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(12) **United States Patent**
Brown

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(54) **ELECTRONIC DATA CAPTURE IN CLINICAL AND PHARMACEUTICAL TRIALS**

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This patent is subject to a terminal disclaimer.

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USPC **600/300**; 705/2; 705/3; 128/920; 128/905

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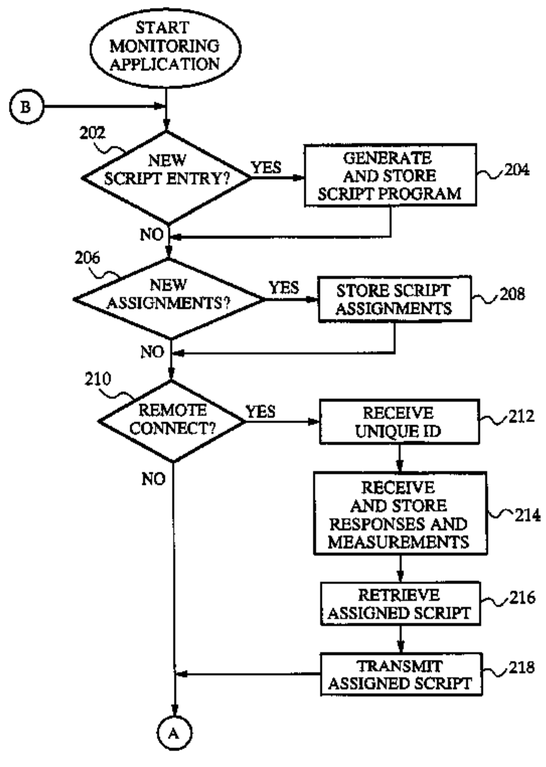
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(57) **ABSTRACT**

A system for remotely monitoring an individual. The system includes a server system for generating a script program from a set of queries. The script program is executable by a remote apparatus that displays information and/or a set of queries to the individual through a user interface. Responses to the queries that are entered through the user interface together with individual identification information are sent from the remote apparatus to the server system across a communication network. The server system also includes an automated answering service for providing a series of questions from a stored set of questions for an individual at the remote apparatus to respond to, storing responses to each provided question in the series of questions and providing a service based on the individual's response to the questions.

21 Claims, 20 Drawing Sheets



Related U.S. Application Data

continuation of application No. 09/658,209, filed on Sep. 8, 2000, now Pat. No. 6,968,375, which is a continuation-in-part of application No. 09/300,856, filed on Apr. 28, 1999, now Pat. No. 6,368,273, which is a division of application No. 08/946,341, filed on Oct. 7, 1997, now Pat. No. 5,997,476, which is a continuation-in-part of application No. 08/847,009, filed on Apr. 30, 1997, now Pat. No. 5,897,493.

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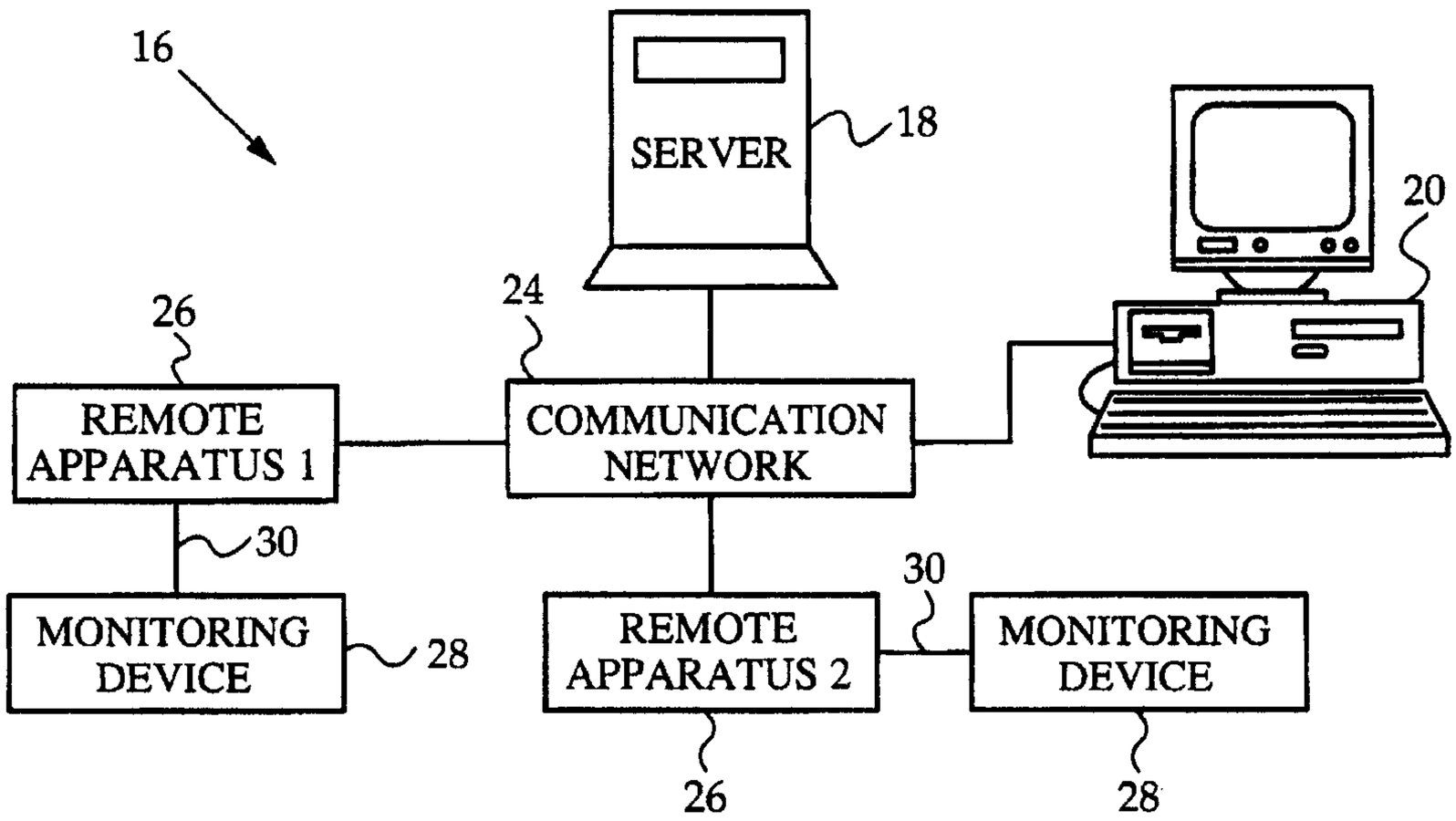

16
SERVER
18
20
24
26
REMOTE APPARATUS 1
COMMUNICATION NETWORK
30
MONITORING DEVICE
28
REMOTE APPARATUS 2
30
MONITORING DEVICE
26
28

FIG. 1

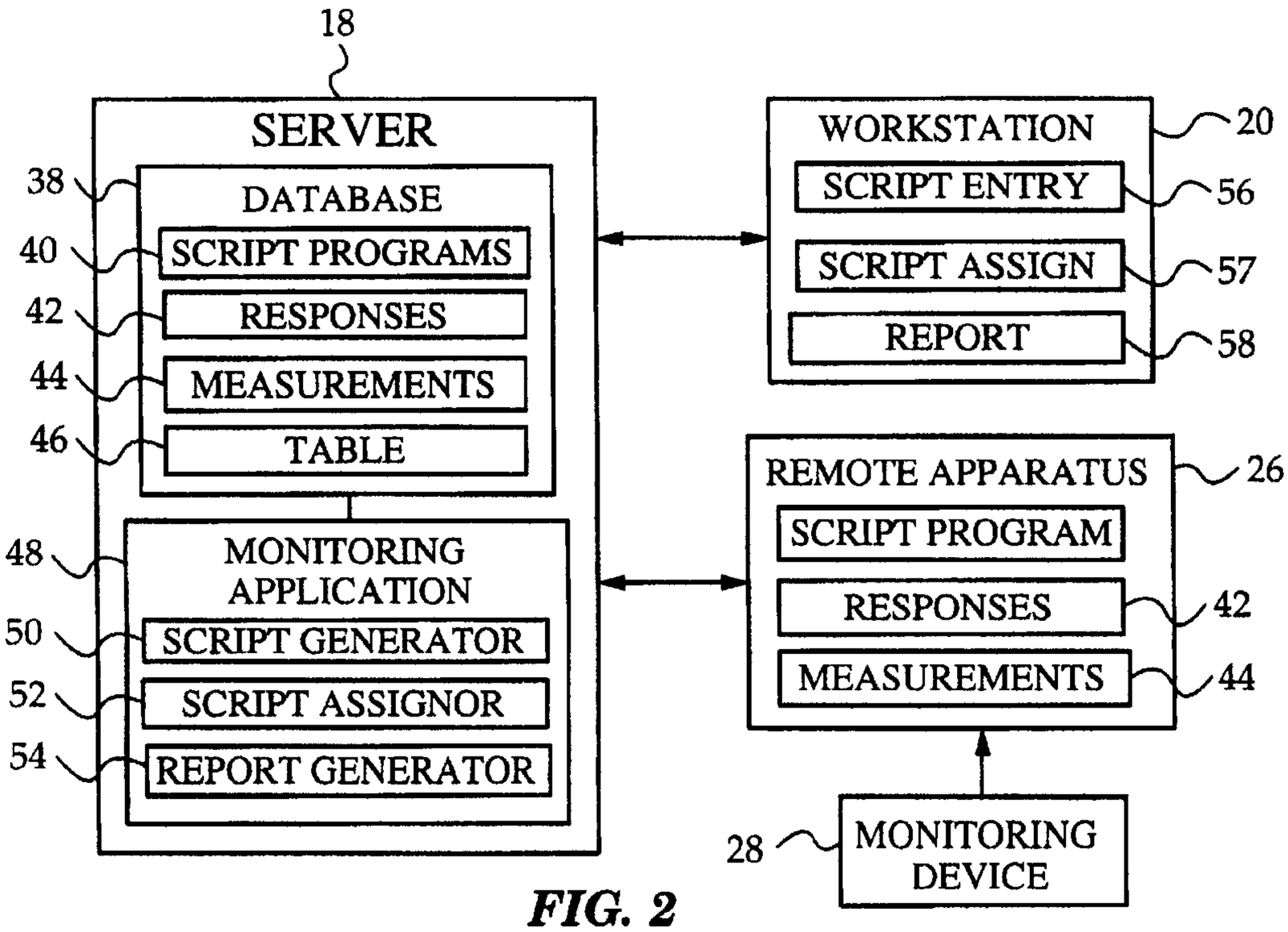

18
SERVER
38
DATABASE
40
SCRIPT PROGRAMS
42
RESPONSES
44
MEASUREMENTS
46
TABLE
48
MONITORING APPLICATION
50
SCRIPT GENERATOR
52
SCRIPT ASSIGNOR
54
REPORT GENERATOR
WORKSTATION
20
SCRIPT ENTRY
56
SCRIPT ASSIGN
57
REPORT
58
REMOTE APPARATUS
26
SCRIPT PROGRAM
RESPONSES
42
MEASUREMENTS
44
28
MONITORING DEVICE

FIG. 2

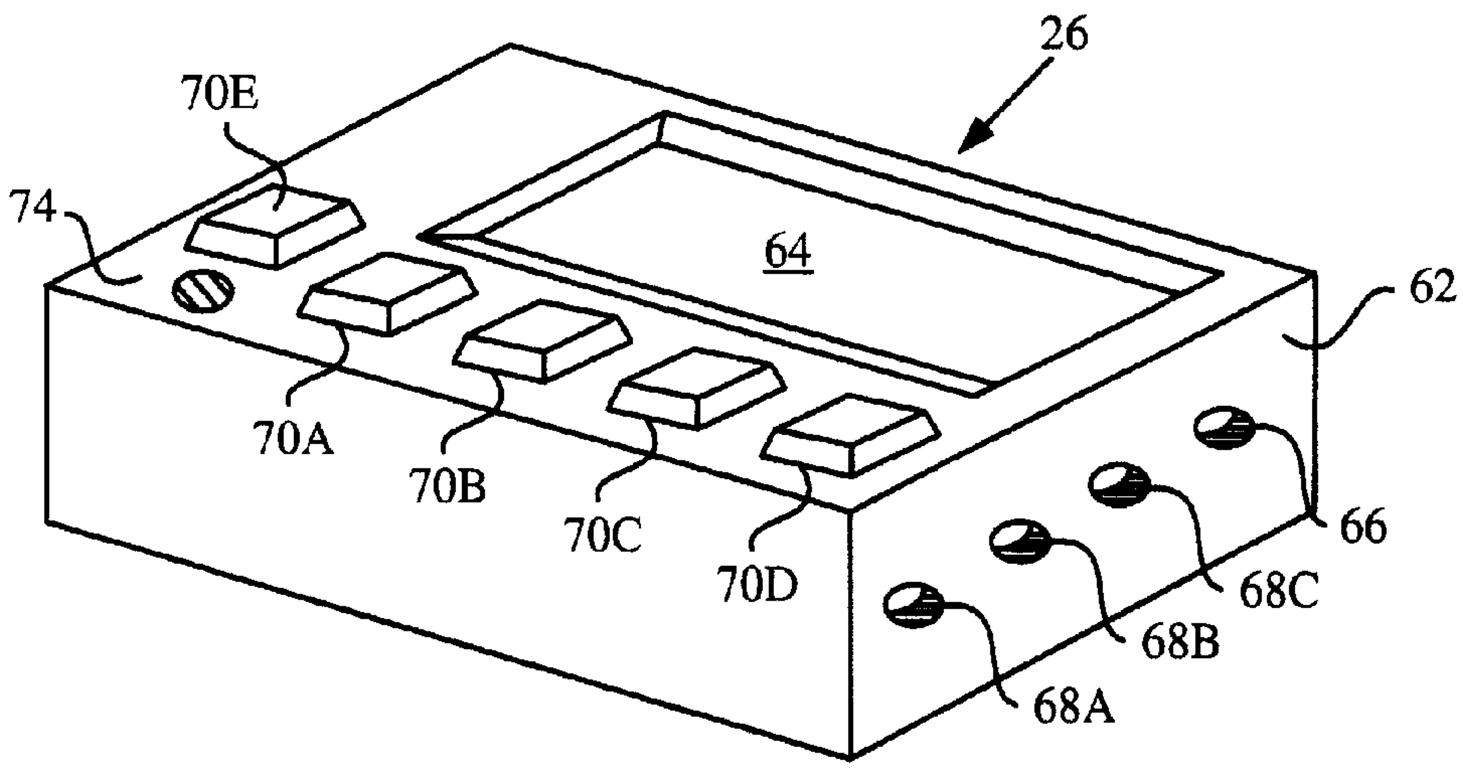


FIG. 3

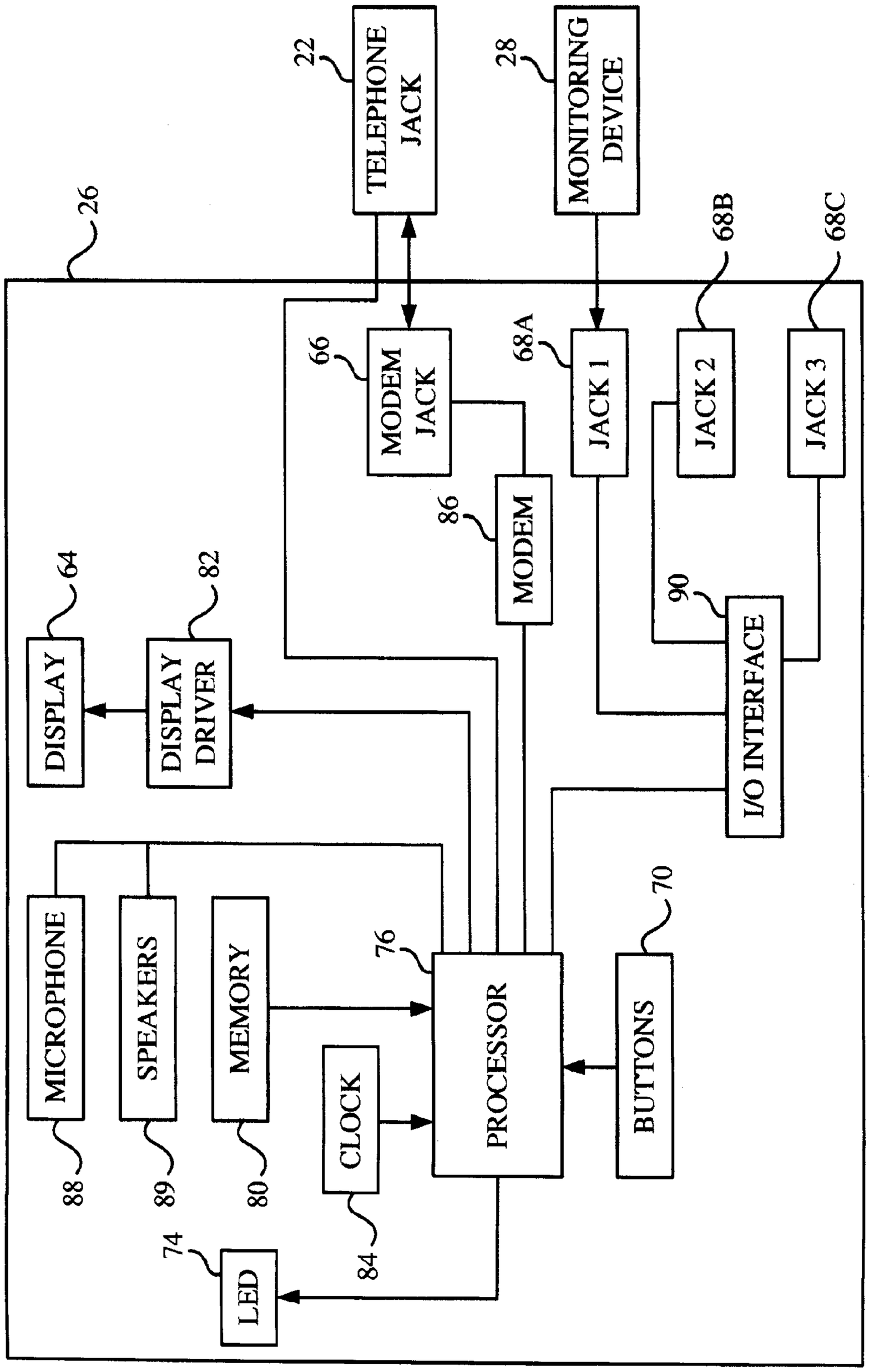

22
TELEPHONE JACK
28
MONITORING DEVICE
26
68B
68C
66
MODEM JACK
68A
JACK 1
JACK 2
JACK 3
86
MODEM
64
DISPLAY
82
DISPLAY DRIVER
90
I/O INTERFACE
70
MICROPHONE
SPEAKERS
MEMORY
CLOCK
PROCESSOR
BUTTONS
88
89
80
74
LED
84
76

FIG. 4

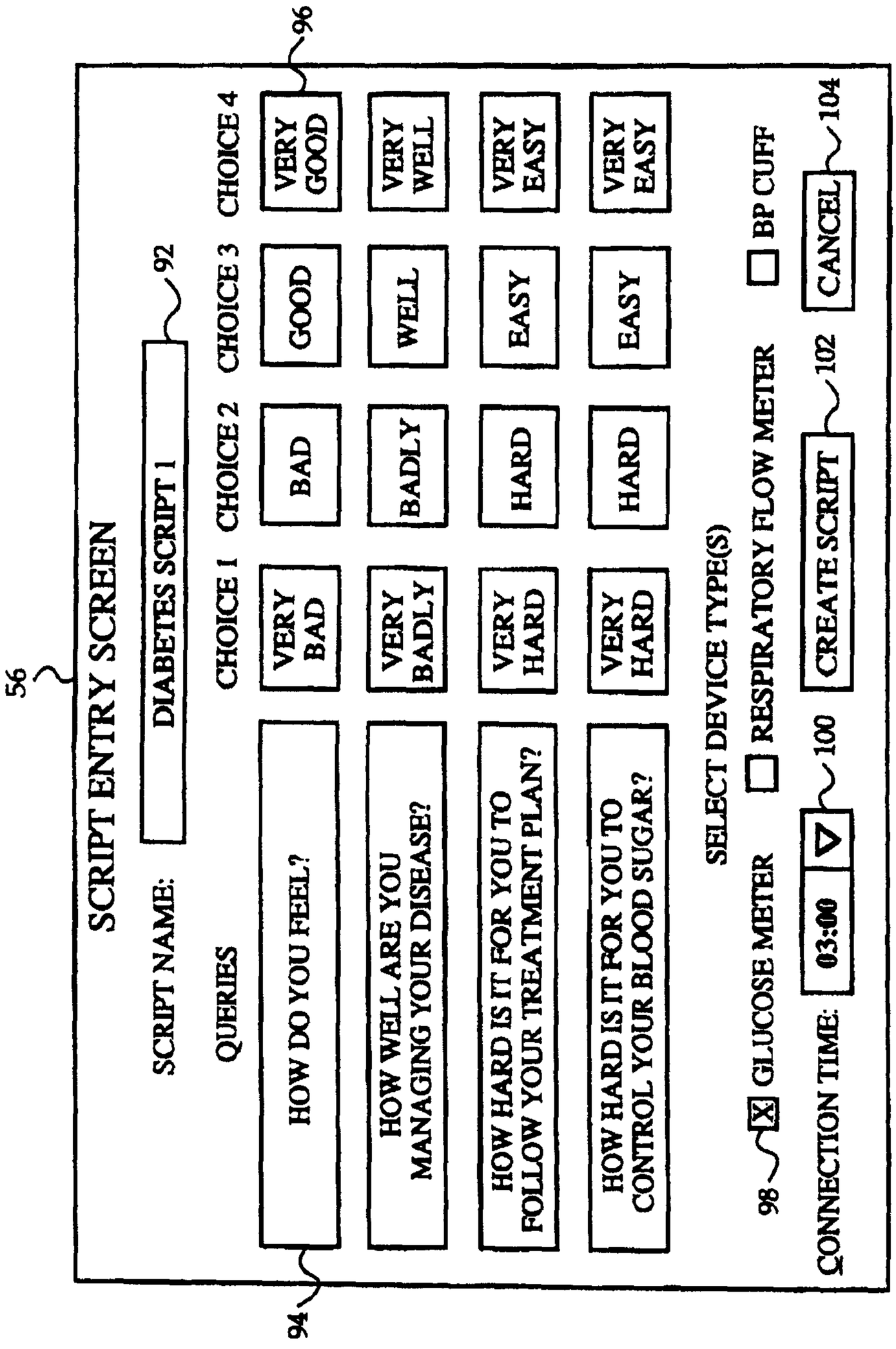

56
SCRIPT ENTRY SCREEN
SCRIPT NAME:
DIABETES SCRIPT 1
92
QUERIES
CHOICE 1
CHOICE 2
CHOICE 3
CHOICE 4
96
HOW DO YOU FEEL?
VERY BAD
BAD
GOOD
VERY GOOD
HOW WELL ARE YOU MANAGING YOUR DISEASE?
VERY BADLY
BADLY
WELL
VERY WELL
HOW HARD IS IT FOR YOU TO FOLLOW YOUR TREATMENT PLAN?
VERY HARD
HARD
EASY
VERY EASY
HOW HARD IS IT FOR YOU TO CONTROL YOUR BLOOD SUGAR?
VERY HARD
HARD
EASY
VERY EASY
94
SELECT DEVICE TYPE(S)
GLUCOSE METER
RESPIRATORY FLOW METER
BP CUFF
98
104
CONNECTION TIME:
03:00
100
CREATE SCRIPT
102
CANCEL

FIG. 5

40

NUMBER: 9001 {LF}
LED: 1 {LF}
ZAP: {LF}
CLS: {LF}
93 DISPLAY: ANSWER QUERIES NOW?
PRESS ANY BUTTON TO STATE {LF}
WAIT: {LF}
CLS: {LF}
DISPLAY: HOW DO YOU FEEL?
VERY VERY
BAD BAD GOOD GOOD {LF}
95 INPUT: OOOO {LF}
CLS: {LF}
DISPLAY: HOW WELL ARE YOU
MANAGING YOUR DISEASE?
VERY VERY
WELL BADLY WELL WELL {LF}
INPUT: OOOO {LF}
CLS: {LF}
DISPLAY: HOW HARD IS IT FOR YOU TO
FOLLOW YOUR TREATMENT PLAN?
VERY VERY
HARD HARD EASY EASY {LF}
INPUT: OOOO {LF}
CLS: {LF}
DISPLAY: HOW HARD IS IT FOR YOU TO
CONTROL YOUR BLOOD SUGAR?
VERY VERY
HARD HARD EASY EASY {LF}

FIG. 6A

INPUT: OOOO {LF}

CLS: {LF}

DISPLAY: CONNECT GLUCOSE METER
AND PRESS ANY BUTTON
WHEN FINISHED {LF}

WAIT: {LF}

CLS: {LF}

DISPLAY: COLLECTING MEASUREMENTS {LF}

97 COLLECT: GLUCOSE_METER {LF}

CLS: {LF}

DISPLAY: CONNECT APPARATUS TO
TELEPHONE JACK AND PRESS ANY
BUTTON WHEN FINSIHED {LF}

WAIT: {LF}

LED: 0 {LF}

CLS: {LF}

DELAY: 03:00 {LF}

DISPLAY: CONNECTING TO SERVER {LF}

CONNECT: {LF}

{EOF}

FIG. 6B

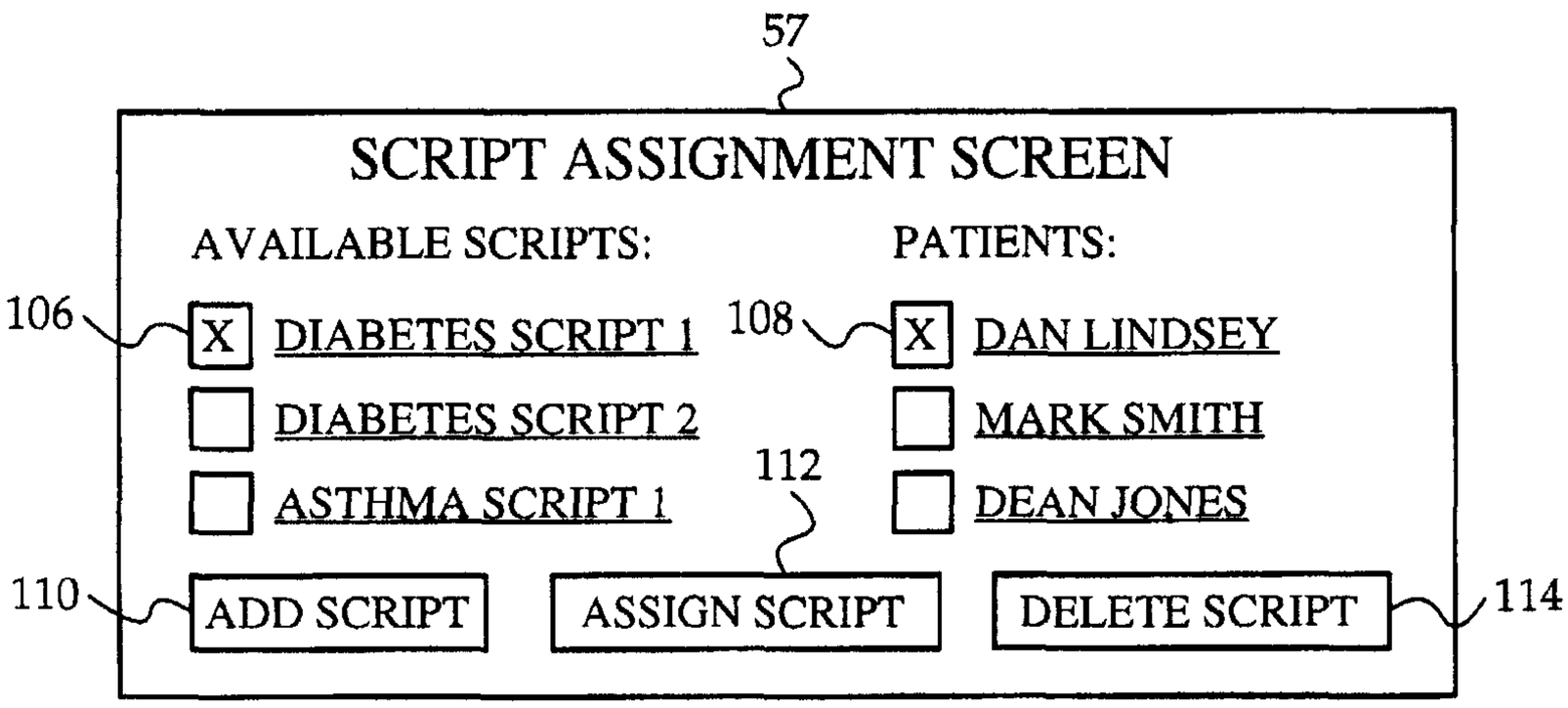


FIG. 7

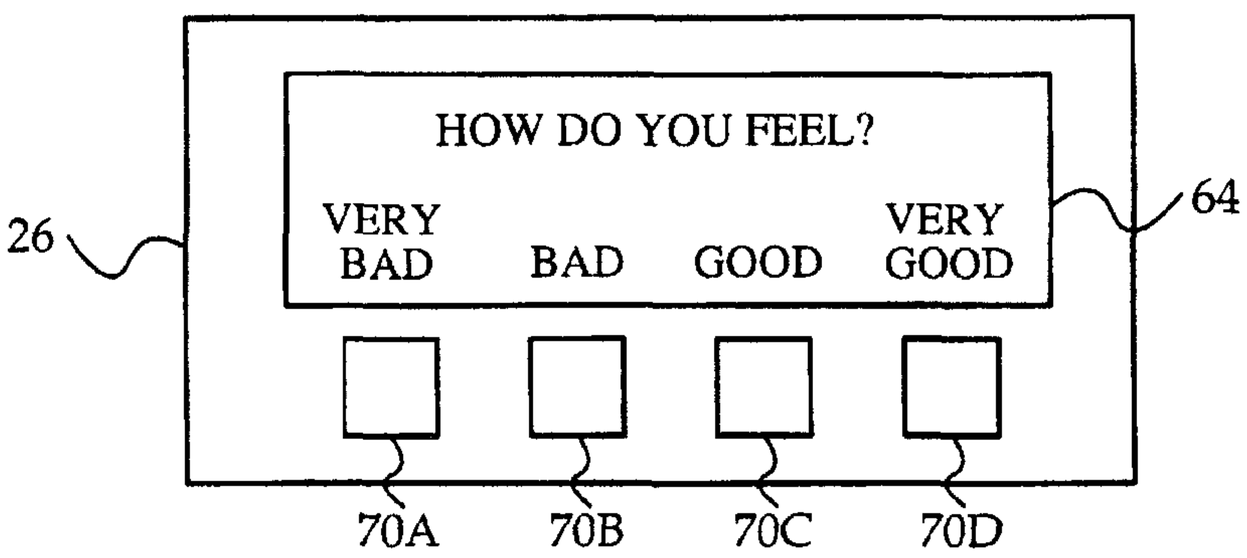


FIG. 8

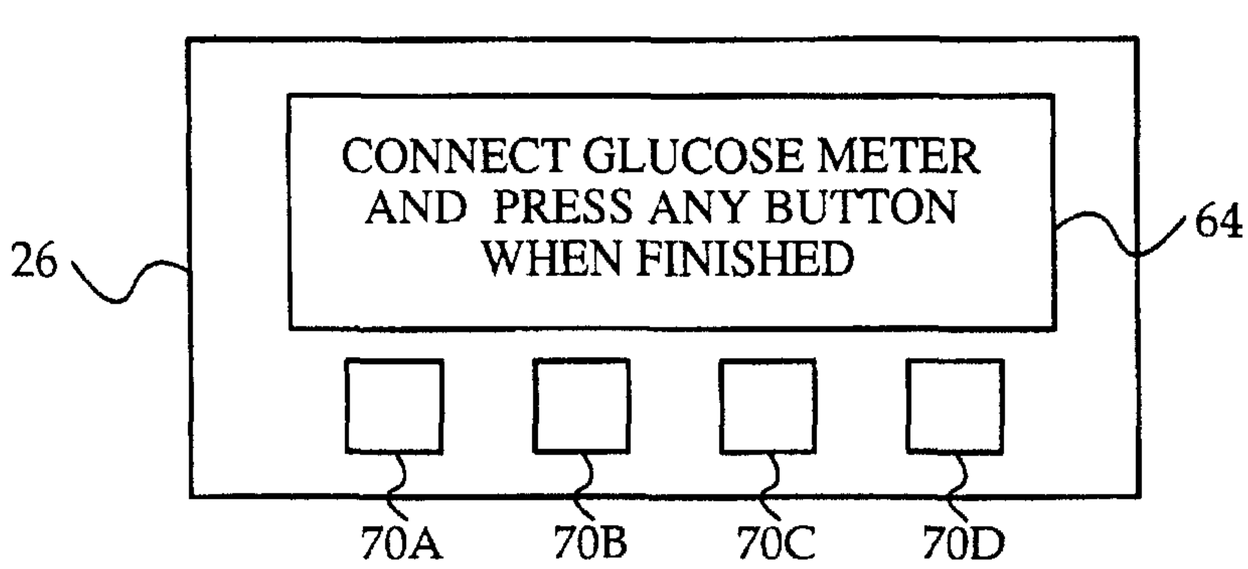


FIG. 9

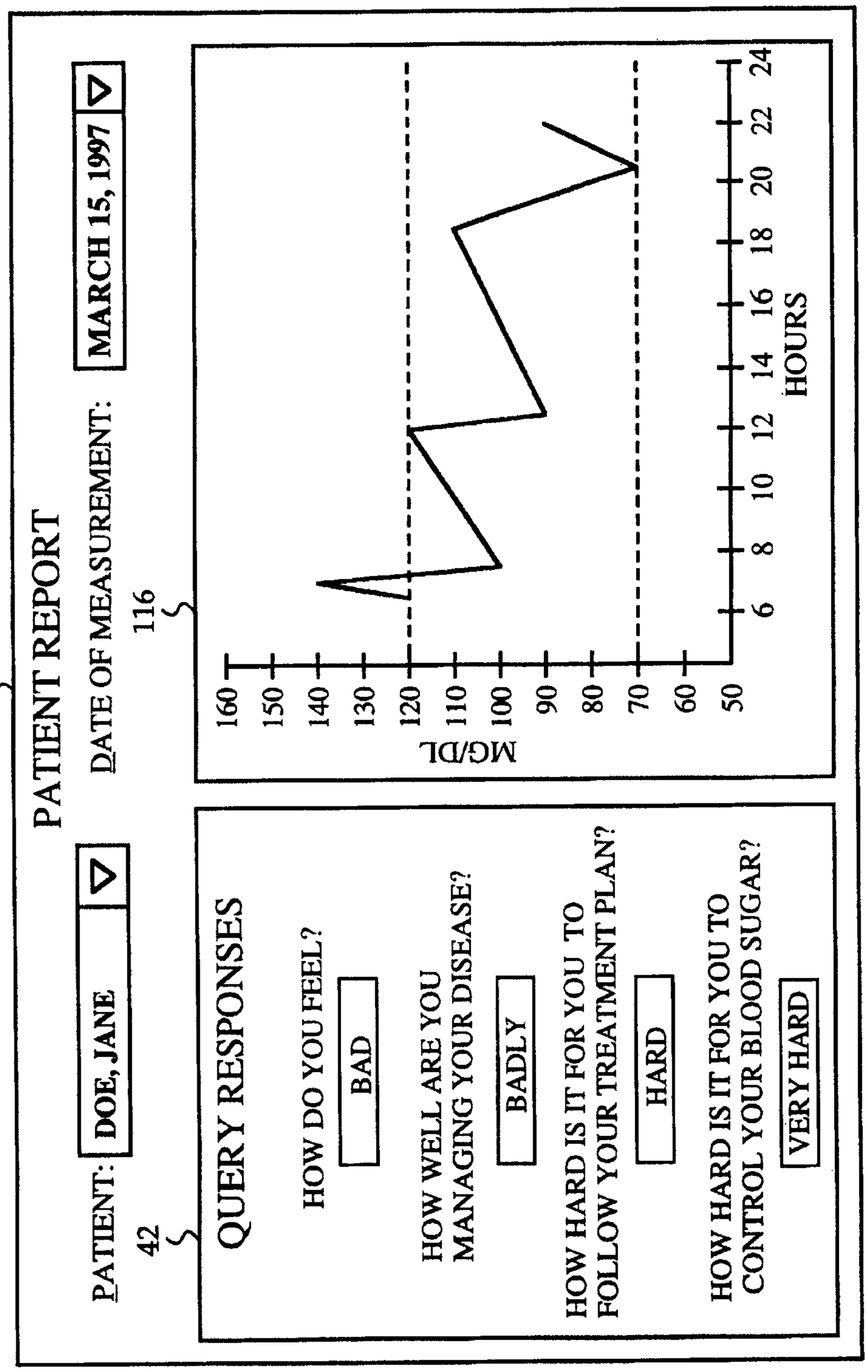

58
PATIENT REPORT
PATIENT: DOE, JANE
42
DATE OF MEASUREMENT: MARCH 15, 1997
116
MG/DL
160
150
140
130
120
110
100
90
80
70
60
50
6
8
10
12
14
16
18
20
22
24
HOURS
QUERY RESPONSES
HOW DO YOU FEEL?
BAD
HOW WELL ARE YOU MANAGING YOUR DISEASE?
BADLY
HOW HARD IS IT FOR YOU TO FOLLOW YOUR TREATMENT PLAN?
HARD
HOW HARD IS IT FOR YOU TO CONTROL YOUR BLOOD SUGAR?
VERY HARD

FIG. 10

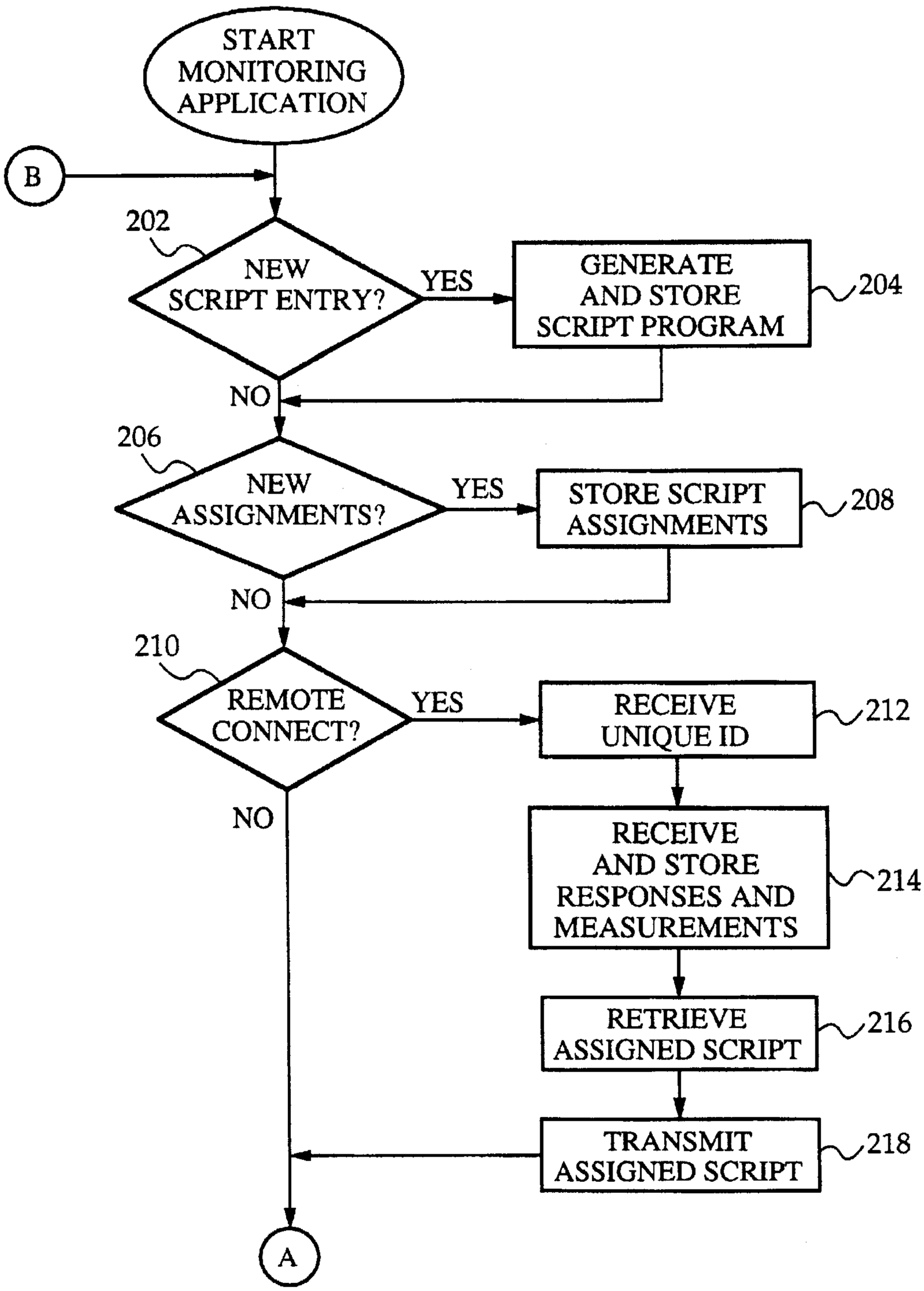

START MONITORING APPLICATION
B
202
NEW SCRIPT ENTRY?
YES
GENERATE AND STORE SCRIPT PROGRAM
204
NO
206
NEW ASSIGNMENTS?
YES
STORE SCRIPT ASSIGNMENTS
208
NO
210
REMOTE CONNECT?
YES
RECEIVE UNIQUE ID
212
NO
RECEIVE AND STORE RESPONSES AND MEASUREMENTS
214
RETRIEVE ASSIGNED SCRIPT
216
TRANSMIT ASSIGNED SCRIPT
218
A

FIG. 11A

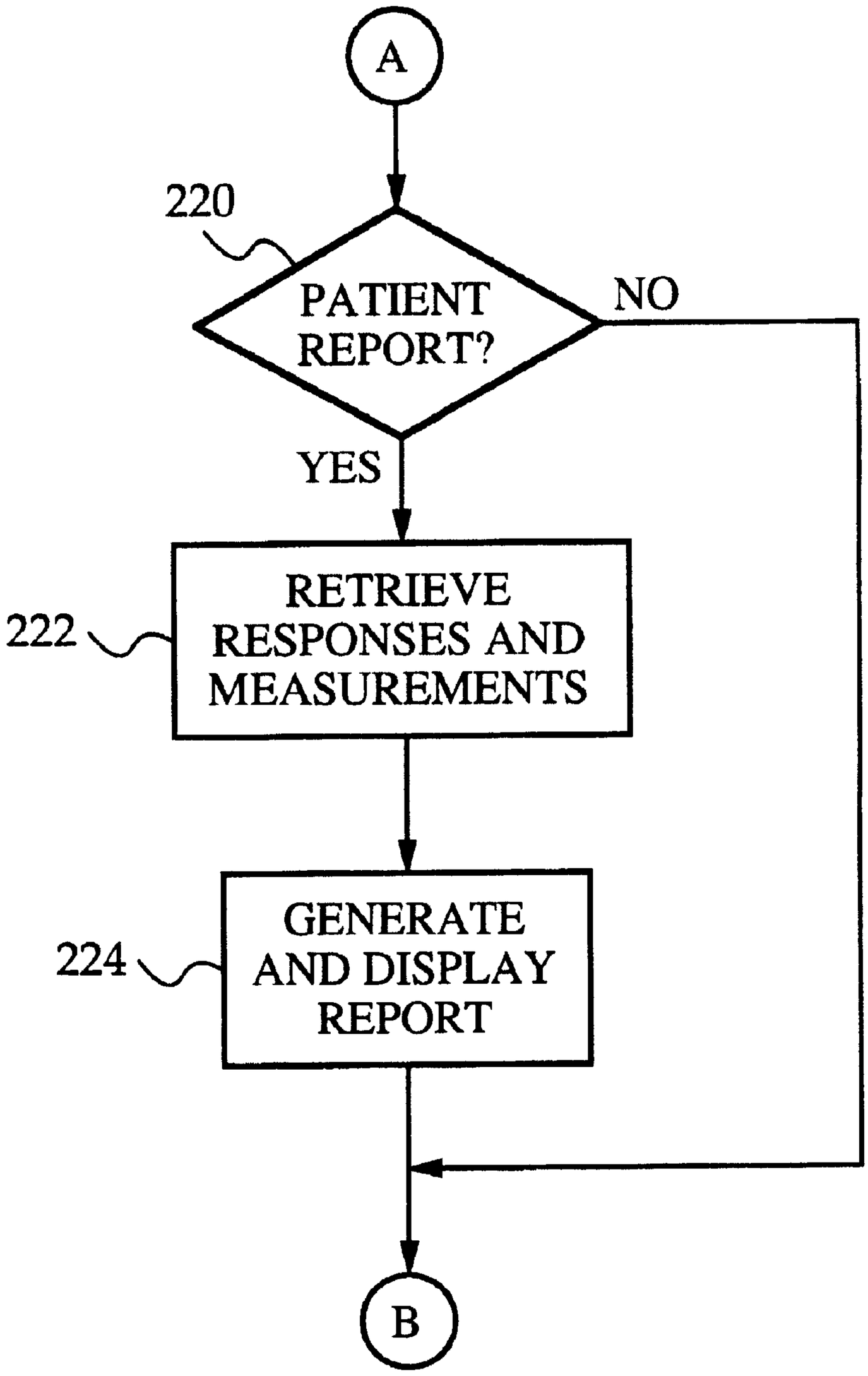

A
220
PATIENT REPORT?
NO
YES
222
RETRIEVE RESPONSES AND MEASUREMENTS
224
GENERATE AND DISPLAY REPORT
B

FIG. 11B

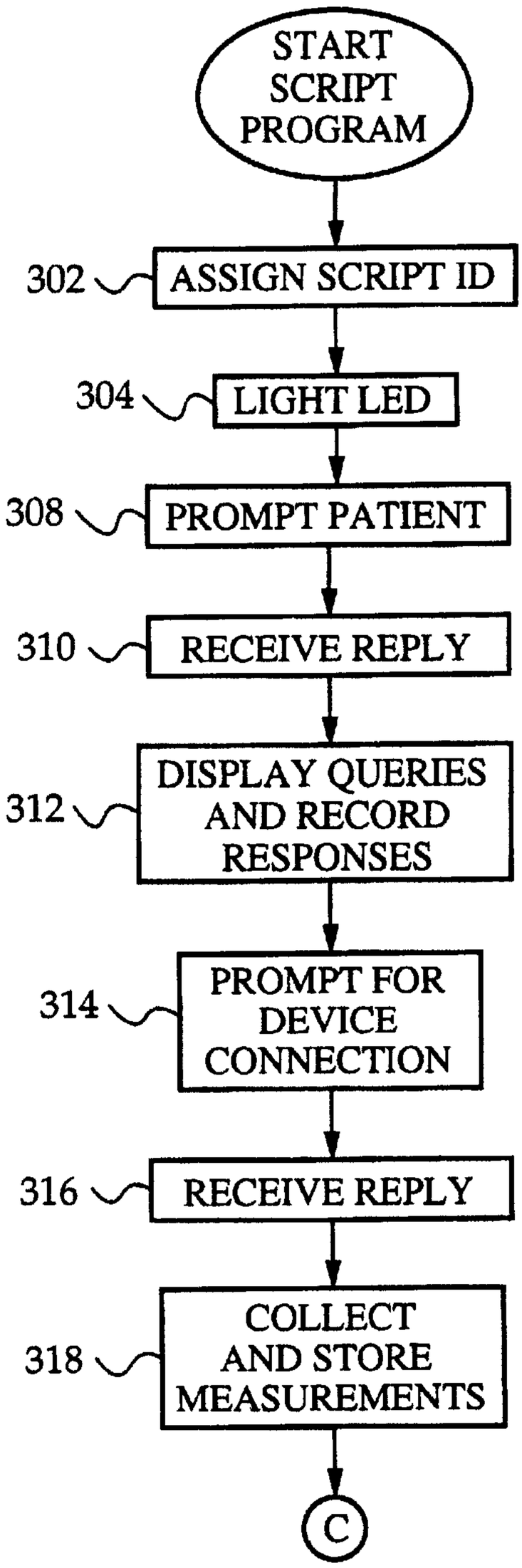

START SCRIPT PROGRAM
302
ASSIGN SCRIPT ID
304
LIGHT LED
308
PROMPT PATIENT
310
RECEIVE REPLY
312
DISPLAY QUERIES AND RECORD RESPONSES
314
PROMPT FOR DEVICE CONNECTION
316
RECEIVE REPLY
318
COLLECT AND STORE MEASUREMENTS
C

FIG. 12A

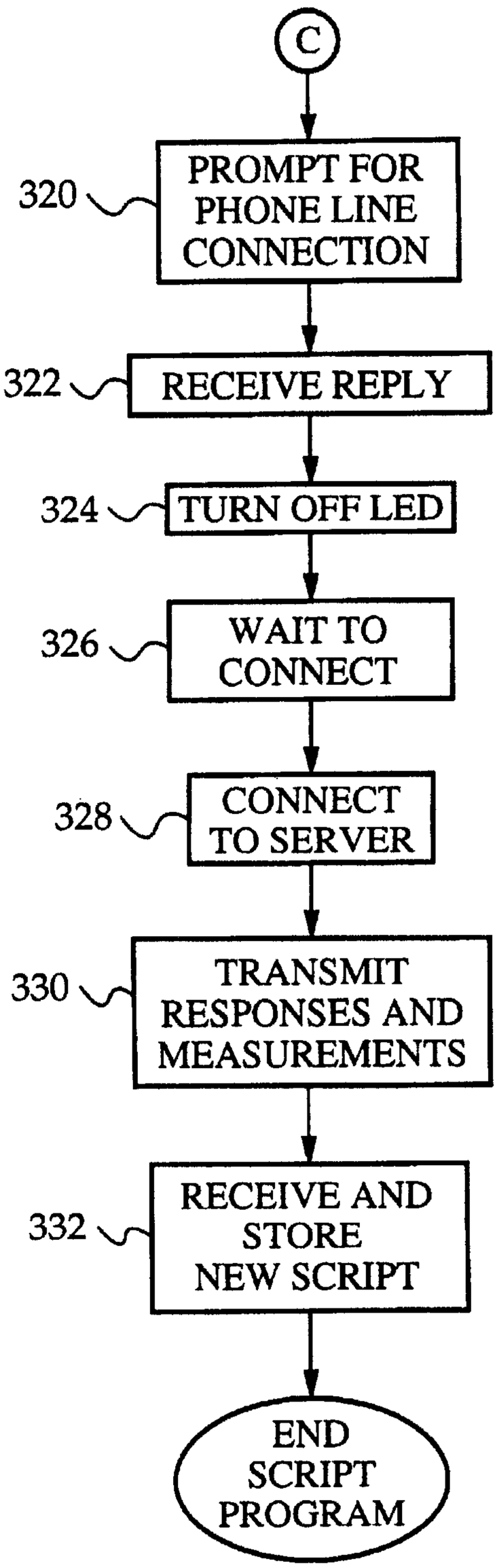

C
320
PROMPT FOR PHONE LINE CONNECTION
322
RECEIVE REPLY
324
TURN OFF LED
326
WAIT TO CONNECT
328
CONNECT TO SERVER
330
TRANSMIT RESPONSES AND MEASUREMENTS
332
RECEIVE AND STORE NEW SCRIPT
END SCRIPT PROGRAM

FIG. 12B

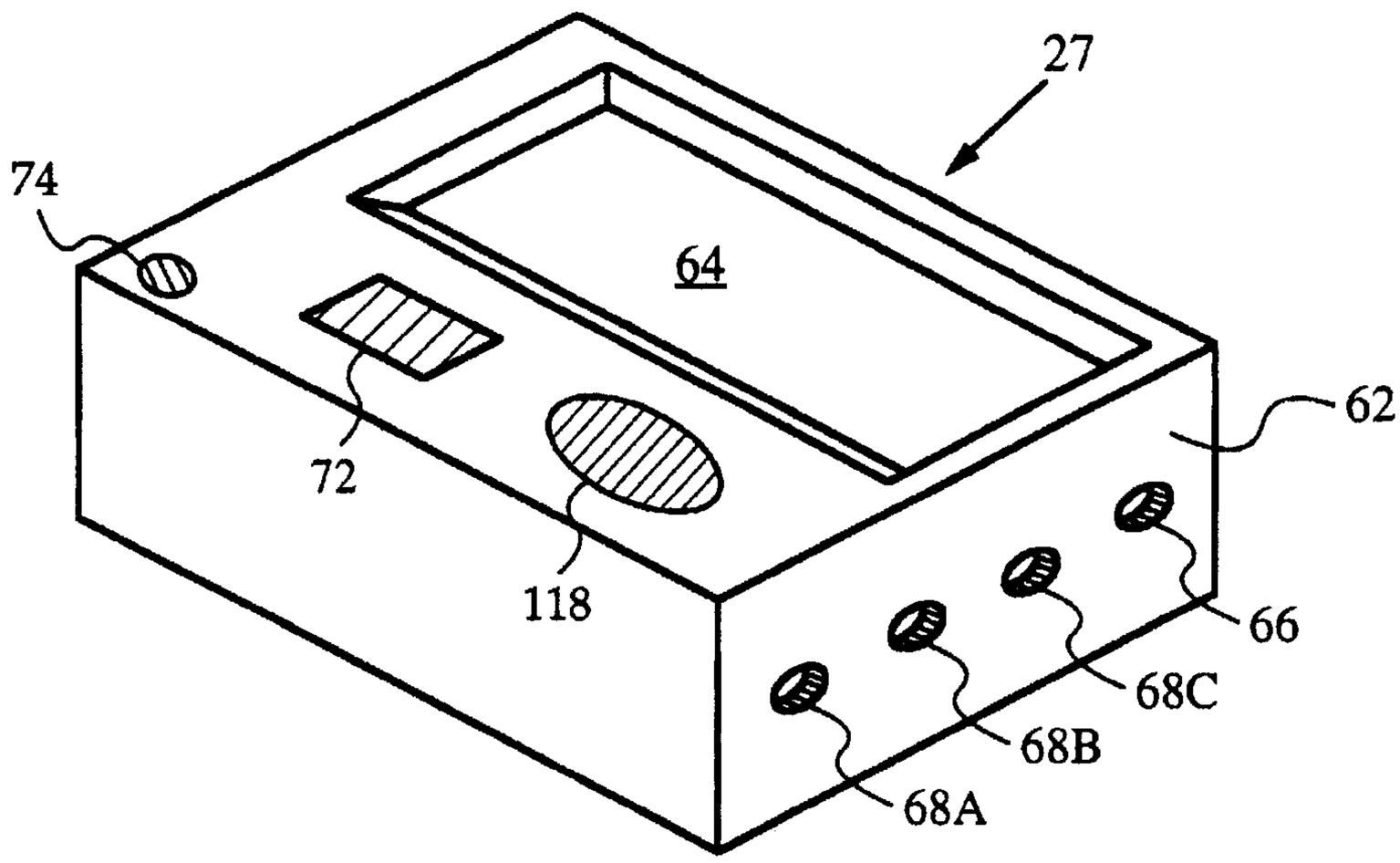

27
74
64
72
118
62
66
68C
68B
68A

FIG. 13

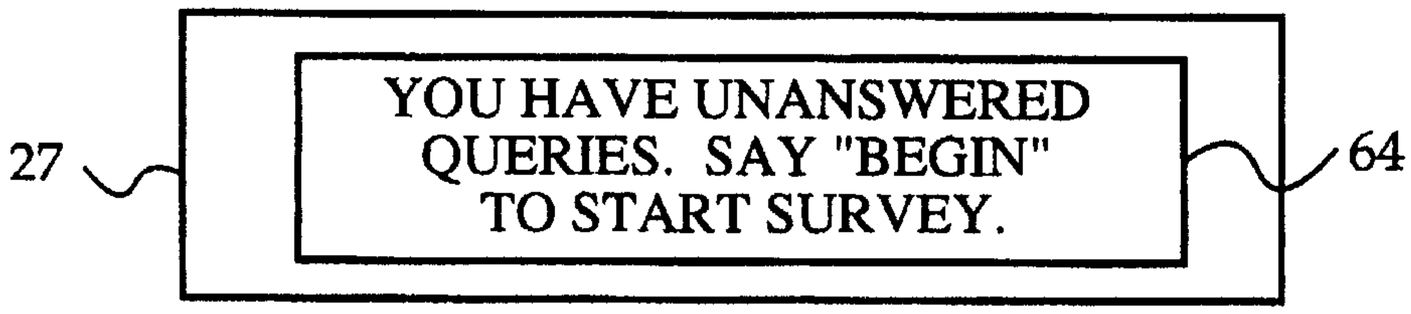

YOU HAVE UNANSWERED QUERIES. SAY "BEGIN" TO START SURVEY.
27
64

FIG. 14

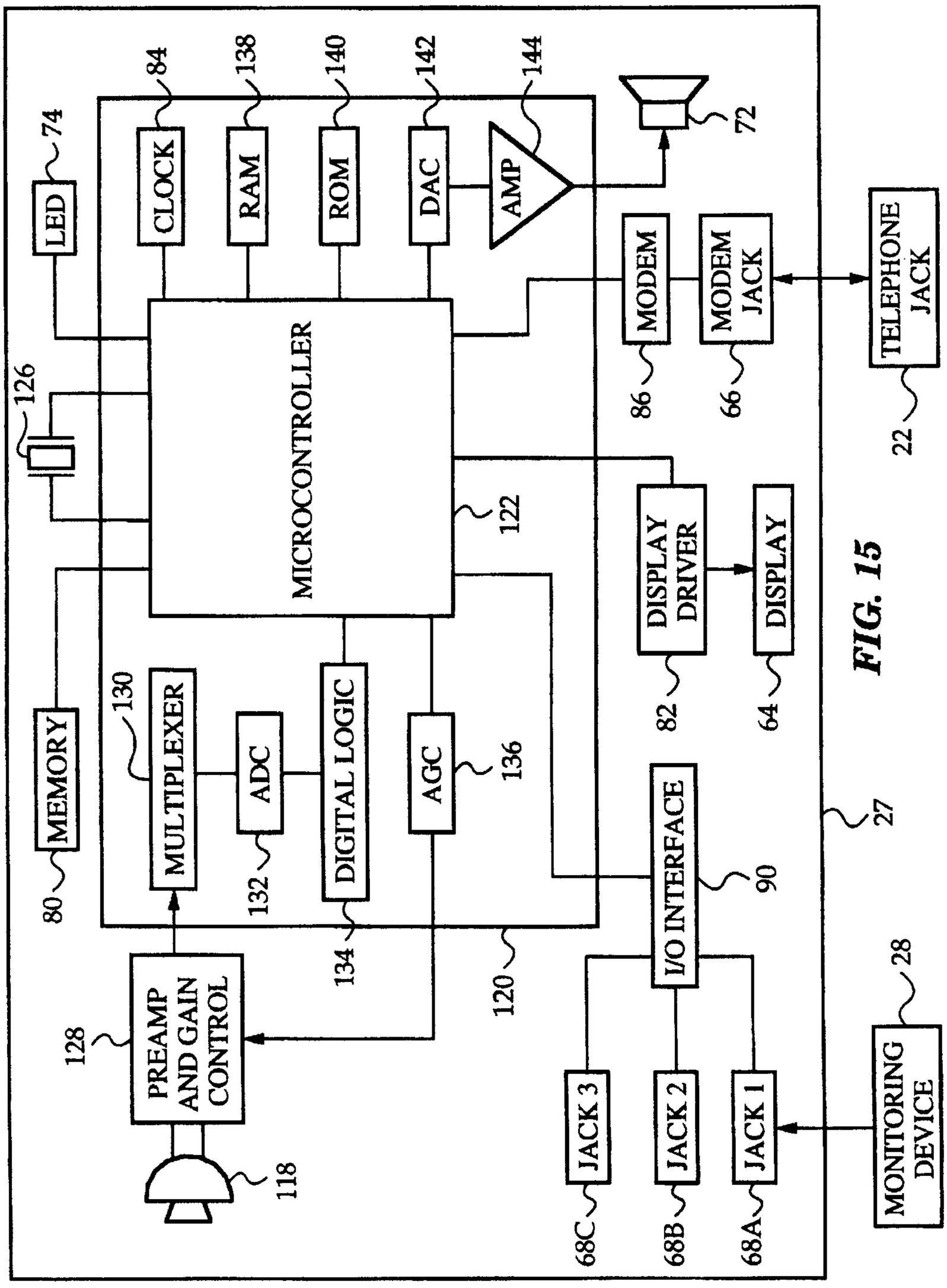

LED
74
CLOCK
84
RAM
138
ROM
140
DAC
142
AMP
144
72
MODEM
86
MODEM JACK
66
TELEPHONE JACK
22
126
MICROCONTROLLER
122
MEMORY
80
MULTIPLEXER
130
ADC
132
DIGITAL LOGIC
134
AGC
136
DISPLAY DRIVER
82
DISPLAY
64
I/O INTERFACE
90
27
PREAMP AND GAIN CONTROL
128
118
120
JACK 3
68C
JACK 2
68B
JACK 1
68A
MONITORING DEVICE
28

FIG. 15

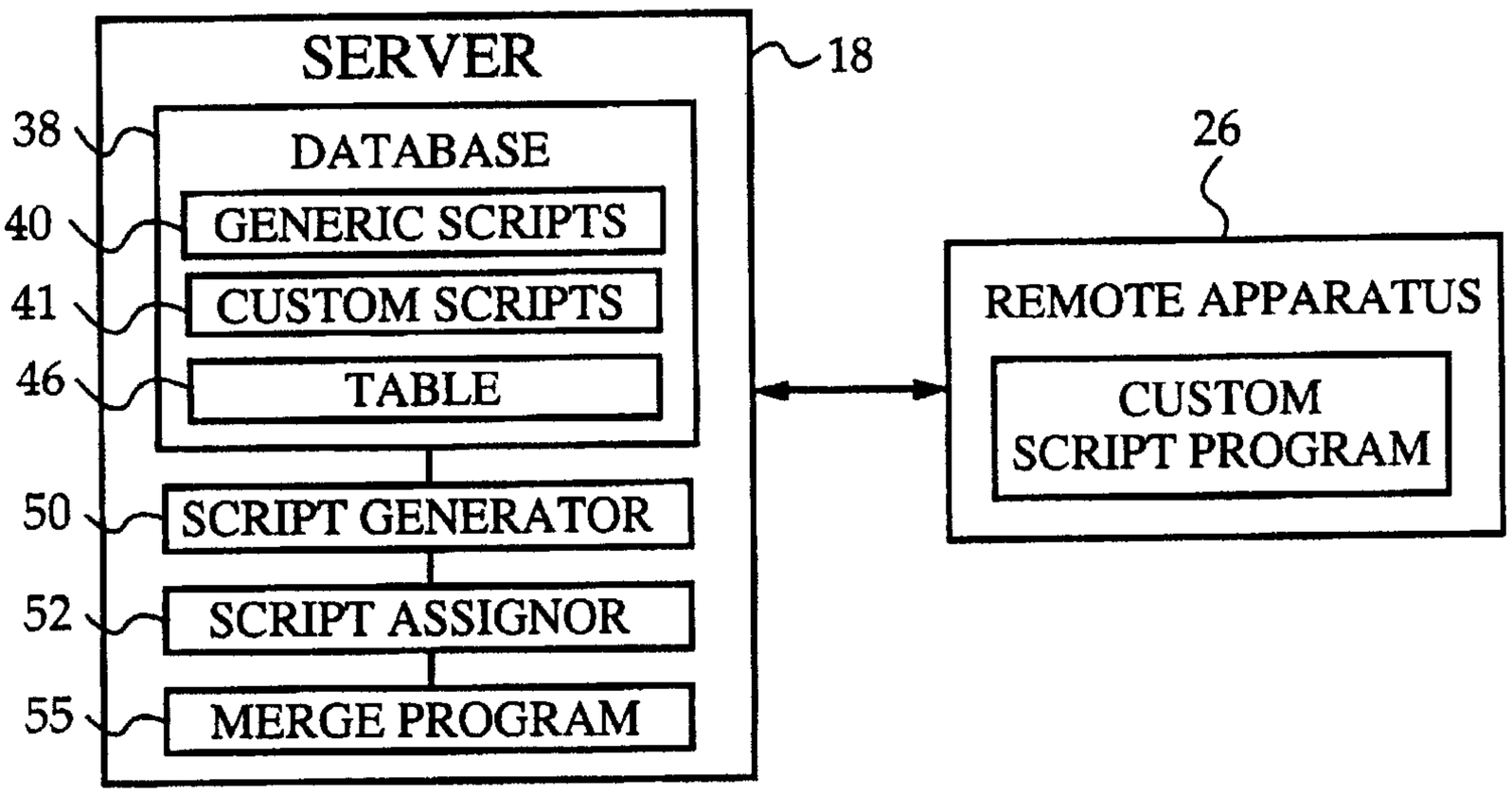


FIG. 16

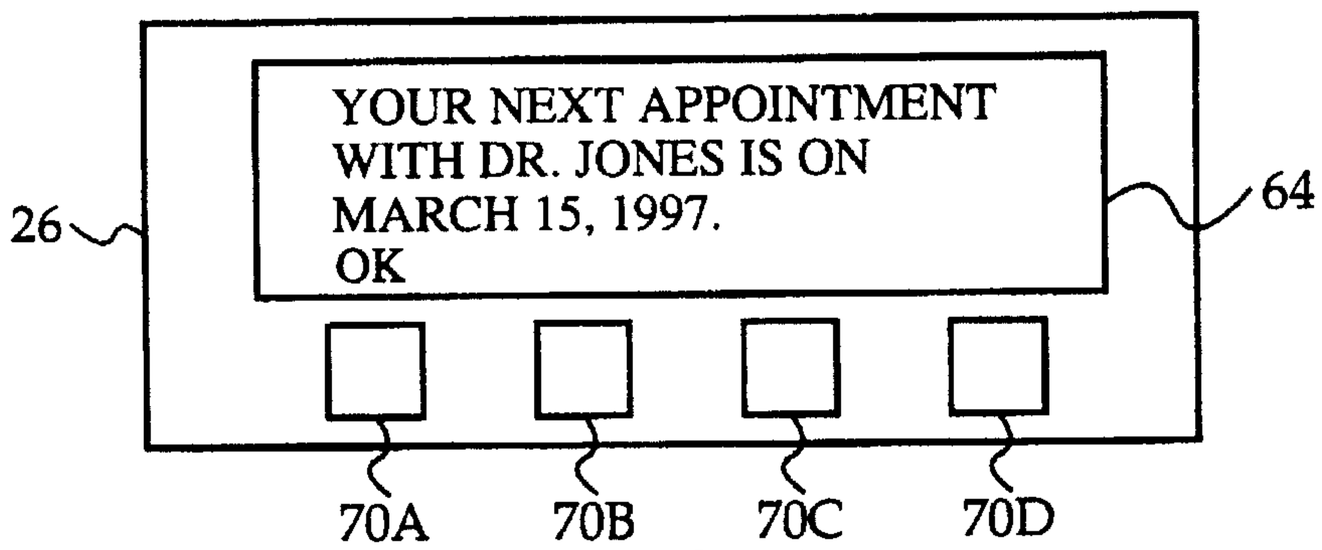


FIG. 17

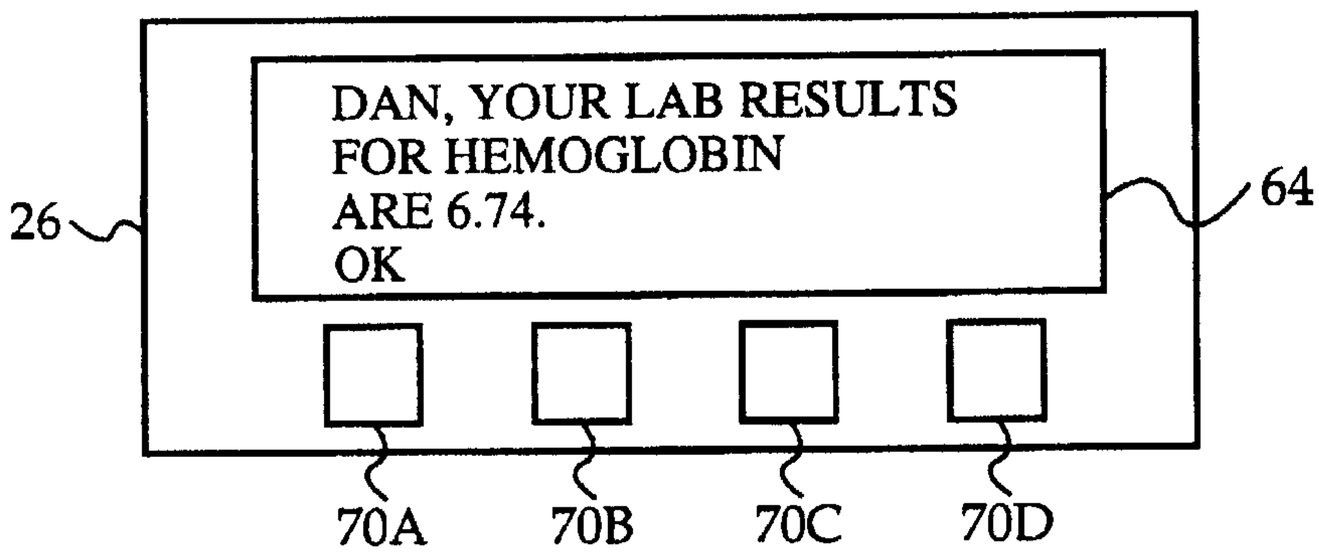


FIG. 18

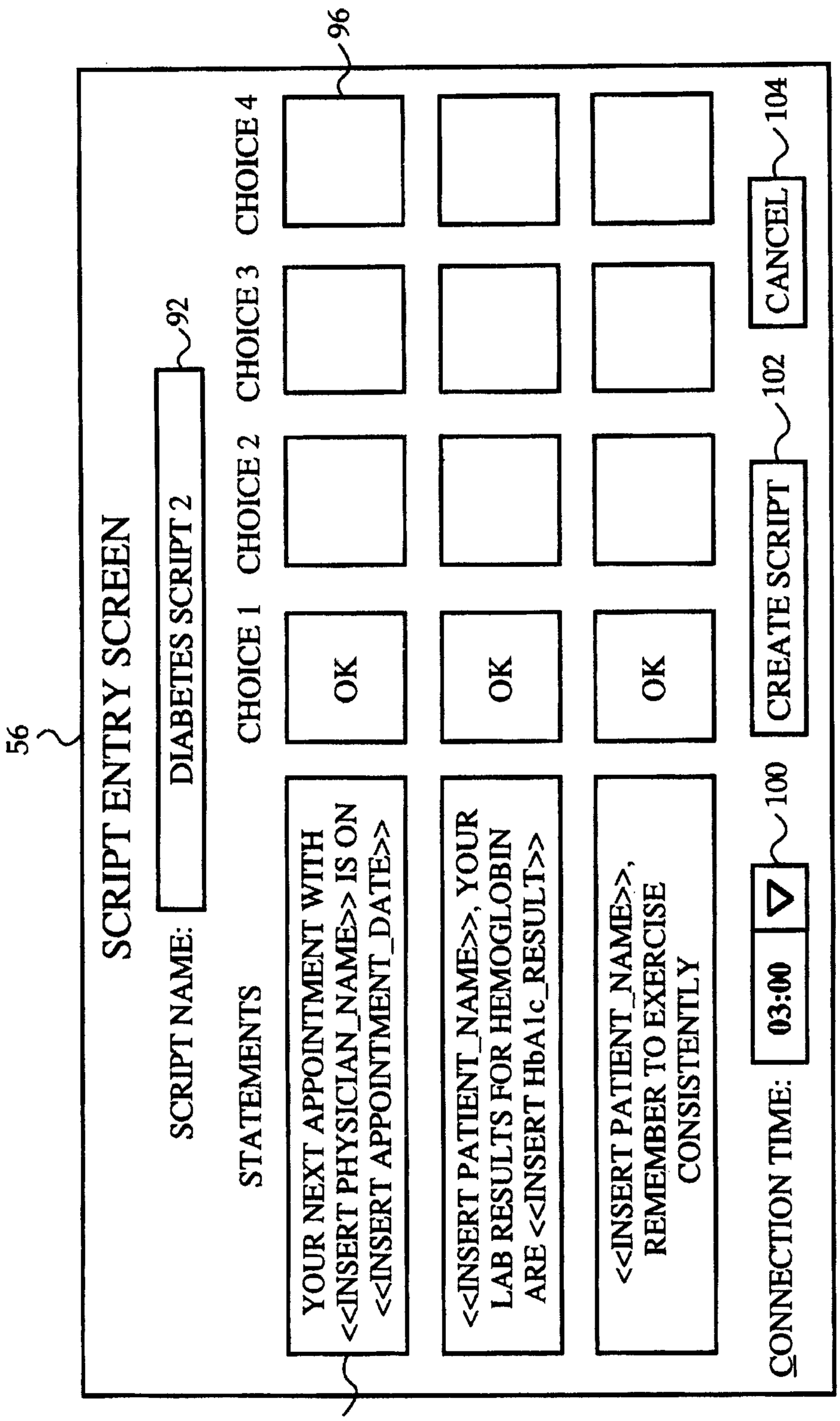

56
SCRIPT ENTRY SCREEN
SCRIPT NAME: DIABETES SCRIPT 2
STATEMENTS
CHOICE 1
CHOICE 2
CHOICE 3
CHOICE 4
OK
OK
OK
YOUR NEXT APPOINTMENT WITH
<<INSERT PHYSICIAN_NAME>> IS ON
<<INSERT APPOINTMENT_DATE>>
<<INSERT PATIENT_NAME>>, YOUR
LAB RESULTS FOR HEMOGLOBIN
ARE <<INSERT HbA1c_RESULT>>
<<INSERT PATIENT_NAME>>,
REMEMBER TO EXERCISE
CONSISTENTLY
CONNECTION TIME: 03:00
CREATE SCRIPT
CANCEL
92
94
96
100
102
104

FIG. 19

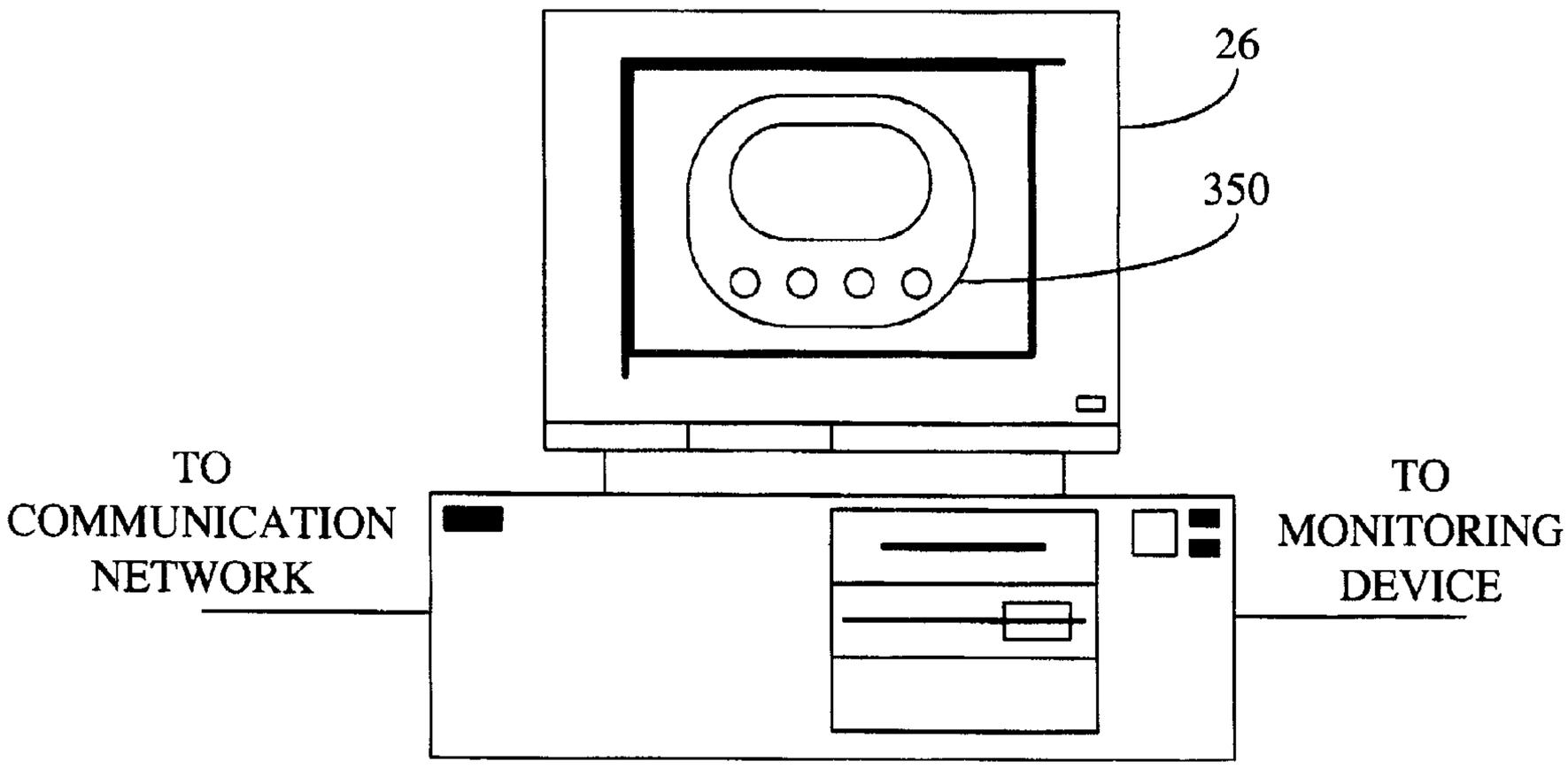


FIG. 20

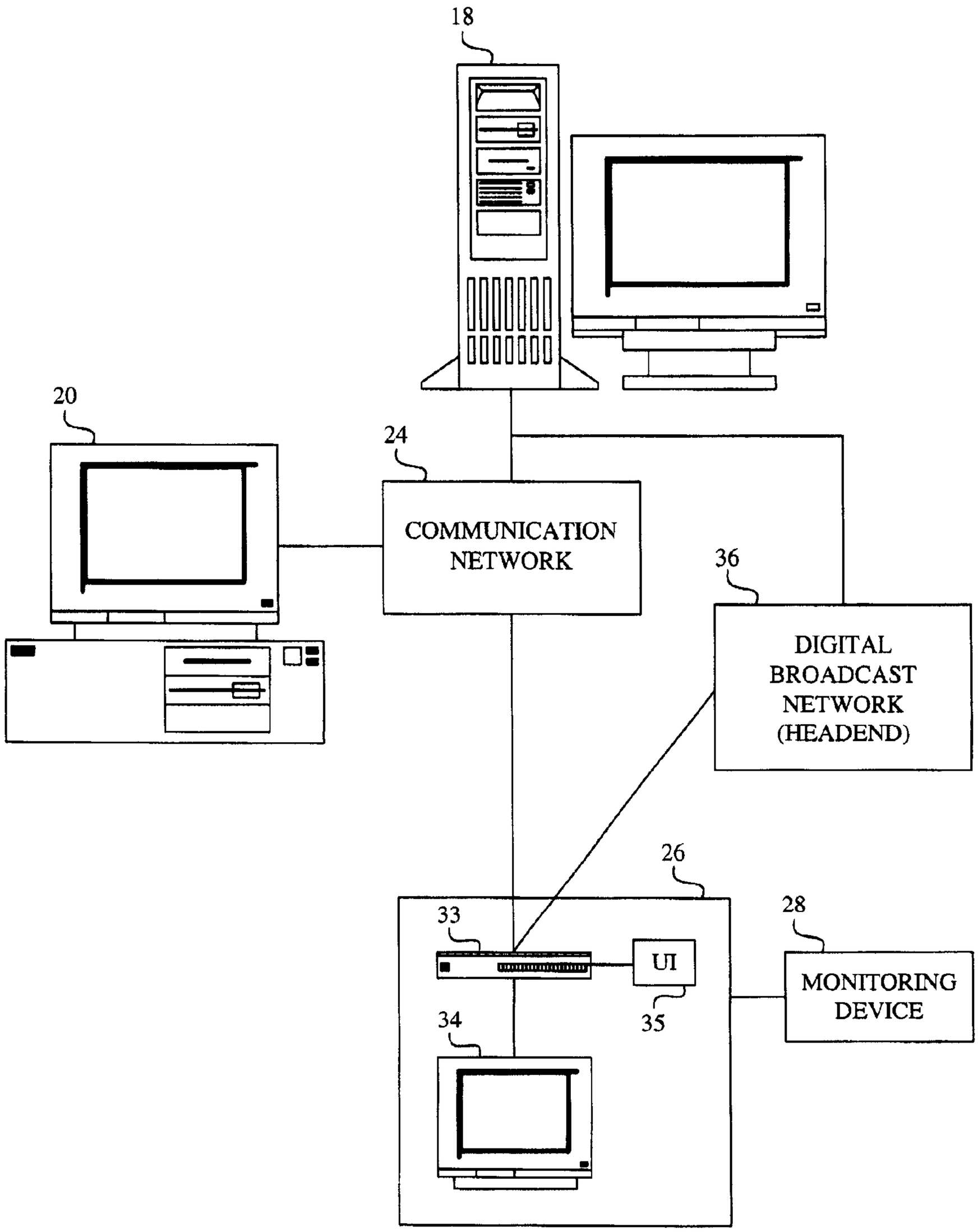

18
20
24
COMMUNICATION NETWORK
36
DIGITAL BROADCAST NETWORK (HEADEND)
26
33
UI
35
28
MONITORING DEVICE
34

FIG. 21

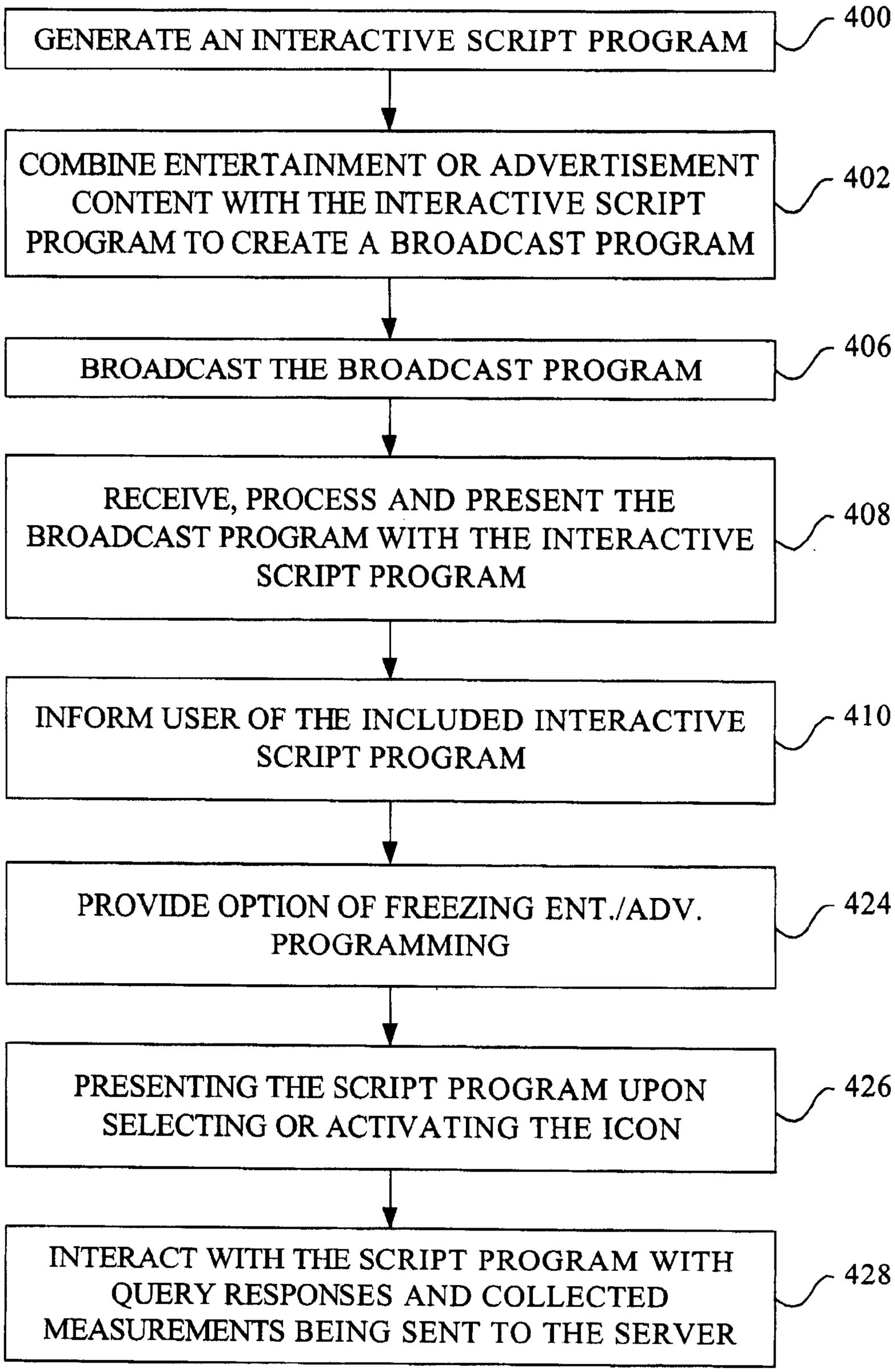

GENERATE AN INTERACTIVE SCRIPT PROGRAM
400
COMBINE ENTERTAINMENT OR ADVERTISEMENT CONTENT WITH THE INTERACTIVE SCRIPT PROGRAM TO CREATE A BROADCAST PROGRAM
402
BROADCAST THE BROADCAST PROGRAM
406
RECEIVE, PROCESS AND PRESENT THE BROADCAST PROGRAM WITH THE INTERACTIVE SCRIPT PROGRAM
408
INFORM USER OF THE INCLUDED INTERACTIVE SCRIPT PROGRAM
410
PROVIDE OPTION OF FREEZING ENT./ADV. PROGRAMMING
424
PRESENTING THE SCRIPT PROGRAM UPON SELECTING OR ACTIVATING THE ICON
426
INTERACT WITH THE SCRIPT PROGRAM WITH QUERY RESPONSES AND COLLECTED MEASUREMENTS BEING SENT TO THE SERVER
428

FIG. 22

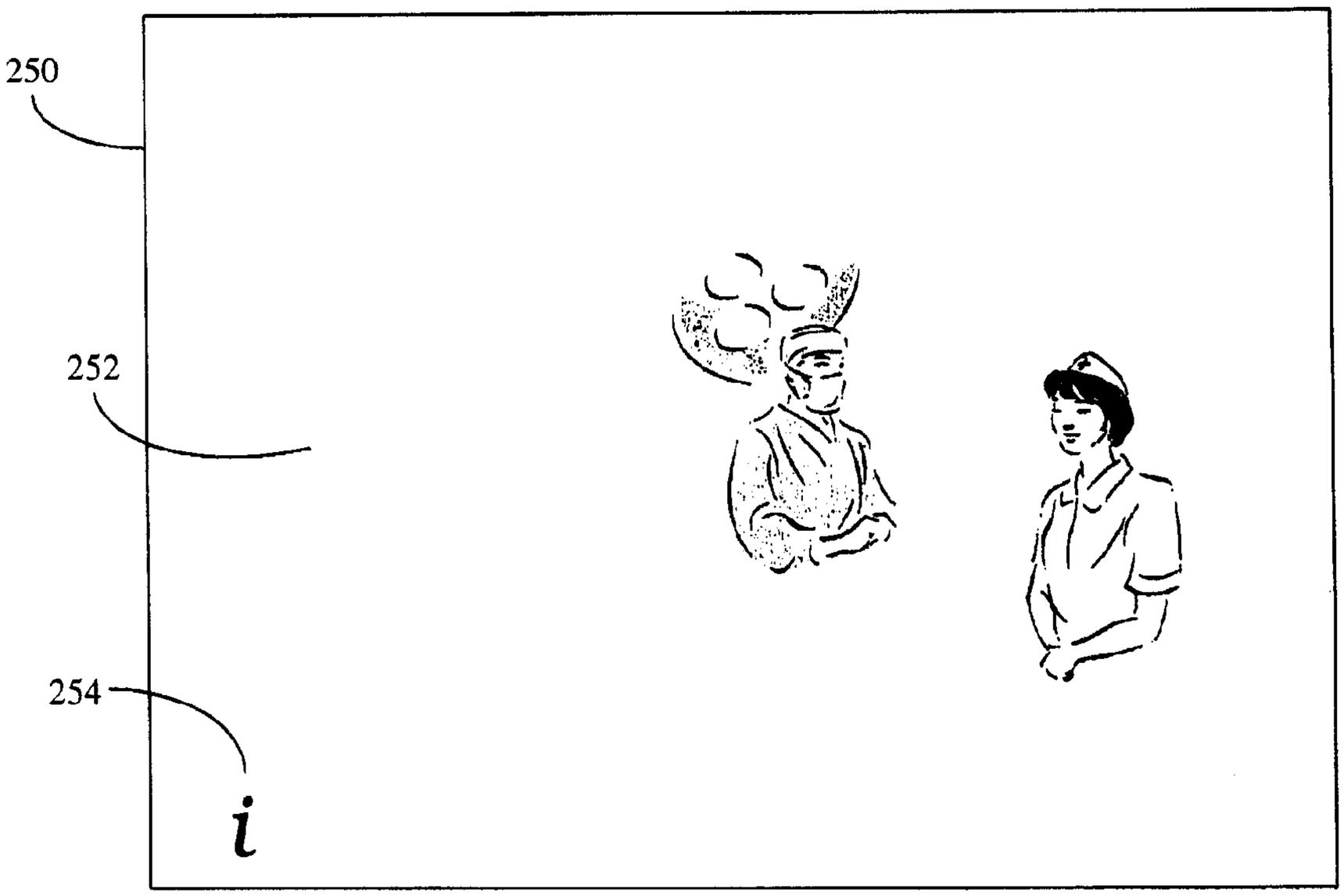


FIG. 23

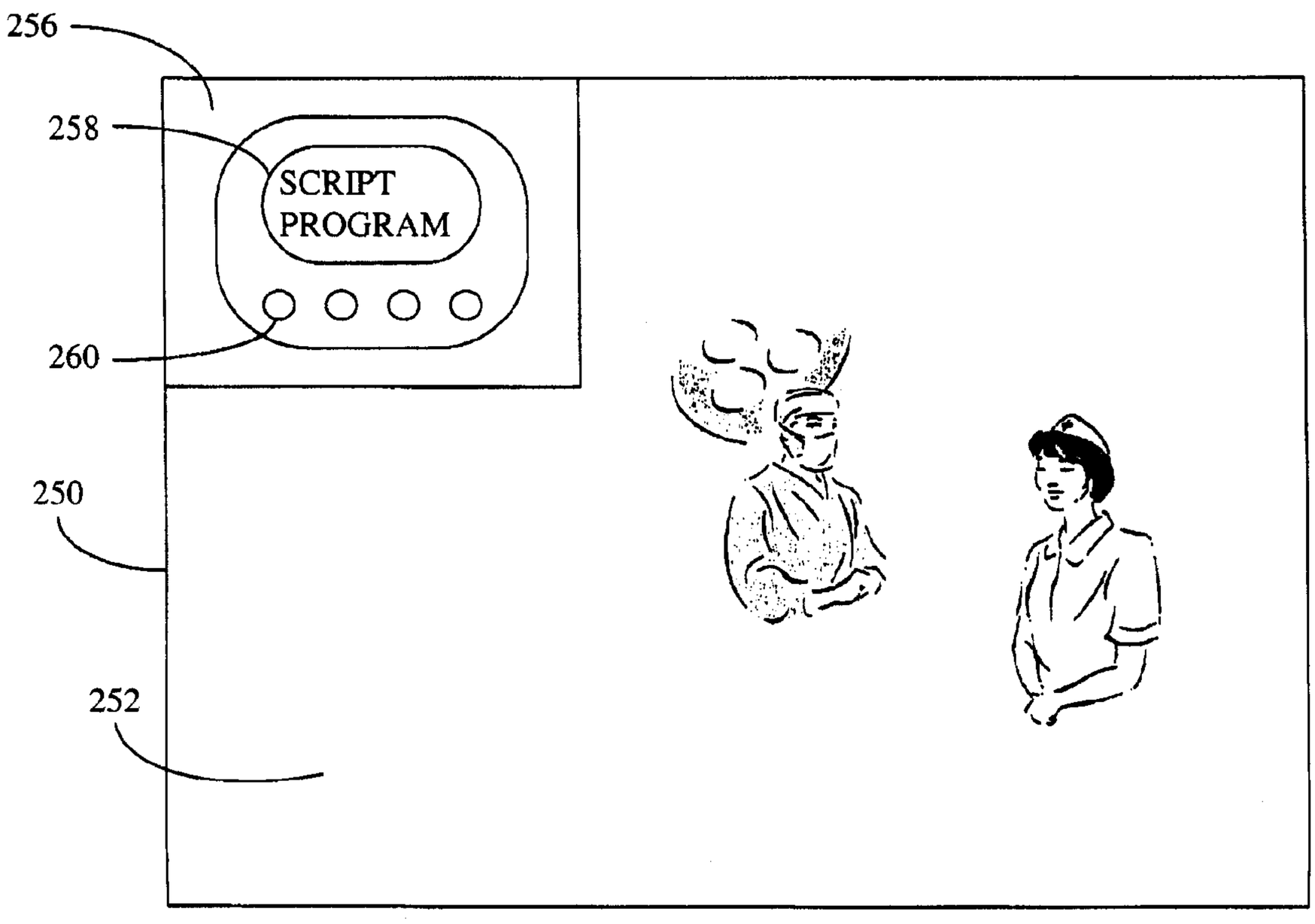


FIG. 24

ELECTRONIC DATA CAPTURE IN CLINICAL AND PHARMACEUTICAL TRIALS

STATEMENT OF RELATED CASES

This application is a continuation of U.S. application Ser. No. 11/150,301, filed Jun. 13, 2005 , now U.S. Pat. No. 8,140,663 which is a continuation of U.S. application Ser. No. 09/658,209, filed Sep. 8, 2000, now U.S. Pat. No. 6,968,375, which is a continuation in part of U.S. application Ser. No. 09/300,856, filed Apr. 28, 1999, now U.S. Pat. No. 6,368,273, which is a divisional application of application Ser. No. 08/946,341, filed Oct. 7, 1997, now U.S. Pat. No. 5,997,476, which is a continuation in part of application Ser. No. 08/847,009, filed Apr. 30, 1997, now U.S. Pat. No. 5,897,493 which, in turn claims the benefit of Provisional applications 60/041,746 and 60/041,751, both filed Mar. 28, 1997.

This application is also related to: (i) U.S. Pat. Nos. 5,985,559 and 6,101,478, both continuations in part of U.S. Pat. No. 5,897,493; (ii) U.S. Pat. No. 6,248,065, a divisional of U.S. Pat. No. 5,997,476; (iii) U.S. Pat. No. 6,270,455, a continuation in part of U.S. Pat. No. 5,997,476; (iv) U.S. Pat. No. 6,381,577, which is a continuation of U.S. Pat. No. 6,101,478; (v) abandoned application Ser. No. 09/531,237, a continuation in part of U.S. Pat. No. 6,368,273 and Ser. No. 09/378,188 a continuation of U.S. Pat. No. 5,985,559; (vi) co-pending application Ser. No. 10/279,749, which is a continuation in part of application Ser. No. 10/233,296, which is a continuation in part of co-pending application Ser. No. 09/665,442, which is a continuation in part of U.S. Pat. No. 6,381,577, and (vii) co-pending applications (a) Ser. No. 11/093,167, (b) Ser. No. 11/093,168, (c) Ser. No. 11/132,427 and (d) Ser. No. 11/150,301. Each of the patents and/or applications referenced are incorporated by reference.

FIELD OF THE INVENTION

The present invention relates generally to communication systems for remote monitoring of individuals, and in particular to a networked system for remotely monitoring individuals and for communicating information to the individuals through the use of script programs.

BACKGROUND OF THE INVENTION

In the United States alone, over 100 million people have chronic health conditions, accounting for an estimated $700 billion in annual medical costs. In an effort to control these medical costs, many healthcare providers have initiated outpatient or home healthcare programs for their patients. The potential benefits of these programs are particularly great for chronically ill patients who must treat their diseases on a daily basis. However, the success of these programs is dependent upon the ability of the healthcare providers to monitor the patients remotely to avert medical problems before they become complicated and costly. Further, success requires compliance with the program, which is often dependent on providing messages or other reminders to patients so that they will stay with the program. Unfortunately, no convenient and cost effective monitoring system exists to accomplish these objectives. While these problems are particularly acute for the poor and the elderly, all demographic groups could significantly benefit from remote communication and monitoring systems.

Prior attempts to monitor patients remotely have included the use of personal computers and modems to establish communication between patients and healthcare providers, either directly or via an Internet site. However, computers are too expensive to give away and the patients who already own computers are only a fraction of the total population.

Other attempts to monitor patients remotely have included the use of medical monitoring devices with built-in modems. Examples of such monitoring devices include blood glucose meters, respiratory flow meters, and heart rate monitors. While these devices can be quite successful, their multimedia capabilities are often limited. In addition, many patients simply may prefer to interact with a device they are more familiar with, such as a television.

Prior attempts to monitor patients remotely have also included the use of interactive telephone or video response systems. Such interactive systems are disclosed in U.S. Pat. No. 5,390,238 issued to Kirk et al. on Feb. 14, 1995, U.S. Pat. No. 5,434,611 issued to Tamura on Jul. 18, 1995, and U.S. Pat. No. 5,441,047 issued to David et al. on Aug. 15, 1995. One disadvantage of these systems is that they either require a patient to call in to a central facility to be monitored or require the central facility to call the patient according to a rigid monitoring schedule.

If the patients are required to call the central facility, only the compliant patients will actually call regularly to be monitored. Non-compliant patients will typically wait until an emergency situation develops before contacting their healthcare provider, thus defeating the purpose of the monitoring system. If the central facility calls each patient according to a monitoring schedule, it is intrusive to the patient's life and resistance to the monitoring grows over time. Further, it is difficult to identify each patient uniquely using these systems. Moreover, these systems are generally incapable of collecting medical data from monitoring devices, such as blood glucose meters, respiratory flow meters, or heart rate monitors.

As such, there exists a need for a simple and inexpensive system for remotely monitoring patients and for easily communicating information to the patients. There is also a need to encourage patient's compliance with a prescribed treatment plan.

SUMMARY

The present invention provides a system for remotely interacting with an individual. The system includes a server, a remote interface device for assigning in the server a set of queries to be answered by the individual, a remotely programmable apparatus for interacting with the individual and a broadcaster in communication with the server and the remotely programmable apparatus.

By using the entertainment medium of interactive television with its ability to receive a large bandwidth of data, the present invention can more easily communicate interactive entertaining/educational information to potential and existing patients. The interactive nature of the received data makes it easy for a user to access interactive programs related to corresponding entertainment/advertisement content or related to user adherence to a predefined regimen.

In accordance with another aspect of the present invention, an answering service sends a series of questions as voice communication from a stored set of questions to the remote apparatus for the individual to respond to, when the voice communication button is activated. The answering service stores responses to each provided question in the series of questions and provides a service based on the individual's response to the questions. The provided service is communication with a health care professional or a service provider. Also, the answering service includes a speech recognition component for receiving spoken responses to the series of

questions and a speech synthesis component for making the set of queries into a series of questions.

In accordance with yet another aspect of the present invention, the remotely programmable apparatus includes an appliance component for providing appliance functionality. The appliance component is an alarm clock, a kitchen appliance, or an entertainment device.

In accordance with still another aspect of the present invention, the remotely programmable apparatus includes a monitoring component for producing measurements of a physiological condition of the individual.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same becomes better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIG. **1** is a block diagram of networked system formed in accordance with a first embodiment of the present invention;

FIG. **2** is a block diagram illustrating the interaction of the components of the system of FIG. **1**;

FIG. **3** is a perspective view of a remotely programmable apparatus of the system of FIG. **1**;

FIG. **4** is a block diagram illustrating the components of the apparatus of FIG. **3**;

FIG. **5** is a script entry screen according to the preferred embodiment of the invention;

FIG. **6**A is a listing of a sample script program according to the preferred embodiment of the invention;

FIG. **6**B is a continuation of the listing of FIG. **6**A;

FIG. **7** is a script assignment screen according to the preferred embodiment of the invention

FIG. **8** is a sample query appearing on the apparatus of FIG. **1**A-D;

FIG. **9** is a sample prompt appearing on the display of the apparatus of FIG. **3**;

FIG. **10** is a sample report displayed on a workstation of the system of FIG. **1**A-D;

FIG. **11**A is a flow chart illustrating the steps included in a monitoring application executed by the server of FIG. **1**A-D according to the present invention;

FIG. **11**B is a continuation of the flow chart of FIG. **11**A;

FIG. **12**A is a flow chart illustrating the steps included in the script program of FIG. **6**A-**6**B;

FIG. **12**B is a continuation of the flow chart of FIG. **12**;

FIG. **13** is a perspective view of a remotely programmable apparatus according to an embodiment of the present invention;

FIG. **14** is a sample prompt appearing on a display of the apparatus of FIG. **13**;

FIG. **15** is a block diagram illustrating the components of the apparatus of FIG. **13**;

FIG. **16** is a schematic block diagram illustrating the interaction of the server of FIG. **1**A-D with the apparatus of FIG. **3** according to another embodiment of the present invention;

FIG. **17** is a first sample message appearing on the display of the apparatus of FIG. **3**;

FIG. **18** is a second sample message appearing on the display of the apparatus of FIG. **3**;

FIG. **19** is a script entry screen according to an embodiment of the present invention;

FIGS. **20** and **21** are block diagrams of alternate embodiments of the present invention;

FIG. **22** is a flow chart illustrating the process performed by the system of FIG. **21**; and

FIGS. **23** and **24** are example broadcast programming presentations with an included script program.

DETAILED DESCRIPTION

The present invention provides a system and method for remotely monitoring individuals and for increasing individual use of health programs. In a first embodiment of the invention, the individuals are patients and the system is used to collect data relating to the health status of the patients. However, it is to be understood that the invention is not limited to remote monitoring of patients. The system and method of the invention may be used for any type of remote monitoring and program adherence application. The invention may also be implemented as an automated messaging system for communicating information to individuals, as will be discussed in an alternative embodiment below.

A first embodiment of the invention is illustrated in FIGS. **1**A and **2**-**12**. Referring to FIG. **1**, a networked system **16** includes a server **18** and a workstation **20** connected to the server **18** through a communication network **24**. The server **18** is preferably a world wide web server and the communication network **24** is preferably the Internet. It will be apparent to one skilled in the art that the server **18** may comprise a single stand-alone computer or multiple computers distributed throughout a network. The workstation **20** is preferably a personal computer, remote terminal, or web TV unit connected to the server **18** via the Internet. The workstation **20** functions as a remote interface for entering in the server **18** messages and queries to be communicated to the patients.

The system **16** also includes multiple remotely programmable apparatus, such as first and second apparatuses **26** for monitoring multiple patients. Each apparatus **26** is designed to interact with a patient in accordance with script programs received from the server **18**. Each apparatus **26** is in communication with the server **18** through the communication network **24**, preferably the Internet. Alternatively, each apparatus **26** may be placed in communication with the server **18** via wireless communication networks, cellular networks, telephone networks, satellite networks or any other network which allows each apparatus **26** to exchange data with the server **18**. It is to be understood that the system **16** may include any number of remotely programmable apparatuses for monitoring any number of patients.

In the preferred embodiment, each patient to be monitored is also provided with a monitoring device **28**. The monitoring device **28** is designed to produce measurements of a physiological condition of the patient, record the measurements, and transmit the measurements to the patient's remotely programmable apparatus through a standard connection cable **30**. Examples of suitable monitoring devices **28** include blood glucose meters, respiratory flow meters, blood pressure cuffs, electronic weight scales, and pulse rate monitors. Such monitoring devices are well known in the art. The specific type of monitoring device **28** provided to each patient is dependent upon the patient's disease or health treatment needs. For example, diabetes patients are provided with a blood glucose meter for measuring blood glucose concentrations, asthma patients are provided with respiratory flow meters for measuring peak flow rates, obesity patients are provided with weight scales, etc.

FIG. **2** shows the server **18**, the workstation **20**, and the apparatus **26** in greater detail. The server **18** includes a database **38** for storing script programs **40**. The script programs **40** are executed by each apparatus **26**, to communicate queries and messages to a patient, receive responses **42** to the queries, collect monitoring device measurements **44**, and to transmit

responses **42** and measurements **44** to the server **18**. The database **38** is designed to store responses **42** and measurements **44**. The database **38** further includes a look-up table **46**. The table **46** contains a list of the patients to be monitored, and for each patient, a unique patient identification code and a respective pointer to one or more script programs **40** assigned to the patient. Each remotely programmable apparatus **26** is designed to execute assigned script programs **40** received from the server **18**. The script programs **40** may include queries, reminder messages, informational statements, useful quotations, or other information of benefit to the patient. See Appendix A for example script programs.

FIG. **3**-**4** show the structure of a remotely programmable apparatus **26** according to the preferred embodiment. Referring to FIG. **3**, the apparatus **26** includes a housing **62**. The housing **62** is sufficiently compact to enable the apparatus **26** to be hand-held and carried by a patient. The apparatus **26** also includes a display **64** for displaying queries and prompts to the patient. In the preferred embodiment, the display **64** is a liquid crystal display (LCD).

The apparatus **26** includes five user input buttons **70**A, **70**B, **70**C, **70**D and **70**E that are located on the same side of the apparatus **26** as the display **64**. The user input buttons **70**A-D are for entering in the apparatus **26** responses **42** to the queries and prompts. In the preferred embodiment, the user input buttons **70**A-D are momentary contact push buttons. In alternative embodiments, user input buttons **70**A-D may be replaced by switches, keys, a touch sensitive display screen, or any other data input device.

The user input button **70**E is a emergency or other services button and is preferably red, but may be of any size, shape, or color that draws special visual or tactile attention to the user. The services provided by the user input button **70**E are described in more detail below.

Three monitoring device jacks **68**A, **68**B, and **68**C are located on a surface of housing **62**. The device jacks **68**A-C are for connecting the apparatus **26** to a number of monitoring devices **28**, such as blood glucose meters, respiratory flow meters, or blood pressure cuffs (not shown in FIG. **3**). The apparatus **26** also includes a modem jack **66** for connecting the apparatus **26** to a telephone jack through a standard connection cord (not shown). The apparatus **26** further includes a visual indicator, such as a light emitting diode (LED) **74**. The LED **74** is for visually notifying the patient that he or she has unanswered queries stored in the apparatus **26**.

FIG. **4** is a schematic block diagram illustrating the components of the apparatus **26** in greater detail. The apparatus **26** includes a microprocessor **76** and a memory **80** connected to the microprocessor **76**. The memory **80** is preferably a non-volatile memory, such as a serial EEPROM. The memory **80** stores script programs **40** received from the server **18**, measurements **44** received from the monitoring device **28**, responses **42** to queries. The microprocessor **76** also includes built-in read only memory (ROM), which stores firmware for controlling the operation of the apparatus **26**. The firmware includes a script interpreter used by the microprocessor **76** to execute the script programs **40**. The script interpreter interprets script commands, which are executed by the microprocessor **76**. Specific techniques for interpreting and executing script commands in this manner are well known in the art.

The microprocessor **76** is preferably connected to memory **80** using a standard two-wire interface. The microprocessor **76** is also connected to the user input buttons **70**, the LED **74**, a clock **84**, and a display driver **82**. The clock **84** indicates the current date and time to the microprocessor **76**. For clarity of illustration, clock **84** is shown as a separate component, but is preferably built into the microprocessor **76**. The display driver **82** operates under the control of the microprocessor **76** to display information on the display **64**. The microprocessor **76** is preferably a PIC 16C65 processor. The modem **86** is connected to a telephone jack **22** through the modem jack **66**. The modem **86** is for exchanging data between the server **18** and the processor **76** through the communication network **24**. The data includes the script programs **40** which are received from the server **18** as well as the responses **42** to queries, the device measurements **44**, the script identification codes, and the patient's unique identification code, which the modem **86** transmits to the server **18**. The modem **86** is preferably a complete 28.8 K modem commercially available from Cermetek, although any suitable modem may be used. The processor **76** also includes a component that connects to the telephone jack **22** and a microphone **88** and a speaker **89**, thereby allowing telephone calls to be processed.

The device interface **90** is connected to the device jacks **68**A, **68**B, and **68**C. The device interface **90** is for interfacing with a number of monitoring devices **28**, such as blood glucose meters, respiratory flow meters, blood pressure cuffs, weight scales, or pulse rate monitors, through device jacks **68**A-C.

The device interface **90** operates under the control of the microprocessor **76** to collect measurements **44** from the monitoring devices **28** and to output the measurements to the microprocessor **76** for storage in the memory **80**. In the preferred embodiment, the interface **90** is a standard RS232 interface. For simplicity of illustration, only one device interface **90** is shown in FIG. **4**. However, in alternative embodiments, the apparatus **26** may include multiple device interfaces to accommodate monitoring devices that have different connection standards.

Referring again to FIG. **2**, the server **18** includes a monitoring application **48**. The monitoring application **48** is a controlling software application executed by the server **18** to perform the various functions described below. The application **48** includes a script generator **50**, a script assignor **52**, and a report generator **54**. The script generator **50** is designed to generate the script programs **40** from script information entered through the workstation **20**. The script information is entered through a script entry screen **56**. In the preferred embodiment, script entry screen **56** is implemented as a web page on the server **18**. The workstation **20** includes a web browser for accessing the web page to enter the script information.

FIG. **5** illustrates the script entry screen **56** as it appears on the workstation **20**. The screen **56** includes a script name field **92** for specifying the name of a script program to be generated. The screen **56** also includes entry fields **94** for entering a set of queries to be answered by a patient. Each entry field **94** has corresponding response choice fields **96** for entering response choices for the query. The screen **56** further includes check boxes **98** for selecting a desired monitoring device **28**, such as a blood glucose meter, respiratory flow meter, or blood pressure cuff, from which to collect measurements **44**.

The screen **56** additionally includes a connection time field **100** for specifying a prescribed connection time at which each apparatus **26** executing the script is to establish a subsequent communication link to the server **18**. The connection time is preferably selected to be the time at which communication rates are the lowest, such as 3:00 AM. The screen **56** also includes a CREATE SCRIPT button **102** for instructing script generator **50** to generate a script program **40** from the information entered in screen **56**. The screen **56** further includes a CANCEL button **104** for canceling the information entered in screen **56**.

In the preferred embodiment, each script program **40** created by script generator **50** conforms to the standard file format used on UNIX systems. In the standard file format, each command is listed in the upper case and followed by a colon. Every line in the script program **40** is terminated by a linefeed character {LF}, and only one command is placed on each line. The last character in the script program **40** is a UNIX end of file character {EOF}. Table 1 shows an exemplary listing of script commands used in the preferred embodiment of the invention.

TABLE 1

SCRIPT COMMANDS

Command	Description
CLS: {LF}	Clear the display.
ZAP: {LF}	Erase from memory the last set of query responses recorded.
LED: b{LF}	Turn the LED on or off, where b is a binary digit of 0 or 1. An argument of 1 turns on the LED, and an argument of 0 turns off the LED.
DISPLAY: {chars}{LF}	Display the text following the DISPLAY command.
INPUT: mmmm {LF}	Record a button press. The m's represent a button mask pattern for each of the four input buttons. Each m contains an "X" for disallowed buttons or an "0" for allowed buttons. For example, INPUT: 0X0X{LF} allows the user to press either button #1 or #3.
WAIT: {LF}	Wait for any one button to be pressed, then continue executing the script program.
COLLECT: device{LF}	Collect measurements from the monitoring device specified in the COLLECT command. The user is preferably prompted to connect the specified monitoring device to the apparatus and press a button to continue.
NUMBER: aaaa{LF}	Assign a script identification code to the script program. The script identification code from the most recently executed NUMBER statement is subsequently transmitted to the server along with the query responses and device measurements. The script identification code identifies to the server which script program was most recently executed by the remote apparatus.
DELAY: t{LF}	Wait until time t specified in the DELAY command, usually the prescribed connection time.
CONNECT: {LF}	Perform a connection routine to establish a communication link to the server, transmit the patient identification code, query responses, device measurements, and script identification code to the server, and receive and store a new script program. When the server instructs the apparatus to disconnect, the script interpreter is restarted, allowing the new script program to execute.

The script commands illustrated in Table 1 are representative of the preferred embodiment and are not intended to limit the scope of the invention. After consideration of the ensuing description, it will be apparent to one skilled in the art many other suitable scripting languages and sets of script commands may be used to implement the invention.

The script generator **50** preferably stores a script program template which it uses to create each script program **40**. To generate a script program **40**, the script generator **50** inserts into the template the script information entered in the screen **56**. For example, FIG. **6**A-**6**B illustrate a sample script program **40** created by the script generator **50** from the script information shown in FIG. **5**.

The script program **40** includes display commands to display the queries and response choices entered in fields **94** and **96**, respectively. The script program **40** also includes input commands to receive responses **42** to the queries. The script program **40** further includes a collect command to collect device measurements **44** from the monitoring device **28** specified in the check boxes **98**. The script program **40** also includes commands to establish a subsequent communication link to the server **18** at the connection time specified in field **100** FIG. **5**. The steps included in the script program **40** are also shown in the flow chart of FIG. **12**A-**12**B and will be discussed in the operation section below.

Referring again to FIG. **2**, the script assignor **52** is used to assign script programs **40** to the patients. The script programs **40** are assigned in accordance with script assignment information entered through workstation **20**. The script assignment information is entered through a script assignment screen **57**, which is preferably implemented as a web page on the server **18**.

FIG. **7** illustrates a sample script assignment screen **57** as it appears on workstation **20**. The screen **57** includes check boxes **106** for selecting a script program **40** to be assigned, and check boxes **108** for selecting the patients to whom the script program is to be assigned. The screen **57** also includes an ASSIGN SCRIPT button **112** for entering the assignments. When button **112** is pressed, the script assignor **52** creates and stores for each patient selected in check boxes **108** a respective pointer to the script program **40** selected in the check boxes **106**. Each pointer is stored in the patient look-up table **46** of the database **38**. The screen **57** further includes an ADD SCRIPT button **110** for accessing the script entry screen and a DELETE SCRIPT button **114** for deleting a script program **40**.

Referring again to FIG. **2**, the report generator **54** is designed to generate a patient report **58** from the responses **42** and the device measurements **44** received in the server **18**.

The patient report **58** is displayed on the workstation **20**. FIG. **10** shows a sample patient report **58** produced by the report generator **54** for a selected patient. The patient report **58** includes a graph **116** of the device measurements **44** received from the patient, as well as a listing of the responses **42** received from the patient. Specific techniques for writing a report generator program to display data in this manner are well known in the art.

The operation of the preferred embodiment is illustrated in FIG. **1-12**. FIG. **11**A is a flow chart illustrating steps included in the monitoring application executed by the server **18**. FIG. **11**B is a continuation of the flow chart of FIG. **11**A. In step **202**, the server **18** determines if new script information has been entered through the script entry screen **56**. If new script information has not been entered, the server **18** proceeds to step **206**. If new script information has been entered, the server **18** proceeds to step **204**.

As shown in FIG. **5**, the script information includes a set of queries, and for each of the queries, corresponding response choices. The script information also includes a selected monitoring device type from which to collect device measurements **44**. The script information further includes a prescribed connection time for each apparatus to establish a subsequent communication link to the server **18**. The script information is generally entered in the server **18** by a healthcare provider, such as the patients' physician or case manager. Of course, any person desiring to communicate with the patients may also be granted access to the server **18** to create and assign script programs **40**. Further, it is to be understood that system **16** may include any number of remote interfaces for entering script generation and script assignment information in the server **18**.

In step **204**, the script generator **50** generates a script program from the information entered in the screen **56**. The script program is stored in the database **38**. Steps **202** and **204** are preferably repeated to generate multiple script programs, e.g., a script program for diabetes patients, a script program for asthma patients, etc. Each script program corresponds to a respective one of the sets of queries entered through the script entry screen **56**. Following step **204**, the server **18** proceeds to step **206**.

In step **206**, the server **18** determines if new script assignment information has been entered through the assignment screen **57**. If new script assignment information has not been entered, the server **18** proceeds to step **210**. If new script assignment information has been entered, the server **18** proceeds to step **208**. As shown in FIG. **7**, the script programs are assigned to each patient by selecting a script program through check boxes **106**, selecting the patients to whom the selected script program is to be assigned through check boxes **108**, and pressing the ASSIGN SCRIPT button **112**. When button **112** is pressed, the script assignor **52** creates for each patient selected in the check boxes **108** a respective pointer to the script program selected in the check boxes **106**. In step **208**, each pointer is stored in the look-up table **46** of the database **38**. Following step **208**, the server **18** proceeds to step **210**.

In step **210**, the server **18** determines if any of the apparatuses are remotely connected to the server. Each patient to be monitored is preferably provided with his or her own remotely programmable apparatus, which has the patient's unique identification code, stored therein. Each patient is thus uniquely associated with a respective one of the apparatuses. If none of the apparatuses is connected, the server **18** proceeds to step **220**. If an apparatus is connected, the server **18** receives from the apparatus the patient's unique identification code in step **212**. In step **214**, the server **18** receives from the apparatus **26** the query responses **42**, device measurements **44**, and script identification code recorded during execution of a previously assigned script program. The script identification code identifies to the server **18** which script program was executed by the apparatus to record the query responses **42** and device measurements **44**. The responses, device measurements, and script identification code are stored in the database **38**.

In step **216**, the server **18** uses the patient identification code to retrieve from the table **46** the pointer to the script program assigned to the patient. The server **18** then retrieves the assigned script program from the database **38**. In step **218**, the server **18** transmits the assigned script program to the patient's remotely programmable apparatus through the communication network **24**. Following step **218**, the server **18** proceeds to step **220**.

In step **220**, the server **18** determines if a patient report request has been received from the workstation **20**. If no report request has been received, the server **18** returns to step **202**. If a report request has been received for a selected patient, the server **18** retrieves from the database **38** the measurements **44** and query responses **42** last received from the patient, step **222**. In step **224**, the server **18** generates and displays the patient report **58** on the workstation **20**. As shown in FIG. **10**, the report **58** includes the device measurements **44** and query responses **42** last received from the patient. Following step **224**, the server **18** returns to step **202**.

FIG. **12**A-**12**B illustrate the steps included in the script program executed by the apparatus **26**. Before the script program is received, the apparatus **26** is initially programmed with the patient's unique identification code and the script interpreter used by microprocessor **76** to execute the script program. The initial programming may be achieved during manufacture or during an initial connection to the server **18**. Following initial programming, the apparatus **26** receives from the server **18** the script program assigned to the patient associated with the apparatus **26**. The script program is received by the modem **86** through a first communication link and stored in the memory **80**.

In step **302**, microprocessor **76** assigns a script identification code to the script program and stores the script identification code in the memory **80**. The script identification code is subsequently transmitted to the server **18** along with the query responses **42** and the device measurements **44** to identify to the server **18** which script program was most recently executed by apparatus **26**. In step **304**, the microprocessor **76** lights LED **74** to notify the patient that he or she has unanswered queries stored in the apparatus **26**. The LED **74** preferably remains lit until the patient answers the queries. In step **306**, the microprocessor **76** erases from the memory **80** the last set of query responses recorded.

In step **308**, the microprocessor **76** prompts the patient by displaying on the display **64** "ANSWER QUERIES NOW? PRESS ANY BUTTON TO START". In step **310**, the microprocessor **76** waits until a reply to the prompt is received from the patient. When a reply is received, the microprocessor **76** proceeds to step **312**. In step **312**, the microprocessor **76** executes successive display and input commands to display the queries and response choices on the display **64** and to receive responses to the queries.

FIG. **8** illustrates a sample query and its corresponding response choices as they appear on the display **64** The response choices are positioned on the display **64** such that each response choice is located proximate a respective one of input buttons **70**A-D. In the preferred embodiment, each response choice is displayed immediately above a respective input button **70**A-D. The patient presses the button **70**A-D

corresponding to his or her response. The microprocessor **76** stores each response in the memory **80**.

In steps **314-318**, the microprocessor **76** executes commands to collect the device measurements **44** from a selected the monitoring device **28**. The script program specifies the selected monitoring device from which to collect the measurements. In step **314**, the microprocessor **76** prompts the patient to connect the selected monitoring device **28**, for example a blood glucose meter, to one of device jacks **68**A-C. A sample prompt is shown in FIG. **9**. In step **316**, the microprocessor **76** waits until a reply to the prompt is received from the patient. When a reply is received, the microprocessor **76** proceeds to step **318**. In step **318**, the microprocessor **76** collects device measurements **44** from the monitoring device **28** through the interface **90**. The measurements **44** are stored in the memory **80**.

In step **320**, the microprocessor **76** prompts the patient to connect the apparatus **26** to the telephone jack **22** so that the apparatus **26** may connect to the server **18** at the prescribed connection time. In step **322**, the microprocessor **76** waits until a reply to the prompt is received from the patient. When a reply is received, the microprocessor **76** turns off the LED **74** in step **324**. In step **326**, the microprocessor **76** waits until it is time to connect to the server **18**. The microprocessor **76** compares the connection time specified in the script program to the current time output by the clock **84**.

In step **328**, the microprocessor **76** establishes a subsequent communication link between the apparatus **26** and the server **18** through the modem **86** and the communication network **24**. If the connection fails for any reason, the microprocessor **76** repeats step **328** to get a successful connection. In step **330**, the microprocessor **76** transmits the device measurements **44**, query responses **42**, script identification code, and patient identification code stored in the memory **80** to the server **18** through the subsequent communication link. In step **332**, the microprocessor **76** receives through the communication network **24** a new script program from the server **18**. The new script program is stored in the memory **80** for subsequent execution by the microprocessor **76**. Following step **332**, the script program ends.

One advantage of the monitoring system of the present invention is that it allows each patient to select a convenient time to respond to the queries, so that the monitoring system is not intrusive to the patient's schedule. A second advantage of the monitoring system is that it incurs very low communications charges because each remote apparatus connects to the server **18** at times when communication rates are lowest. Moreover, the cost to manufacture each remote the apparatus **26** is very low compared to personal computers or internet terminals, so that the monitoring system is highly affordable.

A third advantage of the monitoring system is that it allows each apparatus **26** to be programmed remotely through script programs **40**. Patient surveys, connection times, display prompts, selected monitoring devices, patient customization, and other operational details of each apparatus **26** may be easily changed by transmitting a new script program **40** to apparatus **26**. Moreover, each script program **40** may be easily created and assigned by remotely accessing the server **18** through the Internet. Thus, the invention provides a powerful, convenient, and inexpensive system for remotely monitoring a large number of patients.

FIG. **13-15** illustrate a second embodiment of the invention in which each remotely programmable apparatus includes all of the functionality of the first embodiment described above while also including speech recognition and speech synthesis functionality. FIG. **13** shows a perspective view of the remotely programmable apparatus **27** according to the second embodiment. The apparatus **27** includes a speaker **72** for audibly communicating queries and prompts to the patient. The apparatus **27** also includes a microphone **118** for receiving spoken responses to the queries and prompts. The apparatus **27** may optionally include a display **64** for displaying prompts to the patient, as shown in FIG. **14**.

FIG. **15** is a schematic block diagram illustrating the components of the apparatus **27** in greater detail. The apparatus **27** is similar in design to the apparatus **26** of the preferred embodiment except that the apparatus **27** includes an audio processor chip **120** in place of the microprocessor **76**. The audio processor chip **120** is preferably an RSC-164 chip commercially available from Sensory Circuits Inc. of 1735 N. First Street, San Jose, Calif. 95112.

The audio processor chip **120** has a microcontroller **122** for executing script programs received from the server **18**. A memory **80** is connected to the microcontroller **122**. Memory **80** stores the script programs and a script interpreter used by the microcontroller **122** to execute the script programs. The memory **80** also stores measurements received from the monitoring device **28**, responses to the queries, script identification codes, and the patient's unique identification code.

The audio processor chip **120** also has built in speech synthesis functionality for synthesizing queries and prompts to a patient through the speaker **72**. For speech synthesis, the chip **120** includes a digital to analog converter-(DAC) **142** and an amplifier **144**. The DAC **142** and the amplifier **144** drive the speaker **72** under the control of the microcontroller **122**.

The audio processor chip **120** further has built in speech recognition functionality for recognizing responses spoken into the microphone **118**. Audio signals received through the microphone **118** are converted to electrical signals and sent to a preamp and gain control circuit **128**. The preamp and gain control circuit **128** is controlled by an automatic gain control circuit **136**, which is in turn controlled by the microcontroller **122**. After being amplified by the preamp **128**, the electrical signals enter the chip **120** and pass through a multiplexer **130** and an analog to digital converter (ADC) **132**. The resulting digital signals pass through a digital logic circuit **134** and enter microcontroller **122** for speech recognition.

The audio processor chip **120** also includes a RAM **138** for short-term memory storage and a ROM **140**, which stores programs executed by the microcontroller **122** to perform speech recognition and speech synthesis. The chip **120** operates at a clock speed determined by a crystal **126**. The chip **120** also includes a clock **84** that provides the current date and time to the microcontroller **122**. As in the preferred embodiment, the apparatus **27** includes an LED **74**, display driver **82**, modem **86**, and device interface **90**, all of which are connected to the microcontroller **122**.

The operation of the second embodiment is similar to the operation of the preferred embodiment except that queries, response choices, and prompts are audibly communicated to the patient through the speaker **72** rather than being displayed to the patient on the display **64**. The operation of the second embodiment also differs from the operation of the preferred embodiment in that responses to the queries and prompts are received through the microphone **118** rather than through user input buttons.

The script programs of the second embodiment are similar to the script program shown in FIG. **6**A-**6**B, except that each display command is replaced by a speech synthesis command and each input command is replaced by a speech recognition command. The speech synthesis commands are executed by the microcontroller **122** to synthesize the queries, response choices, and prompts through speaker **72**. The speech recog-

nition commands are executed by the microcontroller **122** to recognize responses spoken into microphone **118**.

For example, to ask the patient how he or she feels and record a response, the microcontroller **122** first executes a speech synthesis command to synthesize through the speaker **72** "How do you feel? Please answer with one of the following responses: very bad, bad, good, or very good." Next, the microcontroller **122** executes a speech recognition command to recognize the response spoken into the microphone **118**. The recognized response is stored in the memory **80** and subsequently transmitted to the server. Other than the differences described, the operation and advantages of the second embodiment are the same as the operation and advantages of the preferred embodiment described above.

Although the first and second embodiments focus on querying individuals and collecting responses to the queries, the system of the invention is not limited to querying applications. The system may also be used simply to communicate messages to the individuals. FIG. **16-19** illustrate a third embodiment in which the system is used to perform this automated messaging function. In the third embodiment, each script program contains a set of statements to be communicated to an individual rather than a set of queries to be answered by the individual Of course, it will be apparent to one skilled in the art that the script programs may optionally include both queries and statements.

The third embodiment also shows how the queries and statements may be customized to each individual by merging personal data with the script programs, much like a standard mail merge application. As mentioned above, the individual may be identified for selection of individualized information either through an individual identification code associated with the remote apparatus **26** and stored in memory **80**. Referring to FIG. **16**, personal data relating to each individual is preferably stored in the look-up table **46** of the database **38**. By way of example, the data may include each individual's name, the name of each individual's physician, test results, appointment dates, or any other desired data. As in the preferred embodiment, the database **38** also stores generic script programs **40** created by the script generator **50**.

The server **18** includes a data merge program **55** for merging the data stored in table **46** with generic script programs **40**. The data merge program **55** is designed to retrieve selected data from table **46** and to insert the data into statements in generic script programs **40**, thus creating custom script programs **41**. Each custom script program **41** contains statements that are customized to an individual. For example, the statements may be customized with the individual's name, test results, etc. Examples of such customized statements are shown in FIG. **17-18**.

The operation of the third embodiment is similar to the operation of the preferred embodiment except that the script programs are used to communicate messages to the individuals rather than to query the individuals. Each message is preferably a set of statements. Referring to FIG. **19**, the statements may be entered in the server **18** through the script entry screen **56**, just like the queries of the preferred embodiment.

Each statement preferably includes one or more insert commands specifying data from table **46** to be inserted into the statement. The insert commands instruct the data merge program **55** to retrieve the specified data from the database **38** and to insert the data into the statement. For example, the insert commands shown in FIG. **19** instruct the data merge program **55** to insert a physician name, an appointment date, a patient name, and a test result into the statements. As in the preferred embodiment, each statement may also include one or more response choices, which are entered in fields **96**.

Following entry of the statements and response choices, CREATE SCRIPT button **102** is pressed. When the button **102** is pressed, the script generator **50** generates a generic script program from the information entered in the screen **56**. The generic script program is similar to the script program shown in FIG. **6**A-**6**B, except that the display commands specify statements to be displayed rather than queries. Further, the statements include insert commands specifying data to be inserted into the script program. As in the preferred embodiment, multiple script programs are preferably generated, e.g., a generic script program for diabetes patients, a generic script program for asthma patients, etc. The generic script programs are stored in the database **38**.

Following generation of the generic script programs, the server **18** receives script assignment information entered through the script assignment screen **57**. As shown in FIG. **7**, the script programs are assigned by first selecting one of the generic script programs through the check boxes **106**, selecting individuals through the check boxes **108**, and pressing the ASSIGN SCRIPT button **112**. When the button **112** is pressed, the data merge program **55** creates a custom script program **41** for each individual selected in check boxes **108**.

Each custom script program **41** is preferably created by using the selected generic script program as a template. For each individual selected, the data merge program **55** retrieves from the database **38** the data specified in the insert commands. Next, the data merge program **55** inserts the data into the appropriate statements in the generic script program **40** to create a custom script program **41** for the individual. Each custom script program **41** is stored in the database **38**.

As each custom script program **41** is generated for an individual, the script assignor **52** assigns the script program **41** to the individual. This is preferably accomplished by creating a pointer to the custom script program and storing the pointer with the individual's unique identification code in the table **46**. When the individual's remotely programmable apparatus connects to the server **18**, the server **18** receives from the remotely programmable apparatus **26** the individual's unique identification code. The server **18** uses the unique identification code to retrieve from the table **46** the pointer to the custom script program assigned to the individual. Next, the server **18** retrieves the assigned script program from the database **38** and transmits the script program to the individual's remotely programmable apparatus **26** through the communication network **24**.

The apparatus receives and executes the script program. The execution of the script program is similar to the execution described in the preferred embodiment, except that statements are displayed to the individual rather than queries. FIG. **17-18** illustrate two sample statements as they appear on the display **64**. Each statement includes a response choice, preferably an acknowledgment such as "OK". After reading a statement, the individual presses the button **70**A-D corresponding to the response choice to proceed to the next statement. Alternatively, the script program may specify a period of time that each statement is to be displayed before proceeding to the next statement. The remaining operation of the third embodiment is analogous to the operation of the preferred embodiment described above.

Although it is presently preferred to generate a custom script program **41** for each individual as soon as script assignment information is received for the individual, it is also possible to wait until the individual's apparatus **26** connects to the server **18** before generating the custom script program **41**. This is accomplished by creating and storing a pointer to the generic script program **40** assigned to the individual, as previously described in the preferred embodiment. When the

individual's apparatus **26** connects to the server **18**, the data merge program **55** creates a custom script program **41** for the individual from the generic script program **40** assigned to the individual. The custom script program **41** is then sent to the individual's apparatus **26** for execution.

Alternate Embodiments

In an alternate embodiment, when the user or patient (the terms user and patient are used interactively) activates the user input button **70**E (hereinafter the red button) a command signal is sent to the processor **76**. The processor **76** dial a preset phone number according to the command signal. The preset phone number is that of an answering service at the server **18** or at a workstation **20**. The answering service identifies the patient or user associated with the remote apparatus **26** that generated the call based on an identifier sent with the call and user information stored in memory in the database (similar to caller ID). The system (server **18** or workstation **20**) that receives the call then retrieves patient information with previous patient/user responses stored at the server's database **38**, within memory at the workstation **20**, or at some other remotely located storage site. The retrieved patient information is displayed to a live person who is in telephonic communication with the patient. This allows the patient to be placed in immediate contact with a person who has displayed before them the patient's personal health information or other patient historical information. The person receiving the call provides effective communication with the patient, because of the ability to view pertinent information.

In an alternate embodiment, an automated answering service is the recipient of the call made by the remote apparatus **26**. The automated answering service asks a series of questions according to the retrieved patient information in order to triage the patient toward different actions depending upon the situation. The patient information also includes previous patient interactions with the automated answering service.

The system receiving the call process patient responses according to the content associated with the question asked. Content is one of the following categories: symptoms; behavior; knowledge. The categories include such things as requests for service or product orders. In one example, the automated answering service asks "do you have difficulty breathing? press the red button if you are." If the patient then presses the red button, the call is forwarded to a case manager or a nurse on call.

In another example, red button selection is associated with a request for service. When the red button is pressed, the automated answering service asks "do you need someone to change your bed? press the red button if yes." If the patient presses the red button, a home care agency coordinating ancillary daily activity services is notified or is forwarded the call. Other service companies, such as transport companies or concierge service companies, are other possible recipients of forwarded calls depending what actions are available to the patients.

The automated answering service is dynamically adaptable based on previous interactions with the automated answering service. For example, the past couple of times the patient activated the red button and answered the question(s), the patient was connected to an emergency health care worker. If the worker determined through review questions of the patient's present condition, maybe information generated by the monitoring device sent over the network **24** to a workstation operated by the worker, and retrieved patient information that no emergency existed, the worker records this situation into the patient's records. If the patient's record includes a number of false alarms that exceed a predetermined limit over a period of time, the automated answering service reprograms itself so that the next time the patient activates the red button the patient is directly connected to a live person that is designated for non-emergency patient interaction or to other questions that direct the patient to the person designated for non-emergency patient interaction. This frees-up emergency healthcare workers from dealing with someone who has a history of not needing their expertise.

FIGS. **20** and **21** illustrate alternate embodiments of the invention illustrated in FIG. **1**. In FIG. **20**, the remote apparatus **26** is a personal computer including a processor and a user interface, e.g., display, keyboard, mouse, or other input and output devices (not all shown), that receives the script program, processes the script program and presents the script program for user interaction. For example, the script program requires that the personal computer present an image of a stand-alone remote apparatus **350**, such as the Health Buddy™, produced by Health Hero Network, Inc., on the display. The user then interacts with the displayed image of the stand-alone remote apparatus by operating the user interface(s) of the personal computer to select displayed responses. The displayed image of the stand-alone remote apparatus presents a virtual image with the same functionality as the apparatuses **26** and **27**, as described above in FIGS. **3** and **13**. It can be appreciated to those of ordinary skill in the art that the system of FIG. **20** provides all or part of the functionality of the apparatuses shown in FIGS. **3** and **13**, but does it on a personal computer.

FIG. **21** includes all the components of the FIG. **1** and a digital television network **36** in communication with the server **18** and the remote apparatus **26**. The remote apparatus **26** of FIG. **21** is an interactive television system that includes a processing unit **33**, such as a satellite broadcast receiving, set-top processor with OpenTV signal processing software, a display **34**, such as a television set, and a user interface **35**, such as a remote control. The remote apparatus **26**, through the processing unit **33**, is coupled to the communication network **24**, the digital television network **36** and the monitoring device **28**.

The processing unit **33** includes a CPU, memory and embedded software for receiving and processing both digital entertainment and advertisement content and digital script programs. Also, the processing unit **33** allows the user to view the entertainment and advertisement content, such as television programming, and interact with (i.e., respond to) the script programs. The script program(s) sent from the server **18** are viewable on the display **34** as they would appear on the display **64** of apparatus **26** or are viewed on a portion of the display **34**. For example, the question with options shown in FIG. **8** would appear on the display **34**. The user makes a selection of one of the choices by using the user interface **35**, i.e., giving voice commands that are processed by a voice recognition system, controlling and activating a cursor, etc. Example methods of making a selection are to control a cursor icon on the display screen of the display **34** and activate the cursor icon when it is co-located with one of the choices, to assign different keyboard keys are designated as a different one of the displayed choices. Another method is to have the user interface include voice actuation software for processing user voice commands that request selection of a desired choice.

With respect to this invention, a "broadcast" includes any form of delivering the content from a source to many viewers, including transmission over the airwaves or via cable, the Internet, a closed-circuit network, or other means of communication. A "broadcast" does not require multiple persons to

watch at once, but rather can include multiple individual and independent viewings, such as in the form of video on demand or access to web pages. Moreover, the term "broadcast" may include a single tailored transmission from a source to a single intended viewer. Accordingly, while a "broadcast" may include a transmission from one point to multiple recipients, it is not limited to that case. Likewise, with respect to this invention, a "broadcast" is "transmitted" in any of the above forms.

The processing unit **33** is a multimedia processor that receives transmitted broadcast programs from a digital broadcast network **36** via a communication link, such as a satellite or cable link. The processing unit **33** also transmits as well as receives data via the communication network **24**. In addition, the multimedia processor has expansion ports to support additional user interface and other devices, such as keyboards, joysticks, trackballs, and to accept add-on circuits for enhanced sound, video, or processing performance.

FIG. **22** is an example for illustrative purposes only of a method for increasing user use of script programs by allowing the user to quickly access the script program during viewing of an entertainment or advertisement program in an interactive TV system. FIG. **22** illustrates a process performed by the system shown in FIG. **21**. At block **400**, the server **18** generates an interactive script program. In an alternate embodiment, the script program is fully or partially created at another remotely coupled computer, such as workstation **20**, and added to multimedia content, then the script program and multimedia content is sent to the server **18** In one embodiment, the script program is specialized for a specific user according to a health care professional request or to a predefined health regimen based on user profile information. In an alternate embodiment the script program is generated in relation to entertainment or advertisement content that it will later be broadcasted with. Next, at block **402**, the generated script program is combined with digitally produced entertainment or advertisement content, i.e., a multimedia presentation, to create digital broadcast programming. The digital broadcast programming is then broadcasted or transmitted over the chosen communication link, block **406**. At block **408**, the processing unit **33** receives and processes the digital broadcast programming then presents the entertainment or advertisement content and the script program. The processing unit **33** as directed by software instructions previously imbedded in the processing unit **33**, included with the digital broadcast programming or a combination of both processes the digital broadcast programming by determining its content and how that content is to be presented on the display **34**. For example, the processing unit **33** determines if the script program is to be referenced by an icon over the entertainment content or displayed on a portion of the display with the entertainment content. As part of the presentation from block **408** the user is informed of any script program included in the broadcast programming, block **410**. Then, at block **426**, the user is presented with the script program after the user selects or activates the indication, e.g., an icon. Lastly, at block **428**, the user interacts with the script program by responding to any queries and inputting any requested measurements or other responses. The interaction with the script program is similar to that described above for the system of FIG. **1**. In another embodiment, the script program is presented in conjunction with the entertainment or advertisement content without requiring the user to select or activate an indicator.

FIGS. **23** and **24** are example images presented on the displays **34** in the system illustrated in FIG. **22**. FIG. **23** illustrates a screen shot of a broadcast program **250** that includes entertainment content **252**, such as a video program on heart surgery, and an icon **254**. The icon **254** indicates that a script program is available for the viewer. In order for the viewer to access the script program, the viewer selects the icon **254**. The program broadcasted from the broadcast network **24** may have included an entire script program or just a portion of a script program. If the entire script program were included with the broadcast, selection of the icon **254** would begin execution of the script program that was received. However, if only a portion of the script program was received and, for example, that portion only required that the icon **254** be displayed with the entertainment content **252**, selection of the icon **254** sends a signal through a back channel, i.e., the link to the communication network **24**, to the server **18**. The sent signal is a request for the rest of or just more of the script program to be sent to the apparatus **26** either through broadcast network **36** or communication network **24**.

FIG. **24** illustrates a screen shot of a broadcast program **250** that includes entertainment content **252** and a section that presents a script program image **256**. In this example the viewer can interact with the script program image **256** while simultaneously viewing the entertainment content **252**. As in FIG. **22** above, the script program may be fully or partially received and processed by the processing unit **33**. And again, if it has only been partially received, viewer interaction at a predetermined spot in the displayed interaction process automatically initiates a request through the back channel to the server **18** for the rest of the script program.

Because the broadcast program **250** is a digital broadcast, it can be readily appreciated by those of ordinary skill in the art of digital interactive television, that the entertainment content may be paused until viewer completion of the script program. The script program which can be sent with an initial broadcast program or during presentation of a previously delivered broadcast program that is being presented on the display may also include instructions to pause the entertainment content until viewer completion of the script program at which time the entertainment program resumes. For example, the viewer's/patient's doctor creates a message at the workstation **20** requesting that the patient as soon as possible send blood pressure measurement readings. This message is generated as a new script program at the server **18**. The server **18** then sends the new script program to the broadcast network **36**. The broadcast network **36** includes hardware and/or software mechanisms for saving the new script program for inclusion with the next patient requested entertainment or advertisement content to be sent to the patient in the case where the patient is not presently viewing a broadcast from the broadcast network **36** or for just broadcasting the script program alone. If the patient is presently viewing entertainment or advertisement content received from the broadcast network **36**, the new script program is received, processed and presented to the patient by the apparatus **26**. The received new script program may include instructions to pause the presently viewed entertainment or advertisement content.

If the script program is specified for a particular patient, the server **18** or broadcast network **36** encodes the script program for that patient. The apparatus of that patient includes a decoding component within the processing unit **33** for decoding the encoded script program received with the broadcast program. For example, the script program includes a weight history chart of the patient. The present invention wants only the patient corresponding to this weight history chart to have viewing access. Therefore, it is encoded for transmission and encoded only by the corresponding patient's apparatus **26**.

It can be appreciated to one of ordinary skill in the art that this decision, as with the other flow diagram decisions, can be

an inherent decision in the processing of the received entertainment/advertisement programming and script program.

The embodiments of FIGS. **20** and **21** may also be implemented without any entertainment or advertisement content and perform the functions as to those that illustrated and described for FIG. **1**.

The script programs or entertainment/advertisement programming can be designed for education and training of users. For example, the script program or information content could show a user, such as a patient, how to effectively use a medical treatment device. Also, the script program or information content could describe to users, such as doctors, nurses or anyone other professional, different treatment styles, plans or new medication.

A wide variety of information may be collected, delivered and analyzed in accordance with the present invention. For example, abandoned U.S. patent application Ser. No. 09/378,188 which is a continuation of U.S. Pat. No. 5,985,559, and U.S. patent application Ser. No. 09/496,893, now U.S. Pat. No. 8,078,407, which is a continuation of U.S. patent application Ser. No. 09/041,809 (the text of which are hereby incorporated by reference) discusses information related to disease causes, treatments, and cures. Script programs include a set of queries for requesting data on lifestyle, environment, behavior, drug compliance, drug response over time, and other aspects. This data is then analyzed to identify trends and establish subgroups with similar responses.

Individuals' behavioral and environmental information in conjunction with their gene sequence information is analyzed to find drug candidates and drug targets. Individuals previously designated as having a high risk for developing a particular disease are each given an apparatus **26**. Queries related to the individuals' behavior and environment are included in a script program sent from a server **18** to the apparatus **26** or from a server **18** to the apparatus **26** through a broadcast network **36**. The individuals' responses are sent back to the server **18**. The process of collecting individuals' information can take place over a long period of time to ensure accurate data and to allow researchers to observe progression of the disease. A data mining program on the server analyzes the individuals' behavioral and environmental information, as well as their gene sequence information. Differences in gene sequence information, or in behavioral and environmental factors between individuals who show a severe disease phenotype and those who show a mild severe disease phenotype can then be distinguished and used to develop new drug candidates, targets, or general treatments.

Genetic testing allows an individual to determine whether or not he or she has a predisposition to a certain disease. The degree of expressivity of a certain disease will be determined in part by an individual's environment and lifestyle. The environment and lifestyle information is retrieved from responses to queries sent from the server **18** to the apparatus **26** or from the server **18** to the apparatus **26** through the broadcast network **36**. The present invention interprets a patient's gene sequence information and his or her environment and lifestyle to come up with a personalized prognosis. This procedure can be repeated many times over the course of a disease state to monitor a patient's condition. In addition, disease-causing pathogens can also have their genes sequenced. Using these sequences in combination with information about a patient's environment and lifestyle, the present invention comes up with a personalized treatment plan, ideally to eliminate the pathogen. It is also possible to use the procedure described above to monitor the course of the disease-state produced by a pathogen. Finally, a genotype-to-phenotype map or database can be constructed for developing better treatments and aiding in research.

Although the above description contains many specificities, these should not be construed as limitations on the scope of the invention but merely as illustrations of some of the presently preferred embodiments. Many other embodiments of the invention are possible. For example, the scripting language and script commands shown are representative of the preferred embodiment. It will be apparent to one skilled in the art many other scripting languages and specific script commands may be used to implement the invention.

Moreover, the invention is not limited to the specific applications described. The system and method of the invention have many other applications both inside and outside the healthcare industry. For example, pharmaceutical manufacturers may apply the system in the clinical development and post marketing surveillance of new drugs, using the system as an interactive, on-line monitoring tool for collecting data on the efficacy, side effects, and quality of life impact of the drugs. Compared to the current use of labor-intensive patient interviews, the system provides a fast, flexible, and cost effective alternative for monitoring the use and effects of the drugs.

The system may also be used by home healthcare companies to enhance the service levels provided to customers, e.g., panic systems, sleep surveillance, specific monitoring of disease conditions, etc. Alternatively, the system may be used to monitor and optimize the inventory of home-stationed health supplies. As an example, the system may be connected to an appropriate measuring device to optimize timing of oxygen tank delivery to patients with chronic obstructive pulmonary disease (COPD).

The system and method of the invention also have many applications outside the healthcare industry. For example, the system may be used for remote education over the Internet, facilitating educational communication with children or adult trainees who lack access to sophisticated and expensive computer equipment. The system may also be used by law enforcement officers to perform on-line surveillance of individuals on probation or parole.

In an alternate embodiment, the software and hardware components of any one of the remote apparatuses **26** or **27** are incorporated directly into a monitoring device. This allows a patient to only have to interact with one device for their entire health monitoring needs.

Further, the invention has numerous applications for gathering data from remotely located devices. For example, the system may be used to collect data from smart appliances, such as identification check systems. Examples of appliances that are used as smart appliances are refrigerator, telephone, stove, clock radio, VCR, or any other electrical or non-electrical device including the monitoring device **28**. The smart appliance includes some or all of the components of the remote apparatuses **26** or **27** as illustrated in FIGS. **4** and **15**. The smart appliance with the necessary hardware or software components provides all the interactive capabilities described and shown for remote apparatuses **26** or **27**, see FIGS. **8-12**, **14**, **17** and **18**. In one embodiment, the assigned scripts are in the form of a recorded voice that is sent over the communication network (e.g., voice over IP) to the appliance or remote apparatus. Also, the user responds to the voice scripts through activation of buttons according to instructions in the voice scripts or by verbally responding to the voice scripts. The verbal responses by the user are sent to the server or workstation over the communication network (e.g., voice over IP). The server or workstation includes a voice recognition component for interpreting the user's verbal responses, records the response and determines the next question or request

(verbal or otherwise) to be sent to the user according to the responses. Live voice communication is also possible between the remote apparatus and the server or workstation over the communication network.

Also, the monitoring device includes a communication component for allowing the monitoring device to send data directly to the server **18**. The server **18** then sends the monitoring device data to the patient's smart appliance for display to the patient. In an alternate additional setup, the monitoring device sends the data to the smart apparatus.

Alternatively, the system may be applied to the remote monitoring of facilities, including safety and security monitoring, or to environmental monitoring, including pollution control and pipeline monitoring. Many other suitable applications of the invention will be apparent to one skilled in the art.

Therefore, the scope of the invention should be determined not by the examples given, but by the appended claims and their legal equivalents.

The invention claimed is:

1. A method of monitoring a clinical trial, comprising:

A) selecting a program from a number of computer programs stored on a server, wherein said program contains one or more queries and one or more corresponding response choices related to efficacy, side effects and quality of life impact of one or more drugs;

B) transmitting the program from said server to a remotely situated apparatus through at least one communication network during a first communication link, wherein the remotely situated apparatus is assigned to a participant of said clinical trial and the program causes the apparatus to present the one or more queries and one or more corresponding response choices to the participant and collect responses, including at least one of the corresponding response choices, from the participant while the remotely situated apparatus is not in communication with said server;

C) receiving the responses from the remotely situated apparatus through the at least one communication network during a second communication link and storing the responses in the server, wherein the program causes the remotely situated apparatus to automatically establish the second communication link with the server at a prescribed time and transmit (i) the responses collected from the participant, (ii) a program identification code, and (iii) an identification code associated with the participant; and

D) generating a report about said clinical trial based upon the responses, wherein said responses are collected in response to the queries related to the efficacy, side effects and quality of life impact of the one or more drugs with respect to said participant during a clinical development or post marketing surveillance period.

2. The method according to claim **1**, further comprising the step of measuring a physiological condition of the participant in order to assess the efficacy, side effects and quality of life impact of said one or more drugs with respect to said participant.

3. The method according to claim **2**, wherein said physiological condition comprises a blood oxygen level.

4. The method according to claim **2**, wherein said physiological condition comprises a blood glucose level.

5. The method according to claim **2**, wherein said physiological condition comprises a blood pressure.

6. The method according to claim **2**, wherein said physiological condition comprises a respiratory flow rate.

7. The method according to claim **1**, wherein said participant is managing a chronic disease or condition.

8. The method according to claim **7**, wherein said chronic disease comprises chronic obstructive pulmonary disease (COPD).

9. The method according to claim **1**, further comprising the steps of:

entering queries related to said clinical trial and corresponding response choices into the server;

generating one or more programs in the server using the queries and the response choices; and

storing the one or more programs on the server.

10. The method according to claim **1**, wherein said program is customized for said participant.

11. The method according to claim **10**, wherein said program is customized to the participant by merging personal data with a generic program.

12. The method according to claim **1**, further comprising:

assigning a unique identification code associated with the participant to the remotely situated apparatus.

13. The method according to claim **1**, further comprising:

notifying the participant when one or more unanswered queries remain in the remotely situated apparatus through activation of a visual indicator controlled by said program.

14. The method according to claim **1**, wherein:

the program includes a connection routine configured to cause the remotely situated apparatus to prompt the participant to connect the remotely situated apparatus to the at least one communication network.

15. The method according to claim **14**, wherein:

the program includes a connection routine configured to automatically cause the remotely situated apparatus to establish the second communication link with the server at a prescribed time, transmit the responses collected from the participant, transmit the program identification code, and transmit the identification code associated with the participant.

16. The method according to claim **15**, further comprising:

transmitting a new program to the remotely situated apparatus through the at least one communication network after receiving the responses collected from the participant, the program identification code, and the identification code associated with the participant; and

instructing the remotely situated apparatus to disconnect the second communication link.

17. The method according to claim **1**, further comprising:

presenting said remotely situated apparatus as an image of a stand-alone remote apparatus on a display of a personal computer of the participant, wherein the individual interacts with the displayed image of the stand-alone remote apparatus by operating one or more user interfaces of the personal computer to select displayed responses.

18. A system for remotely monitoring a pharmaceutical trial, comprising:

a server that communicates through at least one communication network;

at least one remotely situated hand-held portable apparatus provided to at least one participant of said pharmaceutical trial, wherein said at least one remotely situated apparatus is configured to automatically establish a communication link with said server through said at least one communication network;

a user interface that communicates with the server, said user interface adapted for (i) entering, authoring, selecting, or any combination thereof, a set of queries to be

answered by the participant and (ii) entering, authoring, selecting, or any combination thereof, corresponding response choices for each of the queries, wherein said queries and said corresponding response choices relate to said pharmaceutical trial;

a program generator configured to generate a program to be executed by the remotely situated apparatus, wherein the program causes the apparatus to (i) present the queries and the corresponding response choices to the participant and collect responses from the participant, including at least one of the corresponding response choices, after a first communication link between the server and the remotely situated apparatus is terminated and (ii) send the collected responses, a program identification code, and an identification code associated with the participant to the server after autonomously establishing a second communication link between the server and the remotely situated apparatus; and

one or more databases accessible by the server, said one or more databases storing the program, the responses received from the remotely situated apparatus and a list of pharmaceutical trial criteria, wherein the pharmaceutical criteria are assessed based upon the responses received.

19. The system according to claim **18**, further comprising a monitoring device remotely situated from the server, the monitoring device configured to measure a physiological condition of the participant, wherein measurement of the physiological condition of the participant is used in assessing the pharmaceutical criteria.

20. The system according to claim **19**, wherein said physiological condition comprises one or more of a blood oxygen level, a blood glucose level, a blood pressure and a respiratory flow rate.

21. The system according to claim **18**, wherein said pharmaceutical trial is directed to collecting data on efficacy, side effects and quality of life impact of one or more drugs on the participant during a clinical development and post marketing surveillance period.

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