

Simply Assessing  
Vascular Health

EndoPAT™



## + Endothelial Dysfunction - The Earliest Clinically Detectable Marker of Vascular Health

Endothelial Dysfunction, a common indicator of the health of the vessels, is widely validated as an independent risk factor for cardiovascular disease (CVD) and other life threatening diseases. Damage to the endothelium, the most inner layer of vessels, plays a major role in the development of CVD and in the progress of the disease and eventually its outcomes.

The health of the vessels reflects a wide range of sophisticated biological and physiological processes regulated by the endothelium, a 'super organ' with endocrine-like properties. The endothelium layer is known to regulate various biological and physiological effects, among them six key processes known as VIOPAC (Vasodilation, Inflammation, Oxidation, Proliferation, Angiogenesis and Coagulation), that ensure homeostasis.

**It is now evident that Endothelial Dysfunction is treatable and even reversible with optimal medical treatment and lifestyle modifications. In order to optimize patient management, Endothelial Dysfunction must be effectively diagnosed & monitored.**

## + Leading Physicians Worldwide Are Using EndoPAT to Better Guide and Monitor Patient Care

### Clinically Validated Technology

Proprietary PAT® (Peripheral Arterial Tone) technology, clinically proven in hundreds of clinical trials.

### A Novel, Independent Risk Factor

EndoPAT serves as a predictor of cardiovascular disease and is used for better risk stratification and patient management<sup>1</sup>.

### Unique Diagnostic Capabilities

EndoPAT mostly measures small vessels, which are substantially more sensitive to reactive hyperemia procedure, hence correlates to multiple cardiovascular (CV) small vessel disease.

### Non-invasive

Validated vs. invasive gold standard<sup>2</sup>.

### Accurate & Reproducible

The only device that corrects for both vessel baseline size and for non-endothelial related changes that may occur during the course of the test.

### FDA Cleared

The only device cleared for the diagnosis of Endothelial Dysfunction.

### Reimbursable

The EndoPAT test is covered by the Japanese health reimbursement system.

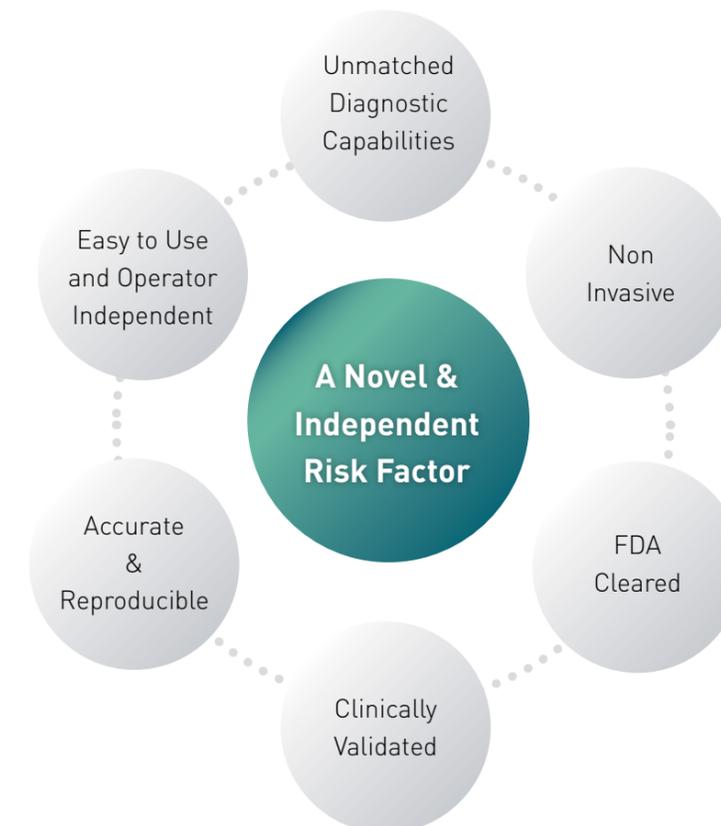
### Easy To Use

Fully automated, both operator & interpreter independent.

## + The Only FDA-Cleared Device Indicated for the Diagnosis of Endothelial Dysfunction

EndoPAT is an innovative, safe, non-invasive testing device for the diagnosis of endothelial dysfunction which is a reflection of the vascular health of small vessels.

The intuitive EndoPAT procedure is office based, lasts merely 15 minutes and is both operator and interpreter independent.



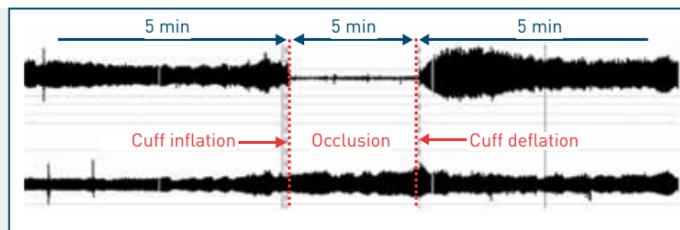
## + How Does EndoPAT Work?

**EndoPAT measures dilatory response through pulsatile volume changes at the finger tips (PAT signal). The signals are interpreted according to a unique algorithm which produces the RHI score – a metric index of Endothelial Dysfunction.**

1. EndoPAT bio sensors are placed on the patient's right and left index fingers. A cuff is wrapped around the non-dominant arm records the baseline for 5 minutes and then inflates and occludes the brachial artery for another 5 minutes.

2. Once the cuff is released, blood flow is restored causing the release of dilating compounds such as NO and EDHF by the endothelium. The larger the dilatory response is, the healthier the Endothelial Function.

3. EndoPAT's software performs an automatic analysis of data obtained from both fingers and provides a post-occlusion to pre-occlusion ratio. The system produces a comprehensive report with multiple test variables and quality control parameters.



## + Clinical Need and Application

**EndoPAT is an effective testing and treatment guiding tool for evaluating individuals who suffer from or are at risk of cardiovascular disease.**

According to the American Heart Association, over 50% of the coronary deaths in men and 64% in women occurred with no previous symptoms and roughly half of heart attacks occurred in patients that were not considered "high risk". It has been shown by numerous studies that cardiovascular risk assessment using traditional risk factors alone may misclassify over half of high risk patient.<sup>3</sup>

Endothelial Dysfunction, as reflected by the RHI may provide important, additional evidence to the traditional clinical risk stratification.

### Optimize Your Treatment Using EndoPAT

#### New Risk Factor

A novel, independent risk factor that may be used for re-stratification of patients

#### Treatment Titration

Monitoring and optimization of treatment effectiveness

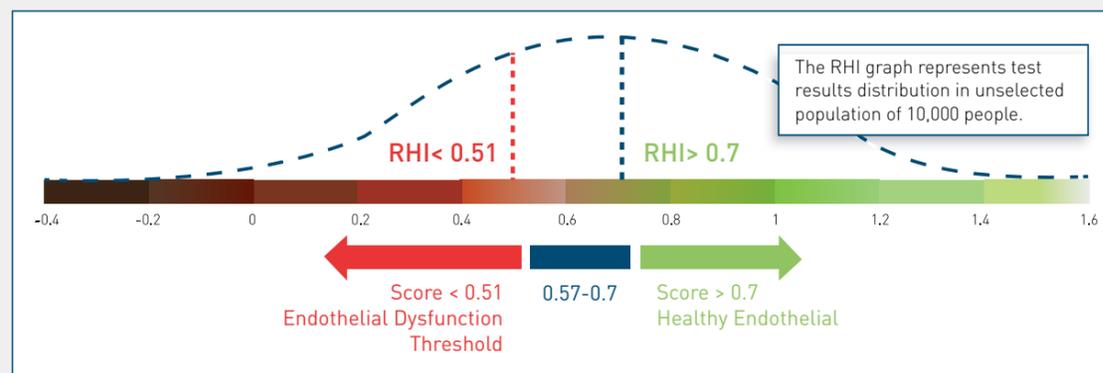
#### Patient Compliance

Achieving higher patients' compliance to prescribed treatment

## EndoPAT Test Results

### The RHI Score

The RHI score is provided in a logarithmic scale and in unselected population has a Gaussian (natural) distribution. An index score below and is abnormal, and correlates with Endothelial Dysfunction; a score greater than 0.7 indicates proper Endothelial Function.



\*In certain essays or clinical publications, EndoPAT's RHI may be referred to as LnRHI and is provided in a logarithmic scale (natural log basis) RHI scores of 0.51 and 0.7 will be equivalent to for previous use of the same RHI but in a linear scale 1.67 and 2.00 respectively.

## + Wide Range of Clinical Uses & Implications

### • Cardio Vascular Disease (CVD):

EndoPAT serves as a predictor of CVD and in identifying near-future cardiac risk.<sup>4</sup>

### • Diabetes:

EndoPAT can assess small vessel function - a key component in diabetes.<sup>5</sup>

### • Women's Health:

EndoPAT effectively helps identify high-risk women who present atypical symptoms and can otherwise go undiagnosed.<sup>6</sup>

### • Erectile Dysfunction (ED):

EndoPAT can attest that ED is an early indicator as well as an independent risk factor for future cardiovascular events.<sup>7</sup>

### • Life style Modification:

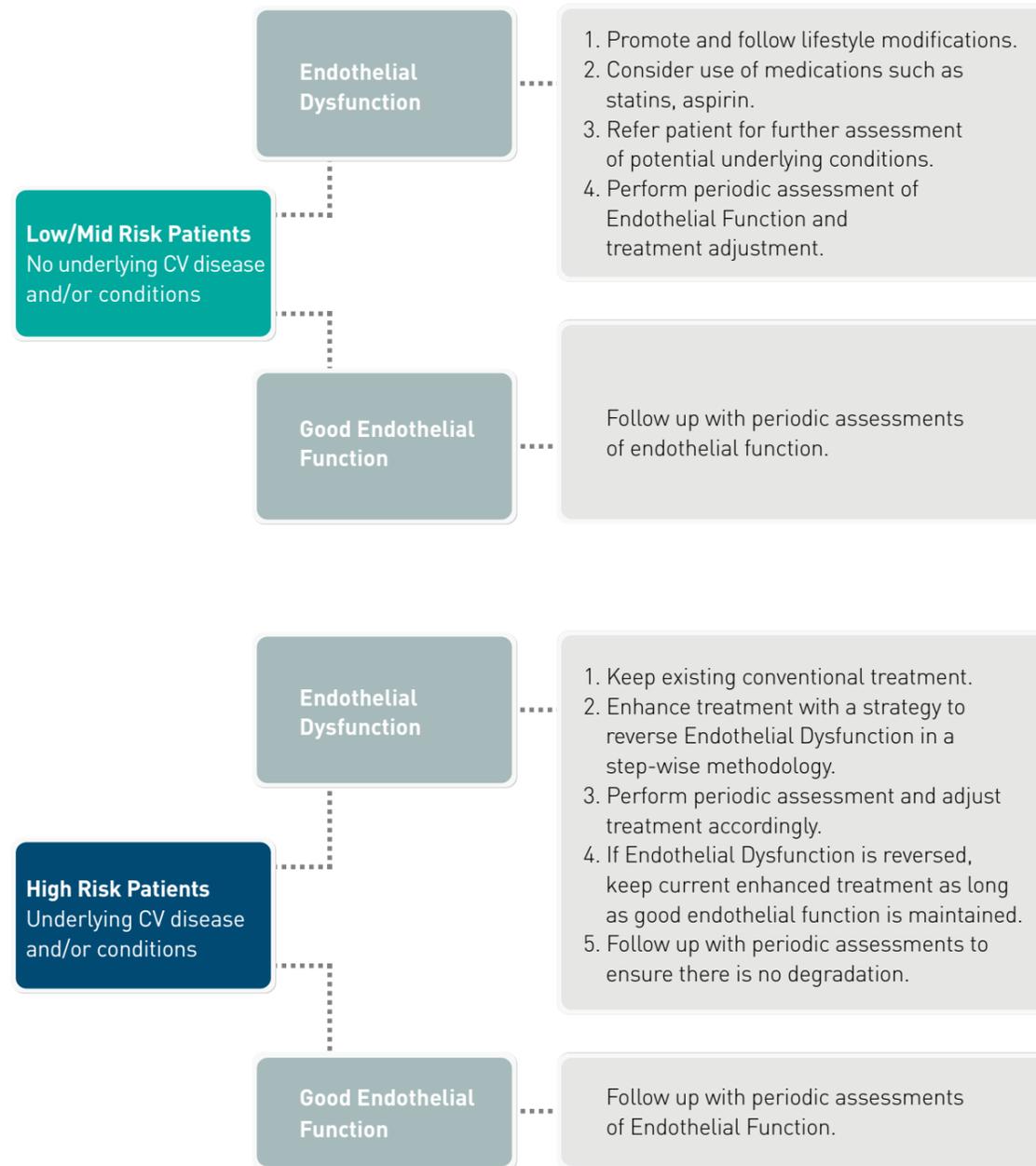
EndoPAT acts as a strong motivating and monitoring tool in lifestyle improvements (smoking cessation, exercising, weight loss and more).<sup>8</sup>

### • Occupational Screening:

EndoPAT can act as a health screening tool for employers/payers.

## + Implementing the EndoPAT Test Results

Life style modifications (such as smoking cessation, dietary change, exercise etc.) as well as proper pharmacological intervention can positively impact endothelial function within a relatively short time, and may have ramifications on therapeutic management and monitoring protocols.



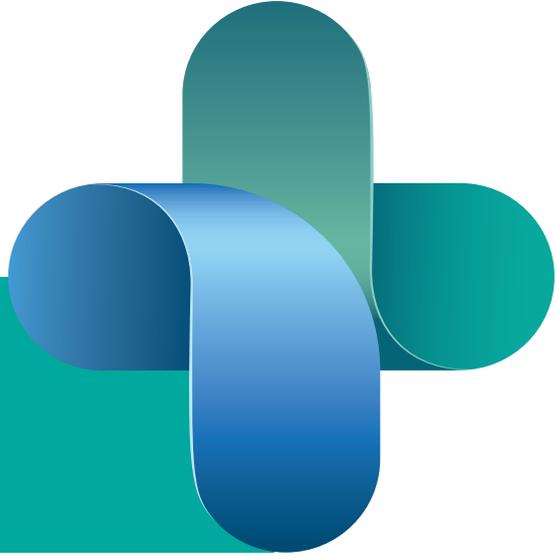
## + Vascular Health at Your Fingertips

### Clinically Validated

EndoPAT was validated according to the accepted gold standard<sup>2</sup> and is supported with a large body of outcome studies resulting in over 400 peer reviewed publications in leading medical journals. EndoPAT is recommended by a wide range of internationally renowned researchers in the field of cardiovascular health.

- <sup>1</sup> Assessment of endothelial function by non-invasive peripheral arterial tonometry predicts late cardiovascular adverse events- Rubinshtein et al European Heart Journal, 2010
- <sup>2</sup> Noninvasive Identification of Patients with Early Coronary Atherosclerosis by Assessment of Digital Reactive Hyperemia- Bonetti et al, JACC 2004
- <sup>3</sup> American Heart Association 2015
- <sup>4</sup> Assessment of endothelial function by non-invasive peripheral arterial tonometry predicts late cardiovascular adverse events- Rubinshtein et al European Heart Journal, 2010
- <sup>5</sup> Effects of exenatide on postprandial vascular endothelial dysfunction in type 2 diabetes mellitus- Torimoto et al. Cardiovascular Diabetology, 2013
- <sup>6</sup> Digital Assessment of Endothelial Function and Ischemic Heart Disease in Women- Matsuzawa et al, JACC, 2010
- <sup>7</sup> Endothelial Function assessment in Patients with erectile Dysfunction- Bahouth et al, IMAJ 2015
- <sup>8</sup> Acute cigarette smoking impairs microvascular function in young moderate smokers: A potential model for studying vasoactive properties of food bioactive - C. Del Bo' et al, pharmanutrition 2014
- <sup>9</sup> Advanced peripheral microvascular endothelial dysfunction and polyvascular disease in patients with high cardiovascular risk, Maeda et al, Journal of Cardiology, July 2015

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# Simple Assessing Vascular Health

Itamar Medical is a leading medical device company that develops, manufactures and markets diagnostic products based on its proprietary PAT (Peripheral Arterial Tone) Signal. The PAT signal is a non-invasive “window” to the cardiovascular system and the autonomic nervous system. PAT based products provide early-stage detection of disease and facilitate follow-ups; improving patient care while reducing the overall cost of healthcare.

Itamar Medical has offices and distribution channels around the world.