Instructions:
- This exam has 5 pages and 18 questions.
- Answer 12 of 18 questions. Answer all parts of the questions you choose.
- You have 180 minutes to complete this exam.
- This is a closed book exam; however, you are permitted to bring one 11” × 17” sheet of notes.
- You are permitted to use a non network-connected calculator.
- Write your answers in an examination booklet.
- Circle the questions you have answered in the list at right of this page.

Background: There is tremendous interest in technology to make driving safer and more efficient. Many of these systems pose interesting scientific, engineering, and ethical issues, which relate to this course.

The first set of technologies are for driver monitoring. Driver safety is severely impacted when the driver is distracted or tired, or worse, when the driver experiences a catastrophic event such as a heart attack or epileptic seizure. Driver monitoring systems use technology to watch the driver for these occurrences, and allow the vehicle to take corrective action, such as slowing down and moving to the side of the road.

Another set of techniques are for autonomous driving. An autonomous vehicle will – either partially or completely – take over the job of driving the car. When completely automatic, it is a “driverless” car. It is hoped that such vehicles will be safer, and allow the passengers to work on activities other than managing the vehicle. In this test, we are primarily interested in the ethical issues, although one report shows autonomous vehicles in more accidents, and others show the car’s computer systems can be vulnerable to cyber-attack.

Even with perfect technology, it is clearly impossible to prevent all crashes. Vehicles must thus be programmed about what to do when a crash is inevitable. One study asked people about the ethical choices they wanted the vehicles to make. Seventy-six percent of participants said they would prefer vehicles respond to impending crashes in a “utilitarian” manner, and chose the action that would save the most lives. But, ironically, respondents said they would ultimately buy a car programmed to preserve their lives as passengers instead of wanting a completely utilitarian vehicle.

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Medical devices and Biomedical Engineering Practice

The implantable cardioverter-defibrillator (ICD) is designed to detect arrhythmia and to then provide a defibrillating shock to the owner’s heart in order to restore a normal heart rhythm. However, after being subjected to such a shock, subjects are exhausted and disoriented. If driving a vehicle while shocked, the driver may be unable to avoid an accident.

To solve this, a new “ICD+V” is invented. This device wirelessly communicates to a special receiver in a semi-autonomous vehicle. In the event of arrhythmia, the ICD+V communicates this to the vehicle, which will take over control from the passenger and try to park on the side of the road.

1. The Medical Devices Bureau of Health Canada has identified four classes of medical devices based on the level of control necessary to assure the safety and effectiveness of the device. **List and briefly describe these classes.** Would this ICD+V device be classified as a medical device? If so, **describe two considerations in classifying it, and suggest an appropriate device class.**

2. If the Heart Institute were considering implanting ICD+V devices, a clinical engineer would be involved in these discussions. **Discuss two roles of a clinical engineer from the following list:** i) technology assessment, ii) regulatory compliance, iii) incident investigation, and iv) training and education. **What is the role of a clinical engineer in managing adverse events with a medical device.** In your answer, explain whom must be notified.

Cells and Electrophysiology

An ICD can function in two roles. First, it can work as a pacemaker, providing either continual or additional pacing. It also provides a shock to re-synchronize the heart when it is in ventricular fibrillation.

3. **Sketch the heart**, showing the four chambers. **Indicate** the location of the SA and AV nodes, and describe their function. **Describe and indicate** the pathways of electrical activation. **Where** does a pacemaker connect? **Explain.**

4. There is bidirectional communication between the heart and brain, although the influence of the heart on brain activity is poorly understood. Some research\(^1\) claims that during stress, neural signals travelling from the heart to the brain inhibit higher cognitive functions.

**Sketch and describe** a synaptic junction between two neurons. **Describe how an action potential** can “jump” the junction to cause a new AP at the post-synaptic neuron. **How does** this process differ at a neuromuscular junction?

5. The pacemaker is highly specialized cell, far different structurally and functionally from the stem cells from which it originates. Some recent research\(^2\) helps clarify this process, which involves the expression of specialized proteins. **Describe the steps** of gene expression whereby a functional protein is produced from a gene. **Describe two ways** in which gene expression can be controlled.

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Biomechanics

A car crash is – obviously – not a good thing for a body. The impact of the driver’s body into the steering column places all sorts of biomechanical stresses onto the body.

6. **Sketch stress-strain curves** of bone, soft tissue and an engineering material such as steel. (only the shape of the curve is required, not the values of stress and strain.) **Compare the curves and discuss** areas in which they differ and briefly explain why.

7. In order to understand the impact of a crash, it is useful to have detailed mechanical models of tissue properties. However, there are many reasons which make tissue property testing difficult. **Discuss three such considerations**, and how they affect the validity of the mechanical models.

Oxygen Transport

An elderly patient with an ICD+V has the following cardiovascular and breathing parameters. Assume inspired air is at body temperature and at 100% humidity. Not all parameters are required.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LVEF:</td>
<td>50%</td>
<td>Left Ventricular Ejection Fraction</td>
</tr>
<tr>
<td>EDV:</td>
<td>120 mL</td>
<td>End-Diastolic Volume</td>
</tr>
<tr>
<td>f_I,O_2:</td>
<td>20%</td>
<td>Fraction of inspiratory oxygen</td>
</tr>
<tr>
<td>f_A,O_2:</td>
<td>15%</td>
<td>Fraction of alveolar oxygen</td>
</tr>
<tr>
<td>F_B:</td>
<td>12 breaths/min</td>
<td>Breathing frequency</td>
</tr>
<tr>
<td>V_T:</td>
<td>350 ml</td>
<td>Tidal Volume</td>
</tr>
<tr>
<td>FRC:</td>
<td>3 L</td>
<td>Functional Residual Capacity</td>
</tr>
<tr>
<td>S_a,O_2:</td>
<td>95%</td>
<td>Saturation of arterial oxygen</td>
</tr>
<tr>
<td>S_v,O_2:</td>
<td>70%</td>
<td>Saturation of venous oxygen</td>
</tr>
<tr>
<td>[Hb]:</td>
<td>10 g/L</td>
<td>Concentration of Hemoglobin</td>
</tr>
</tbody>
</table>

8. **What does** $\dot{V}_O_2$ **measure, and why is it important? Calculate** $\dot{V}_O_2$ **based on the breathing data.** **What is the required** Heart Rate (HR) **in order to deliver the** $\dot{V}_O_2$ **?**

(Recall $C_aO_2 = (1.34 \text{ mL O}_2/\text{g Hb}) \times [\text{Hb}] \times S_aO_2$)

9. **Describe how** LVEF **is calculated, and explain why** is it an important parameter? **How does** LVEF **change** if an aortic valve is insufficient? **Sketch as a function of time** the left ventricular pressure, $P_{LV}$, left ventricular volume, $V_{LV}$, and aortic pressure, $P_a$, for this patient. **How does** LVEF **change** if the heart rhythm becomes disorganized, as in the case of ventricular fibrillation?

10. The patient has a narrowed artery on the surface of the heart, with a reduced diameter because of the accumulation of plaque. **Describe (using a sketch) how** this stenotic artery can result in ischaemic regions of the heart muscle. **What happens** to $O_2$ and $CO_2$ concentrations in the ischaemic tissue? **How does ischaemia** affect the oxygen saturation $S_O_2$? **How does ischaemia** affect the blood acidity?

11. An ischaemic region of the heart has slower electrical conduction than other regions. **Sketch the pattern** of electrical propagation on the surface of a heart with an ischaemic region, and **describe how it differs** from electrical propagation on a healthy heart. **Describe how slower** electrical conduction can result in circuits of reactivation (and thus fibrillation).
Statistical Methods

You read an abstract from a study on ICD+V devices:

An ICD is a device to detect ventricular arrhythmia and rectify the situation by delivering an electric shock. However, this can cause disorientation to the recipient which can be dangerous when such an event occurs while driving. The present study describes the development of an ICD+V device which communicates with an autonomous vehicle and initiates a safe parking maneuver during an arrhythmia event. The effectiveness of the ICD+V device was compared with a classic ICD where the driver takes responsibility for safely parking the vehicle following a shock. Since autonomous parking has its own risks, we wish to establish if there is any difference in accident rate between these two systems. Drivers with a history of arrhythmia were recruited to this study. The first hundred recruited subjects who owned a compatible autonomous vehicle were provided with an ICD+V device while the first hundred recruited drivers of non-autonomous vehicles received a classic ICD. The rate of accidents immediately following ICD-induced shocks were collected for each of the twenty drivers. Results showed a significant difference ($p=0.03$) between the rate of accidents per 100 ICD-induced shocks between the ICD group (3.6) and the ICD+V group (3.2).

You may use the assumption $DF = \infty$, and the following the table of $t$-test critical values, for the one- and two-tail cumulative probabilities:

<table>
<thead>
<tr>
<th></th>
<th>one-tail</th>
<th>0.25</th>
<th>0.20</th>
<th>0.15</th>
<th>0.10</th>
<th>0.05</th>
<th>0.025</th>
<th>0.01</th>
<th>0.005</th>
<th>0.001</th>
<th>0.0005</th>
</tr>
</thead>
<tbody>
<tr>
<td>two-tails</td>
<td>0.50</td>
<td>0.40</td>
<td>0.30</td>
<td>0.20</td>
<td>0.10</td>
<td>0.05</td>
<td>0.02</td>
<td>0.01</td>
<td>0.002</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>$t_{DF=\infty}$</td>
<td>0.674</td>
<td>0.842</td>
<td>1.036</td>
<td>1.282</td>
<td>1.645</td>
<td>1.960</td>
<td>2.326</td>
<td>2.576</td>
<td>3.090</td>
<td>3.291</td>
<td></td>
</tr>
</tbody>
</table>

12. **What was the the null hypothesis in this study. A p-value of 0.03 indicates** 3% chance of what? **Discuss one possible source of bias** in this experiment. **How does the source of bias** affect the interpretation of the results.

13. **Should the authors have used** a 1-tailed or 2-tailed t-test in this study? **Explain. What was the standard deviation** of the accident rate, assuming that each group’s accident rate had the same standard deviation?

14. The company that makes ICD+V wishes to repeat the study but obtain a p-value of no more than 0.01 (so they can publish it in a more prestigious journal). **How many subjects** will need to be recruited if all other variables are held constant (rates, standard deviations, length of study, etc)?

15. To evaluate the new ICD+V, the data from all ICD+V subjects were analyzed over the course of the study. An expert cardiologists examined all collected ECG data and determined that a total of 230 episodes of ventricular arrhythmia had occurred. Of these episodes, the device correctly detected 185. Interestingly, on a further 32 occasions, the ICD+V initiated an emergency parking maneuver when no arrhythmia was present. **What is the sensitivity and precision** of the IDC+V? **Why can’t we measure** specificity here?
Ethical Theories and Research Ethics

Assume government decides that it wants to encourage people to get an ICD+V installed instead of a normal ICD. It wants to find out what kind of incentive is required to encourage people to switch. It asks the Heart Institute to make the following offer to 50 randomly selected people on the waiting list for an ICD:

Offer: if you decide to get an ICD+V installed, you can skip the waiting and get moved to the front of the list. If you don’t, you stay where you are on the list.

You are required to write the research ethics application to obtain ethics clearance for this study.

16. **How would you justify** the research ethics of this study based on the core principles of i) respect for persons, ii) concern for welfare, and iii) justice

When a crash is inevitable, a driverless car must be programmed to make a decision as to which group is put at risk. In the figure below, three scenarios are shown in which the car can swerve or continue straight. Assume the driver is at risk in each swerve scenario, but safe in the “continue straight” scenario.

As discussed, most people think cars should save the greatest number of people (FairCar), but would only buy a car that will preserve their own safety (DriverSafeCar). You are on the board of the “GeneralVolks-Fiazda” car company, which is considering the following three options

i) Building FairCar (and honestly telling their customers)

ii) Building DriverSafeCar (and honestly telling their customers)

iii) Building FairCar, but telling the customers that it’s a DriverSafeCar

You are the ethics consultant hired to consider this issue.

17. **Create a table** of at least four of the groups of people impacted by the decision, and list benefits and disadvantages of the three options for each group.

18. **Explain why this decision** would need to involve ethical considerations (as opposed to simply business or financial considerations). **What decision** would you make? Choose an ethical theory and justify your decision.