DIABETES RISK Profiler

Comprehensive Diabetes Risk Profiler & Analysis Device

DIABETES RISK Profiler

Tests and Interprets :

- Central Arterial Blood pressure
- Endothelial Function
- Peripheral arterial disease
- Overall Arterial health
- Augmentation Index
- Peripheral Nervous system
- Carotid Femoral PWV (cfPWV)
- Sympathetic Nervous system
- Parasympathetic Nervous system
- Lung function

With Patented Technology#

State- of- the-art PC based 'DIABETES RISK Profiler' provides an unparalleled Prognostic approach for clinicians in Diabetic Patients with a Single Page Comprehensive report.

A single page Multi Color Print Report summarizes all the above mentioned tests along with Interpretation. A color band bar-graph in print report indicates the overall health Score of the patient. This score on repeat test denotes a change in terms of improvement or vice versa, thereby encouraging the patient and helping the clinician Titrate/change the medication accordingly.

Altogether 60 plus parameters are analysed and interpreted in the report for the clinicians' perusal at a glance. Exhaustive clinical information with graphs of all test parameters is also displayed and printed in the full disclosure report of 13 pages.

Why is a comprehensive test required?

A singular test (apart from blood chemistry) for a given HTN or Diabetic patient cannot reveal other underlying related diseases/disorders (see following illustrations of a HTN & Diabetic patient).

DIABETES RISK Profiler test, provides complete risk assessment of a patient for the following tests. Using this information based on the comprehensive prognostic report, the clinician can take an informed Therapeutic decision.

Central Aortic blood pressure, Pulse wave velocity, Augmentation index :

Central blood pressure (CBP), Pulse pressure [PP], augmentation index (Aix) and pulse wave velocity [PWV]) provide better insight into the pathophysiology of CV disorders/HTN than brachial pressure. Different antihypertensive drugs produce diverse effects on arterial stiffness variables, despite similar effects on peripheral (brachial) blood pressure. The 'Arterial health analysis' is a combination of parameters which are independent predictors of cardiovascular (CV) morbidity and mortality in patients with hypertension and these parameters can be potential therapeutic targets.

Diabetic/Cardiac Autonomic neuropathy :

One of the most overlooked of all serious complications of Diabetes/Hypertension is cardiac autonomic neuropathy (CAN), which encompasses damage to the autonomic nerve fibers that innervate the heart and blood vessels, resulting in abnormalities in heart rate control and vascular dynamics.
The clinical manifestations eg, resting tachycardia, orthostasis, exercise intolerance, intraoperative cardiovascular liability, silent myocardial infarction [MI], and increased risk of mortality are very severe outcomes of CAN.

Peripheral Neuropathy and PAD :

The nerve damage of the plantar foot only becomes prominent as an unhealing ulcer on the plantar foot. A VPT test can detect this condition (PN) much earlier. Many times the underlying cause is PAD (ABI) wherein the lower extremities' arteries are claudicated.

Pulmonary Function:

Spirometry is used to assess respiratory function and differentiates between normality and diseases causing obstructive and possibly restrictive defects. This can be a cause or an effect of certain physiological conditions. For example, increased arterial resistance can affect the capacity of lungs to breathe. This condition can be an effect of Diabetes. But in some cases, the arterial resistance becomes a cause for type-2 diabetes in future.
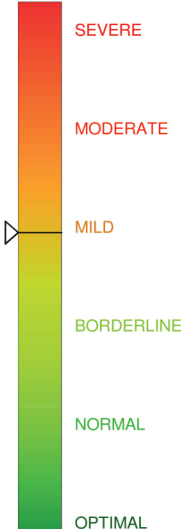
Endothelial Function:

Endothelial function and large artery stiffness are independent determinants of all-cause and cardiovascular mortality. Even in healthy individuals, a decline in global endothelial function is associated with increased aortic stiffness (PWV) and AIx. In addition, global endothelial function correlates more strongly with central, rather than peripheral pulse pressure. Large artery stiffness and central hemodynamics are influenced by endothelial function indicating the importance of NO in the regulation of large artery stiffness in vivo. Therefore, therapeutic strategies that restore NO bioavailability may reduce arterial stiffness and its adverse cardiovascular consequences.

For the First Time, there is a convergence of all these important tests in a single machine.

As a clinician you will be able to correlate the results at a glance of all tests with interpretation of respective tests on a single page, saving you a lot of time.   Additionally saving the patient multiple tests cost and inconvenience.

See the printout below, this patient is diagnosed as a hypertensive (with family history of diabetes) and being medicated accordingly. A test done on DIABETES RISK Profiler reveals his condition is more complicated than the diagnosis of only Hypertension:

1. Though his brachial BP is in the moderate range, his Central Aortic pressure and Pulse pressures are high.
2. His Pulse wave velocities and Augmentation Index are very high.
3. He has developed mild Diabetic Autonomic Neuropathy.
4. He has developed borderline Peripheral Neuropathy.
5. He has endothelial dysfunction.

Hospitals

Diabetes Risk Profiler

PATIENT DETAILS

Name : Balaraju
Sex : M   Wt(kg) : 52   ID : 0001
Age : 67 Yrs   Ht(cm) : 152

Heart-Ankle : 104.54 cm
Heart-Brachial : 31.25 cm
BMI : 22.51kg/m^2

TEST DETAILS

Date : 30 / 08 / 2016   Time : 14 : 36 : 35
Report Date :01 / 09 / 2016   Report Time : 15:26:18

RISK GRADE

- SEVERE
- MODERATE
- MILD
- BORDERLINE
- NORMAL
- OPTIMAL

PATIENT HISTORY

§ Risk Factors:
  Tobacco Use, HTN
§ Daily Activity:
  Light Activity : Office work
§ Reason for visit:
  Checkup
§ Symptoms:
  No reported Symptoms
§ Diseases:
  No reported disease
§ Surgery:
  SURGERY(None)
§ BMI:
  Normal

OBSERVATIONS ON TEST RESULTS

1. Arterial Stiffness:
   Rt: Severe CA Stiffness Lt: Severe CA Stiffness ---   Observed cfPWV indicates High Aortic Stiffness
2. Peripheral Artery Disease:
   Right:ABI Normal:Peripheral ASO may be absent   ---   Left:ABI Normal:Peripheral ASO may be absent
3. Endothelial Function:
   Abnormal Endothelial Function
4. Blood Pressure:
   Moderate hypertension
5. Autonomic Nervous System:
   Normal ANS Function
6. Peripheral Nervous System:
   Right plantar foot nervous system : Abnormal . Left plantar foot nervous system : Abnormal
7. Pulmonary System:
   Mild Res   ESA Obs Low VC

Comments:

All results to be clinically correlated.
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Physician

Hospitals

Diabetes Risk Profiler

CLINICAL INTERPRETATION & THERAPEUTIC SUGGESTIONS*

INTERPRETATION:
Total CardioVascular risk grade :Severe with Severe Arterial Stiffness.
Autonomic Nervous System : Normal ANS Function
Right plantar foot nervous system : Abnormal   Left plantar foot nervous system : Abnormal
Pulmonary System : Mild Res   ESA Obs Low VC

CLINICAL RECOMMENDATIONS:
Consultation for PAD may be advisable.Homocysteine test recommended.Check for ST segment morphology in ECG.Serum Creatinine and Blood Urea test may be advisable.
Exercise Caution while walking barefoot.

THERAPEUTIC SUGGESTIONS:
Arterial System : Systemic vascular therapy required. : Strong   Consider High dose combo:ß-Blockers+ACEI/ARB/CCB   .
Autonomic Nervous System : Lifestyle Modification Required. ARB, ACEI,CCB may be considered.
Peripheral Nervous System : alpha-Lipoic acid may be considered with gamma-Linolinic acid. May consider Anticonvulsants (Gabapentin and Sodium Valproate.) May consider Antidepressants (Amitriptyline, Venlafaxine, and Duloxetine.)
Pulmonary System: None

*All the Interpretations, Recommendations and Suggestions are subject to clinical evaluation by a qualified Physician.

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DIABETES RISK Profiler test details:

1. Cardiac / Diabetic autonomic neuropathy tests include :
   a. Resting Heart Rate
   b. Supine to standing
   c. Valsalva Maneuver
   d. Deep breathing
   e. Complete Time and Frequency domain analysis of HRV as per AHA/ESC guidelines

2. Peripheral neuropathy test :
   a. Vibratory Perception Threshold of both plantar feet at specific locations.

3. Arterial health analysis test:
   a. ABI for PAD detection by fully automated simultaneous BP readings on all 4 limbs.
   b. Central arterial (Aortic) Systolic , Diastolic and Pulse pressures
   c. Endothelial function
   d. Pulse Wave velocities
   e. Aortic Pressure Augmentation Index

4. Lung function tests
   a. FVC
   b. FEV1

The patient is connected with 4 ECG electrodes (2 lead) and four BP cuffs, other accessories are external viz. lung function & Feet sensor. The whole test takes about 20 mins, which includes 5 mins of patient conditioning in supine position.

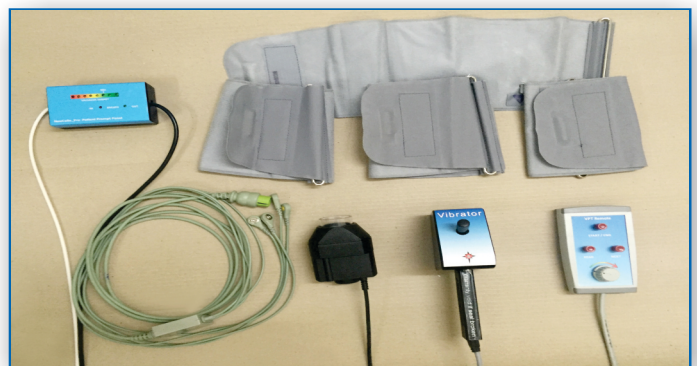## FRONT PANEL:
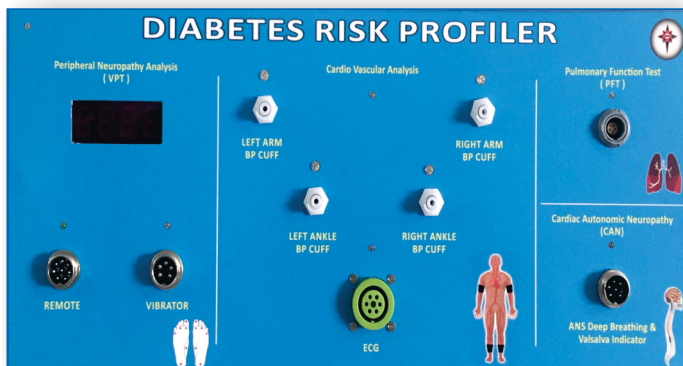
ACCESSORIES:

Minimum PC Requirements

OS   : Windows* 7 / 8 / 10
CPU   : Celeron* 1.8 GHZ / i3 / i5 or better processor
HDD   : 500GB
RAM   : 2GB
Printer : Any Windows* Compatible Inkjet / Laser Jet Printer

$ Specifications are subject to change without prior notice

Power Requirement and other details
Voltage 230 VAC ± 10%,
Frequency 50 Hz, Power consumption 20VA max

ENVIRONMENT REQUIREMENTS
Operating and storage Temp. 15°C to 45°C
Ambient Relative Humidity 15% to 90%, non- condensing
Operating and storage Pressure/Altitude 523 mm Hg to 760 mm Hg

*All regd. Trademarks are acknowledged to their respective owners.
*Laptop & Printer are optional

#DIABETES RISK Profiler uses technology patented by Genesis Medical Systems Pvt. Ltd. as "APPARATUS AND METHODS FOR THE NON-INVASIVE MEASUREMENT OF AORTIC PRESSURE PARAMETERS AND CARDIOVASCULAR SYSTEM PARAMETERS" under Patent No.: 341138

Since R&D is a continuous process, features & specifications are subject to change without notice.

Certifications   C E   EN ISO 13485:2016

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