# Product Design Specifications

**Date:** December 12, 2008

**Clients:** Dr. Ray Vanderby, Dr. Hirohito Kobayashi, and Texas Instruments

**Advisors:** Dr. Tom Yen and Dr. Walter Block

**Function:** Texas Instruments (TI) is interested in finding applications in the medical field for their Digital Signal Processing Chips (DSP's). DSP's specialize in simple mathematical calculations and are able to collect information and process it in real-time (unlike other common micro-processors). The guidelines for this project are that a TI DSP chip be used and that the final product solves a meaningful medical problem. We have chosen to apply the DSP chip in the field of medical imaging, where it would function as a part of a portable ultrasound medical imaging system that would identify and analyze stiffness distribution in tissues on-the-fly. Though significant work can be done on such a project, we have decided on three goals that we would like our device to satisfy:

1. Implement an algorithm that processes stiffness vs. strain in tissues using stored data

2. Optimize this algorithm for near-real time processing

3. Execute this algorithm from a DSP chip

In the future, this device could be used for surgical or clinical diagnostic purposes. However, currently our client just requires a device that can quickly process this data for research purposes.

**Client Requirements:**

- **Device that processes data quickly:** The performance that the client requires from this device is that it must be able to process 434 x 532 pixels in 30 frames of ultrasound video data in less than 5 minutes. As this is a research device, immediate feedback after data gathering is not necessary, but it is helpful. Also, as this device could one day be used in a clinical setting, this standard of 30 frames in less than 5 minutes should be upheld.

A TI C6000 High Performance DSP Chip model ******* will be used. As this chip will take some time to arrive, for this semester, Dr. Yen has made available a TMS320DM6437 DaVinci DSP chip. Though not ideal for the type of processing we wish to do, it should serve as an excellent template to get started from.

- **Interface**

The interface should be relatively easy to use, as any person in the medical field (someone not necessarily well versed in DSP technology) should be able to effectively use it. Currently, the interface is very straightforward as user input is limited to selecting the area of interest, specifying whether it is darker or lighter than the surrounding tissues, and choosing the size of the kernels that the convolution algorithm uses.

- **Compatability**

The device must be compatible with the client's computer as it will be interfacing with it for data storage and display purposes. Also, as this device may one day be used in a clinical setting, it must be compatible with most common computer platforms as it is likely that a computer will still act as this chip's display and storage device.

**Design Requirements:** As this device will primarily be used by the client to process ultrasound data being used in research, the device design has only a few constraints. It must be able to effectively identify tissues and analyze their properties in a matter of minutes, and it must have an effective interface that an expert in this field can easily use. The device must be able to interface with a computer as the ultrasound data will be stored and displayed on the computer. The size of the device should be convenient and weigh less than 10 lb. In the future, it is possible that the device may be used for clinical diagnosis or as a surgical tool, so the detector end should not be damaged by sterilization.

**Physical and Operational Characteristics**

**a. Performance requirements:** The ultimate goal of this device is to process data in a matter of minutes and send the processed data to an output and storage device (most likely a computer). It should be able to consistently identify tissues and analyze their distribution of stiffness change for a given strain rate. The device will initially be used for research purposes, perhaps once a day. The system needs to be portable - including a weight of less than 10 lb, a size smaller than 1 cubic foot, and should run, or have the capability to run, on battery power. Because the device may eventually be used in surgery or clinical diagnosis, the probe must not be damaged by sterilization.

This device must also perform its duties very quickly (on the order of processing 30 frames of 434 x 532 pixels in under 5 minutes). Precautions also need to be taken so that the chip does not run out of memory, as its limited RAM may fill up quickly during the course of the data processing. Another requirement is that it must be compatible with the client's computer (or any common computer platform, for that matter) as a computer will act as the primary data storage and display device. It is likely that the user would also use the computer to pass any necessary user inputs to the chip.

**b. Safety:** Ultrasound imaging has no known negative effects. If the device is used in surgical settings, the probe must be sterilized between uses.

**c. Accuracy and Reliability:** The device must be able to calculate stiffness vs. strain distributions in ultrasound video images accurately. It should be able to provide information about loading and damage of tissues. The techniques for the latter purpose are in the research stage, so final accuracy of the device is difficult to predict at this time.

This device also needs to be able to handle large data sets without running into data storage issues. Another requirement is that the device must be able to interface smoothly with a computer as it is likely that this device will not only be storing and displaying the ultrasound data on a computer, but it will be interfacing with a computer to receive necessary user inputs.

**d. Life in Service:** Due to the nature of its use, the device does not experience much stress. Its lifetime, thus, should be fairly extensive, on the order of several years or more. It will most likely become obsolete before it wears out.

**e. Operating Environment:** The device contains circuitry and plastics. It should not be exposed to very high or low temperatures, high humidity, strong magnetic fields, corrosive materials, physical stresses, or electric shock. If handled with care, the device should fair very well in both clinical and research settings. Care must be taken with it, however, if sterilized for use in a clinical setting, however, to ensure that the sterilization process does not destroy its sensitive electronics.

**f. Materials:** A DSP chip from Texas instruments, the appropriate ultrasound data, a desktop computer, and a device for the DSP Chip to display and store the edited data on.

- Dr. Yen has provided a TMS320DM6437 DaVinci DSP chip for us to work with for this semester. Though this is not ideal for our purpose, this chip should allow us to gain an adequate understanding of how to work with DSP chips.
- We have requested a ****** High Performance DSP chip, which is better suited to our project.
- Sample ultrasound data has been provided by our clients Dr. Kobayashi and Dr. Vanderby.
- The output device that is currently being used is a standard TV. The TV can easily display the device's output, but it can not store any outputted information.
- Dr. Yen provided us with a desktop computer located in the Bioinstrumentation Lab in the Engineering Centers Building.

**Production Characteristics**

**a. Quantity:** Only one is currently needed for our clients. In the future, if the device is useful for research, clinical, or surgical applications, the quantity that will need to be produced is quite large.

**b. Target Product Cost:** The cost of the final device would be cost of the DSP plus accessories such as RAM and a circuit board. Therefore, the target cost will be below $3,000.

**Miscellaneous Requirements**

**A. FDA Approval:**

The device will not need full FDA approval while it is being clinically tested. It will, however, be subject to the Clinical Trials & Investigational Device Exemption, which requires the following (Quoted from FDA, 2003):

- An IDE approved by an institutional review board (IRB). If the study involves a significant risk device, the IDE must also be approved by FDA.
- Informed consent from all patients,
- Labeling for investigational use only,
- Monitoring of the study, and

- Required records and reports.

**B. Customer:** We have two clients, whose expectations are as follows:

- Texas Instruments has agreed to donate "all resources necessary to develop new applications including hardware and software development tools," including a DSP developer's kit, supporting hardware, and consultation with their engineers. In exchange, they expect that their resources will be used to solve "a meaningful medical instrumentation or medical imaging design problem" (BME, 2008)

- Dr. Vanderby and Dr. Kobayahsi are overseeing this ultrasound project. They expect a device that can work in conjunction with a computer to quickly process stored ultrasound data to be developed by the end of the semester. In the future, they expect this device to be able to process 60 frames that are 700 x 700 pixels in size in under 5 minutes and to interface with a computer for data storage and display purposes.

**C. Research and Patient-related Concerns:**

**Sterility** The device will need to be sterilized between uses if used for anything beyond medical research. Due to the sensitivity of the device's electronics to heat, it will probably be sterilized by chemical means.

**Privacy** Clinical testing of the device will involve storage of patent data. This data will need to be stored securely, to protect the privacy of research participants.

**D. Competition** To our knowledge and to the knowledge of our client, no device which measures and displays the stiffness vs. strain distribution in a tissues in real-time exists.