# Reliability and Maintenance of Medical Devices

Dr. Sharareh Taghipour, Assistant Professor, PhD, LEL

Reliability, Risk, and Maintenance Research Laboratory (RRMR Lab)
Ryerson University

همایش
بین‌المللی مدیران فنی و نگهداری و تعمیرات

RYERSON UNIVERSITY

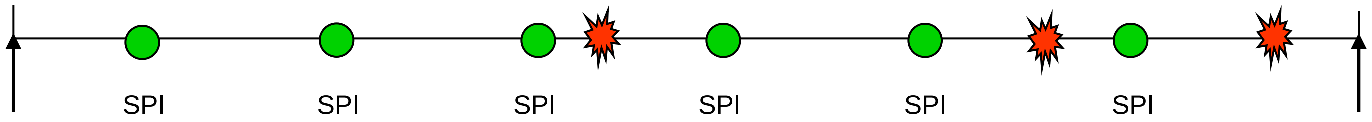
IPAMC 2016, October 23, 24, Tehran, Iran

# Presentation Outline

- Background
- Key problems
- Research contributions
- Prioritization of medical devices
- Failure data, statistical analysis and trend test
- Inspection optimization models
- Conclusion
- Future work

# Background

- Medical Equipment Management Program



Acceptance Test

Retirement/ Replacement

● SPI (Safety and Performance Inspection)

✹ Corrective Maintenance

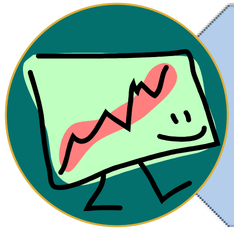
# Key Problems

- Which devices should be included in the MEMP?
- What maintenance strategy should be established for each class of devices?
- Which optimization models should be developed?

# Research Contributions

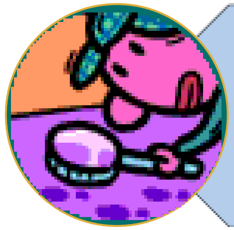
**Prioritization of Medical Devices**

1. Journal of the Operational Research Society, 2011, 62 (9): 1666-1687.



**Reliability and Trend Analysis of Medical Devices’ Failure Data**

2. Quality and Reliability Engineering International, 2011, 27(1): 71-84.
3. Reliability Engineering and System Safety, 2011, V.96 (10): 1340-1348.
4. Computers and Industrial Engineering, 2013, 64(1): 143-152.



**Inspection and Maintenance Optimization Models**

5. Reliability Engineering and System Safety, 2010, V.95(9): 944-952.
6. IEEE Transactions on Reliability, 2011, V.60(1): 275-285.
7. IIE Transactions, 2012, 44 (11): 932–948.
8. European Journal of Operational Research, 2012, V. 220 (3): 649-660.

# Criticality Assessment Model

*Goal*

**Prioritization of Medical Devices**

*Criteria*

**Function**

**ntenance uirements**

**Utilization**

Availability of Alternative Devices

**Device 1**

**Device 2**

**Device 3**

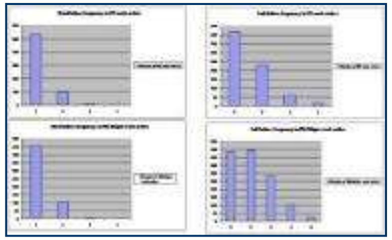
Device m

*Alternatives*

- Ranking medical devices
- Classification and maintenance strategies

# Failure Types: Soft & Hard

## General Infusion Pump



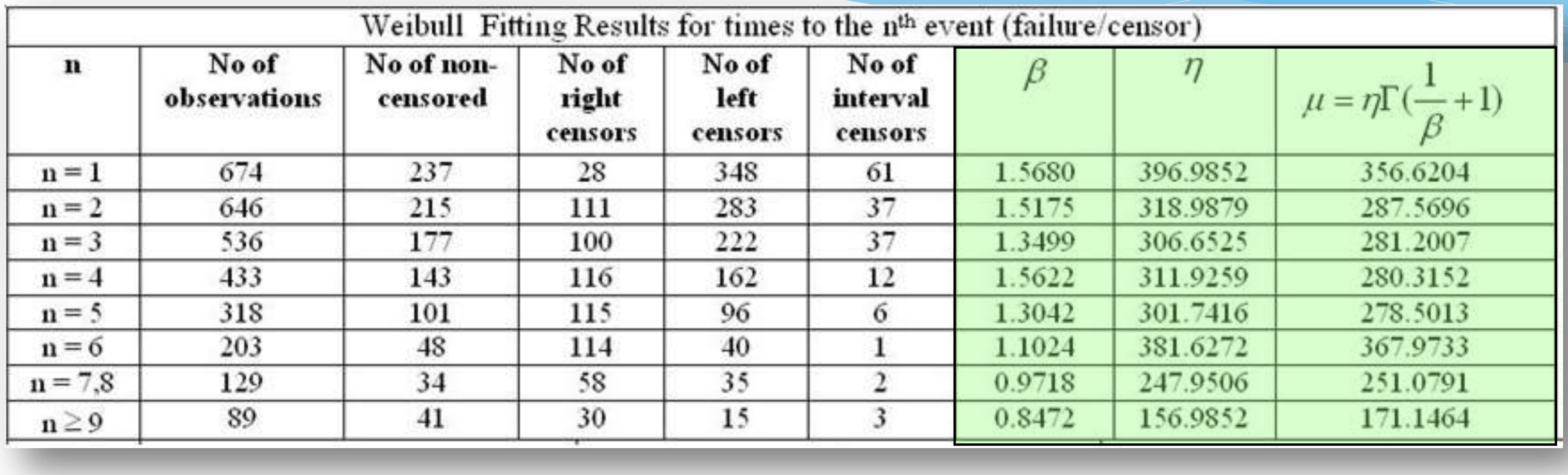
| Components with hard failure |
|---|
| AC Plug/Receptacles |
| Alarms |
| Controls/Switches |
| Indicators/Displays |
| Mount |
| Occlusion Alarm |

- The system stops
- Repaired immediately

| Components with soft failure |
|---|
| Audible Signals |
| Battery/Charger |
| Chassis/Housing |
| Fittings/Connectors |
| Labeling |

- The system can still function
- The performance is reduced
- Rectified at next inspection

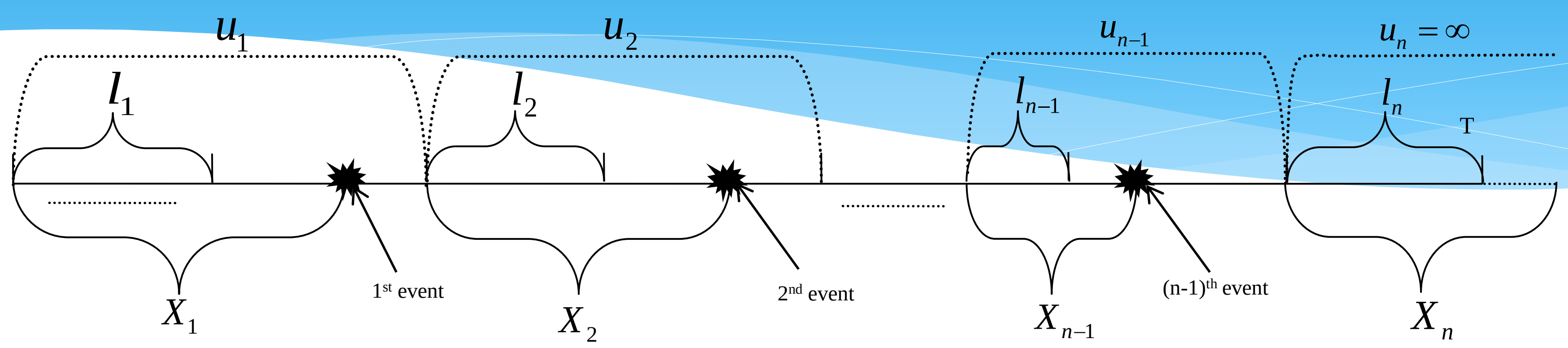
# Sample Results at System Level



Weibull Fitting Results for times to the n<sup>th</sup> event (failure/censor)

| n | No of observations | No of non-censored | No of right censors | No of left censors | No of interval censors | $\beta$ | $\eta$ | $\mu = \eta\Gamma(\frac{1}{\beta}+1)$ |
|---|---|---|---|---|---|---|---|---|
| n = 1 | 674 | 237 | 28 | 348 | 61 | 1.5680 | 396.9852 | 356.6204 |
| n = 2 | 646 | 215 | 111 | 283 | 37 | 1.5175 | 318.9879 | 287.5696 |
| n = 3 | 536 | 177 | 100 | 222 | 37 | 1.3499 | 306.6525 | 281.2007 |
| n = 4 | 433 | 143 | 116 | 162 | 12 | 1.5622 | 311.9259 | 280.3152 |
| n = 5 | 318 | 101 | 115 | 96 | 6 | 1.3042 | 301.7416 | 278.5013 |
| n = 6 | 203 | 48 | 114 | 40 | 1 | 1.1024 | 381.6272 | 367.9733 |
| n = 7,8 | 129 | 34 | 58 | 35 | 2 | 0.9718 | 247.9506 | 251.0791 |
| $n \geq 9$ | 89 | 41 | 30 | 15 | 3 | 0.8472 | 156.9852 | 171.1464 |

# Observed & Unobserved Data



- Repairable unit is inspected periodically
- Failures follow a NHPP with a power law intensity function

$$\lambda(x) = \beta e^{\alpha} x^{\beta-1}$$

- Failures are only rectified at inspections (censored failures)

$n$ events observed over time $T$. Events times $X_1,...,X_r,X_n$ where $X_i$ depends on $X_1+...+X_{i-1}$.

# Trend Analysis Using Likelihood Ratio Test

- We want to test whether the intensity of failures increases, decreases or is constant:

$H_0$ : Homogenous Poisson process $\beta = 1$

$H_1$ : Non-homogenous Poisson process $\beta \neq 1$

$L_0$ = Maximum likelihoods of the data when $\beta = 1$

$L_1$ = Maximum likelihoods of the data when $\beta \neq 1$

| Statistic | $\chi_1^2 = -2\ln(L_0 / L_1)$ |
|---|---|

Reject $H_0$ if $\chi_1^2$ is greater than an appropriate critical value $\chi_{1,\alpha}^2$

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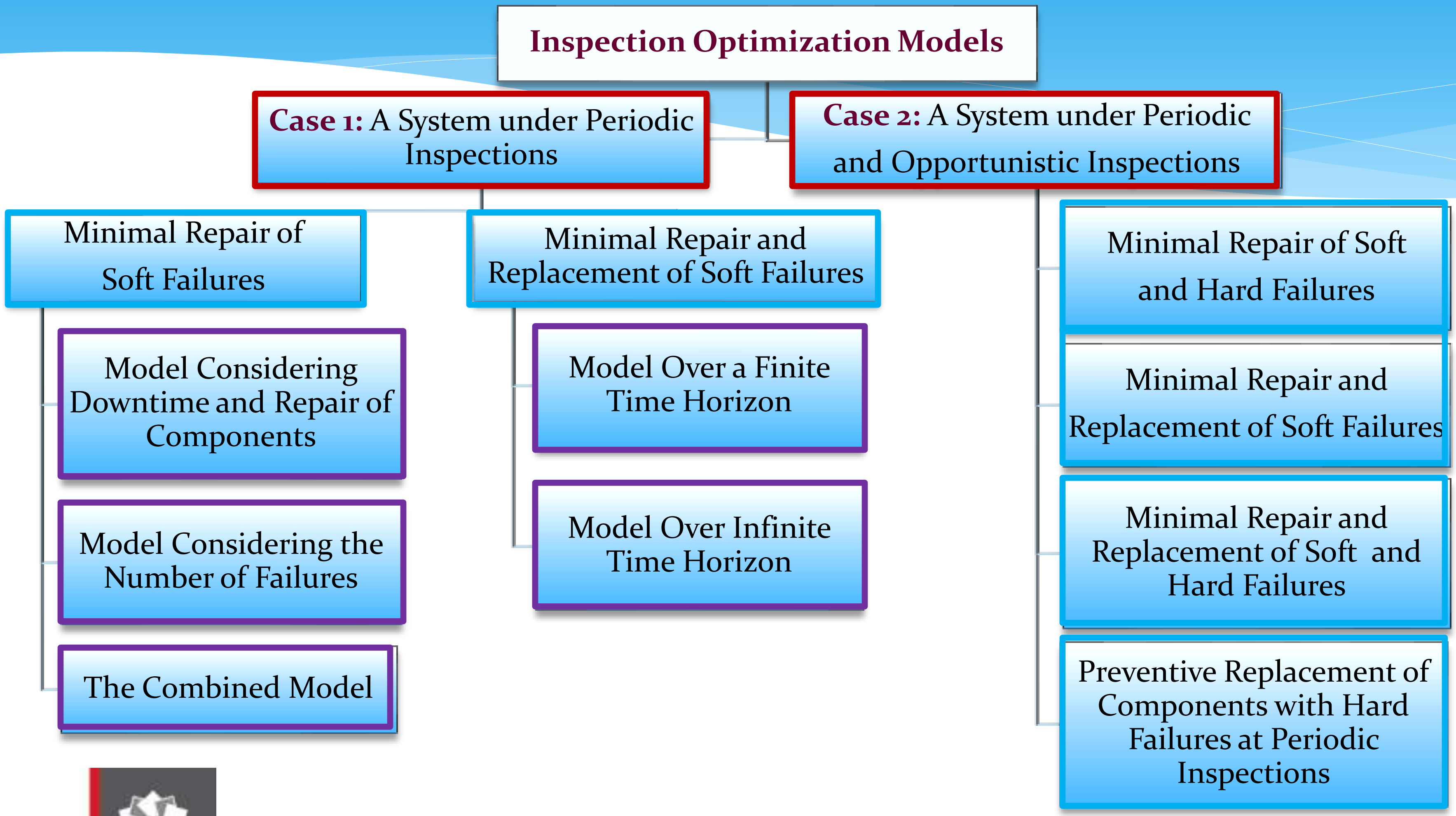
# Results of the Trend Analysis

- Audible signal (125 records, 80 units)
- Housing/chassis (164 records, 38 units)
- Battery (897 records, 674 units)
- Simulated date (690 records, 100 units)

| Component Name | Battery | Housing/chassis |
|---|---|---|
| Maximum Likelihood Using the EM Gradient $(\beta \neq 1)$ | $\hat{\alpha} = -2.912, \hat{\beta}=1.784$<br>$\ln(L_1) = -698.305$ | $\hat{\alpha} = -0.142, \hat{\beta} = 0.917$<br>$\ln(L_1) = -153.425$ |
| Maximum Likelihood $(\beta = 1)$ | $\alpha = -1.926$<br>$\ln(L_0) = -751.228$ | $\alpha = -0.280$<br>$\ln(L_0) = -153.536$ |
| $\chi_1^2$ | 105.846 | 0.222 |
| Conclusion | trend | no trend |

# Structure of the Optimization Models



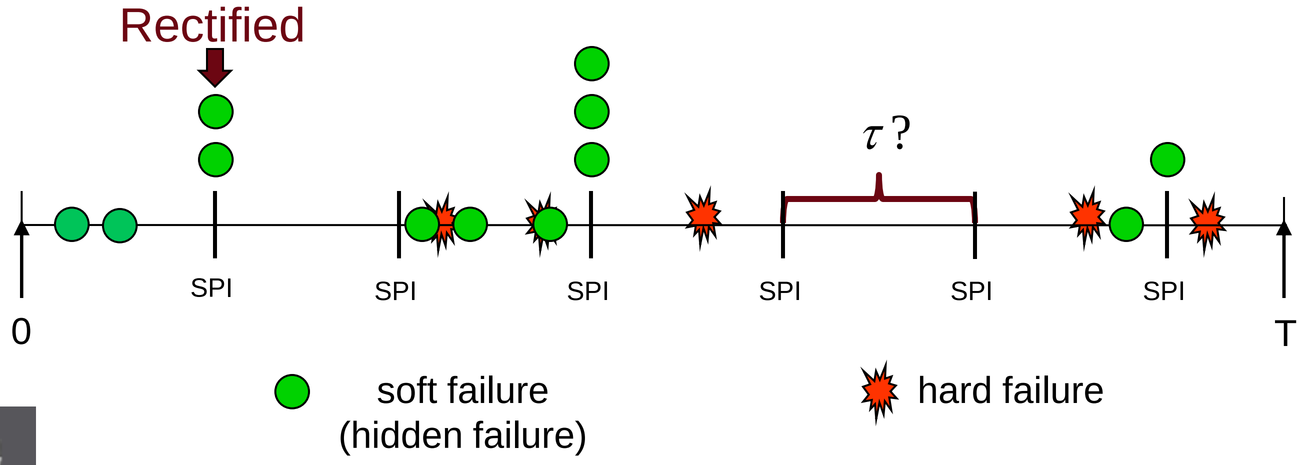
**Inspection Optimization Models**

- **Case 1:** A System under Periodic Inspections
  - Minimal Repair of Soft Failures
    - Model Considering Downtime and Repair of Components
    - Model Considering the Number of Failures
    - The Combined Model
  - Minimal Repair and Replacement of Soft Failures
    - Model Over a Finite Time Horizon
    - Model Over Infinite Time Horizon
- **Case 2:** A System under Periodic and Opportunistic Inspections
  - Minimal Repair of Soft and Hard Failures
  - Minimal Repair and Replacement of Soft Failures
  - Minimal Repair and Replacement of Soft and Hard Failures
  - Preventive Replacement of Components with Hard Failures at Periodic Inspections

# Non-Opportunistic Maintenance

## Assumptions:

- Finite time horizon (T) ☑
- Periodic inspections ☑
- Non-opportunistic maintenance ☑
- Minimal repair and replacement ☑



# Example:
# A Five Components System

| Component | $\beta_j$ | $\eta_j$ (months) | Minimal repair cost | Downtime cost/month | Replacement cost | $a_j$ | $b_j$ |
|---|---|---|---|---|---|---|---|
| 1 | 1.3 | 3.5 | $70 | $100 | $700 | 0.9 | 0.2317 |
| 2 | 1.1 | 4.6 | $45 | $250 | $450 | 0.9 | 0.1763 |
| 3 | 2.1 | 6 | $100 | $220 | $1000 | 0.9 | 0.1352 |
| 4 | 1.8 | 10 | $75 | $170 | $750 | 0.9 | 0.0811 |
| 5 | 1.7 | 3.6 | $150 | $260 | $1500 | 0.9 | 0.2253 |

Parameters of the power law intensity functions, probability of minimal repairs ( $r(x) = ae^{-bx}$ ) and costs for different components

Parameters are obtained from a medical device (infusion pump) case study

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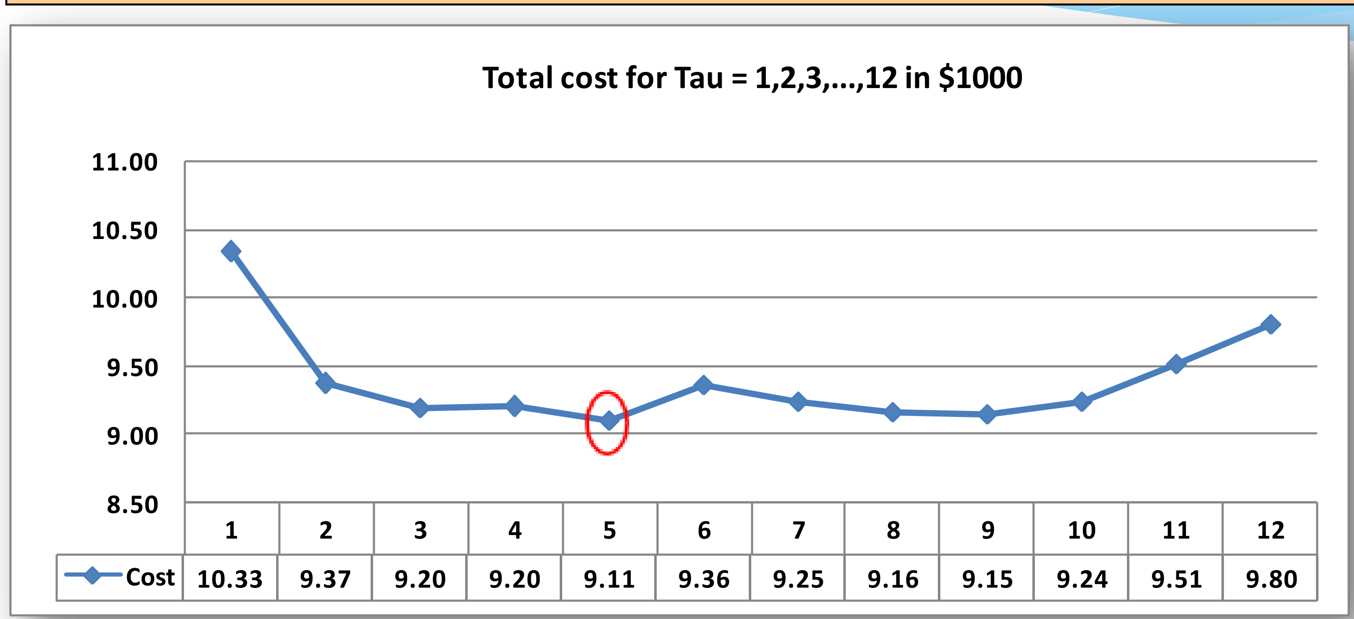
# Example: Cost Function

$$E[C_S^T] = nc_I + \sum_{j=1}^{m}\sum_{k=1}^{n}(C_j^M M_k^j(t) + R_k^j(t) C_j^R) + \sum_{j=1}^{m}\sum_{k=1}^{n-1} C_j^D(\tau - e_k^j(t)) + \sum_{j=1}^{m} C_j^D(\sigma - e_n^j(t))$$



| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Cost | 10.33 | 9.37 | 9.20 | 9.20 | 9.11 | 9.36 | 9.25 | 9.16 | 9.15 | 9.24 | 9.51 | 9.80 |

$c_I = \$200$

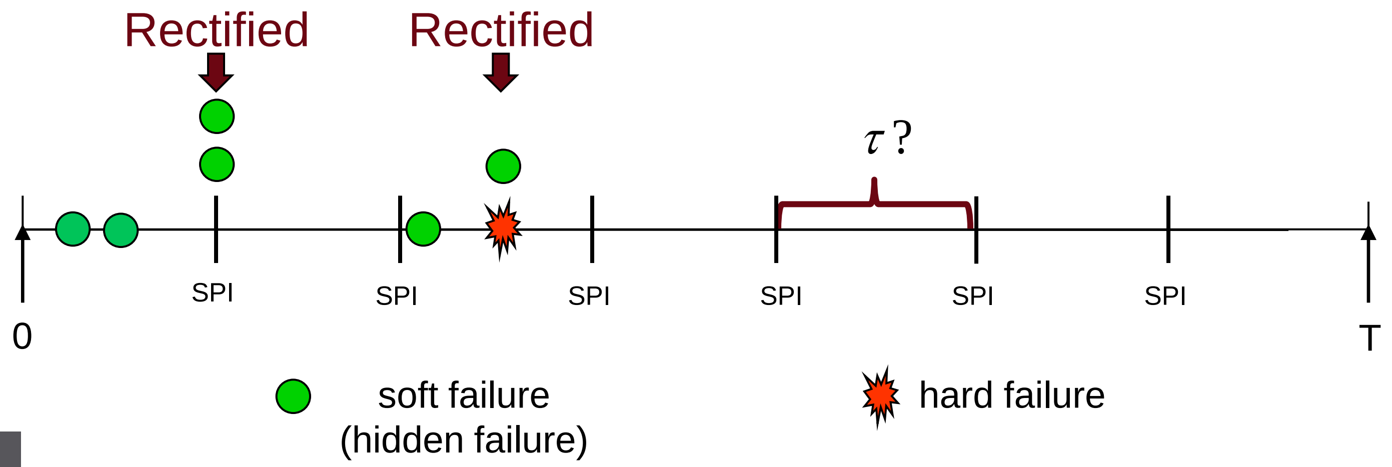
$T = 12$ months

It is optimal to inspect at 5, 10, and 12 months!

# Opportunistic Maintenance

## Assumptions:

- Finite time horizon (T) ☑
- Periodic inspections ☑
- Opportunistic maintenance ☑
- Minimal repair of hard and soft failures ☑



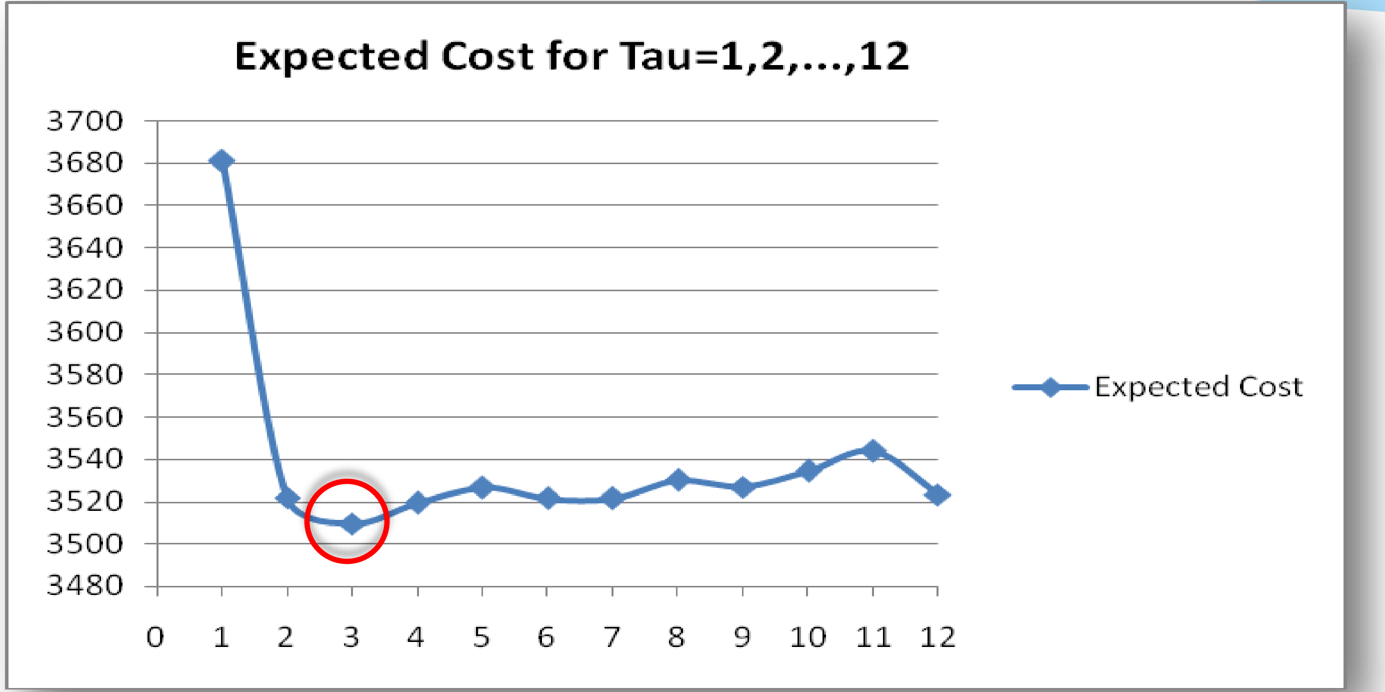
# Example: A System with 5 Soft and 3 Hard Components

| | *Component* | $\beta_j$ | $\eta_j$ *(months)* | *Minimal repair cost* | *Downtime penalty cost/month* |
|---|---|---|---|---|---|
| **Soft Failures** | 1 | 1.3 | 3.5 | $70 | $150 |
| | 2 | 1.1 | 4.6 | $45 | $250 |
| | 3 | 2.1 | 6 | $100 | $300 |
| | 4 | 1.8 | 10 | $75 | $100 |
| | 5 | 1.7 | 3.6 | $150 | $150 |
| **Hard Failures** | 1 | 1.5 | 11 | --- | --- |
| | 2 | 1.2 | 7.2 | --- | --- |
| | 3 | 1.7 | 2.8 | --- | --- |

Parameters are obtained from a medical device (infusion pump) case study

# Example: Cost Curve

$$E[C_S^T] = nc_I + \sum_{j=m_1+1}^{m_1+m_2} [c_j^M M_n^j(\sigma,t,s) + c_j^D (T - e_n^j(\sigma,t,s))]$$



$c_I = \$70$

$T = 12$ months

It is optimal to inspect every 3 months

# Conclusions

- **Prioritization of medical devices**

  Model is comprehensive and incorporates all important criteria, but is expert intensive

- **Data analysis and trend test**

  The common belief that electronic devices fail randomly is not always correct

- **Inspection interval**

  Soft and hard failures, and periodic and opportunistic inspections should be considered in the model

# Future Research

- **Prioritization of medical devices**

  Multi-criteria methodology to select appropriate maintenance strategy

- **Trend test**

  Using other iterative algorithms to compare the results

- **Inspection interval**

  Considering non-periodic and condition-based inspections

# Thanks You

Email:

shararareh@ryerson.ca

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