Sneak Peek

Statistics for Non-Statisticians

Steven Walfish
Statistical Outsourcing Services, USA,
Independent Consultant

ONLINE
TRAINING

SYMMETRIC

STATISTICAL ERROR

Decision		Reality	
		Accept	Reject
	Accept	Correct Decision Confidence $(1-\alpha)$	Type II Error (β) Consumer Risk
	Reject	Type I Error (α) Producer Risk	Correct Decision Power $(1-\beta)$

LINEAR REGRESSION

- Regression analysis is used to predict the value of one variable Y based on another variable(s) X

  - Y is dependent variable such as potency, concentration, purity, etc.

  - X is independent variable such as time

- Mathematically

$$y = \alpha + \beta x_i + \varepsilon_i$$

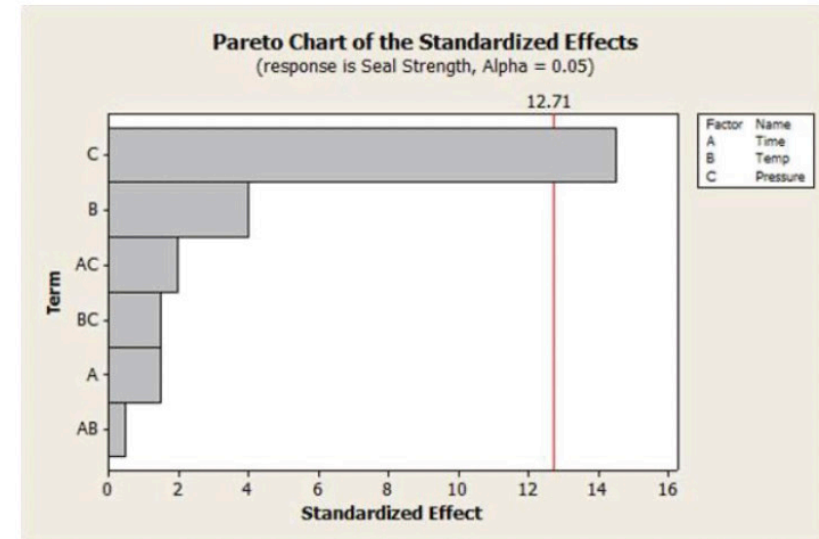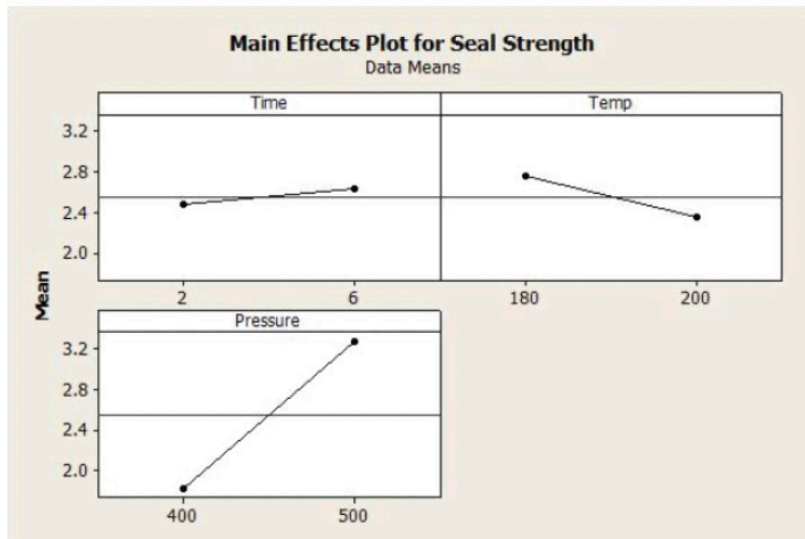$$E(\varepsilon_i) = 0, VAR(\varepsilon_i) = \sigma^2$$

- Model parameters β_0 and β_1 are estimated from data.

ANALYSIS

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Analysis of Variance for Seal Strength (coded units)

Source                 DF    Seq SS    Adj SS    Adj MS        F       P
Main Effects            3   4.57000   4.57000   1.52333    76.17   0.084
  Time                  1   0.04500   0.04500   0.04500     2.25   0.374
  Temp                  1   0.32000   0.32000   0.32000    16.00   0.156
  Pressure              1   4.20500   4.20500   4.20500   210.25   0.044
2-Way Interactions      3   0.13000   0.13000   0.04333     2.17   0.454
  Time*Temp             1   0.00500   0.00500   0.00500     0.25   0.705
  Time*Pressure         1   0.08000   0.08000   0.08000     4.00   0.295
  Temp*Pressure         1   0.04500   0.04500   0.04500     2.25   0.374
Residual Error          1   0.02000   0.02000   0.02000
Total                   7   4.72000
```

ICH TERMINOLOGY

- Accuracy (on average how close to target is a method?)

- Precision (how variable is a method?)

- Linearity (is the outcome measure proportional to the input amount?)

- Limit of Detection (the lowest amount that can be detected)

- Limit of Quantitation (the lowest amount that can be measured with suitable accuracy and precision)

- Range (the interval of amounts that can be measured with acceptable accuracy, precision and linearity)

- Specificity ("the ability to assess unequivocally the analyte in the presence of components which may be expected to be present[1]" in the execution of the method)

WHAT IS A MEASUREMENT SYSTEM ANALYSIS?

- A Measurement System Analysis (MSA) is the process through which the accuracy, precision, linearity, and stability of the system is assessed

- An MSA makes use of experimental methods to assess measurement system performance

- It is not simply a matter of sending the instrument out for calibration

- The purpose of the MSA is to qualify a measurement system for a specific data acquisition task

- Measurement system error must be small compared to process variation and specification limits

Registration

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Mliekarenská 9, 821 09
Bratislava, Slovak Republic
ID: 47 068 124
VAT no: SK2023741973
Office: +421 948 262 346

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