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(54) **CARDIOVASCULAR HEALTHCARE  
MANAGEMENT SYSTEM AND METHOD**

**Publication Classification**

(51) **Int. Cl.<sup>7</sup> ..... A61B 5/00**

(52) **U.S. Cl. .... 600/300; 128/920**

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Carlos, CA (US)

(57) **ABSTRACT**

Correspondence Address:  
**MCDONNELL BOEHNEN HULBERT &  
BERGHOFF**  
**300 SOUTH WACKER DRIVE**  
**SUITE 3200**  
**CHICAGO, IL 60606 (US)**

The invention relates to a cardiovascular healthcare management system which as an infomediary site with databases having information relating to cardiovascular disease risk factors such as age, blood pressure, LDL, HDL and sub-fractions thereof and cardiovascular disease management such as diet, exercise, drugs and cardiovascular educational materials. The physician can communicate electronically with the infomediary site to obtain patient test results and formulate a patient treatment plan from the diet, exercise and drug data. The physician can electronically communicate treatment plans to the patient through a record in the infomediary site. The patient can electronically communicate compliance information to the physician through the patient record. The infomediary site may also provide a case manager to provide initial draft treatment plans to the physician, gather patient history data and/or patient treatment plan compliance data.

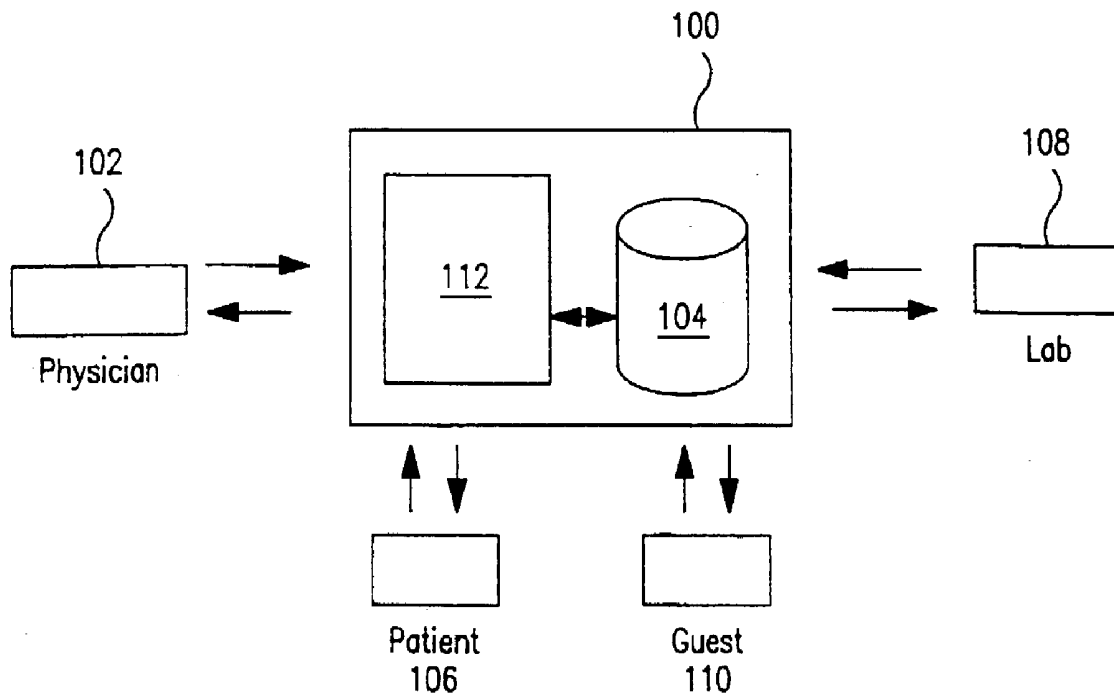
(21) Appl. No.: **10/169,648**

(22) PCT Filed: **Dec. 1, 2000**

(86) PCT No.: **PCT/US00/32833**

**Related U.S. Application Data**

(60) Provisional application No. 60/168,354, filed on Dec. 1, 1999.



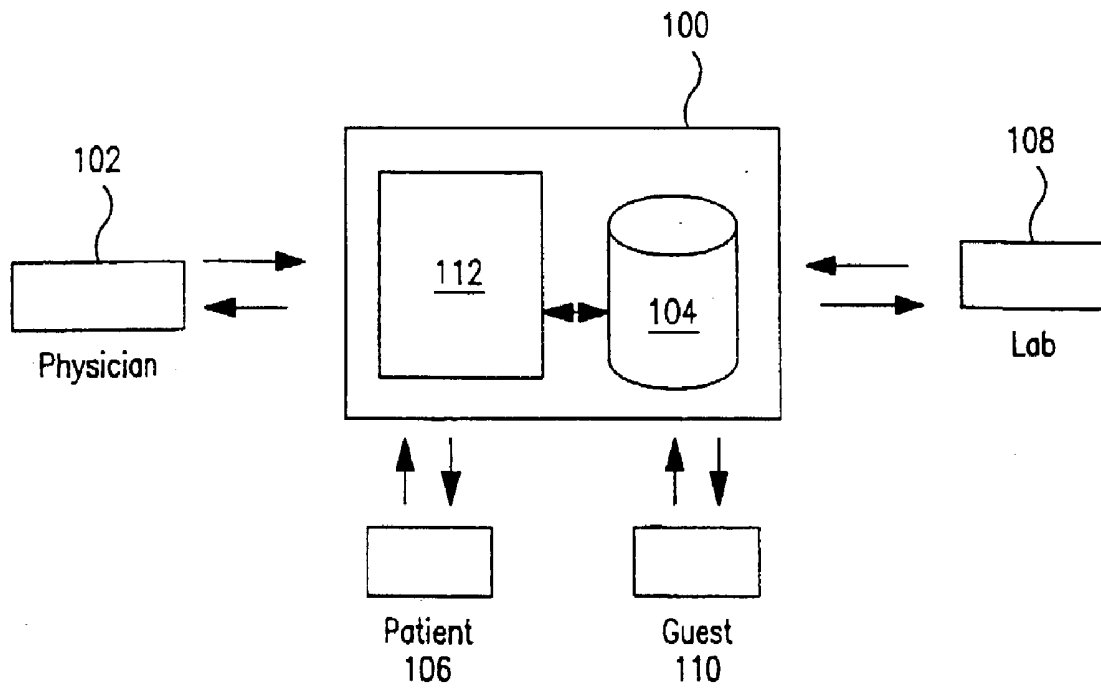


FIG. 1

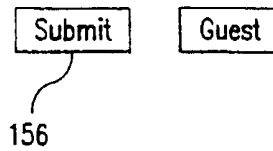
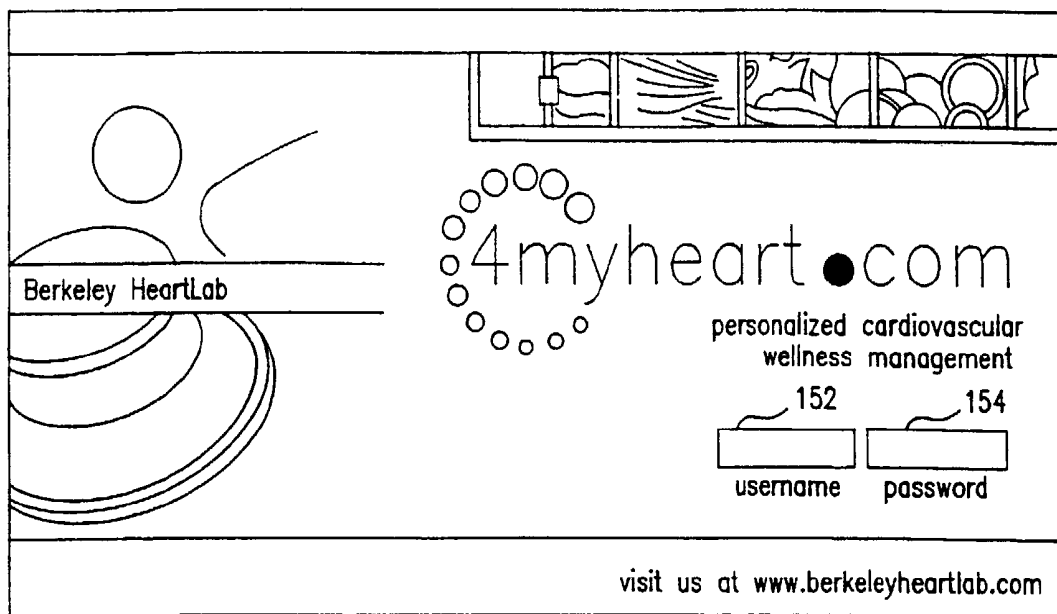
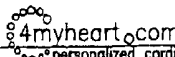


FIG. 2



personalized cardiovascular wellness management

Physicians Front Desk
About 4myheart.com
Contact Us

---

**WELCOME**

161 Patient Activity

162 Patient List

163 E-Mail

164 My Statistics

165 End of Day Report

166 Preferences

---

167 Reference

168 News

169 Product Review

## Welcome to the Physician's Front Desk

Wednesday, March

**My Statistics** 174

Patients	Pattern B	Lp(c)	Complying to Exercise	Complying to
Myself	20%	20%	20%	20%
Community	20%	20%	20%	20%

**Patient Activity** 176

Patients	Email	New Test	FAQ	Compliance
5	20	3	6	4

**Professional News** 178

**Current Major Headlines**

Current major headline introduction

Major Headline Topic 1

Major Headline Topic 2

---


**Current News**

- News Headline
- News Headline
- News Headline
- News Headline
- News Headline

---

**Upcoming Events**

2/12/2000 to 2/12/2000	Event Title
	Event Location
2/13/2000 to 2/17/2000	Event Title
	Event Location
2/13/2000 to 2/17/2000	Event Title
	Event Location



160

FIG. 3

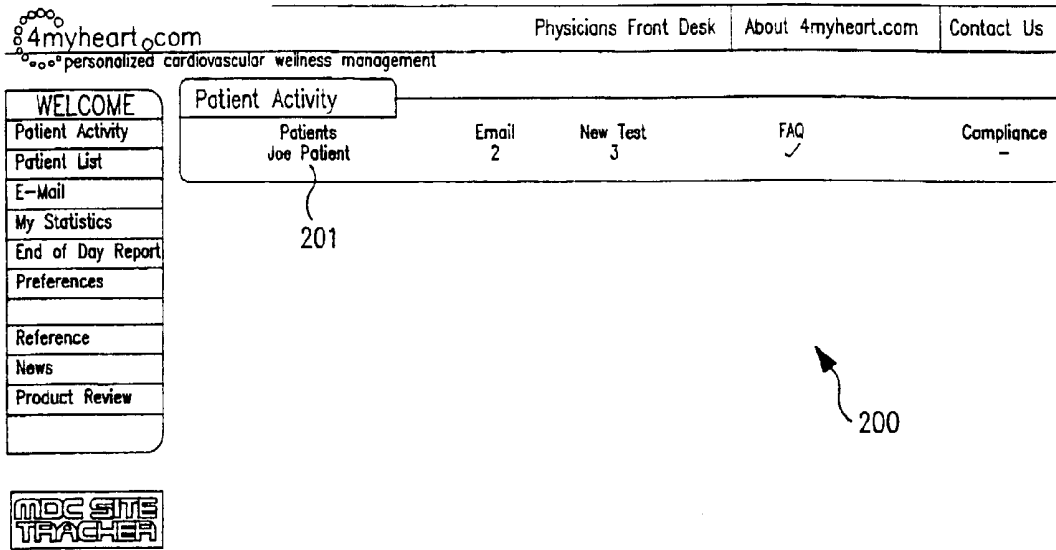


FIG. 4

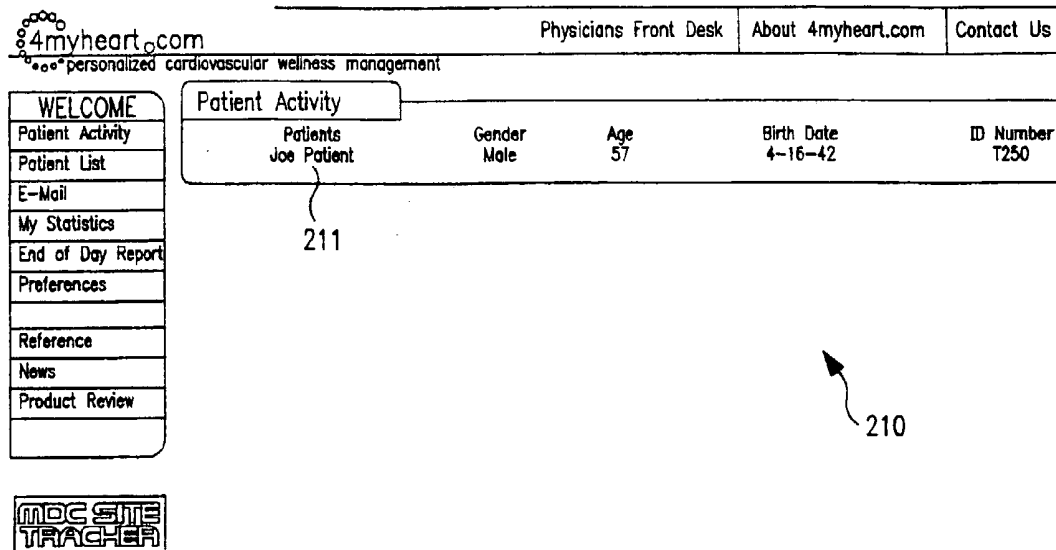


FIG. 5

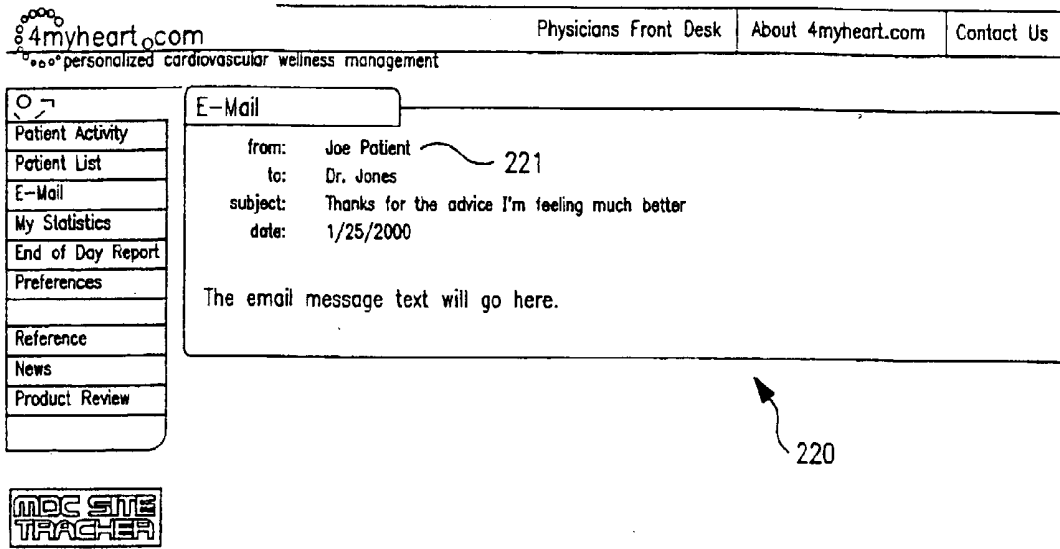


FIG. 6

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254

Diagnosis | Treatment Plan | Letter of Consultation


**WELCOME**  
Patient Activity  
Patient List  
E-Mail  
My Statistics  
End of Day Report  
Preferences  
Reference  
News  
Product Review

**E-Mail**

Patient: Joseph Patient  
Gender: Dr. Jones  
Age: Age  
Birth Date: 4-16-42  
ID Number: T25048

232

250    252



Salient Medical History Information    Current Medications Information

Your Email Inbox

date	time	subject	status	did I respond
1/25/2000	12:36pm	Thanks for the advice I'm feeling much better	235	not yet
1/22/2000	1:14pm	Hello Doctor. I've been having trouble breathing every now and then, should I be worried?	235	yes

234

235

New Test Results

date	time	tests taken	view
5-28-89	12:36pm	HDL GGE	237

236

237

Patient FAQ Audit Trail

238

None Recently

Compliance/Vitals

240

None Recently

230

FIG. 7

- WELCOME
- Patient Activity
- Patient List
- E-Mail
- My Statistics
- End of Day Report
- Preferences
- Reference
- News
- Product Review

E-Mail

Diagnosis Treatment Plan Letter of Consultation

Patient: Joseph Patient  
 Gender: Male  
 Age: 57  
 Birth Date: 4-16-42  
 ID Number: T25048



Salient Medical History Information      Current Medications Information

Test Date 05-28-1999

HDL Gradient Gel Electrophoresis (HDL GGE) Relative HDL Subclass Distribution

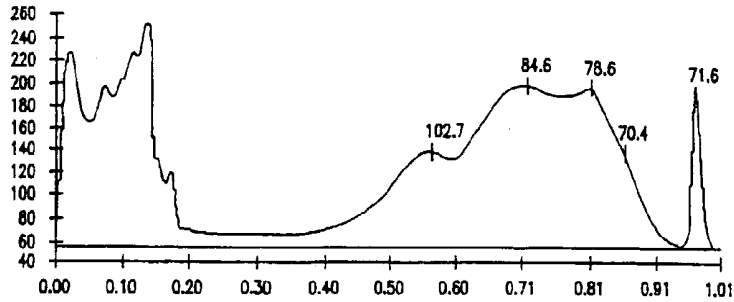
HDL Subclass	results (area%)	10%	50%	90%
2b	15	4	8	18
2a	22	12	18	26
Sum of HDL2	37			

HDL Subclass	results (area%)	10%	50%	90%
3a	32	31	36	40
3b	23	16	26	33
3c	9	5	10	17
Sum of HDL3	64			

HDL2 and HDL3 contribute to HDL-cholesterol measurements. HDL3 levels are more resistant to change than HDL2, which can be increased by weightloss, exercise and estrogen.

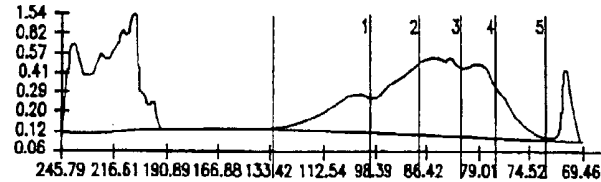
Particle Size (numbers at peaks are particle size in angstroms)

HH0521.B10:8 B89006263 2G



Percent Distribution

HH0521.B10:8



260 ↗

FIG. 8

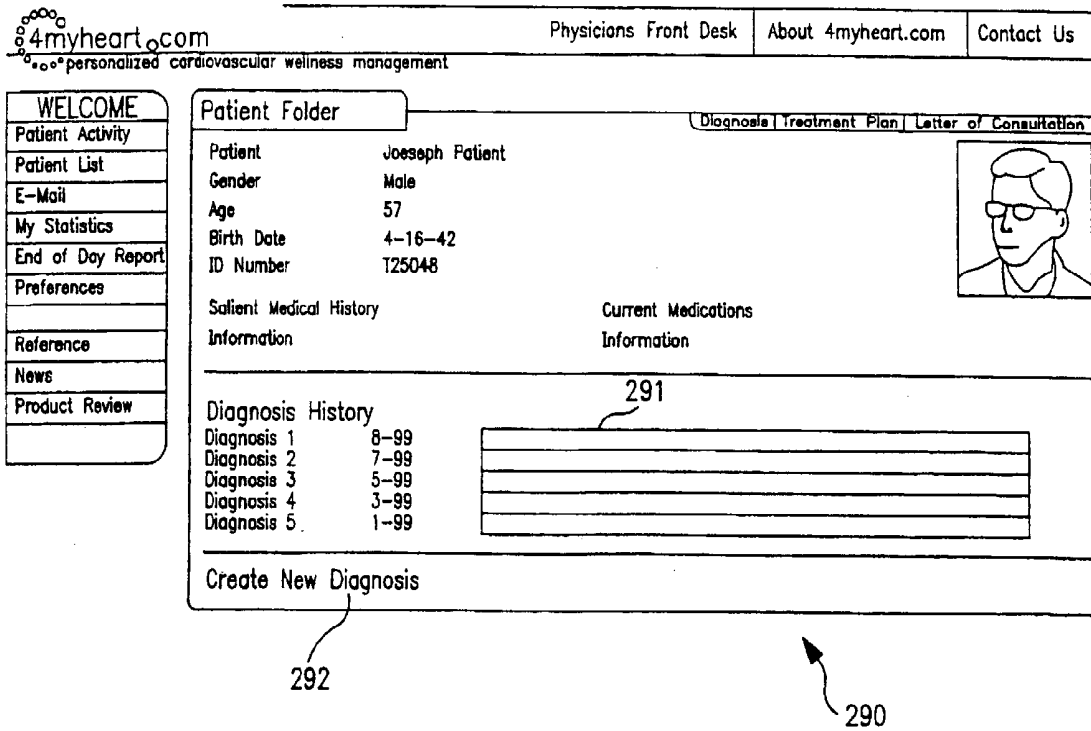
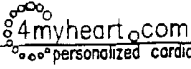


FIG. 9



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WELCOME

Patient Activity

Patient List

E-Mail

My Statistics

End of Day Report

Preferences

Reference


News

Product Review

Patient Folder

[Diagnosis](#) | [Treatment Plan](#) | [Letter of Consultation](#)

Patient	Joseph Patient	
Gender	Male	
Age	57	
Birth Date	4-16-42	
ID Number	T25048	

Salient Medical History Information	Current Medications Information
-------------------------------------	---------------------------------

Overview 302 320 Q

This will be a paragraph explaining the comments of the treatment plan below.

Exercise 304 320 Q

High Caloric Burn

Prescription Medications 306 320 Q

Drug 1-100mg-QAM-250 count-2 Refills-No Food

Diet 308 320 Q

3000 Total Calories

6% Saturated Fat	10% Complex Carbohydrates
15% Polyunsaturated Fat	45% Simple Carbohydrates
10% Monounsaturated Fat	15% Proteins

CV Products 310 320 Q

Product

Product

Product

Product

Suggested Readings 312 320 Q

Title	Type
Title	Book
Title	Journal
<a href="http://www.websites.com">http://www.websites.com</a>	Website

Adjunct Medications 314 320 Q

Name

Name

Name


Name

Follow Up 316 320 Q

Next Office Visit	Next Scheduled Test(s)
3 Months	6 Months-LDL, Lipid Panel

↖  
300

FIG. 10

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<b>WELCOME</b>	<b>Patient Folder</b>	<a href="#">Diagnose</a>   <a href="#">Treatment Plan</a>   <a href="#">Letter of Consultation</a>
<a href="#">Patient Activity</a>	Patient: Joseph Patient	
<a href="#">Patient List</a>	Gender: Male	
<a href="#">E-Mail</a>	Age: 57	
<a href="#">My Statistics</a>	Birth Date: 4-16-42	
<a href="#">End of Day Report</a>	ID Number: T25048	
<a href="#">Preferences</a>	Salient Medical History Information	Current Medications Information
<a href="#">Reference</a>	<hr/>	
<a href="#">News</a>	Letter of Consultation	
<a href="#">Product Review</a>		

FIG. 11



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**WELCOME**

Patient Activity

Patient List

E-Mail

My Statistics

End of Day Report

Preferences


Reference

News

Product Review

Patient Folder

[Diagnosis](#) | [Treatment Plan](#) | [Letter of Consultation](#)

Patient	Joseph Patient	
Gender	Male	
Age	57	
Birth Date	4-16-42	
ID Number	T25048	

Salient Medical History Information

Current Medications Information

---

Diet Prescription

Total Daily Calories

Select Daily Caloric Amount 2000 3000 4000

Total Caloric Breakdown

6% Saturated Fat	10% Complex Carbohydrates
15% Polyunsaturated Fat	45% Simple Carbohydrates
10% Monounsaturated Fat	15% Proteins

6% Saturated Fat	10% Complex Carbohydrates
15% Polyunsaturated Fat	45% Simple Carbohydrates
10% Monounsaturated Fat	15% Proteins


6% Saturated Fat	10% Complex Carbohydrates
15% Polyunsaturated Fat	45% Simple Carbohydrates
10% Monounsaturated Fat	15% Proteins

6% Saturated Fat	10% Complex Carbohydrates
15% Polyunsaturated Fat	45% Simple Carbohydrates
10% Monounsaturated Fat	15% Proteins

Notes

FIG. 12



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**WELCOME**

- 351 ~ Test Results
- 352 ~  Home
- 353 ~ Compliance/Vitals
- 354 ~ E-Mail
- 355 ~ Products
- 356 ~ Preferences
- 357 ~ Reference
- 358 ~ News
- 359 ~ Physician Profile

### Welcome to the Patient's Reception Area

Wednesday, March

Patient: D\*\*\*\*, Frank  
 Gender: M  
 Age: 71  
 Birth Date: 10-20-1927  
 ID Number: T14523

**Test Results** 341

date	tests taken	comments	view
5-28-1999	HDL GGE	Comments from cardiologist	<input type="radio"/>
5-28-1999	LDL GGE	Comments from cardiologist	<input type="radio"/>
5-28-1999	LIPID PANEL	Comments from cardiologist	<input type="radio"/>

**Test Results** 342

Date	Diagnosis
Date	Diagnosis 1
Date	Diagnosis 2
Date	Diagnosis 3

**Treatment Plan** 343

**Overview**  
 This will be a brief paragraph explaining the comments of the treatment plan below.

**Test Results** 344

date	time	subject	status	did
1/22/2000	12:36pm	How are you feeling today?	<input type="radio"/>	no
1/22/2000	1:14pm	About your breathing trouble...	<input type="radio"/>	





FIG. 13

↖ 340



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personalized cardiovascular wellness management

<b>WELCOME</b>	<b>Patient</b>	D****, Frank		
<b>Test Results</b>	<b>Gender</b>	M		
<b>Treatment Plan</b>	<b>Age</b>	71		
<b>Compliance/Vitals</b>	<b>Birth Date</b>	10-20-1927		
<b>E-Mail</b>	<b>ID Number</b>	T14523		
<b>Products</b>	<b>Test Results</b>			
<b>Preferences</b>	<b>Date</b>	<b>Lipid Panel</b>	<b>LDL GGE</b>	<b>HDL GGE</b>
<b>Reference</b>	05-28-1999	✓	✓	✓
<b>News</b>	03-30-1999	✓	✓	✓
<b>Physician Profile</b>	03-05-1999	✓		



FIG. 14



Patient Reception Area About 4myheart.com Contact Us

- WELCOME
- Test Results
- Treatment Plan
- Compliance/Vitals
- E-Mail
- Products
- Preferences
- Reference
- News
- Physician Profile



**Requesting Physician**  
 H. Robert Superko  
 Research Study-Lipid Institute  
 1875 South Grant Street, Suite 700  
 San Mateo, CA 94402  
 FAX (650) 372-1952

**Patient**  
 D\*\*\*\*, Frank Gender Age  
 M 71  
 ID Number Birth Date  
 T14523 10-20-1927

**Report Details**  
 Test Date 05-28-1999

HDL Subclass	results (area%)	10%	50%	90%
2b	15	4	8	18
2a	22	12	18	26
Sum of HDL2	37			

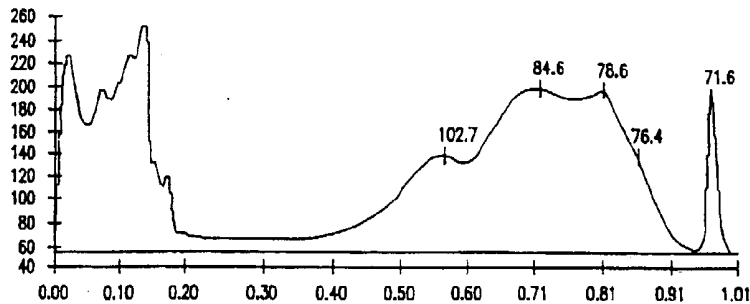
  

HDL Subclass	results (area%)	10%	50%	90%
3a	32	31	36	40
3b	23	16	26	33
3c	9	5	10	17
Sum of HDL3	64			

HDL2 and HDL3 contribute to HDL-cholesterol measurements. HDL3 levels are more resistant to change than HDL2, which can be increased by weightloss, exercise and estrogen.

Particle Size (numbers at peaks are particle size in angstroms)

HH0521.B10:8 B99006263 2G



Percent Distribution

HH0521.B10:8

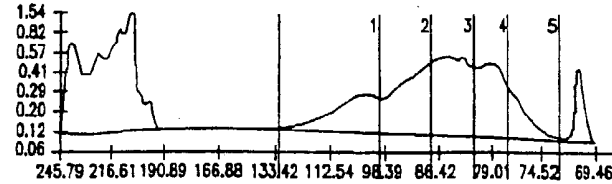



FIG. 15



personalized cardiovascular wellness management

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Wednesday, March

<input type="button" value="Home"/>	Patient <b>D****, Frank</b>
<input type="button" value="Test Results"/>	Gender <b>M</b>
<input type="button" value="Compliance/Vitals"/>	Age <b>71</b>
<input type="button" value="E-Mail"/>	Birth Date <b>10-20-1927</b>
<input type="button" value="Products"/>	ID Number <b>T14523</b>
<input type="button" value="Preferences"/>	<div style="border: 1px solid black; padding: 2px; text-align: center;">Treatment Plan</div>
<input type="button" value="News"/>	Overview <span style="float: right;">-</span> This will be a brief paragraph explaining the comments of the treatment plan below.
<input type="button" value="Physician Profile"/>	Plan Details <span style="float: right;">-</span> Exercise <span style="float: right;">-</span> Information
<div style="border: 1px solid black; padding: 2px; text-align: center;">MDC SITE TRACHER</div>	Medications <span style="float: right;">-</span> Information
	Diet <span style="float: right;">-</span> Information
	Suggested Readings <span style="float: right;">-</span> Information
	Adjunct Medications <span style="float: right;">-</span> Information
	Follow Up <span style="float: right;">-</span> Next Office Visit <span style="float: right;">-</span> Information
	Next Scheduled Test <span style="float: right;">-</span> Information

FIG. 16



		Patient Reception Area		About 4myheart.com		Contact Us	
personalized cardiovascular wellness management							
<b>WELCOME</b>		Patient D****, Frank		Wednesday, March			
Test Results		Gender M					
Treatment Plan		Age 71					
Compliance/Vitals		Birth Date 10-20-1927					
E-Mail		ID Number T14523					
Products		Compliance					
Preferences		yes no Are you following your diet?					
Reference		yes no Are you following your exercise routine?					
News		yes no Have you been taking your medicine regularly?					
Physician Profile		Vitals					
		Weight					
		Blood Pressure					
		Vital Statistic 3					
		Vital Statistic 4					
		Vital Statistic 5					
		Vital Statistic 6					

FIG. 17



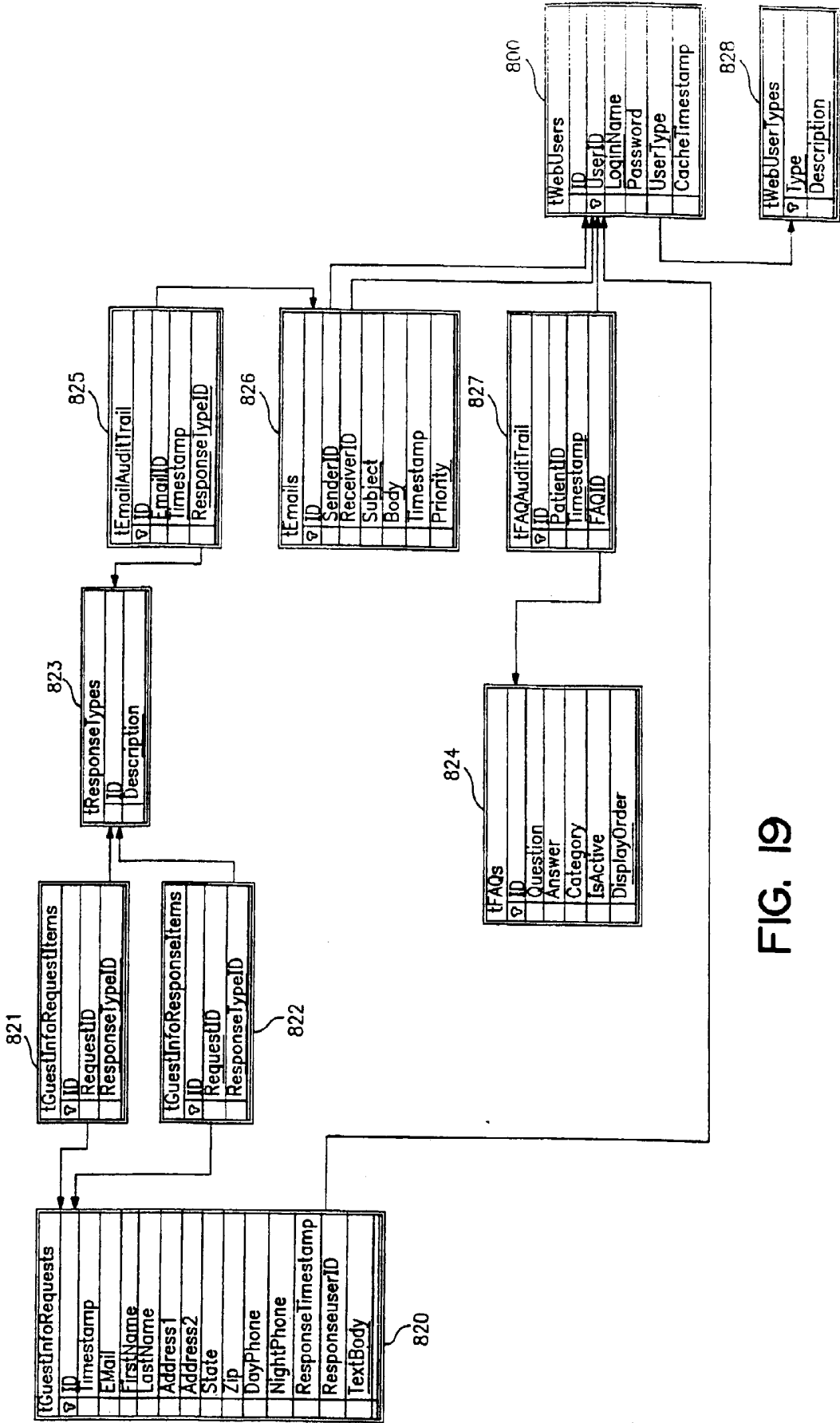


FIG. 19

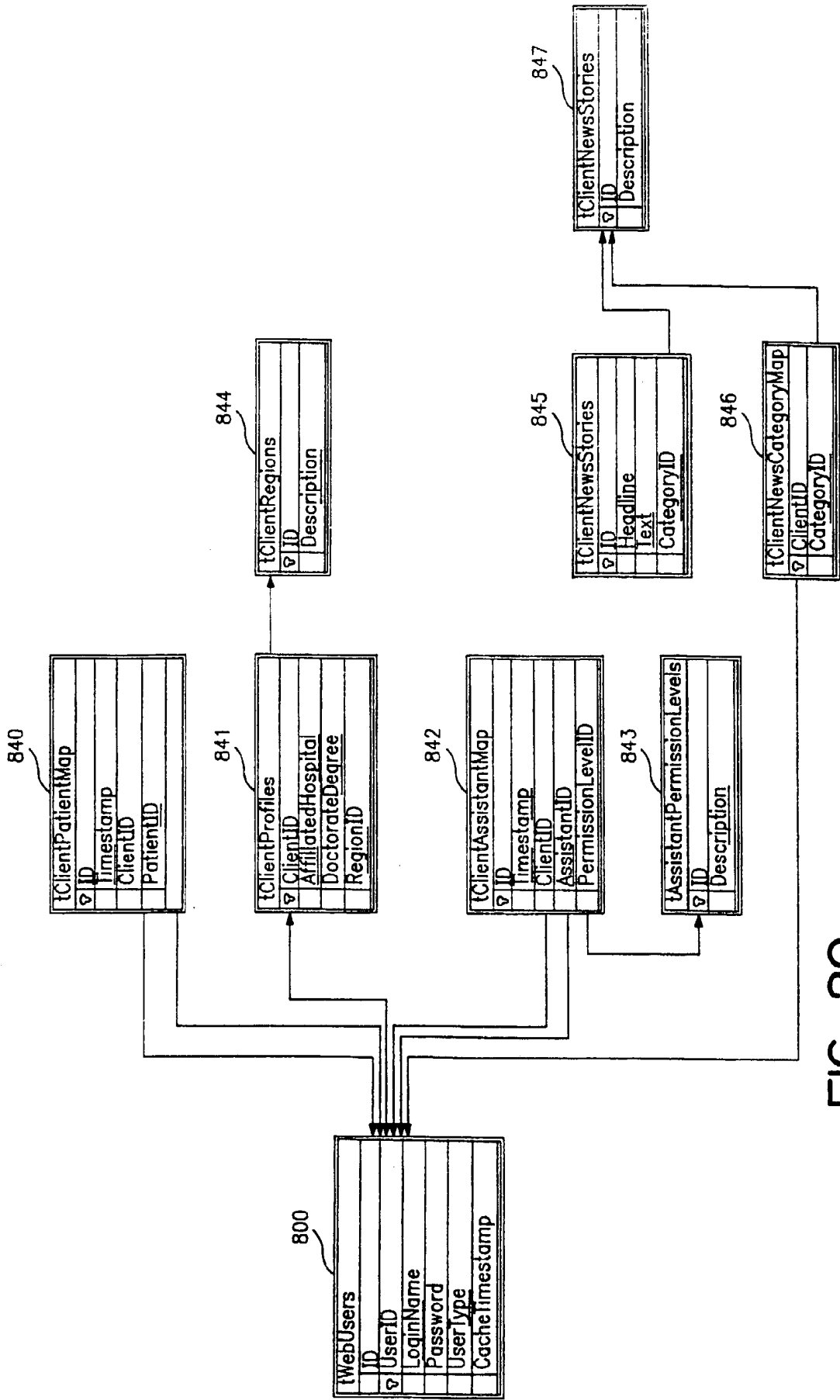


FIG. 20

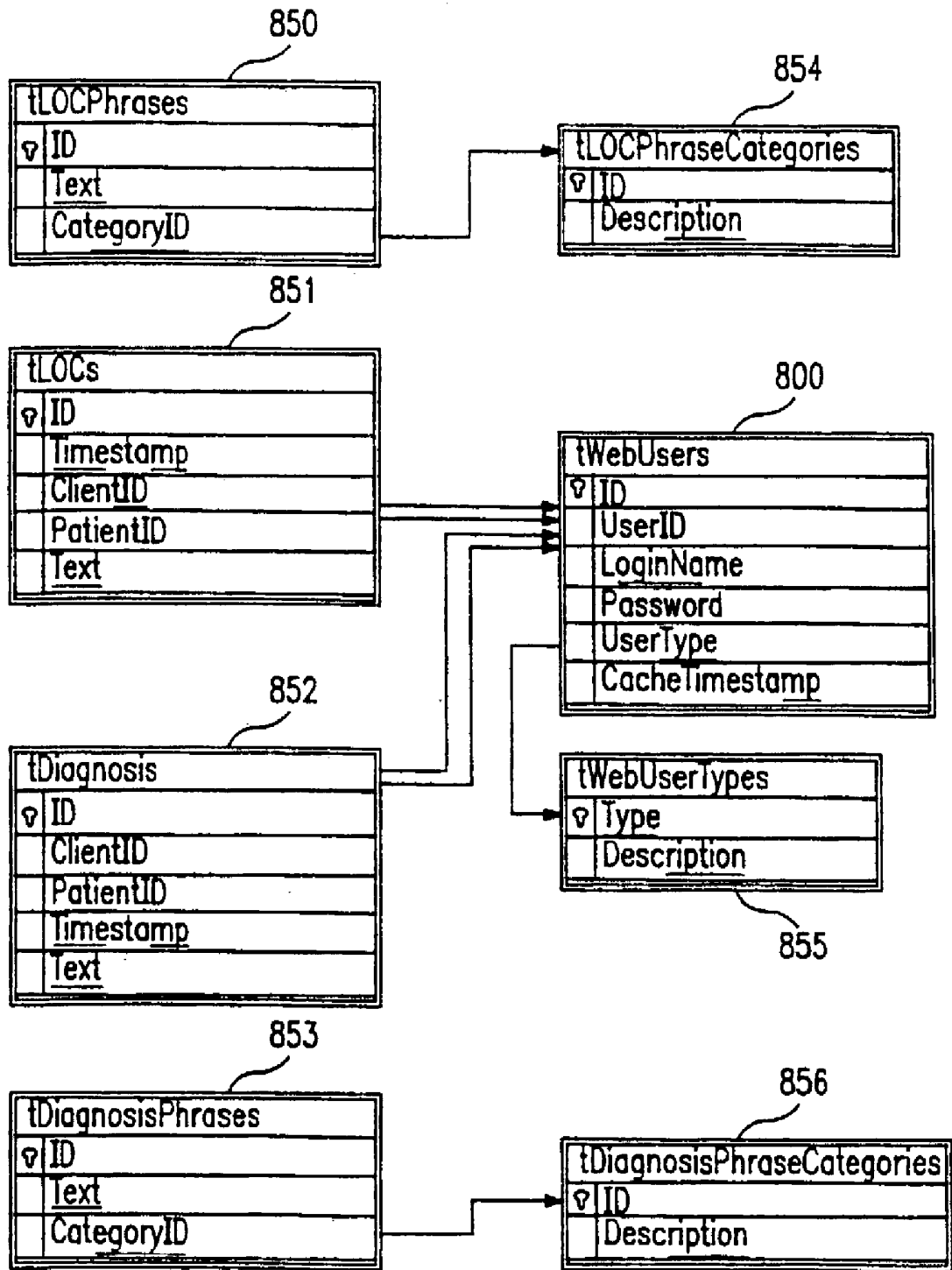


FIG. 21

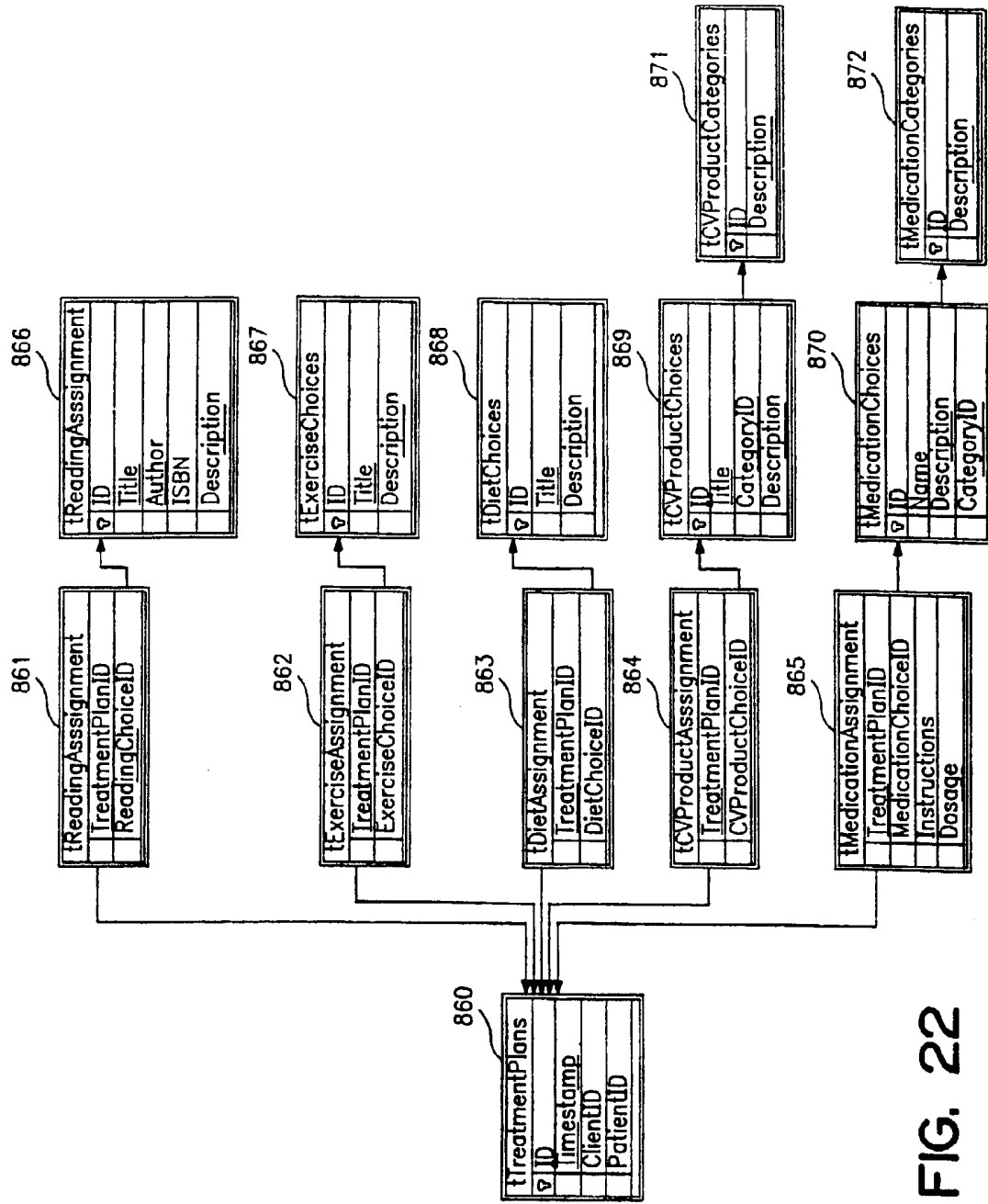


FIG. 22

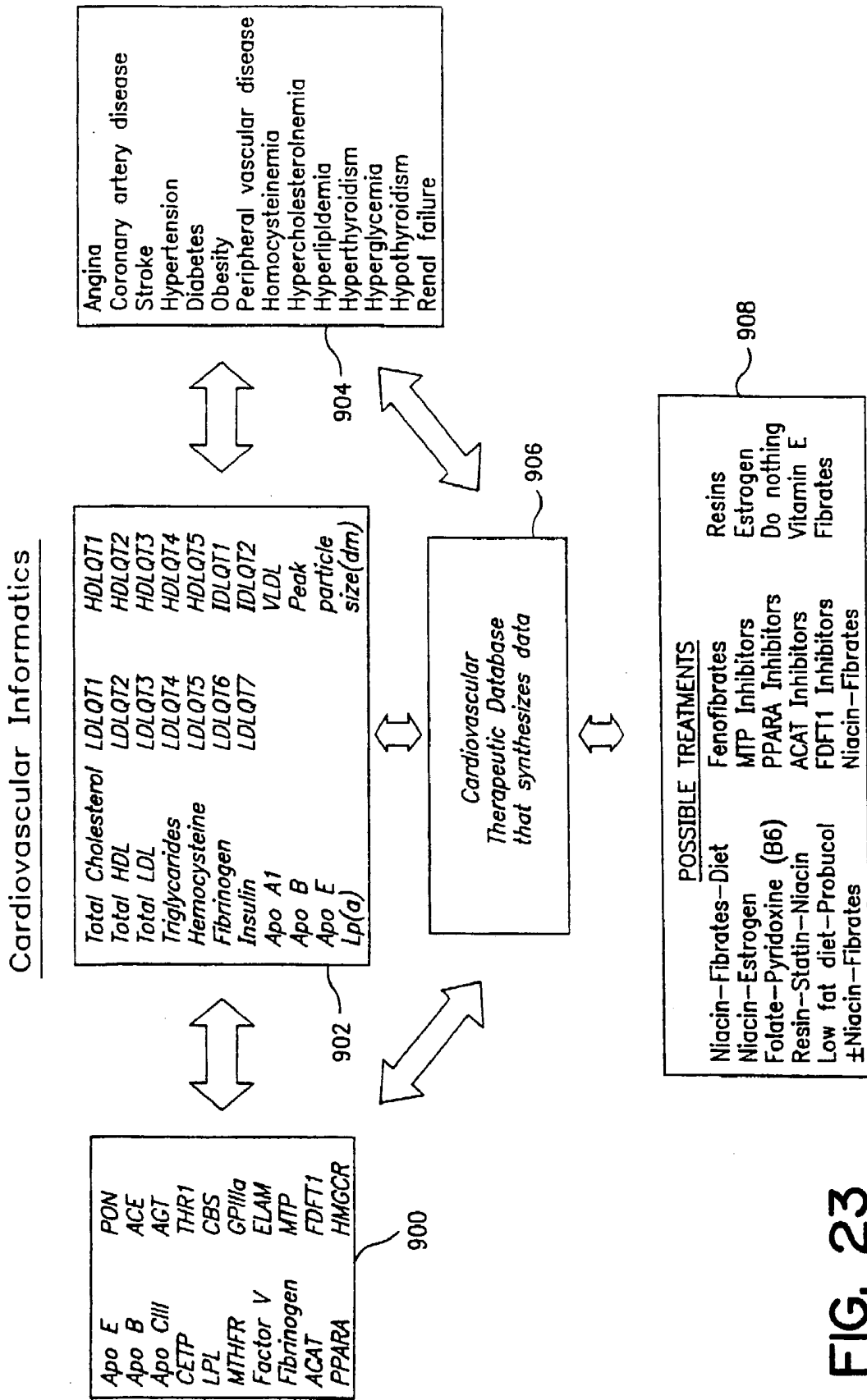


FIG. 23

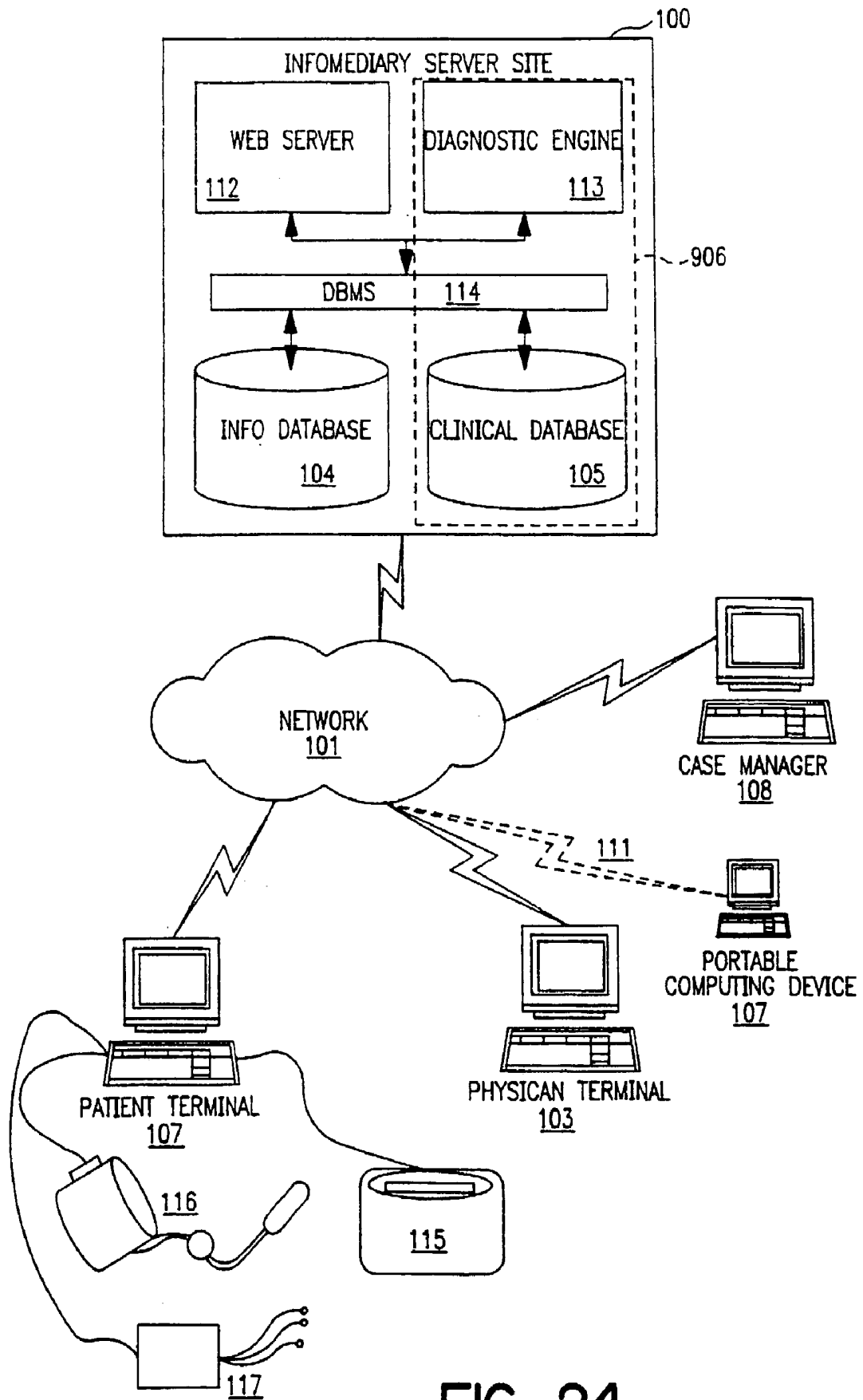


FIG. 24

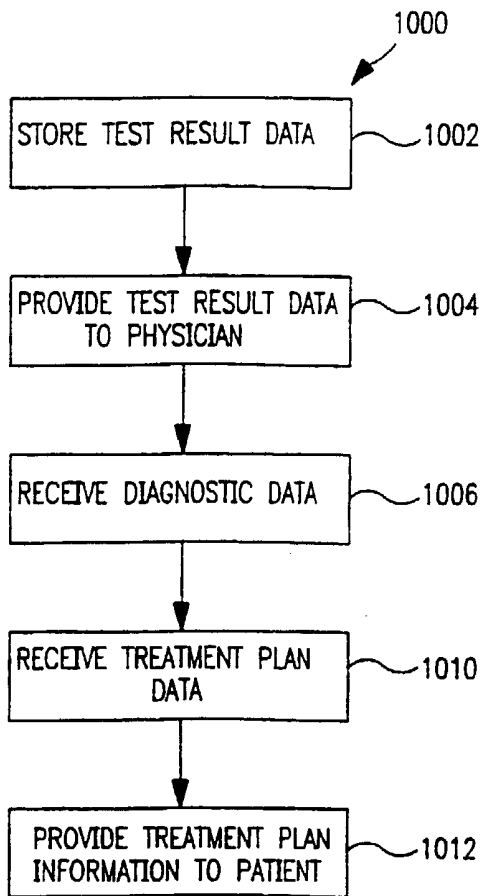


FIG. 25

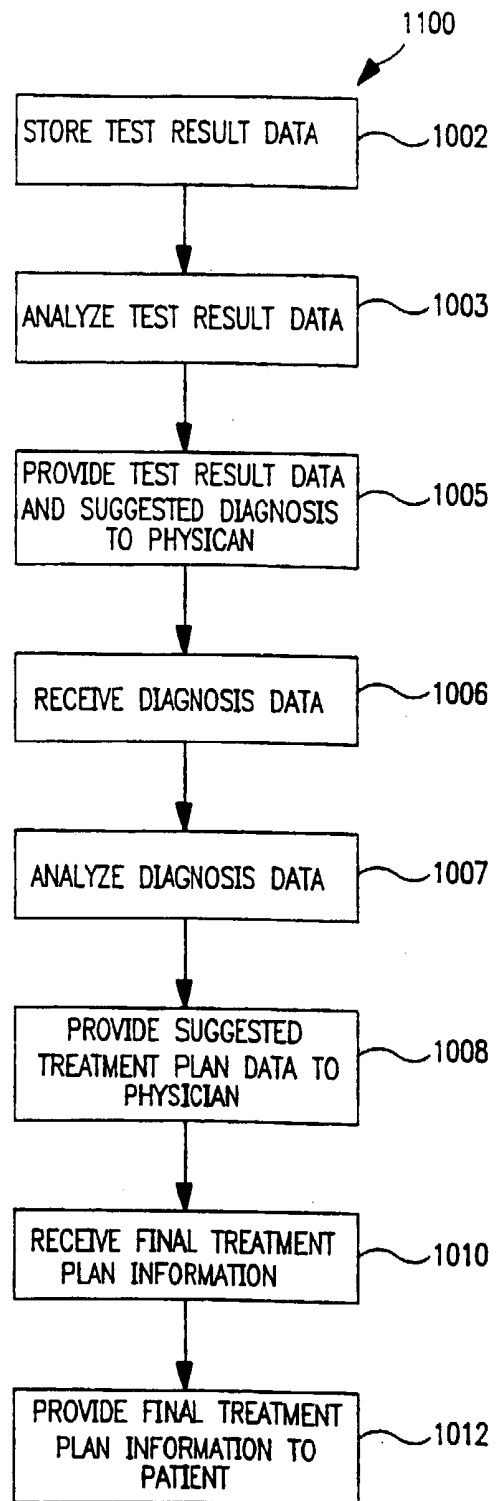


FIG. 26

Physician Composite Page

FIG. 27

1100

1104

1105

1101

1106

1107

1108

1103

1109

1102

1112

1111

1110

Revision\_news Microsoft Internet Explorer

File Edit View Favorites Tools Help

Monday July 3rd 2000

SELECT PATIENT PATIENT ACTIVITY MESSAGES PREFERENCES FRONT DESK

Patient Information

Demographics  
Doe, John, 57, Male  
123 Main St.  
Ryebrook, NY 12345  
D:(555)555-1212 N:(555)555-1213

Medical History  
MI: 4/98  
Stent: 8/97  
Hyperlipidemia  
Heart Rate: 95  
ALLERGY

Vitals 6/27/00  
BP: 120/90  
Weight: 215

Diagnosis  
Coronary, Atherosclerosis  
Guidelines  
Moderately Low HDLC  
Severe Hypertriglyceridemia

Goals & Notes  
Lower LDL-C from 181 mg/dl to <100  
Lower triglycerides from 178 mg/dl to <140

Current Tests

TEST	RESULT	GOAL
Total Cholesterol	261	<180
LDLC	156	<100
LDLc	58	>45
Triglycerides	75	<100
Apo A	132	>120
Apo B	82	<80
Lipoprotein (a)	11	<20
Homocysteine	10.8	<14

APPROVE HISTORY PRINT L.O.C. MESSAGES

Previous Tests

CHOLESTEROL

LBL

Follow-Up

Compliance  
Prescription Filled: Yes 7/15/00  
Adhering to Diet: No 7/15/00  
Weekly Exercises: No 7/15/00

Follow Up  
Next Visit: August 2000  
Next BHL Tests: August 2000  
Apoprotein A, Fibrinogen, HDL CCE

Treatment Plan

Prescription Medication  
Niaspan, 1500 mg, 1/d  
Questran powder, 4g, 1/d

Nonprescription Medication  
Aspirin, 75 mg, twice daily  
Vitamin E, 800mg, once daily  
Vitamin C, 1000mg, once daily

Diet  
Follow Diet Plan A  
Consume 1700 Total Calories  
Plan calls for 6% Saturated Fat,  
15% Polyunsaturated Fat

Exercise  
Low Intensity Program A plan calls  
for 45 minutes of daily running or  
walking. Swimming may be  
substituted.

Cardiovascular Products  
Heart Monitor  
Home Blood Pressure Monitor  
Some Other Product

Educational Material  
The Heart Disease Breakthrough  
Beyond Cholesterol!  
American Heart Assoc. WebSite

Reference Materials and Products

Market Data Corp All Rights Reserved  
http://mdcwebdev.mktdata.com/projects/bhl/resized/stage\_diet.asp

ONLINE VENDORS FAQ GLOSSARY ABOUT MYHEART.COM CONTACT US HELP

Internet

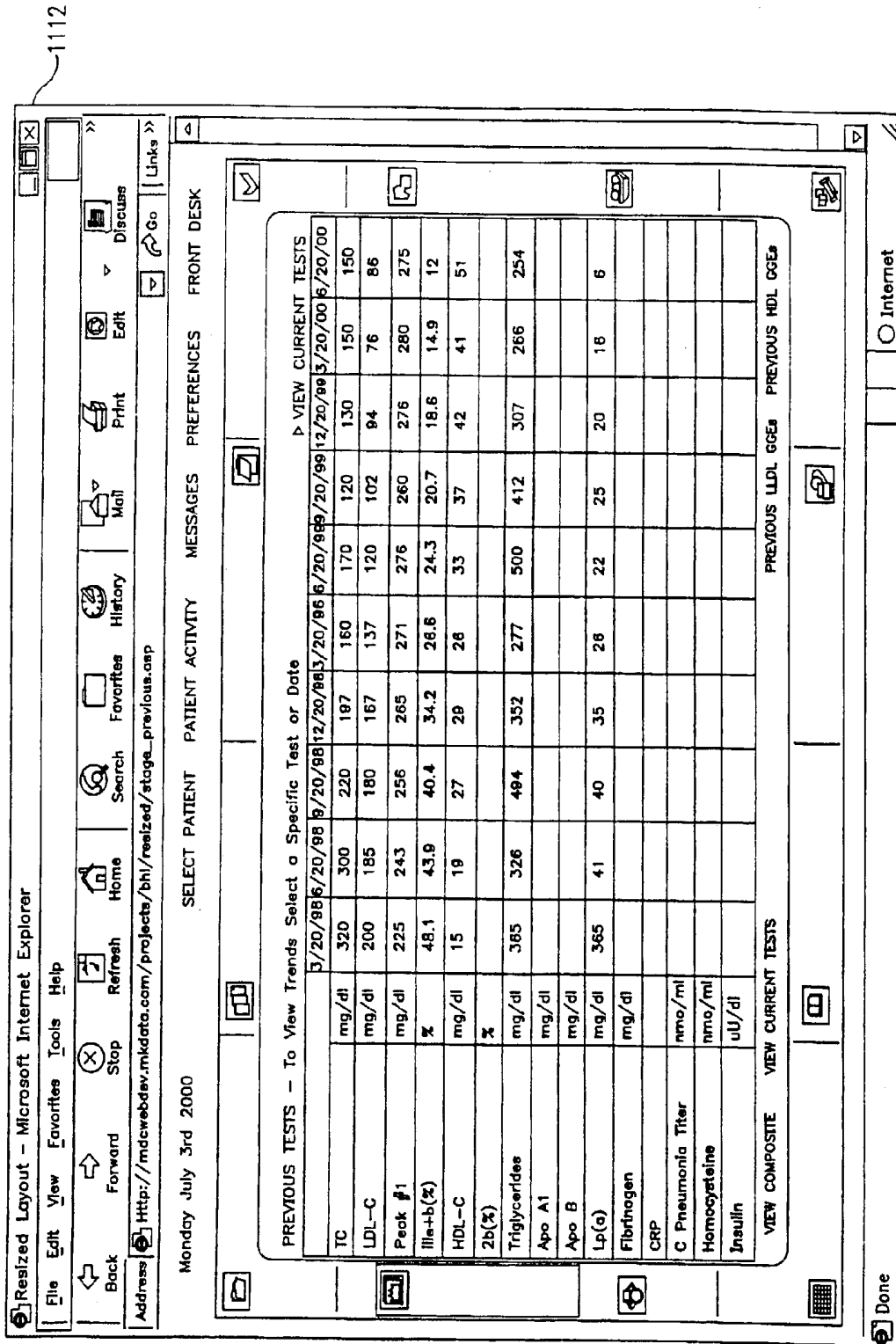


FIG. 28d

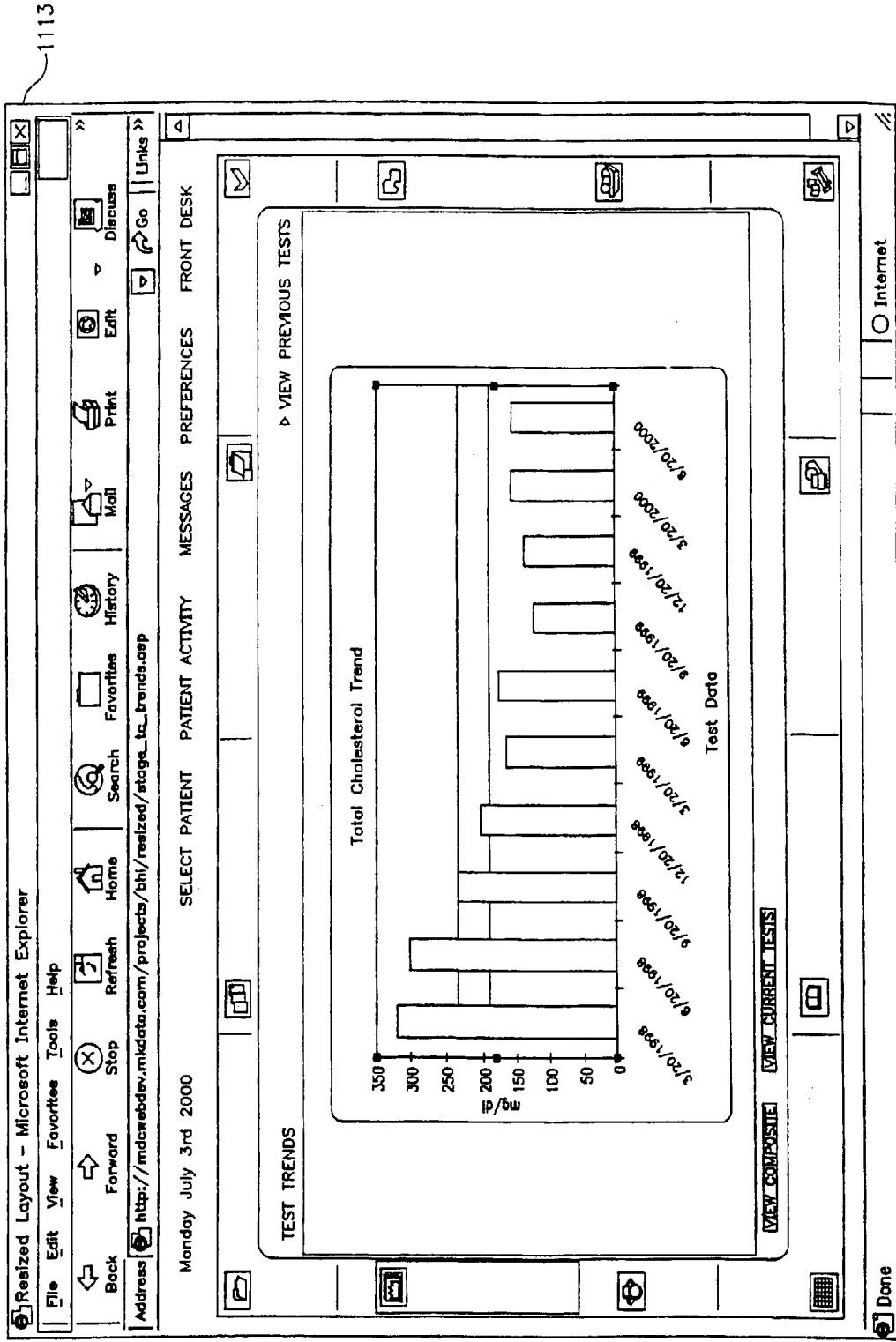


FIG. 28b

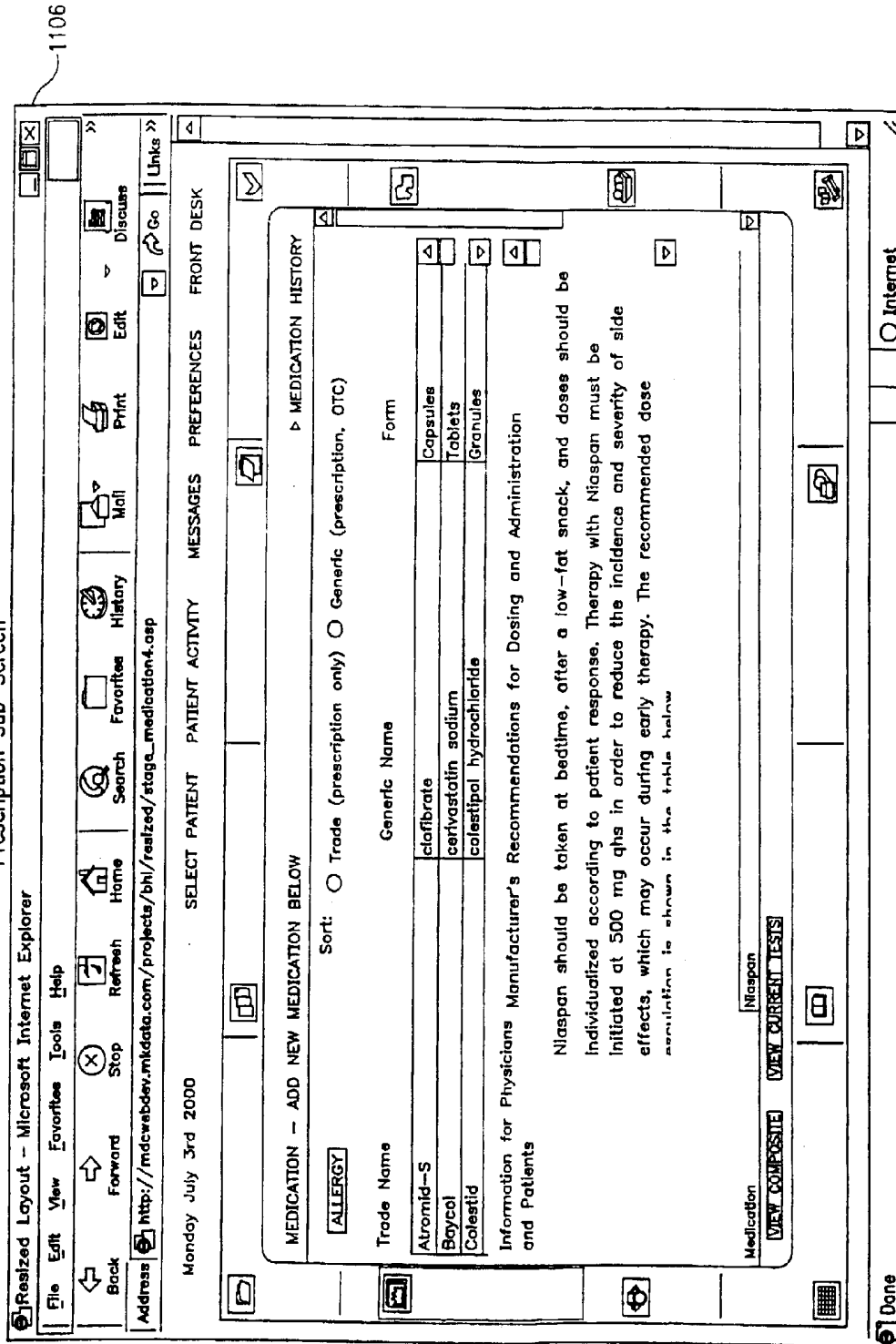


FIG. 29

Treatment Guidelines

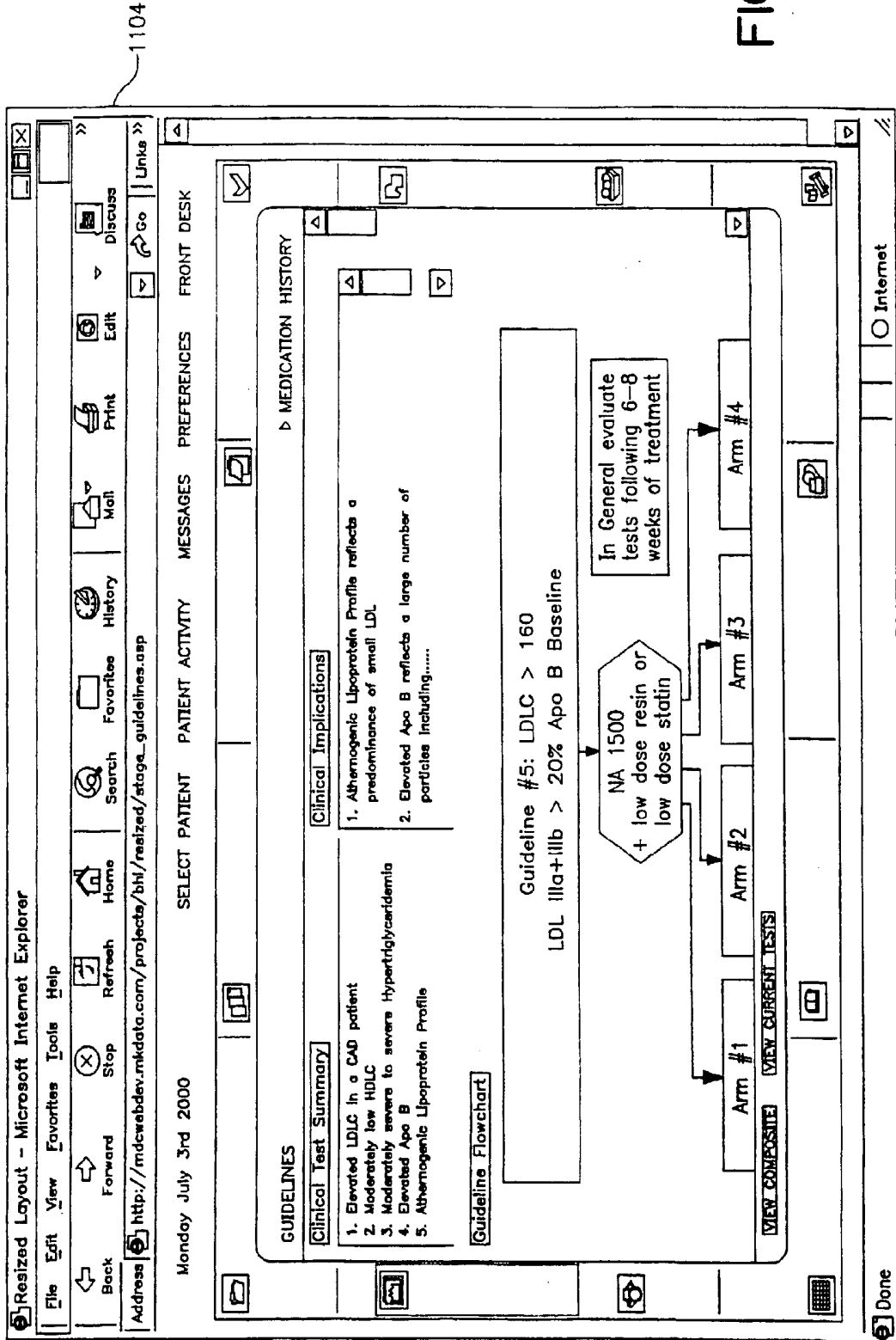


FIG. 30

1104



Compliance Data

Welcome to 4MyHeart.com - Microsoft Internet Explorer

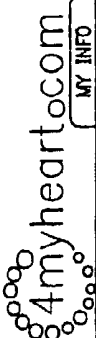
File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites History Mail Print Edit Discuss

Address: <http://mdcwebdev.mktdata.com/projects/bnl/patientproto2/default.htm>

visit us at [www.berkeleyheartlab.com](http://www.berkeleyheartlab.com)

MY INFO MY PHYSICIAN MED HISTORY MESSAGES ABOUT US FAQ GLOSSARY HELP



visit us at [www.berkeleyheartlab.com](http://www.berkeleyheartlab.com)

## Compliance Data

**Enter Compliance Data Below. (Using a date previously entered below will cause the previous entry to be replaced)**

Blood Pressure:  /  Heart rate:   
 Weight:  pounds Prescription Filled Within 5 Days?  N/A  
 Exercise 4 Days Per Week?  N/A Adhering to Diet?  N/A  
 Entry Date:  Submit

**Previously Entered Values:**

Date	Blood Pressure	Heart Rate	Weight	Prescription Filled Within 5 Days?	Exercise 4 Days Per Week?	Adhering to Diet?
06/15/2000	87/105	80	190	Yes	No	No
05/15/2000	85/100	85	185	Yes	No	No
04/15/2000	90/110	90	190	Yes	Yes	Yes
03/15/2000	85/100	80	195	Yes	Yes	Yes
02/15/2000	90/110	80	190	Yes	Yes	Yes
01/15/2000	85/115	90	195	Yes	Yes	Yes
12/15/1999	90/110	85	200	Yes	No	No
11/15/1999	85/100	80	205	Yes	Yes	Yes

Copyright © 2000 Market Data Corporation

Done  Internet

FIG. 32

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## CARDIOVASCULAR HEALTHCARE MANAGEMENT SYSTEM AND METHOD

[0001] This application claims the benefit under 35 U.S.C. §119(e) of U.S. patent application Ser. No. 09/534,946 filed Mar. 24, 2000 entitled "Cardiovascular Management System and Method". This application claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Patent Application Serial No. 60/168,354, filed Dec. 1, 1999, entitled "Method for Individualized Patient Treatment" for all common subject matter disclosed therein, and the contents of said application are hereby incorporated by reference.

### BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] This invention is in the field of managing patient health through an automated online database. More particularly, the system provides for diagnosis and management of cardiovascular disease and includes assessment of cardiovascular risk factors and providing patient treatment plans.

[0004] 2. Background of the Art

[0005] The art describes cardiovascular risk factors such as age, smoking, weight, family history, blood pressure, lipid profiles including low density lipoprotein (LDL) and high density lipoprotein (HDL) and subclasses (fractions) of LDL and HDL. Methods for measuring these factors and relating them to patient treatment are also known. Generally, physicians assess a patient's risk factors, make a diagnosis based on test results and symptoms and manage patient treatment through drugs, exercise, diet and a variety of surgical techniques. Instructions are generally given directly to the patient by the physician. Patient compliance generally involves interview in follow-up office visits.

### SUMMARY OF THE INVENTION

[0006] The present invention provides a cardiovascular healthcare management system that has an infomediary site, which includes databases with cardiovascular disease risk assessment and cardiovascular disease management information. Patient data is stored in an information database, and patient test results are stored in a clinical database, both of which are selectively accessible to both physicians and patients. Patients' test results and personal information are thus added to the databases and may be viewed by the physician to assist in diagnosis.

[0007] A knowledge base may also be included to provide further diagnostic data to a physician. The knowledge base may be used as part of a diagnostic engine that analyzes test results to determine whether they meet certain criteria indicative of a patient's health condition, or might simply contain descriptions of risk factors or combinations of risk factors that are believed to be indicative of specific health conditions. The knowledge base of the preferred embodiment includes software referred to herein as a diagnostic engine that performs risk assessments on specific test results and stores risk assessment information in the database for later viewing by the physician to further assist in diagnosis.

[0008] The database also has information related to managing the patient's cardiovascular health. The cardiovascular disease (CVD) management system provides for the physician having electronic access to the infomediary site for

receiving patient test results and entering diagnosis and treatment information to facilitate the building of a treatment plan. The treatment plan is created after viewing test results and relevant patient data and entering any supplemental information including a diagnosis. The treatment plan may include a recommended diet, prescription (and nonprescription) drugs, an exercise regimen, and alternate cardiovascular products that may be available for purchase through the infomediary site (e.g., blood pressure cuffs to monitor blood pressure, anti-embolism support hosiery, dietary products, educational materials, etc.). Portions of the treatment plan are preferably derived from templates that are provided by the infomediary site 100. In addition, the infomediary site may present templates having the most relevant treatment plan components based in part upon the physician's previously entered diagnosis information.

[0009] The system also provides for electronic communication between the patient and physician by way of access to one or more records in the infomediary site. In this way, a physician can electronically provide cardiovascular disease management instruction such as diet, exercise and medication to the patient and the patient can electronically provide compliance information to the physician directly or indirectly via an alternate input device.

[0010] In another aspect of the infomediary site, a case manager may be provided to collect and input initial patient data and to perform follow-up services like collecting and inputting compliance data to the infomediary site. The case manager may also review initial patient history, test results, and then create a suggested treatment plan for the cardiologist to review. The cardiologist may accept the treatment plan unchanged or modify it, and then electronically release the treatment plan to the patient's folder, which stores personalized information within the CVD management system site. The case manager also proactively contacts patients to advise and assist in the implementation of their treatment plan.

[0011] Alternatively, tele-medicine devices may be used to gather compliance information for submission to the infomediary site.

### BRIEF DESCRIPTION OF THE FIGURES

[0012] FIG. 1 is a block diagram of the infomediary site;

[0013] FIG. 2 is a login screen;

[0014] FIG. 3 is the physician's welcome screen;

[0015] FIGS. 4-12 show additional screens available to the physicians;

[0016] FIG. 13 is the patient's welcome screen;

[0017] FIGS. 14-17 show additional screens available to the patient;

[0018] FIGS. 18-22 show the database tables of the preferred embodiment;

[0019] FIG. 23 is a schematic of the cardiovascular informatics;

[0020] FIG. 24 is a more detailed block diagram of the infomediary site; and

[0021] FIGS. 25 and 26 are flow diagrams for methods associated with the infomediary site.

[0022] FIG. 27 is a physician composite page showing current test and location for accessing other information.

[0023] FIG. 28(a) is a flow sheet which tabulates previous test results.

[0024] FIG. 28(b) presents test results 28(a) in graphical form.

[0025] FIG. 29 is a screen describing medications to the physician.

[0026] FIG. 30 is a screen for treatment guidelines.

[0027] FIG. 31 is a patient composite page for patient/doctor communication.

[0028] FIG. 32 is a screen by which a patient communicates compliance data to a physician.

#### DETAILED DESCRIPTION OF THE INVENTION

[0029] FIG. 1 illustrates a schematic of the infomediary site 100. It shows physician 102 in communication with the site 100 to retrieve test results from a database 104, communication of diagnosis information and a treatment plan or other data to the database 104 by way of server 112. The server scripts 112 generally provide a "front end" to access the records within database 104. Specified records of database 104 are also made accessible to the respective patients 106. The patient 106 can view test results, treatment plans, and communications from the physician 102, and communicate compliance information to the physician 102. The lab 108 provides for inputting test results into the site. There may also be an optional guest 110 access for reviewing limited data in the system.

#### Physician Access

[0030] The physicians 102 can log-on to the infomediary site 100 and communicate with patients 106 and the infomediary site 100 to manage the patient's cardiovascular healthcare. The physician 102 first logs in to the site 100 at the login screen 150 by entering a username in field 152, a password 154, and submitting the data by clicking on submit button 156. The physician is then presented with the welcome screen 160 as shown in FIG. 3. The interface made up of the web pages that provide physician access to the site is referred to herein as the physician data access interface. The physician welcome screen 160 includes a navigation bar having a plurality of links represented by buttons 161-169. The physician welcome screen also includes summary views of certain data such as the physician's statistics at tab 174, patient activity at tab 176 and professional news at tab 178. Tabs 174, 176, and 178 are also links to more detailed screens, which can also be accessed by buttons 164, 161, and 168, respectively. Preferably, the physician is able to customize his or her own welcome screen to provide customized summary information.

[0031] The link underlying patient activity button 161 brings the physician to the patient activity screen 200 as shown in FIG. 4. The patient activity screen 200 is generated by ASP script physician\_patient\_activity.asp. The patient activity screen 200 provides a list of patients who may need attention. The physician's attention may be needed due to the receipt of new test results (input by the Lab 108), the receipt of patient correspondence or compli-

ance data, or the like. The link underlying patient list button 162 brings the physician to the patient list screen 210 as shown in FIG. 5, which is preferably generated by the ASP script physician\_patient\_list.asp. The screen 210 contains a list of all current (and/or past) patients for that particular physician. The link underlying e-mail button 163 brings the physician to the email screen 220 as shown in FIG. 6, which is preferably generated by ASP script physician\_email\_detail.asp.

[0032] The names of one or more of the patients of the particular physician are displayed on the screens in FIGS. 4-6. Preferably, the patient name (e.g., 201, 211, and 221) is also a hypertext link to the patient's data file, thereby providing the physician with convenient access to the detailed patient record displayed on a patient folder screen, one of which is shown at 230 in FIG. 7. The patient folder 230 is preferably generated by ASP script physician\_patient\_activity\_details.asp.

[0033] The patient folder 230 has a general patient information display area 232, patient correspondence display area 234, test results display area 236, FAQ audit trail display area 238, and compliance data display area 240. The patient folder may also contain patient billing and insurance coverage and/or insurance carrier information (not shown). The physician can create initial patient histories by utilizing and editing standard forms. Alternatively, a patient may provide medical background information to the infomediary site 100, either by way of the network through an initial registration procedure, or by calling a data entry specialist provided by the infomediary site 100. Preferably, the infomediary site provides the physician with the services of the case manager, who is typically a lipid nurse, nurse, physician assistant, or other qualified person. The case manager may also act as the data entry specialist.

[0034] The general patient information display area 232 contains general patient information including name, birth date, medications, insurance information, and salient medical history information, etc.

[0035] The patient correspondence display area 234 is referred to herein as a communication interface. It is presented as an email inbox, but preferably does not operate as standard internet email. That is, physicians preferably communicate with their patients by way of the database 104 located at the infomediary site 100. Referring back to FIG. 1, the physicians preferably enter data to be communicated into one or more records of database 104 by way of the infomediary server scripts 112. The server scripts 112 process physician and patient "email" entries to the database 104 and provide an email-type interface. Preferably, actual emails are not sent by the physician, patient or infomediary site 100. Standard email may be utilized in an alternative embodiment; however, less monitoring and control (e.g., delivery verification) of the communication is available when standard email is used. To generate an internet email from an ASP script, for example, an ASP server running with the NT 4.0 Option Pack installed and Microsoft SMTP Service (from the Option Pack) running may use the CDONTS component. The correspondence display area 234 also shows the status of the email with icons 235, as well as an indication of whether the physician has replied to the patient's email. Of course, the infomediary site may utilize standard internet email to notify the patient of upcoming

appointments for lab test work, doctor office visits, compliance conferences with case managers, or to request that the patient log in to the infomediary site to view newly posted treatment plans, compliance requests, or for other similar notifications.

[0036] The FAQ audit trail display area **238** allows the physician to view which general information the particular patient has accessed over the network. This may reveal additional information to the physician about the patient's concerns that the patient would not otherwise convey to his physician. The compliance data display area **240** provides the physician with information provided by the patient as to whether the patient has been complying with his or her treatment plan. Preferably, the patient provides information to the case manager who, in accordance with the treatment plan, initiates follow-up contact with the patient. The case manager solicits information regarding the patient's compliance with the treatment plan such as diet, exercise, medication, and weight and blood pressure, if available. The case manager may input the compliance data into the information database **104**. Alternatively, the patient may input the data directly via the infomediary site **100**. In addition, with reference to **FIG. 24**, the patient may utilize tele-medicine devices to provide compliance-type data. For example, health related measurement devices such as a weight scale **115**, blood pressure cuff **116**, electrocardiogram devices **117**, and the like, may be connected to the network **101** for transmitting data to the infomediary site **100**. The device may be connected directly to the network **101**, or via the patient's home computer, or through a networking device in the patient's home. The tele-medicine devices may also be made available at another location such as a drug store, etc. The device preferably communicates the measured data and automatically submits the data or compliance information to the infomediary site. The tele-medicine device may include software (i.e., a resident device driver, or java-type plug in module) to format appropriately the identification and authentication information along with the data for transmission to the site **100**. The physician may be notified of the presence of compliance data either via the email inbox **234** or by listing that patient in the patient activity display screen **200**.

[0037] The test results display area **236** shows recent test work, and a test results link **237** to allow the physician to view the test results. A typical test results screen **260** is shown in **FIG. 8**. In particular, the test results of **FIG. 8** show the patient's HDL Gradient Gel Electrophoresis in tabular form by HDL subclass, and in graphical form. As seen in the table, the test results show the normalized percentages of HDL subfractions, as well some points (10%, 50% and 90%) on the distribution of normalized percentages. Specifically, the table shows that 10% of people in the sample have a normalized percentage of HDL Subclass 2b of 4% or more, while 90% have a normalized percentage of 18% or less, with the 50% point being 8%. Thus, for example, the physician can see that the particular 2b Subclass test result of 15% is generally within the higher ranges. It should be noted that more complete tables may be provided to show finer resolution of percentages. It should also be noted that the people in the sample to which the test results are compared may vary. In particular, it is often helpful for a physician to be able to compare test results to a population having a similar diagnosis. To illustrate this, in the example shown in **FIG. 8**, the percentages listed are for

those people diagnosed with coronary artery disease (CAD). Thus, the physician is able to determine that the particular results show levels of HDL Subclass 2a and 2b that are higher than average compared to people with CAD, and levels of HDL Subclass 3a, 3b and 3c that are lower than average compared to that same population, and interpret the results accordingly. In a preferred embodiment the physician may dynamically select the reference population to further assist in making a diagnosis. The doctor preferably has the ability to adjust a number of analysis parameters to customize the test result analysis or comparison. The parameters may specify aspects of the general population used as a reference and may include age range, diagnoses, symptoms, LDL and HDL subfraction ranges, etc. The site preferably provides default ranges of many analysis parameters to yield comparisons that have been determined (via research, data mining, etc.) to be useful in the diagnosis or treatment of CVD.

[0038] The physician can also view and print current and prior test results including patient personal information—name, address and telephone number. With the infomediary site **100**, the physician can view cardiovascular risks from the knowledge base, including graphic representation of the patient's condition and test results. Charts or histograms comparing current and prior test results are also available from the infomediary site database.

[0039] The patient folder **230** also includes a diagnosis link **250**, treatment plan link **252**, and letter of consultation link **254**. The diagnosis link **250** retrieves the diagnosis screen **290** as shown in **FIG. 9**. The various diagnoses are shown, with the dates and summary information. For example, Diagnosis 1, made in 8/99, would be displayed in field **291**. The physician may also create a new diagnosis using link **292**.

[0040] The treatment plan link **252** retrieves treatment plan screen **300** as shown in **FIG. 10**. The physician can create treatment plans for their patients from information in databases of the infomediary site **100**. Treatment plan screen **320** includes overview display area **302**, exercise display area **304**, prescription medication display area **306** (generic and brand names, as well as the ability to print the prescription, or to specify a pharmacy to where the prescription may be electronically forwarded), diet display area **308**, cardiovascular (CV) products display area **310**, suggested readings display area **312**, adjunct medications display area **314**, and follow up display area **316**. Each of the display areas **302-316** include links **320** to pages having further details relating to the respective sections. Preferably, the infomediary site provides the physician with a treatment plan template having the above-referenced components. The physician may select specific entries by a number of methods, including drop-down boxes, text boxes, bullet lists, etc. In addition, the template may initially provide selections that are consistent with the patient's data, including one or more of the following: test results, most recent test results, salient patient history, physician diagnosis data, etc. The finalized treatment plan may also be reviewed by the infomediary site to check for consistency of the plan with the same factors, and the physician's attention may be directed to aspects of the treatment plan that appear to conflict with the particular patient's data.

[0041] The link **254** to the letter of consultation allows the physician to construct letters of consultation from standard

forms, patient data, standard paragraphs and phrases in the infomediary site database 104. These letters may be printed, stored and sent electronically or through regular mail.

[0042] The physician can also, through the infomediary site, visit e-commerce vendor's websites to purchase and recommend purchasing to their patients of prescription medication, adjunct medication, exercise equipment, dietary products, cardiovascular products and educational materials, such as reading materials, software, video recordings, etc.

[0043] The infomediary site 100 also provides physicians with educational materials such as recent news and suggested readings. The infomediary site 100 also provides physicians with administrative function capability. The physician can perform administrative functions, including creating or editing a physician profile, managing billing information and logs, and viewing daily activity summaries.

[0044] The infomediary site 100 may also perform insurance pre-certification to ensure that requested tests are covered by the patient's insurance. If the test is not covered, the physician and/or patient is notified, and further instructions are requested as to whether the physician and/or patient nevertheless wishes to have the test performed. The communication can be via telephone from the case manager, or via the infomediary site through the physician's "email" inbox. Typically, the infomediary will telephone the patient to inform them that the test is not covered or partially not covered. The nature of the test and the reason for the test is explained to the patient, and the patient may then elect to pay for the scheduled test or to decline the test. In the event the test is declined, the requesting physician is notified.

#### Patient Communication

[0045] Patients can log-on to the infomediary site 100 and view screens that provide links to other pages or news. The patient 106 first logs in to the site 100 at the login screen 150 (FIG. 2) by entering a username in field 152, a password 154, and submitting the data by clicking on submit button 156. The patient is then presented with the patient welcome screen 340 as shown in FIG. 13. The patient welcome screen 340 includes a navigation bar having a plurality of links represented by buttons 351-359. The patient welcome screen also includes summary views of certain data such as test results 341 (as shown further in FIGS. 14 and 15), diagnosis information 342, treatment plans 343 (as shown further in FIG. 16), and email inbox 344. FIG. 17 depicts a compliance input screen that may be accessed directly by the patient, or by the case manager.

[0046] The patient can communicate with their physician through a communication interface. Preferably, this takes the form of mutual access to records in the infomediary site to obtain doctor treatment plans and report their compliance to the doctor as described above with respect to physician email. The patient can purchase products, including medications, adjunct medications, exercise equipment, dietary products, cardiovascular products and educational material directly from the infomediary site 100. Additionally, or alternatively, the infomediary site may contain links to vendor websites for purchasing the products from a third party.

#### Non-Doctor/Non-Patient Access to the Infomediary System

[0047] The infomediary system is adapted so that patient results from laboratory tests and related information can be

inputted into the system. In particular, the site 100 may be accessed by the lab 108 so that test result data may be input directly through the web site server scripts. Alternatively, test result data may be input to the system by a data entry specialist or by a case manager.

[0048] The infomediary site may also be accessed by guests to the system. Guests may browse information, FAQ lists, physician profiles, physician referral services, or request further information or follow-up contact.

#### Cardiovascular Informatics

[0049] The infomediary site has advanced cardiovascular informatics related to factors such as genetics, diet, exercising and medication. The cardiovascular informatics is illustrated in FIGS. 23 and 24. Table 902 illustrates lipid-related data in the infomediary site 100. The relationship of lipids 902 to genetic markers 900 and other coronary risk and disease factors such as those listed in 904 are analyzed by and stored in the CV Therapeutic database 906. Of course, as an initial matter, an individual patient might not have every test listed in 900 and 902; however, the infomediary site includes a diagnostic engine 113 to identify whether any additional tests should be recommended to a physician. Note that tables 900, 902, 904 and 908 are shown in summary form, but generally take the form of relational database tables such as those shown in FIGS. 18-22, having ID fields, text fields, patient and test ID fields, etc.

[0050] Thus, a cardiovascular risk database is formed from the information in tables 900, 902, and 904 within clinical database 105. Each entry in tables 900 and 902 also includes fields to identify the patient ID, physician/client ID as necessary, and may optionally include one or more suggested diagnosis fields (not shown). The diagnosis fields may also be included in another table associated with the patient within clinical database 105 or information database 104. The diagnosis fields preferably contain diagnosis ID's corresponding to the diagnosis text shown in table 904. The diagnosis fields are populated by the diagnostic engine 113, and are used to convey the analytical results of the diagnostic engine to the physician through the physician access interface. The CV therapeutic database 906 includes algorithms to identify patterns of risk factors, and may compare inputted patient results for lipid subfractions to the normal values. The algorithms are shown in FIG. 24 as a diagnostic engine 113. These algorithms may take the form of software programs or scripts such as SQL scripts or the like. The diagnostic engine 113 preferably operates on new test results to identify those results (in combination with other risk factors) that fall within the parameters specified by the algorithm. Additionally, the CV therapeutic database 906 may analyze the lipid subfractions in combination with other patient data such as that listed in table 900 and 904. The results, including possible treatments 908, can then be related to the physician.

[0051] As described above, the measurement of the patient's lipids, genetic markers and disease and disorder risk factors and comparison to the database provides a patient's specific risk factors which can be related to possible treatments. Furthermore, the book "The Heart Disease Breakthrough" by Thomas Yannios, M.D. John Wiley & Sons in 1999 illustrates additional important principals in

cardiovascular healthcare that are incorporated into the CV therapeutic database **906** and diagnostic engine **113**. This book is incorporated herein by reference. The book points out the important role of LDL and HDL subfractions in cardiovascular disease. This book further discusses the role of genetics, diet, exercising and medication in cardiovascular disease management.

[**0053**] The quantitative measurement of LDL and HDL lipid fractions and other lipid measurements are important patient data that is evaluated in the infomediary site. U.S. Pat. No. 5,925,229 describes methods for quantitating LDL fractions for evaluating cardiac disease risk and that patent is incorporated herein by reference. Typical lipids and their method for measurement are listed in Table I.

TABLE I

Analysis	Methodology	Summary Description of Assay
Apoprotein A1	Immunoturbidimetric Analysis	An insoluble turbid Immunoprecipitate is formed by the reaction between Apo A-1 antigen in human plasma and specific antibodies. Resulting turbidity is measured spectrophotometrically. Concentration of Apo A-1 is determined from a five-point calibration curve. Patients run in duplicate.
Apoprotein B	Immunoturbidimetric Analysis	An insoluble turbid immunoprecipitate is formed by the reaction between Apo B antigen in human plasma and specific antibodies. Resulting turbidity is measured spectrophotometrically. Concentration of Apo B is determined from a five point calibration curve. Patients run in duplicate.
Apoprotein-E Isoforms	Isoelectric Focusing	Isoelectric focusing of plasma sample is followed histochemical visualization of the Apo-E bands.
Lipoprotein (a)	ELISA = Enzyme Linked Immunoabsorbant Assay	Monoclonal/Polyclonal sandwich assay. Monoclonal antibody coated wells are used to capture Lp(a) from the sample. Polyclonal anti-Lp(a) horseradish peroxidase conjugate reacts with substrate and a chromogen producing colored solution. Concentration of Lp(a) mass (mg/dl) quantitatively determined by standard curve
Lipid Profile	Patients run in duplicate:	Photometric quantification
Cholesterol	Enzymatic	Photometric quantification
Triglyceride	Enzymatic	Precipitation of LDL and VLDL from plasma followed by assay of supernatant for cholesterol.
HDL Cholesterol	Dextran & Magnesium sulfate	LDL = T Chol - HDL Chol - VLDL (Trig/5)
LDL Cholesterol	Calculated - Friedewald Formula	Specific monoclonal antibody detection with fluorescently labeled analog tracer detection.
Homocysteine	FPIA = Fluorescence Polarization Immunoassay	Plasma low density lipoproteins (LDL) are characterized for particle size and distribution of lipid stained mass using polyacrylamide gradient gels (2-14%). LDL particle size analysis is based on a four-point curve using lipoprotein standards correlated by analytical ultracentrifugation (ANUC). Results of phenotype analysis are validated by comparison of GGE analysis with ANUC.
LDL GGE	Gradient Gel Electrophoresis	Plasma high density lipoproteins (HDL) are characterized for particle size and distribution of protein stained mass using polyacrylamide gradient gels (14-31%). HDL particle size analysis is based on calibration with globular protein standards. Results validated by comparison of GGE analysis with analytical ultracentrifugation (ANUC).
HDL GGE	Gradient Gel Electrophoresis	

[**0052**] A doctor reviewing the patient's risk factors can formulate an individual course of treatment, and the infomediary site **100** provides a list of possible treatments **908**, including exercise, diet, pharmaceuticals, which are preferably customized by the CV Therapeutic database **906** in response to the risk factors identified by the test results of the patient. The physician sends an individualized treatment plan to a patient record in the infomediary site and the patient sends compliance information to the physician to the patient file. Either may access the relevant treatment plan records, but preferably only the physician may modify the recommended plan, and the patient may add, update or modify the compliance data.

[**0054**] Patient data from lipid analysis and other data have been utilized to develop a knowledge database within the infomediary site. This knowledge base is useful in analyzing an individual patient's data and also identifying new and previously unknown relationships between test results that aid in the diagnosis and treatment of patients. Additional relationships are identified from the tables **900**, **902**, and **904** using standard data mining techniques, including genetic algorithms, decision tree induction, association discovery, fuzzy logic, etc. The relationships are then incorporated into the CV therapeutic database **906**. More particularly, the relationships may be incorporated into programs or scripts (e.g., SQL scripts) within the diagnostic engine **113**.

[0055] Considering 954 patient samples (458 cases and 496 controls), age was a very significant predictor of CVD. Cases are significantly older than controls (60 vs. 52 years of age). After adjusting for the age difference, none of the risk factors are significantly different between the cases and controls. Thus, using the 954 patients, all of the differences in risk factors that exist between cases and controls are due to age, not disease status. All of these patients are high risk and the younger patients have not yet shown clinical manifestation of cardiovascular disease.

[0056] Using a subset of age matched cases (N=173, means 60 yr.) and controls (N=173, means 59 yr.) between 54 and 66 years of age, the cases had significantly:

[0057] Higher homocysteine (9.7 vs. 8.7, P<0.01), and

[0058] Lower TC (179 vs. 201, p<0.0001), LDLC (107 vs. 121, p<0.001), triglyceride (140 vs. 163, p<0.05), apoA1 (112 vs. 123, p<0.01) apoB (85 vs. 96, p<0.001), and TC/HDL2b (14.8 vs. 20.2, p<0.05). These data indicate that the cases are more aggressively treated with medications than the controls.

[0059] Using a subset of age-matched cases (N=146, mean 55 yr.) and controls (N=93, mean 55 yr.) between 44 and 66 years of age without hyperlipidemia, the cases had:

[0060] Higher HDL3b (19.9 vs. 17.9, p<0.05), HDL3 (58.8 vs. 55.7, p=0.08) and LDLII+IV/HDL2+3 (0.40 vs. 0.38, p=0.11), and

[0061] Lower TC (182 vs. 205, p<0.001), LDLC (109 vs. 124, p<0.01), HDLC (44 vs. LDL11A (16.8 vs. 18.2, p=0.09), HDL2b (15.5 vs. 18.6, p<0.05), and HDL2 (41.3 vs. 44.5, p=0.06). These data again indicate that cases may be more aggressively treated with medications than the controls, even though they do not have hyperlipidemia. These data also indicate some important risk factors in the cases: a higher ratio of small LDL to HDL, small LDL size and lower HDL2b.

[0062] The informatics database of the present invention have permitted the discovery of numerous relationships of lipid factions to disease. For example, it has been found that:

[0063] 1. With usual care LDL IIIb change is significantly associated with change in % stenosis and change in average and minimal diameter in control patients. For every 1% change in IIIb there is approximately 0.2% change in % stenosis.

[0064] 2. For every 1A change in peak diameter, there is an approximate 0.05% change in % stenosis.

[0065] 3. With special intervention the LDL IIIb, Iva and peak particle diameter are related to change in average diameter and % stenosis. LDLC is not.

[0066] 4. Change in LDL IIIa and Ivb are related to change in average diameter and mean minimal diameter. Change in LDLC was not.

[0067] 5. Elevated tHcy may be related to the need for subsequent CABG or PTCA over 3 years.

[0068] 6. LDL IIIa is significantly higher in Percutaneous Transluminant Coronary Angioplasty (PTCA) patients requiring a second PTCA. LDLC is not.

[0069] 7. The interaction of small LDL (IIIa) and LP(a) contribute to increased risk for a second PTCA while Lp(a) alone does not.

[0070] Generally it has been found that:

PTCA	LDLC	HDLC	TG	LDLIIIa
Time to 2 nd PTCA	NS*	NS*	NS*	<0.05

\*Not Significant  
 LDL IIIa < 15% repeat PTCA 31 months  
 LDL IIa < 25% repeat PTCA 25 months

[0071] These data illustrate the value of the cardiovascular informatic knowledge base in deriving heretofore unrecognized relationships between data, especially highly discriminating lipoprotein subfractions, in diagnosing risk factors which may govern the treatment of patients.

DETAILED DESCRIPTION OF THE INFOMEDIARY SITE

[0072] In a preferred embodiment, the infomediary (information intermediary) site 100 is accessed over a network 101, either a public network such as the internet, or a private network such as a private LAN/WAN, either of which may be accessed over high speed digital subscriber lines or optional dial up (circuit switched) connections provided by a remote authentication server or the like. The network 101, as shown in FIG. 24, may include landline and/or wireless access (typically CDMA), as is known in the telecommunications art.

[0073] The healthcare information is typically displayed on a web browser running on a personal computer or other web-content viewing device. In the case of patient access, this may include a personal computer 107 with internet access, a television set with a set-top decoder (such as that provided by WorldGate Communications, Microsoft's WebTV, OpenTV interactive television, or the like), and may also include a cable modem or wireless modem, or may be a smaller internet appliance device. The patient may also utilize tele-medicine devices such as a weight scale 115, blood pressure cuff 116, electrocardiogram device 117 or other similar monitoring devices.

[0074] In the case of a physician, any of the above access devices may be used. Preferably, physicians utilize a portable device such as a clipboard or tablet computer 107 such as those available from Fujitsu, a Clio device available from Vadem, or a smaller device such as a Palm Pilot. The device may have wireless access 111 to the network for data transfers, or may store information locally on a computer 103 and periodically synchronize with the infomediary site via the network.

[0075] The information pages are conveyed to the browsing device over the network in the form of a device independent language such as hypertext markup language (html) using hypertext transfer protocol (http). These protocols are typically carried by a lower level transfer protocol such as those associated with the TCP/IP protocol suite. The device independent language is preferably generated dynamically by the infomediary site, using Common Gateway Interface (CGI) scripts, Active Server Pages (ASP), or other content

generation languages and protocols. CGI and ASP are language-independent frameworks for coding of server-side scripts that are executed by Web server 112 in response to a user's request for a universal resource locator (URL). The infomediary site may also be accessible from an interactive television channel having regular multimedia displays of health-related educational information, documentaries, and the like, with the healthcare management features described herein being accessible to patients using software or scripts written in accordance with known interactive television transmission platforms and protocols, such as that provided by OpenTV's suite of EN2 set-top box software, software development tools, studio authoring tools, and Openstreamer data streaming software.

[0076] In response to user requests, the infomediary server scripts 112 access the database 104, which contains numerous data tables as shown in FIGS. 18-22. For example, ASP scripts provide database access via Microsoft's ActiveX Data Objects (ADO), which allows access to ODBC or OLEDB compliant data source including Microsoft Access (Jet), Microsoft SQL Server, and Oracle databases.

[0077] The data tables will now be described with reference to FIGS. 18-22. The various tables in FIGS. 18-22 make up a relational database, where the tables are related as indicated by the interconnecting lines. As is known to those of skill in the art, tables within relational databases may exhibit a one-to-many relationship. An exemplary description of such a relationship will be given with reference to the UserID of the TWebUsers table 800. The remaining tables are related in a similar manner as is apparent from the drawings.

[0078] Table 800 contains a record for each of the users of the infomediary site 100. Each UserID is a unique number defining a particular user's characteristics, including their login name, password, usertype, and a timestamp indicating when the record was created. The tables 801, 803, and 805, all include fields that are linked to the UserID within table 800. The key symbol at the end of the lines connected to table 800 indicate that the value within the UserID field specifies a unique record within the tWebUsers table 800, while the infinity symbol on the other end of the lines connected to tables 801, 803, and 805 indicate that more than one record in those tables can be linked to the same UserID in table 800. As is known to those of skill in the art, relating the tables in this manner results in a more efficient and powerful database structure than a single large data table.

[0079] The table contents will now be generally described, in view of the above-defined relationships. When a patient initially registers with the infomediary site 100, he or she is associated with a physician. The registration is typically performed by the physician's office assistants (independently or with the aid of infomediary site personnel) in advance of the patient's first visit to the infomediary site. With reference to FIG. 20, client patient table 840 links a patient's webuser ID to the relevant physician webuser IDs. Table 841 links physicians (by the clientID) to a physician profile including an affiliated hospital, degree, and region (further described in client region table 844). As shown in client assistant map table 842, each physician assistant has an assistant ID, a clientID (i.e., physician), and a permission level (as described in permission level table 843). Physicians

may be categorized according to client category map table 846 (as described by client news category table 847, and news stories may be categorized as shown in table 845).

[0080] With reference to FIG. 18, tables 801, 802, 803, 804, 807 and 808 are used to gather the patient history data. Either the patient or data entry personnel (such as a physician's assistant or a case manager or technician provided by the infomediary site) using an appropriate interface (preferably a GUI, such as a web browser, or another database entry interface) collects data that is inserted into the tables. The tables are preferably accessed using a data entry interface such as the web pages provided by the web server 112. When the patient or data entry personnel navigate to the relevant input screens, the database management system 115 (or server scripts 112, such as ASP server scripts) queries the question map table 801 to determine which questions the physician wishes to ask his patients. Each physician (identified by the ClientID field in table 801, which is in turn linked to a UserID in table 800) may create a customized list of questions from a question pool. The list of questions is stored as individual records in table 801 corresponding to that physician. The questionIDs are used to retrieve the question text and response format from question pool table 808. The description of the response format is then obtained from table 809, and the question is presented to the patient. If the patient is accessing the site directly, the questions are preferably presented in the form of web pages to the patient. If data entry personnel are utilized, the question may be read to the patient to solicit the response. The responses are entered and submitted to the database system, and are stored in tables 802 and 803. Tables 804, 805, 806, 809, 810 and 811 are used in a similar to gather compliance information.

[0081] With reference to FIG. 19, tables 820, 821 and 822 are used to gather guest information, including requests for information and contact information. Tables 825 and 826 are used to provide a communication interface that facilitates communication between physicians and patients. The sender and receiver are identified, along with the subject, body, date, time and priority, etc. Thus, when a physician logs in and requests to view his email, the communication interface, preferably made up of server scripts and database management software, queries email table 826 for all entries having the physician's UserID (table 800) in either the senderID or receiverID field. Those entries may be looked up in email audit table 825 to check the status.

[0082] Table 827 keeps a log of frequently asked questions (FAQs—as stored in FAQ table 824) that have been accessed by a given patient, thus allowing a physician to obtain further information about potential concerns of his or her patients. With reference to FIG. 21, Letters of consultation may be created using tables 850, 851 and 854. New diagnoses are created via the physician data access interface and stored in table 852. The template for creating a diagnosis may be created using standard diagnostic phrases obtained from tables 853 and 856. The new diagnosis template may present the cardiologist with certain diagnosis suggestions based on the test results. Specifically, the diagnostic 113 engine may perform algorithmic tests on new test results and store one or more diagnosis candidates in diagnosis fields (not shown) in the test results table 902.

[0083] With reference to FIG. 22 treatment plans are stored in tables 860-865. Physicians, through the physician

data access interface, create treatment plans for individual patients. Typically, the treatment plan is created or updated after test results become available. The treatment plan template is preferably generated and stored in treatment plan table 860, reading assignment table 861, Exercise assignment table 862, diet assignment table 863, CV product assignment table 864, and education assignment table 865. Tables 866, 867, 868, 869, 870, 871 and 872 are used to store possible selections for the corresponding tables as shown in FIG. 22. When a treatment plan template is generated for the physician, the diagnostic engine may be utilized to query Diagnosis table 852 and responsively determine suggested treatment plan components to be displayed as a suggested treatment plan within the template.

[0084] The diagnostic engine may also query relevant test result tables, patient history tables, compliance tables and the like to determine the suggested treatment plan. Prior to the cardiologist's review of the suggested treatment plan, the case manager or physician's assistant may initially access it to review it. The case manager may modify the plan or accept it and submit it to the cardiologist for final approval and posting to the patient's folder where the patient may view the plan.

[0085] With respect to FIG. 25, the flow chart for the method 1000 will be described. At step 1002 the test result data is stored. As described herein, the test data may be received over a network from a lab. At step 1004 the test result data is supplied to the physician. Preferably, the test data is provided using web pages conveyed over a network. At step 1006 the site receives diagnostic data from the physician. The diagnostic data is stored in the database as part of the patient's record. At step 1010 the site receives treatment plan information from the physician. The treatment plan is likewise stored in the patient's record. At step 1012 the site provides treatment plan information to the patient, also via web pages conveyed over a network.

[0086] With respect to FIG. 26, the flow chart for the method 1100 will be described. Steps having the same number as in the method 1000 are essentially the same. However, the method 1100 includes additional steps. At step 1003 the test result data is analyzed. The analysis is preferably performed using diagnostic engine 113. The diagnostic analysis information is stored in a table and associated with the relevant test results. The diagnostic analysis data is preferably one or more suggested diagnoses based upon the test results and other salient data from the clinical database 105 and information database 104. At step 1005 the test result data and the diagnostic data is supplied to the physician. At step 1007 the site analyzes the diagnostic data received from the physician. The analysis preferably identifies possible treatment plan information, including possible prescriptions, diets, exercises, CV products, educational materials, etc., as discussed above. It should be noted that information identified as being provided to and received from the physician may actually be submitted and received by a physician's assistant, nurse, or other responsible party. The term physician is used in this context to refer to the fact that the submission of diagnosis and treatment plans should be performed under the supervision of a physician.

[0087] FIG. 27 further illustrates the present invention. FIG. 27 is a Physician Composite Page 1100 which is a screen for physicians to use which shows Current Test 1101

in the center and is surrounded access locations to related screens: Demographics 1102; Medical History 1103; Diagnosis and Guidelines 1104; Goals and Notices 1105; Prescription Medication 1106; Diet 1107; Exercise 1108; Cardiovascular Products 1109; Educational Material 1110; Follow-up; Compliance 1111; Previous Test 1112. Thus, the physician may access current tests by patient and click onto any of the above-identified screens for more information related to the patient or that he can electronically provide to the patient. For example, FIG. 28(a) is the screen for Previous Test 1112 and FIG. 28b is the data in graphic form 1113. FIG. 29 is 1106 and FIG. 30 is the screen for Treatment Guidelines 1104.

[0088] FIG. 31 illustrates a Patient Composite Page which is a patient screen with information communicated between the patient and the doctor. The patient screen 1200 has icons to indicate a mailbox 1201 access; Diagnosis and Goals access 1202; Compliance access 1203; Medication Access 1204; and Test Results access 1205.

[0089] FIG. 32 shows a Compliance screen 1300 in which the patient records compliance data which is made available to a physician. Thus, a patient enters compliance data such as blood pressure, heart rate, weight, medication, exercise and forwards the data electronically to the physician.

[0090] A preferred embodiment of the present invention has been described herein. It is to be understood, of course, that changes and modifications may be made in the embodiment without departing from the true scope of the present invention, as defined by the appended claims. The present embodiment preferably includes logic to implement the described methods in software modules as a set of computer executable software instructions. The Computer Processing Unit ("CPU") or microprocessor implements the logic that controls the operation of the site, diagnostic engine, and database. The microprocessor executes software that can be programmed by those of skill in the art to provide the described functionality.

[0091] The software can be represented as a sequence of binary bits maintained on a computer readable medium including magnetic disks, optical disks, and any other volatile or (e.g., Random Access memory ("RAM")) non-volatile firmware (e.g., Read Only Memory ("ROM")) storage system readable by the CPU. The memory locations where data bits are maintained also include physical locations that have particular electrical, magnetic, optical, or organic properties corresponding to the stored data bits. The software instructions are executed as data bits by the CPU with a memory system causing a transformation of the electrical signal representation, and the maintenance of data bits at memory locations in the memory system to thereby reconfigure or otherwise alter the unit's operation. The executable software code may implement, for example, the methods as described above.

[0092] It should be understood that the programs, processes, methods and apparatus described herein are not related or limited to any particular type of computer or network apparatus (hardware or software), unless indicated otherwise. Various types of general purpose or specialized computer apparatus may be used with or perform operations in accordance with the teachings described herein.

[0093] In view of the wide variety of embodiments to which the principles of the present invention can be applied,

it should be understood that the illustrated embodiments are exemplary only, and should not be taken as limiting the scope of the present invention. For example, the steps of the flow diagrams may be taken in sequences other than those described, and more or fewer elements may be used in the block diagrams.

[0094] It should be understood that a hardware embodiment may take a variety of different forms. The hardware may be implemented as one or more server computers. For example, the web server may reside on one computing platform that accesses the database system residing on another computing platform.

[0095] The claims should not be read as limited to the described order of elements unless stated to that effect. In addition, use of the term “means” in any claim is intended to invoke 35 U.S.C. §112, paragraph 6, and any claim without the word “means” is not so intended. Therefore, all embodiments that come within the scope and spirit of the following claims and equivalents thereto are claimed as the invention.

What is claimed is:

1. A cardiovascular healthcare management system comprising:

- (a) an infomediary site having databases for cardiovascular healthcare management;
- (b) a data entry interface for receiving patient personal data and test results and storing the data and results in the infomediary site databases;
- (c) a diagnostic engine for analyzing patient test results;
- (d) a physician data access interface to allow physician access to the infomediary databases; and
- (e) a communication system allowing the physician to communicate cardiovascular healthcare management information to the patient.

2. The cardiovascular healthcare management system of claim 1 further comprising a cardiovascular knowledge base that stores information related to cardiovascular risk factors.

3. The cardiovascular healthcare management system of claim 1 wherein the diagnostic engine includes algorithms for associating test results with possible treatments.

4. The cardiovascular healthcare management system of claim 1 wherein the diagnostic engine includes algorithms for associating test results with possible diagnoses.

5. The cardiovascular healthcare management system of claim wherein the diagnostic engine includes algorithms for associating diagnosis information with possible treatment plans.

6. The cardiovascular healthcare management system of claim 1 wherein the diagnostic engine for comparing patient's test results compares inputted patient LDL subfraction and HDL subfraction values to normal LDL subfraction and HDL subfraction values.

7. The cardiovascular healthcare management system of claim 6 wherein the normal LDL subfraction and HDL

subfraction values are determined base in part of the values stored in the infomediary database.

8. The cardiovascular healthcare management system of claim 6 wherein the physician dynamically selects parameters for patient test results comparisons.

9. The cardiovascular healthcare management system of claim 1, wherein the patient provides compliance data that is stored in the records for later review by the physician.

10. The cardiovascular healthcare management system of claim 1, further comprising a patient access interface whereby the patient accesses a cardiovascular treatment plan.

11. The cardiovascular healthcare management system of claim 1, wherein the diagnostic engine analyzes test results and provides suggested diagnoses to the physician.

12. The cardiovascular healthcare management system of claim 1, wherein the diagnostic engine analyzes diagnostic information and provides suggested treatment plans.

13. A method of managing cardiovascular healthcare information, comprising the steps of:

- (a) storing test result data in a database;
- (b) providing test result data to a physician via a network;
- (c) receiving diagnostic information from a physician via a network;
- (d) receiving treatment plan information from a physician via a network; and
- (e) providing treatment plan information to a patient via a network.

14. The method of managing cardiovascular healthcare management system of claim 13, wherein the step of providing test result data is performed using internet protocols.

15. The method of managing cardiovascular healthcare management system of claim 13, wherein the step of receiving diagnostic information from a physician is performed using internet protocols.

16. The method of managing cardiovascular healthcare management system of claim 13, wherein all the steps of receiving and providing information are performed using internet protocols.

17. The method of managing cardiovascular healthcare management system of claim 13, further comprising the steps of analyzing the test result data and providing diagnosis information to the physician.

18. The method of managing cardiovascular healthcare management system of claim 13, further comprising the steps of analyzing the received diagnosis information and providing suggested treatment plan information to the physician.

19. The method of managing cardiovascular healthcare management system of claim 13, further comprising the step of receiving compliance information from a patient.

20. The method of managing cardiovascular healthcare management system of claim 13, further comprising the step of receiving compliance information from a patient.

\* \* \* \* \*

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摘要(译)

本发明涉及一种心血管保健管理系统，其作为具有数据库的信息媒体站点，该数据库具有与心血管疾病风险因素有关的信息，例如年龄，血压，LDL，HDL及其亚组分和心血管疾病管理，例如饮食，运动，药物和心血管疾病。教育材料。医生可以与信息中心站点进行电子通信以获得患者测试结果，并根据饮食，运动和药物数据制定患者治疗计划。医生可以通过信息媒体站点中的记录以电子方式将治疗计划传达给患者。患者可以通过患者记录以电子方式将合规信息传达给医生。信息中心站点还可以提供案例管理器以向医生提供初始治疗计划，收集患者历史数据和/或患者治疗计划依从性数据。

