CS – 100

Frequency Cardiograph (FCG ^{R})

Analysis Systems

Diagnostic Manual

Version 3.1

General Information:

Device Name: CS-100 (Cardio Scan-100)

Software System: ECG Data Acquisition and Frequency Cardiograph (FCG^{R}) Analysis

Standard Compliance:

EMC: EC/FCC Class B, UL 60601-1, EN 60601-1.
ECG Data Acquisition: CE directive 93/42/EEC, IEC60601-1, IEC60601-1-1, IEC 60601-1-2, IEC60601-2-25, CE0197;
OEM Manufacture: EN ISO 9001 and/or EN ISO13485.

The Symbol  : Consult the accompanying documents and the Operator's Manual.

Exclusive Supplier: CS Marketing Group, LLC

Service: CS Marketing Group, LLC

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Introduction

CHAPTER

I

1.1 Artificial Variables

The Frequency Cardiograph (FCG [R]) analysis procedure is extremely sensitive to any artificial variables. While operating the CS-100, not only does the recording technique need to be consistent, the electrodes have to be correctly positioned.

From the clinical studies, it has been proven that when more than a 10% variable is artificially introduced into the ECG data acquisition, these variables can distort the frequency components. When this happens, the diagnostic indexes will lose their diagnostic worth and give some diagnostic suggestions with compromised accuracy and reliability.

1.2 System Schematic Diagram

The following schematic diagram outlines the operational flow of the FCG analysis system starting from ECG data acquisition, Fast Fourier Transformation, to diagnostic suggestion.

The device also provides a 12-lead ECG, time domain waveforms, for conventional analysis and diagnosis.

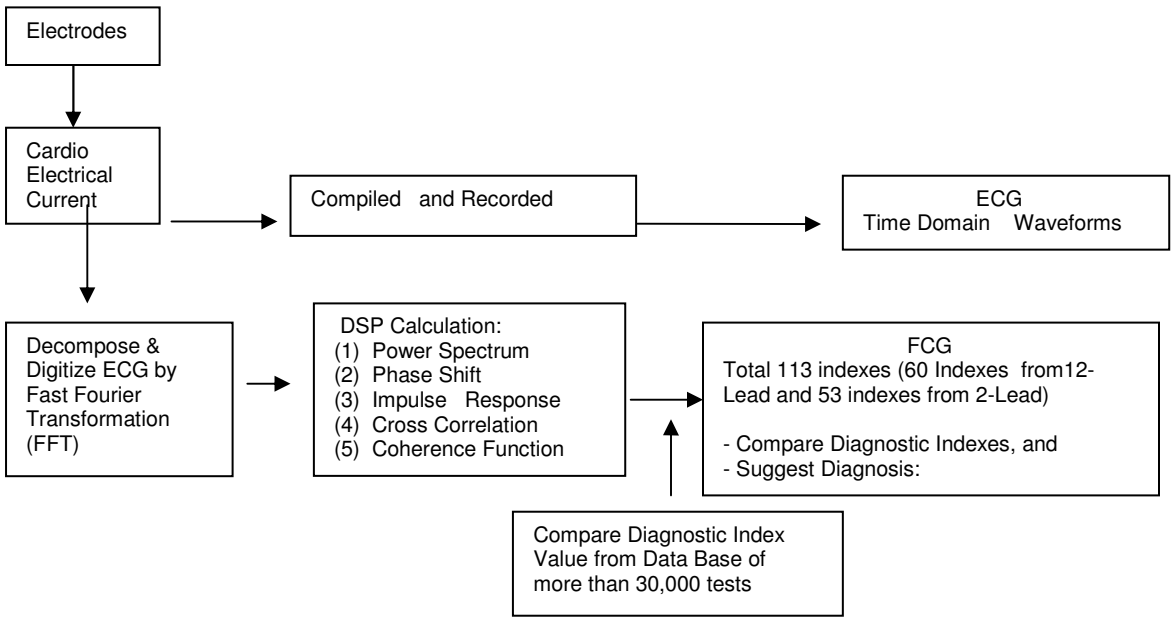


Figure 1.1 - Schematic Diagram of the System

DSP (Digital Signal Processing)

CHAPTER

II

2.1 Digital Signal Processing (DSP)

The five frequency functions measures and used by the Digital Signal Process are: Power Spectrum, Phase Shift, Impulse Response, Cross-Correlation and Coherence Function. The value for each of these functions is calculated based on the following mathematical equations.

After the Fast Fourier Transformation (FFT), the amplitude value S(w) for each of the frequency components from the lead-V5 and lead-V5 and lead-II is calculated.

2.2. Power Spectrum

By taking a square value of the amplitude, the energy value for each of the frequency components can be obtained:

$$G(w) = S(w) \times S(w)$$

With the frequency in Hz as x-axis and energy value in uV/Hz as y-axis, a power spectrum for each lead can be plotted from 0Hz to 25 Hz frequency range:

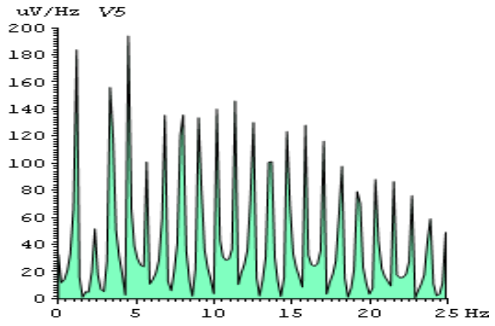


Figure 2.1 - Power Spectrum of lead-V5

2.3 Phase Shift

The phase shift is the measurement of angle shifted between an input current and an output

current. The degree of angle shift can be measured by the energy for both leads:

$G_{xx}(f) = S_x(f) \times S_x(f)$ – Energy at frequency point f of lead-V5

$G_{xy}(f) = S_x(f) \times S_y(f)$ – Cross-energy at frequency point f between lead-V5 and lead-II.

$H_{xy}(f) = G_{xy}(f) / G_{xx}(f)$ - Transfer Function in power ratio at frequency point f between the cross-energy of lead-V5 and lead-II, and the energy of lead-V5.

$\Theta_{xy}(f) = \tan^{-1}\{\text{Image } H_{xy}(f) / \text{Real } H_{xy}(f)\}$

Image $H_{xy}(f)$ is a H_{xy} from an imaginary new heart

Real $H_{xy}(f)$ is the true measured value.

Changes in the angle of phase shift of these two leads within $\pm$180 degree from 6Hz to 20Hz are studied.

2.4 Impulse Response

$IH_{xy}(f) = F^{-1}[H_{xy}(f)]$ - an inverse Fourier Transformation of transfer function.

A mathematical function is used to analyze the time response of two signals. In the ECG frequency analysis, a time response of signals from lead-V5 and lead-II are used.

2.5 Cross-Correlation

A cross-correlation is used to measure the mutual relation between lead-V5 at the time t and lead-II at the time of t+r, where r is the time delay. It is to measure the degree of mutual dependence or match of the electrical activities from two different parts of the heart A study found that the degree of correlation for time lag of two points is related to the transfer and damping characteristics of myocardium activities:

$R_{xy} = F^{-1}[G_{xy}(w)]$

2.6 Coherence Function

It represents the degree of coherence between the electrical activities of lead-V5 and lead-II in their amplitude, frequency and phase angle.

$V^2_{xy}(w) = [G_{xy}(w)]^2 / G_{xx}(w) \times G_{yy}(w)$

When $V^2_{xy}(w) = 1$, there is a complete coherence between the two leads. When $V^2_{xy}(w) = 0$, there is no coherence between the two leads.

ECG Data Acquisition

CHAPTER III

3.1 90 ECG Signal Data Required

Because of the sensitivity of the frequency analysis, the device requires a minimum of 90 separate but continuous ECG signal data to being taken for signal averaging to minimize any interference. For a patient with heart rate of 72 beats per minute, the ECG data acquisition time should be at least 75 seconds. This number should be adjusted upward or downward depending upon the heart rate of the patient.

3.2 A Stable ECG Waveform

No ECG data should be used for analysis if there is any interference during the data acquisition period.

The device operator is required to visually observe the moving ECG waveforms displayed on the screen during the entire acquisition period. Disregard and do not use any of the ECG data when any of the ECG waveforms are seen being distorted and drifting off from the base line.

Diagnostic Index

CHAPTER IV

4.1 Index Identification and Selection

4.1 Index Identification and Selection

The ECG Frequency Analysis has identified and selected a total of 113 indexes for diagnostic purposes as follows:

(a) 2-Lead Power Spectrum - 5 indexes for each lead with a total of 60 indexes;

(b) 2-Lead (V5 and II) frequency analysis – total 53 indexes

- 30 indexes (15 for each lead) for power spectrum;
- 3 indexes for phase shift;
- 6 indexes in impulse response;
- 11 indexes for cross-correlation; and
- 3 indexes for coherence function.

By means of differential diagnosis over 20,000 tested subjects, the measuring threshold and diagnostic value for each of these indexes has been pre-identified and pre-selected, and stored in the data base.

12-Lead Power Spectrum

CHAPTER

V

5.1 Introduction

There are two sets of power spectrum used in the ECG frequency analysis. One set is the12-Lead power spectrum, and the second set is the 2-Lead power spectrum. The usable range of frequency is from 0.70Hz to 25 Hz. Any reading below 0.75Hz frequency is considered to come from an artifact and should be disregarded.

5.2 12-Lead Power Spectrum

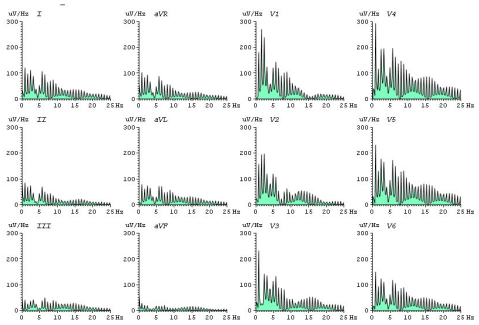


Figure 4.1 – 12-Lead Power Spectra with one for each lead.

There are 12 separate power spectra with one spectrum for each lead as shown in Fig.4.1. This is a visual display for visual comparison and diagnosis.

5.3. Peak Selection of the Power Spectrum

In a power spectrum, the first peak usually appears at 1.2 Hz frequency and is the fundamental peak (heart rate of 72 beats per minute or 1.2 beats per second). Any peak of less than 0.75 Hz in frequency is a noise peak created generally from the respiration noise of a patient and should be ignored.

The frequency position of this peak should be directly related to the number of heart beats per minute which therefore provides a means to determine the heart beat of the patient. The frequency of the first peak will vary for a patient with a variable heart beats. The power spectrum for the frequency analysis is the one from the averaged ECG data:

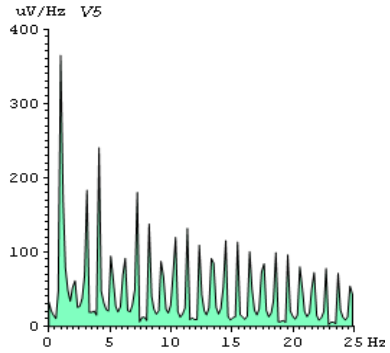


Figure 5.3 - A power spectrum of a normal patient

5.4 Diagnostic Index

Five alphabetical indexes have been selected and each has its own separate independent measuring threshold. For diagnostic purposes, each "+" describes a certain type of myocardial condition as follows:

H - 2^{nd} / 1^{st} > normal ratio.
- Insufficient myocardial power due to insufficient blood supply;
- Early warning of development of myocardial ischemia.

N - Low or no 1^{st} peak and low or no 3^{rd} or 4^{th} peak
- myocardium injuries (recent or old).

B - the average of the first 4 peaks is too high.
- Cardiomyopathy (Ischemic) or Ventricular Hypertrophy.

A - no or low 3^{rd} and/or 4^{th} peak
- Chronic myocardial damages,

E - Any one peak from the 5^{th} to 10^{th} peak / 1^{st} peak > normal ratio.
- myocardial compensation has already set in for one or more years
- ischemic damages to myocardium.

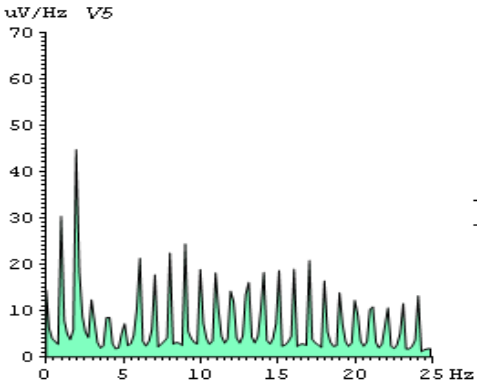


Figure 5.4 – A power spectrum of disease patient

5.5 Five Indexes for Each Lead

With five (5) indexes for each lead, the 12 leads give a total of 60 indexes.

By studying all 60 indexes, one can take a look of the overall myocardial condition of a human heart. This device compares the (+) reading and distribution of these 60 indexes against those (+) reading indexes pattern stored in the data based to detect any presence of ischemia. In addition, some of these (+) reading indexes can be used to derive the diagnostic suggestions for other heart dysfunctions for clinical investigation and studies.

Two Leads (V5 & II) FCG Analysis

CHAPTER VI

6.1 Introduction

To further study the pathological condition of a patient's heart, two leads (V5 and II) are used. The reason of using these two leads is because the electrical signals detected by these two leads travel (1) at the same direction with a phase angle of 90 degree which makes the calculation much less complicated, and (2) they both travel through the left ventricular wall which is the most important area of the heart.

Applying the method of input/output function analysis of the digital signal processing, the 2-lead FCG selects the data from lead-V5 and use it as the input signal and selects the data from lead-II and use it as the output signal, and mathematically calculates their power spectrum estimate in four additional functions and use indexes from all five functions to diagnose and evaluate the pathological state of a patient's heart:

(1) Power spectrum;
(2) Transfer function in phase angle shift;
(3) Impulse response;
(4) Cross-Correlation; and
(5) Coherence.

6.2 Power Spectrum

Additional indexes have been identified and selected from the 2-lead power spectrum to support the diagnostic suggestion.

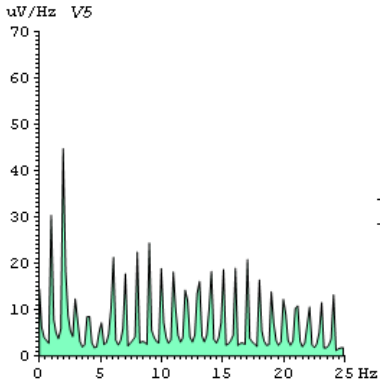


Figure 6.1 - A Lead-V5 power spectrum

½ 2nd peak too high - Insufficient myocardial power

HG One or more peaks of first 4 peaks too high - some form of hypertrophy.

HG1 1st peak too high, high ventricular power

HG2 1st and 2nd peaks too high, high ventricular power.

HG3 2nd peak too high, resulted from chronic heart disease.

HG4 3rd and 4th peaks too high, poor cardio elasticity

HG5 5th peak too high, insufficient blood supply over 1 year.

HG6 6th to 10th peaks too high,

1-N low or no 1st peak, recent injury to myocardium

¾-N low or no 3rd and/or 4th peak, chronic injury to myocardium

TU Multiple & irregular peak distance, possible arrhythmia.

TU1 Multiple peaks - arrhythmia

TU2 Irregular peak distance - arrhythmia

TU3 Peak valley not back to the base line arrhythmia

P Low average peaks for 1st to 3rd peaks

6.3 Transfer Function in Phase Angle Shift

For a patient with a normal heart, the phase shift curve travel smoothly within the $\pm$ one unit zone.

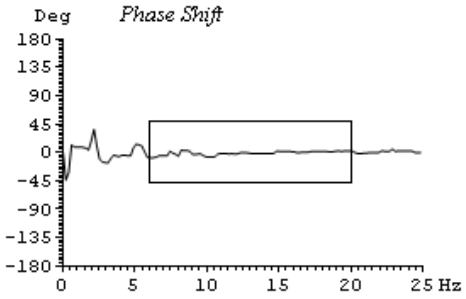


Figure 6.1 - Phase angle shift of a healthy heart

In a patient with a damaged heart, the phase angle shift curve travels across over or below the ± one unit zone which signals a time lead or time delay between these two cardio electrical signals. It has been found through clinical study that this discrepancy is caused by an unstable cardio electric current, poor conduction, poor blood flow and/or poor auto-compensation of a human heart.

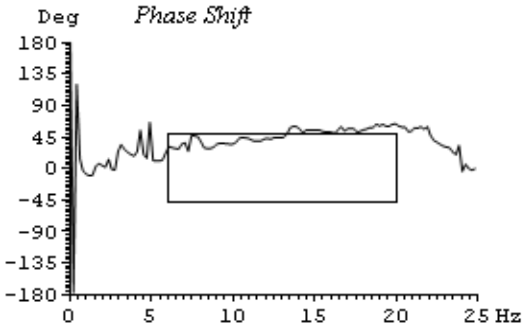


Figure 6.2 – Abnormal Phase Shift Curve

Some time the phase shift curve shows greater deviations and fluctuations (axis deviation). This usually indicates poor or defective conduction function (changes in the sequence of ventricular activation), poor blood circulation in the blood vessels and change of blood dynamics. For severe deviation, it indicates a left bundle branch conduction block.

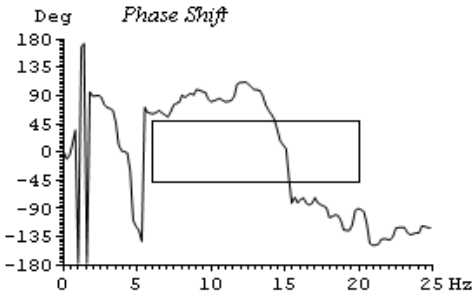


Figure 6.3 - Abnormal Phase Shift

Sharp oscillation of a phase angle shift curve indicates time delay caused by CAD of coronary artery blockage, poor blood circulation, or myocardial infarction.

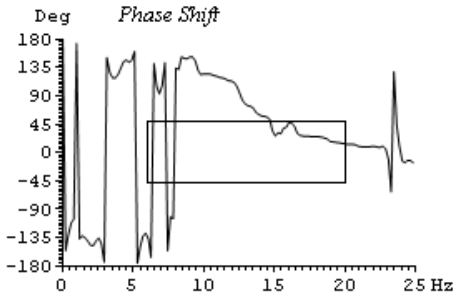


Figure 6.4 – Abnormal Phase Shift

The degree in the Phase Angle Shift (line deviation) is also directly related to the flexibility of the myocardial cells. A sharp oscillation indicates thickening of the heart muscle (ventricular regions being incapable of being activated), infarct tissue or myocardial injuries (scarring) due to ischemia, old age or some other reasons.

6.4 Transfer Function In Amplitude

Transfer function in phase shift measures the shift in angle between the two ECG electrical currents (lead-V5 and lead-II). The transfer function in amplitude measures the amplitude ratio between lead-V5 and lead-II. It is used to detect any instability of the cardio functions due to early change in myocardium that has been caused by insufficient blood supply or aged decay. The following two figures show the different in Transfer Function in Amplitude for a normal heart and abnormal heart:

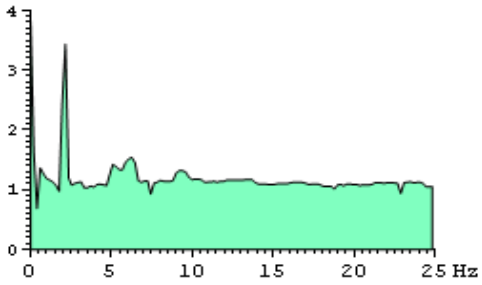


Figure 6.5 – Normal Transfer Function

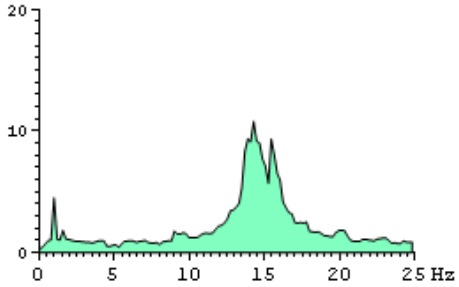


Figure 6.6 – Abnormal Transfer Function

6.5 Impulse Response

Another measurement of a heart condition is the application of the frequency response estimation.

For a human heart, we use this measuring method and mathematically use cardio electrical signals of Lead-V5 and Lead -II to check the myocardial regulatory function and quality. The study found that by analyzing the cardio electric signals of these two different leads, it can examine the stability of the electrical activities from two different locations of the heart to diagnose its quality.

The impulse response of a human heart is dependent of the physical parameters of the cardiac muscle, the damping characteristic between the cardiac muscle, and blood flow and viscosity. For a healthy heart, the impulse response should show a narrow sharp tall peak located at the zero point above the base line without any sub-response on either side of the main peak.

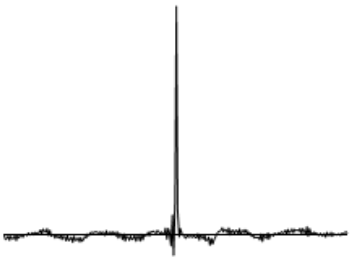


Fig. 6.7 - Normal Impulse Response

For a damaged heart, a number of differences in the impulse response were noticed such as the change of the main peak into multiple shorter peaks, the inversion of the main peak, and the appearance of the sub-response relative to the main peak. Throughout the study of differential diagnosis, all of those variances were identified to be associated with changes in the physical condition of the heart or a portion thereof. Based on that study, six (6) alphabetical indexes have been identified and selected for diagnostic purpose: PV, M1, M2, M3, RS and CS.

PV - This index will have a (+) reading when the main peak is significantly inverted as shown in Fig. 6.8. This phenomena indicates a decreased compliance or conduction block or disturbance of reaction function of the heart, usually caused by CAD, MI, ischemia or conduction blockage.

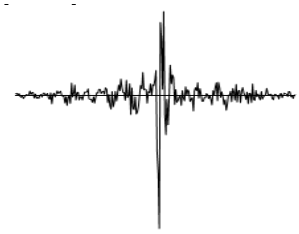


Figure 6.8 – Impulse Response showing a inverted main peak

M1, M2, M3 - These indexes will have (+) finding where the impulse response exhibits double or multi inverted main peak. It indicates a poor conduction, increased in compliance or left ventricular malfunction.

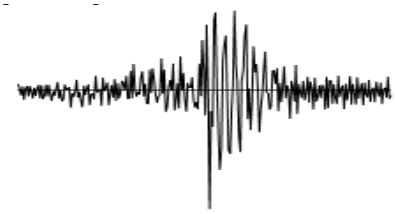


Figure 6.9 – Impulse Response showing multiple peaks

There are two other indexes, RS and CS, that have been found to be useful:

RS - Regular Sub-Response (RSR) peaks are pairs identical peaks appearing on each side of the main peak of the impulse response and the distance from the RSR peak to the main peak equals to the integral of the response peaks distance. RS index will give a (+) reading when there are RSR peaks.

Figure 6.10 – Impulse response with RSR peaks

The appearance of RSR peak usually indicates the unstable cardio electricity prior to the formation of MI that have been caused by the narrow arteries or existence of plaque deposits in the arteries. There is an obvious increase in localized ischemia or in the area that has sustained permanent muscle damages (myocardial infarction).

When there is an increase in RSR peak height, the possibility of a re-occurrence of MI also increases. This index has been proven to provide a preventive diagnostic value in the early detection of MI.

CS - Causal Sub-Response (CRR) peaks are pairs of identical peaks appearing on each side of the main peak of the impulse response, but the distance between the CSR peak and main peak does not equal to the integral of the response peak distance. CS index gives a (+) reading when there are Causal Sub-Response(CSR) peaks.

Figure 6.11 - Impulse response with CSR peaks

The appearance of CSR peaks is found to be related to the unstable cardio electrical activities at the beginning of contraction. Currently, an ECG can only detect any apparent pre-contraction cardio electrical activities. A CS index can therefore be used to detect any abnormal latent activity such as latent arrhythmia of a human heart.

6.6 Cross-Correlation

The degree of cross-correlation for the time lag of lead-V5 and lead-II is related to the transfer and dampening characteristics of the physical activity of the cardiac muscle. Though the clinical study, 11 following alphabetic indexes have been identified and selected for diagnostic purpose.

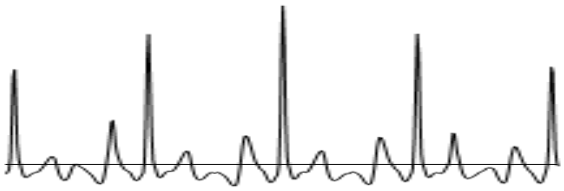


Figure 6.12 - Normal Cross-Correlation

RV Inversed main center peak, insufficient blood to myocardium.

RH center main peak too high, hypertrophy due to high blood pressure, myocardiopathy.

RL center main peak too low, insufficient blood supply

LR1 Low 1st peak with high 2nd peak, severe arrhythmia.

LR2 High 1st peak with low 2nd peak, arrhythmia

RDH main peak deviated to the right, asynchrony

RDL main peak deviated to the left, asynchrony

FP no peak between 1st and 2nd peak,

HBR Peak between 1st and 2nd is higher than second peak

NW+ Right side of R1 lower than that of left side, differential index of valvular diseases, or myocarditis

NW- Left side of R1 lower than that of right side, same as NW+ for differential diagnosis.

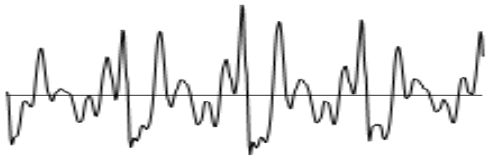


Figure 6.13 - Abnormal Cross-Correlation

6.7 Coherence Function

The coherence function between lead-V5 and lead-II is measured from 1 for being totally coherent to 0 for being no coherent at all between the two leads.

Through clinical studies, it has been observed that there is a marked difference for the coherence

function between how the ECG electrical currents will act between a normal heart and an abnormal heart. Three alphabetical indexes have been identified and selected:

CP 1st peak too low

CT coherence value at 4Hz is too low

CbL poor coordination from different parts of heart. CbL.

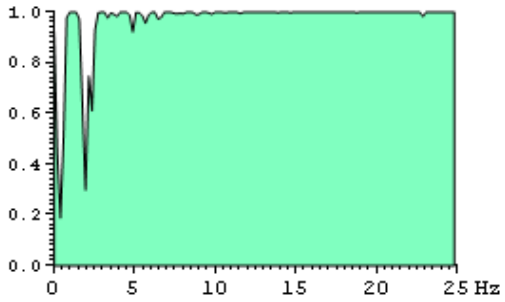


Figure 6.14 - Normal Coherence Function

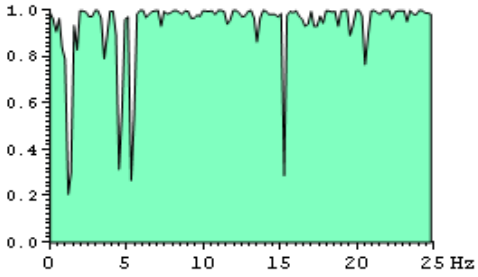


Figure 6.15 - Abnormal Coherence Function

Although the anatomical area pointed out by the Lead-V5 and Lead-II is limited to left ventricular area of the heart, it is clinically the most important area. These indexes provide the insight of the physical condition of the heart and can be used to characterize the myocardial functionality such as the contractility, fluidity of blood (viscosity or flow dynamics), poor conduction, early stage of coronary insufficiency, or myocardial infarct

Ischemic Condition

CHAPTER

VII

It has been well established that ischemia developed in the early stages can be reversed by changes in dietary habits and regular exercise. The ability to detect whether or not a patient has developed an early ischemic condition can be a very useful diagnosis for the doctors to prescribe the proper measures to reverse the ischemia or to prevent the worsening of the ischemic condition to develop into coronary heart disease. It has been well established that ischemia developed in the early stages can be reversed by changes in dietary habits and regular exercise. The ability to detect whether or not a patient has developed an early ischemic condition can be a very useful diagnosis for the doctors to prescribe the proper measures to reverse the ischemia or to prevent the worsening of the ischemic condition to develop into coronary heart disease.

7.1 Ischemia

Two indexes from the 12-lead power spectrum have been found to have diagnostic value for ischemia detection:

H - This index has been found to indicate that the patient's heart has insufficient myocardial power due to insufficient blood supply to the myocardium. It is a warning of the development of early myocardial ischemia.

E - Positive finding of this index indicates that patient's myocardial compensation has already set in for one or more years and ischemic damages to myocardium has occurred.

7.2 Level of Ischemia

By studying the distribution of these two diagnostic indexes, the system can determine: (1) whether this patient has developed ischemia, and (2) what level of ischemia.

The system categorizes and reports the ischemic condition of a patient into three levels:

(1) Low level CAD,
(a) CAD, or
(b) Advanced CAD.

Upon detecting "CAD" or "Advanced CAD", the device will determine the location of the coronary artery disease (CAD).

Coronary Artery Disease

CHAPTER VIII

Each of the 12 ECG leads measures the cardio electrical activity at a certain area of the heart. From the positive E(+) index reading and the corresponding leads, the ECG Frequency Analysis system is able to locate the anatomical area at where some form of coronary artery disease has developed.

8.1 Where Each Lead is Looking At

It has been well established that each lead of the 12-lead looks at a certain area of a human heart.

The following figure shows a drawing of a frontal and horizontal picture of a human heart with each of the 12-leads pointing at a certain area of the heart:

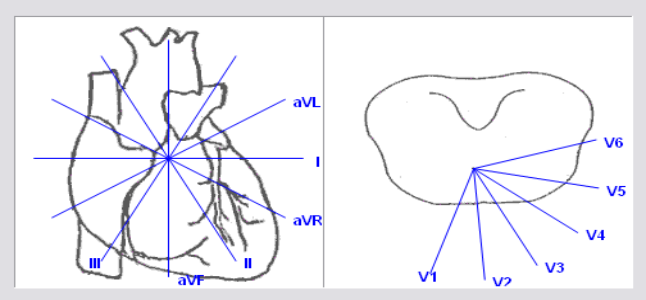


Fig. 8.1 Frontal view (Limb Lead) Horizontal view (Chest Lead)

(a) Limb Leads – I, aVR, II, aVF, III, aVL

I - Lateral wall of left ventricle (same direction as aVL)
aVR - Right atrium and upper portion of the right ventricle, from its perspective on the right shoulder
II - Interior wall of left ventricle
aVF - Inferior wall of the ventricle
III - Inferior wall of left ventricle
aVL - Left atrium and upper side portion (lateral) of the left ventricle

(b) Chest Leads – V1, V2, V3, V4, V5, V6

V1 - Right ventricle and septum
V2 - Right ventricle and septum
V3 - Anterior wall of the left ventricle
V4 - Anterior wall of the left ventricle
V5 - Anterior and lateral wall of the left ventricle
V6 - Lateral wall of the left ventricle

8.2 Diagnosis of CAD Location

DISCLAIMER: THE METHOD TO LOCATE THE ISCHEMIC AREA HAS NOT BEEN FDA CLEARED. IT IS INCORPORATED IN THE DEVICE FOR THE CLINICAL INVESTIGATION AND STUDIES ONLY.

The device provides a single CAD location diagnosis page. This page consists of three parts:

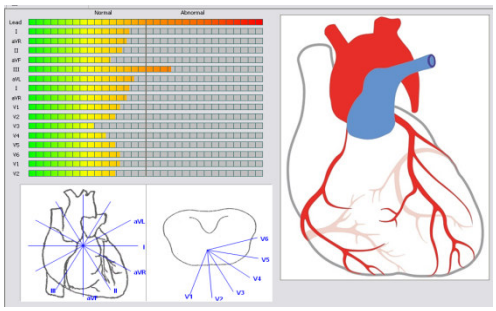


Figure 8.2 - CAD location diagnosis page

Other than Fig. 8.1 above, it has a multi-color table of ischemic condition listing 12 leads and a normal-abnormal cut-off line:

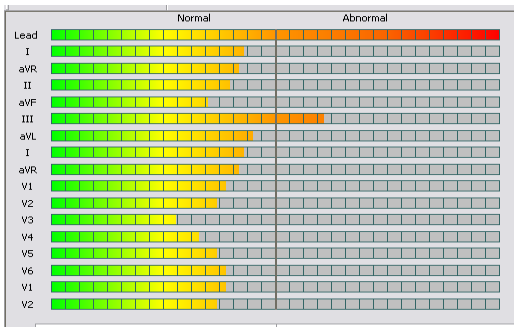


Fig. 8.2(a) – Multi-color Ischemic Condition Table

The first row of this table, Fig. 8.2(a)-1, is the heading listing the “Lead”, “Normal” and “Abnormal”, a “Normal-Abnormal” cut-off line in the middle and the color progression from “Green” to “Orange” and “Red”

Fig. 8.2(a)-1 - Table heading

After the first row, there are 16 additional rows: first 8 rows for the limb leads, Fig. 8.2(a)-2, followed by another 8 rows for the chest leads, Fig. 8.2(a)-3:

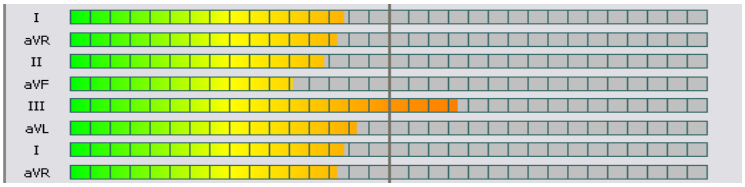


Fig. 8.2(a)-2 – 8 rows for the limb leads

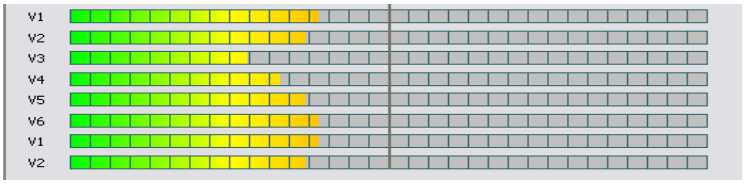


Fig. 8.2(a)-3 - 8 rows for the chest leads

As the bar progressing from normal to abnormal and the color changing from green to orange and red, it indicates the ischemic condition changes from normal to borderline and to abnormal. The degree of severity of ischemia corresponds to how far the bar travels into the abnormal zone.

The third picture, Fig. 8.2(b), below is an artistic two color (Red and Blue) drawing of human heart showing the coronary arteries.

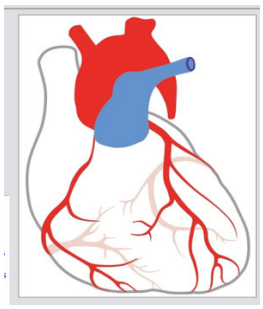


Fig. 8.2(b) – Artistic drawing of a human heart

8.3 Example

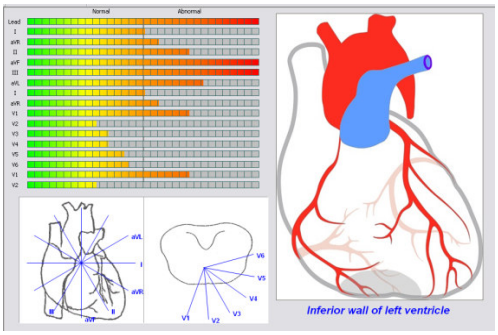


Figure 8.3 – CAD located at Interior wall of the left ventricle

CAD Diagnostic page of a patient indicates that

(1) Multi-color ischemic condition table shows that
   (a) Different degrees of ischemic condition have developed at the areas where the leads aVR, II, aVF, III, aVL and V1 point at;
   (b) The ischemic condition at the areas where leads aVF and III point is more advance or serious.

(2) The two color drawing of a human heart shows that CAD may have developed in the interior wall of the left ventricle.

Diagnosis from Index Reading

CHAPTER IX

DISCLAIMER: METHOD TO DIAGNOSE OTHER FORMS OF HEART DYSFUNCTION HAS NOT BEEN FDA CLEARED. IT IS INCORPORATED IN THE DEVICE FOR CLINICAL STUDIES AND INVESTIGATIONS ONLY.

9.1 Probability of Matching

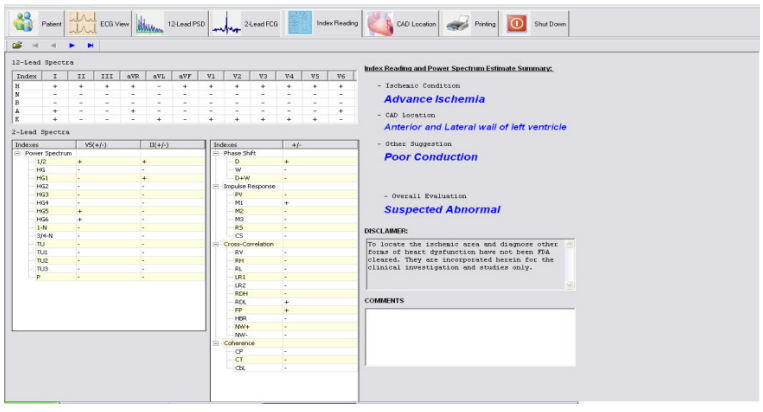
Measurement standards over a hundred indexes from the digital signal processing of the ECG data were first identified. After clinical study over 20,000 tested patients, a group of indexes of diagnostic value (Diagnostic Indexes) were deemed useful and selected. Following the principle of probability of matching that the higher is the probability, the closer of the similarity is between the tested subject and the clinical case.

There are 113 indexes and their measuring standards that have been stored in the database. Based on the probability of matching, CS-100 is able to make an overall evaluation the pathological condition of the patient's heart.

It is very important to remember that CS-100 merely suggests a possible pathological change in a patient's heart. It does not nor has ever been intended to provide a final diagnosis of any heart disease.

9.2 Index Reading Page

CS-100 provides a single page for "Diagnostic Indexes and Suggestion":

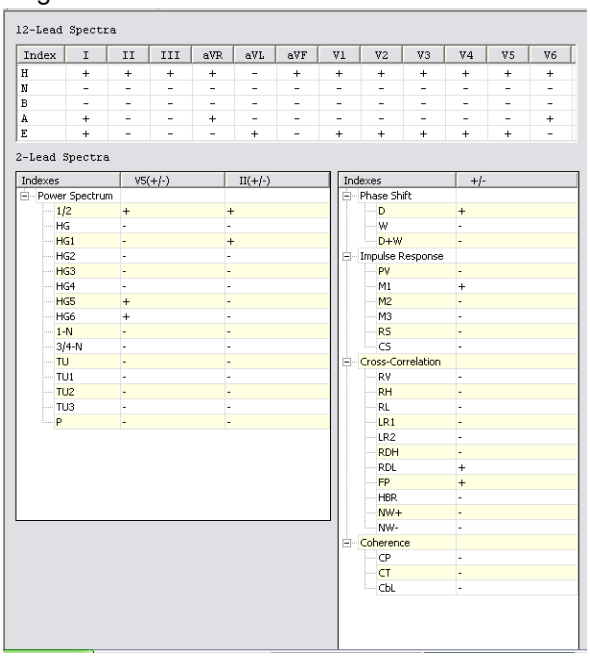


[-- Index Reading --] [-- Diagnostic Suggestion --]

Fig. 9.1 – Index Reading Page

9.3 Index Reading and Diagnostic Suggestion

(a) Index Reading – It consists two index tables: one for the 12-lead and the other is for the 2-lead.



12-Lead Spectra

Index	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
H	+	+	+	+	-	+	+	+	+	+	+	+
N	-	-	-	-	-	-	-	-	-	-	-	-
B	-	-	-	-	-	-	-	-	-	-	-	-
A	+	-	-	+	-	-	-	-	-	-	-	+
E	+	-	-	-	+	-	+	+	+	+	+	-

2-Lead Spectra

Indexes	V5(+/-)	II(+/-)
Power Spectrum		
1/2	+	+
HG	-	-
HG1	-	+
HG2	-	-
HG3	-	-
HG4	-	-
HG5	+	-
HG6	+	-
1-N	-	-
3/4-N	-	-
TU	-	-
TU1	-	-
TU2	-	-
TU3	-	-
P	-	-

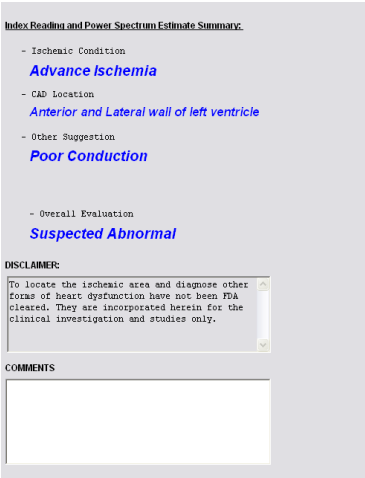
Indexes	+/-
Phase Shift	
D	+
W	-
D+W	-
Impulse Response	
PV	-
M1	+
M2	-
M3	-
RS	-
CS	-
Cross-Correlation	
RV	-
RH	-
RL	-
LR1	-
LR2	-
RDH	-
RDL	+
FP	+
HBR	-
NW+	-
NW-	-
Coherence	
CP	-
CT	-
CbL	-

Fig. 9.2(a)-1: List of index and "+" or "-" reading

After acquiring a stable ECG signal, the device will analysis the signal to identify and measure the value for each index, and compare the measured value against the measuring standard value in the data base to give that index a "+" or "-" reading. A "+" reading represents a positive finding of an abnormal condition, and a "-" reading represents a negative finding that no abnormal condition is detected.

From all the "+" index reading, the device selects a group of (+) index combinations to give various diagnostic suggestions for myocardial ischemia and/or other myocardial dysfunctions. No single index by itself alone can be used for diagnostic purpose.

(b) Diagnostic Suggestion –



Based on the index reading, the device will provide diagnostic suggestion in three categories

1) Index Reading and Power Spectrum Estimate Summary for

(a) Ischemic Condition – Low Level CAD, CAD, Advanced CAD;
(b) CAD Location;
(c) Other Suggestion of dysfunctions (see 9.3 below); and
(d) Overall Evaluation – see chapter 10.

2) Disclaimer. **METHOD TO DIAGNOSE OTHER FORMS OF HEART DYSFUNCTION HAS NOT BEEN FDA CLEARED. IT IS INCORPORATED IN THE DEVICE FOR CLINICAL STUDIES AND INVESTIGATIONS ONLY.** This disclaimer is to all the users of CS-100.

3) Comments: This space is reserved for the doctors to type in their diagnosis after evaluating the **PATIENT'S MEDICAL HISTORY IN COMBINATION WITH THE RESULTS OF OTHER TESTING METHODS, AND PHYSICIANS' CLINICAL JUDGEMENT.**

9.3 Heart Dysfunctions

ECG Frequency Analysis System provides diagnostic suggestions for the following heart related diseases. Cautions: any of These suggestions is not to be used as a final diagnosis but rather for the clinical investigation and studies only.

(1) Ventricular Hypertrophy or Hypertensive Cardiac Disease
(2) Coronary Heart Disease
    - Early Ischemia
    - Advanced Ischemia
(3) Valvular Diseases
    - Rheumatic Heart Disease - Valvular Dysfunction (Chronic)
    - Mitral Valvular Disease
(4) Pulmonary Heart Disease
(5) Chronic Heart Disease
(6) Fibrillation
    - Atrial Fibrillation
    - Ventribular Fibrillation
(7) Myocarditis
(8) Myocardiopathy
(9) Arrhythmia
(10) Bradycardia
(11) Tachycardia

Overall Evaluation

CHAPTER

X

10.1 Pathological Score Table

The device has an internal scoring system to evaluate the overall pathological condition of patient's heart. This scoring system has been developed based on the study of (+) indexes from both 12-lead and 2-lead systems over 20,000 plus patients. Judging the existence of heart diseases and matching the pattern of positive indexes, a pathological score table is established.

10.2 Four Groups of Patient

From that pathological score table, the device is able to evaluate the overall condition and categorize patients into four (4) groups:

(1) Normal - patient has no or minimum pathological change or dysfunction of the heart.

(2) Borderline - patient has some but not definite pathological change of the heart.

(3) Suspected Abnormal – patient has no disturbance of heart function which results in change in cardiac functions and possible presence of cardio diseases.

(4) Abnormal – definite pathological change in patient's heart and presence of heart dysfunction.

List of Indexes

CHAPTER XI

11.1 **12-Lead Power Spectrum** - look for positive (+) index

H $2^{nd}/1^{st}$ peak ratio too large - Insufficient myocardial power caused by lack of blood supply (Early Ischemia)

N no or low 1st peak - Myocardium injuries (Recent)

B average of first 4 peaks too high - Ventricular hypertrophy or Ischemic cardiomyopathy

A no or low 3^{rd} and/or 4^{th} peak - Chronic myocardial injuries

E high 5^{th} peak - Myocardial compensation has set in for one or more years

11.2 **2-Lead Frequency Analysis** – look for positive (+) index

(1) Power Spectrum

½ 2^{nd} peak too high - Insufficient myocardial power

HG One or more peaks of first 4 peaks too high - some form of hypertrophy.

HG1 1^{st} peak too high, high ventricular power

HG2 1^{st} and 2^{nd} peaks too high, high ventricular power.

HG3 2^{nd} peak too high, resulted from chronic heart disease.

HG4 3^{rd} and 4^{th} peaks too high, poor cardio elasticity

HG5 5^{th} peak too high, insufficient blood supply over 1 year.

HG6 6^{th} to 10^{th} peaks too high,

1-N low or no 1^{st} peak, recent injury to myocardium

¾-N low or no 3^{rd} and/or 4^{th} peak, chronic myocardium injury

TU Multiple & irregular peak distance, possible arrhythmia.

TU1 Multiple peaks - arrhythmia

TU2 Irregular peak distance - arrhythmia

TU3 Peak valley not back to the base line arrhythmia

P Low average peaks for 1st to 3rd peaks

(2) Phase Shift (3 indexes)

D curve travels out of bound, poor conduction

W severe deviation with some oscillation, abnormal conduction, poor blood circulation.

D+W severe deviation with sharp oscillation. Left bundle branch conduction block., poor blood circulation.

(3) Impulse Response (6 indexes)

PV Inversed main peak, poor blood supply to myocardium

M1 double high peaks, poor conduction

M2 Multiple peaks, poor conduction

M3 three or more main peaks, poor conduction

RS regular interval response. unstable cardiac electricity.

CS Casual response peaks, latent arrhythmia

(4) Cross-Correlation (11 indexes)

RV Inversed main center peak

RH center main peak too high, hypertrophy

RL center main peak too low, insufficient blood supply

LR1 Low 1st peak with high 2nd peak

LR2 High 1st peak with low 2nd peak

RDH main peak deviated to the right

RDL main peak deviated to the left

FP no peak between 1st and 2nd peak.

HBR Peak between 1st and 2nd is higher than second peak

NW+ Right side of R1 < that of left side

NW- Left side of R1 < that of right side

(5) Coherence (3 indexes)

CP 1st peak too low

CT value at 4Hz is too low, poor coherence

CbL low value after 6Hz, poor coordination.