

## COURSE SYLLABUS

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### 1 ECE 5900 - TOP:Medical Device Technology Lecture/Lab

#### 2 Meeting Information

3 credits, 3 contact hours 2.5-hour Lecture/Lab Session

a. **Section 001:**

Lecture: Thursdays from 08:30 am to 11:00 am in Tolentine Hall 409., **Tolentine Hall 309**

Lab: Thursdays from 08:30 am to 11:00 am in Tolentine Hall 409., **Tolentine Hall 309**

#### 3 Course Instructor(s), TA(s)

a. **Section 001:**

Class Instructor: [Edward A. Berde](#)

Office Hours: Thursday from 11:00 am to 3:00 pm, or by appt.

Lab Instructor: [Edward A. Berde](#)

Office Hours: Thursday from 11:00 am to 3:00 pm, or by appt.

TA: None

#### 4 Textbook

This course does not have a prescribed textbook

- a. **Other Supplemental Materials:** <https://www.fda.gov/medical-devices/premarket-notification-510k-510k-submission-process>; <https://www.fda.gov/medical-devices/premarket-notification-510k/content-510k>; <https://www.amazon.com/Play-Bigger-Dreamers-Innovators-Dominate/dp/0062407619>; <https://www.amazon.com/Hard-Thing-About-Things-Building/dp/0062273205>; [https://www.espressif.com/sites/default/files/documentation/esp32\\_datasheet\\_en.pdf](https://www.espressif.com/sites/default/files/documentation/esp32_datasheet_en.pdf); [https://www.espressif.com/sites/default/files/documentation/esp32\\_technical\\_reference\\_manual\\_en.pdf](https://www.espressif.com/sites/default/files/documentation/esp32_technical_reference_manual_en.pdf)

- b. **References:**

#### 5 Specific Course Information

a. **Catalog Description**

Addresses a special topic in electrical and/or computer engineering of interest to faculty and students.

- b. **Prerequisites:** None; **Co-requisites:** None

- c. N/A

#### 6 Learning Objectives

- a. Upon successful completion of this lecture/lab course, students will: (a) be proficient in the design of medical devices with an understanding of considerations unique to the health-tech

industry. (b) understand and be able to implement basic and advanced microcontroller concepts, including Bluetooth, Wi-Fi, multi-threading, interrupts, and deep-sleep states. (c) be familiar with various protocols used to interface with microcontrollers, including UARTs, SPIs, I2Cs, I2Ss, and low-level bit banging. (d) be able to interface external components to microcontroller-based health-tech devices, including SD and eMMC-based memory, Pulse-Oximeter sensors, accelerometers, and RFID receivers. (e) be able to design, build, test, and deploy a microcontroller-based health-tech device. (f) understand concepts around medical data capture and transmission. (g) understand concepts around medical databases, cloud-based storage, security, and encryption. (h) understand concepts around HIPAA compliance, Protected Health Information, Personally Identifiable Information, Minimum Necessary Standard, Covered Entities, and Business Associate Agreements. (i) understand the progression of Medical Technology Startups. (j) understand FDA Medical Device Manufacturer Registrations and Medical Device Listings. (k) understand internal controls necessary for FDA-Registered Device Manufacturers. (l) understand the FDA 510(k) Process, Class I / II / III Risk Stratifications, De Novo Pathway, and 510(k) Exempt Pathway and Requirements.

ABET Student Outcomes															
b.	1a	1b	2a	2b	2c	2d	3	4a	4b	4c	5	6a	6b	7a	7b
	X	X													

The above student outcomes are defined by the Accreditation Board for Engineering and Technology (ABET) as:

- 1a. an ability to identify and formulate complex engineering problems by applying principles of engineering, science, and mathematics
- 1b. an ability to solve complex engineering problems by applying principles of engineering, science, and mathematics

## 7 List of Covered Topics

1. Introduction to Health Technology Devices
2. Design Considerations for Medical Devices
3. Microcontroller-Based Applications in Health Technology
4. Sensor Technologies for Healthcare Monitoring
5. Wireless Communication Protocols for Health Tech Devices
6. Data Capture and Transmission in the Medical Industry
7. Medical Data Security and Encryption Requirements
8. HIPAA Compliance and Penalties
9. Introduction to Medical Databases and Cloud-Based Medical Data Storage
10. Health Tech Startups and Entrepreneurial Concepts
11. FDA Regulations for Medical Device Manufacturers
12. Medical Device Design, Development, and Testing
13. Ethics and Risks in Health Tech Device Development
14. Clinical Studies, Consenting, and Institutional Review Boards
15. Market Analysis and Product Features Design

16. Business Models and Sales Strategies
17. Non-Dilutive Grants, VC Funding, and Alternate Investment Sources for Health Tech Startups

## 8 Tentative Schedule

Tentative schedules for all sections follow. Be sure to refer to the schedule for your specific section, if more than one is provided.

Tentative Schedule for **All Sections**

Week	Lecture Series	Lab Series
1	Introduction to Health Tech Devices	Introduction to Microcontrollers for Health Technologies
2	Overview of the Health Tech Industry	Sensor Integration
3	Design Considerations for Medical Devices	Wireless Communication: Transmitting Data via Bluetooth
4	Microcontroller Basics and Applications in Health Tech	Data Logging: Storing Sensor Data
5	Sensor Technologies in Healthcare Monitoring	Data Transmission
6	Wireless Communication Protocols for Health Tech Devices	HIPAA-Compliant Database Design
7	Data Capture and Transmission in the Medical Industry	Database Integration: Storing Sensor Data in the Cloud
8	Security and Encryption for Medical Data	Implementing Data Encryption
9	HIPAA Compliance in Health Tech	User Interface Development for Health Tech Devices
10	Introduction to Medical Databases and Cloud-Based Storage	Real-Time Monitoring
11	Entrepreneurial Concepts in Health Tech and the Medical Industry	Building Web Portals for Healthcare
12	FDA Regulations for Medical Device Manufacturers	Integration to EMR/EHR Systems
13	Ethics and Risk Management in Health Tech Devices	Implementing Alerts for Abnormal Data Readings
14	Prototyping and Testing Health Tech Devices	Generating Reports from Patient Data
15	Market Analysis and Product Positioning	Final Project: Medical Device Design
16	Business Model Analysis and Health Tech Entrepreneurship	Final Project: Medical Device Build
17	Funding and Investment Strategies for Health Tech Startups	Final Project: Medical Device Presentation

## 9 Grading Policy

Letter grade scale: A(93–100), A–(90–92), B+(87–89), B(83–86), B–(80–82), C+(77–79), C(73–76), C–(70–72), D+(67–69), D(63–66), D–(60–62), F(<60)

## 10 HW Assignment and Laboratory Report Submission Policy

Homework is assigned weekly and is due in one week. Late homework is accepted with the permission of instructor only. There is 25% penalty for late homework. Grades are reviewable up to a week after graded work is returned.

## 11 Attendance Policy

### General Rules

The full version of the official Villanova class attendance policy is posted at <https://live-villanova-catalog.cleancatalog.io/class-attendance>, but the main points are as follows.

The full version of the official Villanova class attendance policy is posted at <https://live-villanova-catalog.cleancatalog.io/class-attendance>, but the main points are as follows. Attendance is required. Whenever possible, students should inform the instructor if they plan to be late or absent from class. In all cases, documentation is required to petition for excused absences to the Associate Dean for Student and Strategic Programs, Dr. Stephen Jones. The excused absence form is posted at: <https://forms.office.com/r/H2kbHKLUmw>. Excused absences do not count towards a failure in the course for first year students. Absence from class does not release the student from assigned work. Students who miss an in-class obligation such as an exam, a presentation, etc., due to an excused absence will not be penalized - the instructor may offer a make-up test, arrange an alternative time for a presentation, exempt a student from the assignment, or provide another arrangement. In the case of illness or injury, the form must be submitted within 24 hours of missing a class. The University's list of excused absences for all students includes the following: 1. Participation in NCAA athletic competitions 2. Participation in special academic events such as: conferences, field trips, project competitions, etc., and in official university business such as student representatives attending meetings related to university governance 3. Attendance at significant events of the immediate family such as: funerals, weddings, etc. 4. Religious holidays - see the University's policy on Religious Holidays 5. College-approved participation in placement activities such as: job interviews, graduate school interviews, job fairs 6. Legally required absence such as: jury duty, court appearance, short-term military service 7. Documented serious illness or disability

Whenever possible, students should inform the instructor if they plan to be late or absent from class. In all cases, documentation is required to petition for *excused* absences to the Associate Dean for Student and Strategic Programs, Dr. Stephen Jones. The excused absence form is posted on this page: <https://villanova.sharepoint.com/teams/COECurrentUndergrads/SitePages/Catalog.aspx> under the heading "Engineering Academic Policies and Forms".

Excused absences do not count towards a failure in the course for first year students. Absence from class does not release the student from assigned work. Students who miss an in-class obligation such as an exam, a presentation, etc., due to an excused absence will not be penalized - the instructor may offer a make-up test, arrange an alternative time for a presentation, exempt a student from the assignment, or provide another arrangement. In the case of illness or injury, the form must be submitted within 24 hours of missing a class. The University's list of excused absences for all students includes the following:

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6. Legally required absence such as: jury duty, court appearance, short-term military service
7. Documented serious illness or disability

## Personal Days

Personal Days are NOT allotted for laboratory sessions and courses that meet once a week. For all other courses that meet at least twice a week, students are entitled to excused absences for any reason that may contribute to their personal wellness. The following rules apply.

Students must advise the instructor by email *before* class of their intent to utilize a Personal Day as the reason for their absence. A Personal Day will not be approved retroactively. Students may, but are not required, to provide additional information regarding their absence. A Personal Day does not grant an automatic extension for items due. Students remain responsible for all assignments, exams, presentations, etc. due on that date. The instructor may apply her/his discretion on a case-by-case basis to determine whether an extension on a deliverable item is appropriate.

For classes that meet thrice a week (50 mins  $\times$  3), TWO personal days are allowed in the semester. These personal days may not be used ...

1. on consecutive class days
2. in the same week
3. immediately preceding or following a University holiday or break period, and
4. on days when exams, presentations or other major assignments are scheduled.

For classes that meet twice a week (75 mins  $\times$  2), ONE personal day is allowed in the semester. This personal day may not be used ...

1. immediately preceding or following a University holiday or break period, and
2. on days when exams, presentations or other major assignments are scheduled.

## 12 Examination Policy

The College of Engineering has adopted the following general examination guidelines:

1. Students must arrive before the start of the examination. Under exceptional circumstances a student may need to arrive late, but he/she can enter the examination room no later than 5 minutes after the start of the exam.
2. All cell phones and smart devices must be turned off and stored away until the student exits the exam room, unless explicitly permitted by the instructor.
3. The official [Villanova class attendance policy](#) must be followed when requesting excuses for absences or lateness to an examination.
4. Each student must write and sign the following statement, "I have neither given nor received any unauthorized assistance in the completion of this examination."

5. In the case of virtual exams, the instructor may implement video proctoring or other measures to ensure academic integrity. For consent purposes, the instructor will announce ahead of time to students if they plan to use any form of video proctoring during an assessment and whether a recording will take place.

## 13 Academic Integrity Policy

The College of Engineering is committed to creating an environment of academic integrity and ethical decision-making that we hope is reflected in the actions of our students and graduates. As Villanova students, integrity is central to the University mission. As engineers, our code of conduct requires us to place honor and integrity at the forefront of everything we do. As engineering students, it is expected that you will begin to adopt these values and instill them into your work habits. Students violating the academic integrity policy will receive a zero on that assignment or exam and the violation will be reported to the Associate Dean for Academic Affairs. The University's academic integrity policy can be found on the following web page:

<https://live-villanova-catalog.cleancatalog.io/academic-integrity-0>.

## 14 Adherence to the Student Code of Conduct

Students are expected to act in a professional and respectful manner to their fellow students, faculty, and staff. Students should become acquainted with and understand the responsibilities set forth in the Student Handbook, especially those in the sections on Policy and Regulations. Adherence to university regulations is expected and required for successful completion of the program of studies. Enforcement within the classroom of policies regarding classroom behavior is the responsibility of the faculty member. All other discipline problems are to be referred to the Dean of Students.

## 15 Inclusive Classroom

This classroom is a place where you will be treated with respect; we welcome individuals of all ages, backgrounds, beliefs, ethnicities, gender, gender identities and expressions, sexual orientation, and other visible and non-visible differences. All members of this class are expected to contribute to a respectful, welcoming, and inclusive environment to allow all among us to learn and flourish.

## 16 Students with Disabilities

It is the policy of the university to make reasonable academic accommodations for qualified individuals with disabilities. If you are a person with a disability (non-physical) please register with the office of [Learning Support Services \(LSS\)](#) by emailing [Learning.support.services@villanova.edu](mailto:Learning.support.services@villanova.edu) or by phoning 610-519-5176 as soon as possible. Registration is *required* in order to receive accommodations. In addition, please contact the instructor during office hours in order to make the appropriate arrangements.

The [Office of Disability Services \(ODS\)](#) collaborates with students, faculty, staff, and community members to create diverse learning environments that are usable, equitable, inclusive and sustainable. The ODS provides Villanova University students with physical the necessary support to successfully complete their education and participate in activities available to all students. If you have a diagnosed disability and plan to utilize academic accommodations, please contact and register with Gregory Hannah, advisor to students with disabilities at 610-519-3209 or visit the office on the second floor of the Connelly Center.

## 17 Tutoring Services

Villanova's tutoring services include [The Writing Center](#), [The Learner's Studio](#), and [The Center for Speaking and Presentation](#). These services are offered free of charge to students. Drop in as-needed or book a regular weekly session to supercharge your academic success. Sessions can be 30 or 60 minutes in length.

Register for an account and book sessions in advance at [villanova.mywconline.com](http://villanova.mywconline.com). If you don't see your class listed, request a tutor for a missing subject at: [tutorrequest.villanova.edu](mailto:tutorrequest.villanova.edu) For more information, contact Juliana Struder at [juliana.studer@villanova.edu](mailto:juliana.studer@villanova.edu) or at 610-519-5862.

## 18 Online Expectations

Some or all sessions of this class may be recorded for educational purposes and for later playback. In order to foster a professional environment, please wear appropriate clothes, refrain from eating, mute your microphone when you are not talking so as to eliminate background noise, and select an appropriate setting free of distractions. You may turn off your webcam for privacy reasons unless explicitly instructed not to do so by the instructor (such as during the conduct of online examinations).

## 19 Electronics Policy

The use of electronic devices, such as phones, laptops, tablets, calculators, etc., during class is generally allowed, unless their use causes a disturbance to others. During examinations, the use of any electronic device is prohibited, unless it is expressly authorized by the instructor.

Students are prohibited from making any audio or visual recordings (including taking photographs) of lectures, discussions, or other classroom activities, unless a student (1) has written permission in advance from the instructor, or (2) is permitted to record under terms and conditions as approved by the University's Office of Disability Services or Learning Support Services. Students who have received approval to record classes as an academic accommodation must provide supporting documentation from the Office of Disability Services or Learning Support Services in advance of any recording. Students may use authorized recordings only for the purposes of individual study in the course, and may not disseminate or share them with a wider audience without explicit permission.

## 20 Copyright Policy

The materials used in Villanova University courses ("Course Materials") generally represent the intellectual property of course instructors, third parties and/or the university which may not be disseminated or reproduced in any form for public distribution (e.g., sale, exchange, etc.) without the written permission of the course instructor. Course materials include all written or electronic documents and materials, including syllabi, current and past examination questions/answers, and presentations such as lectures, videos, slides, etc., provided by a course instructor. Course materials may only be used by students enrolled in the course for academic (course-related) purposes.

Published course readings (book chapters, articles, reports, etc.) available in "Blackboard" are copyrighted materials. These works are made available to students through licensed databases or fair use. They are protected by copyright law, and may not be further disseminated or reproduced in any form for distribution (e.g. uploading to websites, sale, exchange, etc.) without the permission of the copyright owner.

Follow these links for more information on [Intellectual Property](#), [Copyright](#), and [Computer Acceptable Use](#).

## 21 Professorial Duties

It is important to note that teaching is one of the many duties that professors perform as part of their job responsibilities. In addition to teaching, professors perform research, advise graduate students, edit journals and review journal articles, serve on committees for the university and professional societies, travel to conferences to remain abreast of current developments and to present their results... to name just a few commitments.