Customer/Clinical need
A recent health care analysis have demonstrated an increase in cardiac problems associated with intense exercise in young people/smokers, revealing a clear need for ECG monitoring during severe physical activity. A small, portable and inexpensive ECG device will offer the option of monitoring heart activity in these cases, allowing for early detection of cardiac problems during high physical stress. While most of users will not be favorable to use medical equipment in their everyday life, they expressed a favorable opinion for using a device that will not interfere with their daily life activities. Computer-based ECG monitoring systems are expected to drive growth within the youth and middle age market for resting and/or stress ECG products by offering cost-effective solutions as well as scalability. As a growing number of people add standard ECG monitoring to their quotidian life, fewer patients will be referred to hospitals for ECG monitoring. Professional ECG machines can cost anything from $4000 up in the USA. These devices generally use 3, 5 or 12 leads to monitor the ECG signals in heart. While the full set of leads is required to develop a complete diagnosis of heart function, these devices are considered by some costumers as impractical to monitor ECG during an emergency or in a daily basis, suggesting a high potential of commercialization for a basic ECG system, for which the acquisition of 3, 5 or 12 leads is not required.

Market Research
In a Market Research Report Published in December 2003, Frost & Sullivan stated that Advancements in Technology is Boosting Demand Within the Electrocardiograph (ECG) Monitoring Equipment Market. As the incidence of cardiovascular disease grows, hospitals and physicians' offices continue to experience a significant rise in the number of diagnostic ECG monitoring tests being performed. The growing volumes of ECG monitoring have created a strong need among end-users to demand equipment that facilitates effective and reliable management of patient data. As a result, ECG monitoring equipment with enhanced communication capabilities has been a primary driver of revenue growth in the ECG monitoring equipment market. Today, ECG monitoring systems are increasingly being networked across various hospital information systems to allow fast and reliable access to complete patient information. This trend has been further promoted by the FDA's decision in 2002 requiring all ECG data submitted in support of drug applications to be in digital format. Many manufacturers are also focusing on
improving system accuracy, reducing errors, and providing additional clinical capabilities to enhance workflow. As larger hospitals implement these developments, smaller clinics and physicians' offices are expected to follow. This trend is forecast to increase revenues in the Resting ECG and ECG data management segments. Furthermore, Frost & Sullivan affirm that the actual **Growth of Computer-based Systems Improve the Market Penetration of ECG Devices.** The emergence of personal computer (PC) based ECG monitoring systems is expected to drive growth within market for Resting/Stress ECG products by offering cost-effective solutions as well as scalability. "PC-based ECG monitoring systems allow software components to be added to a core PC system that is part of the diagnostic instrument," says the author. "This enables end users to download relevant software applications and run them on a Mac/Windows desktop or notebook computer."

1. Specifications

**Required specifications (mandatory)**

The design of a system for acquisition of ECG signals is requested. The system of ECG acquisition must be able to monitor changes to your heart under various physical conditions, as in bed rest or after exercise. The quality of the ECG waveforms is expected to be comparable with ECG's signals acquired with medical grade devices.

**Desired specifications (optional)**

The simplest design in terms of cost, size, weight, noise rejection, robustness and energy consumption is desired. Due to time limitations, development of digitizer hardware will not be required. The Analog signal from the ECG will be digitized using existing hardware in the Design Laboratory. Existing acquisition software packages may be used but user-friendly interfaces should be incorporated. ECG's waveforms will be recorded or printed out using a personal computer. The system should be usable by an individual with minimal technical background (you may assume computer literacy but not biomedical engineering background). The hardware itself may include user-feedback (LED light or sound on heartbeat, low-battery warning, error light, etc.) to assist with proper use. The hardware/software may be tunable by the user however this tuning must be optional.

The system may be designed to fulfill the FDA and electrical safety regulations.

2. Project Proposal

**Introduction**

The muscles of your body are controlled by electrochemical impulses. These impulses are distributed to the muscles by the nervous system. On reaching their
destination, the nerve impulses cause the muscles to contract and produce much larger electrical voltages. A small proportion of these voltages are conducted out through to the surface of the skin where they can be detected using sensitive equipment like an ECG (often also called EKG).

Because the heart is a large and rather complex group of muscles, which contract cyclically in a preset sequence, it is possible to study the overall condition of the heart by measuring the amplitude, periodicity and waveform of the heart muscle voltage components found on the skin. This is the reason for capturing ECG waveforms, which are obtained using two or more electrodes (pads) attached to the skin via conductive saline gels or paste.

Capturing ECG waveforms can be a challenge, because the voltage components found on the surface of the skin are small in amplitude: around 1mV peak to peak, depending on the positions of the electrodes and the resistance between them and the skin.

**Objectives**

The goal of this project is to design and improve a basic system for acquisition of hearts’ electrical activity (electrocardiography)

The different steps involved in the design process will be demonstrated throughout this mini-project example, preparing the student for the main design project of the BME design course.

**Product Description**

A single channel ECG machine will fulfill the market needs previously described. This small/portable electrocardiograph might let emergency medical services to perform hospital-quality electrocardiograms in the field and relay that information quickly to doctors in another location. The planned device will take advantage of advanced technology: selection of small, low-power chips, combined with high level of space-saving packaging technology will result in reduced energy consumption and extended battery life while creating smaller, lighter, and a more portable ECG device.

The system is designed to be fully automatic, so that minimal operation of the user is required throughout the test. This may facilitate the acceptance of the device and improve the management of the patient data. The ECG waveforms will be presented in digital format and in real time, allowing for immediate recognition of cardiac pathologies. The ECG device will be interfaced with a PC-based or handheld device. By using common computer devices, the cost of the overall system is reduced (as the user needs only to purchase the ECG device).

Easy software upgrades to existing hardware platform also help reduce the need for major system upgrades. This approach has the advantage of reducing the cost of the device by using the microprocessor, display, hard drive, ports, etc. from the user's PC or handheld device.
3. Schedule

The following schedule describes the most important target completion dates. It also contains key decision points and completion of the primary deliverables throughout all phases of development and implementation. *Students are strongly encouraged to stay ahead of schedule.*

**Week 1:** Initial product development (Block Diagram). Construction of the basic ECG from a given design.

**Week 2:** Evaluation of multiple design proposals to obtain the design to be prototyped (Paper design and engineering analysis). Detailed design and acquisition of materials.

**Week 3:** Construction in breadboard, preliminary tests and redesign if needed.

**Week 4:** Design and fabrication of electric board. Mounting of components and preliminary tests. Design and fabrication of final product (case, label, etc).

**Week 5:** Tests of ECG device under different conditions (patient in bed rest, standing up, after exercise) and elaboration of 1 page summary of results. Oral presentation to class/demonstration of the final design.

4. Prior Art of ECG device

The design of the ECG device can be developed by modification/improvement of the following basic circuit using Operational Amplifiers or an Instrumentation Amplifier.
5. Paper Design and Engineering Analysis

A block diagram is hereafter suggested for completing the ECG design

- **Electrodes**
- **AC Coupling**
- **Instrumentation Amplifier**
- **LP Filter**
- **Additional Gain Amplifier**
- **Isolated Power supply**
- **To Digitizer**

**Technical Description**

This system will use only two electrodes and cables to detect the voltage between two points in the body skin generated from the cardiac activity. The detected signal needs to be amplified, filtered, and digitally converted to output waveforms on a display or printer for analyzing cardiac function. The ECG must be designed robust enough to be used under various physical conditions, including standing up, in bed/rest or after exercise. In order for this new device to be competitive in the ECG market, it is required to display, record or print out using a personal computer/hand-held device the same quality of ECG waveform as acquired using medical grade devices. Moreover, the product should fulfill the FDA and electrical safety regulations to the extent possible.

**Gain**

The ECG signals usually have amplitudes on the order of microvolts to a few millivolts. The voltage of such signals must be amplified to levels suitable for digitization or driving a display/analog recording equipment. Thus, most biopotential amplifiers must have gains of 1000 or greater. Most often the gain of an amplifier is measured in decibels (dB).

**Bandwidth**

The frequency bandwidth of a biopotential amplifier should be such as to amplify, without attenuation, all frequencies present in the electrophysiological signal of interest. The bandwidth of any amplifier is the difference between the upper and the lower cutoff frequencies. The gain at these cutoff frequencies is 0.707 of the gain in the midfrequency plateau. If the percentile gain is normalized to that of the midfrequency gain, the gain at the cutoff frequencies has decreased to 70.7%. The cutoff points are also referred to as the half-power points, due to the
fact that at 70.7% of the signal the power will be \((0.707)^2 = 0.5\). These are also known as the \(-3\) dB points, since the gain at the cutoff points is lower by \(3\) dB than the gain in the midfrequency plateau: \(-3\) dB = \(20 \log(0.707)\). In general, the ECG electrical potential is an AC signal with bandwidth of 0.05 Hz to 100 Hz, however, if the patient has a pacemaker, the recommended bandwidth must be extended up to 1 kHz.

**Common Mode Rejection (CMR)**

The common-mode rejection ratio (CMRR) of a biopotential amplifier is measurement of its capability to reject common-mode signals (e.g., power line interference), and it is defined as the ratio between the amplitude of the common-mode signal to the amplitude of an equivalent differential signal (the biopotential signal under investigation) that would produce the same output from the amplifier. Common mode rejection is often expressed in decibels. For ECG applications, a CMR>1000 is required.

**Noise and Drift**

Noise and drift are additional unwanted signals that contaminate a biopotential signal under measurement. Both noise and drift are generated within the amplifier circuitry. The former generally refers to undesirable signals with spectral components above 0.1 Hz, while the latter generally refers to slow changes in the baseline at frequencies below 0.1 Hz. Other noise or higher frequencies within the biophysical bandwidth come from movement artifacts that change the skin-electrode interface, muscle contraction or electromyographic spikes, respiration (which may be rhythmic or sporadic), electromagnetic interference (EMI), and noise from other electronic devices that couple into the input.

**Recovery.**

Certain conditions, such as high offset voltages at the electrodes caused by movement, stimulation currents, defibrillation pulses, and so on, cause transient interruptions of operation in a biopotential amplifier. This is due to saturation of the amplifier caused by high-amplitude input transient signals. The amplifier remains in saturation for a finite period of time and then drifts back to the original baseline. The time required for the return of normal operational conditions of the biopotential amplifier after the end of the saturating stimulus is known as recovery time.

**Input impedance.**

The input impedance of a biopotential amplifier must be sufficiently high so as not to attenuate considerably the electrophysiological signal under measurement.
**Electrode polarization.**

Electrodes are usually made of metal and are in contact with an electrolyte, which may be electrode paste or simply perspiration under the electrode. Ion-electron exchange occurs between the electrode and the electrolyte, which results in voltage known as the half-cell potential. The front end of a biopotential amplifier must be able to deal with extremely weak signals in the presence of such dc polarization components. These dc potentials must be considered in the selection of a biopotential amplifier gain, since they can saturate the amplifier, preventing the detection of low level ac components.

**Power Supply**

As in most other applications, the system supply voltage in biophysical monitoring continues the trend toward low, single-supply levels. While bipolar supplies are still used, 5-V systems are now common and trending to single 3.3-V supplies. This trend presents a significant challenge for the designer faced with a 500-mV electrode potential and emphasizes the need for a precision signal conditioning solution. The choice of power supply will directly affect some of the specifications of the device: price, size, weight, energy consumption, selection of components, etc.

**Electrical safety**

A very important issue related to the design of biomedical devices in which the patient is monitored using electrodes is the electrical safety. Imagine the case in which (1) the earth connection of the device becomes broken and (2) the power supply also develops a direct short circuit to active 120VAC; the potential current that could flow through the body between the electrodes may cause a patient injury. Special attention must be taken to isolate the patient from the power supply of the system.