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(54) Title: INFORMATION NETWORK INTERROGATION OF AN IMPLANTED DEVICE

(57) Abstract: A communication system is provided which permits of communication between a deployed implantable medical device (IMD) and a computing resource capable of storing and distributing patient and device data. A deployed IMD may be polled by a network interface external to the host patient, and data may be received by wireless communication. This data may be transmitted to a computer for storage and distribution, and changes to a treatment or instruction regimen, or firmware or software upgrades, may then be transmitted to the network interface for immediate or eventual loading into the IMD via wireless communication. The system is adapted to provide communication service between multiple IMDs deployed in a patient or a number of patients.

INFORMATION NETWORK INTERROGATION OF AN IMPLANTED DEVICE

FIELD OF THE INVENTION

The present invention generally relates to implantable medical devices (IMDs). Specifically, the invention pertains to an information network for remotely directing patient device data retrieval and device instruction updates. More specifically, the invention enables autonomous interrogation of the IMDs, without the intervention of an operator or a clinician, in real time. The collected data may be reviewed by a clinician or may be archived to compare patient history and for other future use. An interface medical unit or a programmer may be used to uplink the IMDs to the remote information network.

BACKGROUND OF THE INVENTION

In the traditional provision of any medical services, including routine check-ups and monitoring, a patient is required to physically present themselves at a provider's office or other clinical setting. In emergency situations, health care providers may travel to a patient's location, typically to provide stabilization during transport to a clinical setting, e.g., an emergency room. In some medical treatment applications, accepted medical practice for many procedures will naturally dictate physical proximity of medical providers and patients. However, the physical transport of patients to clinical settings requires logistical planning such as transportation, appointments, and dealing with cancellations and other scheduling complications. As a result of such logistical complications, patient compliance and clinician efficiency may suffer. In certain situations, delays caused by patient transport or scheduling may result in attendant delays in detection of medical conditions including life-threatening situations. It is desirable, therefore, to minimize situations in which the physical transport of a patient to a clinical setting is required. It may also be desirable to minimize the extent to which an patient or patient information must be considered by a clinician at a particular time, i.e. during an appointment.

After the implantation of an IMD, for example, a cardiac pacemaker, clinician involvement with respect to the IMD has typically only begun. The IMD usually cannot be merely implanted and forgotten, but must be monitored for optimal results, and may require occasional adjustment of certain parameters or settings, or even replacement, in response to or in anticipation of changes in patient condition or other environmental factors, or based on factors internal to the device. IMDs may also contain logic devices such as digital controllers, which may need to undergo firmware or software upgrades or modifications. In addition, information about the IMD may be gathered for treatment or research purposes. For example, many IMDs are capable of storing certain state information or other data regarding their operation internally in addition to physiological data.

Because IMD operation and patient physiology is preferably monitored to help effect the desired patient outcome, it would be desirable if data collected by an IMD could be viewed remotely. Similarly, it would also be desirable that the instructions installed in an IMD may be modified in response to patient physiologic information, or perhaps be upgraded remotely as well.

In the event a change, modification or reprogramming of the IMDs is indicated, it would be desireable if the instruction could be implemented in the IMD as soon as possible, thus providing more continuous monitoring to proactively effect changes in the IMDs for efficient therapy and clinical care. This scenario may be contrasted with existing practice of responding to an adverse patient event or subjecting the patient to the inconvenience or expense of frequent in-person encounters with a clinician, for example after an unexpected therapy by the device, or to effect other monitoring of device functioning, e.g., spontaneous therapies by the device. For example, an implanted cardioverter defibrillator may administer to the host patient a cardioversion or defibrillation therapy. After such therapy, it is typically desirable to determine the parameters of, for example, an arrhythmia that a therapy was administered in response to, or of the therapy administered.

Despite the limitations of IMDs with regard to processing power, IMDs are in a unique position to monitor physiological systems continuously. High-resolution data can be collected, but implantable devices are ill suited to storage and processing

of large amounts of complex physiological data. In contrast, computing power and data storage capacity (processor capability, memory, and adequate power supply) is abundantly available in the non-implantable ("external") world. The computing industry is still following Moore's Law (stating that transistor density will double every 18 months), delivering increasingly sophisticated computing devices yearly, and some of these gains accrue to the computer power of IMDs. However, frequent upgrading and replacement of IMDs based on more powerful models subjects a patient to additional stresses, and additional costs are imposed on the patient or health care system.

Prior art methods of clinical services, particularly IMD monitoring and adjustment, are generally limited to in-hospital procedures or other scenarios involving patient transportation to a clinical setting. For example, if a physician needs to review the performance parameters of an IMD in a patient, it is likely that the patient has to go to the clinic. Further, if the medical conditions of a patient with an IMD warrant a continuous monitoring or adjustment of the device, the patient would have to stay in a hospital indefinitely. Such a continued treatment plan poses both economic and social problems. Under the prior art, as the segment of the population with IMDs increases, many more hospitals and clinics, and attendant clinicians and service personnel will be needed to provide in-hospital service for the patients, thus escalating the cost of healthcare. Additionally, the patients will be unduly restricted and inconvenienced by the need to either stay in the hospital or make very frequent visits to a clinic.

Yet another condition of the prior art practice requires that a patient visit a clinic center for occasional retrieval of data from the implanted device to assess the operations of the device and gather patient history for both clinical and research purposes. Such data is acquired by having the patient in a hospital/clinic to download the stored data from the IMD. Depending on the frequency of data collection, this procedure may pose serious difficulty and inconvenience for patients who live in rural areas or have limited mobility. Similarly, in the event a need arises to upgrade the software of an implantable medical device, the patient will be required to come into the clinic or hospital to have the upgrade installed.

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