



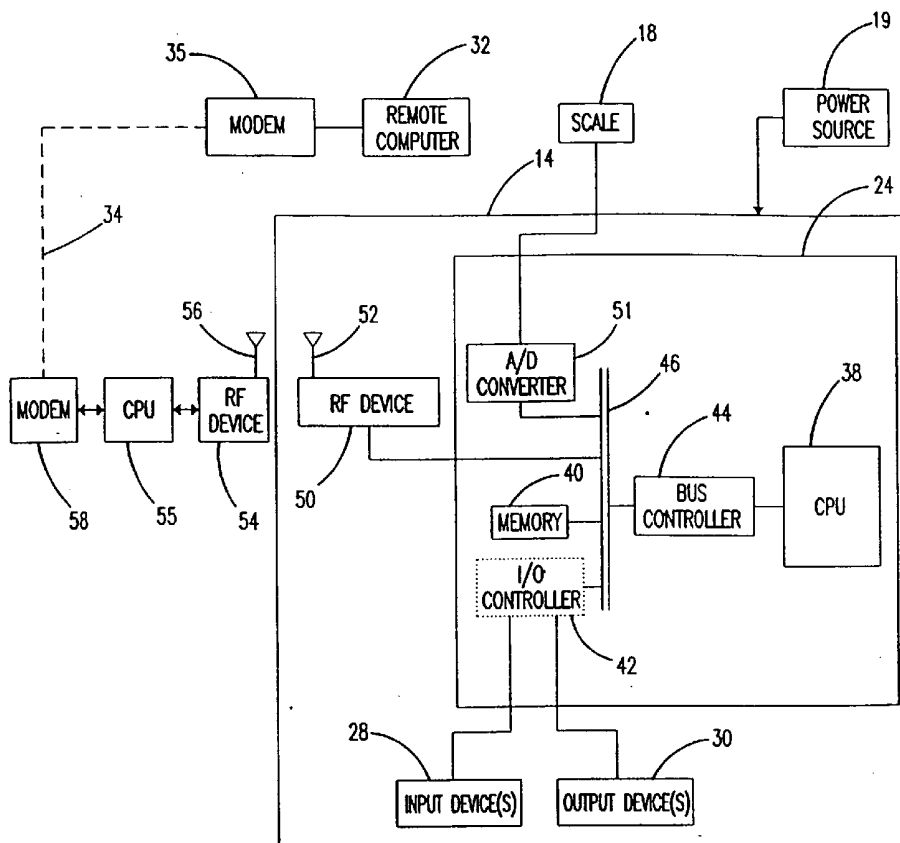
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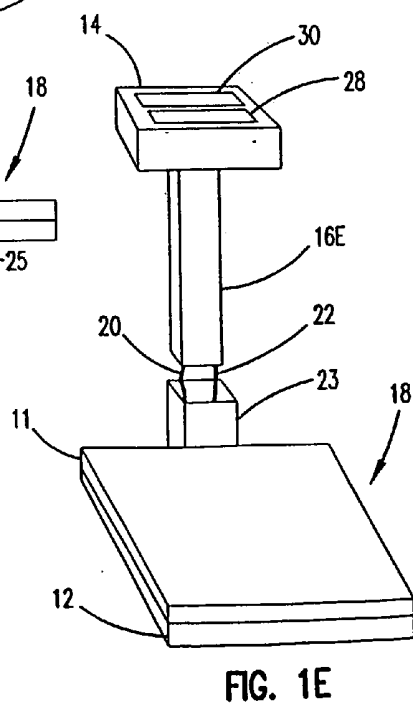
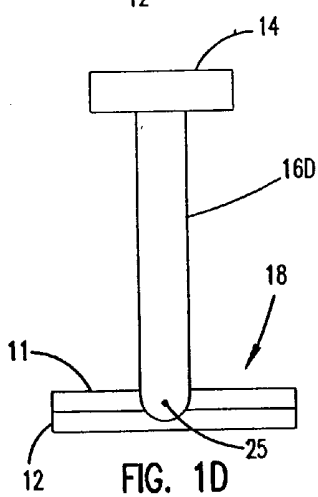
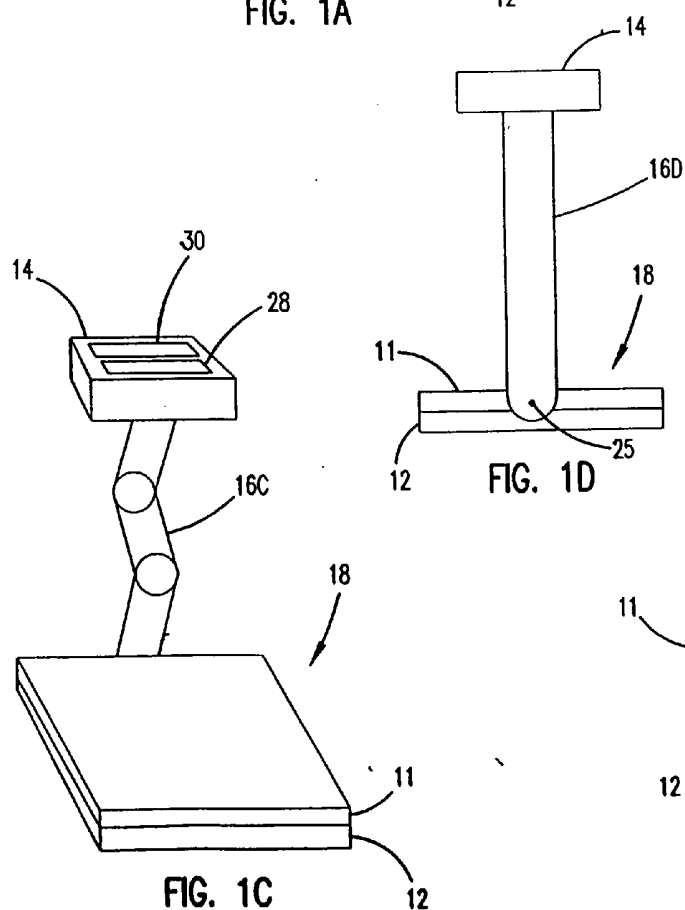
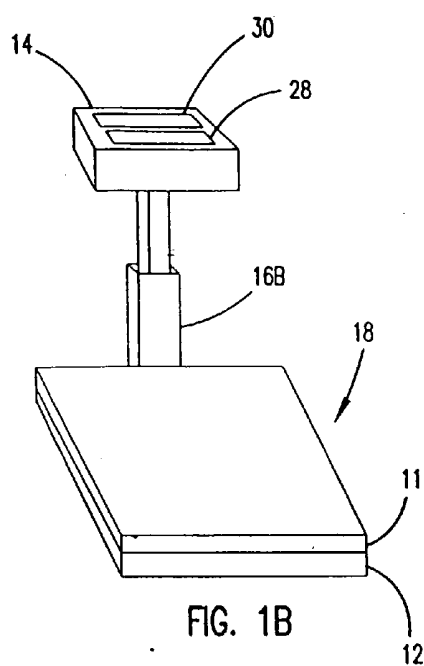
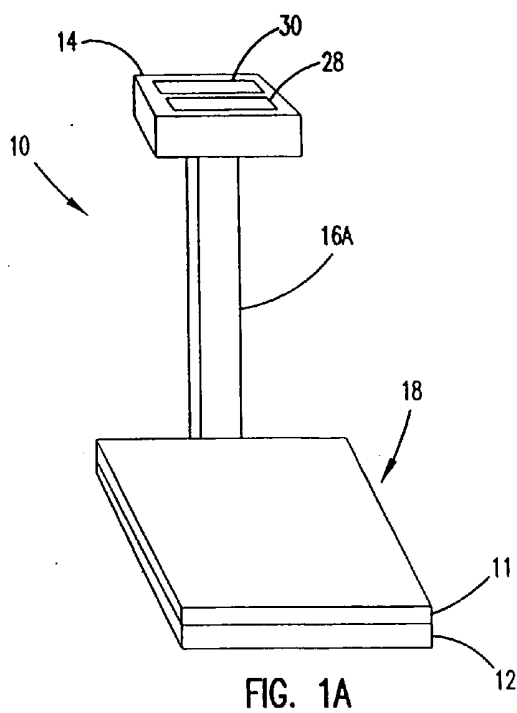
(19) **United States**(12) **Patent Application Publication**  
**Cosentino et al.**(10) **Pub. No.: US 2006/0015017 A1**(43) **Pub. Date: Jan. 19, 2006**(54) **APPARATUS AND METHOD FOR  
MONITORING AND COMMUNICATING  
WELLNESS PARAMETERS OF  
AMBULATORY PATIENTS**continuation of application No. 09/918,247, filed on  
Jul. 30, 2001, now Pat. No. 6,723,045, which is a  
division of application No. 09/293,619, filed on Apr.  
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Minneapolis, MN 55402-0903 (US)**(57) **ABSTRACT**

The monitoring device incorporates transducing devices for converting the desired measured parameters into electrical signals capable of being processed by a local computer or microprocessor system. The device interacts with the ambulatory patient and then, via a modem or other electronic communication device, transmits the measured parameters to a computer located at a remote site. At the remote location, the various indicia of the ambulatory patient's condition are monitored and analyzed by the medical professional caregiver. To provide the ambulatory patient with an added level of convenience and ease of use, such monitoring device is contained in a single integrated package.

(73) **Assignee:** **Cardiacom**, Excelsior, MN(21) **Appl. No.:** **11/230,811**(22) **Filed:** **Sep. 19, 2005****Related U.S. Application Data**(60) Continuation of application No. 10/719,498, filed on  
Nov. 20, 2003, now Pat. No. 6,946,806, which is a



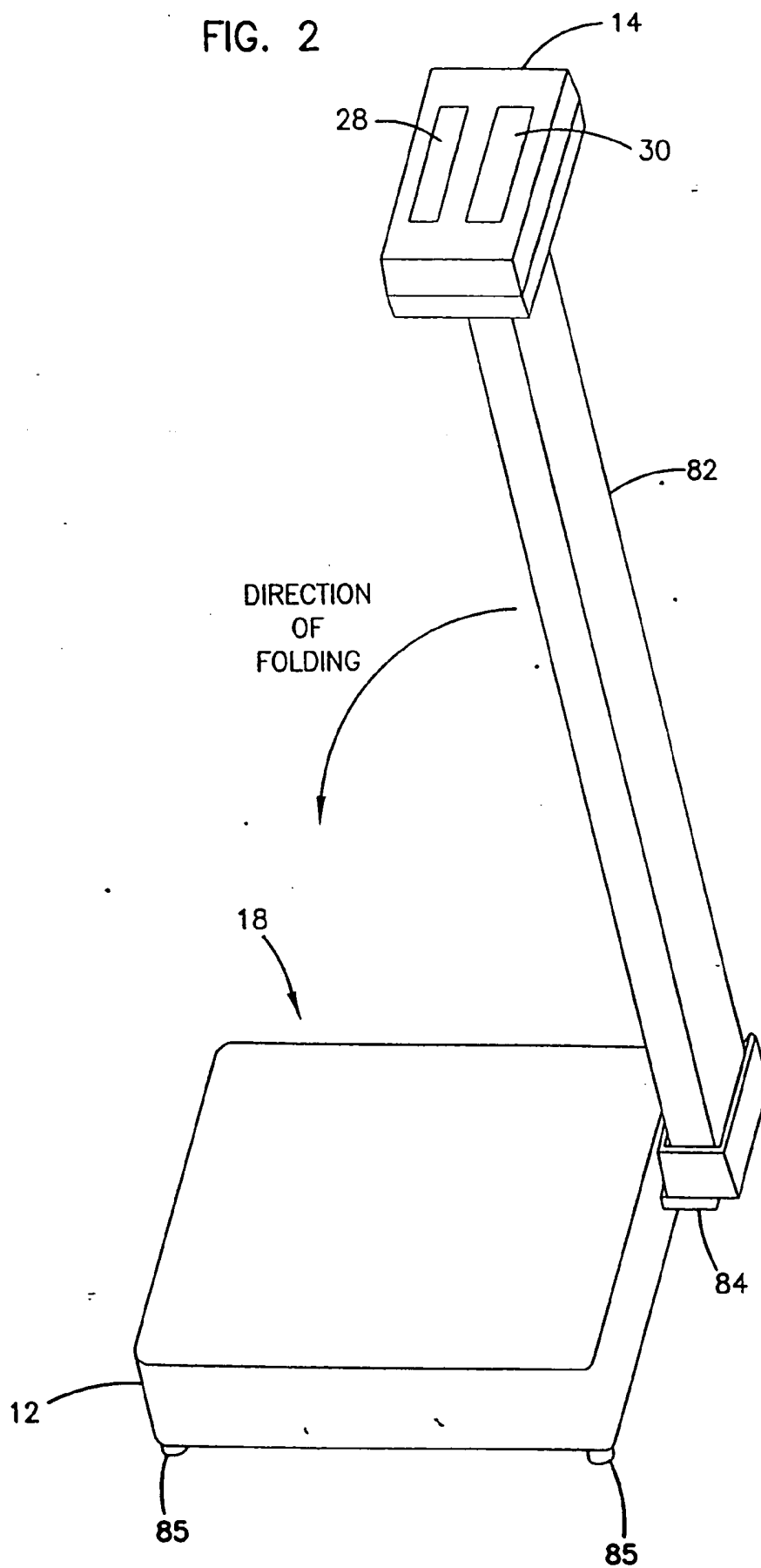


FIG. 3

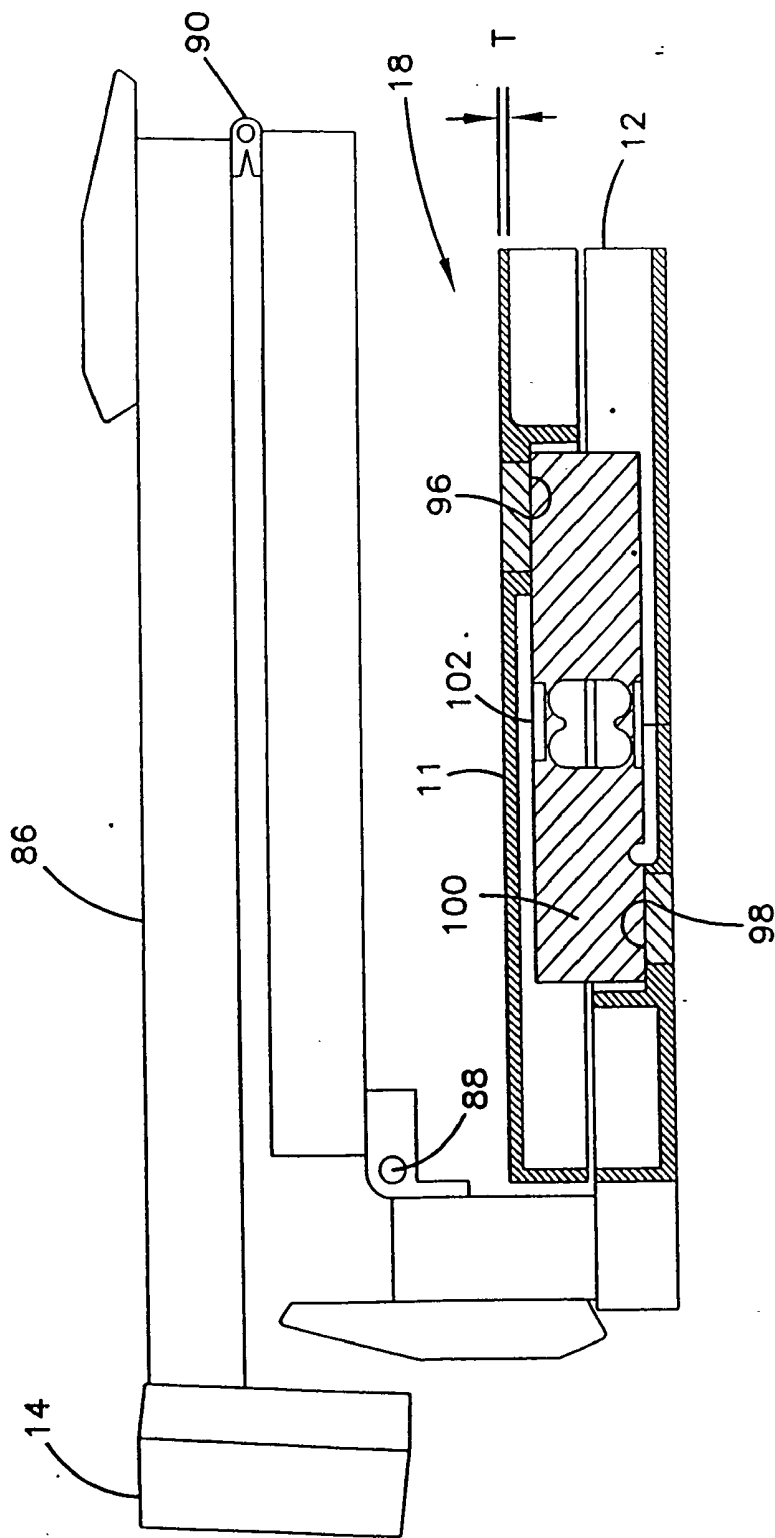


FIG. 4

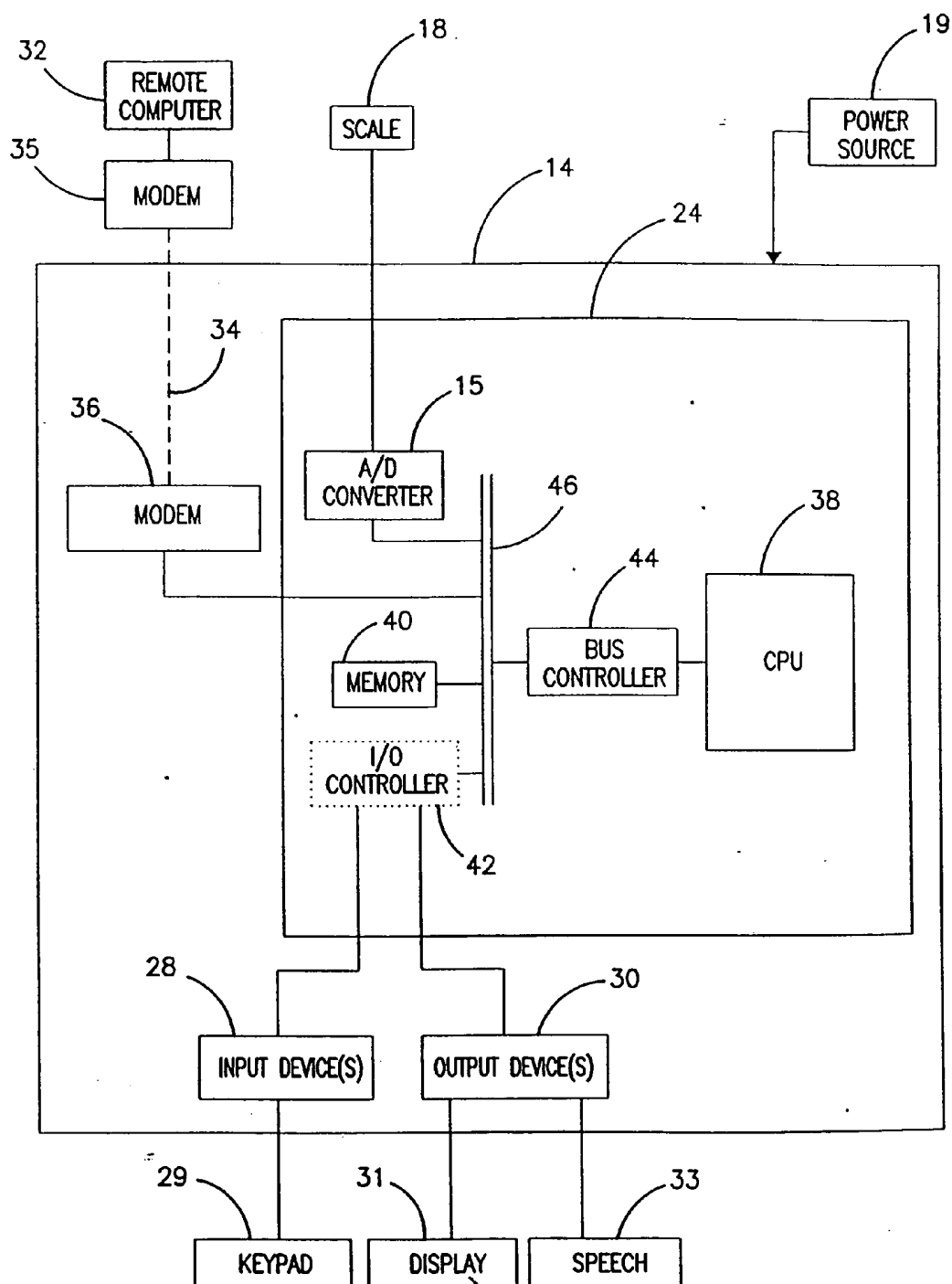


FIG. 5

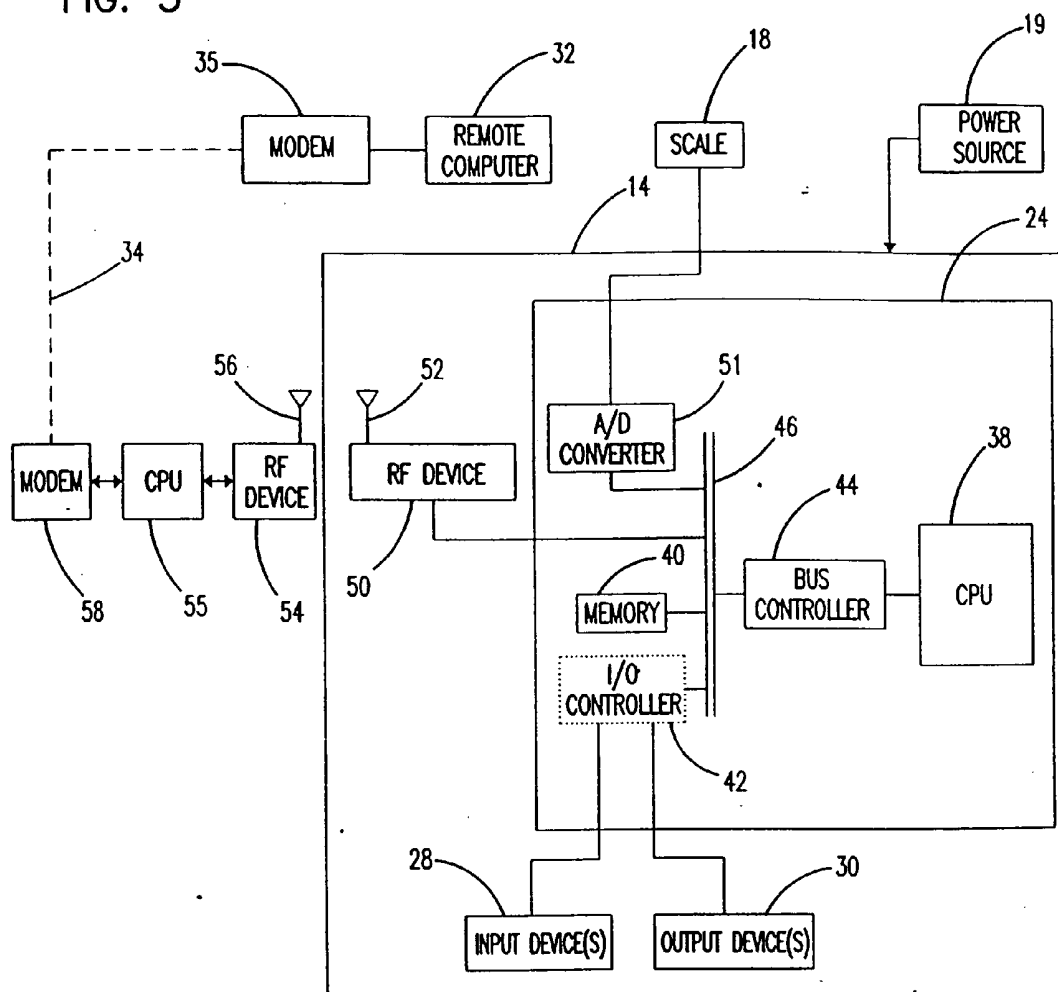


FIG. 6

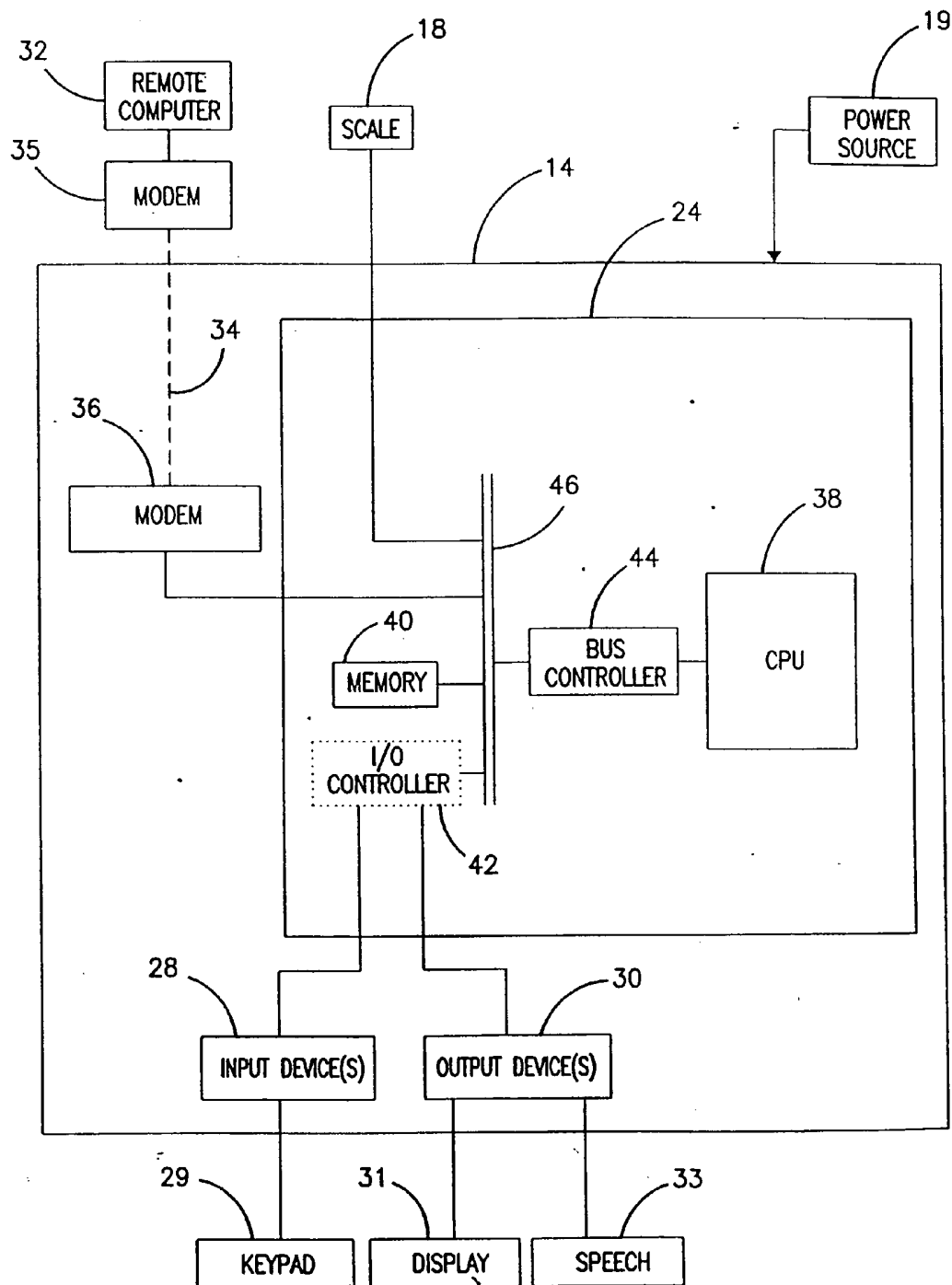


FIG. 7

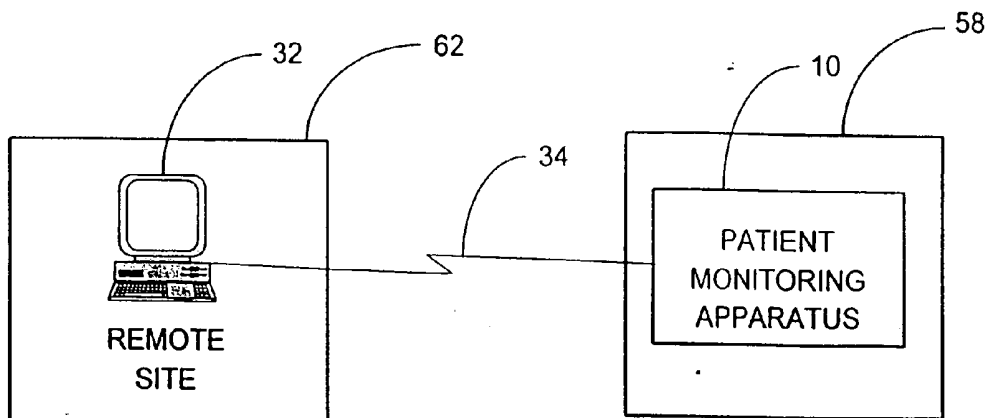
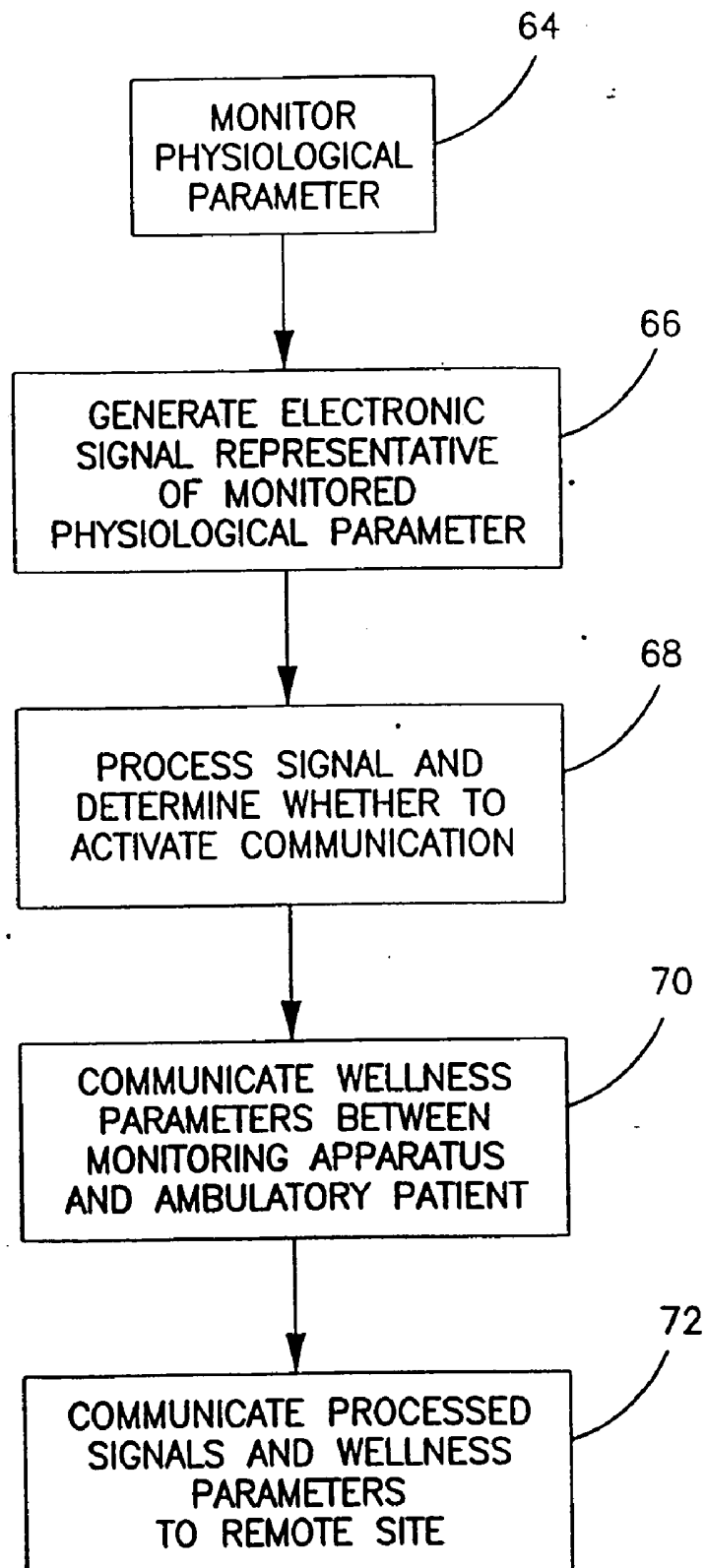
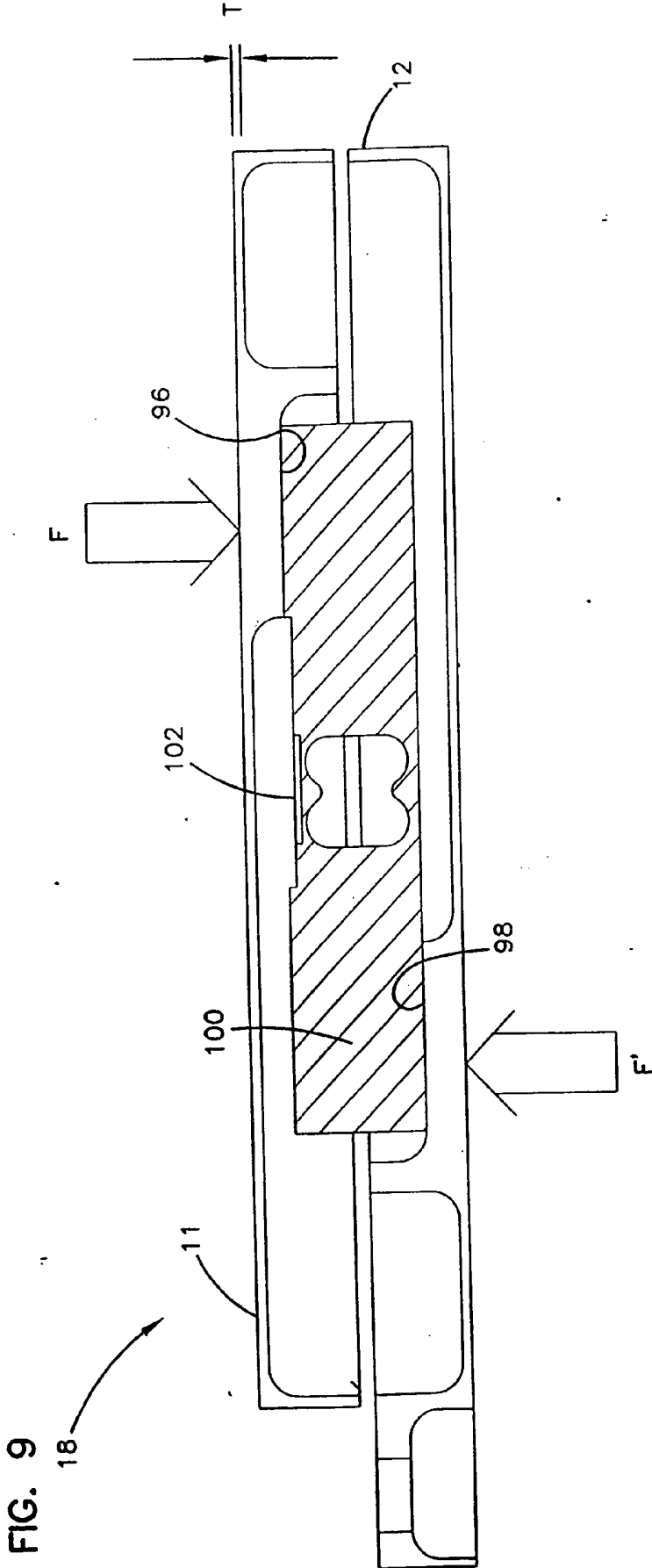
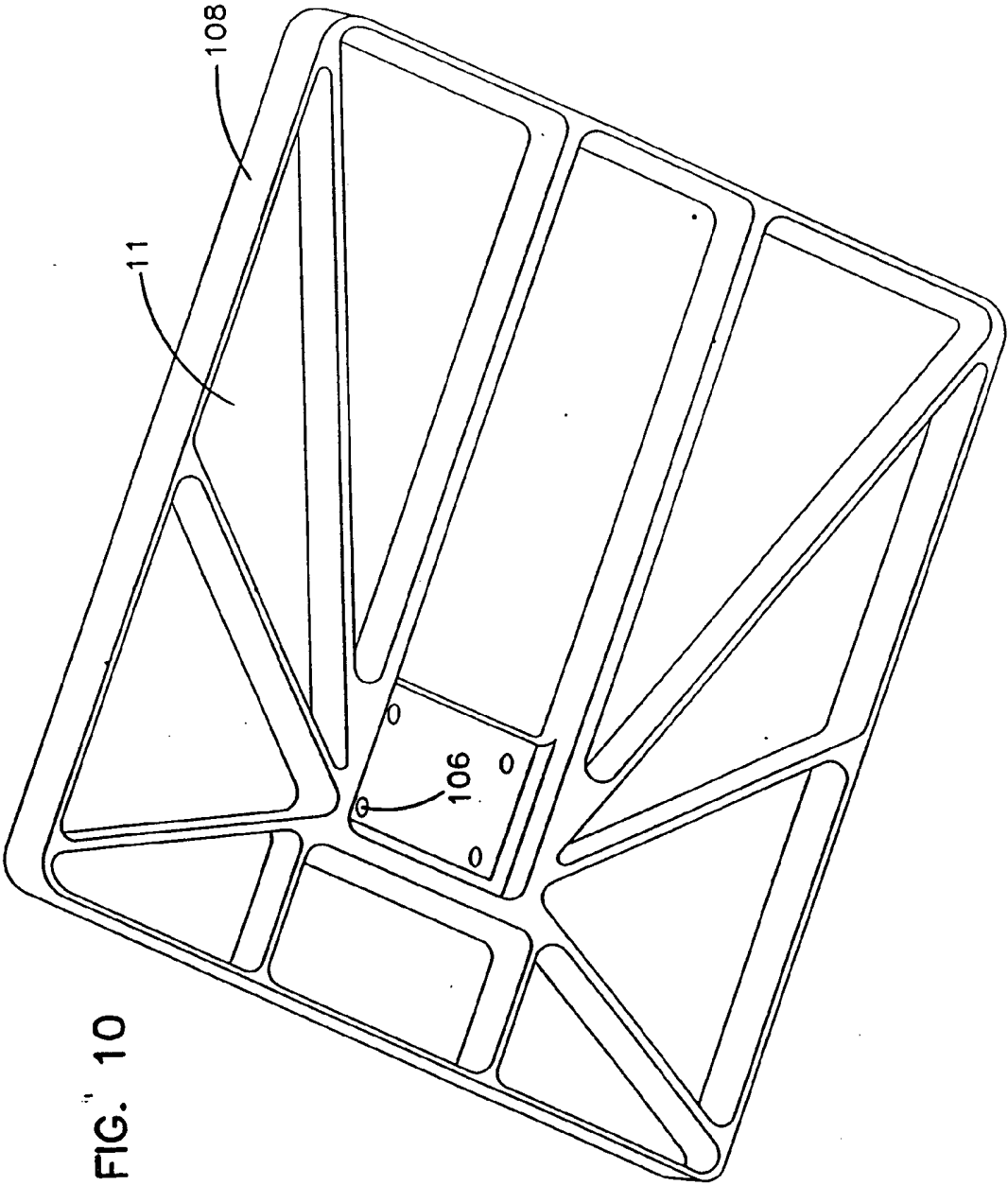




FIG. 8







## APPARATUS AND METHOD FOR MONITORING AND COMMUNICATING WELLNESS PARAMETERS OF AMBULATORY PATIENTS

### BACKGROUND

[0001] There is a need in the medical profession for an apparatus and method capable of monitoring and transmitting physiological and wellness parameters of ambulatory patients to a remote site where a medical professional caregiver evaluates such physiological and wellness parameters. Specifically, there is a need for an interactive apparatus that is coupled to a remote computer such that a medical professional caregiver can supervise and provide medical treatment to remotely located ambulatory patients.

[0002] There is needed an apparatus that monitors and transmits physiological and wellness parameters of ambulatory patients to a remote computer, whereby a medical professional caregiver evaluates the information and provokes better overall health care and treatment for the patient. Accordingly, such an apparatus can be used to prevent unnecessary hospitalizations of such ambulatory patients.

[0003] Also, there is needed an apparatus for monitoring and transmitting such physiological and wellness parameters that is easy to use and that is integrated into a single unit. For example, there is a need for an ambulatory patient monitoring apparatus that comprises: a transducing device for providing electronic signals representative of measured physiological parameters, such as weight; an input/output device; and a communication device as a single integrated unit that offers ambulatory patients ease of use, convenience and portability.

[0004] Patients suffering from chronic diseases, such as chronic heart failure, will benefit from such home monitoring apparatus. These patients normally undergo drug therapy and lifestyle changes to manage their medical condition. In these patients, the medical professional caregiver monitors certain wellness parameters and symptoms including: weakness, fatigue, weight gain, edema, dyspnea (difficulty breathing or shortness of breath), nocturnal cough, orthopnea (inability to lie flat in bed because of shortness of breath), and paroxysmal nocturnal dyspnea (awakening short of breath relieved by sitting or standing); and body weight to measure the response of drug therapy. Patients will also benefit from daily reminders to take medications (improving compliance), reduce sodium intake and perform some type of exercise. With the information received from the monitoring device, the medical professional caregiver can determine the effectiveness of the drug therapy, the patient's condition, whether the patient's condition is improving or whether the patient requires hospitalization or an office consultation to prevent the condition from getting worse.

[0005] Accordingly, there is needed an apparatus and method for monitoring the patients from a remote location, thus allowing medical professional caregivers to receive feedback of the patient's condition without having to wait until the patient's next office visit. In addition, there is needed an apparatus and method that allows medical professional caregivers to monitor and manage the patient's condition to prevent the rehospitalization of such patient, or prevent the patient's condition from deteriorating to the point where hospitalization would be required. As such, there are social as well as economic benefits to such an apparatus and method.

[0006] The patient receives the benefits of improved health when the professional caregiver is able to monitor and quickly react to any adverse medical conditions of the patient or to any improper responses to medication. Also, society benefits because hospital resources will not be utilized unnecessarily.

[0007] As a group, patients suffering from chronic heart failure are the most costly to treat. There are approximately 5 million patients in the U.S.A. and 15 million worldwide with chronic heart failure. The mortality rate of patients over 65 years of age is 50%. Of those that seek medical help and are hospitalized, 50% are rehospitalized within 6 months. Of these, 16% will be rehospitalized twice. The patients that are hospitalized spend an average of 9.1 days in the hospital at a cost of \$12,000.00 for the period. Accordingly, there is a need to reduce the rehospitalization rate of chronic heart failure patients by providing improved in-home patient monitoring, such as frequently monitoring the patient's body weight and adjusting the drug therapy accordingly.

[0008] Approximately 60 million American adults ages 20 through 74 are overweight. Obesity is a known risk factor for heart disease, high blood pressure, diabetes, gallbladder disease, arthritis, breathing problems, and some forms of cancer such as breast and colon cancer. Americans spend \$33 billion dollars annually on weight-reduction products and services, including diet foods, products and programs.

[0009] There is a need in the weight management profession for an apparatus and method capable of monitoring and transmitting physiological and wellness parameters of overweight/obese patients to a remote site where a weight management professional or nutritionist evaluates such physiological and wellness parameters. Specifically, there is a need for an interactive apparatus that is coupled to a remote computer such that a weight management professional or nutritionist can supervise and provide nutritional guidance to remotely located individuals.

[0010] The apparatus allows overweight individuals to participate in a weight loss/management program with accurate weight monitoring from home. The apparatus improves the convenience for the individual participant by eliminating the need to constantly commute to the weight management center and "weigh-in." Furthermore, the individual can participate in a weight management program while under professional supervision from the privacy and comfort of their own home. Moreover, the apparatus allows the weight management professional to intervene and adapt the individuals diet and exercise routine based on the weight and wellness information received.

[0011] For the foregoing reasons, there is a need for an apparatus, system and method capable of monitoring and transmitting physiological and wellness parameters of ambulatory patients, such as body weight, to a remote location where a medical professional caregiver, weight management professional or nutritionist can evaluate and respond to the patient's medical wellness condition.

### SUMMARY

[0012] The invention is directed to an apparatus, system and method that satisfies this need. The apparatus having features of the invention is capable of monitoring an ambulatory patient and establishing two way communication to a

medical professional caregiver, weight management professional or nutritionist regarding the wellness parameters of such an ambulatory patient.

[0013] The apparatus comprises a physiological parameter transducing device. The device generates an electronic signal that is representative of the value of the physiological parameter being monitored. The apparatus further comprises a central processor device. The central processor device is operatively coupled to the parameter transducing device and processes the electronic signals that are representative of the physiological parameters. The apparatus further comprises an electronic receiver/transmitter communication device. The communication device having one end operatively coupled to the processor and another end operatively coupled to a communication network. The communication device is activated whenever the central processor recognizes a physiological parameter within a predetermined range. The apparatus further comprises an input device. The input device is operatively coupled to said processor and configured to receive external commands. The apparatus further comprises an output device. The output device is coupled to the processor and provides information comprising external commands, physiological symptoms, wellness parameters, and queries from the communication device. All of these devices are integrated into a single unit.

[0014] The system having features of the invention monitors an ambulatory patient and establishes communication to a caregiver, regarding the wellness parameters of such an ambulatory patient, between a first location and a remote central office location. The system comprises a monitoring apparatus located at the first location. The monitoring apparatus comprises: (a) a physiological parameter transducing device that generates an electronic signal representative of the value of the physiological parameter being monitored; (b) a central processor device that is operatively coupled to the parameter transducing device for processing the physiological parameter electronic signals; (c) an electronic receiver/transmitter communication device, said communication device having one end operatively coupled to the processor and another end operatively coupled to a communication network that is activated whenever the central processor recognizes a physiological parameter within a predetermined range; (d) an input device that is operatively coupled to the processor and configured to receive external commands; (e) an output device coupled to the processor that provides information comprising external commands, physiological symptoms, wellness parameters, and queries from the communication device, wherein these devices are integrated into a single unit. The system further comprises a processing computer at a remote central office location that is in communication with the remote monitoring apparatus and exchanges information with the monitoring apparatus.

[0015] The method having features of the invention monitors an ambulatory patient and establishes communication to a caregiver regarding the wellness parameters of such an ambulatory patient. The method comprises monitoring a physiological parameter; generating an electronic signal representative of the value of the physiological parameter; in a central processor device, processing the physiological parameter electronic signals; communicating the processed electronic signals between a first location and a remote central location; inputting external commands into the processor; and outputting the information.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0016] These and other features, aspects and advantages of the invention will become better understood with regard to the following description, appended claims and accompanying drawings where:

[0017] FIGS. 1A-E illustrates several embodiments of the monitoring apparatus in accordance with the invention;

[0018] FIG. 2 illustrates a monitoring apparatus with a support member in accordance with one embodiment of the invention;

[0019] FIG. 3 illustrates a monitoring apparatus with a support member in accordance with one embodiment of the invention;

[0020] FIG. 4 is a functional block diagram of a microprocessor system forming an environment in which one embodiment of the invention may be employed;

[0021] FIG. 5 is functional block diagram of a microprocessor system forming the environment in which one embodiment of the invention may be employed;

[0022] FIG. 6 is a functional block diagram of a microprocessor system forming the environment in which one embodiment of the invention may be employed;

[0023] FIG. 7 illustrates a system in which one embodiment of the invention may be employed;

[0024] FIG. 8 is a logic flow diagram illustrating the steps utilized to implement one embodiment of the invention;

[0025] FIG. 9 illustrates a sectional view of the electronic scale in accordance with one embodiment of the invention; and

[0026] FIG. 10 illustrates a top plate of the electronic scale in accordance with one embodiment of the invention.

## DESCRIPTION

[0027] The embodiments of the invention described herein are implemented as a medical apparatus, system and method capable of monitoring wellness parameters and physiological data of ambulatory patients and transmitting such parameters and data to a remote location. At the remote location a medical professional caregiver monitors the patient's condition and provides medical treatment as may be necessary.

[0028] The monitoring device incorporates transducing devices for converting the desired measured parameters into electrical signals capable of being processed by a local computer or microprocessor system. The device interacts with the ambulatory patient and then, via an electronic communication device such as a modem, transmits the measured parameters to a computer located at a remote site. At the remote location the various indicia of the ambulatory patient's condition are monitored and analyzed by the medical professional caregiver. To provide the ambulatory patient with an added level of convenience and ease of use, such monitoring device is contained in a single integrated package.

[0029] Communication is established between the monitoring apparatus and a remote computer via modem and other electronic communication devices that are generally well known commercially available products. At the remote

location, the caregiver reviews the patient's condition based on the information communicated (e.g. wellness parameters and physiological data) and provokes medical treatment in accordance with such information.

[0030] Referring now to **FIG. 1A**, as this embodiment of the invention is described herein, an integrated monitoring apparatus is shown generally at **10**. The integrated monitoring apparatus **10** includes an electronic scale **18**. The electronic scale **18** further includes a top plate **11** and a base plate **12**. The integrated monitoring apparatus **10** further includes a housing **14** and a support member **16A**. The base plate **12** is connected to the housing **14** through the support member **16A**. The housing **14** further includes output device(s) **30** and input device(s) **28**. The apparatus **10** is integrated as a single unit with the support member coupling the base plate **12** and the housing **14**, thus providing a unit in a one piece construction.

[0031] It will be appreciated that other physiological transducing devices can be utilized in addition to the electronic scale **18**. For example, blood pressure measurement apparatus and electrocardiogram (EKG) measurement apparatus can be utilized with the integrated monitoring apparatus **10** for recordation and/or transmission of blood pressure and EKG measurements to a remote location. It will be appreciated that other monitoring devices of physiological body functions that provide an analog or digital electronic output may be utilized with the monitoring apparatus **10**.

[0032] Referring to **FIGS. 1B, 1C, 1D** and **1E** it will be appreciated that the support member **16A** (**FIG. 1A**) can be made adjustable. For example, **FIG. 1B** illustrates an embodiment of the invention utilizing a telescoping support member **16B**. Likewise, **FIG. 1C** illustrates an embodiment of the invention utilizing a folding articulated support member **16C**. **FIG. 1D** illustrates yet another embodiment of the invention utilizing support member **16D** that folds at a pivot point **25** located at its base. It will also be appreciated that other types of articulated and folding support members may be utilized in other embodiments of the invention. For example, **FIG. 1E** illustrates an embodiment of the invention providing a support member **16E** that is removably insertable into a socket **23**. A cable **22** is passed through the support member **16E** to carry electrical signals from the electronic scale **18** to the housing **14** for further processing. A tether **20** is provided to restrain the movement of the support member **16E** relative to the base plate **12** once the it is removed from the socket **23**.

[0033] **FIG. 2** illustrates an embodiment of the invention where the support member **82** folds about pivot point **84**. Folding the integrated monitoring apparatus about pivot point **84** provides a convenient method of shipping, transporting or moving the apparatus in a substantially horizontal orientation. The preferred direction of folding is indicated in the figure, however, the support member **82** can be made to fold in either direction. Furthermore, an embodiment of the invention provides rubber feet **85** underneath the base plate **12**.

[0034] Furthermore, **FIG. 3** illustrates one embodiment of the invention providing an articulated, folding support member **86**. The support member **86** folds at two hinged pivot points **88, 90**. Also illustrated is a sectional view of the scale **18**, top plate **11**, base plate **12**, load cell **100** and strain gage **102**.

[0035] Referring now to **FIG. 4**, a microprocessor system **24** including a CPU **38**, a memory **40**, an optional input/output (I/O) controller **42** and a bus controller **44** is illustrated. It will be appreciated that the microprocessor system **24** is available in a wide variety of configurations and is based on CPU chips such as the Intel, Motorola or Microchip PIC family of microprocessors or microcontrollers.

[0036] It will be appreciated by those skilled in the art that the monitoring apparatus requires an electrical power source **19** to operate. As such, the monitoring apparatus may be powered by: ordinary household A/C line power, DC batteries or rechargeable batteries. Power source **19** provides electrical power to the housing for operating the electronic devices. A power source for operating the electronic scale **18** is generated within the housing, however those skilled in the art will recognize that a separate power supply may be provided or the power source **19** may be adapted to provide the proper voltage or current for operating the electronic scale **18**.

[0037] The housing **14** includes a microprocessor system **24**, an electronic receiver/transmitter communication device such as a modem **36**, an input device **28** and an output device **30**. The modem **36** is operatively coupled to the microprocessor system **24** via the electronic bus **46**, and to a remote computer **32** via a communication network **34** and modem **35**. The communication network **34** being any communication network such as the telephone network, wide area network or Internet. It will be appreciated that the modem **36** is a generally well known commercially available product available in a variety of configurations operating at a variety of BAUD rates. In one embodiment of the invention the modem **36** is asynchronous, operates at 2400 BAUD and is readily available off-the-shelf from companies such as Rockwell or Silicon Systems Inc. (SSI).

[0038] It will be appreciated that output device(s) **30** may be interfaced with the microprocessor system **24**. These output devices **30** include a visual electronic display device **31** and/or a synthetic speech device **33**. Electronic display devices **31** are well known in the art and are available in a variety of technologies such as vacuum fluorescent, liquid crystal or Light Emitting Diode (LED). The patient reads alphanumeric data as it scrolls on the electronic display device **31**. Output devices **30** include a synthetic speech output device **33** such as a Chipcorder manufactured by ISD (part No. 4003). Still, other output devices **30** include pacemaker data input devices, drug infusion pumps or transformer coupled transmitters.

[0039] It will be appreciated that input device(s) **28** may be interfaced with the microprocessor system **24**. In one embodiment of the invention an electronic keypad **29** is provided for the patient to enter responses into the monitoring apparatus. Patient data entered through the electronic keypad **29** may be scrolled on the electronic display **31** or played back on the synthetic speech device **33**.

[0040] The microprocessor system **24** is operatively coupled to the modem **36**, the input device(s) **28** and the output device(s) **30**. The electronic scale **18** is operatively coupled to the central system **24**. Electronic measurement signals from the electronic scale **18** are processed by the A/D converter **15**. This digitized representation of the measured signal is then interfaced to the CPU **38** via the electronic bus **46** and the bus controller **44**. In one embodiment of the

invention, the physiological transducing device includes the electronic scale **18**. The electronic scale **18** is generally well known and commercially available. The electronic scale **18** may include one or more of the following elements: load cells, pressure transducers, linear variable differential transformers (LVDTs), capacitance coupled sensors, strain gages and semiconductor strain gages. These devices convert the patient's weight into a useable electronic signal that is representative of the patient's weight.

[0041] It will be appreciated that Analog-to-Digital (A/D) converters are also generally well known and commercially available in a variety of configurations. Furthermore, an A/D converter **15** may be included within the physiological transducing device or within the microprocessor system **24** or within the housing **14**. One skilled in the art would have a variety of design choices in interfacing a transducing device comprising an electronic sensor or transducer with the microprocessor system **24**.

[0042] The scale **18** may provide an analog or digital electronic signal output depending on the particular type chosen. If the electronic scale **18** provides an analog output signal in response to a weight input, the analog signal is converted to a digital signal via the A/D converter **15**. The digital signal is then interfaced with the electronic bus **46** and the CPU **38**. If the electronic scale **18** provides a digital output signal in response to a weight input, the digital signal may be interfaced with electronic bus **46** and the CPU **38**.

[0043] FIG. 5 illustrates one embodiment of the invention where the communication device is a radio frequency (RF) transceiver. The transceiver comprises a first radio frequency device **50** including an antenna **52**, and a second radio frequency device **54**, including an antenna **56**. The first radio frequency device **52** is operatively coupled to the microprocessor system **24** via the electronic bus **46**, and is in radio communication with the second radio frequency device **54**. The second radio frequency device **54** is operatively coupled through a microprocessor **55** which is operatively coupled to a modem **58**. The modem **58** is coupled to the communication network **34** and is in communication with the remote computer **32** via the modem **35**. The first radio frequency device **50** and the second radio frequency device **54** are remotely located, one from the other. It will be appreciated that such radio frequency devices **50**, **54** are generally well known and are commercially available products from RF Monolithics Inc. (RFM).

[0044] In one embodiment of the invention, such transceivers operate at radio frequencies in the range of 900-2400 MHz. Information from the microprocessor system **24** is encoded and modulated by the first RF device **50** for subsequent transmission to the second RF device **54**, located remotely therefrom. The second RF device **54** is coupled to a conventional modem **58** via the microprocessor **55**. The modem **58** is coupled to the communication network **34** via a in-house wiring connection and ultimately to the modem **35** coupled to the remote computer **32**. Accordingly, information may be transmitted to and from the microprocessor system **24** via the RF devices **50**, **54** via a radio wave or radio frequency link, thus providing added portability and flexibility to the monitoring apparatus **10**. It will be appreciated that various other communications devices may be utilized such as RS-232 serial communication connections, Internet communications connection as well as satellite

communication connections. Other communications devices that operate by transmitting and receiving infra-red (IR) energy can be utilized to provide a wireless communication link between the patient monitoring apparatus **10** and a conveniently located network connection. Furthermore, X-10™ type devices can also be used as part of a communication link between the patient monitoring apparatus **10** and a convenient network connection in the home. X-10 USA and other companies manufacture a variety of devices that transmit/receive data without the need for any special wiring. The devices works by sending signals through the home's regular electrical wires using what is called power line carrier (PLC).

[0045] Referring now to FIG. 6, one embodiment of the invention wherein a digital electronic scale **21** is provided. Digital weight measurements from the digital electronic scale **21** may be interfaced with the microprocessor system and CPU **38** without requiring additional amplification, signal conditioning and A/D converters.

[0046] Referring now to FIG. 7, a two way communication system in accordance with the principals of the present invention is shown. The physiological data of an ambulatory patient is monitored utilizing monitoring apparatus **10** at a local site **58** and is transmitted to a remote computer **32** located at a remote computer site **62** via communication network **34**. At the remote computer site **62** a medical professional caregiver such as a nurse, physician or nurse practitioner monitors the patient data and provokes treatment in accordance with such data.

[0047] Operations to perform the preferred embodiment of the invention are shown in FIG. 8. Block **64** illustrates the operation of monitoring or measuring the ambulatory patient's physiological parameter. In one embodiment of the invention, namely for chronic heart failure patients, the physiological parameter monitored is the patient's weight. However, it will be appreciated by those skilled in the art that the physiological parameters may include blood pressure, EKG, temperature, urine output and any other.

[0048] Block **66** illustrates the operation of converting a monitored or measured physiological parameter from a mechanical input to an electronic output by utilizing a transducing device. In one embodiment of the invention the transducing device is an electronic scale **18**, which converts the patient's weight into a useable electronic signal.

[0049] At block **68**, the microprocessor system **24** processes the electronic signal representative of the transduced physiological parameter. If the resulting parameter value is within certain preprogrammed limits the microprocessor system **24** initiates communication within the remote computer **32** via the communication device **36** over the communication network **34**.

[0050] Block **70** illustrates the operation whereby information such as wellness parameters and physiological data are communicated between the monitoring apparatus **10** and the ambulatory patient. An exemplary list of the questions asked to the patient by the monitoring apparatus are provided in Table 5.

[0051] Referring now to FIGS. 7 and 8, upon establishing communication between the local monitoring apparatus **10**, at the local site **58**, and the remote computer **32**, at remote site **62**, block **72** illustrates the operation of communicating

or transmitting processed signals representative of physiological data and wellness parameters from the local site **58** to the remote site **62**.

[0052] FIG. 9 is a sectional view the scale **18** portion of one embodiment of the invention. The scale **18** comprises a top plate **11** and a base plate **12**. The top plate **11** and the base plate **12** having a thickness "T". A load cell **100** is disposed between the top plate **11** and the base plate **12** and rests on support/mounting surfaces **96** and **98**.

[0053] The load cell **100** is a transducer that responds to a forces applied to it. During operation, when a patient steps on the electronic scale **18**, the load cell **100** responds to a force "F" transmitted through the top plate **11** and a first support/mounting surface **96**. The support/mounting surface **96** is contact with a first end on a top side of the load cell **100**. A force "F" that is equal and opposite to "F" is transmitted from the surface that the electronic scale **18** is resting on, thorough the base plate **12** and a second support/mounting surface **98**. The second support/mounting surface **98** is in contact with a second end on a bottom side of the load cell **100**. In one embodiment, the load cell **100** is attached to the top plate **11** and the base plate **12**, respectively, with bolts that engage threaded holes provided in the load cell **100**. In one embodiment the load cell **100** further comprises a strain gage **102**.

[0054] The strain gage **102** made from ultra-thin heat-treated metallic foils. The strain gage **102** changes electrical resistance when it is stressed, e.g. placed in tension or compression. The strain gage **102** is mounted or cemented to the load cell **100** using generally known techniques in the art, for example with specially formulated adhesives, urethanes, epoxies or rubber latex. The positioning of the strain gage **102** will generally have some measurable effect on overall performance of the load cell **100**. Furthermore, it will be appreciated by those skilled in the art that additional reference strain gages may be disposed on the load cell where they will not be subjected to stresses or loads for purposes of temperature compensating the strain gage **102** under load. During operation over varying ambient temperatures, signals from the reference strain gages may be added or subtracted to the measurement signal of the strain gage **102** under load to compensate for any adverse effects of ambient temperature on the accuracy of the strain gage **102**.

[0055] The forces, "F" and "F", apply stress to the surface on which the strain gage **102** is attached. The weight of the patient applies a load on the top plate **11**. Under the load the strain gage(s) **102** mounted to the top of the load cell **100** will be in tension/compression as the load cell bends. As the strain gage **102** is stretched or compressed its resistance changes proportionally to the applied load. The strain gage **102** is electrically connected such that when an input voltage or current is applied to the strain gage **102**, an output current or voltage signal is generated which is proportional to the force applied to the load cell **100**. This output signal is then converted to a digital signal by A/D converter **15**.

[0056] The design of the load cell **100** having a first end on a top side attached to the top plate **11** and a second end on a bottom side attached to the base plate **12** provides a structure for stressing the strain gage **102** in a repeatable manner. The structure enables a more accurate and repeatable weight measurement. This weight measurement is repeatable whether the scale **18** rests on a rigid tile floor or

on a carpeted floor. FIG. 10 illustrates one embodiment of the top plate **11** that provides four mounting holes **106** for attaching the base plate **12** to one end of the load cell **100**. The base plate **12** provides similar holes for attaching to the other end of the load cell **100**. The top plate **11** and the base plate **12** (not shown) each comprise a plurality of stiffening ribs **108** that add strength and rigidity to the electronic scale **18**.

[0057] Table 1 shows multiple comparative weight measurements taken with the electronic scale **18** resting on a tile floor and a carpeted floor without rubber feet on the scale **18**. The measurements were taken using the same load cell **100**. The thickness "T" of the top plate **11** and supporting ribs was 0.125" except around the load cell, where the thickness of the supporting ribs was 0.250". The thickness of the load cell **100** support/mounting surfaces **96**, **98** (FIG. 9) was 0.375". As indicated in Table 1, with the scale **18** resting on a tile floor, the average measured weight was 146.77 lbs., with a standard deviation of 0.11595. Subsequently, with the scale **18** resting on a 0.5" carpet with 0.38" pad underneath and an additional 0.5" rug on top of the carpet, the average measured weight was 146.72 lbs., with a standard deviation of 0.16866.

TABLE 1

Thick Scale Parts Around Load Cell 0.250"	
TILE (lbs.)	CARPET (lbs.)
146.9	146.7
146.7	147
146.9	146.6
146.8	146.7
146.6	146.6
146.8	147
146.8	146.5
146.7	146.6
146.9	146.8
146.6	146.7
0.11595 (stddev)	0.16866 (stddev)
146.77 (average)	146.72 (average)

[0058] Table 2 shows multiple weight measurements taken with the scale **18** on a tile floor and a carpeted floor with rubber feet on the bottom of the scale **18**. The measurements were taken using the same load cell **100**. The thickness "T" of the top plate **11** was 0.125" including the thickness around the load cell. As indicated in Table 2, with the scale **18** resting on a tile floor on rubber feet, the average measured weight was 146.62 lbs., with a standard deviation of 0.07888. Subsequently, with the scale **18** resting on a 0.5" carpet with 0.38" pad underneath and an additional 0.5" rug on top of the carpet, the average measured weight was 146.62 lbs., with a standard deviation of 0.04216.

TABLE 2

Thin Scale Parts Throughout 0.125"	
TILE (lbs.)	CARPET (lbs.)
146.7	146.7
146.7	146.7
146.6	146.6
146.6	146.6
146.6	146.6



TABLE 2-continued

<u>Thin Scale Parts Throughout 0.125"</u>			
TILE (lbs.)		CARPET (lbs.)	
146.6		146.6	
146.5		146.6	
146.7		146.6	
146.5		146.6	
146.7		146.6	
0.07888	(stddev)	0.04216	(stddev)
146.62	(average)	146.62	(average)

[0059] Table 3 shows multiple weight measurements taken with an off-the-shelf conventional electronic scale. As indicated in table 3, with the off-the-shelf conventional scale resting on the tile floor, the average measured weight was 165.5571 lbs., with a standard deviation of 0.20702. Subsequently, with the off-the-shelf conventional scale resting on a 0.5" carpet with 0.38" pad underneath and an additional 0.5" rug on top of the carpet, the average measured weight was 163.5143 lbs., with a standard deviation of 0.13093.

TABLE 3

<u>Off-The-Shelf Conventional Scale</u>			
TILE (lbs.)		CARPET (lbs.)	
165.9		163.5	
165.5		163.4	
165.8		163.7	
165.4		163.6	
165.5		163.6	
165.4		163.5	
165.4		163.3	
—		163.4	
0.20702	(stddev)	0.13093	(stddev)
165.5571	(average)	163.5143	(average)
2.042857	(% of difference)	1.249345	(% of difference)

[0060] The summary in Table 4 is a comparative illustration of the relative repeatability of each scale while resting either on a tile floor or on a carpeted floor.

TABLE 4

<u>SUMMARY OF DATA:</u>					
TRIAL	TILE	STDDEV	CARPET	STDDEV	TILE VS. CARPET
<u>Heavy Scale Parts All 0.125" Except Cell Around the Load Cell 0.250"</u>					
1	146.77	0.1159	146.72	0.1686	0.05
2	146.67	0.0823	146.72	0.1906	0.05
<u>Thin Scale Parts All 0.125"</u>					
1	146.62	0.0788	146.62	0.04216	0.00
<u>Off-The-Shelf Conventional Scale</u>					
1	165.55	0.207	163.51	0.1309	2.04

[0061] The foregoing description was intended to provide a general description of the overall structure of several embodiments of the invention, along with a brief discussion of the specific components of these embodiments of the invention. In operating the apparatus 10, an ambulatory

patient utilizes the monitoring apparatus 10 to obtain a measurement of a particular physiological parameter. For example, an ambulatory patient suffering from chronic heart failure will generally be required to monitor his or her weight as part of in-home patient managing system. Accordingly, the patient measures his or her weight by stepping onto the electronic scale 18, integrally located within the base plate 12 of the monitoring apparatus 10.

[0062] Referring now to FIG. 4, the modem 36 of the monitoring apparatus 10 will only activate if the measured weight is within a defined range such as  $\pm 10$  lbs,  $\pm 10\%$  or any selected predetermined value of a previous weight measurement. The patient's previous symptom free weight (dry weight) is stored in the memory 40. The dry weight is the patient's weight whenever diuretics are properly adjusted for the patient, for example. This prevents false activation of the modem 36 if a child, pet, or other person accidentally steps onto the electronic scale 18.

[0063] Upon measuring the weight, the microprocessor system 24 determines whether it is within a defined, required range such as  $\pm 10$  lbs. or  $\pm 10\%$  of a previously recorded weight stored in memory 40. The monitoring apparatus 10 then initiates a call via the modem 36 to the remote site 62. Communications is established between the local monitoring apparatus 10 and the remote computer 32. In one embodiment of the invention, the patient's weight is electronically transferred from the monitoring apparatus 10 at the local site 58 to the remote computer 32 at the remote site 62. At the remote site 62 the computer program compares the patient's weight with the dry weight and wellness information and updates various user screens. The program can also analyze the patient's weight trend over the previous 1-21 days. If significant symptoms and/or excessive weight changes are reported, the system alerts the medical care provider who may provoke a change to the patient's medication dosage, or establish further communication with the patient such as placing a telephone to the patient. The communication between the patient's location and the remote location may be one way or two way communication depending on the particular situation.

[0064] To establish the patient's overall condition, the patient is prompted via the output device(s) 30 to answer questions regarding various wellness parameters. An exemplary list of questions, symptoms monitored and the related numerical score is provided in Table 5 as follows:

TABLE 5

<u>Health Check Score</u>		
Question	Symptom	Value
Above Dry Weight?	Fluid accumulation	10
Are you feeling short of breath?	Dyspnea	10
Did you awaken during the night short of breath?	Paroxysmal nocturnal dyspnea	5
Did you need extra pillows last night?	Congestion in the lungs	5
Are you coughing more than usual?	Congestion in the lungs	3
Are your ankles or feet swollen?	Pedal edema	5
Does your stomach feel bloated?	Stomach edema	3
Do you feel dizzy or lightheaded?	Hypotension	5
Are you more tired than usual?	Fatigue	2
Are you taking your medication?	Medication compliance	7

TABLE 5-continued

Health Check Score		
Question	Symptom	Value
Has your appetite decreased?	Appetite	2
Are you reducing your salt intake?	Sodium intake	1
Did you exercise today?	Fitness	1

[0065] At the remote site 62 the medical professional caregiver evaluates the overall score according to the wellness parameter interrogation responses (as shown in Table 5). For example, if the patient's total score is equal to or greater than 10, an exception is issued and will either prompt an intervention by the medical professional caregiver in administering medication, or prompt taking further action in the medical care of the patient.

[0066] The output device(s) 30 varies based on the embodiment of the invention. For example, the output device may be a synthetic speech generator 33. As such, the wellness parameters are communicated to the patient via the electronic synthetic speech generator 33 in the form of audible speech. It will be appreciated that electronic speech synthesizers are generally well known and widely available. The speech synthesizer converts electronic data to an understandable audible speech.

[0067] Accordingly, the patient responds by entering either "YES" or "NO" responses into the input device 28, which may include for example, an electronic keypad 29. However, in one embodiment of the invention, the input device may also include a generic speech recognition device such as those made by International Business Machines (IBM), Dragon Systems, Inc. and other providers. Accordingly, the patient replies to the interrogations merely by speaking either "YES" or "NO" responses into the speech recognition input device.

[0068] In embodiments of the invention that include electronic display 31 as an output device 30, the interrogations as well as the responses are displayed and/or scrolled across the display for the patient to read. Generally, the electronic display will be positioned such that it is viewable by the patient during the information exchanging process between the patient and the remote computer 32.

[0069] Upon uploading the information to the remote computer 32, the medical professional caregiver may telephone the patient to discuss, clarify or validate any particular wellness parameter or physiological data point. Furthermore, the medical professional caregiver may update the list of wellness parameter questions listed in Table 5 from the remote site 62 over the two way communication network 34. Modifications are transmitted from the remote computer 32 via modem 35, over the communication network 34, through modem 36 and to the monitoring apparatus 10. The modified query list is then stored in the memory 40 of the microprocessor system 24.

[0070] Thus, it will be appreciated that the previously described versions of invention provide many advantages, including addressing the needs in the medical profession for an apparatus and method capable of monitoring and transmitting physiological and wellness parameters of ambula-

tory patients to a remote site whereby a medical professional caregiver can evaluate such physiological and wellness parameters and make decisions regarding the patient's treatment.

[0071] Also, it will be appreciated that the previously described versions of invention provide other advantages, including addressing the need for an apparatus for monitoring and transmitting such physiological and wellness parameters that is available in an easy to use portable integrated single unit.

[0072] Also, it will be appreciated that the previously described versions of the invention provide still other advantages, including addressing the need for medical professional caregivers to monitor and manage the patient's condition to prevent the rehospitalization of the patient, and to prevent the patient's condition from deteriorating to the point where hospitalization may be required.

[0073] Although the invention has been described in considerable detail with reference to certain preferred versions thereof, other versions are possible. For example a weight management and control apparatus. Therefore, the spirit and scope of the appended claims should not be limited to the description of the preferred versions contained herein.

#### 1-60. (canceled)

61. A computer-implemented method of detecting an impending decompensation of heart failure in a patient, the method comprising:

receiving data measured by a cardiac rhythm management device implanted in the patient;

obtaining a weight measurement of the patient; and

detecting impending decompensation of acute heart failure, based at least in part upon the weight measurement and the data received from the cardiac rhythm management device.

62. The method of claim 61, further comprising posing one or more questions to the patient.

63. The method of claim 62, wherein the act of detecting impending decompensation of heart failure is further based upon answers provided by the patient to the one or more posed questions.

64. The method of claim 63, wherein the act of detecting impending decompensation of heart failure comprises generating a score based at least in part upon the answers provided by the patient or the weight measurement and comparing the score to a threshold.

65. The method of claim 61, further comprising generating an alert when it is determined that decompensation of heart failure is impending.

66. The method of claim 65, further comprising communicating the alert to a health care provider.

67. The method of claim 61, wherein the cardiac rhythm management device is a pacemaker.

68. A computer-implemented method of detecting impending decompensation of heart failure in a patient, the method comprising:

receiving data measured by a cardiac rhythm management device implanted in the patient;

posing one or more questions to the patient;

receiving answers to the one or more questions;

detecting impending decompensation of heart failure, based at least in part upon the answers and the data received from the cardiac rhythm management device.

69. The method of claim 68, further comprising obtaining a weight measurement of the patient.

70. The method of claim 69, wherein the act of detecting impending decompensation of heart failure is further based upon the weight measurement.

71. The method of claim 70, wherein the act of detecting impending decompensation of heart failure comprises generating a score based at least in part upon the answers provided by the patient or the weight measurement and comparing the score to a threshold.

72. The method of claim 68, further comprising generating an alert, upon determining that decompensation of heart failure is impending.

73. The method of claim 72, further comprising communicating the alert to a health care provider.

74. The method of claim 68, wherein the cardiac rhythm management device is a pacemaker.

75. A computer-implemented method of detecting impending decompensation of heart failure in a patient, the method comprising:

receiving, with a processor device external to the patient, data measured by a cardiac rhythm management device implanted in the patient;

measuring a physiological parameter of the patient;

communicating the physiological parameter to the processor device;

receiving, with the processor device, answers to one or more questions posed to the patient; and

detecting, with the processor device, impending decompensation of heart failure, based at least in part upon a score generated based upon the answers and the physiological parameter.

76. The method of claim 75, further comprising communicating the physiological parameter, answers, and data received from the cardiac rhythm management device to a remote computer.

77. The method of claim 75, wherein the score is generated based at least in part upon the data measured by the cardiac rhythm management device, the answers and the physiological parameter.

78. The method of claim 75, further comprising generating an alert, upon determining that decompensation of heart failure is impending.

79. The method of claim 78, further comprising communicating the alert to a health care provider.

80. The method of claim 75, wherein the cardiac rhythm management device is a pacemaker.

\* \* \* \* \*

专利名称(译)	用于监测和传达非卧床患者的健康参数的装置和方法		
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外部链接	<a href="#">Espacenet</a> <a href="#">USPTO</a>		

# 摘要(译)

监视装置包括转换装置，用于将所需的测量参数转换成能够由本地计算机或微处理器系统处理的电信号。该设备与移动患者交互，然后通过调制解调器或其他电子通信设备将测量的参数发送到位于远程站点的计算机。在偏远的位置。由医疗专业护理人员监控和分析门诊患者病情的各种标记。为了给门诊患者提供额外的便利性和易用性，这种监测装置包含在单个集成包装中。

