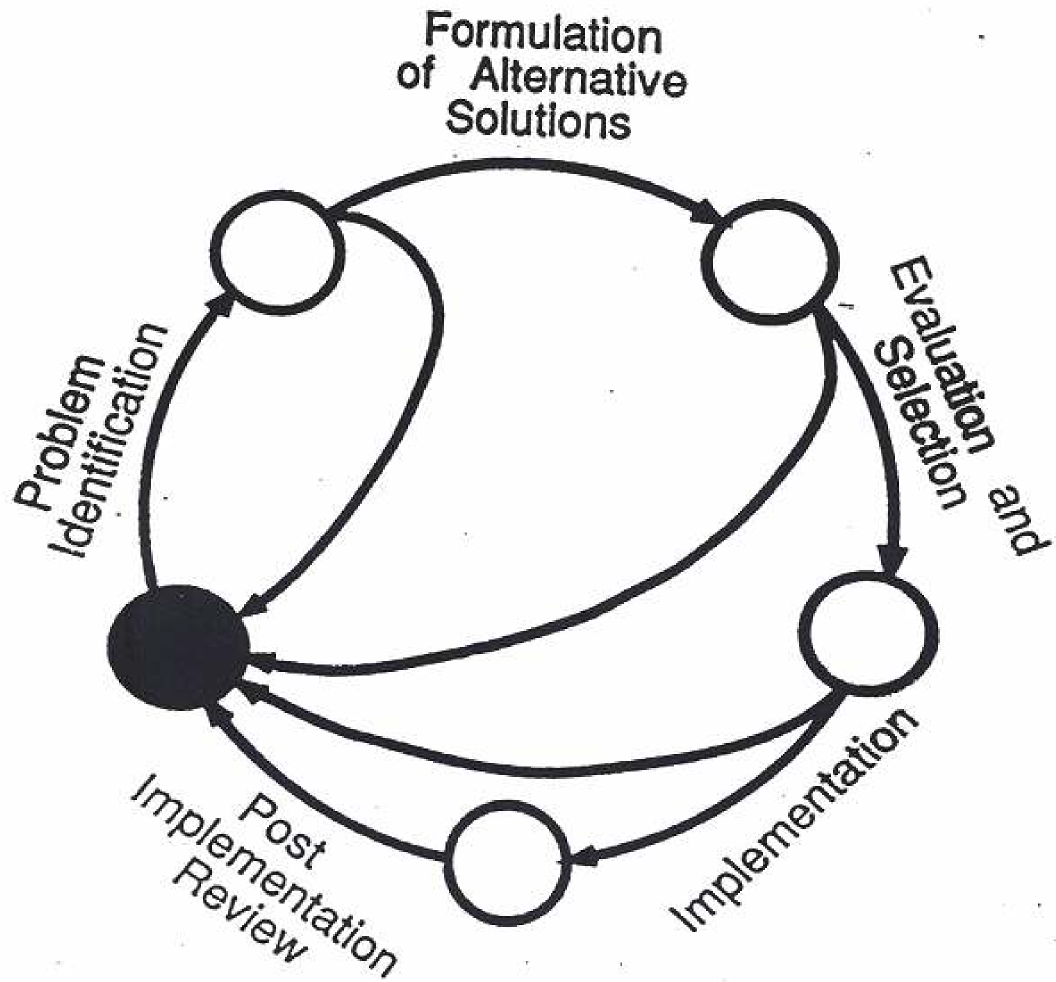
Medical Devices

Lecture 5 – Medical Devices

Medical Devices Design and Development
A Case Study

- System Design and Development
- System Testing
- Project Management



Dynamic Management Cycle.

How to Design an Artificial Organ

A. System Design and Development

- Goal setting (Problem identification)
- Requirement identification
  - Regulatory requirements
  - Competition requirement (life span, weight, human anatomical compatibility, cost restraints)
- Conceptual Design (alternative solutions)
- Evaluation of concept against:
  - Requirements/specifications
  - Political/environmental
  - Cost/economy
- Selection of optimum conceptual system
- Detailed design
- Prototyping

How to Design an Artificial Organ

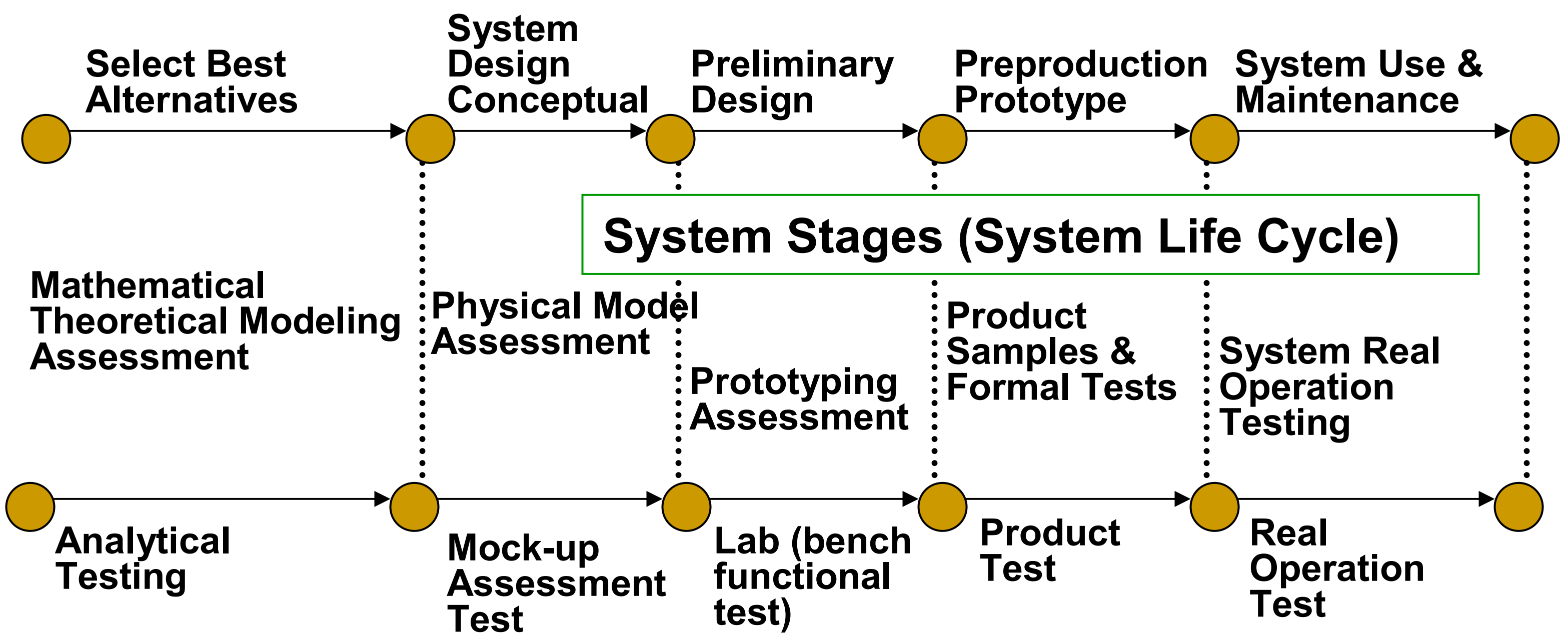
B. Testing

- Test (Verification) - Performance Testing
  - Keep all the positive performances.
  - Revise all negative performances.
- Iterations.
  - Go back and try again with changes in the negative performance items.
- Pre-final unit.
- Pre-final Preliminary Critical Review
  - With best expertise (consultants).
  - Unless overall positive review, “no go”.
- Pre-production unit.
- In Vitro and In Vivo Testing.
- Commercialization of product (first version).
- Go to next version immediately.

Assessment

- Assessment is a continuous process at all stages to ensure the system meets specified performance criteria, is cost efficient and highest safety and efficiency standards.
- Assessment will be based on testing the system against a set of requirements developed earlier.
- Test and performance assessment begins with conceptual design to system utilization.
- Analytical testing.
- Mock up assessment (physical models evaluation).
- Bench functional testing.
- Product test.
- Real operation test.

System Testing



Analytical Testing

- Assessment of systems by analytical means:
  - Mathematical modeling.
  - Numerical analysis.
  - Theoretical modeling.
  - Other paper assessment means.
- The end point is assessment of conceptual system design.

Functional Testing

- Formal testing demonstrating performance of the system.
- Test for prototype (preproduction unit) close to production unit.
- System will be tested under a series of individual performance functions.

Performance Assessment

- Does it stand the intended load (pipe under pressure)?
- Does it provide the intended output (electrical motor, pump, artificial heart)?
- Does it perform its intended mission successfully?
- Does the process and design perform the required output (so many units of production per period of time)?
- Does the software of hardware perform as the designer expected?

Environmental Testing

Examples:

- Temperature (coldest, warmest, exposure time)
- Shock
- Vibration
- Humidity
- Harsh environment (salt)
- Dust sand (desert storm war)
- Bacteria, fungi
- Acceleration and deceleration
- Noise
- Pollution
- Explosion (batteries, nuclear plants)
- Electromagnetic interference
- Radiation

Material and Structural Tests

The objective is to determine material compatibility characteristics such as:

- Stress/strain relation
- Fatigue
- Bending
- Torsion
- Decomposition (breast implants, submarines, space shuttle)

Reliability Testing

- Determine how reliable the system is.
- Determination of mean time between failures (MTBF)
- Mean time between maintenance determination (MTBM)
- Number to be tested
- Component testing
- Mode of failure analysis and testing (confirmation)

Maintainability

- To determine the values for mean active maintenance time.
- How to correct the problem and how long will it take (mean corrective maintenance time).
- Determine mean preventative maintenance cells.
- How long does it take for each maintenance.
- Type of maintenance required.
- Preventative maintenance.

Supporting Requirements

- Types of tools and equipment needed to support the system.
- How the system is transported (if needed).
- How the system is prepared for utilization.
- Other types of considerations.

Skill and Human Resources Requirements

- Determine the types of skills required to operate the system.
- Types of training required.
- System organization requirements.
- User-friendly level testing.

Software Verification

- **To determine the operational maintenance of software.**
- **Determine the reliability of the hardware and software.**
- **Determine compatibility of software and hardware.**
- **Determine the reliability, maintainability, documentation, etc.**

Product Testing

- Those tests required for real production of the system.
- Formal test to demonstrate the qualifications of the system prior to production.
- Formal and must be done by a specific user, customer, representative.
- Must be done at designated field sites.
- The operational procedures and documentation must be completed.
- Test can be long, over a period of time, covering systems components, etc.
- Formal test requiring all elements of the system to demonstrate their performance as a part of the system and/or individual.

Real Operation Tests

- During product use by customers.
- This testing is required to improve the product, provide maintenance and service and correct any errors.
- This test has to be done in a real, operational environment.

Documentation

- The objective of documentation is to document concepts, designs, rationale, materials, supplies, test results, etc.
- Documentation must begin at an early stage, from conceptual design to the final operation and service.
- Documentation requires more than lip service from senior management and requires resources, funds and authority.
- Example of system documentation (Canadian Artificial Heart - System 3).

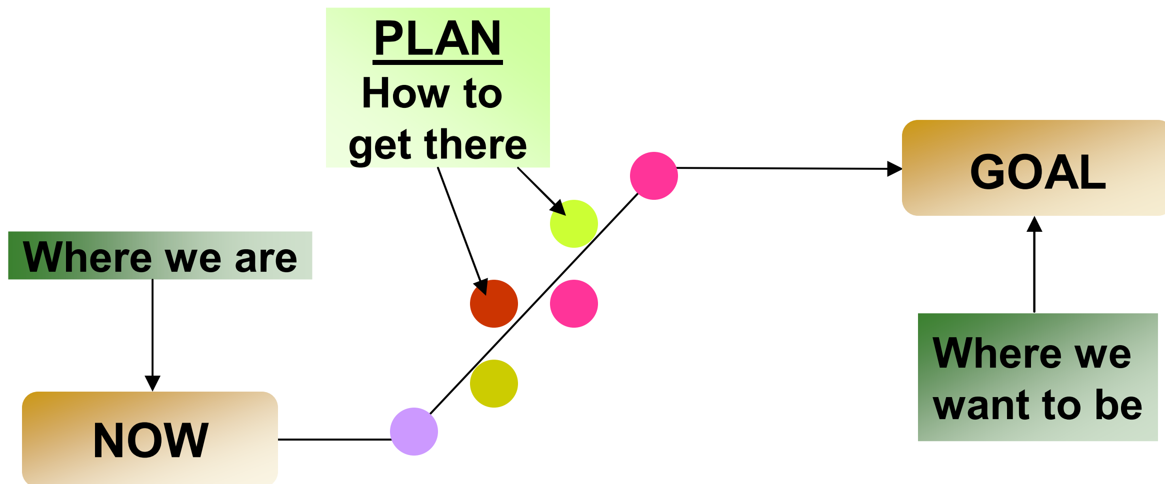
SYSTEM TREE

Overall Unified System

- **1. Implanted System**
  - **1. Blood Pump Unit**
    - **1. Internal Controller**
    - **2. Energy Converter**
    - **3. Passive Filling**
    - **4. Blood Diaphragm Position Detection**
    - **5. Diaphragms**
    - **6. Feed-Through Assemblies**
    - **7. Hydraulic Oil**
    - **8. Oil Filling**
    - **9. TEIT Interface Cable & Connector**
    - **10. Battery Interface Cable & Connector**
    - **11. Unit Shell and Hardware**
  - **2. Internal TEIT**
  - **3. Internal Battery**
  - **4. Cannulae**
  - **5. Cardiac Valves**
- **2. External System**
  - **1. External Controller**
  - **2. External TEIT Antenna Assembly**
  - **3. Support Garment and Harness**
  - **4. External Batteries**
- **3. Support Equipment**
  - **1. Patient Support Equipment**
    - **1. Home Battery Charge/Storage**
    - **2. Spare Batteries**
  - **2. Clinical-Surgical Support Equipment**
    - **1. Specialized Surgical Equipment and Instruments**
    - **2. System Monitoring and Analysis PC Software**

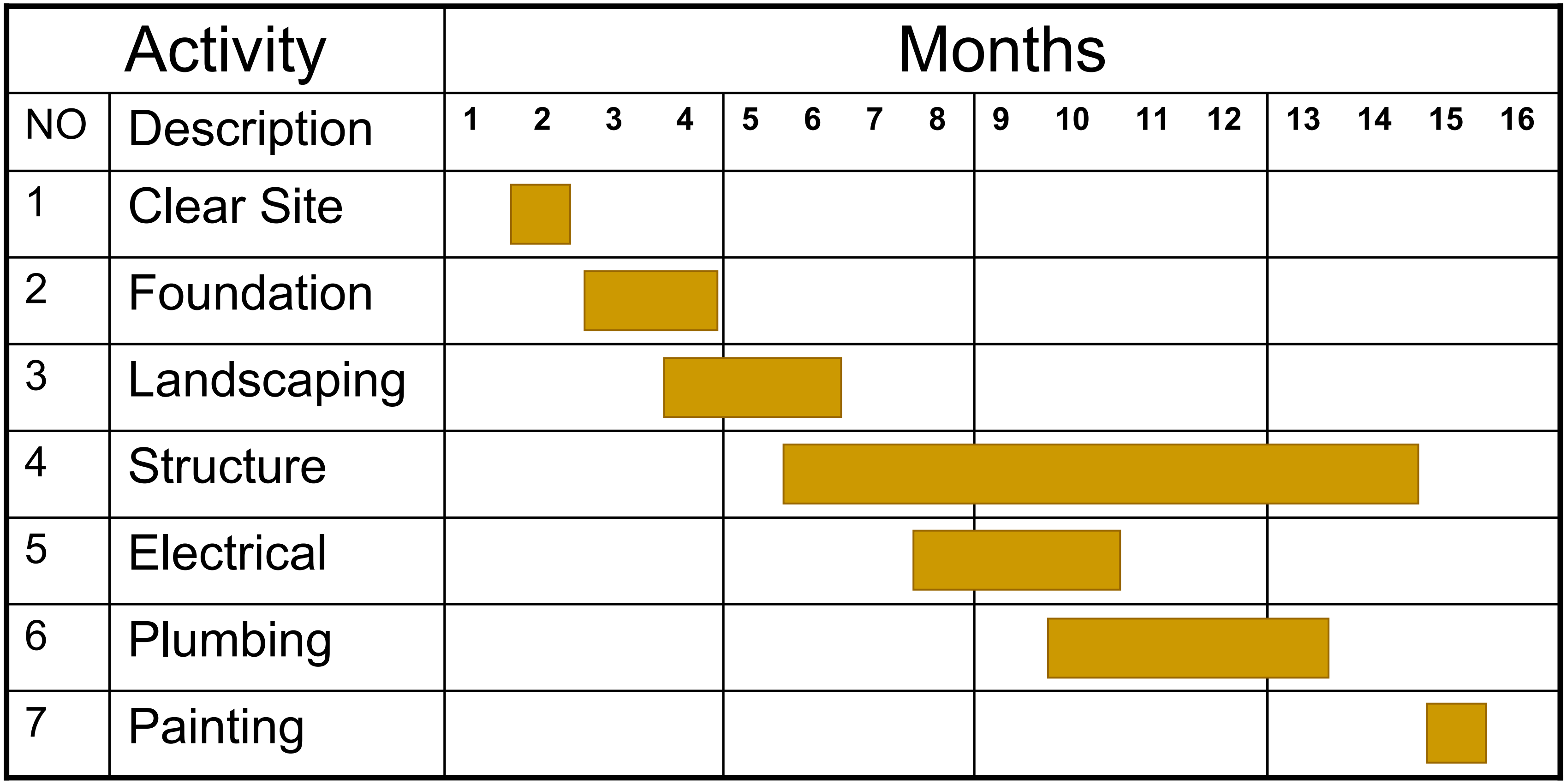
Project Management

- In order to meet a project's objective the project passes through distinct stages just as the development of a system. These stages begin with a concept from which the objectives or the requirements are analyzed. The project is then defined in terms of the best strategy to complete the project. Once a strategy or design is adopted, the project can then implemented following which a post implementation review is undertaken. The significance of each phase is parallel to those of the system's development process.



- Each phase of the project requires that activities be done to ensure that the phase is completed and that the output or deliverables are in time for the subsequent phases. For this, the project (or systems) manager must have a plan by which he can measure performance during the phases of the project and when necessary take the necessary steps to bring the project back on track (control) whenever it deviates from this plan. The plan (or model) of the project is usually in the form of a chart or graph that illustrates the activities of the project in a time related scale.

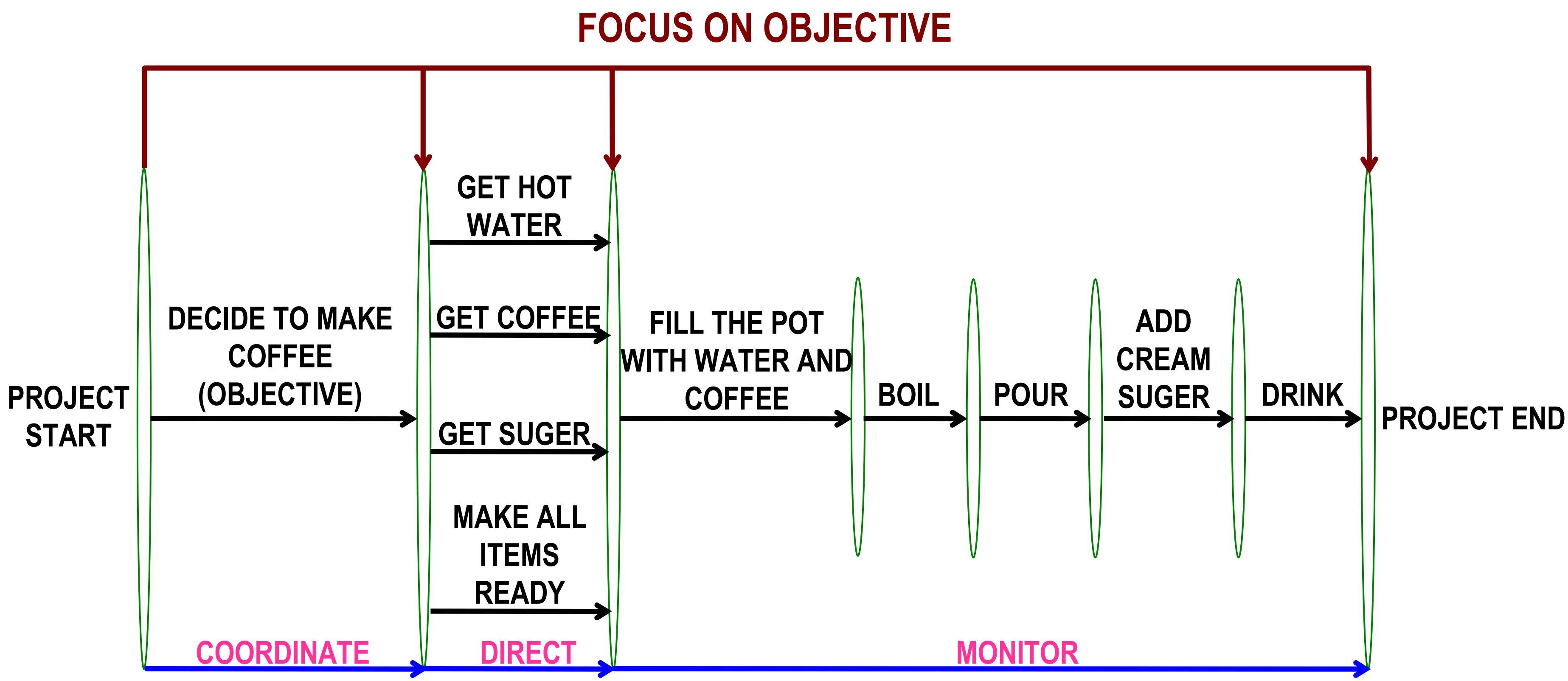
An example of such a chart is the bar chart in which each activity is represented by rectangular bar, the length of which is proportional to its duration:



Critical Path Analysis

- The bar chart however is limited in that it cannot resolve the logical interrelationships between activities. The logical relationships are as follows:
  - Concurrence - activities being performed simultaneously
  - Precedence - activities that must be completed before the next is started
  - Succession - activities that can only start after the completion of others
- A method used to generate a graphical model of a project that enforces these logical relationships is the critical path analysis. This method imposes logic on the sequence of activities to determine the longest duration of the project. The longest duration comprises the flow of activities form which is any of the individual duration is changed the project duration is altered. This sequence of activities form what is called the critical path and all activities on it are critical.

An illustration of how the logic is applied is shown here; a simple “Coffee Making Project”:



A Simple Coffee Making Project (Mussivand)

Critical Path Method (CPM) & Program Evaluation and Review Technique (PERT)

- There are two widely known methods which can be used to develop a graphical model or network of the project using a critical path analysis.
  - The first is called the Critical Path Method (CPM) and the other the Program Evaluation and Review Technique (PERT). Both were introduced in about the 60's but with different applications.
  - CPM was first used in 1956 by Du Pont to schedule activities related to design and construction.
  - PERT was Developed in 1958 by a management consultant group working under the US Navy, to manage the Polaris Fleet Ballistic Missile.
- Despite their different backgrounds, the use of both CPM and PERT is consistent with the organization, implementation and control of undertakings, to ensure that they are completed successfully.

Critical Path Method

- **Critical Path Method (CPM)**
  In a graphical network format, the activities (tasks) of the project become the system components, and the system structure reflects the logical interconnections of these tasks. There are two modeling formats that have evolved for the CPM network. The first is called the circle notation where each task is represented by a node and the relationships are shown by arrows (activity on node). The other format is called the arrow diagram where the tasks are modeled by arrows and the nodes indicate the relationships between the tasks (activity on arrow). It should be noted that for arrow notation to depict the proper scheduling of activities, it is necessary to add a logic branch known as a dummy activity. The use of the dummy activity maintains the logic in the ordering of the activities. It is referred to as a dummy activity because no time is allowed for it.

- **Critical Path Analysis**
  Given the duration for each activity in both the circle and arrow notations we are able to analyze the scheduling of the activities to determine the following;
  - The earliest time at which an activity may be started (earliest start time)
  - The latest time at which an activity may be started (latest start time)
  - The earliest time at which an activity may be finished (earliest finish time)
  - The latest time at which an activity may be finished (latest finish time)
  - The minimum time in which the total project may be completed (project duration)
  - Slack or float time for an activity; the difference between the earliest start time and latest start time

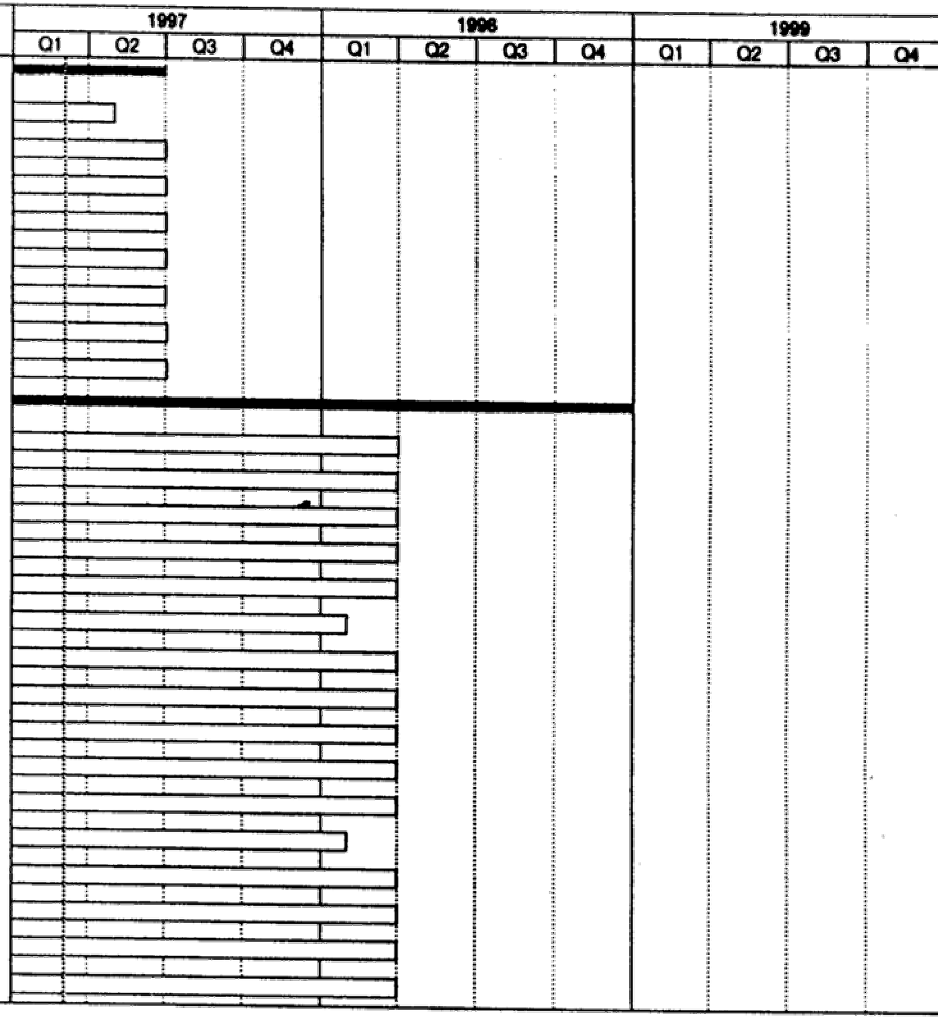
  The minimum time in which the project can be completed is given by the sum of the duration of activities for which the slack time is zero. These activities form the critical path and any delay on the critical path will cause the project's completion date to be delayed also. The following section will illustrate how these times are calculated and how they are used to determine the critical path. The format used will be the arrow notation but the principle is equally valid for the circle notation.

HeartSaver VAD Commercialization Plan

Date	Milestone
1989 4th Qtr	Specification & Development Concept Proven
1996 4th Qtr	Final Specifications & Design Freeze
1997 2nd Qtr	Development & Manufacturing
1998 1st Qtr	Formal System Testing (In Vitro & In Vivo)
1999 1st Qtr	Regulatory Approvals for Clinical Trials
1999 3rd Qtr	Clinical Trials (First Revenue) & Pre-market Regulatory Approvals
2001 4th Qtr	Commercial Production & Distribution

Figure 2. Heart Saver VAD Task Breakdown

ID	WBS	Task Name
1	1	***Final Specifications & Design Freeze***
2	1.1	Fabricate 10 HeartSaver Systems (ver. 5.1)
3	1.2	System Level Specification
4	1.3	Control System Specification
5	1.4	VAD Unit Specification
6	1.5	Test Equipment Specification
7	1.6	Battery Systems Specification
8	1.7	Clinical Tools & Accessories Specificiation
9	1.8	User Carrying System Specification
10	2	***Development & Manufacturing***
11	2.1	HeartSaver VAD Assembly
12	2.2	Energy Convertor
13	2.3	Implantable Connectors
14	2.4	Passive Fill Valve
15	2.5	Internal Controller Electronics
16	2.6	Internal Controller Software
17	2.7	Cannulae Development
18	2.8	Internal Battery
19	2.9	TEIT Coil Assemblies
20	2.10	External Controller Assembly
21	2.11	External Controller Electronics
22	2.12	External Controller Software
23	2.13	External Battery
24	2.14	User Carrying System
25	2.15	Homer User Interface
26	2.16	User External Battery Charger



ID = Serial Identification Number
WBS = Work Breakdown Structure

Summary | Task | Milestone ◆

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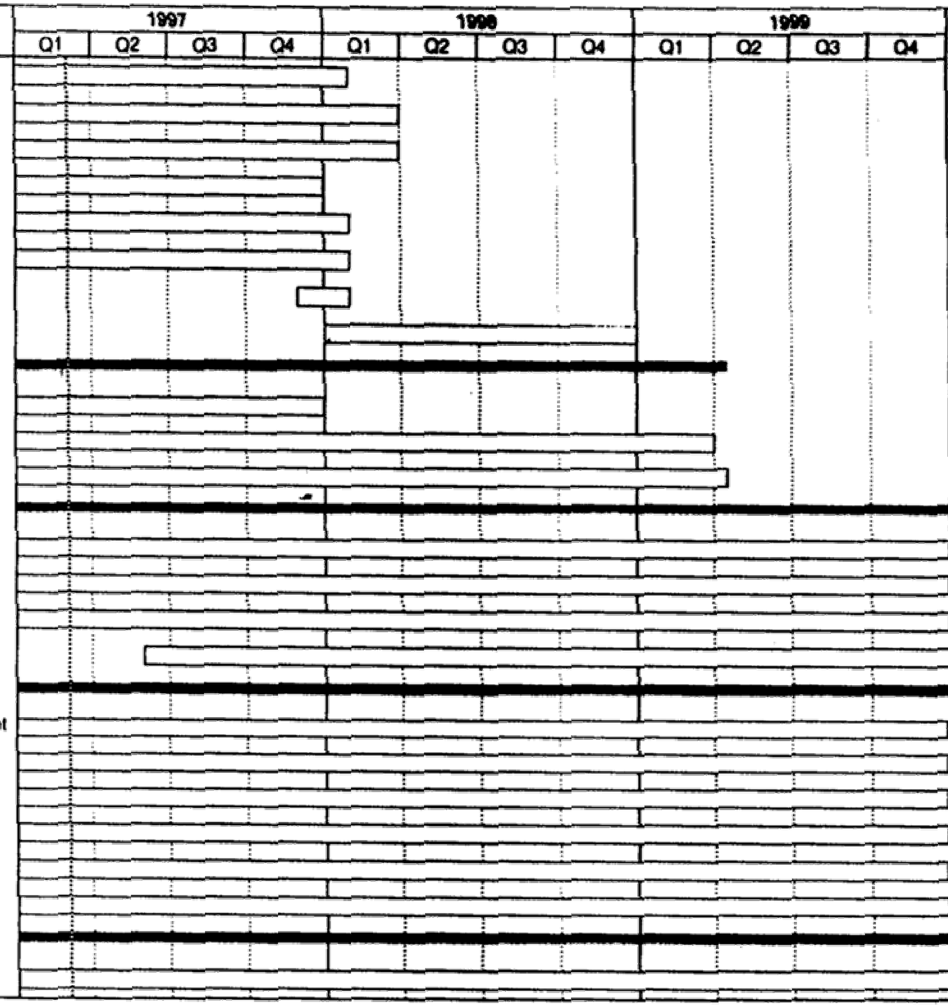
Figure 2. Heart Saver VAD Task Breakdown

ID	WBS	Task Name
27	2.17	Clinical Control Interface
28	2.18	Clinical Internal Battery Charger
29	2.19	Clinical Tools & Accessories
30	2.20	Pilot Facilities Development
31	2.21	Special Purpose Test Equipment
32	2.22	Special Purpose Fixtures & Jigs
33	2.23	System Level Design Evaluation
34	2.24	Ongoing Component Fabrication
35	3	***Testing (In Vitro & In Vivo)***
36	3.1	In Vitro Test Equipment
37	3.2	Formal In Vitro Test
38	3.3	In Vivo Test
39	4	***Regulatory Approvals for Clinical Trials***
40	4.1	Device Documentation
41	4.2	Regulatory Affairs
42	4.3	Quality Assurance
43	4.4	Facility Certification
44	5	***Clinical Trials Preparation***
45	5.1	Protocol, Procedures & Training Development
46	5.2	Clinical Trial Center Recruitment
47	5.3	Clinical Trial Data Collection & Analysis
48	5.4	Preparation for Distribution & Service
49	5.5	Sales & Marketing
50	5.6	Clinical Trial Coordination
51	6	***Project Management & Coordination***
52	6.1	Project Management



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Summary — Task — Milestone ◆

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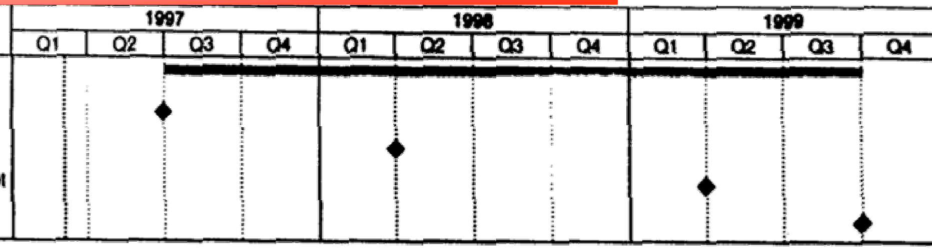
Figure 2. Heart Saver VAD Task Breakdown

ID	WBS	Task Name
53	7	*Milestones*
54	7.1	Final Specification & Design Freeze
55	7.2	Formal System Level Testing Start
56	7.3	Clinical Trials Regulatory Submission Complet
57	7.4	Clinical Trials Start



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Summary Task Milestone ◆

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Figure 2. Heart Saver Family Tree