

Client Background

C.A.R.S.

- Center for Assessment of Radiological Services
- Patient Safety Organization based at the University of Wisconsin
- Goal: Establish new standards in radiation treatment
- Radiological Incident Reporting and Assessment System (RIRAS)



Leo Cancer

Leo Cancer is responsible for pioneering radiation treatment machines that deliver care from a seated position, rather than the traditional horizontal position. Their emphasis on patient autonomy drives their solutions.

Middleton, WI
West Sussex, UK



Client Visit

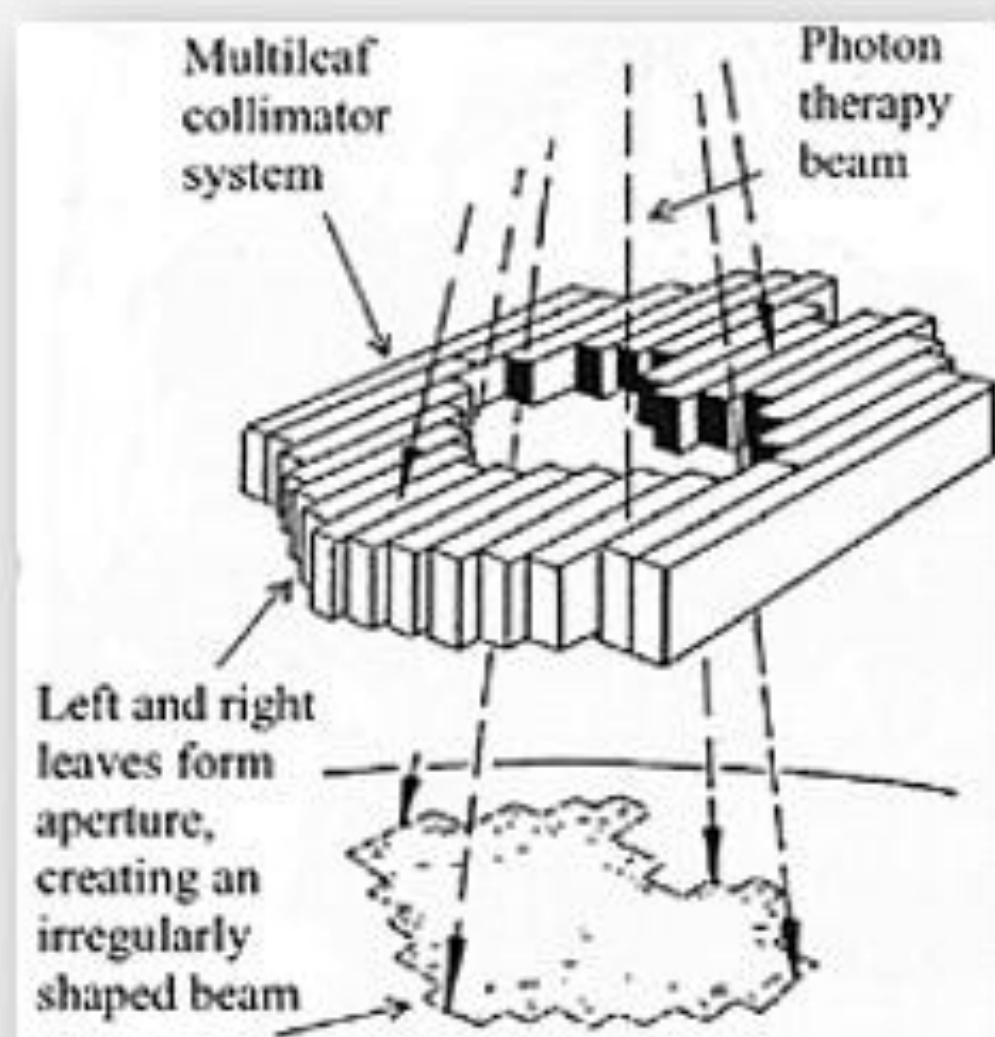
SSM Health St. Mary's Radiation and Oncology Department
Janesville, WI



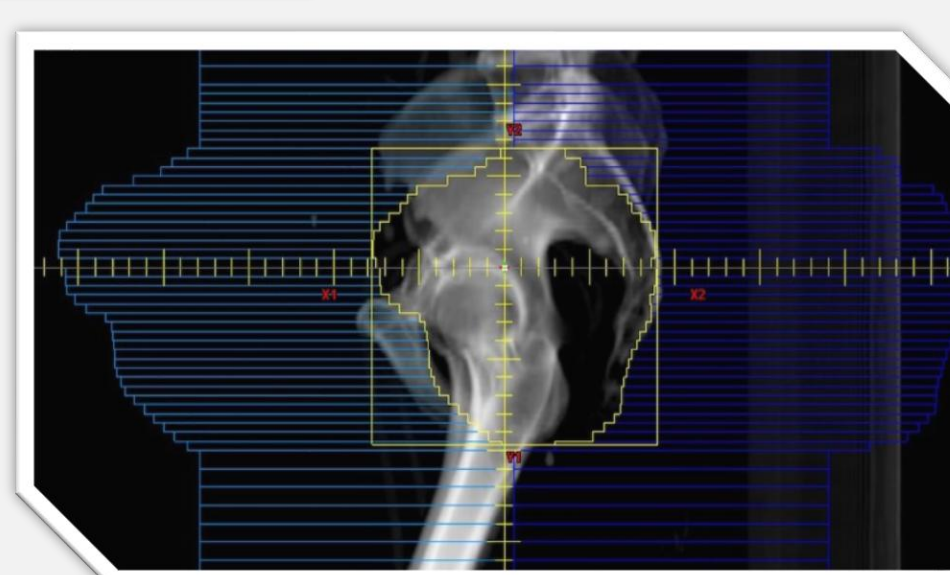
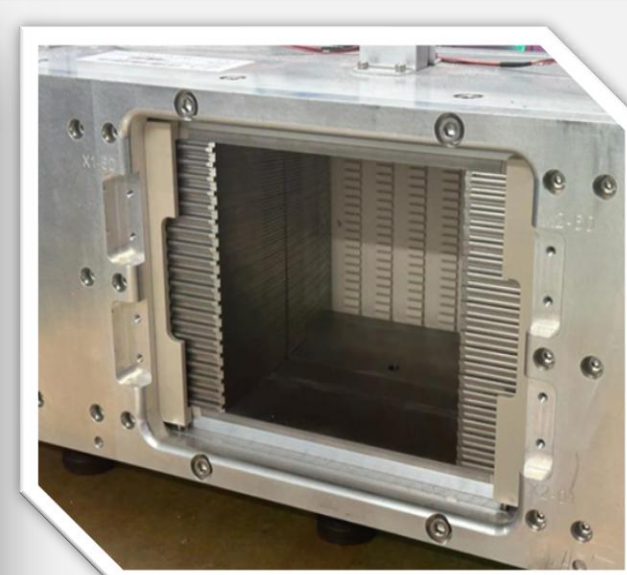
Problem Statement

Due to the cutting edge and unique design of Leo Cancer's new upright positioned radiation treatment device, the team does not have a process that clearly analyzes key equipment components to predict downtime and analyze performance of sub-systems within the machine. Extended downtime leads to financial losses for Leo Cancer and clinics using their system. Unpredicted failures and a lack of predictive maintenance planning can pose health risks to patients both in delay of care and potential for incorrect administration of dosing.

MLC System



A multileaf collimator (MLC) system.



- The MLC is a device used in radiotherapy to shape and modulate a radiation beam according to a customized, targeted contours
- Minimizes radiation exposure to surrounding healthy tissue



Figure above: Depiction of MLC leaves general main function.
Figure center: Image of Leo Cancer MLC as an unfinished build.
Figure upper right: Image of MLC leaves following the contour of cancerous tissue
Figure lower right: Image of Leo Cancer seated-upright RT solution

Solution

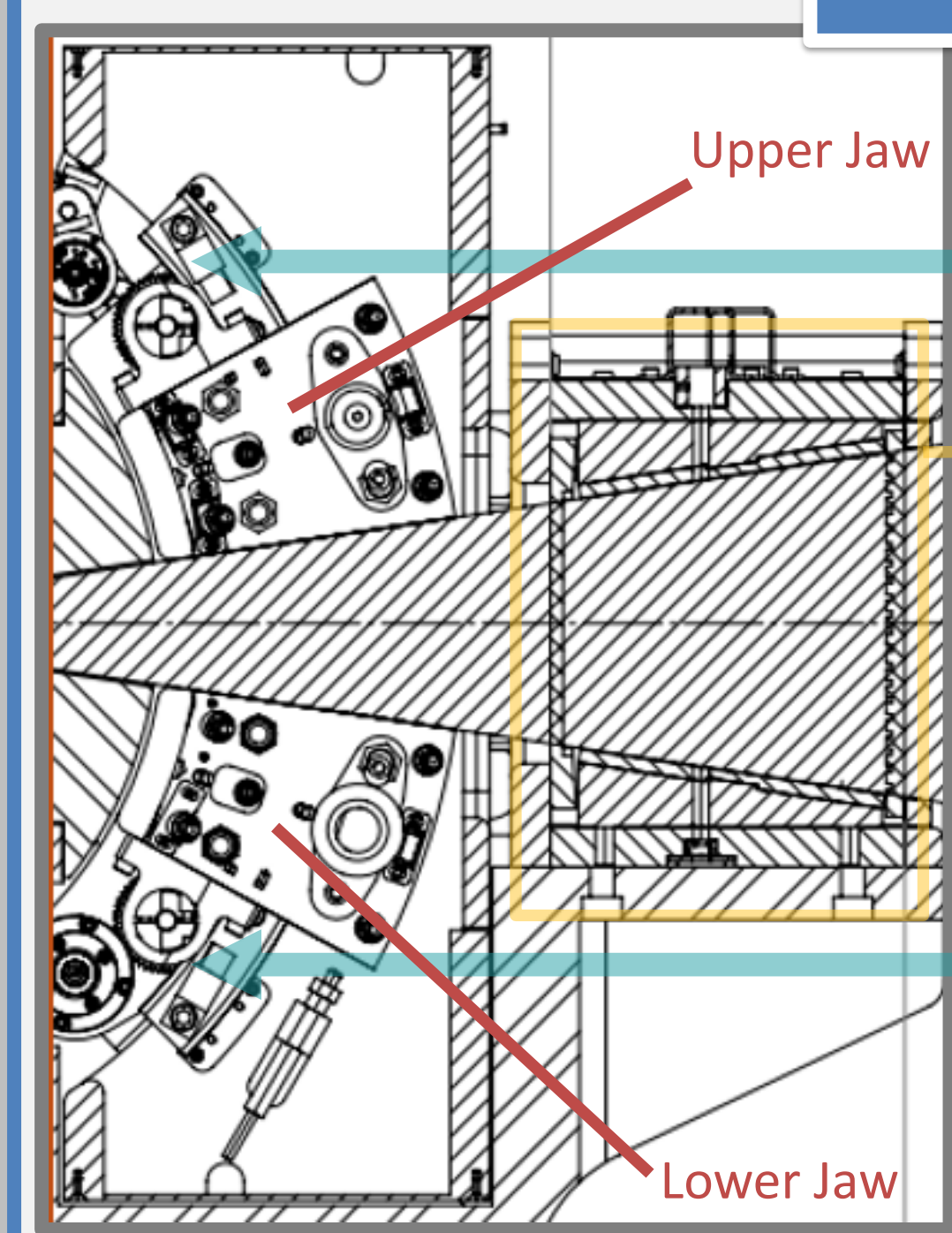


Figure Above: Leo Cancer unit model depicting the jaws and MLC mechanisms (cropped to meet NDA purposes)

Synthetic data

- Simulated after small Brushed DC motors:
- Speed: 5 – 20 mm/s
- Torque: 0.01 – 0.4 Nm
- Load: 10 – 30 N
- Data shown is of a **worn** motor

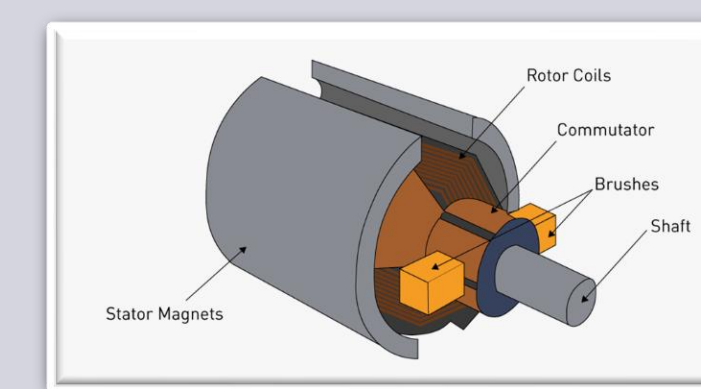


Figure above: Brushed DC motor diagram.

Proof of Concept

Analyzing motor performance with S.P.C.

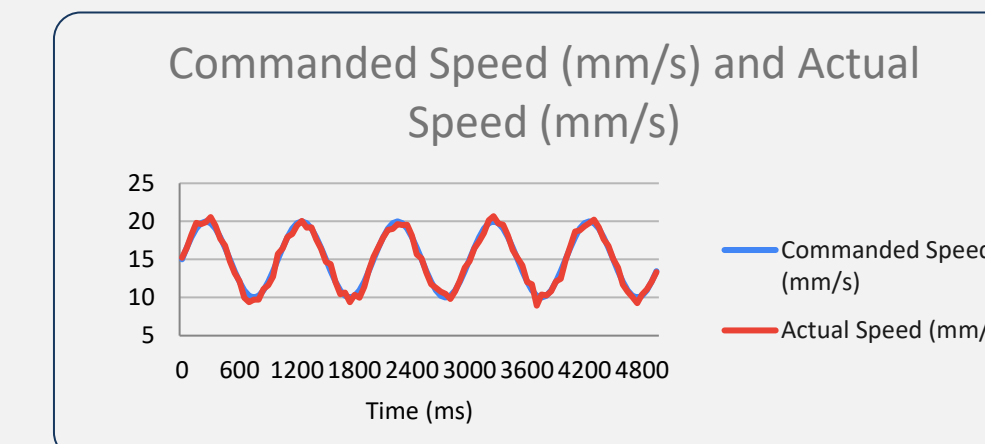


Figure above: Commanded Speed vs Actual Speed, showing slight deviation.

Data specifics:

- Mechanical system
- Periodic behavior

What to look for?

- Trends in data reflecting performance

Possible Reason for Failures:

- Degradation
- Radiation exposure
- Positioning errors

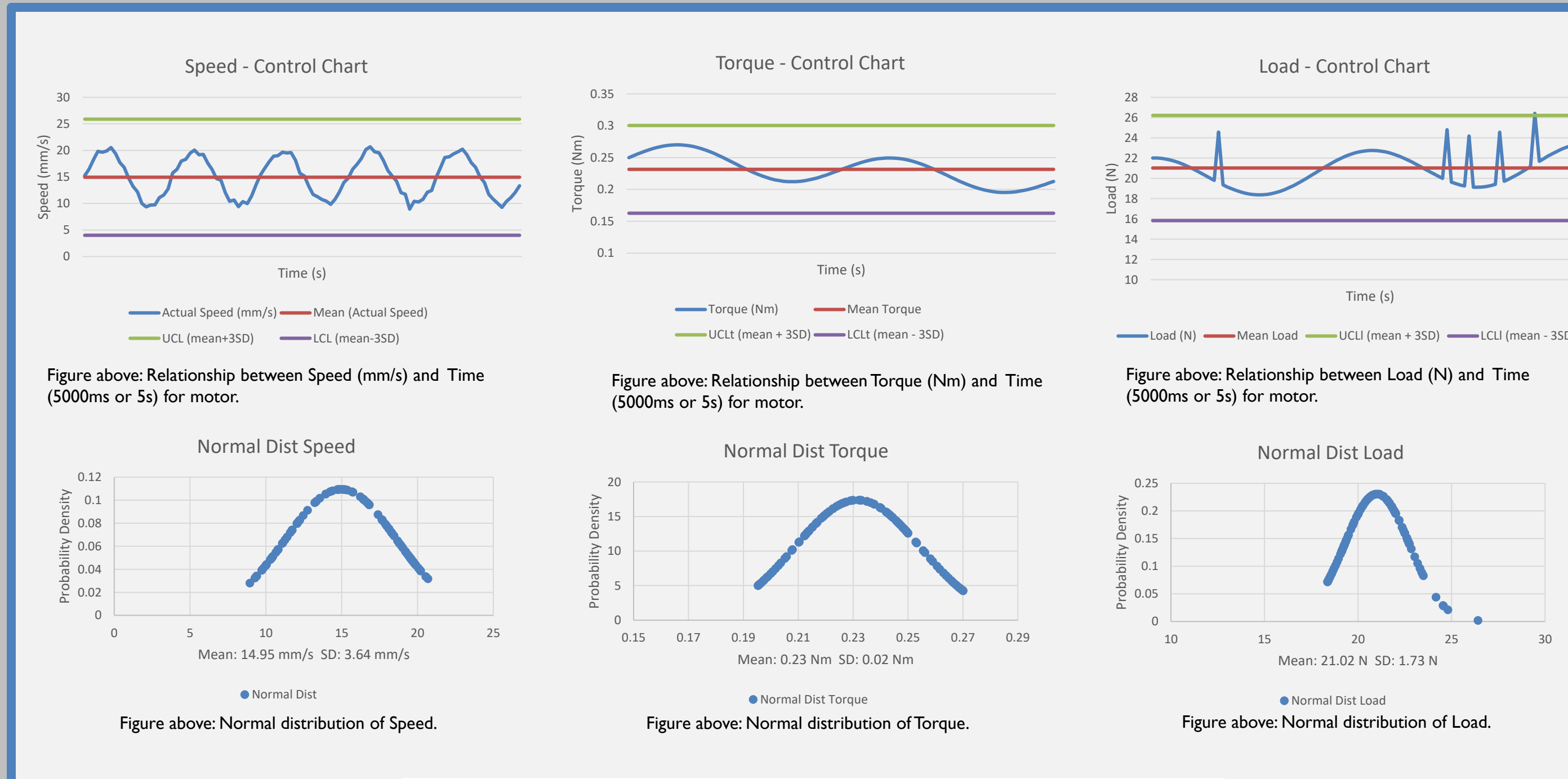
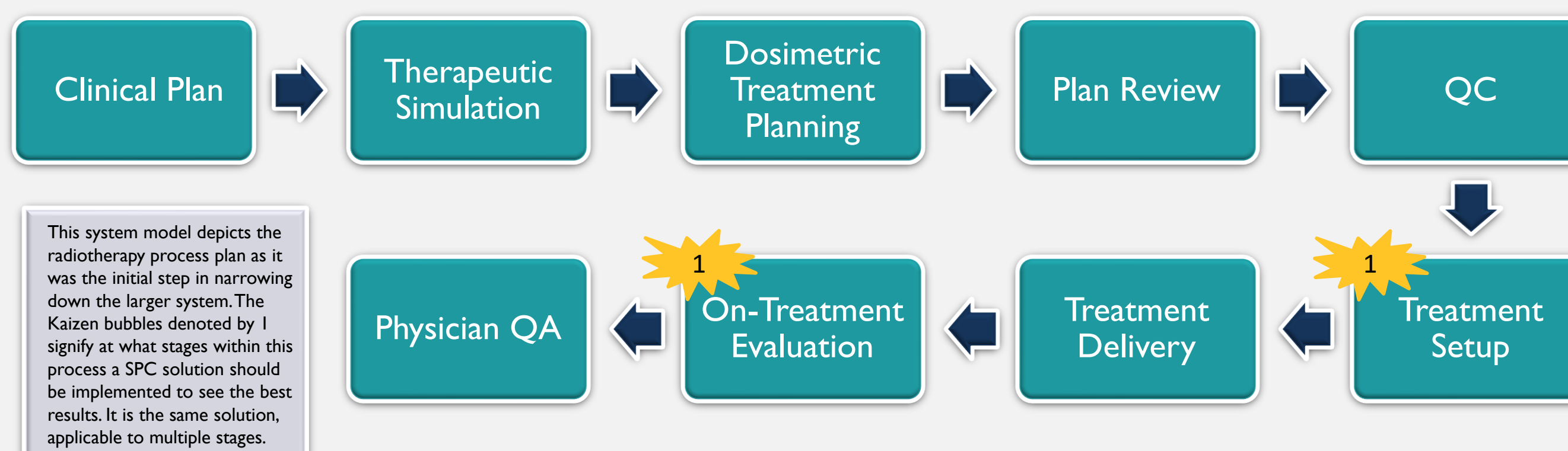


Figure above: Normal distribution of Speed.

Figure above: Normal distribution of Torque.

Figure above: Normal distribution of Load.

System Model



This system model depicts the radiotherapy process plan as it was the initial step in narrowing down the larger system. The Kaizen bubbles denoted by 1 signify at what stages within this process a SPC solution should be implemented to see the best results. It is the same solution, applicable to multiple stages.

S.P.C.

Methodology

Collecting/Obtaining data

Calculating mean, standard deviation, upper control limit, and lower control limit

Plotting on a control chart to visualize center line, Upper control limit, and Lower control limit

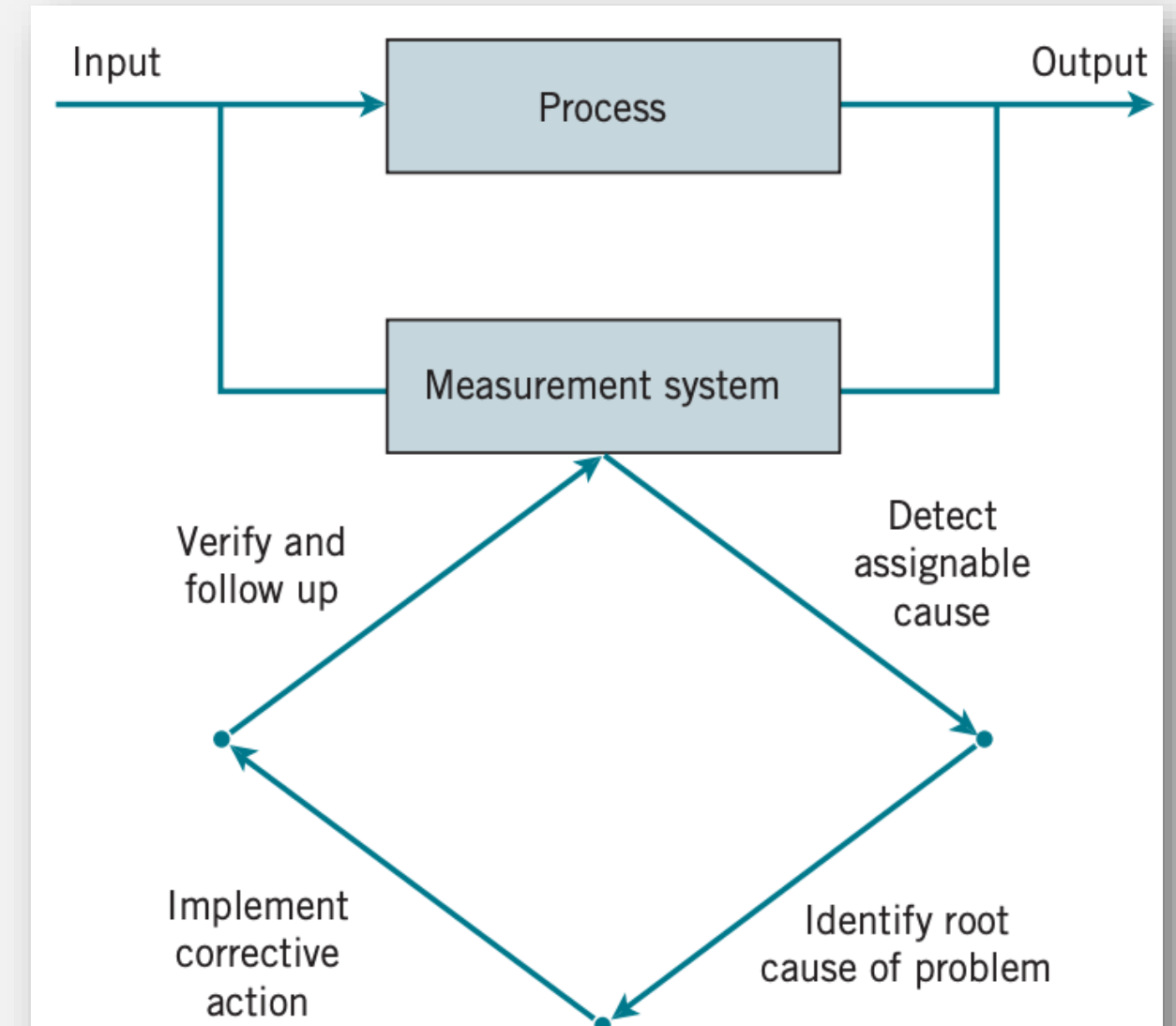
Statistical Process Control

$$UCL = \mu_w + k\sigma_w$$

$$CL = \mu_w$$

$$LCL = \mu_w - k\sigma_w$$

- One point plots outside 3-sigma control limits.
- Two of three consecutive points plot beyond a 2-sigma limit.
- Four of five consecutive points plot at a distance of one sigma or beyond from the center line.
- Eight consecutive points plot on one side of the center line.



Decision Matrix

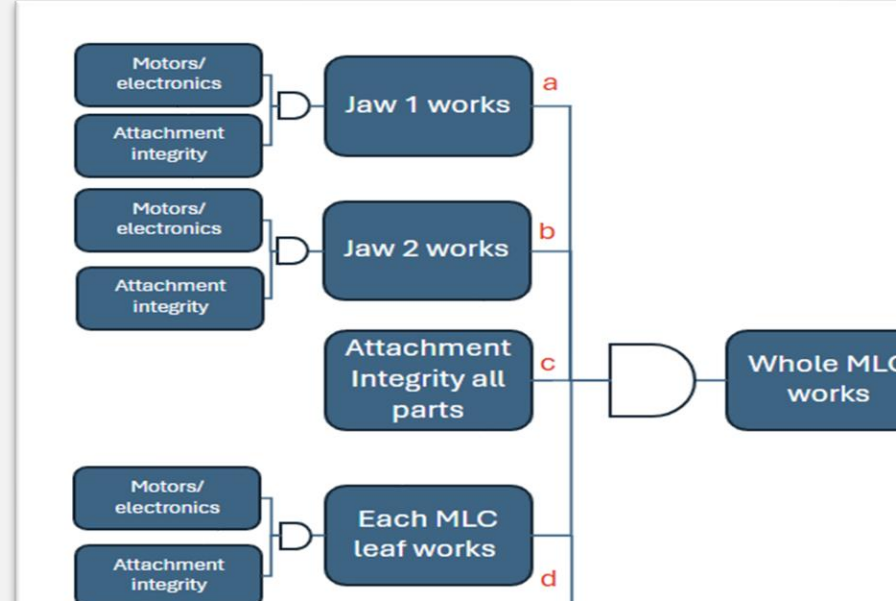


Figure Left: Go chart on MLC function formulated by Leo Cancer engineer

Figure Right: Decision matrix formulated based on Leo Cancer machinery specifications

Features	Multileaf Collimator (MLC)	Immobilization Techniques	Seat (Couch/Gurney)	Beam Production Technology
New technology used	✓	✓	✓	
New material used	✓			
Impactful on patient care	✓	✓	✓	✓
Impactful on radiology treatment success	✓	✓	✓	✓
Feasible functional data	✓			✓

Expected Results

Decreased Downtime

- Increased Treatment Capacity
- Improved Scheduling Reliability
- Minimized Treatment Delays
- Higher Equipment Utilization
- Enhanced Patient Throughput



Increased Patient Safety

- Enhanced Monitoring of Safety-Critical Metrics
- Supports Regulatory Compliance and Safety Standards
- Improved Treatment Precision
- Proactive Error Prevention



Next Steps

How will SPC act as a tool?

