**PROJECT CHARTER**

**<Project Name>**

**Team 6**

**Team Members:**

Steven Said

Elliot Ische

Ryan Choi

Daniel Silva Rios

Ritchie School of Engineering and Computer Science

University of Denver

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**Course Instructors:**

Dr. Jones

Dr. Gordon

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# Document Change History

|  |  |  |
| --- | --- | --- |
| Release version | Date | Description of changes |
| 1 | 3/29/23 | First set of revisions of design requirements |
| 2 | <date> | <Provide a brief description of major additions and / or changes to the document’s contents. For example: Updated CONOPs to include recovery procedure and revised Functional Decomposition chart.> |
| … |  |  |

# 

# Introduction

## Project Description / Customer Needs & Requirements

<The Design Control Spreadsheet and this Project Charter Document present a technical foundation for the design problem. This document details the motivation for the effort and a clear set of objectives through a complete set of customer/user needs and design requirements which will be validated/verified at the completion of the project.

This section provides a broad and brief overview of the project and its objectives. It is important to capture narrative/story of what the project is about, the problems facing the customer and their needs and requirements for a satisfactory solution. The “story” of the problem needs to be translated into a list of stated customer needs and requirements and captured in the design control spreadsheet.

First, as narrative, describe the motivation for the project by giving background and context for the problem. Consider questions such as: Who is your sponsor and what is their mission? What problem have they asked you to address? Why is this project of value to your sponsor? Who will it impact? Then describe the project objectives, e.g. What does this project aim to accomplish? Include visuals that aid the reader in understanding the overall project context and objectives. Translate these into a list of customer needs/requirements on your design control plan. Be thorough and capture the customer’s perspective clearly

Be sure to cite references.

Technical writing reminder: Remember that visuals should first be introduced and explicitly referenced in the text, immediately followed by the figure with its descriptive caption below. Table captions appear above tables. Figures and tables should be numbered sequentially according to the section numbers, e.g., the first figure in this section would be Figure 1.1.1 and the first table would be Table 1.1.1. The second figure would be Figure 1.1.2 and the third figure would be Figure 1.1.3 and so on for this section.

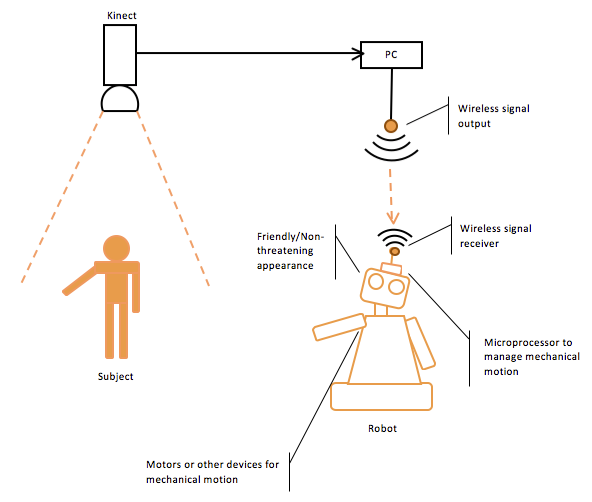


Figure 1.1.1 Figure captions appear below the figure.

Table 1.1.1. Table captions appear above a table.

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| --- | --- | --- |
| Column 1 | Column 2 | Column 3 |
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>

## Concept of Operations (CONOPs)

The following Concept of Operations presents a descriptive shared vision between the stakeholders and design team regarding how this system will operate from the end user’s perspective. <You may use the preceding text to introduce this section or substitute with your own introduction.>

<A Concept of Operations (CONOPs) creates a shared vision between stakeholders and designers regarding the ways the system will be used and what it needs to do. The CONOPs can really help you clarify the customer needs and requirements. It is sometimes described as a “day in the life” of the product from the user’s perspective and is critical for determining the customer’s actual, rather than perceived, needs and requirements.

The concept of operations should be a narrative communicated in everyday language. The focus is on *what* the system does and *not on how* the system accomplishes its tasks. Include input from your customer and other stakeholders addressing:

* Initialization of the system
* Normal operation in standard operating modes for all environments in which the system may be placed
* Extremes of operation due to extremes in the external environment or external systems
* Standard maintenance
* Failure modes due to internal problems
* Reaction to external failure modes
* Shutdown of the system
* End of life of the system *>*

# Project Scope and Deliverables

## Scope and Dependencies

<All designs are part of a larger context, and it is helpful to explicitly clarify what parts of the design your team is responsible for and what will be done by the sponsor, an external consultant, or other entity. For example, the team might be responsible for developing the hardware and software to control a test apparatus while the sponsor will provide the computer science expertise to process the resultant data.

This statement of scope informs the reader that the project (and therefore the document) details only the aspects described and refers to the larger system as far as is necessary. >

## Deliverables

<Provide a brief description of the items that will be delivered to the customer at the end of the project. Do not forget to include prototypes as well as support resources such as software, user manuals, maintenance schedules, etc.>

# Design Inputs/Requirements

The following requirements specify the criteria that the system must satisfy to assure suitability for its intended purpose. <Again, you may use the preceding text to introduce this section or substitute with your own introduction.>

<This section details the design inputs/requirements the system must meet to be acceptable. **The design inputs/requirements and associated targets can be copied directly from your Design Control Spreadsheet.** In other words, compliance with these requirements will ensure the suitability of the system for its intended purpose. Every customer need will have one or more design requirements connected to it but not every design requirement will have a direct connection to a “spoken” customer need or requirement.

Remember, well-written requirements are:

* Complete – all significant, necessary requirements are included
* Verifiable – each requirement can be confirmed/verified
* Attainable – specified criteria are feasible within budget, schedule, and technical constraints
* Clearly stated – every requirement has only one interpretation

Your project may include design requirements related to, but not limited to, the following categories. Include only those that are important for your system.

* Functionality – what must it do?
* Performance metrics – how well must it do it?
* Operation and users – how must it be able to be used? Who must be able to use it?
* Compatibility – how must it interface with related systems?
* Size – what dimensions and weight must be satisfied?
* Fabrication / Manufacturability – how can it be made?
* Maintenance and reliability – what maintenance and frequency of maintenance are allowable? How long must it last?
* Safety – what safety hazards must be alleviated?
* Environments – what chemical, electrical, or physical environments must the system endure?
* Sustainability – what environmental impacts must be addressed? are there end of life considerations?

If your project has goals that you hope to meet, but that are not necessary for the success of the project, clearly differentiate these goals from requirements using the word “should.” For example, “4.1.1 The system shall weigh less than 35 kg.” and “4.1.2 Goal: The system should weigh less than 30 kg.” >

<Example:

## Functionality

* + 1. The system shall titrate the medium to a pH between 6.3 and 6.8.
    2. The system shall fully automate the titration process except for post-titration sterilization of equipment, loading medium (e.g., citric acid) in storage tanks, and monthly calibration of the pH probe.
    3. The system shall complete the titration process in under 2 hours (assuming a starting pH of 13).
    4. The system should complete the titration process in under 1.5 hours (assuming a starting pH of 13).

## 

## Data Display

* + 1. The system shall continuously display the most recent pH measurement.

## Status Indicators

* + 1. The system shall visually indicate when the titration process is in progress.
    2. The system shall visually indicate when the titration process is complete.
    3. The system shall visually indicate when data transfer is complete.
    4. The system shall visually indicate if the fluid pH does not change after citric acid is dispensed (which may indicate a malfunction of the system or pH probe).

## 

## Titration Dose / Accuracy

* + 1. The system shall be capable of dispensing between 20 and 2000 μL per dose.
    2. The system shall dispense liquid with an accuracy of +/- 10 μL.

>

## <Physical Requirements>

* + 1. <Formal statement of the requirement. Underline the word shall.>
    2. <Formal statement of the requirement. Underline the word shall.>

## <Keyword title of this requirement or group of requirements>

* + 1. <Formal statement of the requirement. Underline the word shall.>

# Preliminary Verification Plans

The following preliminary verification plans aim to make early connections between the above project requirements and the methods required to verify that the requirements are met. Detailed verification plans will be provided later. <You may use the preceding text to introduce this section or substitute with your own introduction.>

<The four fundamental methods of verification are inspection, demonstration, test, and analysis as described below. Verification requiring testing or analysis is the most complex so use this section to provide a preliminary description of each of these major verifications you anticipate needing to perform to show whether your system performance meets the requirements.

* *Inspection* is the nondestructive examination of a product or system using visual, auditory, olfactory, tactile, or taste senses. It may include simple physical manipulation and measurements. Examples of corresponding requirements include: “...shall be at least 24 in long…”, “...shall have the company X logo…”, and “...shall be painted white…”.
* *Demonstration* is the observation and recording of a system’s functional operation without the use of special test equipment or quantitative evaluation of data. Examples of corresponding requirements include: “...shall be accessible…,” “...shall take less than one hour…,” and “...shall provide the following displays in the X mode of operation….”
* *A test* is the operation of part or all of the system under a set of controlled conditions to determine that quantitative requirements have been met. The analysis of data derived from tests is an integral part of the test protocol. Testing is the preferred method of requirement verification when: 1) analytical techniques cannot provide adequate reliability, 2) failure modes could compromise safety or adversely affect performance, or 3) for any critical system interfaces. Examples of corresponding requirements include: “…shall provide 50 Hz…”, “…shall be settable over a range of 0 to 30० C…”, and “…shall not be larger than 10 microns, at once per rev frequency…”.
* *Analysis* is the verification of a system using models, calculations, and simulations. Analysis is selected when test or demonstration techniques cannot adequately or cost-effectively address all the conditions under which the system must perform. Examples of corresponding requirements include: “…shall be designed to…” and “…shall have a probability of….” >

## <Narrative of Short, descriptive title of demonstration, test, or analysis>

<Give a brief description of one of the major demonstrations, tests, or analyses you anticipate needing to perform to verify that the system performance meets the requirements described. Please identify the requirement by number, but you are not expected to provide quantitative details or specific test protocols at this point. **The primary method of verification can be copied directly from your Design Control Spreadsheet.**>

## <Short, descriptive title of demonstration, test, or analysis>

<Give a brief description of one of the major demonstrations, tests, or analyses you anticipate needing to perform to verify that the system performance meets the requirements described. Please identify the requirement by number, but you are not expected to provide quantitative details or specific test protocols at this point. >

# References

<Provide a full and complete list of sources referenced within this document, e.g., following a standard convention, MLA, IEEE, etc. All sources must be explicitly cited by [number] or [last name, date] within the text. There are free bibliography tools that you can use as plug-ins to word – ask if you are interested in learning more about them>

# Appendices

## Appendix A: Definitions, Acronyms, and Abbreviations <Include only if applicable. Otherwise delete this section.>

<Provide a list of definitions, acronyms, and abbreviations utilized in this document>

## Appendix B: Definitions for your reference <This is a list of definitions which you may find useful as you progress through your project.>

**DESIGN & DEVELOPMENT DEFINITIONS:**

* **Project Charter:** outlines the planned project and problem seeking to tackle. It should outline the perceived size and scope of the project and problem to be addressed along with the investigational efforts that will be undertaken.
* **Customer requirements/user needs**: collection of information gathered from the customer detailing the problems they are facing and their needs and requirements for a satisfactory solution. These form the user needs and intended uses of the device.
* **Design inputs/requirements**: the physical and performance requirements of a device that are used as a basis for device design. This involves the translation of the customer requirements, intended uses, plus standards, regulations and practical factors into technical requirements defining what the solution must do to be successful.
* **Design outputs/specifications**: the results of a design effort. These are the created solutions and specifications which are anticipated to satisfy the needs and requirements of the design inputs. This may be in the form of drawings and/or other types of specifications defining the product to be manufactured. Design outputs/specifications are recorded in the Fabrication Plan (see Project Control Documentation).
* **Design verification**: the information that confirms that the design outputs meet the criteria set by the design inputs and may be in the form of equivalence rationales, calculations, testing and acceptance trials.
* **Design transfer:** the process and procedures that translates the device design correctly into production specifications
* **Design validation**: establishing by objective evidence that device specifications conform with user needs and intended uses. This information confirms a product specifically meets the customer requirements and ensures the product is what we want and is usable. Note that medical devices carry the onus to ensure that the product continues to perform as desired into the future.
* **Process validation**: objective evidence that characterizes the production process and ensures the product will be produced consistently meeting its specifications.
* **Process verification:** confirmation by examination (inspection methods) and provision of objective evidence that a product is meeting specifications.

**PROJECT CONTROL DOCUMENTATION:**

* **Project Charter:** document which outlines the planned project and problem seeking to tackle. This document is updated and refined as the project progresses. It should outline the perceived size and scope of the project and problem to be addressed along with the investigational efforts that will be undertaken. This document also incorporates the written elements of the design input requirements of your design control plan.
* **Design control plan:** A spreadsheet which captures and tracks the creation and connection from customer requirements to design inputs to design outputs to verifications to validations confirming no loose ends remain.
* **Project Plan:** A list of tasks and activities with assigned responsibilities for each and sequenced to accomplish the project in a timely manner.
* **Project and Design Risk registers:** Documents the potential failure modes of the proposed product and its components as well as other associated risks to the successful completion of the project. Each failure mode/identified risk must be tracked in the register with its associated mitigation plan and resolution.
* **Fabrication Plan:** The (proposed) collection of all documentation containing the design outputs/specifications, i.e., the procedures and specifications necessary to define and build the final product (see Design & Development definitions). This includes drawings, material specifications, process specification, quality inspection criteria and methods, supply agreements and any other required information.
* **Design Review:** A documented, comprehensive, systematic examination of a design/project to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements and to identify problems. This is to be done by appropriately identified people at specific points in the process.