BME Design Courses
The Product Design Specification (PDS)

Definition and Purpose: The PDS sets out in as much detail as possible the requirements that must be met to achieve a successful product. It is the basic reference source and should be used throughout the entire design process.

Preparation and Evolution of the PDS: The PDS is a **comprehensive** document, which contains all the facts relating to the product outcome, and should contain all the realistic constraints to be imposed upon the design by the client.

Items in the PDS should be as **quantitative** (in SI units) as possible. (e.g., the device must weigh less than 2 kg.; the device must fit in a 3 m x 3 m x 2 m space), and ranked in order of importance.

The PDS is a **dynamic** document that should evolve as the project scope develops. This is because frequently at the start of a project it is not always clear what is achievable and to what extent certain parameters are essential.

CONTENTS OF PDS

Title: The PDS should have all team members names listed, as well as the title of the project. It should also be dated, to avoid conflicts arising from different versions.

Function (a general statement of what the device is supposed to do): The PDS should begin with a brief, concise paragraph describing (in words) the overall function of the device. In the initial stages, this will be the problem statement, and will become more specific as you decide on a final design.

Client requirements (itemize what you have learned from the client about his / her needs): Briefly describe, in bullet form, the client needs and responses to your questions.

Design requirements: This device description should be followed by list of all relevant constraints, with the following list serving as a guideline. (Note: include only those relevant to your project):

1. Physical and Operational Characteristics

a. *Performance requirements*: The performance demanded or likely to be demanded should be fully defined. Examples of items to be considered include: how often the device will be used; likely loading patterns; etc.

b. *Safety*: Understand any safety aspects, safety standards, and legislation covering the product type. This includes the need for labeling, safety warnings, etc. Consider various safety aspects relating to mechanical, chemical, electrical, thermal, etc.

c. *Accuracy and Reliability*: Establish limits for precision (repeatability) and accuracy (how close to the "true" value) and the range over which this is true of the device.

d. *Life in Service*: Establish service requirements, including how short, how long, and against what criteria? (i.e. hours, days of operation, distance traveled, no.of revolutions, no. of cycles, etc.)

e. *Shelf Life*: Establish environmental conditions while in storage, shelf-life of components such as batteries, etc.

f. *Operating Environment*: Establish the conditions that the device could be exposed to during operation (or at any other time, such as storage or idle time), including temperature range, pressure range, humidity, shock loading, dirt or dust, corrosion from fluids, noise levels, insects, vibration, persons who will use or handle, any unforeseen hazards, etc.

g. *Ergonomics*: Establish restrictions on the interaction of the product with man (animal), including heights, reach, forces, acceptable operation torques, etc..

h. *Size*: Establish restrictions on the size of the product, including maximum size, portability, space available, access for maintenance, etc.

i. *Weight*: Establish restrictions on maximum, minimum, and/or optimum weight; weight is important when it comes to handling the product by the user, by the distributor, handling on the shop floor, during installation, etc.

j. *Materials*: Establish restrictions if certain materials should be used and if certain materials should NOT be used (for example ferrous materials in MRI machine).

k. *Aesthetics*, *Appearance, and Finish*: Color, shape, form, texture of finish should be specified where possible (get opinions from as many sources as possible).

2. Production Characteristics

a. *Quantity*: number of units needed

b. *Target Product Cost*: manufacturing costs; costs as compared to existing or like products

3. Miscellaneous

a. *Standards and Specifications*: international and /or national standards, etc. (e.g., Is FDA approval required?)

b. *Customer*: specific information on customer likes, dislikes, preferences, and prejudices should be understood and written down.

c. *Patient-related concerns*: If appropriate, consider issues which may be specific to patients or research subjects, such as: Will the device need to be sterilized between uses?; Is there any storage of patient data which must be safeguarded for confidentiality?

d. *Competition*: Are there similar items which exist (perform comprehensive literature search and patents search)?