

BME 5920
Special Topics Biomedical Engineering: Cardiovascular Devices
Spring 2016
Thurs 2:30-3:20
Bruininks Hall, Room 432A

Prerequisites: BME 3011, 3111, 3211, or equivalents with department consent

Other Suggested Prerequisites: None

Brief Description: In this seminar, weekly guest speakers from local medical device industry will present students with an overview of current and emerging technologies in the field of devices for the treatment of cardiovascular diseases, while providing industry perspective on the process, considerations and challenges of bringing these technologies to market. Speakers will deliver an overview of clinical need and market analysis, generic design, relevant engineering principles, typical testing and validation methods as well as comment on the limitations of the devices and possibly future directions. As a whole, the series of lectures will provide a picture of the current landscape of cardiovascular devices, the companies in the industry, as well as the engineering roles involved in medical device development. At the end of each session, time will be provided for students to ask questions.

Instructor: Prof. Bruce H. KenKnight, PhD E-mail: kenknight.bruce@gmail.com

Grading Assistant: Jared Hierman E-mail: hierm001.edu

Course Format: 1 lecture per week

Course Credit: 1 Credit

ABET Students Outcomes: You should develop (g) an ability to communicate effectively (from writing your report) and (j) a knowledge of contemporary issues (from our speakers).

Important Dates:

Apr 7: Prospectus Draft Submission Due Date

Apr 28: Report Submission Due Date

Course Grading (A through F):

- Participation (30%)
- Report on design and testing of a cardiovascular device (70%)

• Attendance Policy: 100% attendance is required for a passing grade, as documented by sign-in each week, except for excused absence due to documented medical reasons, personal emergency, or extraordinary circumstances approved by the instructor. Unexcused absences include not signing-in even if you were present. As a courtesy to our invited speakers, you must be seated by 2:30 and stay with rapt attention until the instructor adjourns the class - students who arrive after 2:30, or leave the classroom before the end of the end of class without pre-approval by the instructor, or do something besides listen to the speaker (texting, doing homework, reading the Daily, etc.) may have their attendance credit cancelled. An **I** (Incomplete) is assigned if 100% attendance (including make-ups) is not attained by the end of classes; when make-ups for all remaining unexcused absences are completed, the **I** will be converted to the report

grade. Note that by University policy, an **I** converts to an **F** automatically one year of the last day of final examinations of the term in which the **I** was given.

- Attendance Records: Our records are posted on UMN Moodle 2.0 – consult the Instructor about any discrepancies. You can access the Moodle site from <http://www.myu.umn.edu> under the My Courses tab.
- Class Make-up Procedure: Unexcused absences can be made up by attending a BMEN 8602 Graduate Seminar (held 3:30-4:30 Mondays and some Wednesdays in 2-101 NHH – check the schedule at <http://bme.umn.edu/news/seminar.html>), writing 1 page describing what you thought was the most interesting technical aspect of the presentation, and why (don't write a summary!), and emailing it to the Instructor by the class meeting of 5920 that follows the date of the seminar or it will not be accepted (note: you do not need to attend the first 8602 seminar that takes place after the missed class!).
- Extra Credit Policy: To encourage your participation, the Instructor will have the prerogative to select one or more particularly insightful questions related to design considerations or testing for their device as “extra credit” – those students will have their report grade increased by one increment (e.g. B+ to A-); a student can earn more than one increment during the semester. Submit your question by email (kenknight.bruce@gmail.com) within 24 hours following the class session.
- Class will be adjourned when the speaker has been thanked – please remain seated until class has been formally adjourned by TA or Course Coordinator.
- Grade Basis: Passing grades will be decided entirely upon a report. The report must be on a specific, high impact biomedical device different from what you reported on in BMEN 1601 or 1602, if you have already taken these courses.
- Report Format/Requirements:

- Exactly **4-5** pages (11 pt Times font, 1.5 line spacing, 1” margins, not including references and figures; note you may simply reference figures in the key reference attached to your report)
- About 2 pages should be used to describe the device, and 2 pages to explain what you consider to be the key technical design consideration – make sure you explicitly describe this point.
- The report should demonstrate understanding of the device, it's technical aspects and clinical evidence supporting safety and efficacy. Please use your best writing skills; poor writing style, including misspelling, will adversely affect the grade; use resources like <http://composition.cla.umn.edu/> as necessary.
- Cite at least 4 references, 3 of which are journal publications, 1 of which (the key reference), must be attached to your prospectus. Note: not all references are “high quality references.” Be mindful of the significance of various journals by investigating their *Impact Factor*.
- You must highlight the text in your key reference, when you reference it in your report, so it will be obvious why it is your key reference (i.e. highlighting will show us where and why you made reference to it).
- The approved prospectus (see below) must be bound to your report if you pick it up after its review and approval, using a binder clip to secure it to your report.

- Key Reference:

It must be a technical, not a “clinical study”, original research article published in a peer-reviewed journal. A technical research article reports a study performed in a controlled setting, usually in an animal model or some sort of laboratory setting, generally *not* in human patients. Clinical studies take a device or therapy that as already been developed and reports its safety and efficacy in human patients.

It should be obvious when an article presents original research results. Note that if your reference is classified as a "Review" article, then it is definitely not an original research report.

- Plagiarism: You should make explicit use of your references in the text, wherever appropriate, so there is no chance that your report would be cited for plagiarism, which will result in an F for the course. For example: “Providing directional information to regenerating axons should be a powerful strategy for improving peripheral nerve regeneration (Dubey et al, 1999).” See <http://writing.umn.edu/tww/plagiarism/> and / or <http://ori.dhhs.gov/education/products/plagiarism/> if you

have any questions about what constitutes plagiarism and how to ensure you avoid it. While sparing use of *verbatim* text (i.e. cut and paste) if quotations are used and with citation is acceptable, excessive use (more than 5% of your text) will reduce the grade assigned (even though appropriately referenced) -- you should synthesize your sources into your own original exposition (which will also generally require frequent citations!). Minor editing of cut and pasted text from multiple sources that is strung together might be determined as plagiarism and at best will result in a lower grade for not should synthesizing your sources into your own original exposition. Plagiarism will result in an F for the report grade and F for the course grade, and reporting to the Office of Student Conduct and Academic Integrity. Obviously, your report must contain at least one reference to your key reference that makes it crystal clear why you chose it as the key reference.

- **Report Topic Advice:** Select a cardiovascular device that was not presented by a speaker during the course lectures. Ideas for topics may be generated from perusing www.bmes.org, grants.nih.gov/grants/becon/becon.htm, medical device company websites, and/or journals (e.g. Journal of Medical Devices, Medical Devices & Surgical Technology Week) via the MEDLINE (OVID) database accessible via <http://www.lib.umn.edu/> or a similar search engine. Downloadable PDFs of many recent journal publications (as well as on-line access to many journals) can be had via http://tc.liblink.umn.edu/sfx_local/azlist/default. You may use any resource (e.g. Google Scholar: <http://scholar.google.com/>) to identify journal references.
- **Prospectus Definition and Due Date:** A 100 word prospectus of the report (from <http://www.merriam-webster.com/dictionary/prospectus>: prospectus is “something, such as a statement or situation, that forecasts the course or nature of something”; in our case, how it will meet the report requirements regarding impact and technical aspects as supported by the key reference) along with the at least 4 references listed, a copy of the key journal paper, and a printout from the journal website showing it is a peer-reviewed journal, bound together with a binder clip, is due in class on April 7. (These will be reviewed for suitability with students being promptly notified of any problems via email (please include your email in prospectus) if submitted before the deadline or via the Moodle site for those submitting on the deadline.)
- **Report Submission and Due Date:**
 - The report is due at the start of class on Apr 28th, including your complete prospectus if you picked it up following its review/approval. Late reports will not be accepted without a documented medical reason, personal emergency or extraordinary circumstance approved by the instructor.
 - Electronic submission on the due date will also be required. Details will be sent via email just prior to the due date. Late e-submissions will not be accepted.

Schedule (subject to change)

Date	Name	Topic	Suggested Reading
21-Jan	Quan Ni	Neuromodulation for obstructive sleep apnea	Ramirez, J.-M. <i>et al.</i> Central and Peripheral factors contributing to Obstructive Sleep Apneas. <i>Respiratory physiology & neurobiology</i> 189 , 344–353 (2013).
28-Jan	Curt Deno	Mapping of cardiac arrhythmias	Willems, S. <i>et al.</i> Mapping and ablation of ventricular fibrillation—how and for whom? <i>Journal of Interventional Cardiac Electrophysiology</i> 40 , 229–235 (2014).
4-Feb	Mark Wisniewski	Left atrial appendage occlusion device	Alli, O. & Holmes, D. Left atrial appendage occlusion. <i>Heart</i> 101 , 834–841 (2015).
11-Feb	Eric Lovett	Baroreceptor activation therapy	Shen, M. J. & Zipes, D. P. Interventional and Device-Based Autonomic Modulation in Heart Failure. <i>Heart Failure Clinics</i> 11 , 337–348 (2015).

18-Feb	Jim Georgakopoulos	LV assist via Counterpulsation	Capoccia, M., Bowles, C. T., Pepper, J. R., Banner, N. R. & Simon, A. R. Evidence of clinical efficacy of counterpulsation therapy methods. <i>Heart Failure Reviews</i> 20 , 323–335 (2014).
25-Feb	Eddy Warman	Atrial therapies in pacemakers and ICDs	Yap, Y. G. & Camm, J. in <i>Essentials of Atrial Fibrillation</i> (eds. Yap, G. Y. & Camm, J. A.) 21–36 (Springer Healthcare Ltd., 2014).
3-Mar	Paul Krause	Implantable cardiac monitors	Fung, E. <i>et al.</i> Electrocardiographic patch devices and contemporary wireless cardiac monitoring. <i>Frontiers in Physiology</i> 6 , 149 (2015).
10-Mar	Aparna Bhave	Cardiac stent design	Sigwart, U. Living history of medicine: vascular scaffolding, from dream to reality. <i>European Heart Journal</i> (2016). doi:10.1093/eurheartj/ehv656
24-Mar	Paul Robinson	Transcatheter cardiac valves	Zeeshan, A., Tuzcu, E. M., Krishnaswamy, A., Kapadia, S. & Mick, S. Transcatheter aortic valve replacement: History and current indications. <i>Cleveland Clinic journal of medicine</i> 82 , S6–S10 (2015).
31-Mar	Mark Brown	ICD sensing	TBA
7-Apr	Dawn Bardot	Computational models	TBA
14-Apr	Bruce Jones	Rate responsive pacing (flex dates)	TBA
21-Apr	Cassie Morris	Renal denervation	Iliescu, R., Lohmeier, T. E., Tudorancea, I., Laffin, L. & Bakris, G. L. Renal denervation for the treatment of resistant hypertension: review and clinical perspective. <i>American Journal of Physiology - Renal Physiology</i> 309 , F583–F594 (2015).
28-Apr	Stephen Hahn	S-ICD	De Maria, E., Olaru, A. & Cappelli, S. The entirely subcutaneous defibrillator (S-Icd): state of the art and selection of the ideal candidate. <i>Current cardiology reviews</i> 11 , 180–186 (2015).
5-May	Jeffrey Vogel	Self-expanding vascular stent	TBA