HAEMOSEIS 256®

3 Dimensional Vasculography™

The Future of Cardiovascular Diagnosis, Management and Prognosis.

organization *de*
SCALENE

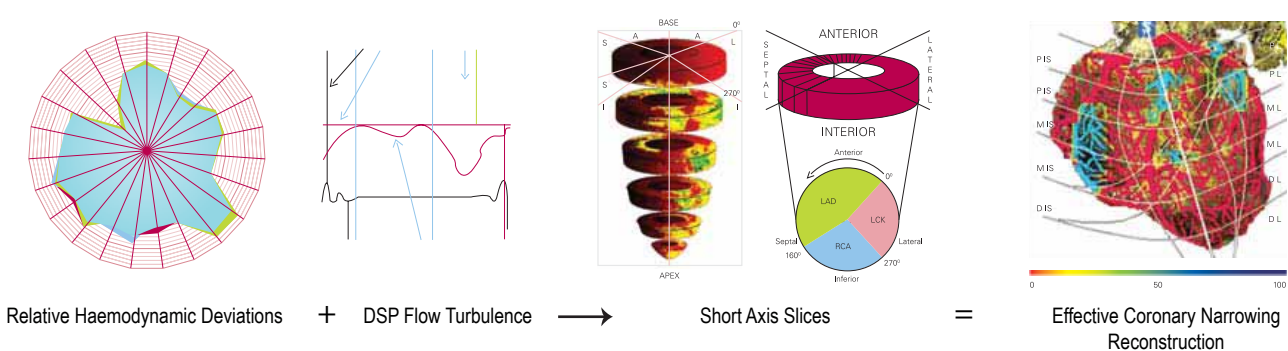**Shréis**
Scalene
Cardiotech

Overview

Haemoseis 3D Vasculography is a revolutionary non-invasive technique for early identification and management of life threatening cardiovascular diseases. It provides a detailed analysis of cardiovascular haemodynamics, electrodynamics, pulmonary pathology, by providing more than sixty vital cardiovascular parameters such as detailed regional and myocardial blood flow functions and many more to identify and characterize electro-haemodynamic patterns which are consistent with coronary artery disease and other cardiac disease states. With a complete vital haemodynamic picture of the heart, Haemoseis 256 brings new and powerful cardiovascular information to the out-patient clinic, emergency rooms, intensive care units, cath labs and operation theatres. Haemoseis provides unique details of minute deviation in flow patterns, invaluable for accurate monitoring of cardiac functions.

Technology

Haemoseis 3D Vasculography uses advanced patented technologies of Transaortic signal wave modulation (TASWM) and Flow Turbulence Accelerometry (FTA) to measure and record minute changes in the cardiovascular system every millionth of a second. It provides more than sixty vital cardiovascular functional variables, which directly aids the doctor in making decisions not only in cardiac care but also in other areas of medical practice. 3D Vasculography brings advanced techniques such as simulation, neural networks and dynamic fluid mechanics, parameters used in space technology, to conveniently get a comprehensive functional status of the heart and arteries that can be used for cardiovascular diagnosis and management. The procedure is called 3 Dimensional Vasculography Scan or 3DVG.

Structural Function to Functional Structures Reconstruction

Relative Haemodynamic Deviations + DSP Flow Turbulence ⟶ Short Axis Slices = Effective Coronary Narrowing Reconstruction

During coronary filling, the flow turbulence provides the 3rd dimension required for the short axis slices (SAS) reconstruction. SAS maps the exact origin of the turbulence in 3 dimension by associating and rendering with the minute haemodynamic changes that are obtained by kinetic modeling in 3D Vasculography. From the SAS, the culprit vessel supplying the regions are identified. Effective coronary narrowing (ECN) is then calculated based on the regional blood flow. ECN is not the anatomical 'blockade' seen in coronary angiograms, but it is the net contribution of culprit vessel in reducing flow in the region.

> " 3 Dimensional Vasculography produces a complete cardiovascular physiological profile of the patient consisting of over sixty functional parameters that directly aid in perfecting diagnosis and treatment. "
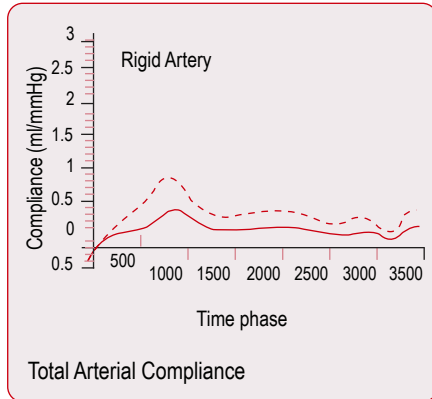
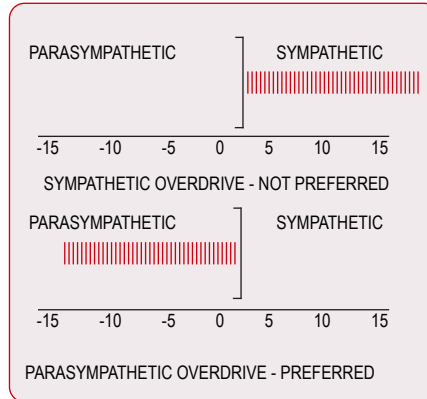### Real Time Cardiac Cycle with Other Physiological Curves
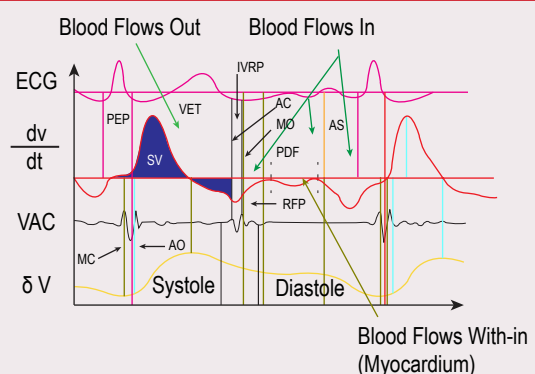
Features

Till late, emphasis has been laid on structure rather than function, but by shifting focus, new height are scaled in medical and biological vasculography by having the ability to map the functions of the organs in the body.

Arterial Compliance

Rigid Artery

Compliance (ml/mmHg): 3, 2.5, 2, 1.5, 1, 0.5, 0, 0.5

Time phase: 500, 1000, 1500, 2000, 2500, 3000, 3500

Total Arterial Compliance

Arterial compliance is the ability of the artery to comply elastically to the changing pressures and volumes.
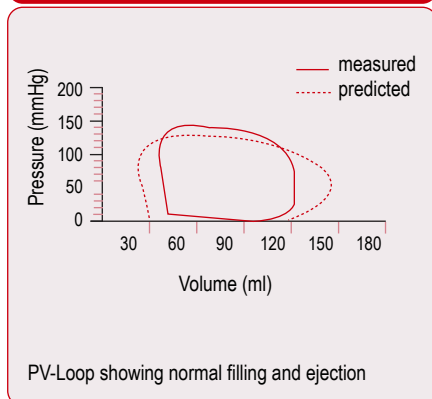
ANS Predominance

PARASYMPATHETIC — SYMPATHETIC

-15, -10, -5, 0, 5, 10, 15

SYMPATHETIC OVERDRIVE - NOT PREFERRED

PARASYMPATHETIC — SYMPATHETIC

-15, -10, -5, 0, 5, 10, 15

PARASYMPATHETIC OVERDRIVE - PREFERRED

ANS predominance is an excellent indicator of forced cardiac activity.

Myocardial Demand and Supply

100%, 80%, 60%, 40%, 20%, 0%
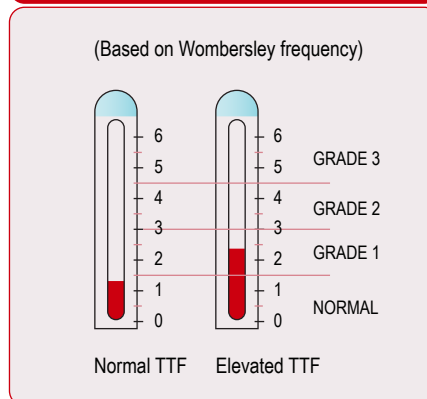
ISCHEMIC ZONE

N

- Demand
- Supply
- Reserve

Relative DSR Normal demand
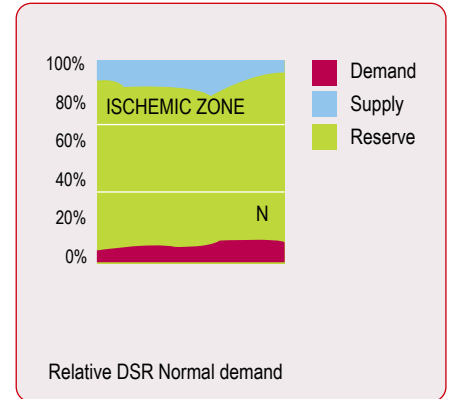
Myocardial oxygen demand, supply and reserve is the best indicator of cardiac ischemia.

Pressure Volume Loop

— measured
···· predicted

Pressure (mmHg): 200, 150, 100, 50, 0

Volume (ml): 30, 60, 90, 120, 150, 180
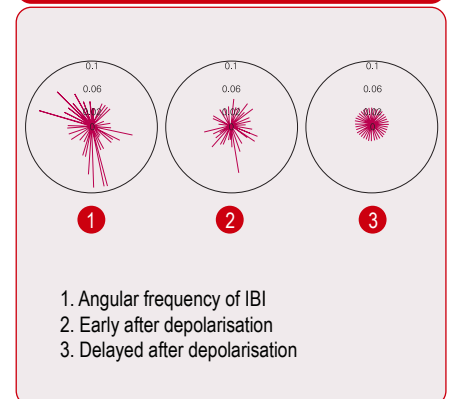
PV-Loop showing normal filling and ejection

Pressure Volume Loop is the most sensitive method to assess overall cardiac function and identify early changes. It is the gold standard in assessment of cardiac contractility.

Thrombus Formation Factor

(Based on Wombersley frequency)

6, 5, 4, 3, 2, 1, 0

6, 5, 4, 3, 2, 1, 0

GRADE 3
GRADE 2
GRADE 1
NORMAL

Normal TTF   Elevated TTF

It is well known that the turbulence and blood viscosity plays an important role in thrombus formation. TFF enables to handle thromogenic patients with care.

Inter Cycle Electrophysiology

0.1
0.06

1   2   3

1. Angular frequency of IBI
2. Early after depolarisation
3. Delayed after depolarisation

Early and delayed after depolarisation are substrates for arrhythmogenicity. This status is of great help to prognosis, as some drugs may also trigger arrhythmia in prone patients.

Studies and Publications

- Simultaneous measurement of stroke volume during heart catheterisation were made in heterogeneous group of patients in comparision to stroke volume value determined during catheterisation by applying Fick's Principle., (Pianosi et., al., The American Journal of Cardiology, 1996).

- The haemodynamics of ventricular arrhythmias were studied by Markely Bela et., al., and the results were presented in 1996 at the Twelth International Congress on new frontiers of arrhythmias.

- Assessment of the accuracy of cardic volumes in children with cystic fibrosis were studied at the department of pediatrics and child health at the Children's Hospital of Winnipeg. (Paul T. et., al., Chest 1997).

- A blinded study was conducted in comparing the outcome of 3D Vasculography with coronary angiography in 273 patients and the results were published in IEEE CBMS 2001, 26-27, July 01, National Institutes of Health, Bethesda, Maryland, USA.

- A joint study was conducted by the All India Institute of Medical Sciences and the Indian Institute of Technology, New Delhi, to access the haemodynamic parameters in patients with coronary artery disease and in normal groups. The results were presented at the National Conference on Computational Instrumentation. (Evaluation of haemodynamic parameters on coronary artery disease patients with normal group using real time 3 Dimensional Cardiovasculography; Sneh Anand et., al., NCCi - 2010, CSIO Chandigerh, India, 19-20, March 2010).

A glance of the parameters of the human cardio vascular system obtained through 3 DVG Scan:

Physiological Parameters	Functional Parameters
• Stroke volume - ml • Stroke index - ml / m² • Cardiac output - l / min • Systemic vascular resistance - dyne.sec.cm $^{-5}$ • Mean arterial blood pressure - mmHg • End systolic volume beat to beat • End diastolic volume beat to beat • Global myocardial blood flow - ml / min / 100gm • Regional myocardial blood flow - ml / min / 100gm • Total coronary resistance - dyne.sec. cm $^{-5}$ • Mean coronary perfusion pressure - mmHg • Systolic and diastolic time intervals - milliseconds • Pulmonary air retention - % • Pulmonary fluid retention - % • Pulmonary capillary pressure - mmHg • Pulmonary vascular resistance - dyne.sec.cm^{-5} • Renal glomerular filtration rate (GFR) - ml / min • Urine output - ml / min	• Complete real time cardiac cycle • Left ventricular ejection fraction LVEF beat to beat • Left ventricle regurgitant fraction • Left cardiac work • Maximal oxygen consumption • Myocardial oxygen demand, supply & reserve • Coronary flow reserve • Global myocardial flow deficiency index • Collateral flow index • Global cardiac efficiency • Thrombus formation factor • Adrenergic analysis • Total myocardial burden • Pliability of mitral and aortic valve • Body fat mass estimate - Kgs • Basal metabolic rate - Kcal / hr / m²

Clinical Application

- Can be used effectively before, during and after procedures like External Counter Pulsation (ECP) or Intra Aortic Balloon Pump (IABP), where measurement of coronary perfusion pressure, coronary blood flow, valvular pliability is important.
- Establishing arrhythmogenic focus of Early and Delayed after depolarisation (EAD and DAD) in CAD and myocardial diseases and proneness to sudden cardiac death syndrome (SCDS).
- Measurement of arterial elasticity and thus the endothelial function and progression of atherosclerosis process in diabetes and hypertension.
- Understanding underlying causes of chest pain in the absence of CAD and early detection in asymptomatic subjects.
- Determination of actual working point of the heart and establishes working capacity in post-infarction recovery.
- Establishing ANS activity in patients with diabetic neuropathy and in controlling thrombogenicity.
- Forecast signal of myocardial ischemia, prior to the development of angina.
- The only way to follow up neonates where invasive techniques are impossible.
- Reliable detection of coronary artery disease (CAD) and its severity.
- Measurement of iontrop effects.
- Measurement of ventricular elasticity and diastolic stretch in hypertrophy analysis.
- In Anaesthesia-during general narcosis and regional techniques.
- Pre-operative assessment of cardio-pulmonary fitness.
- In critical care medicine for monitoring vital functions non-invasively and understand drug action.
- Optimising AV delay in dual chamber pace makers.
- Estimation of GFR, renal fraction, urine output and of fluid overload during dialysis, plasmapheresis.
- Early detection of pulmonary oedema, before the development of clinical symptoms.
- Early detection of COPD, its progression and effect of treatment.
- Aids in the decision making while choosing the line of management.
- Follow up of CABG and PTCA patients.
- Establishment of functional effectiveness of drugs and medicines.
- Establishment of pliability of mitral and aortic valves in valvular patients.

Haemoseis 256 3D Vasculography is used in various fields of medicine. Though not limited, some popular medical applications are in the fields of:

- **Cardiology**
- **Anesthesiology**
- **Nephrology**
- **Pharmacology**
- **Sports Training Facilities**
- **Teaching and Training Medical Students**
- **Critical Care Medicine**
- **Neonatology**
- **Operating Theatres**
- **Drug Testing**
- **Emergency Evacuation Systems**

> ...the more information a doctor has about his patient, more are the
> treatment options and better will be the outcome...

Currently, Haemoseis 256 3D Vasculography is being used in several countries and the numbers are growing as more and more doctors are recognizing the edge it provides in treating patients.

Haemoseis 256® - A Snapshot

- Non invasive
- Affordable
- Extremely Safe

- Procedure to be conducted by technicians and can be interpreted by doctors after 6 days training.
- Dynamic and continuous real time monitoring enables early detection of functional changes and realistic determination of coronary artery patency by measuring myocardial blood flow.
- Measures, evaluates and computes more than sixty vital applied physiological parameters (comprising beat to beat pressure, volume and time changes) in three to four minutes.

Technical Specification :

Electrical

Operating Mains Voltage	:	100~230VAC
Mains Frequency	:	50Hz – 60Hz
Power Consumption	:	650W

Transaortic Signal Modulation Channel

Frequency of measuring current	:	100 KHz ± 10 % sinus
Measuring current	:	Max 4mA eff.
Input Resistance	:	Min 2*100K
Common Mode Signal Suppression	:	Min 80db (50Hz)
Base Impedance	:	Max 100 Ohms
Change in Impedance	:	Max 5 Ohms
Transmission Frequency	:	0.1 – 35 Hz (-3db)
Accuracy of Measurement	:	± 5 %
Measuring Signal	:	Sinusoidal
Input	:	Differential

Electro Cardiograph Channel

Input Resistance	:	Min 2*10M Ohms
Common Mode Signal Suppression	:	Min 80db (50Hz)
Polarization Voltage	:	Max +300 mV
Transmission Frequency	:	0.5-50Hz (-3db)
Input Voltage	:	Max 20m Vpp
Input	:	Differential

Vertical Acceleration (VAD)

Cardiac Sound Piezo Transducer	:	ASK M3 or Equivalent
Frequency Transmission Band Width	:	10 Hz – 200 Hz

Blood Pressure Channel

Data Acquisition Card	:	ASKIT
Max Pressure	:	240 mmHg
Type	:	Automatic
Interface	:	IEEE-RS232

Digitisation

Sampling Rate	:	500Hz + 0.1 % (Per Channel)

No. of sampled channels	:	7
Resolution	:	12 bit

Imaging

Method	:	RGCI
Array	:	3 Dimensional 36, 100 units (max)
Model	:	RGCAM
Reconstruction	:	From real time deviation difference of haemodynamic modeling and turbulence
Angulation	:	Fixed 30 & 60 degrees
Projection	:	Short Axis and Lateral Split Reconstruction

Modeling

Superimposition	:	Real Time
No. of model variable	:	24
Domain	:	Time and Frequency
Software	:	Scalene, CCG Software Ver: 6.3.2.0

Mechanical

Dimensions	:	433(W) x 346(H) x 227(D)
Net Weight	:	14 kgs (Max)

Performance (Regional Myocardial Blood Flow vs CAG)

Last presented data	:	July 27, 2001
Correlated with	:	Coronary Angiography
Total measurement made	:	3465
Population (Angiogrammed)	:	300
Eligible population (after filtering)	:	273
Sensitivity	:	90.5%
Specificity	:	92.1%
Positive predictive accuracy	:	98.4%
Negative predictive accuracy	:	75.6%

Compliance

EN 60601-1, EN 60601-2-25
EN 46001, ISO 13485

* Owing to continuous development, specifications are subject to change without notice.

Canada
USA
Russia
The Netherlands
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Middle East
Pakistan
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Singapore
South Africa

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BSI

U K A S
QUALITY
MANAGEMENT
003

ANAB
ACCREDITED

Medical engineering • Biotechnology • Telecommunication • Nanosciences • Automation • Robotics • Hydrocarbons • Oil and Gas