

Design for biomedical engineers

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Abstract: We are developing a text for a capstone design course in biomedical engineering. The course will start with a biomedical need or problem defined at the user level and proceed to an exercise in development of a biomedical engineering device or process for a company or institution. We will solicit and develop a large number of suitable topics so the design course can be run many years without repeating a topic. The text will provide background material on all the aspects of design including project selection, specification development, concept design, analysis, construction, evaluation and documentation. We will class test the manuscript and offer it to others willing to class test it.

Need: We have observed that most graduates of biomedical engineering programs find employment in industry. Many of these are employed in the medical device industry and design new biomedical engineering products to serve health care needs. ABET in their publication "Engineering criteria 2000" states: "Engineering programs must demonstrate that their graduates have an ability to design a system, component, or process to meet desired needs." However most university programs emphasize analysis rather than design. We are developing a text and course as a capstone design course in biomedical engineering.

Philosophy: The text will emphasize needs defined at the user level. It will consider several kinds of users: patients, health care workers, and health care researchers. The problem can be any related to health care or rehabilitation. The problem will be formulated in engineering terms leading to the definition of a candidate product. Thus we will select a biomedical engineering product to meet a need. By so doing, we will put more emphasis on biomedical products intended to satisfy a basic need, as opposed to common consumer products where the need is sometimes generated by the availability of the product. This product will be a biomaterial, biomechanical product, biochemical product or bioelectrical product or process such as those in the appendix 2. We will use a biomedical engineering product as an example in each of the chapters in the text outline to show how the various procedures in the design process will be handled for that biomedical product. For many procedures, the design process will be similar to that for a nonbiomedical engineering product. Other procedures, such as animal trials, FDA approvals, clinical testing and design aspects concerning the interface with living tissues are unique to biomedical products.

Content: By using the design of a biomedical product as an example, the student will be guided through the design process and at the same time become involved in design. Hence, a course based on the text can provide not only a description of design but also the application of design principles. This way, the student learns the science of design and also gets acquainted with the art of design. As much as possible, the text will use examples from previous courses in

biomaterials, biomechanics, biosignals, biosystems, cellular and tissue engineering, transport phenomena, bioinstrumentation, and life sciences. Thus the text will encourage synthesis of this material in this capstone course.

Biomedical engineering curriculum: The course will easily be placed in the senior or graduate year of a biomedical engineering curriculum so it could take advantage of student knowledge learned in previous courses. However it could also be used by those schools who schedule a design experience that lasts more than one year.

Please suggest improvements to the outline, the list of topics in the appendix and the references.

DESIGN FOR BIOMEDICAL ENGINEERS (Outline)

1 DESIGN PROCESS

1.1 Defining design

- Problem solving to meet a need
- Design environment: business, legal, social

1.2 Design process

- Establish the user need
- Design specification and project planning
- Conceptual design
 - Concept generation
 - Concept evaluation
- Detail design
- Production
- Sales

1.3 Product development process

1.4 Designing biomedical products

- Interfaces
 - Living system interface
 - External
 - Internal
 - Operator interface
- Specifications, recommendations, standards, codes and regulations
 - Performance standards
 - Test method standards
 - Codes of practice
 - Medical device regulations
 - International bodies (ISO, IEC, HWO, BIPM, IAE, GATT)
 - Governmental bodies (FDA, FCC, OSHA, NRC)
 - Professional, Trade and Private organizations (AAMI, AMA, ANSI, ASChE, ASM, ASME, ASTM, EIA, IEEE, ISA, UL)

Ethics

- Morals, ethics and religion
- Professional competence and responsibility
- Law and ethics
- Codes of engineering ethics
- Loyalty and whistle blowing

Health care provision schemes

- U.S. Medicare and Medicaid
- National Health Authorities

- Health insurance companies
- Health maintenance organizations (HMOs)
- Nonprofit hospitals
- Home care
- Societal costs
 - Lowering medical costs
 - Environmental awareness
 - Influencing public opinion

2 ACQUIRING AND PRESENTING THE IDEA

2.1 Information sources

People:

- Users (patients)
- Health care people
 - Health care workers
 - Health care researchers
- Design-related
 - Sales personnel
 - Company workers
 - Consultants
 - Inventors
 - Biomedical design educators

Institutions

- User institutions
 - Medical professional societies
 - User groups
- Health care institutions
 - Public Health Authorities
 - Veterans Administration
 - Associations for the handicapped
 - Private nonprofit health care organizations
 - Investor-owned hospitals
- Design-related institutions
 - Industry and trade associations
 - Professional societies
 - Testing and evaluation laboratories
 - Health care assessment agencies

Databases

- Journals (Biological Abstracts, Environmental Periodicals Bibliography, MEDLINE)
- Conference proceedings (Biological Abstracts, Bioethicsline, Chemical Abstracts, Chemical Engineering and Biotechnology Abstracts, COMPENDEX, Ergonomics Abstracts, INSPEC, Lexis/Nexis, Metadex Collection)
- Patents
- Standards (World Standards Service)

Publications

- Books
- Conference proceedings (BES, Biomaterials Society, IEEE EMBS)
- Government publications
- Periodicals
- Reports
- Literature from competitors

- Technical notes from laboratories
- Web
 - Search engines (Altavista, Excite, Yahoo)
 - Web sites
- Conferences and Expositions
 - Visits
 - Exhibitor lists and products
- 2.2 Presenting the idea
 - Keeping engineering notebook Design records, engineering notebooks
 - Records, accountability and liability
 - Preparation, presentation and preservation
 - Communication
 - Elements in the communication process
 - Requirements for effective communication
 - Technical report writing
 - Oral presentations
 - Preparation and rehearsal
 - Delivery
 - Feedback
 - Software for presentations, planning, design, manufacturing and analysis

3 MINIMAL CRITERIA FOR DESIGN

- 3.1 Establishing health care needs
 - Defining the problem statement
 - Biomedical device marketplace for different types of health care providers and users
 - Hospital products
 - Health office products
 - Ambulatory products
 - Laboratory products
 - Home care products
 - Biological research instruments
 - Drug manufacturing processes
 - Sport, fitness and other nonmedical health products
- 3.2 Efficacy
 - Technology assessment
 - Valid scientific evidence
 - Classes of clinical trials
 - Nonrandomized
 - Randomized
 - Efficacy vs. efficiency
- 3.3 Safety
 - Biological
 - Infection
 - Infection-control practices
 - Disinfection
 - Concept
 - Methods
 - Sterilization
 - Concept
 - Methods:
 - Dry heat sterilization
 - Steam sterilization
 - EtO sterilization

Radiation sterilization

Tests

Chemical

Toxic and hazardous substances

Chemical hazards

Hazard communication Standard

Physical hazards

Combustible liquid

Compressed gas

Explosive

Flammable

Organic peroxide

Corrosive

Pyrophoric

Unstable (reactive)

Water-reactive

Health hazards

Carcinogenic

Acutely toxic

Chronically toxic

Reproductive toxin

Irritant

Corrosive

Sensitizer

Hepatotoxin

Nephrotoxin

Neurotoxin

Agents damaging to the lungs, skin, eyes, or mucous membranes

Agents which act on the hematopoietic system

Electrical

Physiological effects of electrical currents

Current perception

Let-go current

Respiratory paralysis, fatigue, pain

Ventricular contraction

Sustained myocardial contraction

Burns, injury

Equipment design for patient protection from electrical hazards

Equipment classification

Risk current limits

Electrical safety provisions in equipment design

Mechanical

Mechanical trauma (injury)

Mechanical hazards

Sharp edges and points

Entanglement

Pinch points, trapping

Impact by machine or material in motion

Ejected parts and materials

Weight and pressure

Fluid pressure

Design for mechanical safety

Safety by design

Mechanical guarding

Other mechanical safety provisions

- Radiation: nonionizing
 - Electromagnetic spectrum (RF, microwave, laser, UV)
 - Thermal effects of electromagnetic radiation
 - Nonthermal effects of electromagnetic radiation
 - Acceptable doses for electromagnetic field exposure
 - Safe use of lasers and other optical radiation sources
- Radiation: ionizing (NRC)
 - Types of ionizing radiation: nuclear, x rays
 - Biological effects of ionizing radiation
 - Dose levels
 - Protection against ionizing radiation
- Software safety
 - Causes of software errors
 - Safeguards in software design
- Thermal
 - Burns and skin damage
 - Temperature vs. time curves
- Ultrasound
 - Interactions between ultrasound and living tissues
 - Biological effects of ultrasound
 - Acceptable ultrasound power levels
- The hazard-assessment matrix (MIL-STD 8828)
- 3.4 Biocompatibility
 - Host reaction to biomaterials
 - Inflammation
 - Cellular response to repair
 - Blood-material interactions
 - Thrombosis and hemostasis
 - Thrombolysis
 - Protein adsorption
 - Nonthrombogenic surfaces
 - Biomedical materials
 - Polymers
 - Elastomers
 - Plastics
 - Metals and alloys
 - Ceramics, glasses and glass-ceramics
 - Composites
 - Hydrogels
 - Natural materials
 - Grafts and coatings
 - Fabrics
 - Deterioration of biomedical materials
 - Metallic implants corrosion
 - Polymer deterioration
 - Biomaterial calcification
 - Implants
 - Implant sterilization
 - Implant encapsulation
- 3.5 Ecological impact
 - Emissions and waste discharge
 - During manufacturing
 - Discharged to the atmosphere

- Discharged to the earth
 - During operation
 - Discharged to the atmosphere
 - Discharged to the earth
 - Toxic releases (EPA) (OSHA)
 - Resource consumption
 - During manufacturing
 - During operation
- 3.6 Maintainability and cost of operation
 - Product lifetime
 - Product insurance
 - Maintenance
 - Design elements to call for maintenance
 - Instruments required
 - Accessibility for preventive and corrective maintenance
 - Preventive maintenance schedule
 - Repair strategies
 - Discard and replace
 - Return for repair
 - Call in a maintainer
 - Module replacement: return, repair and inventory
 - Repair in place
 - Multiechelon maintenance
 - Disposable materials needed
 - Disposal costs
 - Reusable parts
- 3.7 Ethics in biomedical engineering
 - Conflicts of interest in Biomedical Engineering
 - Creating misleading expectations
 - Patient rights
 - Informed consent
 - Human life value
 - Quality of life
 - Allocation of scarce medical resources
 - Abuse of animals
 - Human experimentation
 - Devices and procedures creating ethical concerns
- 3.8 Biomedical product liability
 - Legal bases for liability: The Product Liability Act
 - Liability from design work
 - Factors relevant to defendant's liability
- 3.9 Societal costs of biomedical technology
 - Biomedical technology costs and health care expenditure
 - Biomedical technology potential and promises, and patient expectations.

4 PRODUCT CHECKLIST FOR THE TEAM

- The Quality Function Deployment (QFD) technique
 - Identify the customer
 - Determine customer requirements (in customer's terms)
 - Determine relative importance of requirements
 - Competition benchmarking
 - Translate customer requirements into measurable engineering requirements
 - Set engineering targets for the design

4.2 Health care needs

- Functional performance requirements
- Physical requirements
- Time requirements
- Regulatory and standards requirements
 - Product classification
 - FDA
 - International standards
- Cost requirements

4.3 Market research and analysis

- Market publications
- Questionnaires
- Interviews

4.4 Competing products

- Benchmarking

4.5 Sales analysis, reimbursement

- Product life cycle
- Capital expenditure
- Manufacturing costs
 - Material
 - Labor
 - Factory
 - General
 - Sale expenses

4.6 Company resources

4.7 Patents and trademarks

- The patent system
- Intellectual property treaty arrangements of the General Agreement on Tariffs and Trade (GATT) negotiations
- Patent classification
- Patent search
- Patent infringement
- Patent application
 - In the U.S.
 - In the E.U.
 - In Japan
 - In other countries
- Trademark registering

4.8 Manufacturing capability

- Facilities and procedures available
- Outsourcing

4.9 Service

5 WRITING THE DESIGN SPECIFICATION

5.1 Explain the biomedical device or process

- Function
- Performance specification
- Benefits

5.2 Marketing rationale

- Market research results
- Intended users
- Product distribution
- Service

- Product retirement
 - Approval procedure required
- 5.3 System description
 - Functional blocks and subsystems
 - Accessories
 - Compatible devices
 - Consumable materials
- 5.4 Design details
 - Technical fields involved
 - Expertise required
- 5.5 Schedule
 - Define tasks
 - State the objective for each task
 - Estimate human and time resources for each task
 - Develop a planning chart (Tasks vs. Time)
 - Critical Path Method (CPM)
 - Program Evaluation and Review Technique (PERT)
 - Timelines or Gantt charts
- 5.6 Cost estimates, budgeting
 - Design labor
 - Prototype materials
 - Testing
 - Reports

6 CONCEPT DESIGN

- 6.1 Medical product design team, team building
 - Group characteristics: roles, norms, cohesiveness
 - Design group roles
 - Biomedical product design engineer: links need, to design concept, to device or process
 - Biomedical product manager: links product to customer
 - Biomedical manufacturing engineer: links design concept to product
 - Group development
 - Forming
 - Storming
 - Norming
 - Performing
 - Decision making methods
 - Top down
 - Majority rule
 - Minority rule
 - Expert member
 - Unanimous consent
 - Consensus
 - Reaching consensus
- 6.2 Develop engineering requirements
 - Functional requirements
 - Compatibility requirements with existing products
 - Manufacturing requirements
 - Cost requirements
- 6.3 Generate concepts, consider and discuss all possibilities
 - Functional decomposition
 - Processes on energy, material and information

Work, power and heat

Energy

Categories

Internal
Kinetic
Potential

Types

Chemical
Electrical
Magnetic
Mechanical
Optical
Thermal

Processes

Storage
Transference (Power transmission)
Conversion

Material processes

Flow

Through (material conserving)
Diverging flow (separation)
Converging flow (assembling, mixing)

Storage

Connecting matter and energy (moving parts, state changes)

Information

Sensing
Processing
Storage
Communication

Generate concepts from functions and combine them into a complete design

Methods for generating ideas

Conventional methods

Literature search
Analysis of natural systems
Inversion (analysis of existing solutions)
Analogy
Measurements and model tests

Methods with an intuitive bias

Brainstorming
Controlled convergence
Method 635
Delphi method
Synectics
Combination

Methods with a discursive bias

Systematic study of physical processes
Systematic search using classification schemes
The use of design catalogs
Attribute listing
Checklists

6.4 Conceptual design evaluation

Feasibility judgment

Technology readiness assessment

Go/no-go screening

- Decision matrix (Pugh's method)
- Controlled convergence technique
- 6.5 Generate design records: The importance of design records
- 6.6 Summary of design records
 - Design notebook
 - Progress reports
 - Final design report
- 6.7 Iteration and convergence to final design

7 DESIGN EVALUATION

- 7.1 Biomedical device or process design trade-offs (cost-quality-time)
- 7.2 Evaluate energy, materials and information processes
 - Hardware-software partitioning
 - Power supply (including batteries) and protection
 - Thermal management of medical equipment
 - Connectors and interconnection devices
 - Wiring and cabling for hospital equipment
 - Enclosures, spilled liquid entry
- 7.3 Ergonomics
 - User interface:
 - control and display design
 - software design
 - component installation
 - Alarms
 - Human factors and the new GMP rule
- 7.4 Design for compatibility
 - Functional (system) compatibility
 - Electromagnetic compatibility
 - Compliance with medical equipment standards
- 7.5 Design for manufacturability
 - Manufacturing processes
 - Material processing
 - Material handling
 - Assembly methods
 - Subcontracting
- 7.6 Design for testability
 - Inspection methods
 - Test equipment needed
- 7.7 Design for reliability
 - Causes of deterioration
 - Failure modes
 - Reliability analysis and prediction
 - Mean time before failure (MTBF)
 - Failure models
 - System modeling
 - Reliability evaluation
 - Reliable system design
 - Redundancy
 - Design simplification
 - Design for corrective maintenance
- 7.8 Optimal design

8 DETAILED TECHNICAL DESIGN

- 8.1 Dividing up the work
- 8.2 Computer aids for design
- 8.3 Performing biomedical device or process design
 - Design management
 - Electrical/Electronic design
 - Mechanical design
 - Fluid system design
 - Electromechanical design, motion control
 - Material selection
 - Thermal design
 - Software design
 - Industrial design
- 8.4 Breadboard
- 8.5 Biomedical product design review
 - Performance
 - Safety
 - System compatibility
 - System requirements
 - Human factors
 - Environmental compatibility

9 DEVICE OR PROCESS DEVELOPMENT

- 9.1 Prototype
- 9.2 Biomedical product performance evaluation
 - Functional performance evaluation
 - Safety evaluation
- 9.3 Evaluate product by health care workers
- 9.4 Testing
 - Environmental testing
 - Accelerated life testing
 - Safety testing
 - EMC testing
- 9.5 Animal trials
 - Animal Welfare Act
 - Biostatistics
 - Design of experiments
- 9.6 Clinical trials
 - Design of the clinical trial
 - The protocol
 - Clinical trial conduct
 - Clinical trial analysis
- 9.7 FDA approval
 - Product development protocol
 - Premarket approval application (PMA)
 - Investigational device exemption (IDE)
 - Device modifications
- 9.8 Final design review
 - Developing a design review checklist
 - Failure mode effects analysis
 - Reliability assessment

10 PILOT PRODUCTION

- 10.1 Concurrent engineering
 - Time to market
 - Concurrent engineering of static products
 - Concurrent engineering of dynamic products
- 10.2 Documentation release
 - Design history file (DHF)
 - Production documentation
 - Test documentation
 - Specifications
 - Procedures
 - User manuals
 - Operation manual
 - Maintenance manual
 - Troubleshooting manual
 - Device master record (DMR)
- 10.3 Production interface
 - Selection and evaluation of components and suppliers
 - Specifications for manufacturing processes
 - Develop packaging
- 10.4 Engineering change orders

11 VOLUME PRODUCTION

- 11.1 Quality assurance systems
 - Quality control
 - Good manufacturing practices
 - Product design assurance
 - ISO 9000 series of international QA standards
 - Total quality assurance
- 11.2 FDA good manufacturing procedures
 - The Medical Device Quality Systems Manual, 1st ed.
- 11.3 Engineering change orders
- 11.4 Service and maintenance
- 11.5 Field failure analysis statistics
 - Medical Device Reporting (MDR) regulation
- 11.5 FDA product recalls

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Appendix 1: Desirable criteria for topic selection

The criteria for student projects are:

- 1 Requires use of biomedical engineering prerequisites
- 2 Requires storage space < 1 cubic meter
- 3 Can be built by students
- 4 Requires use of other resources (faculty, library, computers, software)
- 5 Has > 2 possible solutions
- 6 Breaks into small subprojects
- 7 Current designs can be observed and understood
- 8 Health care needs can be assessed
- 9 Competitor designs exist to be evaluated by benchmarking
- 10 Design criteria can be generated from health care needs
- 11 Multiple design priorities exist and can be assessed
- 12 Proposed solutions can be evaluated by health care workers
- 13 Interesting to students

Appendix 2: Possible topics for design

Grouped according to the main engineering discipline involved and ordered from simple to difficult inside each group

CHEMICAL

Prevent cross infection from physician's stethoscope
 Alcohol test to start car
 Lidocaine drug level monitor
 Drug uptake tester
 Blood volume during dialysis
 Labor/delivery ion monitor
 Enzyme kinetics tester
 Glucose sensor
 Saliva estrogen sensor
 Food borne salmonella tester
 Platelet activation sensor
 Cardiac enzymes after MI
 Fetal lung maturity test
 Third world hepatitis test
 Filter for neutralization of heparin following surgery
 p53 cancer screener
 Drug delivery through the skin
 Antibiotic release from a subcutaneous implant.
 Implantable drug pump
 Removal of blood components,
 Electroporation for gene transfer
 Kidney dialysis system
 Plasmapheresis to remove hormone or antibody
 Anesthesia system
 Oxygenation during surgical procedures
 Artificial lung

ELECTRICAL

For blind, wire a mouse for sound. Higher pitch near the top of screen, lower near bottom
 Wet diaper alarm
 Hand held device for scanning bar codes or items at home or store for people who are blind
 Pill counter for the elderly
 Voice activated remote control for a VCR or stereo
 Computer keyboard for a one-handed individual
 Keyboard for children with cerebral palsy
 Braille to video converter
 Communication board
 Talking thermometer for the visually impaired
 Blood coagulation timer
 Cost-effective, reliable Braille display
 Electrical safety tester
 Defibrillator analyzer
 Cardiac pacemaker tester
 Electrical safety analyzer
 Telephone for the deaf
 Object detector for blind
 Eye movement interface
 Ambulatory temperature monitor
 Ambulatory heart rate monitor
 Incubator
 Defibrillator
 Cell counter
 Ambulatory blood pressure measurement

Ambulatory impedance plethysmograph
 Neonatal endotracheal tube position detector
 ICU continuous blood pressure monitor
 Full-page dynamic tactile display
 Sensorimotor tester
 Alcoholism tester
 Alzheimer's disease test
 Way for people who are blind to perceive graphic information
 Universally accessible touchscreen ATM
 Intravenous flow monitor

MATERIALS

Tissue growth cell
 Tissue strength tester
 Determine material characteristics of different biomaterials (e.g. modulus, Poisson's coeff.)
 Protein adhesion tester
 Design (and perform) in vitro biocompatibility assays with standard biomaterials (extract testing, cell culture tests).
 Cancer cell adhesion for metastatic potential
 Extracellular matrix for bone regeneration
 Liver regeneration scaffold
 Design a 3-D scaffold system for use in culturing aggregates of hepatocytes
 Infection resistant catheter
 Angioplasty catheter
 Treat vein grafts to improve blood flow
 Device and solution for storage and transport of a donor heart while recipient is being prepared
 Biomaterial for implantation
 Heart valve
 Hip-joint replacement
 Knee replacement
 Transdermal prosthesis attached to bone
 Bioactive bone plate and screws
 Artificial blood vessel

MECHANICAL

Wheelchair storage compartments not behind (strength too low to reach behind) not as saddle bags (won't fit through doorways)
 Neck restraint for auto collision
 Ring binder opener/closer for persons with little or no finger manipulation
 Jar opener for disabled/handicapped
 Wheelchair umbrella
 Muscle exerciser
 Joint stability measurement
 Page turner for a handicapped individual who has partial arm mobility but no finger mobility
 Force detector for fingers of myoelectric arm
 Door opener for a private home
 Balloon pump
 Positive airway pressure for sleep apnea
 Grabber to access books from a shelf out of reach for a person in a wheelchair with grip strength too low to use a regular grabber
 Joystick-controlled spoon for feeding a handicapped individual

Opener for child-proof containers for persons with limited strength and dexterity
Arm-movement actuated, head-mounted gripper for a handicapped individual to pick up objects
Car door for disabled
Head rest for back surgery
Patient manipulators for imaging (x ray, CT, MRI) and surgery position
Hand-powered cycle so a handicapped individual can travel faster than in a wheelchair
Wheelchair seat lift
Powered wheelchair
Wheelchair that is useable in woodland
Chest vibrator for mucus transport
Burned skin stretcher
Vascular graft tool for surgery
Ventilator
Artificial arm