A Tool for Designing High-Confidence Implantable BioSensor Networks for Medical Monitoring

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Abstract - In this work we describe a software tool for designing implantable *biosensor network* (BSN) applications. BSNs are next generation medical monitoring systems, which provide continuous monitoring and actuation capabilities to medical personnel. They usually form a wireless network on a subject's body and can be controlled remotely. Before deploying any mission critical systems, it is important to be able to evaluate their performnce in the appropriate settings, and fine tune the design choices made. This is especially important for BSNs which are *cyber-physical* in nature – they interact and influence their environment of deployment.

Toward this goal we present the development of a software tool which can be used by developers and medical personnel to emulate an actual deployment of biosensor applications and evaluate its performance in different scenarios. We use Architecture Analysis and Design Language (AADL) in order to implement our tool as it provides an easy to use interface for specifying complex systems, and their environments. In this paper we discuss various aspects of developing such a tool including prinicipal characteristics of BSNs that need to be considered by it along with its functional architecture. We also provide an example scenario of how the tool can be used to evlauate a specific biosensor application.

1. Introduction

Recent technological advances in the fields of MEMS, integrated circuits, and low power design have lead to the development of implantable network of health monitoring sensors and devices. The RAND Corp. report on future technologies [RAND] predicts that the first applications resulting from the synergistic efforts of various disciplines will be out for public use by the year 2015. These **Biosensor Networks** (BSNs) are *cyber-physical systems* which have the potential to save lives by continuously monitoring the human body and taking corrective actions by triggering a response in case of medical anomalies. Biosensors communicate using the wireless medium with one another and with the external world. Medical personnel can use the Internet to remotely monitor and control implanted sensors, which not only provides them with valuable diagnostic feedback but also actuation capabilities. Figure 1 illustrates an example BSN embedded inside the human body.

Given the cyber-physical nature of BSNs – their close coupling with the human body – care has to be taken to understand the effects of their operation on their environment (body). As it may not be feasible to test BSNs in a real-life setting (through actual deployment), it is important to develop tools which can 'emulate' such deployments and allow designers of BSNs to be able to evaluate the consequences of their design choices and thereby improve the performance of the BSNs.

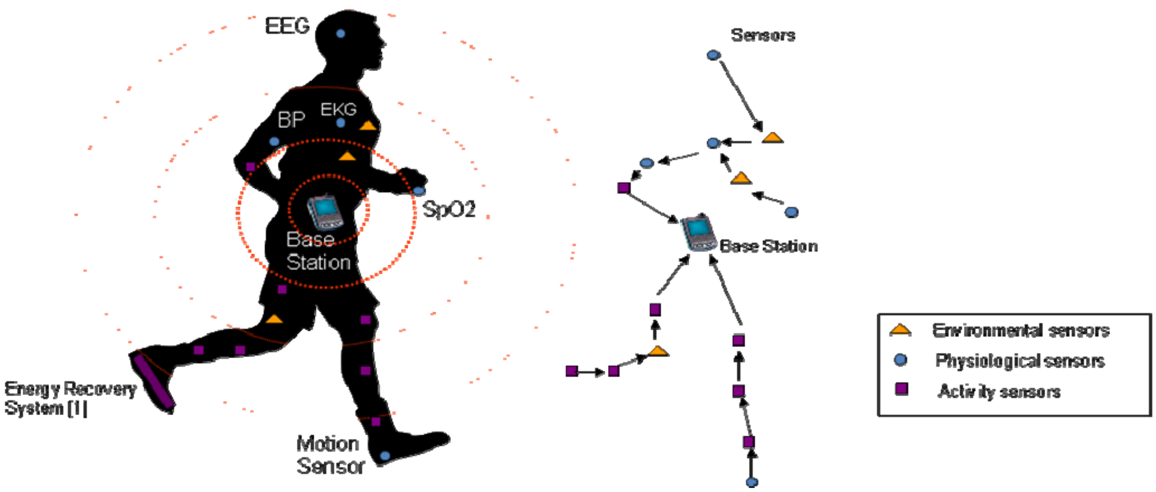

Figure 1: Example Biosensor Network

Typically, developing any application including those based on biosensors begins with an idea and conceptualization. This is then followed by the preliminary design. The design will then have to be analyzed against models of the target environment. Design and analysis are iterative steps and are repeated until the design team is confident that they have taken care of all issues. This refined design is then used to build a prototype that will be tested in the target environment (tissue medium). Here, the design and analysis phases are especially important as they are used to identify potential problems and address them at a very early stage. The goal of this paper is to present an overview of our tool and some of the issues involved in developing it. We use the Architecture Analysis and Design Language (AADL) in order to implement the tool. Some of the applications where such a tool could be useful include: analyzing the effects of signal propagation through the human body [GLP+03]; and studying energy-efficient coding and modulation techniques for biosensor networks [PG03] [69], techniques for minimizing heat dissipation in biosensor networks [TSG] [TTG], energy-efficient wireless communication protocols [SNG+01] [SGA+02], and cyber-physical security solutions of BSNs [VBG08].

2. Preliminaries

Biosensor applications can be of many types. Table 1 shows some of the important applications of BSNs. Even though the individual application requirements vary, all BSN applications have some properties in common. Each of these characteristics has to be considered carefully within our tool. In this section we summarize some of the prominent characteristics of BSNs.

Table 1: Types of monitoring needed for different applications of biosensors [SGW+01].

Type of sensors	**Continuous/Discrete monitoring**
Organ monitoring (Heart, Liver, Kidney)	Continuous
Cancerous Cell monitoring	Continuous
Glucose monitoring	Discrete
General Health monitoring	Discrete

Network Topologies: Unlike individual medical devices, BSNs have a group of devices (sensors) working in tandem performing patient monitoring and actuation. To be energy efficient the sensors typically organize themselves into different topologies. However, this organization of the sensors into different network topologies directly affects the deployment environment. For example, if sensors are located too close to each other, the cumulative heat generated between the sensors during their operation may be difficult to drain away and may result in unsafe temperature rise. But if the sensors are locate too far from each other the longer distance may need higher power wireless communication between sensors, which means higher RF power consumption and higher radiation into the surrounding tissue. The tool should be able to specify and handle a variety of sensors with wide ranging capabilities.

Sensor Hardware: The type of sensor used in building the network is of importance. Smaller sensors can only be equipped with low capacity battery and limited computational capability. Since such sensors cannot cover a large area, they may require a higher density of distribution. Then more scalable and complicated network algorithms have to be designed to support more powerful and efficient data exchange for the large number of sensors. The tool should be able to specify and handle a variety of sensors with wide ranging capabilities.

Bio-safety Considerations: Bio-safety is a critical issue that should be considered at every step of biosensor design and implementation. Strict regulation of bio-safety may require smaller antenna and lower radiation. Also, sensors may not be allowed to recharge continuously in order to avoid sustained heating of sensors and the surrounding tissue medium. The ability to consider these requirements into the analysis of the BSN design, in an automated manner within the tool is extremely important for achieving a practical design.

It should be noted that looking at each of these requirements in isolation is not sufficient. Every aspect of the biosensor application influences the characteristics and performance of other parts of the system. Trade-offs between all the factors and requirements must be thoroughly considered and measured. Coordination and integration among different parts are essential to achieving a successful design.

3. BSN Design Tool Requirements

It is desirable for the tool to be applicable to a wide variety of biosensor applications and hence its analysis capabilities should be a common denominator of the various possible analysis methods. At the heart of such a tool will be a generic workflow control mechanism that is customized by specifying the application-specific plug-in modules and a user-specified array of third party tools. A modular design with well-defined interfaces will allow different researchers to work on different problem domains and implement their work as modules that can be plugged into the tool. As more knowledge becomes available to the community through ongoing research, the tool can be refined by swapping specific modules with newer and better ones. Thus the tool will be flexible. The tool will also be extensible in the sense that new functionality can be added later. This entails an open architecture design from the very beginning. We are using the *Architecture Analysis & Description Language* (AADL) from the Software Engineering Institute (SEI) for implementing the tool. The AADL provides an easy to use language with various constructs allowing system architecture model specifications.

3.1 Functional Requirements

In this section we present some of the principal functional requirements of the BSN design tool. We divide the requirements into two parts –operation specification and usability.

3.1.1 Component Specification

These describe the ability of the tools to specify the various components of the BSN application, how they function and how the results from the operation of the application are analyzed. Some of the requirements in this category are:

Workflow Specification: This will allow BSN developers to describe their application to the tool without having to modify the tool itself. Workflow is specified using AADL, which will be extended as and when required using new constructs which will be incorporated as an annex to the language.

Unified Bio-heat, Communication and Energy Consumption Analysis: BSNs work in a difficult environment. The wireless channel in the human body is prone to high path loss factors due to high water content. Further due to organ, bone and blood vessel boundaries there will be severe multipath fading. Specific propagation models have to be developed for the biosensors. Based on the model used, the range of a transmission can be estimated. Further, if there are multiple transmissions, propagation models that can be used to estimate the level of interference and hence the bit error rate that can be expected in the transmitted data. While analyzing heat, we have to account for multiple sources and sinks. We also have to take note of the fact that heat and communication affect each other. Communication produces heat which in turn affects the communication channel.

Sensor Deployment Specification: This will allow the developers to take sensor properties, placement and energy supply requirements into consideration. As these parameters can significantly affect bio-heat, communication and energy consumption, it is important for them to be explicitly specified by the biosensor application developer. Further, these parameters are hardware implementation dependant and vary from manufacturer to manufacturer.

Regulatory Requirements Management: The tool should have a controller that will maintain data consistency and enforce government mandated rules and regulations. The controller should be flexible enough to allow changes since different countries or states may have varying and conflicting guidelines

3.1.2. Usability

These requirements describe the tool in terms of its utility to the application developers in developing and analyzing the BSN application. Some of the requirements in this category are:

Graphical User Interface: The user interface provided by the tool should hide the complexity of models from users not well versed in the intricacies of specific models. At the same time, the interface should also provide enough flexibility for a researcher to change modules and models easily. New modules should be addable in a plug-n-play fashion and users should be able to control simulation parameters without having to write scripts.

Interfacing the Third Party Analysis Tools: In order for a tool to be useful, its data should be available for further analysis. Instead of developing new data analysis and simulation tools specifically for this application, we should take advantage of the numerous tools that are already available to the research community. To avoid being tied to any particular third party tool, we have to have some data exchange interface in which data from our tool is output in a standard format. We can then write tool specific drivers that will convert the standard data format to a format amenable to the tool. As and when researchers want to add new tools to the simulator environment, drivers can be written specifically for those tools without affecting anything else.

Customizability and Extensibility: Users should be able to use this tool with as many biosensor applications as possible. Since the nature of individual applications cannot be known beforehand, users should be able to easily customize the tool to their specific applications. It should have pluggable and swappable modules for models of body (2-D or 3-D shape, size, density, resolution), radio propagation, heat absorption, energy consumption, sensor properties (obtainable from manufacturer) etc.

4. Tool Architectural Description

Our vision of the tool architecture is shown in Fig. 3. It consists of 5 logical blocks as described below.

Design and Evaluation Tool: At the heart of the *Design and Evaluation Tool (DET)* will be the modules for bioheat, communication and energy analysis. Parameters and instructions to these modules can be fed through the Graphical User Interface (GUI). These modules will perform the required analyses using inputs from the other four modules. A workflow execution engine will perform the biosensor application operations as specified in the application workflow that is fed to the tool via the GUI. The GUI will allow the user to specify application parameters such as sensor type and location, energy constraints etc. It will provide an interactive visual interface to help place sensors in the body and also provide a visualization of the human body model that will be constructed with information obtained from third party databases. Only the important functionality will be executed in the DET. Functionality that are prone to change with the biosensor application and supporting functionality such as checking for regulations compliance are implemented in the other modules. In order to provide flexibility and extensibility, the Tool will have standard interfaces for each of the four surrounding modules as shown in Figure 3.

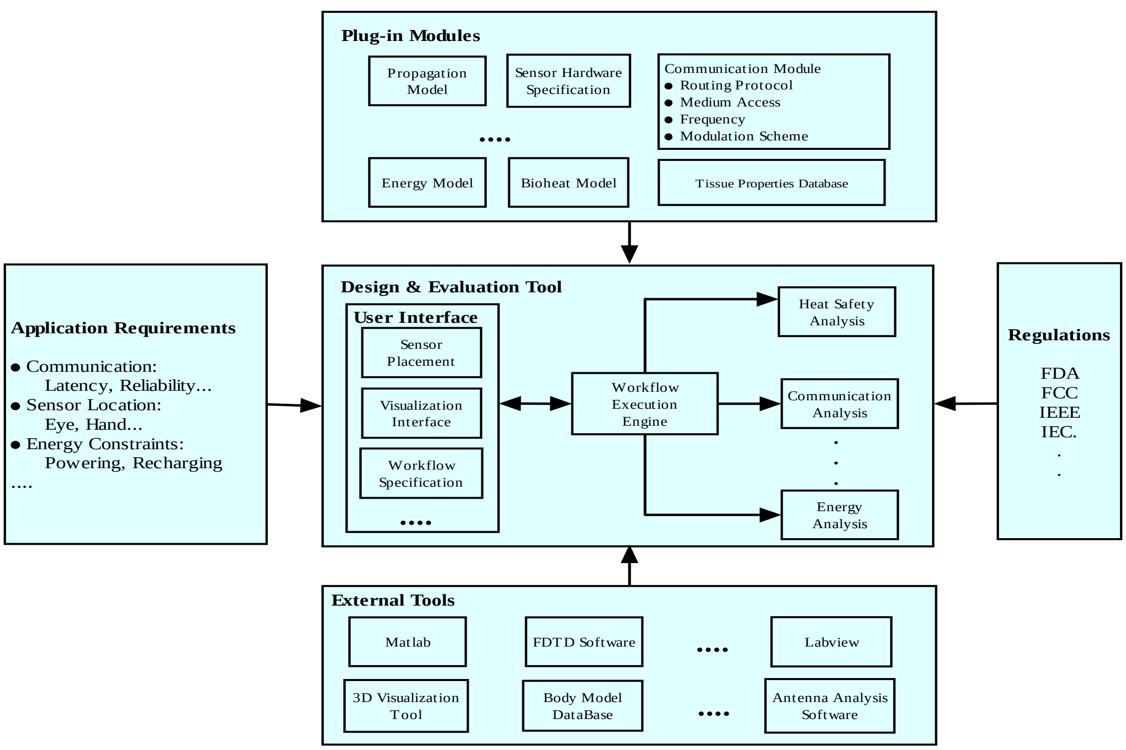

Figure 3: System Architecture.

Plug-in-Modules: Biosensors applications are very complicated may involve many technnologies. We can think of the biosensor system as composed of several subsystems including those for wireless communication, energy supply, and tissues. Each of these subsystems are research problems in their own right and have a continually evolving body of knowledge associated with them. Researchers have developed theoretical and empirical models to mathematically formulate these research problems. Therefore each subsystem in the of the biosensor application will be a model or mathematical approximation of the real world. As research in these areas continue, better and more accurate models will be developed. By implementing these models as plug-in models, we can easily replace old models with new ones. The design and analysis tool should also be flexible enough to allow each subsystem to be implemented in different ways. For example, power supply to sensors can be through RF induction, supersonic powering or an embedded battery. We should be able to change the way power model for an application by simply plugging in the appropriate module. The actual model used will affect the outcome of the analysis but will not affect the architecture of the tool. Some of the plug-in modules that may be implemented are: 1) *Propagation model*: The medium in which EM waves are transmitted can be homogeneous, heterogeneous, or layered. Its impact on attenuation and phase shift of EM waves would be various. We will provide some widely used propagation models but users can customize by adding their own propagation models; 2) *Energy model*: Provides some regular and basic options for various power supply methods such as RF induction, supersonic, and B-field. Parameters such as the capacity of battery and performance of transductor can be adjusted to meet different requirements. Users' own customized power supply models are acceptable as well; and 3) *Tissue properties database*: Has information on tissue properties that can be obtained from publicly avalaible sources [EMF].

External Tools: Commercial and open-source software are available to perform several useful tasks that may be performed in the design and analysis of biosensor applications. To avoid reinventing the wheel and save development time, it may be useful to exploit the capabilities offered by these third party software tools rather than rewrite them. However, these tools may be developed by different parties and may be incompatible. To simplify interaction, it will be necessary to develop a data exchange standard. For any new software tool that has to be supported, a tool driver can be written that will convert between the standard format and the format accepted by the new tool. Useful tools include but are not limited to: 1) Mathematical computing and signal processing tools such as MatLAB and LabVIEW; Electromagnetic simulation tools such as FDTD or FED analysis software; 2) Antenna analysis and propagation simulation tools; 3) Human body modeling and simulations tools. We are considering some publicly available human model, such as Visual Man Project [NLM] or other public tissue model, such as NIH model organization [NIH]. These models will be used by our tool in the form of an input data file or database; and 4) Visualization and graph-plotting software that will help researchers better understand analysis results.

Application Requirement Specifications: This module consists of those parts of the application specifications that change often during the iterative process of design and analysis. It has data structures to store parameters that can be used to tweak an application. The actual parameter definitions and values have to be provided by the application developer and are specific to that application. Some of common application requirements specifications include: 1) Communication*:* Frequency of operation, data latency limits, data loss tolerance; 2) *Sensor Location*: Placement of individual sensors and base station. Depending on the human body model used, location may be specified in terms such as right eye, left elbow, heart or may be specified Cartesian co-ordinates; and 3) *Energy Information*: Power supply (embedded battery, RF inductance), energy consumed by individual sensors for different operations.

Regulation Compliance: This module is used to define the International or governmental regulations that should be followed for implantable biosensor applications. Regulations cover issues such as the permitted operation frequency for implanted medical devices, the Specific Absorption Rate limit and maximum temperature rise allowed for bio-safety. This functionality has been put into a separate module because regulations change with time and different applications may use a different set of regulations. Also, different countries and regions may have different regulations. In our implementation, we plan to support most widely used regulations of biomedical or electrical engineering. These include: 1) *Food and Drug Administration (FDA)* regulations on medical devices; 2) *Federal Communications Commission (FCC)* regulations on using the ISM (Industrial, Scientific and Medical) band and other requirements on frequency and bandwidth management. FCC also has the Medical Implant Communications Service (MICS) standard for communication between medical implants; 3) IEEE defines many standards on issues such as the measurement of SAR, IEEE C95.1 RF human exposure standard, and Standard for Medical Device Communications (IEEE 1073); and 4) *IEC* defines the safety limit of exposure to RF radiation. IP68 (IEC 601.2.2) and IP20 have stringent requirements for medical devices. Other regulating organizations will also be considered including EU and ISO. It is important to take these regulations into account while developing biosensor applications.

5. Example of an Analysis Model: Bioheat Problem

Operation of implanted devices inside human body will cause tissue heating. Heating is caused by both the sensor circuitry as well as absorption of radiation by tissue. Specific Absorption Rate (SAR) is a measure of the rate of radiation energy that is absorbed by dielectric materials, such as biological tissues. Normally it is expressed in watts per kilogram (W/kg) or milliwatts per kilogram (mW/kg). These limits, which are based on the current International Electrotechnical Commission (IEC) 60601-2-33 standard, are 8 W/kg in any gram of tissue in the head or torso for 15 minutes, or 12 W/kg in any gram of tissue in the extremities for 15 minutes [FDA99]. Also ANSI/IEEE C95.1-1992 has a limit on partial body exposure, to 8 or 1.6 W/kg (controlled or uncontrolled exposure) averaged over any gram of the exposed tissue.

Different parts of body have various sensitivities to temperature rise. For example, the eye is expected to be more sensitive to heating because of a lack of blood supply to cool down its temperature once increased. And exposure to RF fields results in increased retinal temperatures, which can lead to eye dryness and ocular discomfort. Some research results show that a long-term exposure to RF could also lead to cataract. Understandably, bio-safety is an essential issue and should be considered when implementing implanted biosensor. Strict calculation and prediction should be done to estimate the SAR (Specific Absorption Rate) and temperature rise inside body tissue.

5.1. Heating Factors

In our previous work, we have studied the temperature rise inside body tissue due to an implanted biosensor [TTG05]. In that case, the internal sensors are powered by RF inductive power. Sensors and an external base station exchange data wirelessly using the 2.4 GHz ISM frequency band. The heat factors we considered were:

Heating caused by RF inductive powering: If the implanted devices are powered by RF inductive power supply, the frequency of RF power supply is normally operated in 2 MHz to 20 MHz range [He88] [MS01].

Radiation from Implanted device communication: Implanted devices need to exchange data between other implanted devices or an external device using wireless communication. The wireless signal also has radiation effect on tissues surrounding the implanted sensors.

Power dissipation by implanted node circuitry: When a sensor node processes the data, there will be power consumed by its circuitry. The sensor circuitry may also need to perform data aggregation and various other functions which consume power. This power is transformed into heat which may add to the already heated tissue. The power consumed by the sensor circuitry depends on its implementation technology and architecture.

Effect of Metallic Implants: Several research findings show that metallic implants may couple with the RF used in magnetic resonance imaging (MRI) and may lead to a heating hazard [YSA02] [Ho]. The presence of the metallic implant results a local amplification of the SAR, and this effect is not seen with the external transmitter alone.

5.2. Calculating Temperature Rising

The above mentioned sources for heating the tissue can cause a rise of temperature inside the control volume. The rate of rise in temperature is calculated by using the Pennes bioheat equation as follows.

$$\rho C_p \frac{dT}{dt} = K\nabla^2 T + \rho SAR - b(T - T_b) + P_{circuitry} + Q_m$$

The left hand term measures the rise in temperature in the control volume, the terms on the right side respectively indicate the heat transfer rate by conduction, heat transfer due to radiation, heat

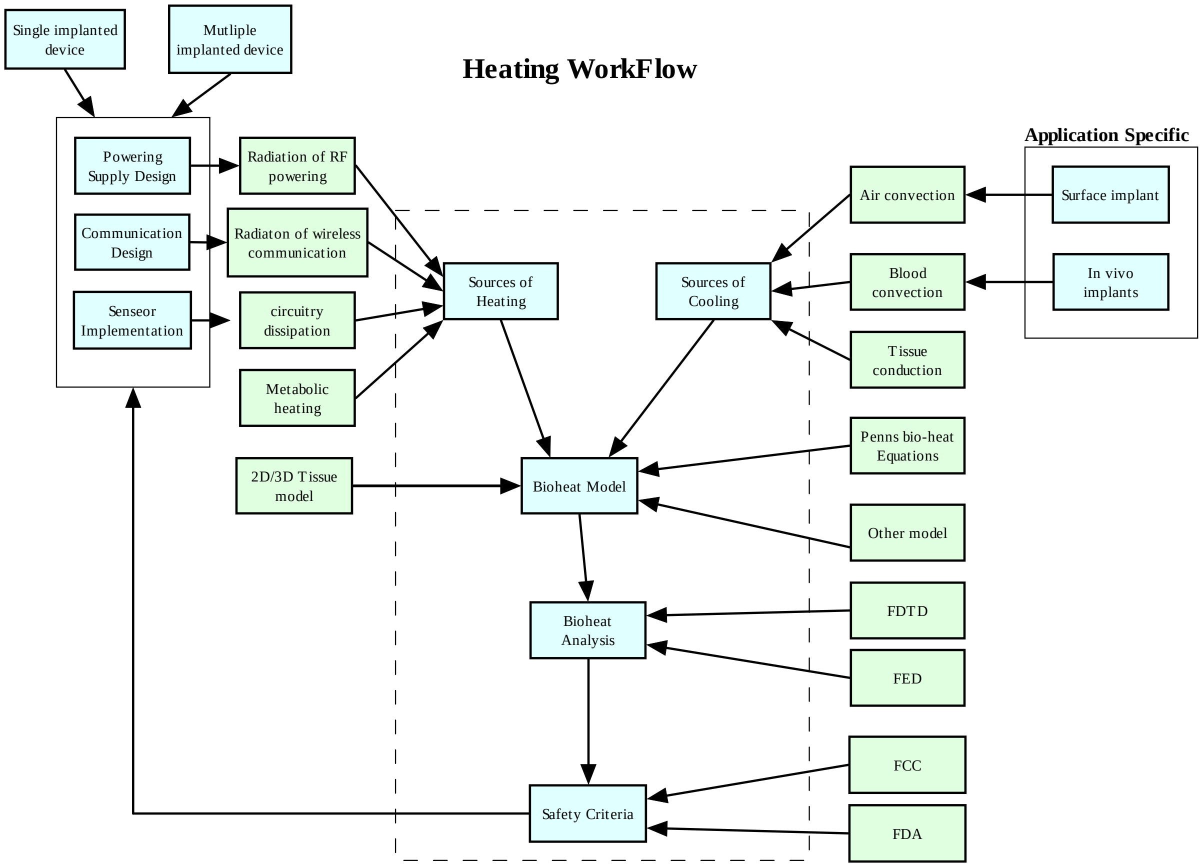

Figure4: Heating Workflow.

transfer due to blood perfusion, power consumed by circuitry and heat generated by metabolic heating .Where is the rate of rise in temperature in the control volume, ρ is the mass density, C_p is the specific heat of the tissue, K is the thermal conductivity of the tissue, b is the blood perfusion constant which indicates how fast the heat can be taken away by blood flow inside the tissue, T_b is the temperature of the blood. Once we know the properties of mediums and blood flow, and the power or heat absorbed by the tissue, we can calculate the temperature change rate within a period of time by $\frac{dT}{dt}$. With this equation we can predict the SAR inside tissue and the resulting temperature rise.

5.3. Workflow of Heating Problem

Actual calculation of the temperature rise is not be straightforward as many factors are dependent on the design and implementation of other parts of the biosensor system as shown in Figure 4. Factors that affect heating include power supply design, communication design and sensor implementation. Researchers may work with Matlab, LabView or other wireless simulation software, propagation software to design those parts. If part of the communication design is changed (ex. different encoding scheme or radio frequency), then its impact on heating would be changed too. Sources of cooling have a similar problem and depend on where to implant the sensors, the properties of tissues etc. Further, researchers may use different models, or use different software tools (Matlab, VC++) and algorithms (FDTD, FEM) to evaluate the SAR and temperature rise. The final result would be compared with different regulations according to the specific application. Final results may lead to redesign of other parts of the system.

All the blocks outside the dash box are factors that depend on other application requirements and system implementations. Any change to any of them would lead to a change in the heating effect. Researchers have to work with several different software packages and repeat the whole heating work flow several times.

With proper interface drivers and software platform, the heating analysis inside the dash box can be automated. Researchers only need to interact with the integrated platform to use the different software. The data generated from different sources will be managed and aggregated together to realize an automatic heating estimation workflow. If any part of the system has changed to a different scheme, researcher only needs to re-execute the automated workflow again without having to deal with individual software packages.

5.4. Communication System Workflow

A researcher may use various software tools for antenna simulation and signal modulation simulation. With different antenna schemes and transmission medium, RF signals have different attenuation and phase shift. Signal strength also depends on the location and distance between sensors or base-station. This interdependence of various components and design decisions are shown in Figure 5. If we consider propagation model, modulation scheme and environment interference together, link budget analysis can be performed. The output can be used in designing communication hardware for the sensor.

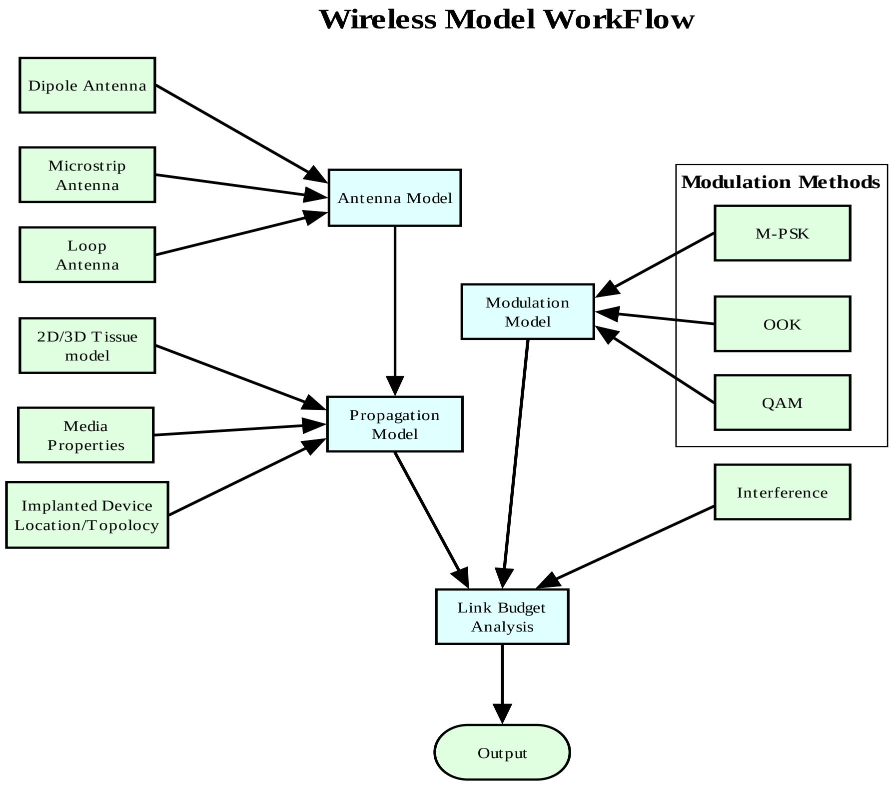

Figure 5: Communication Workflow.

Models inside the dash box will be integrated as an automatic process in our platform. Once a user changes the requirements and implementation antenna model, modulation model, network routing model, the workflow of communication system will automatically run and the result will be input to other related workflow and will trigger those workflow to process again.

5.5 Power Workflow

Power system design is influenced by the application requirements, the implementation of sensors and design of the communication system. The work flow that specifies the inter-relationship among the different requirements and design decisions are shown in Figure 6. The total power consumption is composed of power consumed by sensor circuitry, communication system and the base station. Users may select different implementation options of power system which have different impact on heating the surrounding tissue. At the same time, regulations or application may have some strict requirements on lifetime of battery, size of power supply etc. This workflow can be automated by our proposed platform.

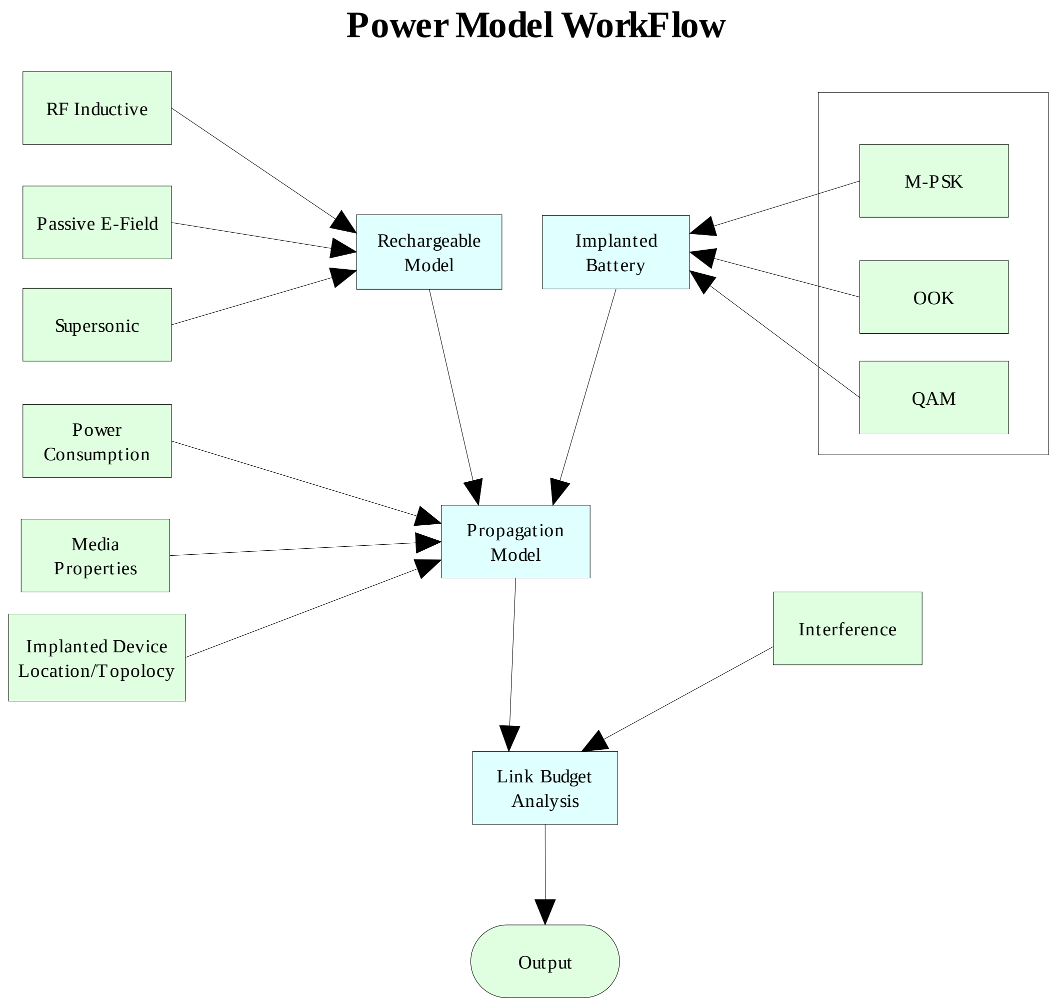

Figure 6: Power Workflow.

5.6. Interaction between different workflow

The relationship between the different models is shown in Figure 7. The whole design process will work on an integrated and automated mode. All the subsystems rely on the detailed application specifications and regulations. These subsystems work together to decide whether reasonable power consumption criteria, stable communication, and bio-heat safety criteria can be met. The change of input of one workflow would automatically generate new results for this workflow and then trigger the re-computation of related workflows.

Finally, users can expect to get simulation and analysis results with a few mouse clicks and the output will show if the result is in accordance with specifications and regulations.

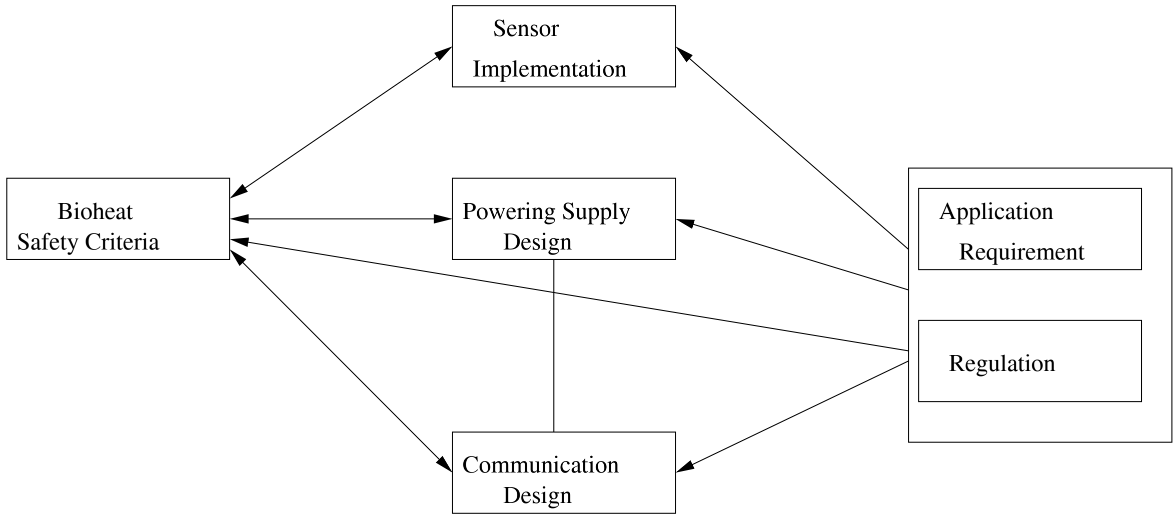

Figure 7: Module Interaction.

6. Development with AADL

A model description language is required to develop the biosensor network application analysis tool. In this regard we use AADL [FGH] which has the following properties:

- High level architectural model of the tool can be specified in AADL using various constructs that it provides.
- The functionality of the AADL model can be extended with the help of appropriate *annex* to the language
- Analysis of the entire system can be performed in AADL by designing appropriate plug-ins.

Given the system architecture of the tool in Figure 3 we endeavor to develop an AADL specification. Figure 8 [CPS] shows the AADL specification for the biosensor network that is designed for analyzing the heat safety of the system.

- To specify the system we first need models of the physical objects and devices, that comprise the system. These are required to be specified in AADL specific constructs. As shown in Figure 8 we specify the model of the human tissue in the physical component named *Tissue* where we can incorporate its thermal characteristics as a set of attributes. The sensors are modeled as the *Node* device wherein we need to specify the computing states of the sensors and the associated energy dissipation.

- In order to incorporate the effect of energy dissipation of the sensors nodes on the tissue we have to specify the bioheat model using AADL language constructs. Specification of models of different physical phenomenon in AADL involve the development of appropriate annexes.

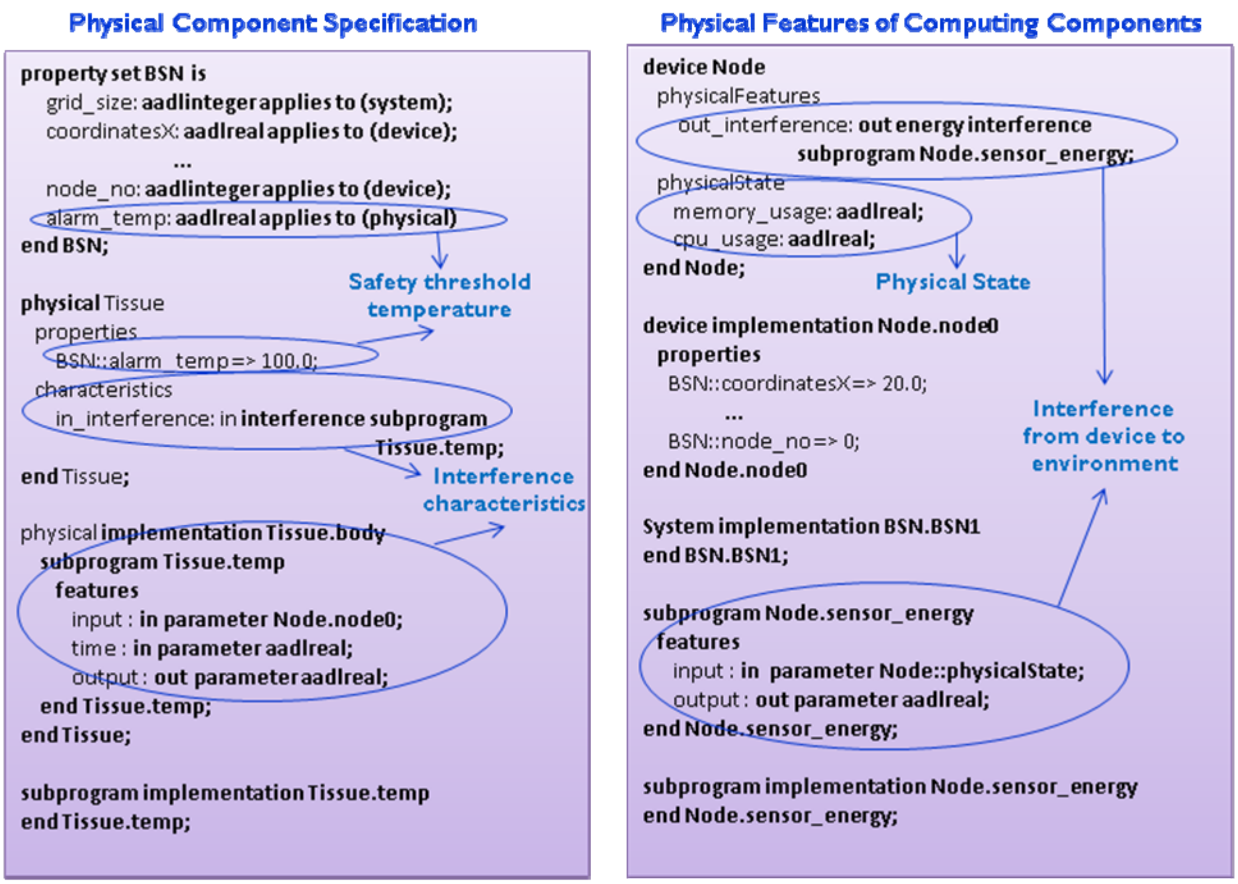

Figure 8: AADL specification for Heat Safety analysis

We specify the bioheat model as a subprogram *Tissue.temp* in the physical component specification of the tool (as shown in Figure 8). In this subprogram we can specify the input variables and the output variables of the bioheat model and also specify a mapping between them.

- The application requirements and regulations of the tool need to be specified in AADL by properly setting values of attributes of different componenets. An application requirement in our tool is to provide a system alarm whenever the temperature of the tissue crosses a threshold. This requirement is specified in the AADL model as an attribute to the *Tissue* component.

- The tool in order to analyze the thermal behavior of the BSN will require inputs from external softwares. The bioheat model would require several parameter values that are not possible to compute in AADL given the present status of its infrastructure. In our tool we need to parse the output provided by Matlab and convert it to AADL recognizable format and provide as input to the bioheat subprogram. Thus ouputs from different software modules need to be properly parsed and provided to the analysis infrastructure of AADL.

- An important aspect of this tool is the analysis of the interaction of the BSN with the physical environment (Tissue). The interaction is very complex and current AADL infrastructure does not provide a method to specify and analyze this cyber-physical property of the BSN. We are currently working towards the development of an annex for AADL that supports the evaluation of the cyber-physical interaction of a system. In the case of the tool for BSN we have incorporated the physical interaction of the BSN with the body tissue by implementing two subprograms in each of the componenets *Tissue* and *Node*. The subprogram *Node.sensor_energy* specifies the amount of energy that is being transferred as heat to the sensor's physical environment (body tissue). *Tissue.temp* subprogram is then utilized to calculate the temperature rise in the tissue due to the energy dissipation in the sensor.
- An intuitive GUI is essential for the tool in order to provide an easy interface to the user. The GUI that currently exists in the AADL framework does not enable the user to fully utilize all the functionalities of AADL. One of our goals in this development of the tool is to develop a GUI through which the user can provide complete information about the system such as placement location of sensors, tisue heating parameters, work flow for analysis of different policies.

7. Conclusions

In this paper we have discussed some important issues in developing a software tool for designing and analyzing BSN applications. In this regard we presented a design of a software tool which can be used by developers and medical personnel to emulate an actual deployment of biosensor applications and evaluate its performance in different scenarios. We use Architecture Analysis and Design Language (AADL) in order to implement our tool as it provides an easy to use interface for specifying complex systems, and their environments. Further, we discussed various aspects of developing such a tool including the principal characteristics of BSNs that need to be considered by it along with the tool's functional architecture.

Acknowledements

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