provision center for PROTONTHERAPY

Reliability and Uptime in Proton Therapy Accelerator and Beam Delivery Systems;

The Need for a Fresh Medical Device Design Methodology.

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Outline

- Current systems
- Fail Safe thinking – some misconceptions
- Lessons from the airline industry
- Case Studies
- Down-time Tracking + Management
- New Thinking

Disclaimers

- **There is no compromise for**

  a) Patient safety

  b) Personnel safety

- **Nothing that I propose here should compromise safety**

- **There is no excuse for an improperly designed System.**

- **There is no excuse for an improperly tested / commissioned System**

Misconceptions in Current Systems

- **Incorrect Technical Approaches**
  - Fail the system if anything goes wrong / out of tolerance.
  - Let the control systems make all the decisions.
  - Slowing things down improves safety.
  - Limiting functional capabilities improves safety.
  - Proton Therapy systems are more dangerous than X-Ray Systems.
  - The more checks, the more safe the system becomes.

- ***The safest system is one that does never treats a patient.***

Revised Title

The Clinical Medical Physicist's Perspective on Designing a Proton Therapy System

Misconceptions in Current Systems

- **Incorrect Operational Approaches / Paradigms**
  - The trained staff's only objective is to harm the patients or damage the equipment.
  - More emphasis on protecting the equipment rather than finishing the treatment.
  - Proton Therapy systems are more dangerous than X-Ray Systems.
  - Untrained people are operating the systems.
  - Completing a treatment at the scheduled time is less important than fixing the system.

“Fail Safe” thinking

- **Great idea but the focus should not be on “FAIL”**
- **Only “FAIL” the system after a treatment has been completed**
  - Delivering a partial treatment is worse than delivering a treatment with a small uncertainty /risk
- **Paradigm Shift**
  - There are very few things in a radiation therapy system that can harm the patient
- **Lets try to list those**
  - Over dose – many ways to protect against this.
  - Too high beam current – operational parameters within certain windows.
  - Beam scanned to the wrong position – several redundancies can be implemented.
- **Operational risks are much higher**
  - wrong dose / # fractions delivered perfectly correct.
  - Treat wrong site / setup errors.

Learning From the Airline Industry

- **Never Fail the plane in “Mid-Air”**
  - “First land the plane” – get the passengers off – then take the plane to the hanger – fix it
- **Preventative + Predictive maintenance**
- **Redundancies**

  e.g. Manual / Pilot emergency landing at the nearest airport

  - the control systems did not prevent the pilot to land on the Hudson River
- **Checklists rather than controls systems that are in full control**
- **Many more**

The Radiation Therapy Reality

- **Machines are operated by highly trained people**
- **Nobody wants to harm anybody**
- **Its very important (clinically and emotionally) to deliver treatments on time.**
- **Treatment deliveries must be delivered within certain tolerances**
  - Systematics errors are bad
  - Random errors often cancel out
- **Treatment plans are designed according to certain tolerances**
- **Fractionated treatments are more forgiving**
- **Operational risks are much higher**

Challenge

- **Design a traffic light**

- **The only way a traffic light can work is for the driver to obey the lights –**
  - Red → STOP; **Yellow** → Clear the intersection; Green → Go

- **What is required to drive a car**
  - Learn to drive the car + 16 years old
  - Obtain Drivers license
  - Can be done in 3 months
- **What is required to treat a patient**
  - Rad Onc → 11 years of training + ABR
  - Medical Physicist → 7 years of training + ABR
  - RTT → 3 years of training + ASRT

Much more that can go wrong
Much more dangerous

Systems Don't allow any user autonomy – Safety systems are in control

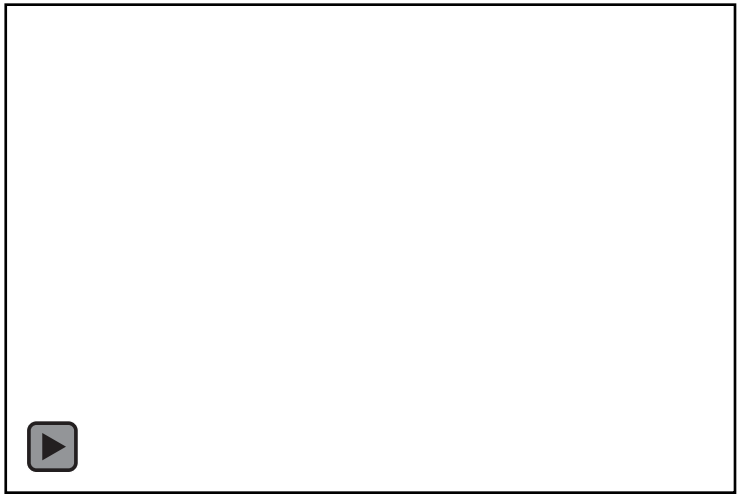
Control systems are in Full control – Why not ?

- **Users stop thinking**
  - The Computer must be correct (NY Accident)
  - Computers are always correct !!!
  - I cannot do anything anyhow – no user rights / permissions
  - Just going through the motions

- **Allow overrides at the discretion of the trained user**
  - Overrides expire automatically – time window depends on the risk
  - *This will allow to land the plane and take it to the hanger*

Limiting Capabilities improve safety

- **Allow only one motion at a time**
  - Current systems allow you to crash the systems –
    a) At slow speed
    b) One at a time



- **Multiple motions should be allowed**
  - Move as many things as the user can control
  - This will automatically attract undivided attention from the operator

- **IF the RTT Could move the Patient Positioner while the gantry is rotating this would not have happened**
- **Commercial linear Accelerators allow simultaneous motions**
- ***Let the trained and responsible staff decide what is safe***

Slowing things down improve safety

- **The user needs to multitask to get things done in time.**
- **Does other things instead of keeping an eye on the patient and equipment.**
- **Let the trained and responsible staff decide what is a safe speed of motion.**
- ***NOTE: there is nothing wrong with sensible warnings and alerts, but disallowing things that are potentially safe and that will improve efficiencies is the problem***

More Checks are More Safe ?

- **Checklists should not have more than 7 things to check**
- **Rather focus on the 7 top and most important things than checking 25 less important things.**
- **Human nature states that *"The more checks you have, the less important the initial checks / screening checks become"***
  - Someone will catch it at the bottom of the waterfall
- **The more unnecessary check there are, the more unnecessary failures can occur.**

New Thinking

- **FMEA must be done with the emphasis on completing a treatment**
- **Use a flagger – road works ahead**
  - Something is not right
  - Take extra care
  - Cross check – not all the checks are in place
- **Allow conditional overrides for all Interlocks that can be verified with at least one other method / tool**
  - Visually / inspection
  - Mechanically
  - Optically
  - Audibly

New Thinking

- **Modular Design Approaches**
  - Faster / more efficient trouble shooting.
- **Treatment rooms should be independent from each other**
  - Software Upgrades are easier.
- **Efficient Trouble shooting is as important as Reliability**
  - Things will break – BUT - How quick can you recover
  - Efficient trouble shooting will reduce downtime

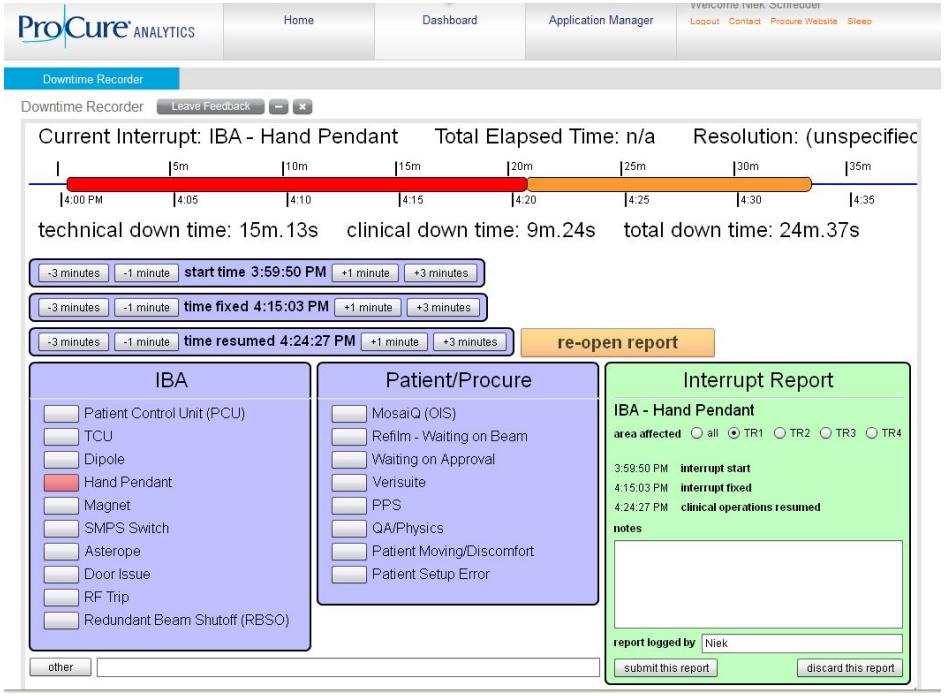
Use cases

- **X-Ray panels do not retract**
  - The protons never go through the patient
  - Shield the panel for flash beam
- **PPS goes unhealthy during a treatment**
  - Stop and verify that the patient is still in position
  - Appoint a flagger
- **Scan beam parameters are marginally out of tolerance**
  - Increase / override the tolerances to a next level
  - Tolerances reset automatically after the beam has beam delivered
- **Non Critical Inter system communication errors**
  - Verify that things are still good
  - Record data manually
  - Appoint a Flagger

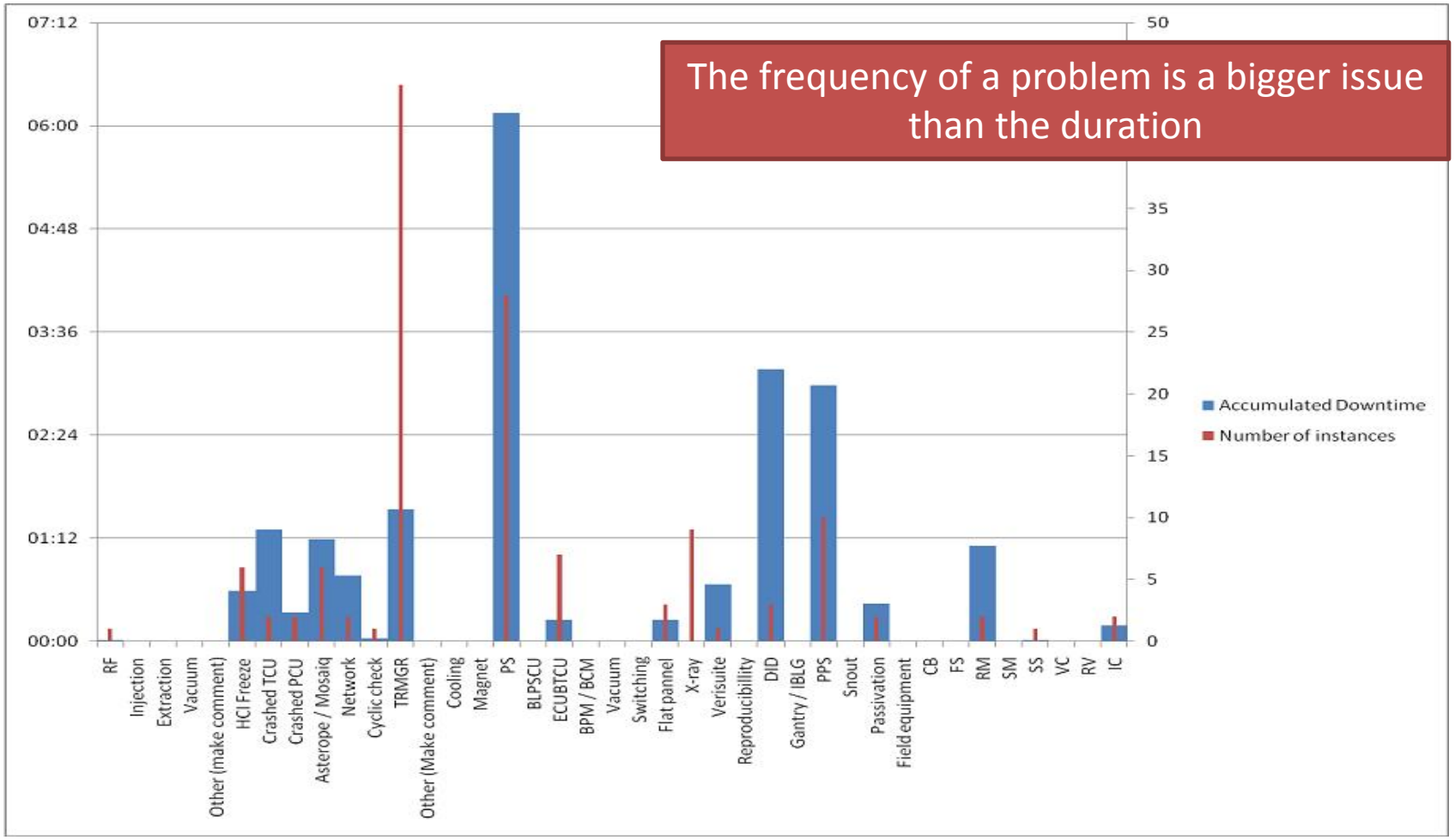
Down-Time tracking / Management

- **Technical Down-time vs Clinical Downtime**
- **A short technical down-time can easily lead to a large clinical downtime**

  - Patient ready to treat → need to take patient off the table due to a problem
  - Fix the problem
  - Treatment start from scratch again → Large clinical down-time



Downtime Duration vs Frequency



Desired Uptime

- **Ideal Definition → % of patients treated as scheduled.**
- **Typical Definition → System is available as scheduled per the contractual agreements.**

- **More than 98 % uptime is desired**
- **Less than 96 % uptime – things become extremely painful**
  - Staff morale ↓
  - Patient satisfaction ↓
  - *Clinical care is compromised*

Conclusions

- **Proton Therapy Systems are not more dangerous than X-Ray Therapy Systems.**
- **Proton Therapy Systems must be designed according to the same operational principles and safety guidelines as X-Ray Therapy Systems.**
- **Slowing things down and limiting functionalities does not improve safety.**
- **Completing a patient treatment must take priority over shutting the system down for repairs.**
- **Treating patients as scheduled is clinically and emotionally very important.**