# PORTABLE MODULAR DIAGNOSTIC MEDICAL DEVICE

## FIELD OF THE INVENTION

This invention relates generally to diagnostic medical devices, and particularly to such devices that are portable and modular.

## BACKGROUND OF THE INVENTION

Quality and cost-effectiveness are significant issues in health care. The diagnosis and treatment of a patient by a clinician is the underlying core of the health care process. The clinician, such as a doctor, a nurse, or other medical professional, typically relies upon medical instrumentation to provide objective measurements of the patient that are used to prescribe treatment. The quality and cost of health care, therefore, are directly linked to the quality, availability, and cost of the medical instrumentation utilized.

The criteria typically used to evaluate diagnostic medical instruments include safety, efficacy, and cost-effectiveness. The safety standards are explicitly defined by the Association for the Advancement of Medical Instrumentation (AAMI). For example, the AAMI's safety standards for electrocardiographic (ECG) devices are described in "American National Standard Diagnostic Electrocardiographic Devices," ANSI/AAMI EC11-1991, which is hereby incorporated by reference.

Efficacy and cost-effectiveness, however, are not as clearly defined and depend greatly upon the clinician's needs. For a medical instrument such as an electrocardiogram (ECG) or electroencephalogram (EEG) device, the effectiveness of the device involves not only how well it measures the biopotential in question, but also its ability to provide useful information in a timely, usable, and appropriate manner. Equipment with a poor user interface or inadequate controls, as typically found within the prior art, is unlikely to be used, and not at times when the information needs are time critical. Bulky or heavy equipment, as is also usually the norm within the prior art, cannot be easily moved to remote locations or carried into emergency situation environments.

Conversely, portable equipment found within the prior art such as holter ECG monitors available as the Digitrak Holter Monitor from Zymed, Inc., of Camarillo, Calif., require additional hardware to permit viewing of the stored signal. On-line, real-time diagnosis cannot be made at a remote location with such prior art portable medical diagnostic equipment without telemetry to a base unit or transmission over a telephone line. The patient data needed to make diagnoses quickly and effectively cannot be accessed readily; therefore, the instrumentation fails to meet user needs in a real-time manner.

Cost-effectiveness is also critical to meeting user needs. Inexpensive diagnostic equipment must be accessible to the medical practitioner for application to the end customer—the patient. If requisite diagnostic medical equipment is not available because of budgetary constraints, the quality of health care suffers. The average price of major manufacturer ECG equipment is typically in the $5,000–$10,000 range. Many underfunded clinics within and outside the United States cannot afford basic equipment such as simple ECG machines.

The cost of medical diagnostic equipment is high because, in part, product development costs continue to increase. Each new product typically has its own specific hardware and software. Little common instrumentation architecture is available. Existing solutions within the prior art do not fully overcome these shortcomings.



One prior art approach is the medical data acquisition hardware card, for insertion into and use with a PC-compatible computer. However, computers are still expensive, typically costing upwards of $1,000–$2,000. In the case where a desktop computer is used, the resulting diagnostic medical device is still not portable.

Furthermore, a PC-compatible computer-based approach tends to have high support and installation costs. A given medical hardware card may not run on a given PC-compatible computer without significant user involvement during the installation process, because of differences across such computers. The hardware card usually does not include necessary software built in; the software must itself be separately loaded onto the computer, and thus raises another compatibility concern for a given computer. Computer-wary clinicians may not be likely to trust the computer to provide it with medical diagnoses, and non-computer-savvy clinicians may find using such software as difficult as learning a complex word-processing or spreadsheet program.

Most significantly, the PC-compatible platform may not have the stability that is required of medical diagnostic devices. While the "crashing" of a computer is inconvenient in the situation where a word-processing program is being run on the computer, for example, the crashing of such a computer may literally cause a life-threatening situation where the computer has been transformed into a medical diagnostic device via a hardware card and corresponding software. Ominously, because of the great variability in different PC-compatible platforms, there is no way to guarantee that such crashing will not occur on a particular PC-compatible computer.

Other standard architectures exist to provide the backbone of diagnostic medical devices, such as the EasiView EKG System available from Zymed, Inc., of Camarillo, Calif., and the CardioVoice Phone/System available from Paceart Associates of Wayne, N.J. However, these architectures are themselves typically specific to only diagnostic medical devices. Because the market for such medical devices is much smaller than that for PC-compatible computers, for example, the economies of scale with these standard architectures are still not great enough to permit a markedly great reduction in medical device cost.

Furthermore, the architectures represent only an initial starting point in the development of a diagnostic medical device, around which the architectures are designed. The resulting medical device is not modular. Its designed-for medical functionality cannot be switched out for different medical functionality for use with the same physical instance of the backbone architecture. The medical functionality and the architecture are permanently interconnected and prevent modularity.

Finally, these backbone architectures are typically still PC-compatible based, integrating a PC-compatible motherboard into the architecture. Therefore, many if not all of the shortcomings of utilizing PC-compatible computers as platforms for medical devices carry over to the utilization of these backbone architectures as medical device platforms as well.

## SUMMARY OF THE INVENTION

The above-mentioned shortcomings are addressed by the present invention, which will be understood by reading and