MEDICAL DEVICE ELECTRONICS DEVELOPMENT IN RESOURCE LIMITED SETTINGS: A UGANDAN PERSPECTIVE

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ABSTRACT

The availability of vital medical equipment for the care of children under-five in developing countries remains very limited, largely due to the prohibitively high cost. The majority of this equipment is imported and for the most part inappropriate for use in a low resource environment. Devices that are electrically operated are usually unable to withstand prevailing intermittent power supply which is a common occurrence in both urban and rural areas of Uganda. Early, accurate diagnosis and prompt treatment can significantly reduce preventable child deaths. The use of embedded technology in designing medical devices for diagnostics and therapeutic treatment offers a high level of efficiency, reliability and robustness. This paper explores the design considerations for embedded systems in resource limited settings with a focus on results from the design of a low cost solar powered electronically controlled infusion set.

Keywords – accuracy, infusion, medical devices, low resource, affordable, appropriate

INTRODUCTION

In addition to the disease burden that Uganda faces, the delay in accessing quality care, which includes availability of appropriate monitoring, diagnostic and therapeutic tools at healthcare facilities, remains a challenge. This situation is particularly dire in rural and hard to reach areas of the country that lack the necessary medical equipment and skilled clinical personnel. Government hospitals and health centers are heavily congested and experience a serious shortage of health workers resulting in severe workload challenges faced by medical staff. These factors are already adversely affecting patient care and health outcomes.

The vast majority of available medical equipment in Uganda is imported and usually rendered ineffective due to frequent breakdowns and the absence of an effective management system for medical devices [1]. Many developing countries such as Uganda are heavily dependent on donor assistance to meet the equipment needs of their healthcare systems. Despite the intended goodwill of donors, important parameters such as calibration, voltage and frequency ratings, availability of mains power supply, ease of accessing spare parts and appropriate training are usually not taken into consideration. As a result, capacity for utilization is low and these donations do not achieve their desired objectives and could even constitute an added burden to the recipient healthcare system [5]. Figure 1.1 shows donated equipment that has been shelved overtime due to frequent breakdowns. Repair is usually an arduous task due to difficulty sourcing spare parts locally, design for countries with different voltage and frequency ratings, lack of manufacturer support for equipment that has reached end of life and the overall lack of technician skills to calibrate, maintain and troubleshoot the equipment.

Figure 1.1 Unused donated medical equipment at the Mulago Hospital Workshop, Kampala, Uganda

BACKGROUND ON INFUSION

In Uganda, intravenous fluid or drug administration is predominantly done through manual operation using a roller clamp retrofitted on the tubing of standard fluid giving sets. This approach has potentially fatal outcomes for it requires a fairly well-trained clinician to infer and set the rate of fluid flow accurately. It is critical to control the amount of fluid administered to a patient effectively, for a given time, based on prescribed patient requirements. Accordingly, manual operation and control of fluid or drug delivery is rendered problematic by chronic staff shortages. The design of a low cost solar powered electronically controlled infusion set which automates the infusion process and dynamically controls flow rate while optimizing power consumption will ensure the safe and less labour-intensive delivery of fluids or drugs to patients, especially young children. The resultant effect would be the alleviation of the human resource burden, providing convenience, usability, performance and risk reduction. Furthermore, devices that are electrically operated are usually unable to withstand prevailing intermittent power supply which is a common occurrence in both urban and rural areas of Uganda.

METHOD

Embedded System Design Process

The design process of a medical device embedded system involves an initial needs assessment exercise in a clinical setting, to fully understand the context in which the medical device will be used. Planning the design process at this stage is critical for three reasons; firstly to keep track of the desired medical device design requirements, ensuring they have all been met; secondly to develop modules that break the process into manageable steps which will in the future ease maintenance and troubleshooting tasks; and lastly to communicate seamlessly and integrate the system into a final product [6]. Figure 1.2 summarizes the critical steps during this top-down design process.

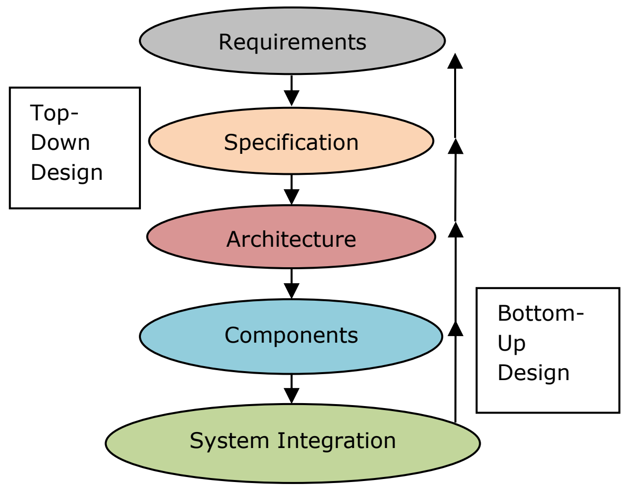

Figure 1.2 Critical levels of abstraction in the Embedded System Design Process [6]

The system requirements are developed through consultation with the end users, the clinicians, and assessment of how existing devices operate in a clinical context. The objective of this process is to define the clear scope of the solution and understand possibilities of how the new design could be used. The next step, specification, will create a more detailed description of how the desired system behaves but excludes the steps taken during the development process. The actual design begins in the third step, the architecture, which gives the system structure in terms of large components. Once the components have been clearly established design work commences that includes both specialized hardware and software modules for each component. These components will then be integrated into a final complete system. During the design process previous steps may be iteratively revisited for clarity as there may be instances that the top-down process may not yield the desired results or meet the requirements that are expected. This bottom-up design process will be simultaneously used with the top-down approach.

Challenges in Embedded Computing Design in a Low Resource Setting

Critical external constraints are factored into the embedded design process to achieve the desired functionality for the device application these are; i) available system memory, ii)available processor speed, and iii) the necessity to limit power dissipation when running the system continuously in cycles of 'wait for events', 'run', 'stop', 'wake up' and 'sleep' [3]. As such the hardware must be optimized according to the performance, power dissipation and other design metrics that include physical size, prototype development and manufacturing costs. Performance under stress and strain i.e. environmental conditions of the low resource country of implementation, such as humidity and excessive dust, must be factored in during the choice of electronic components.

Hardware Considerations

The amount and type of hardware needs to be assessed from the start of the application design as it is an important determinant in meeting performance deadlines and manufacturing cost constraints. Insufficient hardware results in the system failing to meet deadlines. This is unacceptable in the design of medical devices that are hard real time systems as it can lead to harmful consequences to the recipient patient. Conversely, excessive hardware increases the cost of the design.

Defining the desired computing power requires an appropriate selection of the type of microprocessor used, selection of the amount of memory RAM, ROM or internal and external flash or secondary memory in the system and the relevant peripheral devices. Typically an ideal microprocessor would be one that can issue one machine instruction per clock cycle i.e. the best performance that can be achieved would be the completion of one critical instruction for every cycle. Therefore the processor's choice of instructions can lead to an efficient implementation of the task at hand.

Optimizing Power Dissipation

The two goals of optimization are, firstly, to decrease the total number of cycles required to achieve a particular task by reducing the number of cycles wherein no useful work is done and, secondly, to make the most effective use of the cycles consumed. In the real world many factors can cause deviation from an ideal performance. Power consumption of CMOS processors comes from three main sources: (i) dynamic power consumption due to the charging and discharging of capacitors (ii) short circuit power consumption i.e. short circuit path between supply rails during switching and (iii) leaking diodes and transistors as a result of the shrinking size of semiconductor technology today. The Dynamic Voltage Scaling (DVS) method is used to reduce the overall power consumption of the embedded medical device. DVS tries to address the tradeoff between performance and battery life by taking into account two important characteristics of most embedded systems: (i) the peak computing rate needed is much higher than the average throughput that must be sustained; and (ii) the processors are based on CMOS logic. The first characteristic effectively means that high performance is needed only for a small fraction of the time, while for the rest of the time, a low-performance, low-power processor would suffice [2]. We can achieve the low performance by simply lowering the operating frequency of the processor when the full speed is not needed. Considering power consumption of CMOS circuits ignoring leakage, power for the embedded system can be approximated as shown in equation (1).

$$P^{\sim}\partial C_L V^2_{dd} f \qquad (1)$$

V_{dd}: supply voltage

∂: switching activity

C_L: load capacity

f: clock frequency

Decreasing V_{dd} reduces P quadratically provided f remains constant. The amount of energy consumed can therefore be approximated as shown in equation (2).

$$E \tilde{} \partial C_L V^2_{dd} ft = \partial C_L V^2_{dd} \quad (2)$$

Therefore to maximally save energy for the system it is necessary to reduce the supply voltage, reduce the switching activity and reduce the load capacitance which will ultimately translate in a decrease in the number of cycles as shown in equation (3).

$$\partial C_L V^2_{dd} = \#cycles \quad (3)$$

Effective optimization is dependent on working around a particular factor to mitigate its effect on performance.

DISCUSSION

Our case study will focus on the design and verification of a low cost solar-powered electronically controlled gravity-feed infusion set. This medical device comprising of two key modules, a drop sensor and an actuator module, can be retrofitted on any standard drip equipment as an add-on device. It has the capability to control dynamically the flow rate based on feedback from a drop monitoring module [4]. The processor of choice is the Microchip PIC18F2480 microcontroller. This processor hosts a number of modules and features that are well suited for operation of the device. It features low power with nanoWatt XLP eXtreme Low Power Technology with sleep currents as low as 20nA. The extremely low sleep current and numerous wake-up features provide an ideal combination for battery operation. The power and battery management system automatically manages the power supplied to the device. The system includes a rechargeable battery and automatically determines, via a purposely designed hybrid power source controller, the power source used to supply power to the charging unit, effectively being able to charge with either the Mains (AC) or Solar (DC). To maximize battery life, the system design uses switch-mode voltage regulators for any substantial power level. Low-Dropout linear regulators (LDOs) are used only in the lowest power circuitry where their low efficiency can be tolerated, or where the output voltage of the LDO is not much lower than the input voltage, which keeps efficiency high [4]. The design, implemented on a printed circuit board was subjected to a series of tests against varied test criteria to ascertain functionality, accuracy, precision, repeatability as well as to establish a correlation between the linear stepper motor actuator unit movement and the flow rate module pitted against a physical user count. The results yielded an appropriate accuracy of ±1 count [4].

CONCLUSIONS

In this paper we have presented appropriate criteria to design an embedded medical device for a low resource setting with design constraints. This involves a modular approach in designing each component of the system, careful choice of an appropriate processor to achieve desired functionality and the use of the Dynamic Voltage Scaling method for full optimization of power consumption. This approach has been proven successful as exemplified by the design of a low cost solar powered electronically controlled infusion set that appropriately regulates fluid flow through a drop sensor and actuator module mechanism with an accuracy of ±1 count.

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