US 20020035336A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2002/0035336 A1

Henkin (43) Pub. Date: Mar. 21, 2002

(54) VIRTUAL HOLTER

(75) Inventor: Raphael Henkin, Dana Point, CA (US)

Correspondence Address:
W.D. ENGLISH, ESQ.
DEL MAR MEDICAL SYSTEMS, LLC
1621 ALTON PARKWAY
IRVINE, CA 92606-4801 (US)

(73) Assignee: Del Mar Medical Systems, LLC

(21) Appl. No.: 09/944,846

(22) Filed: Aug. 31, 2001

Related U.S. Application Data

(63) Non-provisional of provisional application No. 60/230,520, filed on Sep. 1, 2000.

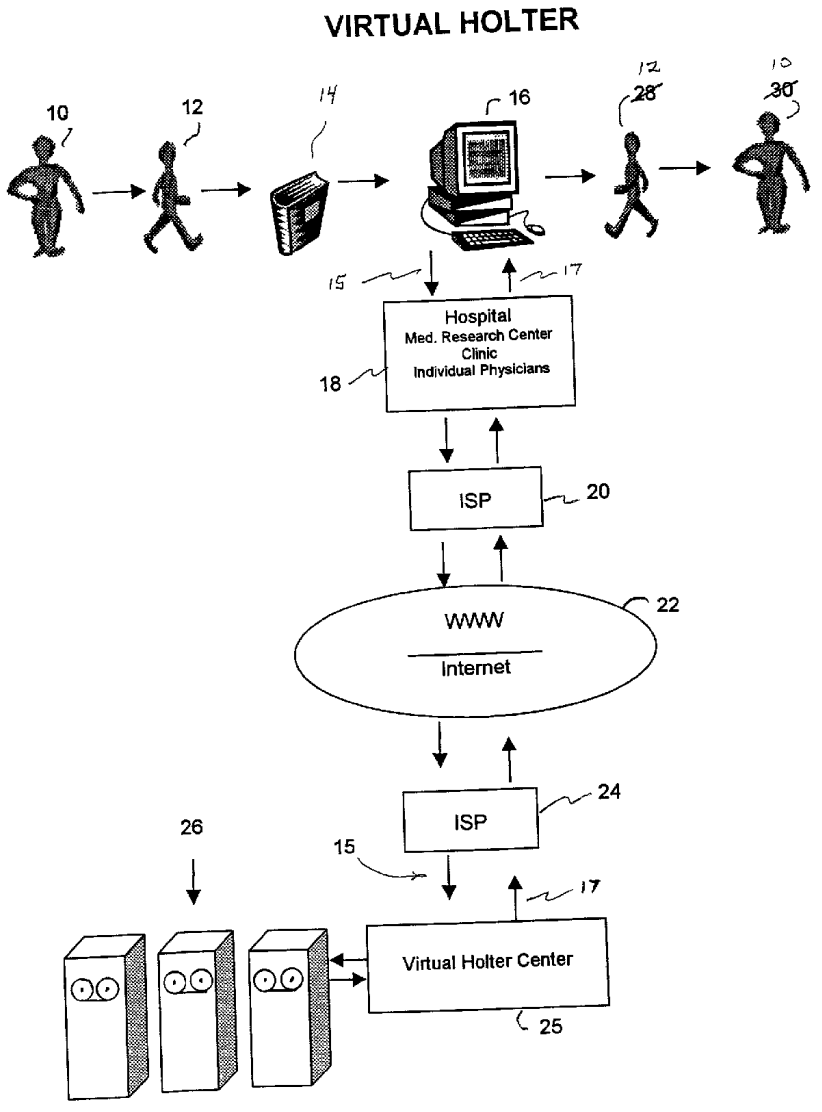
Publication Classification

(51) Int. Cl.[7] A61B 5/04

(52) U.S. Cl. 600/523

(57) ABSTRACT

The Virtual Holter process involves obtaining a Holter recording by conventional means, then down loading that analog or digital data to a PC, then going on line via said PC through and ISP such as DSL, capable of large data transfer, through a USB to tie into a URL web address for a Central Computing Facility, then downloading the Holter data to said URL, then scanning and analyzing said downloaded data at said Central Facility in real time from the remote site, then choosing which alternative analysis sub programs need be run on the stored data, and finally tagging, storing and archiving the raw ECG data and patient demographics, along with results of the various analyses performed on that data in the Central Facility archives for future access.



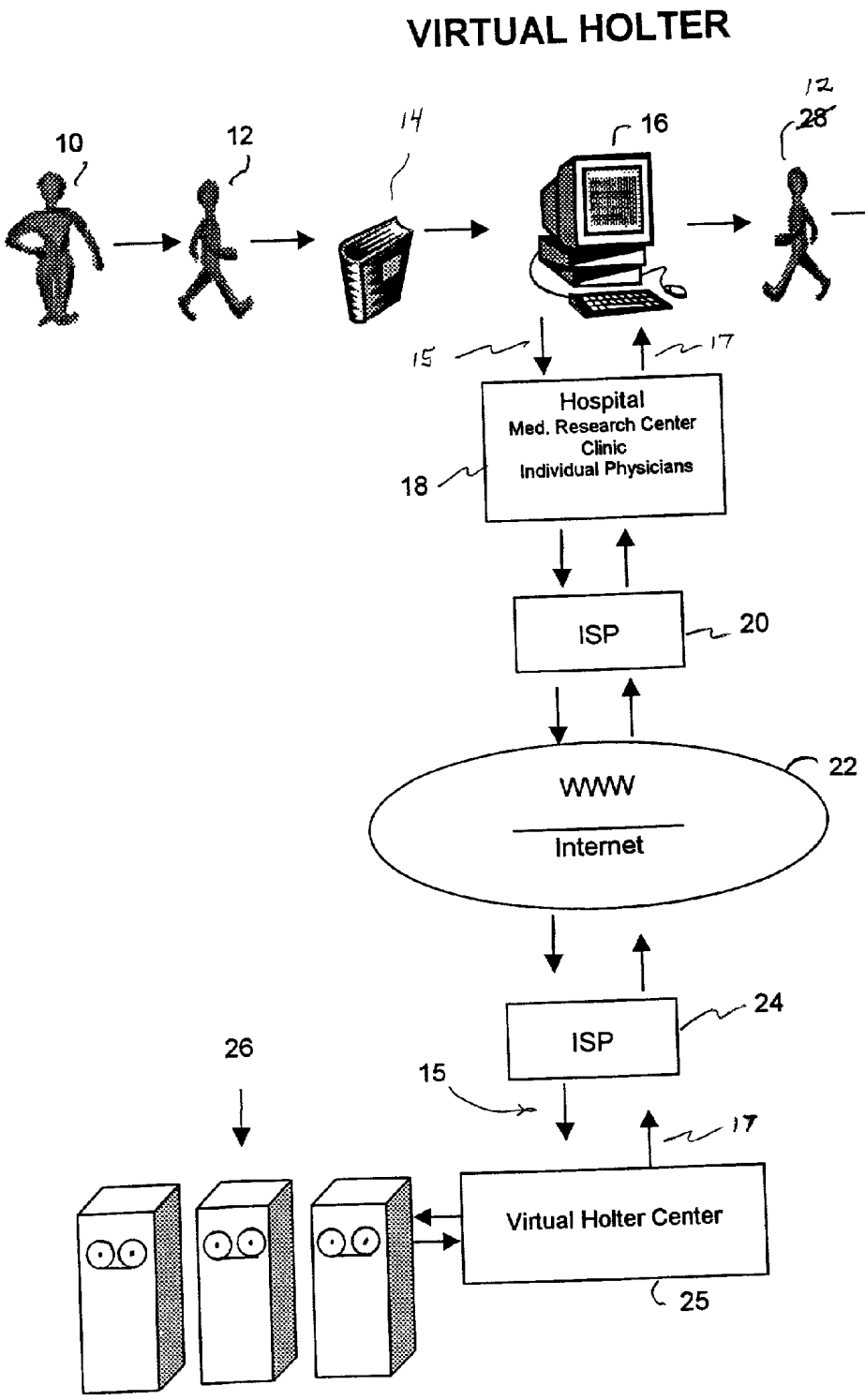

VIRTUAL HOLTER
10
12
14
16
12
28
10
30
15
17
Hospital
Med. Research Center
Clinic
Individual Physicians
18
ISP
20
WWW
Internet
22
ISP
24
26
15
17
Virtual Holter Center
25

Fig 1

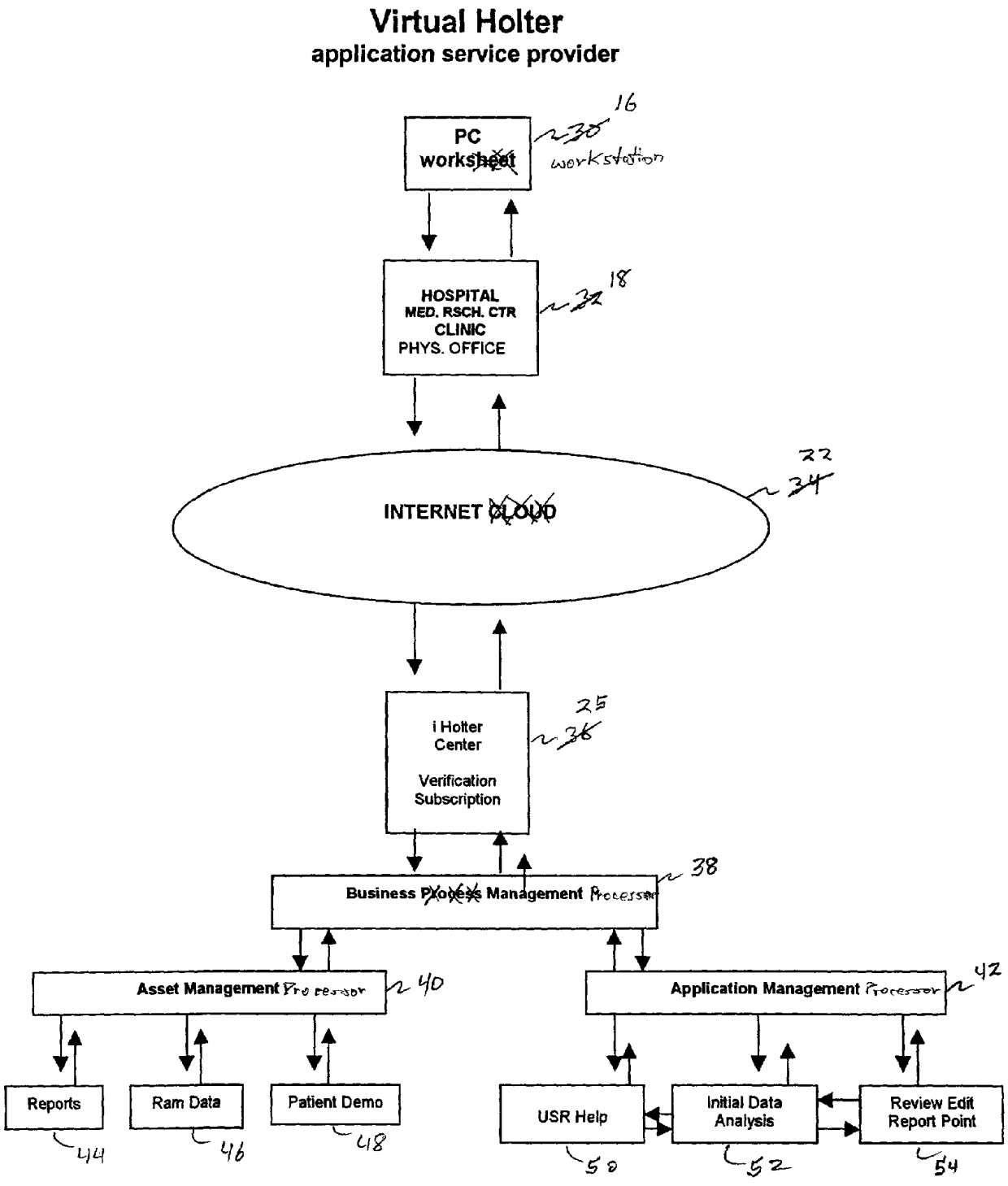

Virtual Holter
application service provider
16
PC
worksheet
workstation
HOSPITAL
MED. RSCH. CTR
CLINIC
PHYS. OFFICE
18
22
INTERNET CLOUD
25
i Holter
Center
Verification
Subscription
38
Business Process Management Processor
Asset Management Processor
40
Application Management Processor
42
Reports
Ram Data
Patient Demo
USR Help
Initial Data
Analysis
Review Edit
Report Point
44
46
48
50
52
54

FIG. 2

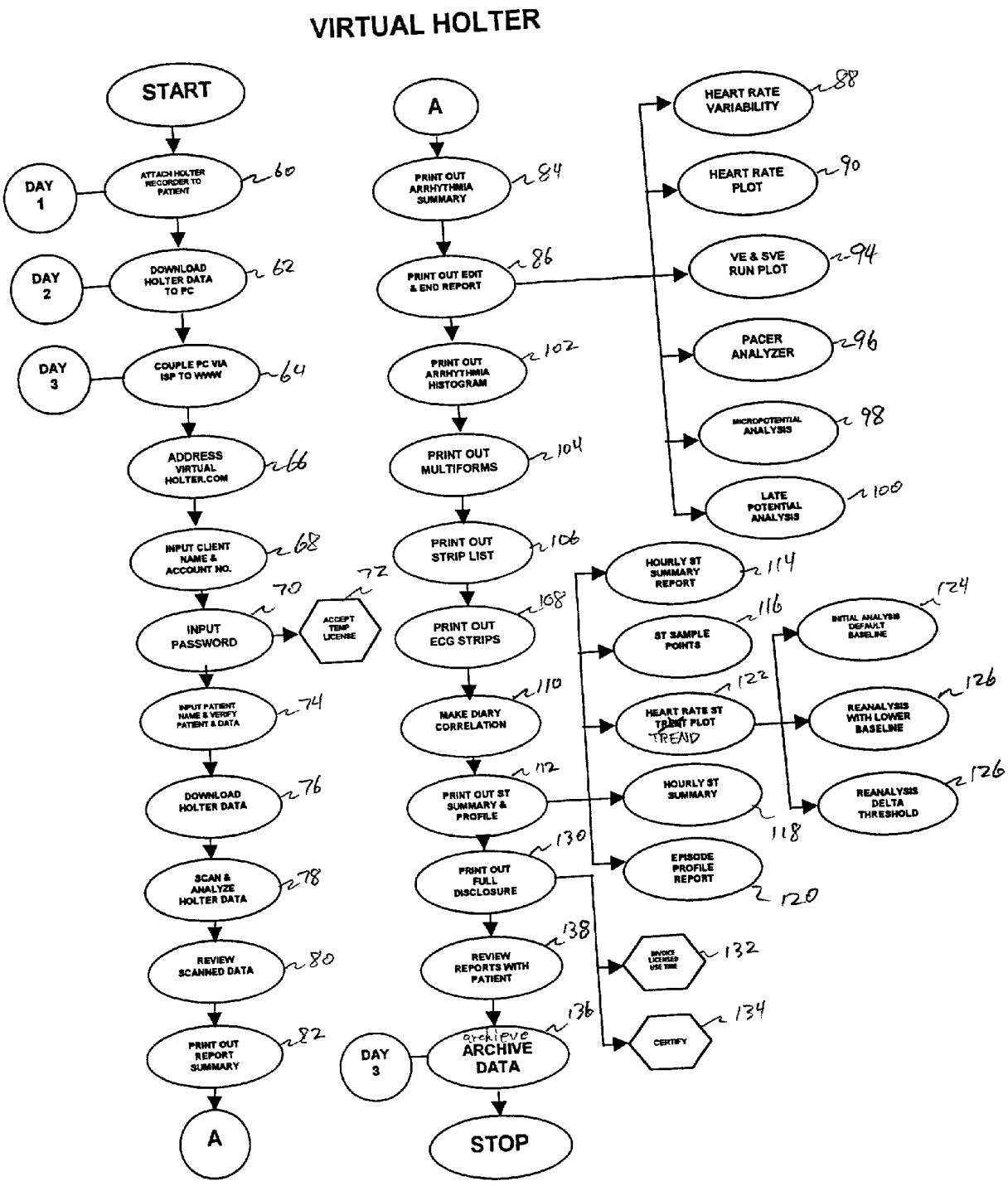

VIRTUAL HOLTER
START
DAY 1
ATTACH HOLTER RECORDER TO PATIENT
60
DAY 2
DOWNLOAD HOLTER DATA TO PC
62
DAY 3
COUPLE PC VIA ISP TO WWW
64
ADDRESS VIRTUAL HOLTER.COM
66
INPUT CLIENT NAME & ACCOUNT NO.
68
INPUT PASSWORD
70
ACCEPT TEMP LICENSE
72
INPUT PATIENT NAME & VERIFY PATIENT & DATA
74
DOWNLOAD HOLTER DATA
76
SCAN & ANALYZE HOLTER DATA
78
REVIEW SCANNED DATA
80
PRINT OUT REPORT SUMMARY
82
A
A
PRINT OUT ARRHYTHMIA SUMMARY
84
PRINT OUT EDIT & END REPORT
86
PRINT OUT ARRHYTHMIA HISTOGRAM
102
PRINT OUT MULTIFORMS
104
PRINT OUT STRIP LIST
106
PRINT OUT ECG STRIPS
108
MAKE DIARY CORRELATION
110
PRINT OUT ST SUMMARY & PROFILE
112
PRINT OUT FULL DISCLOSURE
130
REVIEW REPORTS WITH PATIENT
138
DAY 3
archieve ARCHIVE DATA
136
STOP
HEART RATE VARIABILITY
88
HEART RATE PLOT
90
VE & SVE RUN PLOT
94
PACER ANALYZER
96
MICROPOTENTIAL ANALYSIS
98
LATE POTENTIAL ANALYSIS
100
HOURLY ST SUMMARY REPORT
114
ST SAMPLE POINTS
116
HEART RATE ST TREND PLOT
122
TREND
HOURLY ST SUMMARY
118
EPISODE PROFILE REPORT
120
INVOICE LICENSED USE TIME
132
CERTIFY
134
INITIAL ANALYSIS DEFAULT BASELINE
124
REANALYSIS WITH LOWER BASELINE
126
REANALYSIS DELTA THRESHOLD
126

FIG. 3

VIRTUAL HOLTER

[0001] This patent application eminants from a provisional application of the same title and same inventor, Application No. 60/230,520, filed Sep. 1, 2000.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The invention disclosed herein lies in the general field of medical instrumentation and processes. In particular, the invention relates to a method for more expeditious and expansive analysis of Holter data, i.e. a long term, ambulatory electrocardiograph (ECG). More specifically, the invention discloses a Holter analysis process, whereby Holter data accessed from an ambulatory patient in virtually any part of the earth can be submitted by a clinician via a personal computer (PC) through an Internet Service Provider (ISP) over the Internet to a centralized massive computer center where the clinician can purchase a short term license for proprietary software and hardware to analyze the submitted data in real time and in a variety of processes and formats that might otherwise be too costly to perform. The concept of the Virtual Holter invention is a potentially generic business model for use of the Internet as a means for connecting clinicians world wide to a portal whereby the physician can acquire a short-term license to use sophisticated computer hardware and proprietary software.

[0004] 2. Description of the Prior Art

[0005] The application of ECG data collected from an ambulatory or mobile patient in an uncontrolled ambulatory environment, wherein the data is further analyzed and output in a variety of reports and formats has been in practice since the early 1960's. Known as Holter monitoring the technique is based upon the subject wearing a device that while worn collects ECG data. After a 24 to 48 hour period of continuous ECG recording, the device is removed from the patient, and the storage media (e.g. cassette tape, digital memory, etc.) is further analyzed by a trained clinician in a Holter center with a expensive Holter scanners and analyzers to create a summary document that may be accurately reviewed for diagnostic relevance by a physician or cardiologist.

[0006] The recording devices can exist at any clinical site; however, the Holter scanners and analyzers that contain proprietary software modules to summarize the collected data stream are located in clinical facilities or scanning centers that can afford the cost of the software and hardware as well as the technical staff required to operate the Holter system. The data distribution model in its most basic form assumes the collected ECG data makes its way by conventional mail or hand delivered to the site where analysis and reporting occur. The clinician who cannot justify the purchase of the expensive Holter scanners and analyzers has no alternative but to contract a facility capable of performing the analysis of Holter data and to provide a summary report. The accompanying delays in turnaround time of the report delivered by hand or by mail and the multiple parties involved in accessing the relevant reports only adds layers of unnecessary costs and loss of time, personnel intervention and accompanying opportunity for loss of data and error in reports.

[0007] A great variety of various wireless or telemetric, remote Holter monitoring devices have been conceived in the prior art that bear some distant relationship to the development of **20** and need for the Virtual Holter invention at hand. U.S. Pat. No. 5,544,661 issued to Davis disclosed an ambulatory ECG monitoring device that tabulated and analyzed data, which data was subsequently transferred by a cell phone to a centralized monitoring and information management system for further evaluation by a clinician or primary physician. U.S. Pat. No. 5,678,562 issued to Sellers describes a similar ambulatory physiological monitor that accumulates data that can be transferred by modem and cellular telephone to a remote PC wherein the PC can in turn operate upon and control the ambulatory monitor. In still another U.S. Pat. No. 5,704,351, Mortara, yet another digital telemetry system is disclosed that transfers by telemetric means up to eight channels of ECG data. In U.S. Pat. No. 5,752,976, Duffin, a world wide global positioning satellite, patient location and data telemetry system for implantable medical devices is disclosed. The system has the capacity to remotely locate a particular patient with an implanted medical device and can selectively monitor and operate upon a particular device world wide by telemetric means. U.S. Pat. No. 5,944,659, Flach, discloses yet another telemetric system for collection of physiological data that transmits data in real time to a centralized real time data distribution network. In U.S. Pat. No. 6,093,146, Filangeri, a pair of wireless transmission circuits are utilized in a physiological monitoring system, one for transmitting data to a centralized facility and the other acting as a communications link between the patient monitor and a base station.

[0008] It should be appreciated that applicant's invention is not a telemetric ECG system; however the only prior art systems that may relate to applicant's invention by attempting to pass ECG data to a central facility for further analysis by the clinician all relate to telemetric devices. And all of the known telemetry systems have had one or more disadvantages. Telemetry systems are typically designed for use within a limited geographical area, such as a hospital or the home. In past Holter telemetry systems, the patient's mobility is limited, and data is lost if the patient goes outside the coverage area of the system. In addition, telemetry systems transmit raw data continuously, thus requiring a dedicated transmission channel. Furthermore, prior art telemetry systems are relatively complex and expensive to operate.

[0009] Although there are numerous telemetric physiological monitoring systems for transmitting long term, ambulatory, physiological or ECG data monitors to a centralized facility for analysis or archival storage, there are no systems transmitting Holter data over a hard wired low cost medium of a local call, telephone interlink world wide, i.e. over the Internet, to a sophisticated computer facility with a wide variety of relevant software whereby one can purchase a limited license to use the centralized computer and proprietary software to perform in real time an analysis of the Holter data in a variety of differing formats and reports. The appears to be a long standing need for the implementation of a system where even very small scale clinics in any part of the world can have immediate access to very expensive computer hardware and relevant sophisticated, proprietary software to make a real time analysis of data in various formats.

SUMMARY OF THE INVENTION

[0010] The invention discloses a process for implementing and producing a Holter electrocardiograph any where in the

world followed up by submitting the recorded data therefrom on a local phone line via a PC or independent modem over the Internet to a centralized and sophisticated Holter data analysis and processing facility where the clinician or physician at a remote facility can periodically purchase a short term license to actively use on line, in real time the sophisticated computer hardware and software of the Holter center to conduct a variety of extended and detailed reports of the analysis of the long term, ambulatory ECG data from the remote clinic or medical facility. Many remote facilities around the world may not have sufficient funds and amenities to provide access to expensive, complex, elaborate and sophisticated computer hardware and software to adequately perform a through ECG analysis with any great degree of depth and breadth of understanding.

OBJECTS OF THE INVENTION

[0011] It is a primary object of the invention to provide an inexpensive and world wide access (from major urban centers to remote jungle villages) to a large, sophisticated, state of the art, expensive and centralized Holter ECG data scanning, analysis and archiving hardware and software system.

[0012] It is another object of the invention to provide a world wide, real time access to a centralized Holter scanning and analysis service.

BRIEF DESCRIPTION OF THE DRAWING

[0013] **FIG. 1** illustrates a general block flow diagram of the invention process.

[0014] **FIG. 2** illustrates a more specific explanation of the invention process.

[0015] **FIG. 3** illustrates a specific process a physician or clinician may use in real time evaluation of an ECG.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

[0016] In the proposed model, the Virtual Holter, InternetHolter, iHolter process will provide an opportunity for a clinician or physician to download Holter ECG recordings to perform a scan, analysis, review and edit of data collected from patients, without the need to purchase an up to date, complete ECG scanning and analysis system. In the proposed process, the Internet will mediate the transmission and data download process, and costs will be accrued at the centralized Holter facility based upon invocation of the recording for analysis. By such means, a clinician with a small cardiology clientele, that would not justify the purchase of requisite expensive instrumentation and software, would have the capacity to perform tests directly, online and in real time by "renting" or more accurately "obtaining a temporary license" to access a world centralized Holter data scanning and analysis facility, thereby having access to analysis capability in state of the art hardware and software to adequately address his limited and infrequent needs.

[0017] Applicant envisions three possible scenarios that a physician might take after performing a lengthy Holter ECG on a patient:

[0018] 1. A clinician can download a complete Holter recording via a Personal Computer (PC) through an Internet Service Provider (ISP) over the Internet to access the on-line centralized Holter data scanning and analysis system, thus enabling the physician to scan and analyze ECG in real time on line, and to obtain a complete analysis, review and edit of the data prior to printing the report.

[0019] 2. The clinician can download an array of post-processing and editing tools from the centralized scanning and analysis system capable of a complete retrospective review of the data. The assumption is that the data will have been previously analyzed

[0020] 3. The clinician can be provided with a limited review, edit and commentary application, which would enable a complete overview of pre-analyzed data. The assumption again is that the data will have been previously analyzed.

[0021] For each of these scenarios, the proposed website will provide the ability for the clinician to send and upload the ECG data, call for, activate and receive a summarized report from the data, and provide other asset management features as well. The archival of these data will create a digital file for each specific repository tailored to the clinicians needs.

[0022] Features for the site are to include:

[0023] 1. A home page directing the flow of data and data analysis.

[0024] 2. An education level for the use of the site and its content.

[0025] 3. A subscriber level for the protected and secure upload and download of pertinent data.

[0026] 4. A training and help site enabling the clinician to gain assistance in the use of the data analysis system and the applications.

[0027] 5. An e-commerce level for subscription to application use, as well as enrollment in the asset management abilities.

[0028] 6. A secondary e-commerce level for the purchase of recording devices and associated accessories.

[0029] 7. A level dedicated to the subscriber who employs the asset management segment of site.

[0030] The foregoing features are part of the proposed site; however, the site is not limited to these features exclusively and may require modifications to address other environments outside the Holter field.

[0031] For a more detailed flow diagram of the Virtual Holter process, reference is made to **FIG. 1** of the attached Drawing. In **FIG. 1, a** physician **10** consults with a patient **12** and attaches a long term, ambulatory electrocardiograph recorder (i.e. Holter recorder) **14** to the patient on day 1. The next day on day 2 the completed 24 hour ECG recording of real time ECG analog or digital data "raw data"**15** on recorder **14** taken from the patient and is downloaded to a Personal Computer (PC) terminal **16** in a hospital, medical research center, university, clinic or an individual physician's office **18**. The attending physician or clinician would then, by means of the PC modem and Universal Serial Buss (USB) port, go on line through his Internet Service Provider (ISP) **20**, which preferably should be via an ISDN, DSL, T1-T3, or cable account, i.e. high data transmission account

to accommodate the high data transmission capability needed, then over the Internet/world wide web (WWW) **22** to a "Virtual Holter or iHolter Center"**25** through its ISP **24**. Raw ECG data **15** is passed to a massive, centralized computer hardware facility **26** where the raw data is scanned, processed and analyzed in real time to the attending physician **10** by highly sophisticated and complex proprietary software. The attending physician **10** is granted a limited user license each time he logs on, and is thereby granted access for a specified cost /unit time via negotiated contracts between the individual physician, hospital, university, etc. and the Virtual Holter facility. The scan and analysis occurs at the central facility **25** and is observed in real time by the clinician at his PC terminal **16**. Alternatively, the clinician my simply download his ECG data over the internet and pay an additional fee to have personal at the Center **25** perform a specifically requested scan and analysis. In which case, the scanned and analyzed data could be returned within the hour via the reverse path from computer center **26** to Virtual Holter Center **25**, to ISP **24**, over the Internet **22** to ISP **20** to PC terminal **16** in the hospital, clinic or physician's office **18** from which the ECG data was submitted. A consulting physician **28** then discusses the analyzed results on patient day 3 for a swift, relatively inexpensive Holter diagnosis.

[**0032**] Referring now to **FIG. 2, a** more detailed analysis is delineated on the data process distribution at the centralized Holter analysis facility. In **FIG. 2 a** clinician would be situated at a PC Workstation **30** situated in his office **32** and communicating on line over the Internet **34** with a Holter Center **36**. At the Holter Center **36**, data input/output is time shared and multiplexed through a Business Management processor **38** which directs traffic to either an Asset Management processor **40** or to an Applications Management processor **42**. Data and communication as falling under Asset Management are in turn distributed to relative functional categories of Reports **44**, RAM data **46** and Patient Demographics **48**. Correspondingly, data and communications falling under Applications Management are in turn distributed to functionally relative categories of USR help **50**, Initial Data Analysis **52**, and Review Edit Report Point **54**.

[**0033**] Referring now to **FIG. 3, a** detailed description of a typical ECG analysis process that might be utilized by a clinician in real time at the Computer Center **25** from a remote clinic **18**. On day 1, a Holter recorder **60** is attached to an ambulatory patient. On day 2, or 24 to 48 hours later, the patient returns to the clinic, the recorder is downloaded to a PC **62**. On the same day or day 3, a clinician at the clinic goes on line with the PC **64** to couple the remote computer site with the main frame computers at the Computer Center at its URL of VirtualHolter.com **66**. Once on line, the Computer Center will make inquiry as to the users qualification to enter; client name, account number and pass word must be inserted to be allowed to enter **68**. Upon entering the proper password, the clinician is allowed to pass **70** and must then agree to an on line limited license **72**.

[**0034**] Now that the clinician is admitted, his computer access billing time commences. The new patient account is now entered by entering patient name and appropriate verification factors **74**. At this point the raw Holter data is downloaded **76** from the remote site computer terminal **16** to the Central Computer Facility **25**. Once all Holter data is downloaded, the command for Scan and Analyze is implemented **78**. In a few brief minutes the Holter data is scanned before the clinician's eyes on his remote terminal. The command prompt to review scanned data is then made **80** and is followed by a command to print out a report summary **82**.

[**0035**] At this point, the clinician may invoke one or all of several proprietary software packages to evaluate different aspects of cardiology interpretation. The clinician may print out an arrhythmia summary **84**. The clinician may also print out an "editrend report"**86** which in turn gives rise to related reports: Heart Rate Variability **88**, Heart Rate Plot **90**, Ventricular Eptopic and Supra Ventricular Eptopic Plots **92** and Run Plots **94**, a PaceMaker/Pacer Analyzer report **96**, a Micro Potential Analysis report **98**, and a Late Potential Analysis report **100**. The clinician may then proceed to print out an arrhythmia histogram **102**, multiforms **104**, strip list **106**, ECG strips **108**, and a diary correlation **110** can be made with respective ECG PQRST wave form events. The clinician, still in real time over the Internet, can still print out yet other descriptive reports such as the ST Summary and Profile **112**. In the ST Summary software, the clinician can also obtain and hourly ST Summary report **114** and ST Sample Points **116**, an Hourly ST Summary **118**, an Episode Profile report **120**, and a ST Heart Rate ST Trend Plot **122** that is further defined by an Initial Analysis Baseline **124**, a Reanalysis Lower Baseline **126** and a Reanalysis Delta Threshold **128**. At the end of a lengthy ECG

We claim:

1. A method for performing a Holter diagnosis, comprising the following steps:

accumulating ECG data by conventional Holter means,

downloading said data to a PC,

passing said data from the PC over the Internet to a large and complex centralized Holter data analysis computer facility,

scanning and analyzing said Holter data in real time, at the remote site coupled to the Holter Computer Center, on proprietary software on sophisticated computer hardware and software on a temporary/limited license use per hour basis,

returning said processed and analyzed ECG data as it is being scanned and analyzed by an identical reverse path over the Internet to the remote site sending PC, and

disclosing said Holter analysis by conventional means to the patient.

2. Apparatus for performing complex physiological data analysis in real time on patients in remote areas, comprising:

recorder means for accumulating physiological data over an extended period of time from an ambulatory patient in a remote area;

remote computer terminal means for accessing and uploading said recorded data through an Internet Service Provider to the Internet;

central computer site means for coupling with said remote computer terminal over the Internet;

means disposed at said central computer site that enable an operator at said remote site for obtaining a limited and periodic license to access sophisticated software and hardware at said central computer site for performing in real time selectable, specialized data analysis of said physiological data not otherwise accessible at said remote site.

* * * * *

专利名称(译)	虚拟动态心电图		
公开(公告)号	US20020035336A1	公开(公告)日	2002-03-21
申请号	US09/944846	申请日	2001-08-31
[标]申请(专利权)人(译)	del Mar的医疗SYST		
申请(专利权)人(译)	del Mar的医疗系统，LLC		
当前申请(专利权)人(译)	太空实验室医疗，有限责任公司		
[标]发明人	HENKIN RAPHAEL		
发明人	HENKIN, RAPHAEL		
IPC分类号	A61B5/00 A61B5/04		
CPC分类号	A61B5/0006		
优先权	60/230520 2000-09-01 US		
其他公开文献	US6701184		
外部链接	Espacenet USPTO		

摘要(译)

虚拟动态心电图过程包括通过常规方式获取动态心电图记录，然后将该模拟或数字数据下载到PC，然后通过所述PC通过和诸如DSL之类的ISP上线，能够进行大数据传输，通过USB连接到中央计算设备的URL网址，然后将Holter数据下载到所述URL，然后从远程站点实时扫描和分析所述中央设施处的所述下载数据，然后选择需要运行哪些备选分析子程序存储的数据，最后标记，存储和存档原始ECG数据和患者人口统计数据，以及对中央设施档案中的数据进行的各种分析的结果，以供将来访问。