GROUP ASSESSMENT COVERSHEET

Unit of Study, Assignment: MECH3921/MECH5921, 10 Page report (worth 20%, marked out of 30)

DECLARATION:

We the undersigned declare that we have read and understood the **University of Sydney Academic Honesty in Coursework Policy***, and except where specifically acknowledged, the work contained in this assignment/project is our own work, and has not been copied from other sources or been previously submitted for award or assessment. We understand that failure to comply with the Academic Dishonesty and Plagiarism in Coursework Policy can lead to severe penalties as outlined under Chapter 8 of the University of Sydney By-Law 1999 (as amended). These penalties may be imposed in cases where any significant portion of my submitted work has been copied without proper acknowledgement from other sources, including published works, the internet, existing programs, the work of other students, or work previously submitted for other awards or assessments. We realise that we may be asked to identify those portions of the work contributed by each of us and required to demonstrate our individual knowledge of the relevant material by answering oral questions or by undertaking supplementary work, either written or in the laboratory, in order to arrive at the final assessment mark.

TEAM NUMBER: _____

Note: "Sections contributed to" includes contribution to testing, talk prep., report collation, presenting, minute taking, chairing in addition to report sections.

	Full Name	SID	Sections Contributed To:	Hours spent	Signature
1					
2					
3					
4					
5					
6					
7					
8					

1. Project Aim & Background

[3 Marks] 1 page total

Aim:

1-3 Succinct sentences outlining the overall objective(s) of the project including main specific deliverables.

Aim Example: In consultation with < Clinician/Expert name(s) > this report provides a preliminary overview of the design and development of a < novel system > concept.

Background:

Using IEEE ordered number referencing please summarize literature in a very factual and abbreviated manner. A compact table (with font size 6 and minimal margins) can be used to summarize prior art in literature with columns used to list differences in features between the prior art. Eg configuration, mechanism, materials, value, disad, ref, could be the column headings. The ref column is for listing references for the prior art example. It will be best to categorize similar versions of prior art together if there are many examples of prior art. Eg manual mechanical, automatic systems, self-administered systems could be examples of categories where there may be >15 prior art systems.

You should list keywords used, including all combinations, and search engines (USPTO, WIPO, Google, ScienceDirect etc) in a table. This table is to be included in the appendix. The appendix section/page can be references in this section to allow the reader to flick back.

2. Specification Requirements:

[3 Marks] 1 page

A table of categorized specification requirements with numbered reference (eg SPR1-SPR12).

Specification requirements may relate to a design to be developed, a method for evaluation of a device, usage, workflow or service.

The requirements should be listed in decreasing order of importance or provided with a priority score.

Table 1. Specification Requirements

#	NAME	CATEGORY	SHORT EXPLANATION	REFERENCES	RANK
SPR1.1	User friendliness	User	The software needs to be intuitive and clear	2,3-6	1
SPR1.2	Usage tracking	User	Usage history and improvement feedback	2,5	1
SPR1.3	Compatible	User	System must be compatible with major smartphones	2-7,10	2
SPR1.4	Aesthetics-Accesibility	User	GUI must meet user expectations, based on survey	2,3	2
SPR2.1	Accuracy	Technical	Estimates should be valid with acceptible error limit	2	1
SPR2.2	Functionality	Technical	Add-in saving and exporting and emailing functions	2,10	3
SPR2.3	Reliability	Technical	app should meet software standards for stability	2,4,10	1

An explanation of the table (Titled Table 1. Specification Requirements), discussing several of the most important requirement should be included (1-2 paragraphs). The requirements SPR1.1-SPR1.4 are of the user category and are often sourced from clinicians, nurses, health managers, experts, users, people close to the coal face. By using unique number identifiers for requirements and risks and follow through in the V&V table/plan this allows continuity and traceability in the report. References allow you to demonstrate due diligence as there may also be a literature context for the design requirement, including papers (documenting success or failure, or issues), review papers are particularly valuable to include, patents commenting on advantages, FDA articles, websites etc..

3. Design Risks:

[3 Marks] 1 page

A table of categorized specification risks with numbered reference (eg RSK1-RSK12)

The risks should include ratings for likelihood and probability and be listed in decreasing order of importance or provided with a priority score. These are not just concerning patient safety, but whatever will cause the design to fail. This may include aesthetics and user friendliness, manufacturability and cost.

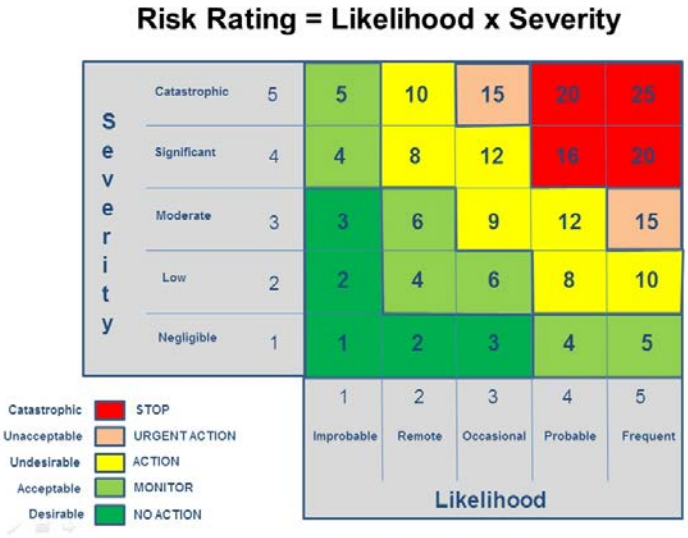

Table 2. Specification Risks

REF	RISK	CATEGORY	MITIGATION METHOD	REFERENCE	Severity (1-5)	Liklihood (1-5)	RISK RATING (/25)
RSK1.1	Tool causes strain/injury	User	Device undergoes rigorous design process and user testing	1,4,20	3	2	4
RSK1.2	Not intuitive / user friendly	User	User design input, Usage history and improvement feedback	1,3	2	1	2
RSK1.3	Not cleanable/sterilizable	User	Design process & cleaning & sterilization validation testing	5-10	5	1	2
RSK2.1	Fracture or fatigue of tool	Technical	Device undergoes rigorous mechanical and worst-case testing	1,11-13	5	1	5
RSK2.2	Not biocompatible	Technical	Cell, animal testing followed by clinical trials	1,3,15-21	5	1	5
RSK2.3	Rapidly goes blunt	Technical	Choice of hard wearing material, extensive cut-wear testing	23	2	1	2
RSK2.4	Difficult or costly to make	Technical	Design process input & Rigorous manufacturing validation	1,2,18	3	1	3

An explanation of the table, discussing several of the most important risks should be included (1-2 paragraphs)

A table of categorized specification risks with numbered reference (eg RSK1-RSK12)

The risks should include ratings for likelihood and probability and be listed in decreasing order of importance or provided with a priority score. The ratings in this instance are for after the mitigation method is applied, whereas in an ISO13485 both the before and after ratings will normally be listed to demonstrate the action of the mitigation method.

4. Design Solution Specifications

Describe the solution mostly using drawings and bullet points. Refer to the literature background and contrast against alternative options available.

This should account for the logic and rationale of the solution.

This should include engineering drawings, models or diagrams. Avoid including photographs in this section.

Include a summary of how you assembled your prototype solution using labelled diagrams and/or a flowchart.

Summary of materials/components and succinct reasons for selections.

A full BOM can summarized here, and referenced to where it should be in the appendix.

[3 Marks] 2 pages total

5. Ideation Explanation

Use a rating table to explain how the solution and its components satisfied the input criteria best.

This may mean you use a 10 column table if there were a good number of requirements and risks accounted for by your technical selection criteria, in addition to health value/economics consideration.

By considering your meeting minutes and email conversations as well as design activity, use a flow chart with potential diagrams/sketches to explain the historical milestones of how your team progressively arrived at the final solution and configuration. In concept idea terms, there should be an inverted funnel leading to many ideas, followed by an upright funnel where ideas are filtered down to one specific solution.

This section helps to further explain section 5. In writing up this section, the team at some point should have deliberately allocated devil's advocate role(s) and attempted to robustly argue against the "chosen" idea. The arguments used to refute all undermining arguments should be bulleted here.

This content is what would normally be included in a design history file for ISO13485 technical file and quality manual document.

[3 Marks] 1 page

6. V&V Plan and Proposal

[3 Marks] 1 Page

Table 3. Verification & Validation Test Plan

V&V	REQ	RISK	DESCRIPTION	REFERENCES	PROTOCOL	REPORT	LITERATURE	PASS/FAIL
1	SPR1.1-1.7	RSK1.1-1.4	Device mechanical performance	User/Tech	TPR1.1	REP1.1	[1], [10-20]	-
2	SPR1.1-1.7	RSK1.2	Electrical Safety testing	User/Tech	TPR1.2	REP1.2	[2-3]	-
3	SPR1.8	RSK1.3	Quiet, Occupational sound safety	User/Tech	TPR1.3	REP1.3	[5-7]	-
4	SPR2.1-2.2	RSK2.1	Tough, survive dropping	User/Tech	TPR1.4	REP1.4	[9]	-
5	SPR2.3-2.5	RSK2.2	Clinical trial	Technical	TPR1.5	REP1.5	[21]	-
6	SPR3.1-3.3	RSK2.3	Device simulated wear testing	Technical	TPR1.6	REP1.6	[22-24]	-
7	SPR3.4	RSK2.4	Budget for Manufacturing Process	Business	TPR1.7	REP1.7	[25-29]	-

An explanation of the V&V plan table, discussing several of the most important tests should be proposed, a summary budget or cost estimate may be included (1-2 paragraphs). References are particularly important here as tests are often arrived at through consultation with relevant standards and scientific papers with current accepted approaches

Preliminary Testing & Evaluation

Preliminary verification/validation of your proof of concept may be summarized at the end of this section.

7. Development & Delivery

(0.5 page) Gantt Chart Planner with key setup, technology, clinical trial and accreditation/registration milestones

Your plan should bullet point summarize or table detail such as the following:

Infrastructure (hot desks in an incubator/leasing offices/industrial suite)

Human Resources / Consulting / Outsourcing

Manufacturing

Shelf-life, Packaging & Terminal Sterilization

Market, User Group, Distribution Networks

Funding & Stages

End-game (licensing, sell-out, partnership etc)

[3 Marks] 2 pages

8. Final Solution Summary

This should read like a conclusion to the report, addressing both a technical challenge and a health value proposition, a summary of findings and a succinct proposal for the future development. 2-3 paragraphs, potentially as bullet points accompanied with an interesting image relating to the solution or intended aim

(the image must look good, not just be a photo of a rough prototype, CAD isometric can be a good option).

[3 Marks] 1 Page

9. Acknowledgements, 9. References, 10. Appendices

All assistance received should be acknowledged by name and activity.

Referencing should be consistent with IEEE format. *Double check this as it could lead to loss of marks*

[3 Marks] (Not included in page count)

OVERALL QUALITY OF REPORT

[3 Marks]

The logical coherence, correctness, detail and appearance of the report will be assessed.