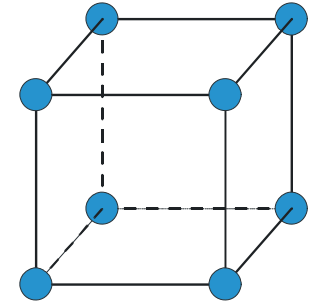


Factorial Design Planning Process



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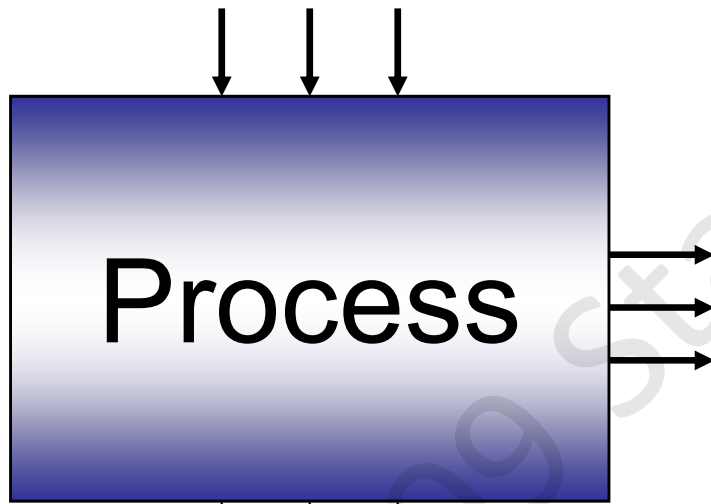
Factorial Design Planning Process

Our talk has three parts:

- 1. Broad brush description of the DOE planning process**
2. Illustrate key points via an example
3. Summary

Design of Experiments

Controllable Factors “x”



Noise Factors “z”

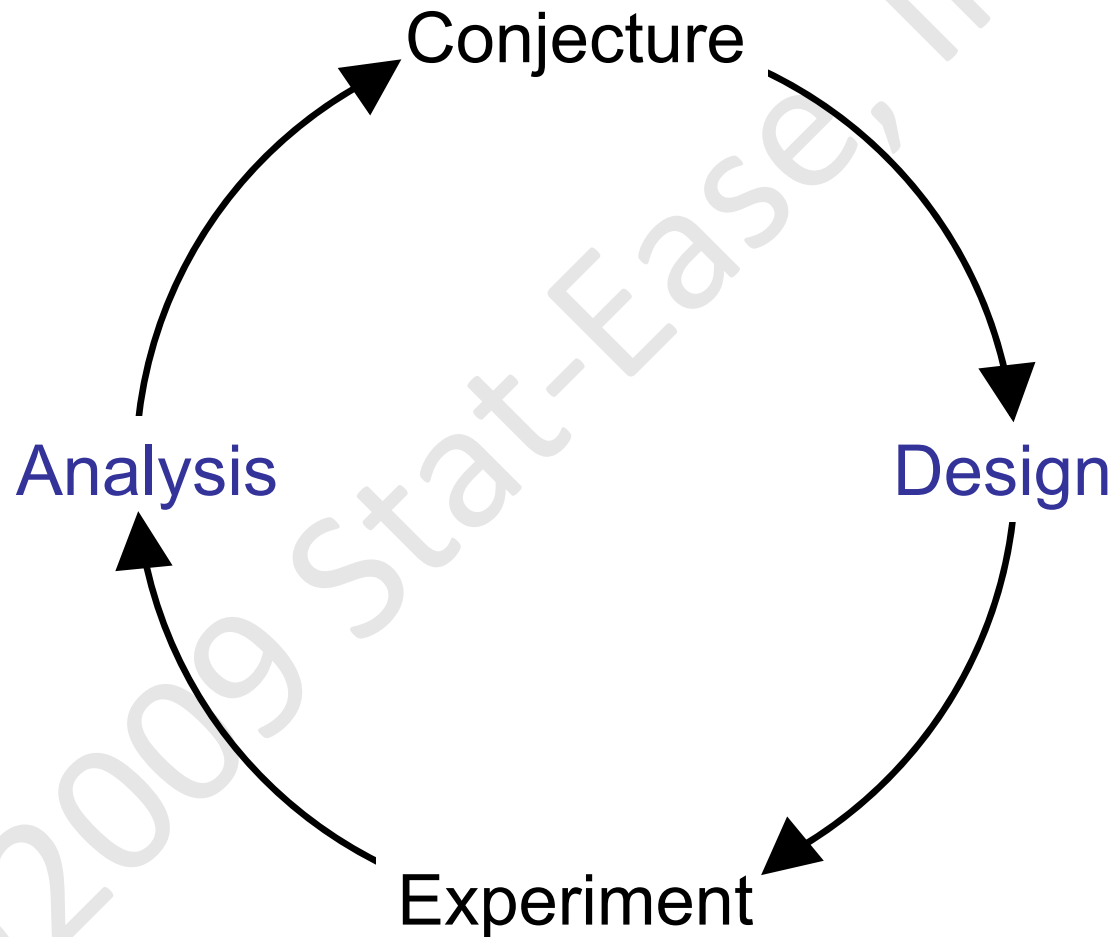
DOE (Design of Experiments) is:

“A systematic series of tests, in which purposeful changes are made to input factors,

Responses “y”

so that you may identify causes for significant changes in the output responses.”

Iterative Experimentation



Expend no more than 25% of budget on the 1st cycle.

1. Identify opportunity and define objective.
2. State objective in terms of measurable responses.
 - a. Define the change (Δy) that is important to detect for each response.
 - b. Estimate experimental error (σ) for each response.
 - c. Use the signal to noise ratio ($\Delta y/\sigma$) to estimate power.
3. Select the input factors to study. (*Remember that the factor levels chosen determine the size of Δy .*)

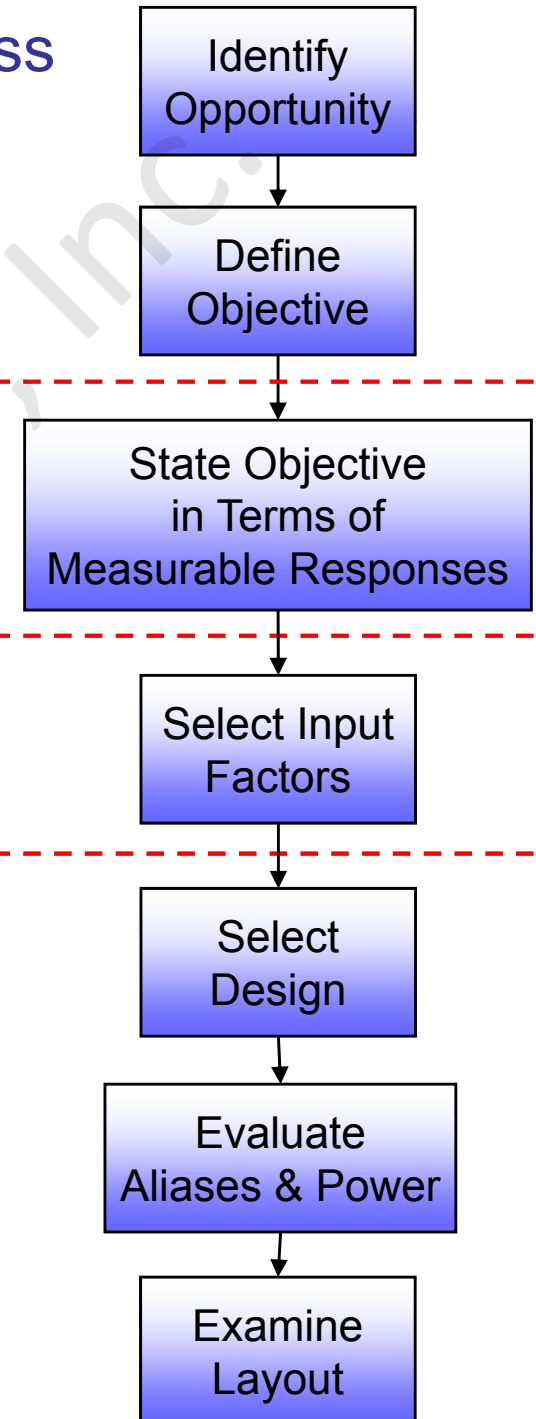
4. Select a design and:

- Evaluate aliases (fractional factorials and/or blocked designs); generally use two-factor interaction (2FI) model.
- Evaluate power (desire power $> 80\%$ for effects of interest); generally use main effects (ME) model (for robust design use only 1 ME).
- Examine the design layout to ensure all the factor combinations are safe to run and are likely to result in meaningful information (no disasters).

Factorial Design Planning Process

Tools:

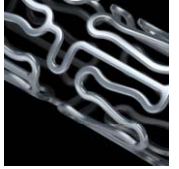
- Brainstorming (*fishbone*)
 - Consensus
-
- Outputs Voting Form
 - Outputs, Δy , σ , %Contribution
-
- Factors Voting Form
 - DOE inputs, levels, operating range
 - Other inputs
-
- Select an appropriate factorial design
 - Evaluate aliases (*fractional factorials and/or blocked designs*)
 - Evaluate power
 - Examine the design layout



Factorial Design Planning Process

Our talk has three parts:

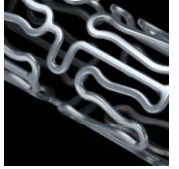
1. Broad brush description of the DOE planning process
2. **Illustrate key points via an example**
3. Summary



A stent is a wire mesh tube used to prop open an artery that's recently been cleared using angioplasty. The stent is collapsed to a small diameter over a balloon catheter. It's then moved into the area of the blockage.



When the balloon is inflated, the stent expands, locks in place and forms a scaffold. This holds the artery open. The stent stays in the artery permanently, holding it open to improve blood flow to the heart muscle.



1. Identify opportunity and define objective.
Relate stent deliverability and safety to process factors.

Guidelines for Brainstorming a Designed Experiment

Team Make Up: “Experts”

“Semi-Experts” or Peripheral Experts

Technicians or Operators

“Customers”

Scheduling: Two meetings no more than 2 days apart.

First day spend approximately 1 to 2 hours
discussing Goal, Objective, Outputs and Inputs.

Second day spend approximately 2 to 4 hours
developing DOE.

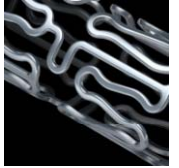


2. State objective in terms of measurable responses. Deliverability is quantified by Trackability and Pushability; safety is quantified by Burst pressure. Want to estimate 2FI model, this requires a resolution V (or higher) design.
 - a. Define the change (Δy) that is important to detect for each response.
 - b. Estimate experimental error (σ) for each response.
 - c. Use the signal to noise ratio ($\Delta y/\sigma$) to estimate power.

Outputs Voting Form

Objective as Measurable Responses

Evaluation of Outputs Voting Form											
Response Output (y)	Type of Response (V) Variable (D) Destructive (A) Attribute	Team Member's Ranking of Importance of the Responses 1: low rank; 5: high rank								Average	Standard Deviation
		M1	M2	M3	M4	M5	M6	M7	M8		



2. Typical of responses in actual DOE:

Response	Unit of Measure	Specification or Target	Practical Difference Δ	Std Dev σ	%MC*
Y_1 : Burst	psig	Maximize	6	8	27%
Y_2 : Push	g/cm	Maximize	15	30	75%
Y_3 : Track	g*cm	Minimize	10	6	19%

* % measurement contribution



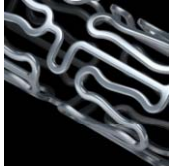
3. Select the input factors to study. (*Remember that the factor levels chosen determine the size of Δy .*)

Typical factors include:

- Lengths and diameters of various components, e.g. tip, balloon, catheter, etc.
- Materials used for the components.
- Assembly parameters, e.g. weld locations, how the balloon is folded, etc.
- Stent geometry, wall thickness, how it is crimped on the balloon, etc.

<i>Factor</i>	<i>Unit of Measure</i>	<i>F</i>	<i>M</i>	<i>V</i>	<i>B</i>	<i>Target</i>	<i>Range</i>	<i>Comments</i>

- F: Fixed** –factors that do not change for the duration of the experiment, e.g. One batch of raw material, one operator, etc.
- M: Monitor** – factors allowed to vary during the course of the experiment and will be monitored, e.g. temperature, humidity, etc.
- V: Vary** – factors allowed to vary, but will not be monitored, e.g. temperature, humidity, etc.
- B: Block** – factors used to block experimental runs, e.g. time of day, machine, etc.



3. Select the input factors to study.

Factor	Type	Low Level (-)	High Level (+)	Operating Range
A	numeric	-1	+1	
B	numeric	-1	+1	
C	numeric	-1	+1	
D	numeric			
<p><i>There were 11 factors: 10 numeric and 1 categoric; the actual factor details are proprietary.</i></p>				
G	numeric			
H	numeric	-1	+1	
J	numeric	-1	+1	
K	numeric	-1	+1	
L	categoric	L1	L2	

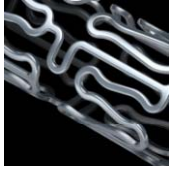


4. Select a design (*want resolution V*):

- Evaluate aliases (fractional factorials and/or blocked designs)
- Evaluate power (desire power $> 80\%$ for effects of interest)

Evaluation; Order: Main effects

- Examine the design layout to ensure all the factor combinations are safe to run and are likely to result in meaningful information (no disasters)



Candidate resolution V designs:

- A regular fraction requires a 2^{11-4} or 128 runs.
- An “irregular” algebraic fraction requires 96 runs.
- A MR5* fraction requires 68 runs.
- Add center points to check for curvature.

Used the MR5 design with 4 center points at each level of the categoric factor for a total of 76 runs.

* “Small, Efficient, Equireplicated Resolution V Fractions of 2^k designs and their Application to Central Composite Designs”, Gary Oehlert and Pat Whitcomb, 46th Annual Fall Technical Conference, Friday, October 18, 2002.

A PDF copy of this paper is available at: www.statease.com/pubs/small5.pdf



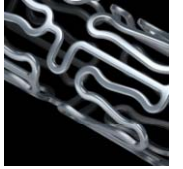
Stent Delivery System

Build the MR5 Design

1. Build an **11 factor MR5** design (the first ten factors are numeric and the **last factor is categoric**). Use the default factor names (letters A – L) and levels (± 1 for numeric factors; L1 and L2 for the categoric factor).
2. Add **4 center points**. (*Because factor “L” is categoric the number of center doubles to eight.*)
3. There are three responses:

Responses: (1 to 999)

	Name	Units	Diff. to detect Delta("Signal")	Est. Std. Dev. Sigma("Noise")	Delta/Sigma (Signal/Noise Ratio)
	Burst	psig	6	8	0.75
	Push	g/cm	15	30	0.5
	Track	g*cm	10	6	1.66667



All the main effects (MEs) and two-factor interactions (2FIs) are partially aliased with scores three-factor (and higher) interactions. But MEs and 2FIs are not aliased with one another.

If the three factor (and higher) interactions are ignored during design evaluation:

No aliases found for 2FI Model



Power is reported at a 5.0% alpha level to detect the specified signal/noise ratio.
 Recommended power is at least 80%.

Burst psig

Signal (delta) = 6.00 Noise (sigma) = 8.00 Signal/Noise (delta/sigma) = 0.75

A	B	C	D	E	F	G	H	J	K	L
85.6%	85.6%	85.7%	85.6%	85.5%	85.3%	85.9%	86.0%	85.9%	85.8%	88.9%

Push g/cm

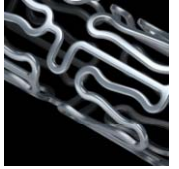
Signal (delta) = 15.00 Noise (sigma) = 30.00 Signal/Noise (delta/sigma) = 0.50

A	B	C	D	E	F	G	H	J	K	L
52.2%	52.3%	52.4%	52.3%	52.1%	51.9%	52.5%	52.7%	52.5%	52.4%	56.4%

Track g*cm

Signal (delta) = 10.00 Noise (sigma) = 6.00 Signal/Noise (delta/sigma) = 1.67

A	B	C	D	E	F	G	H	J	K	L
99.9%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%



Power is low (**~52%**) for Push; to increase power:

1. Increase design size: replicating the design $76 \times 2 = 152$ runs gives adequate power (**~82%**).
No – there are too many runs to be practical.
2. Increase $\Delta_{\text{Push}} = 15$ g/cm. **No** – we are interested in a difference of 15 g/cm.
3. Decrease $\sigma_{\text{Push}} = 30$ g/cm: By partitioning the variance, we determine that the push measurement contributes most (**75%**) of the variation.
Yes – repeating the push test (not replicating the DOE runs) to reduce σ is the answer.

See next slide.



$$\sigma_{\text{Push}} = 30 \quad \& \quad \sigma_{\text{Push}}^2 = \sigma_{\text{Process}}^2 + \sigma_{\text{Measurement}}^2$$

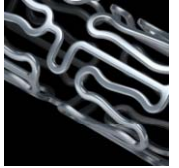
$$900 = 225 + 675 \quad \therefore \quad \% \text{Contribution} = 675/900 = 75\%$$

Make three independent push measurements for each run.
Enter the average of the measurements as the response:

Then by the CLT $\left(\sigma_{\text{Average}}^2 = \frac{\sigma_{\text{Measurement}}^2}{n} \right)$:

$$\sigma_{\text{Push}}^2 = 225 + \frac{675}{3} = 450 \quad \% \text{Contribution} = 50\%$$

$$\sigma_{\text{Push}} = \sqrt{450} \approx 21 \quad \frac{\Delta}{\sigma} = \frac{15}{21} = 0.71$$



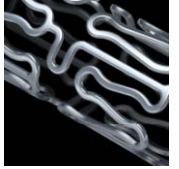
Power at 5 % alpha level for effect of

Term	StdErr**	VIF	Ri-Squared	0.71 Std Dev	0.75 Std Dev	1.67 Std Dev
A	0.12	1.02	0.0148	81.6 %	85.6 %	99.9 %
B	0.12	1.01	0.0140	81.7 %	85.6 %	99.9 %
C	0.12	1.01	0.0109	81.8 %	85.7 %	99.9 %
D	0.12	1.01	0.0139	81.7 %	85.6 %	99.9 %
E	0.12	1.02	0.0183	81.5 %	85.5 %	99.9 %
F	0.12	1.02	0.0237	81.3 %	85.3 %	99.9 %
G	0.12	1.01	0.0070	81.9 %	85.9 %	99.9 %
H	0.12	1.00	0.0035	82.1 %	86.0 %	99.9 %
J	0.12	1.01	0.0070	81.9 %	85.9 %	99.9 %
K	0.12	1.01	0.0101	81.8 %	85.8 %	99.9 %
L	0.12	1.02	0.0230	85.4 %	88.9 %	99.9 %

**Basis Std. Dev. = 1.0

Summary:

- Replicating runs will reduce the system error; from both process and measurement.
- Repeating the measurement reduces only the measurement error.
- The magnitude of each of these errors and the relative cost of replicating runs versus repeating measurements dictates which will give the most “bang” for your buck.



- Examine the design layout to ensure all the factor combinations are safe to run and are likely to result in meaningful information (no disasters)

Each run in the DOE builds a stent delivery system by combining different components and using a variety of assembly techniques. A knowledgeable engineer must look at each DOE run to ascertain that the unit can be made and will result in an operable stent delivery system.

Stent Delivery System

Results – Burst

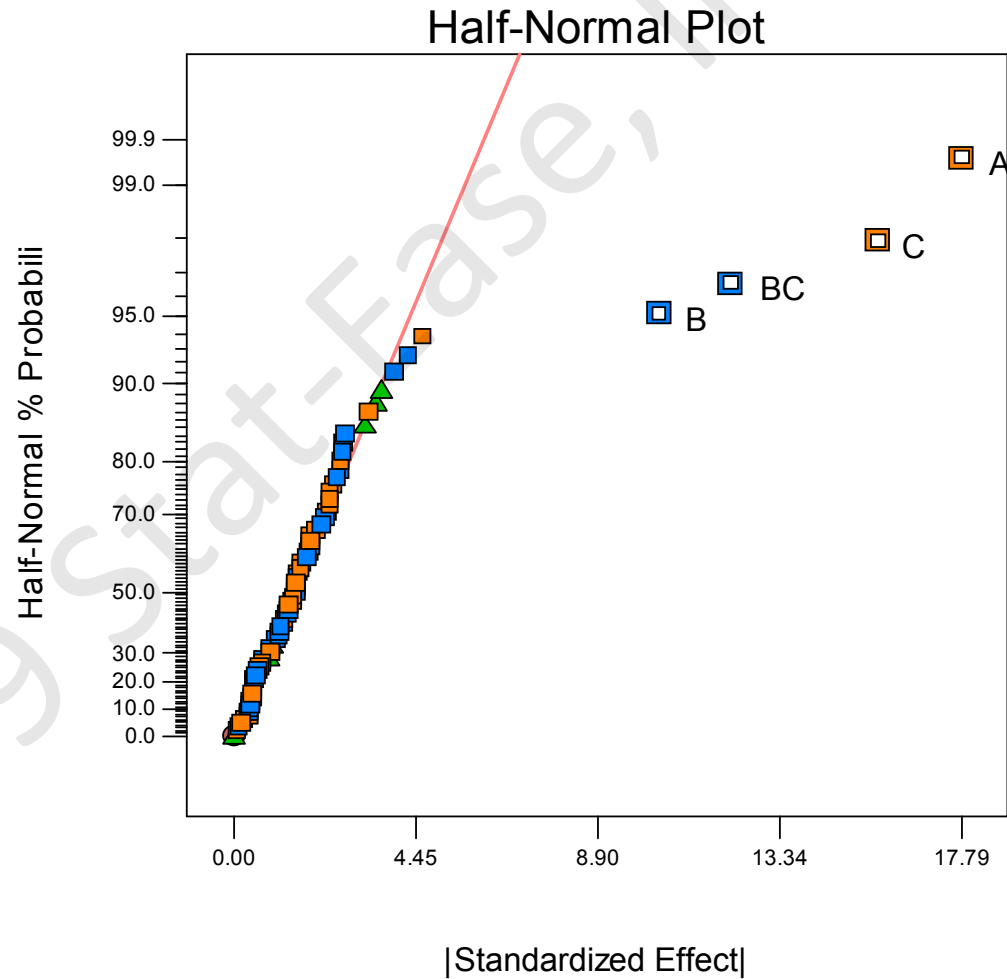
Design-Expert® Software
Burst

▲ Error from replicates

Shapiro-Wilk test
W-value = 0.987
p-value = 0.771

- A: A
- B: B
- C: C
- D: D
- E: E
- F: F
- G: G
- H: H
- J: J
- K: K
- L: L

■ Positive Effects
■ Negative Effects



ANOVA for selected factorial model
Analysis of variance table [Partial sum of squares - Type III]

Source	Sum of Squares	df	Mean Square	F Value	p-value Prob > F
Model	13264.56	4	3316.14	65.14	< 0.0001
A-A	5324.51	1	5324.51	104.60	< 0.0001
B-B	1820.10	1	1820.10	35.75	< 0.0001
C-C	4172.29	1	4172.29	81.96	< 0.0001
BC	2482.47	1	2482.47	48.77	< 0.0001
Curvature	43.69	1	43.69	0.86	0.3574
Residual	3563.38	70	50.91		
Lack of Fit	3071.38	64	47.99	0.59	0.8667
Pure Error	492.00	6	82.00		
Cor Total	16871.63	75			

Stent Delivery System

Results – Push

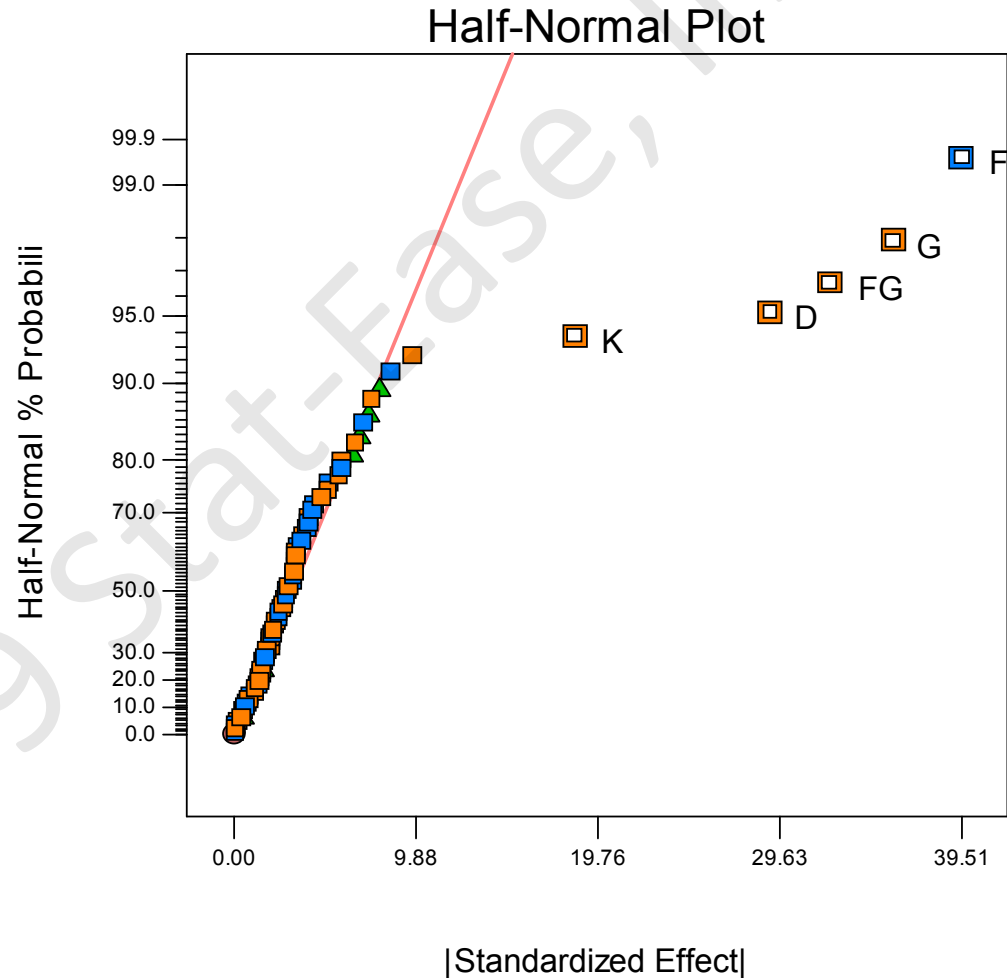
Design-Expert® Software
Push

▲ Error from replicates

Shapiro-Wilk test
W-value = 0.993
p-value = 0.978

- A: A
- B: B
- C: C
- D: D
- E: E
- F: F
- G: G
- H: H
- J: J
- K: K
- L: L

- Positive Effects
- Negative Effects



ANOVA for selected factorial model
Analysis of variance table [Partial sum of squares - Type III]

Source	Sum of Squares	df	Mean Square	F Value	p-value Prob > F
Model	85628.80	5	17125.76	48.14	< 0.0001
<i>D-D</i>	14300.39	1	14300.39	40.20	< 0.0001
<i>F-F</i>	26366.49	1	26366.49	74.12	< 0.0001
<i>G-G</i>	21637.78	1	21637.78	60.83	< 0.0001
<i>K-K</i>	5796.68	1	5796.68	16.30	0.0001
<i>FG</i>	17673.16	1	17673.16	49.68	< 0.0001
Curvature	116.64	1	116.64	0.33	0.5688
Residual	24545.29	69	355.73		
<i>Lack of Fit</i>	22153.54	63	351.64	0.88	0.6466
<i>Pure Error</i>	2391.75	6	398.63		
Cor Total	1.103E+005	75			

Stent Delivery System

Results – Track

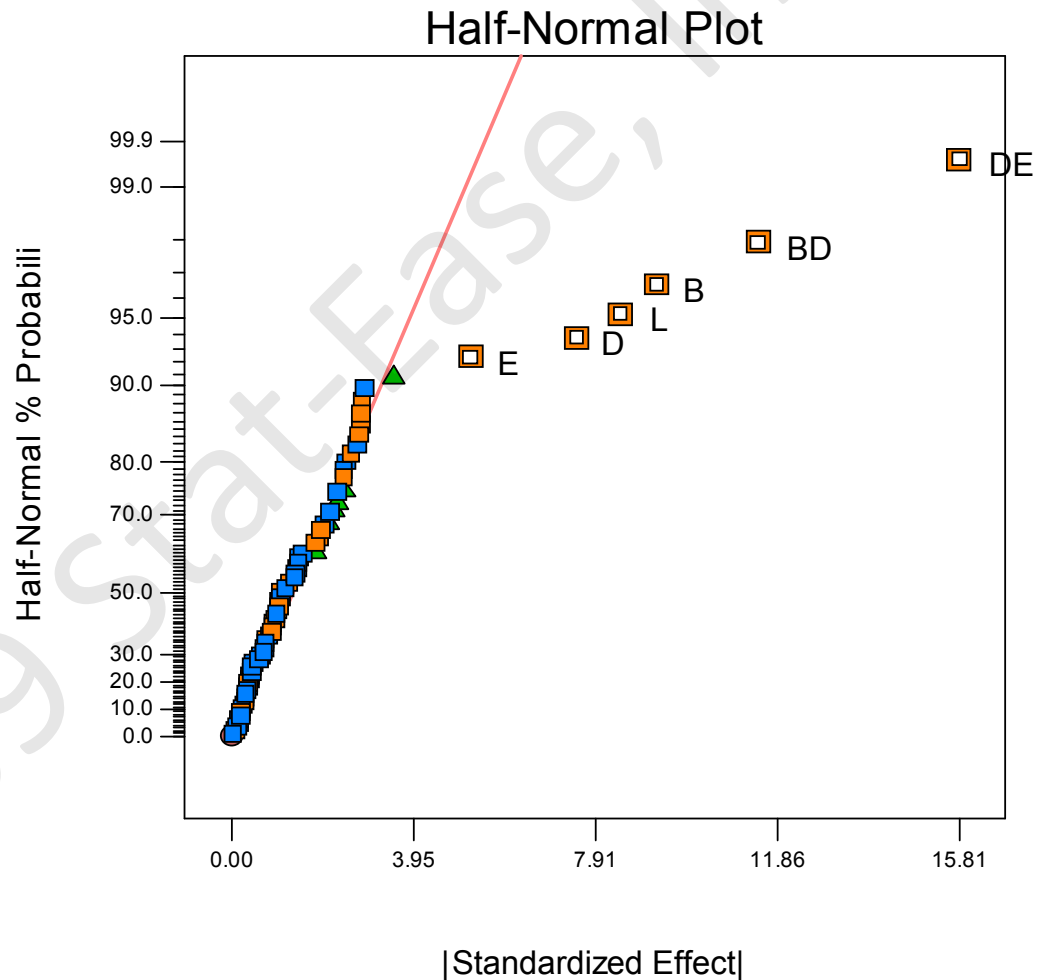
Design-Expert® Software
Track

▲ Error from replicates

Shapiro-Wilk test
W-value = 0.972
p-value = 0.181

A: A
B: B
C: C
D: D
E: E
F: F
G: G
H: H
J: J
K: K
L: L

■ Positive Effects
■ Negative Effects



ANOVA for selected factorial model
Analysis of variance table [Partial sum of squares - Type III]

Source	Sum of Squares	df	Mean Square	F Value	p-value Prob > F
Model	11175.64	6	1862.61	52.19	< 0.0001
<i>B-B</i>	1388.59	1	1388.59	38.91	< 0.0001
<i>D-D</i>	982.81	1	982.81	27.54	< 0.0001
<i>E-E</i>	477.87	1	477.87	13.39	0.0005
<i>L-L</i>	1223.48	1	1223.48	34.28	< 0.0001
<i>BD</i>	2355.11	1	2355.11	65.99	< 0.0001
<i>DE</i>	4457.51	1	4457.51	124.90	< 0.0001
Curvature	178.00	2	89.00	2.49	0.0902
Residual	2391.15	67	35.69		
<i>Lack of Fit</i>	1962.40	61	32.17	0.45	0.9471
<i>Pure Error</i>	428.75	6	71.46		
Cor Total	13744.79	75			

Find optimal factor settings

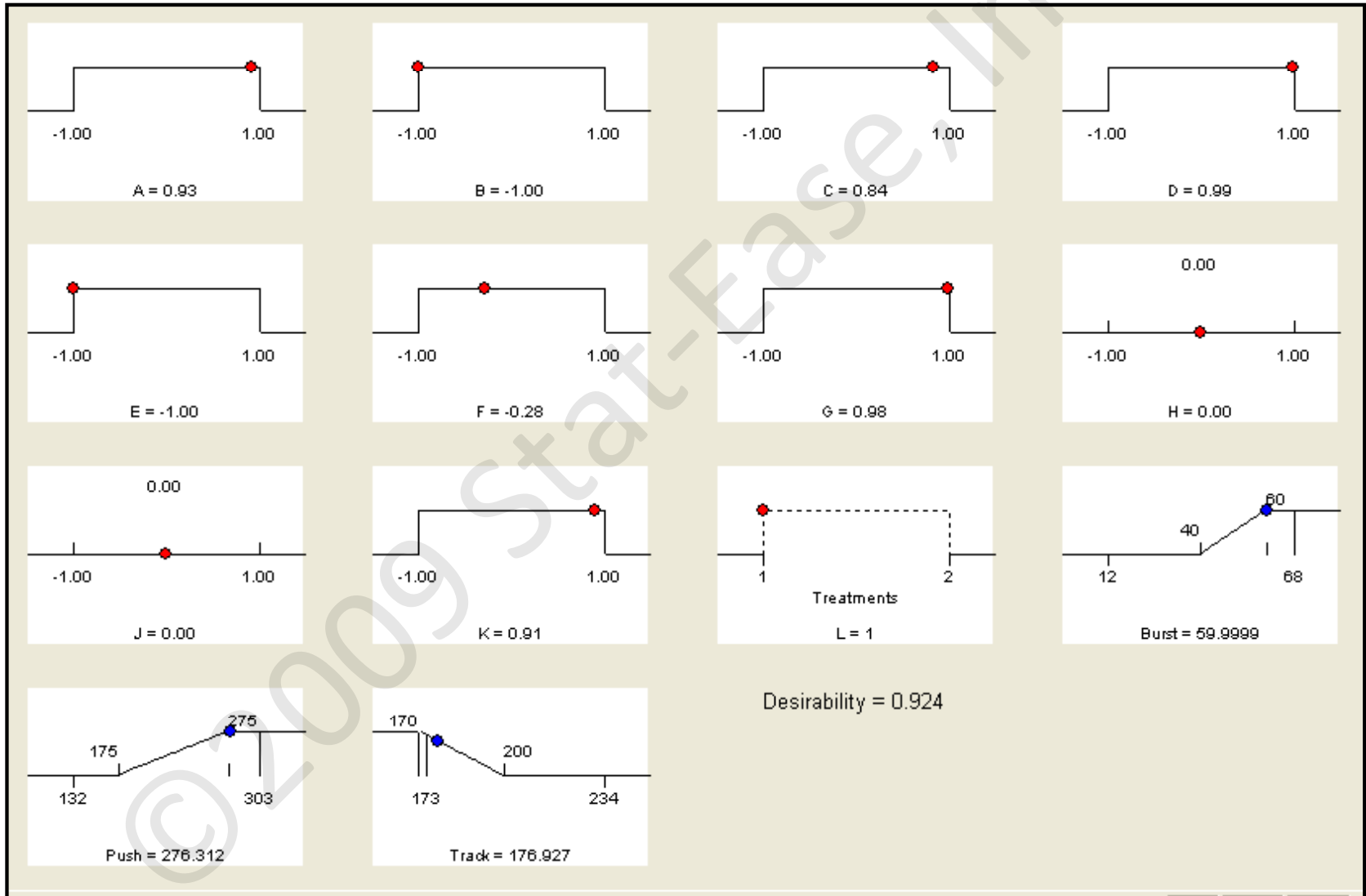
- Burst, Maximize (LL=40, UL=65) importance ++++
- Push, Maximize (LL=175, UL=275) importance +++
- Track, Minimize (LL=170, UL=200) importance +++

* Derringer, G. C., “A Balancing Act: Optimizing a Product's Properties”, *Quality Progress*.
© 2002 American Society for Quality

A PDF copy of this paper (with permission) is available at:
www.statease.com/pubs/derringer.pdf

Stent Delivery System

Optimal Factor Settings



Factorial Design Planning Process

Our talk has three parts:

1. Broad brush description of the DOE planning process
2. Illustrate key points via an example
3. **Summary**

1. Identify opportunity and define objective.
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 - a. Define the change (Δy) that is important to detect for each response.
 - b. Estimate experimental error (σ) for each response.
 - c. Use the signal to noise ratio ($\Delta y/\sigma$) to estimate power.
3. Select the input factors to study. (*Remember that the factor levels chosen determine the size of Δy .*)

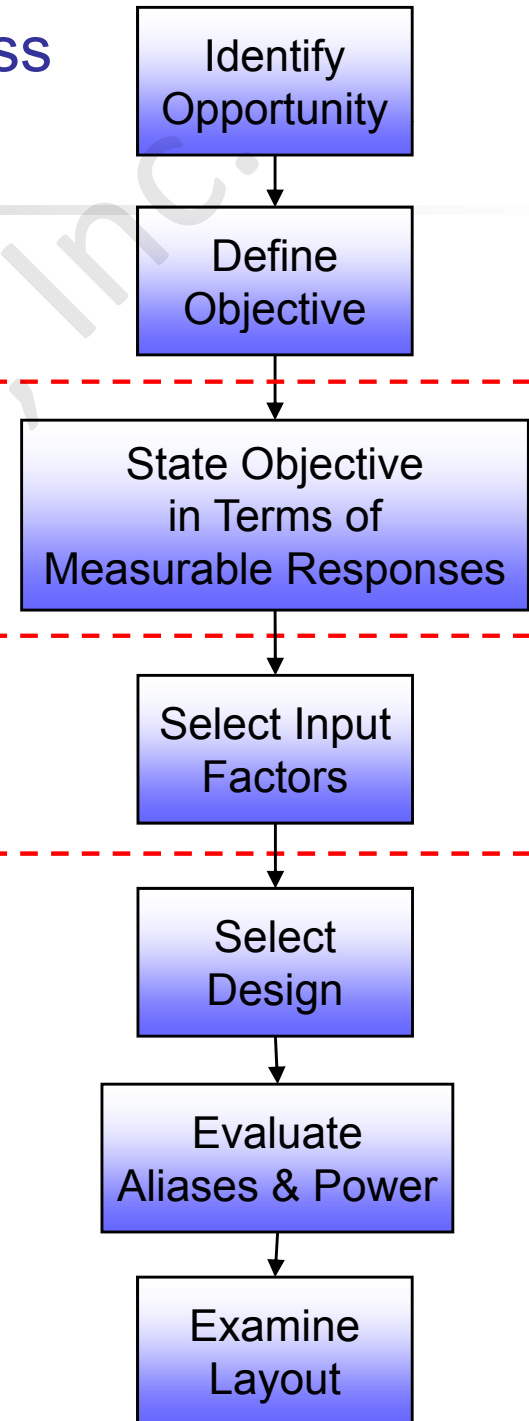
4. Select a design and:

- Evaluate aliases (fractional factorials and/or blocked designs); generally use 2FI model.
- Evaluate power (desire power $> 80\%$ for effects of interest); generally use ME model (for robust design use only 1 ME).
- Examine the design layout to ensure all the factor combinations are safe to run and are likely to result in meaningful information (no disasters).

Factorial Design Planning Process

Tools:

- Brainstorming (*fishbone*)
 - Consensus
-
- Outputs Voting Form
 - Outputs, Δy , σ , %Contribution
-
- Factors Voting Form
 - DOE inputs, levels, operating range
 - Other inputs
-
- Select an appropriate factorial design
 - Evaluate aliases (*fractional factorials and/or blocked designs*)
 - Evaluate power
 - Examine the design layout



The factorial design planning process emphasis on power should not be applied to response surface or mixture design.

- Precision should be used to size response surface and mixture designs.
- Sizing for precision will covered in future webinars.

Thank You for Attending

If you have questions please email them to:

stathelp@statease.com

and reference the September 19th webinar.