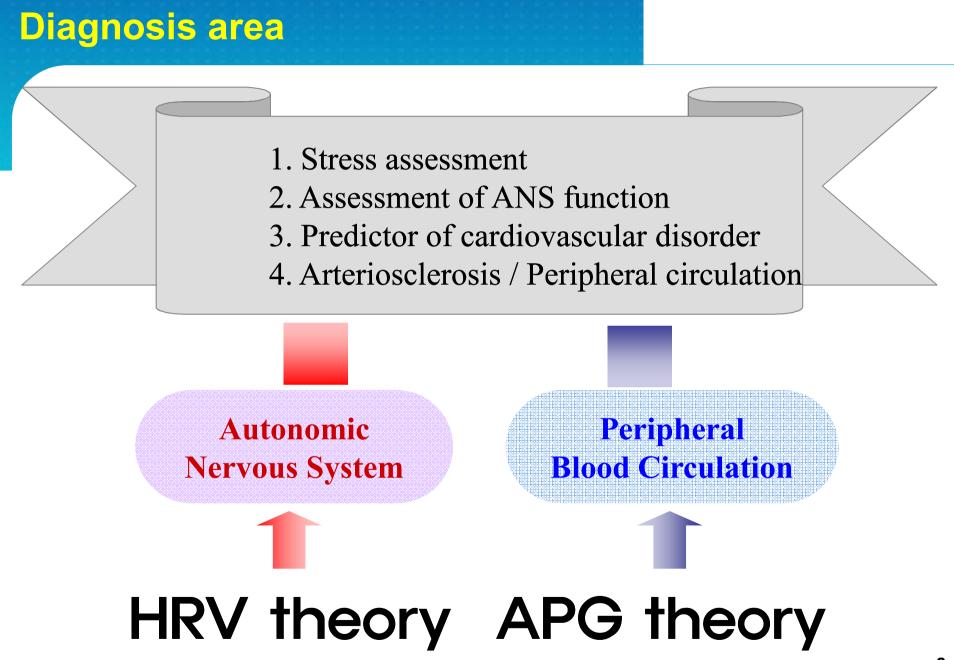
At the Core of Medical Technology www.medi-core.com

INTRODUCTION SA3000P



Stress is the root of almost disease.





What's the ANS ?

The Aims of ANS – \rangle To maintain homeostasis

- ANS innervated in internal organs, regulates key functions involuntarily through its 2 branch, SNS (Sympathetic Nervous System) and PNS (Parasympathetic Nervous System)
- ANS acts for heart rate control including hormonal, enzymatic, respiratory, pulmonary, urinary and uterine neural control
- SNS : Metabolic energy supply to the cardiovascular system for blood pressure, heart rate and blood circulation control
- **PNS** : Organic protection, Energy conservation and restoration

Branch	Heart beat	Blood vessel	Respiration	Pupil	Digestive liquor	Sweat
SNS	Accelerate	Constrict	accelerate	dilate	Inhibit	Accelerate
PNS	Inhibit	relax	Inhibit	contract	accelerate	Inhibit

Recently, a lot of people suffers with somatic diseases without pathological abnormality. It's realized for the importance of the ANS

Diseases related to ANS dysfunction

Diabetes, Hypertension, Irritable Bowel Syndrome, Headache, Sudden Death after MI, Depression, Anxiety, Sleep disorder

ANS analysis method

HRV(Heart Rate Variability)

Gastrointestinal Motility Assessment

Analysis for the Neurotransmitter in blood

Electrophysiological Assessment

GSR (Galvamic skin response)

Pupillary reflex

Most Reliable ANS Index, HRV

There are about 12,000 papers on PubMed site till Apr. 2009

S N	A service of the U.S. National Library of N and the National Institutes o						
All D	atabases PubMed Nucleotide Protein Genome Structure						
Search P	ubMed Y for Heart Rate Variability Go						
Limits							
Display	Summary Show 20 😪 Sort By 😪 Send to 😪						
All: 11	Review: 7 n Jac						
Items 1	Page 1 of 583 Next						
	dices of autonomic nervous system activity in women with mild hypertension in ne perimenopausal period. 요 activity: 활발한 움직임;활동						
	zarnecka D, Pośnik-Urbańska A, Kawecka-Jaszcz K, Kolasińska-Kloch W, /ojciechowska W, Fedak D.						
K: PI	Ardiol Pol. 2009 Mar;67(3):243-251. MID: 19378230 [PubMed - as supplied by publisher] elated Articles						
	Autonomic modulation in patients with congenital generalized lipodystrophy (Berardinelli-Seip syndrome).						
	aria CA, Moraes RS, Sobral-Filho DC, Rego AG, Baracho MF, Egito ES, randão-Neto J.						
PI	uropace. 2009 Apr 17. [Epub ahead of print] MID: 19376819 [PubMed - as supplied by publisher] elated Articles						
m	hite matter lesions are associated with the results of 123I- etaiodobenzylguanidine myocardial scintigraphy in type 2 diabetes mellitus atients.						
	nan F, Masaki T, Shinohara T, Yufu K, Takahashi N, Nakagawa M, Eshima N, aikawa T, Yoshimatsu H.						
M	etabolism 2009 May 58(5) 696-703						

Chronic fatigue **Excessive stress** Functional indigestion Headache / Migraine Obesity Adult diseases (Hypertension, Diabetes, Hyperlipidemia) Inertia, drowsy Failure of the concentration & memory

Disease prevention and management by objective diagnosis

Clinical research

Oriental reference

1. Clinical reference research at 8 major hospitals in Korea

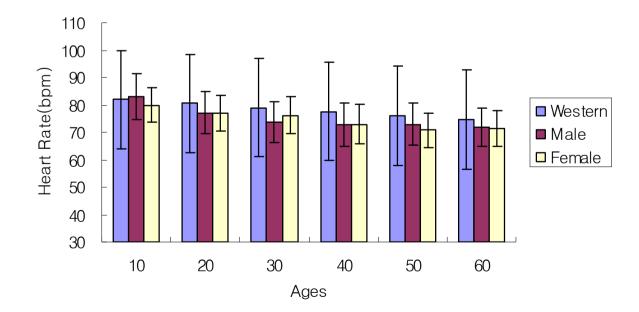
- Pusan University Hospital
- Donga University Hospital
- Seoul Baek Hospital of Inje University
- Eulgy University Hospital
- Ihwa University Hospital
- Dankuk University Hospital
- Ghil University of Ghachun Medical College
- Sungshim University of Hanlim University
- 2. Clinical research for 2 years (from May 2001 to June 2003)
- 3. Acquired 3,600 normal cases
- 4. Build Oriental Reference for the 1st in the world and get its Patent
- 5. There are big difference of normal range between western and oriental people

Comparison for the REF

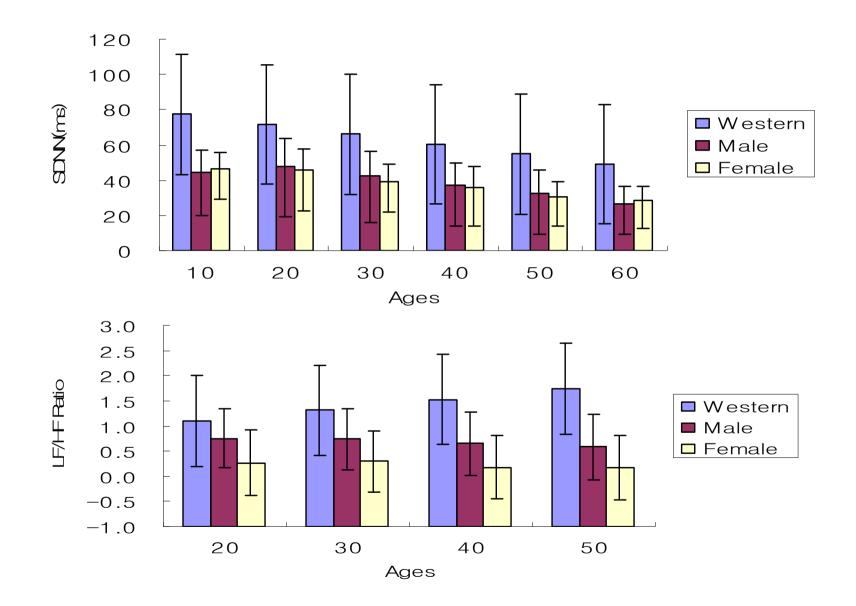
3239 people(M:1753, F:1486)

- Male 1753 (40.8±11.4 years old)
- Female 1486 (39.7±12.8 years old)

Comparing to the data of HeartMath Research Center in USA



Comparison for the REF





• Patent in Korea •



• Patent in Japan •

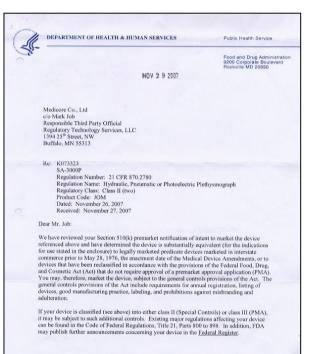


Certificates

	CE	
<u> </u>		

FULL QU	EC CERTIFICATE IALITY ASSURANCE SYSTEM CERTIFICATE	APPROVAL	Nemko	
		Cer	tificate No.: Order No.:	EU0404404 20868
"Regulation no. 25 of 12 th Janua relating to medical devices, transubjected, confer EEA agreement chapter XXX". We certify that the	ination has been carried out following 1995 relating to modical devices sposing directive 93/42/ECC into N ent, proposition no. 100 (1991-92) a ne production quality system confor b) of the aforementioned directive.	s pursuant to act no lorwegian law to wh special appendix no	. 6 of 12 ^m Ja ich the unde . 2, volume 2	nuary 1995 rsigned is A/3 A, goods,
Name and address of the manufacturer:	Medicore Co., Ltd. 4F Lunar B/D, 72-3, Chungdam- Kangnam-gu, Seoul, Korea	dong,		
Name and address of the factory:	Medicore Co., Ltd. 549, Nungpyung-1 ri, Opo-up, Kr Kyunggi-do, Korea	wangju-si,		
Device categories:	Heart rate variability analysis sys	tem		
Model/type:	SA-3000P			
Standards/provisions:	The audit of the quality system w and the provisions in Annex II of of section 4.			
Date of initial audit:	2004-02-26/27			
Date of the end of the validity:	2009-04-01			
Conditions in Annex II:	See sub clause 3.4 and 5.1			
Other relevant conditions:	Article 17.2 of the EU-Directive 9	3/42/EEC		
Nemko EC notification No.:	0470			
Remarks:	This certificate replaces our certi	ficate EU0404404,	issued 2004-	03-20
Conformity and affix the CE-ma	or the European authorised repres- rking as indicated below together w he conformity audit and inspection	ith the Nemko EC r	notification n	umber to each
Date of issue: 2004-05-10	Date of	verification: 2004-0	05-10	
Jack Sharp	820	field Hon	nand	
Signature: Frank Skarpsno	Signature	Arild R. Hansgård	0.	
.ead auditor /Principal Engineer		Principal Engineer	04	70
Nemko AS P.O. Box 73, Blindern N-0314 Oslo, Norway	Office address Te Gaustadailéen 304 OsloEr	lephone 7 22 96 03 30	Fax +47 22 9 NO 94435	6 05 50

• FDA •

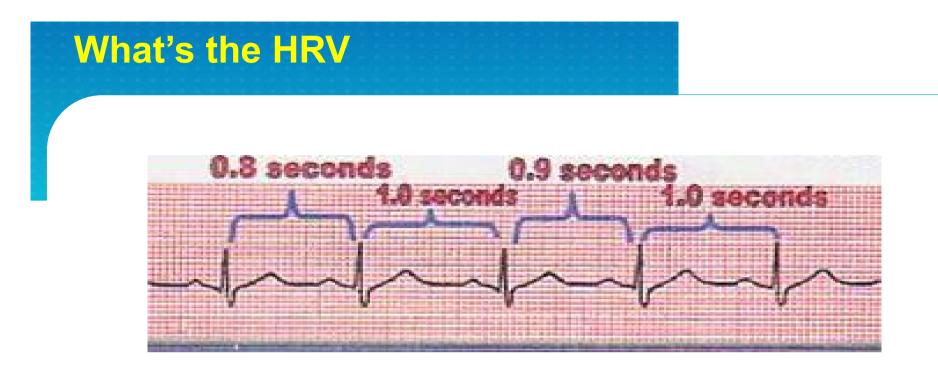


• SFDA •

中华人民共和国
中平八氏天神国 PEOPLES REPUBLIC OF CHINA
医疗器械注册证
REGISTRATION CERTIFICATE FOR MEDICAL DEVICE 注册号: 国食药监祗(进)字 2004 第 2211449 号 REG.NO: SFDA(I) 20042211449
韩国 Medicore:
你单位生产的心率变异分析系统,经审查,符合
医疗器械产品市场准入规定,准许注册。自批准之日
起有效朝四年。
特此证明。
Medicore:
This is to certify that the medical product Heart Rate Variability Analysis System manufactured by your company has been inspected by our office and is permitted to register on the Chinese market. This registration certificate is valid for four years from the date of issue.
1. 品牌放
国家会品药品里含管理局 State Food and Drug Administration 2004年8月26日
C Star
附件: 医疗器域产品注册登记表 ATTACIMENT: M_DRALDEVICE REGISTRATION RECORD
ALCOULDERT. MEDIAL DEVICE ACCULATION RECORD

1. H R V

Heart Rate Variability



0.8 -> 1.0 -> 0.9 -> 1.0 (sec) 845 -> 1049 -> 911 -> 1023 (msec)

Autonomic Nervous System which affects the sinoatrial node, is changed every moment by internal or external environment. HRV, heart rate variability is the degree of fluctuation in the length of the intervals between heart beats.

The History of HRV

- 18th Century Albrecht von Haller noticed heart beat not regular
- 1965 Hon & Lee noticed that the beat to beat interval changes are the first alteration before fetal distress occurs. R-R change precedes HR change
- 1971 Sayers and others focused on rhythm imbedded in beat-to-beat HR
- 1977 Wolf et al showed association of HR to sudden death post MI

The History of HRV

- 1981 Akselrod introduced Power Spectral Analysis (PSD)
- Late 1980's HRV confirmed strong predictor of mortality after an acute MI
- 1996 Task Force publish Standards of Measurement for HRV

Circulation 1996:93:1043-1065

 2000 publications over the last decade, found with a MEDLINE search, key word heart rate variability "HRV"

The history of HRV

The Task Force (1996)

Establish guideline about HRV analysis in 1996

European Heart Journal (1996) 17, 354-381

Guidelines

Heart rate variability

Standards of measurement, physiological interpretation, and clinical use

Task Force of The European Society of Cardiology and The North American Society of Pacing and Electrophysiology (Membership of the Task Force listed in the Appendix)

Introduction

The last two decades have witnessed the recognition of a significant relationship between the autonomic nervous system and cardiovascular mortality, including sudden cardiac death¹⁻¹. Experimental evidence for an association between a propensity for lethal arrhythmias and signs of either increased sympathetic or reduced vagal activity has encouraged the development of quantitative markers of autonomic activity. DVD research one of the arrhores of autonomic activity. DVD research one of the analysis of the second seco

activity has encouraged the development of quantitative markers of autonomic activity. Heart rate variability (HRW) represents one of the most promising such markers. The apparently easy derivation of this measure has popularized its use. As measurement of HRV, the cardiologist has been provided with a seemingly simple tool for both research and clinical studies¹⁸. However, the significance and meaning of the many different measures of HRV are more complex than generally appreciated and there is a potential for incorrect conclusions and for excessive or unfounded extrapolations.

Recognition of these problems led the European Society of Cardiology and the North American Society

Key Words: Heart rate, electrocardiography, computers, autonomic nervous system, risk factors.

The Task Force was established by the Board of the European Society of Cardiology and co-gootneeted by the North Anterican by the Working Croups on Arrhythmias and on Compares of Cardiology of the European Society of Cardiology. After exwriting core of the Task Force society of Cardiology. After exwriting core of the Task Force society of Cardiology. After was approved by the Board of the European Society of Cardiology Society of Pasing and European Society of Cardiology Society of Pasing and Electrophysiology on October 3, 1995.

Correspondence: Marek Malik, PhD, MD, Chairman, Writing Committee of the Task Force. Department of Cardiological Sciences, St. George's Hospital Medical School, Cranmer Terrace. London SW17 0RE, U.K.

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of Pacing and Electrophysiology to constitute a Tas Force charged with the responsibility of developin sprce charged with the responsibility of developin Force were to: standardize nomenclature and develo definitions of terms: specify standard methods or measurement: define physiological and pathophysis logical correlates: describe currently appropriate clinic applications, and identify areas for future research.

In order to achieve these goals, the themosys of the Task Force were drawn from the fields of mathematics, engineering, physiology, and clinical medicine. The standards and proposals offered in this text should not limit further development but, rather, should allow appropriate comparisons, promote circumspect interpretations, and lead to further progress in the field. The newnomenon that is the floxus of this repoort

is the oscillation in the interval between consecutive heart beats as well as the oscillations between consecutive instantaneous heart rates. Heart Rate Variability variations of both instantaneous heart rate and RR intervals. In order to describe oscillation in consecutive cardiac cycles, other terms have been used in the literature, for example cycle length variability, heart period variability. RR variability and RR interval tachogram. The interval between consecutive beats that is being analyzed ratible than the heart rate perse. However, these terms have not gained as wide acceptance as HRV, thus we will use the term HRV in this document.

Background

The clinical relevance of heart rate variability was first appreciated in 1965 when Hon and Lee⁶⁸ noted that fetal distress was preceded by alterations in interbeat intervals before any appreciable change occurred in the heart rate itself. Twenty years ago. Sayers and others focused attention on the existence of physiological rhythms imbedded in the beat-to-beat heart rate signal^{97–80}.

© 1996 American Heart Association Inc.; European Society of Cardiolog

HRV STANDARD GUIDELINE

By The European Society of Cardiology & The North American Society of Pacing and Electrophysiology

The concept of HRV

Under steady state condition, the heart rate is monotonously regular.

Old

11 11

- * 1929 Walter B. Cannon : "homeostasis"
- * Physiology all cells, tissues and organs maintain a static or "steady-state" condition in their internal environment

continuous time series data from physiologic processes such as

Heart rate, Blood pressure, Nerve activity...

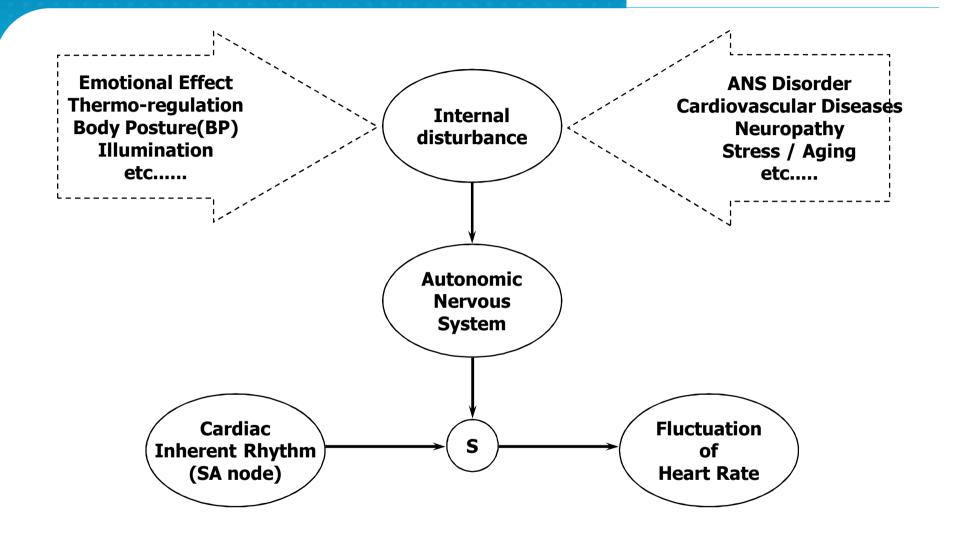
New concept

Biological Process vary in a complex and nonlinear way even during "steady-state" condition

 \bigcirc

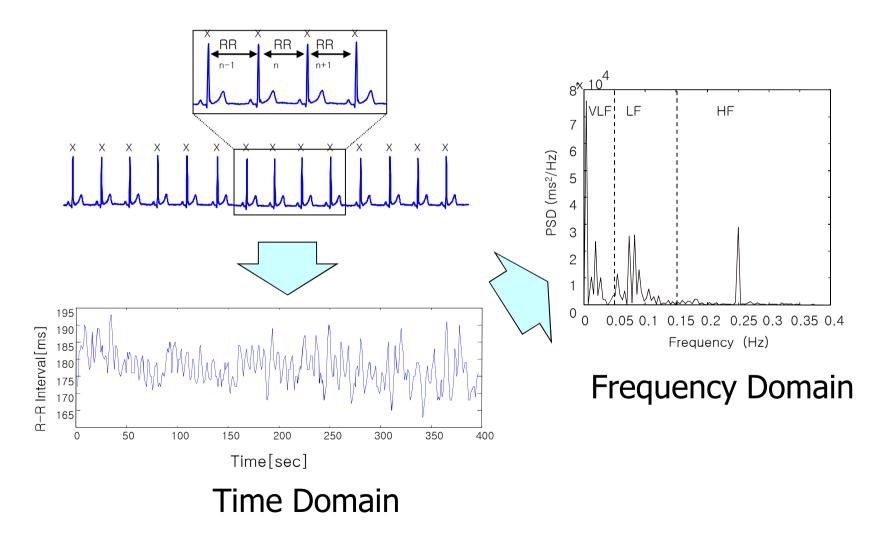
Under steady state condition, the heart rate is also not regular.

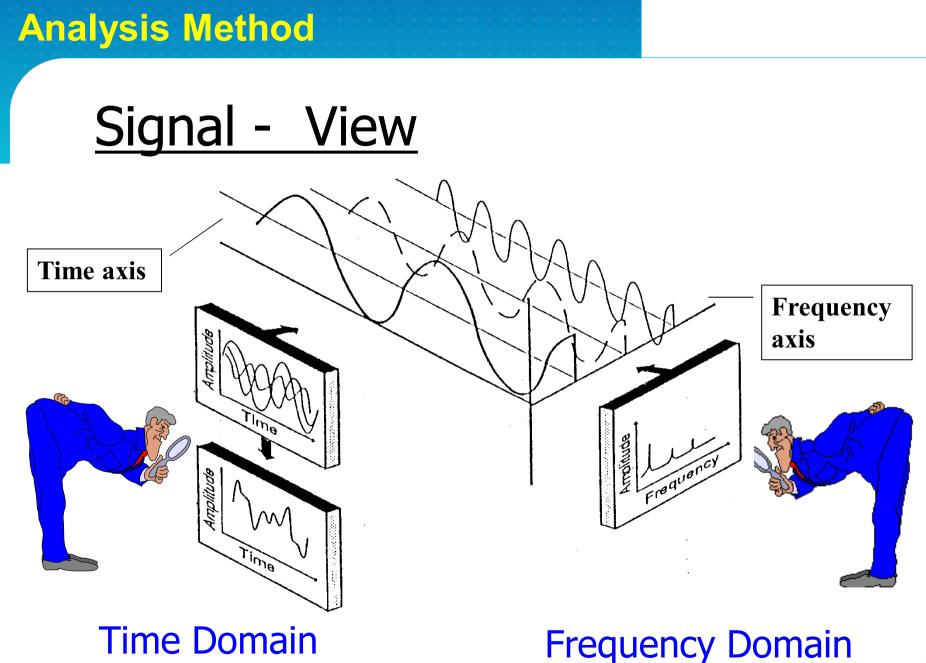
The generation of HRV



Proper ANS regulation lead to bigger fluctuation of HR

HRV Signal Induction



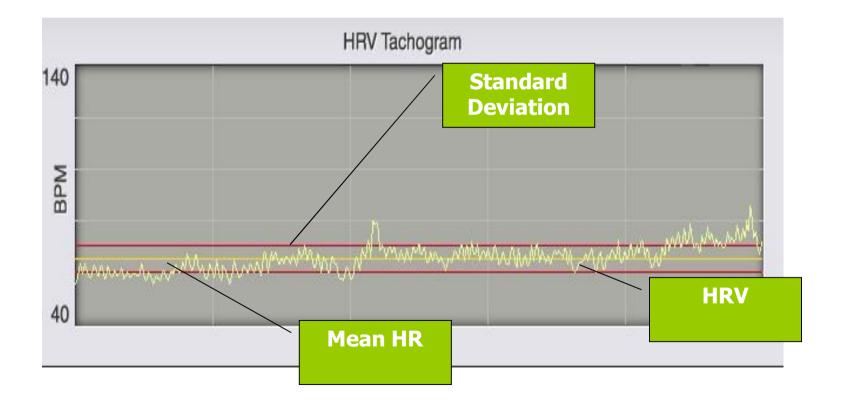


Time Domain Analysis	Frequency Domain Analysis	
Mean HR	TP	
SDNN	VLF	
RMSSD	LF	
PSI	HF	
ApEn	LF norm	
SRD	HF norm	
	LF/HF ratio	

Parameter – Time Domain

1.SDNN (Standard Deviation Normal to Normal)

- Standard deviation of total N-N intervals
- Reflect the variation of HR



Parameter – Time Domain

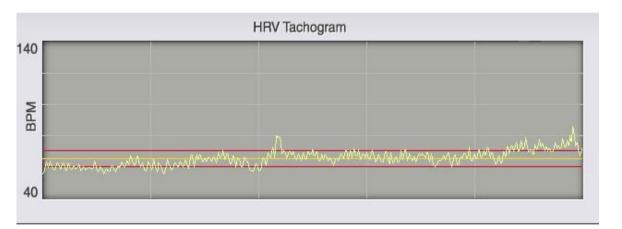
1. SDNN (Standard Deviation Normal to Normal) - Stress dissolution ability

Time Domain Analysis		Above 50	Good	
Meann HITT(Spm)	60.9			
SDNN(ms)	59			
RMSSD(ms)	31.4	25-50	Normal	
PSI	15.4			
ApEn	0.814	15-25	Note	
SRD	1.067	Below 10	High risk of functional disorder	
TSRD	165.5			
			or disease	

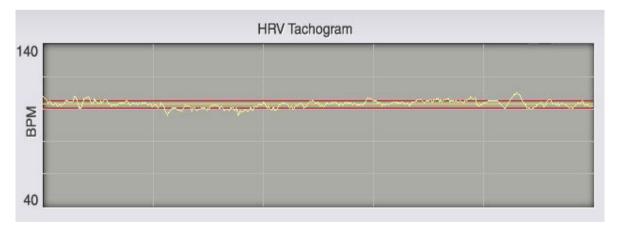


(Graphic view of SDNN)

1) HRV Tachogram : Irregular, complex as healthy



Healthy

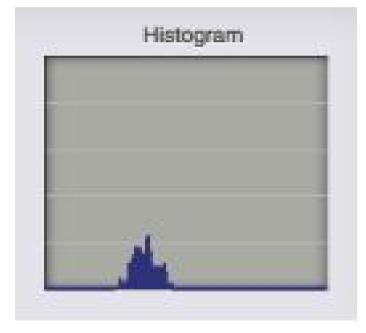


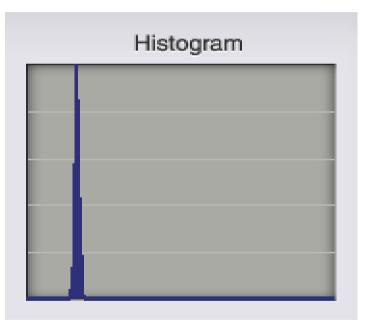




2) Histogram : X axis is RR interval , Y axis is Numbers

As the healthier, X axis is wide, and Y axis is low



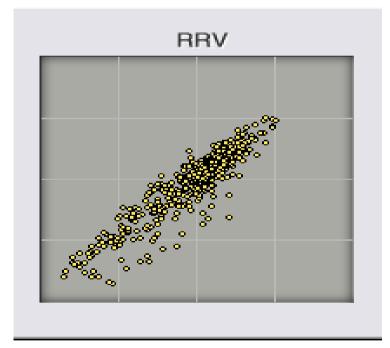


Healthy: wide,flat

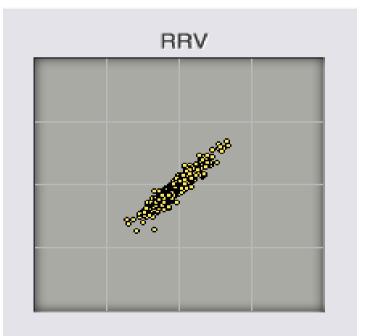
Unhealthy: narrow ,sharp

Time Domain (SDNN)

3) RRV : Both X and Y axis indicate heart beats For the healthier person, RRV spreads widely



Healthy :wide, spread



Unhealthy : narrow, concentrate ²⁷

Time Domain

2. RMSSD

(Square root of the mean of sum of the square of differences between adjacent NN intervals)

- Assessment of parasympathetic nervous activity which is one of Autonomic Nervous Systems related to the heart.
 - Before coming the heart dysfunction or disorder symptom , RMSSD shows lower than the healthy person
 - -> SDNN decrease and RMSSD decrease (10 \downarrow)
 - : Increases the risk of heart disease

Parameter – Time Domain

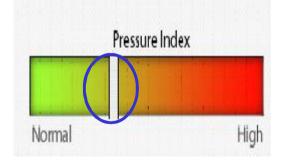
3. PSI (Physical Stress Index) The pressure loaded on regulation system

- By the virtue of exercise or other physical activity, Heart Rate(HR) increases

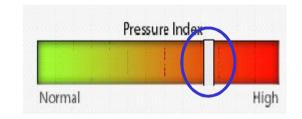
-> At the moment, HRV (Heart Rate Variability) lessens

-> increases the pressure loaded regulation system

-The degree of pressure loaded on regulation system, drawn from the time domain parameters such as HR, the distribution of HRV & RR interval



Healthy: green normal zone



Unhealthy: higher stress lead to place the bar on red higher zone

Time Domain

4. ApEn (Approximate Entropy)

Statistic value of complexity for the beat to beat interval

- Healthier person has higher value
- 5. SRD (Successive Approximate Entropy)
- compare the fixed section of fore part as baseline with the change degree, result of rear part during the test
- Index to judge if the regular status keeps going
- If the value is '1', it indicates the regular status maintains

Parameter – Frequency Domain

1. VLF,LF,HF

1). VLF (Very low frequency)

- 0.0033-0.04Hz
- provide the additional information of sympathetic and parasympathetic nervous system

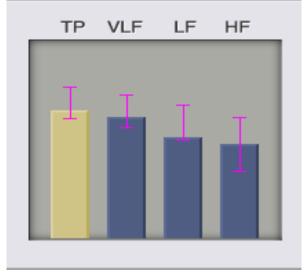
2). LF (low frequency)

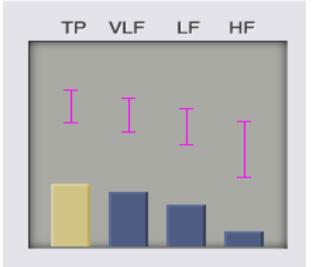
- 0.04-0.15Hz. Also known as "Mayer" waves.
- Relative low frequency element in adjacent 0.1 Hz to control the blood pressure and reflect the activities of mechanism
- Seems to be related to both SNS and PNS activity

3). HF (High frequency)

- 0.15-0.4Hz
- Respiratory band : Relative high frequency element related to respiratory activity
- Indicative of parasympathetic nervous system (vagus nerve)

Parameter – Frequency Domain





Healthy

Unhealthy

Reduction of TP	Reduction of VLF	Reduction of LF	Reduction of HF
*Decreased ANS function *Lowered regulation competence *Decreased ability to cope with the requirement of continuously changing environment	*Lessen the ability of body temperature regulation *Hormone disorder	*Loss of energy *Fatigue *Insufficient Sleep *Lethargy	*Chronic stress *Aging *Reduced electrical stability of heart *Functional indigestion

Frequency Domain

2. LF norm , HF norm

- The ratio of value subtracts VLF from Total Power to LF or HF LF norm = LF / LF + HF -> Sympathetic nervous system HF norm = HF / Lf + HF -> Parasympathetic nervous system
- Reflects the regulation and balance degree of autonomic nervous system.

3. LF / HF ratio

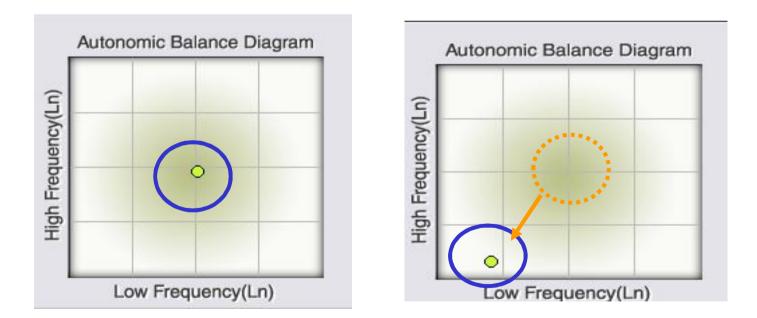
- Reflects the general balance degree between sympathetic and parasympathetic nerve by LF:HF ratio
- This value is direct proportion about the activity of sympathetic nerve. In the other hand, it is inverse proportion about the activity of parasympathetic nerve.

Frequency Domain

4. Autonomic Balance Diagram

: X axis is LF, Y axis is HF

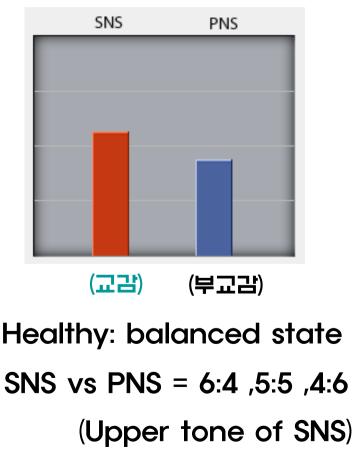
If LF and HF value are in normal range, the spot marks around the center. Otherwise, in the ill state, fall down from the center.

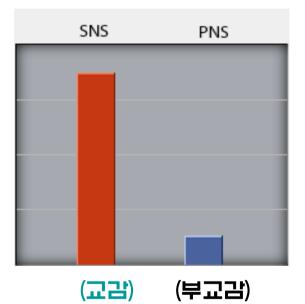


Parameter – Frequency Domain

<u> {LF/HF ratio</u>}

1) SNS & PNS: relative ratio between sympathetic and parasympathetic activity

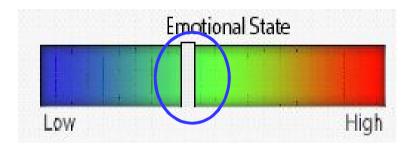


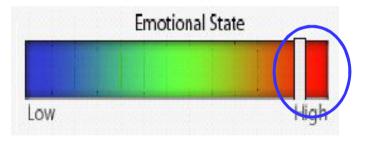


Unhealthy: ANS dysfunction SNS dominant state

Parameter – Frequency Domain

2) Emotional State: reflects stability of the emotional state based on LF/HF ratio





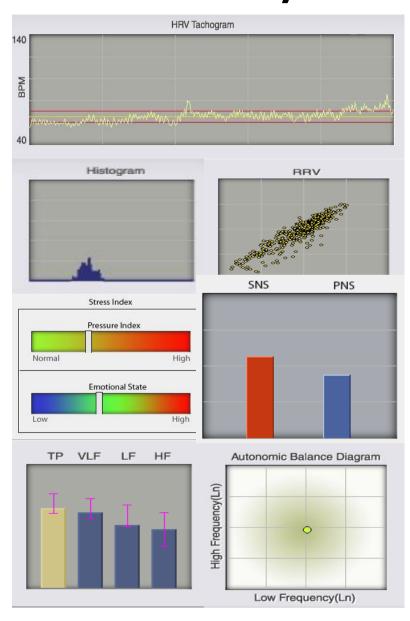
Healthy

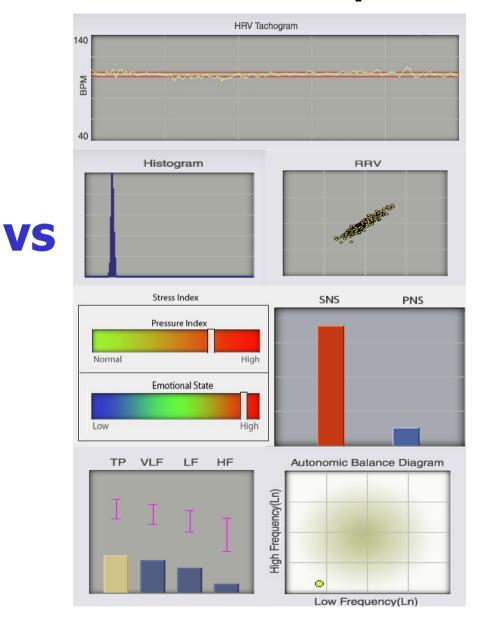
At the middle green zone, steady emotional state Under emotional Stress - Low : depression mood - High : Anxiety mood

Healthy vs Unhealthy

Healthy

Unhealthy





37

HRV Report

ANS Balance Test Report (for professional)

Patient In	formation	Þ	Date	2005-06-28 02	52	Sex	Ferr	ale
			Chart ID	0001 CHOI		Age Birthday	23 1982-02-24	
			Name					
Result				-				
+ Time Analysis					cy Analysis			
Mean HRT(bpm)	67	ApEn	0.832	TP(ms2)	2989.003	8.003	LF Norm(n,u,)	71.928
SDNN(ms)	71.525	SRD	1.140	VLF(ms2)	844,827	6,739	HF Norm(n,u)	28.072
RMSSD(ms)	49.872	TSRD	166.232	LF(ms2)	1542.264	7.341	LF/HF	2.562
PSI	12.285			HF(ms2)	601.922	6,400		
HRV Tachog	HALL BUILDE							
e end				SNS PNS	5	Histogra tress Index	Pressure index	
Power spectral d	lonsity				5		Pressure index	Hgy
Power spectral d		HF			SI	tress Index	Pressure index	-

DDR (Direct Diagnosis Result) Report (for the patient)

		Autonome		ERVE BALA	KIGHIL!	.ə1			
Name	choi	Chart No.	0001	Ser/Age	F/23	Date	2005	-06-28 04:4	
	he latest and a	dvanced tests to che ice of your ANS(Au		ral health status includ e System).	fing body rey	gulation capac	ity, stress r	esistance, ar	
(ANS ▶									
2		ANS is composed of SNS(Sym		ANS Stability		ANS activity			
60	PNS (Parasympathetic PNS) (Parasympathetic Systems, mainly distr		Nerve		ling ling	Roor Norm	till Idi Good	130 19 1 Excedent	
The start		o-internal organs.		0		ANS BOK			
a de la companya de l	ANS helps you keep homeo -stasis of your body.		someo		Harley United	and Linkeler		Balanced	
(Stress »			1.5		egny touts	root arasata		poronoso.	
130.05.9	14	tress makes you feel	Industry						
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(X)		scessive stress is ha o you. Such physiol		Stress Index	150 .030	110		74 9	
20	1	liseases as chronic f nd insomráa are clos	atigue.	(90)	Bod	Poor Norr			
137	-E	ated to stress.		Fatigue Index		110	-	7	
	-			(141)	lod	Hoor Norr	nal Good	Excelent	
(Heart ►									
		learts supplies blood t ody, contributing to		Mean Heart Rate					
-un		ing oxygen and nur		70	Very Low	Low Norr	na High	Very High	
d and		e each part of organ		Eletro-Cardiac Stability	10 10		110	100 10	
1 43		ells of the body. Ho our heart may be da		100	Roll	Poor Nor	nar (9000	t Excellent	
	6	by decreased ANS from exce -ssive stress.		Ectopic Béat	ς .				
Comment on	your test res	alt 🕨							
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since you may be in danger of having heart or adult diseases, or stress related diseases. 2)Stress index : You are in normal conditions. You need to keep healthy conditions by practicing appropriate stress relaxation program.

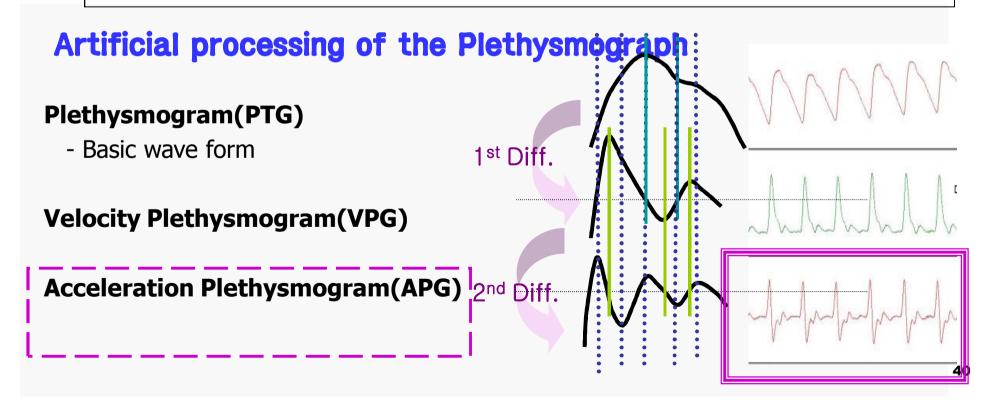
3)Fatigue index : Your fatigue level is very high. If this level continues, you may suffer physical or mental diseases. See your doctor.

Part 2. A P G

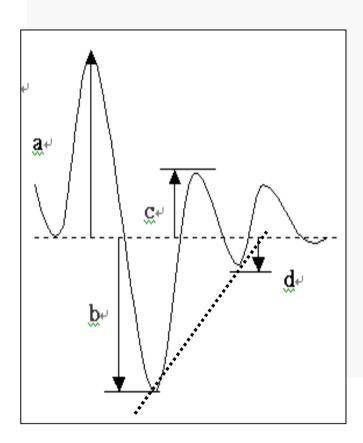
Accelerated PlethysmoGraph

Plethysmograph (PTG)

- Regional classification: carotid pulsation, radius arterial pulsation, femoral arterial pulsation
- Classification by detection method: Oscilation, Plethysmograph
- Artificial processing of Plethysmograph: PTG, VPG, APG



APG waveform



- **a** : Basic point to evaluate APG waveform
- b : Cardiac constriction power (Cardiac output)
 - The deeper (-) value is better shape

• c : Arterial Elasticity

- Higher (+) value is better

d : Remaining blood volume

- Higher value, smaller (-) value is better
- Differential Pulse Index(DPI):

b-c-d / a

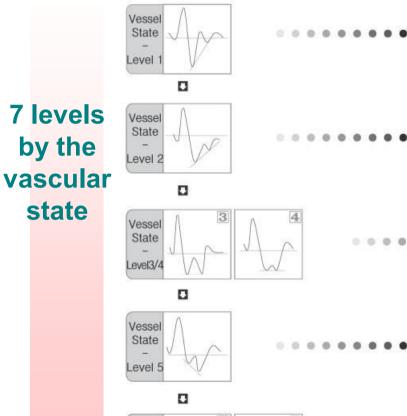
- * The gradient of b, d point
- : vascular state and its aging degree

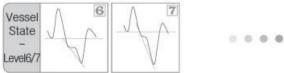
Accelerated Plethysmograph (APG)

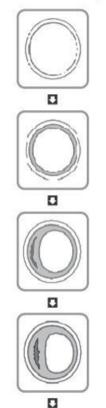
Classifying the wave type as aging

<Waveform Classification>

<Arteriosclerosis Progress>







Blood circulation and its vessel are good

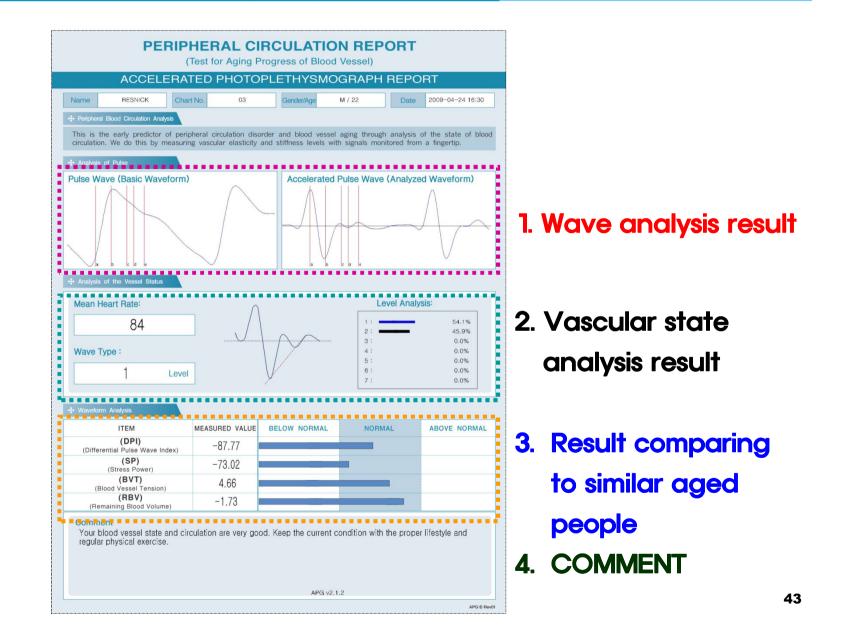
Current blood circulation and its vessel are good, but may go bad



Not good at the blood circulation and aged state in the vessel

Blood circulation disorder

APG REPORT



Parameters

- 1) DPI (Differential Pulse wave Index)
 - : Aging degree of the blood vessel

b-c-d / a

bigger (-) value means younger state in the vessel

- 2) EC (Eccentric Constriction Power) b/a
 - : Cardiac constriction power. Bigger (-) value means better state in the peripheral circulation
- 3) AE (Arterial Elasticity) -c/a

: The degree of arterial constriction and relaxation function. It reflect tension of the wall in the blood vessel. The bigger (+) value is better.

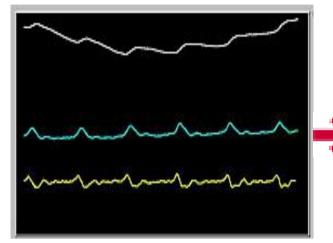
4) RBV (Remaining Blood Volume – d/a

: It reflect remained blood volume after arterial constriction. The higher value, smaller (-) value is better

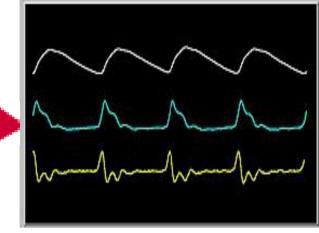
Clinical significance

- **Y** Peripheral blood circulation disorder
- ^v Early detection of arteriosclerosis and its processing
- Y The cardiovascular system dysfunction including myocardiac infarction
- **v** Judgment about Medicine treatment

Clinical cases (pre, post-treatment)

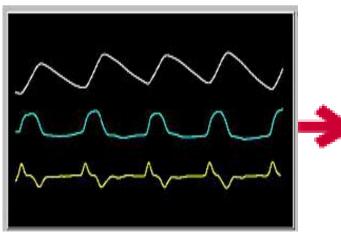


level 5

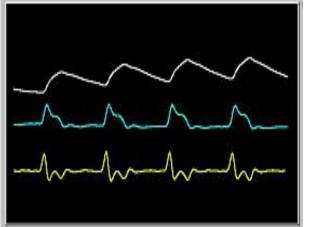


level 3

Pneumonia



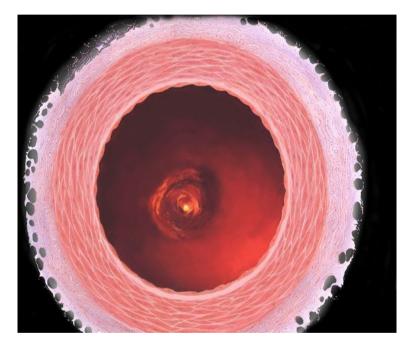
level 6



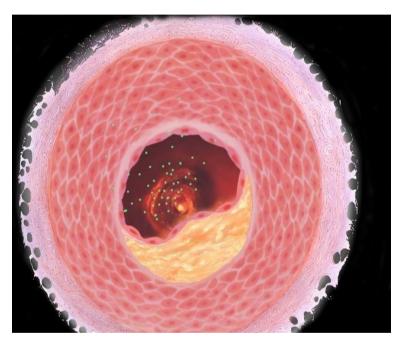
level 3



Correlation to the Artery



Normal artery



Abnormal artery with plagues

Cautions for measurement

- Do not move or talk during the measurement.
- Do not exercise and relax about 10 minutes in measuring room before taking measurement.
- Do not strain and then take regular breath. Refrain slow breath during taking measurement.
- Keep the height of the sensor same to the heart.
- The measurement should be taken with eye open.
- Consult with doctor in case of arrhythmia or cardiac disease.
- Measuring in the morning recommended
- Refrain from smoking, taking drug or coffee 3 hours prior to the measurement.
- Refrain drinking the day before taking measurement.
- Refrain from wearing accessories (ring, watch, manicure on a nail) that may interfere accurate measurement.
- Avoid measurement after meal.
- Keep quiet and comfortable conditions in the room.
 (room temp.22 °C ~26 °C)

Thank you