BME 405 BIOMEDICAL ENGINEERING SENIOR DESIGN 1

Fall 2007 BME Design Mini-Project

Project Title
Robust portable heart-rate monitor

Overall design objective:

A develop a portable, self-contained, robust, and user friendly heart rate monitor. The device will be used by adults in a wide-range of settings including a hospital setting (ambulatory care, intensive care, transport, etc...), at home (sleeping, elderly, high-risk patient monitoring), or during sporting activity (e.g. running) or physical training (but not swimming). The device must be robust against all foreseeable “practical” situations including drops, tugs, perspiration, heat/cold, battery run-down, motion, etc.... The output of the device should be a simple display that provide the user or clinician with an easy to see and understand qualitative (audio or visual) or quantitative (display) indicator of the individuals heat-rate. You will need to consider how to usefully address normal/pathological fluctuations in heart-rate (if at all). The system sensing modality(s) is not specified but should be optimized for all the issues indicated above.

Required specifications (mandatory)

Note that every specification must be addressed explicitly and quantitatively.

A portable system for acquisition and display of heart rate.

The system should be usable by an individual with minimal technical background; this includes the initial set-up (e.g. placement) and any maintenance (if required). The system should be ‘fully automatic’ with no use/patient specific adjustments necessary.

The system size and weight should be minimized (maximum dimensions 5”x3”x2”, maximum weight 2 pounds).

The system display must provide a simple a clear indication of instantaneous heart rate (either qualitative or quantitative). The system may optionally average several preceding heart-rates to increase accuracy and readability (in the case of a numeric display) but fluctuation in heart-rate that may reflect pathology should be detected.

The entire system (including any sensors / leads) must be able to withstand normal ‘wear and tear’ associated with a range of health and sick subject activity
including rotation in bed, exercise, perspiration, movement, patient transport etc……

The use of the system, including leads/sensors should not affect motion of comfort.

The unit must in no way and under no conditions affect the safety or well-being of the monitor or user (for this reason, battery power is recommend but not required). The unit cannot use any invasive sensors.

The unit does not need to be able to withstand water immersion but perspiration or humidity (as might be encountered under a blanket) should be considered.

The system must be function continuously for 6 hours, without need for any intervention by clinician or user.

The unit should also provide an 'on' or normal function indicator.

When first activated/used the unit should provide an indicator that it is properly functioning.

You must consider how to address sensor/lead wear and/or device power run-down. In addition what is done if the patient needs to be temporarily washed (and the device perhaps removed) or if the battery runs down?

You do not need to provide a user or operation manual for the patient/physician (though a full technical and operation description should be included in your report). The device itself may be labeled as necessary.

You do not need to consider mass-production of the device, any aspects of marketing or market penetration. You do not need to consider restrictions relating to proprietary technology (e.g. you can use whatever components and design approached are optimal, regardless of if they are protected in a patent).

Device cost should be minimized to less than $50 dollars at proto-type stage including all sensors (see exception below).

**Desired specifications (optional)**

The unit may provide a warning (visual and/or audio) when heart rate increases/decreases outside normal levels. Moreover, this level may be adjusted based on the device use. Additionally, there may be a mechanism to (transiently) silence this alarm.
The unit may measure additional physiologically relevant measurands (e.g. temperature); however these or any additional feature should in no way compromise the device required performance specifications.

The unit may store digital data and/or transmit such data to an external device via a physical connector (e.g. BNC wire) or telemetry. However, the device must be able to operate independent of any external devices. A existing software package may be used/adapted or software package may be developed to analyzed/transmit the data.

If additional sensors/measurands, data storage, or telemetry is included, these factors may not count toward the $50 required component cost limit.

If time varying signals such as an ECG waveform or blood-oxygen saturation are acquired, this signal may be displayed, stored, and/or transmitted.

The unit may sense heart rate using multiple modalities in order to improve robustness/accuracy. In this case, multiple displays may be used to indicate with measurand is indicated OR multiple measurand may be ‘averaged’ to produce a more robust output.

Inevitably, under some situations (very robust motion, patient disconnect, improper use) the signal will be interrupted. You should address how the device deals with (minimizes) such interruptions.

Both hardware/software main contain self-test/evaluation features.

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

The unit should be functionally and cosmetically appealing (which includes minimizing size).

3. Mile-stones / Mini-project organization

The following mile-stones are recommended. Document all steps.
1: Initial product development (Block Diagram). What features will it have? What sensor/patient interface?
2: Through paper design and theoretical engineering analysis, evaluation of multiple design proposals (including potential component performance) to obtain the design to be prototyped. Detailed design and acquisition of materials
3: Construction in breadboard, preliminary tests (no exterior/packaging), including sensors, and redesign as needed
4: Optional design and fabrication of electric board, redesign as needed.
5. Mounting of physical and electrical components, and preliminary tests including prototype exterior. Design and fabrication of final product (case, label, etc), redesign as needed.
6. Complete testing of ‘final’ device under different conditions addressing all points in required specifications (e.g. patient in bed rest, standing up, after exercise). Careful and intelligent testing is critical. The ‘final’ device may be modified and fixed time allowing. Be prepared to answer quantitative questions along the lines of “how do you know that?”

7. Written summary of results including quantitative validation of individual device components and over-all device performance (did the device meet required/selected desired specifications; what are the successful/unusual features of you specific device; what are the limitations in device use-potential further improvements). Consider factors such a recovery. Oral presentation to class/demonstration of the final design. Note, how/what you present written/orally is as important as the design and testing itself.

The scope of what you can accomplish will be severely limited by the project timeline. There will be no extensions, no accommodations for poor planning, for poor team organization, or inability to obtain parts or access to B41. Students are highly encouraged to speak to previous design students for advice on all aspect of the mini- and main-projects including time and resource management. Students are encouraged to be conservative in their design / time estimated and may develop both a basic simple attainable design first and add complexity/features time allowing. A successful team will plan on ‘nothing working at fist’ and allow plenty of time to address deficits prior to deadlines.

In the mini-design project all teams are working under the same design specifications. Each team will receive a single grade. Neither the design process nor the grading is competitive (though understandably teams will take pride in their specific product). Teams are welcome and encouraged to discuss approaches and solutions with each-other. However, each team must make every design decision on its own (‘because they did it’ is not an appropriate design decision factor, though ‘because it worked for them’ is a factor). None-the-less, each design team must fully understand all aspects of its own design. Given the very wide range of design approaches, components, etc. it is unlikely any team products will be the same. Note, your final product along with your report may be made available to the entire class and subsequent design classes.

Unlike the main-project, in the min-project each team does not have a specific assigned TA; in fact there is no TA at all for the mini-project. Students must be realistic about what they can accomplish technically on their own and not expect technical or time micro-management by the course directors. For the mini-project the course director and course technician will be available only on limited basis to address technical questions. However, do not hesitate to address project scope / course organization questions to the course directors (e.g. what should the device do?, is this a good test for this specification?). Students, You are ultimately responsible yourselves (as a team and individuals) for your success in Design I and II; if you do not systematically organize and work well ahead of deadlines, the results will be disastrous.
For 2007/2008, Senior Design has implanted a weekly written summary/plan system which must be maintained by the team leader. Every student must be named in each report listing accomplished/unaccomplished objectives and future objectives. For the 2007/2006 Senior Design cycle either teams or students whose performance is found sub-standard during any point in the course (including the mini-project) will receive a formal warning from the course directors which can be followed by restrictions on allowable senior design projected (e.g. the student may not be allowed to work on an external sponsored project) or dismissal from course.

4. Prior Art / Final Presentations

For the mini-project design you are not required to research or comment on any prior-art or existing products; however you may research or reference any previous produces / designs (including previous senior/junior design projects). In your final report, do not compare your device performance against other devices or against other mini-design projects.

In your final presentation you may speculate on why any components of your design did not work / potential solutions but ‘excuses’ do not approach the value of a working solution. A partial and simple working solution is better than an ambitious not working idea. Refinements / additional features which are partly developed / not tested may be briefly commented on, but count relatively little compared to working components. In the mini- and main-project it is thus emphasized that you focus on attainable and simple designs, leaving refinements / complex features for time-allowing. A design or concept that is not fabricated and tested is worth very little (largely because concepts usually don’t work on first testing and need to be repeatedly refined). ‘Future plans/improvements’ similarly have little technical value.

NOTE this approach to prior art DOES NOT apply to the main project.