FET	Forced expiratory time
MVV	Maximum voluntary ventilation

Technical Specifications

Gas analyser

(Photoacoustic Spectroscopy)

Components and ranges N₂O 0-2.5%, SF₆ 0-0.5%, CO₂ 0-10%
Accuracy after calibration ± 1.5% rel.
Signal-to-noise ratio > 1000 @ half-scale (N₂O and SF₆)
. > 400 @ half-scale (CO₂)
Sampling frequency 100 Hz
Sampling flow rate 120 ml/min
Rise time (10-90%) < 200 ms

Oxygen sensor

(Laser diode absorption spectroscopy)

Range 5-100%
Accuracy after calibration ± 1.5% rel.
Signal-to-noise ratio > 500 @ 21% O₂
Sampling frequency 100 Hz
Sampling flow rate (same flow as above) 120 ml/min
Rise time (10-90%) < 170 ms

Flowmeter

(Differential pressure pneumotachometer)

Range ±15 l/s
Resolution < 1 ml/s
Flow accuracy ±2% rel. or ±20 ml/s
Volume accuracy ±3% rel. or ±50 ml
Sampling frequency 100 Hz

Rebreathing valve

(Pneumatic, with silicone valve insert)

Deadspace 100 ml
Flow resistance without bacterial filter 1.5 cm H₂O @ 5 l/s

Gas supply

Gas composition 5% N₂O, 1% SF₆, 94% O₂
Cylinder capacity 18 litres (0.15 l @ 124 bar)
Typical number of tests using automatic dilution with air 75

Pulse oximeter

Oxygen Saturation Range 0 - 100%
Pulse Rate Range 40 - 240 BPM

Non-invasive Blood Pressure

(Oscillometric NIBP)

Systolic pressure range 40 - 260 mmHg
Diastolic pressure range 20 - 200 mmHg
Heart Rate Range 40 - 200 BPM

Mechanical

Size 35 x 29 x 26 cm (W x H x D)
Weight (depending on configuration) 8-9 kg

Electrical

Power supply 100-120V / 200-240V, 50/60 Hz
Power consumption 45 W nom., 100 W max.
Protection Class I type BF according to EN 60601-1

Environmental

Operating temperature 10 - 40 °C
Operating pressure 525 - 800 mmHg

Colour LCD Display

Size/resolution 12.1" SVGA (800x600 pixels)
Touch screen High-resolution resistive type

Integrated computer

Processor 1.6 GHz
Operating system Windows XP Embedded

Electrical interfaces

Printing Windows compatible printers
Networking PCI 10/100 Mbps Ethernet
PC interfaces 2 x USB 1.1

INNOVISION reserves the right to change specifications without further notice.

Certification/ Safety standards

- EN ISO 13485
- MDD 93/42/EEC (CE marking)
- FDA 510(k) clearance
- Meets ERS and ATS recommendations
- EN 60601-1
- EN 60601-1-1
- EN 60601-1-2
- EN ISO 9919
- EN 1060-3



Innovision specializes in the design, development and production of medical instruments using advanced gas exchange methods for non-invasive cardiopulmonary measurements. The key technologies represent the results of more than 20 years of space development activities. Innovision is ISO 13485 certified.

The headquarters are located in Denmark, with sales and service office in the USA.

Innovision ApS
Skovvænget 2
DK-5620 Glamsbjerg
Denmark

Tel. +45 65 95 91 00
Fax +45 65 95 78 00
info@innovision.dk
www.innovision.dk

Innovision, Inc.
7 Piedmont Center, Suite 300
3525 Piedmont Rd. NE
Atlanta GA 30305, USA

Tel. +1 866 443 5060
Fax +1 404 671 9422
usa.sales@innovision.dk
www.innovision.dk