Medtronic
Engineering the extraordinary

Medtronic Juncos Campus (MJC)

Medtronic
Engineering the extraordinary

Agenda

- Medtronic Overview (F Costa)
- Site Overview (F Costa)
- Product Lifecycle Process & NPIs (L Torres)
- Design For Reliability and Manufacturability - DRM (J Merced)
- Process Development & Equipment/System Development
- Closing Remarks (M Mellado)

Medtronic Overview

Frazer Costa

Medtronic

Leading healthcare technology innovation since 1949

For more than 70 years, we have led the way with purpose-driven healthcare technology. That history compels us to relentlessly pursue therapies that change lives.

1949: The garage gang

Earl Bakken, a graduate student in electrical engineering, and his brother-in-law Palmer Hermundslie, an enterprising engineer, started a repair business focused on medical electronics. They named it Medtronic. The pair were driven by passion and a deep purpose to use their scientific and entrepreneurial skills to help others. As the work increased, they added a handful of employees, who called themselves "the garage gang," a reference to their spartan office in two boxcars used as a garage at the Hermundslie family's Minneapolis home.

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1957: The first battery-operated pacemaker

The power went out in Minneapolis on Halloween in 1957, endangering the lives of open-heart surgery patients who were often attached to a pacemaker. Existing pacemakers were bulky boxes wheeled around on carts and plugged into electrical outlets. Concerned for his patients, a University of Minnesota heart surgeon asked Bakken if he could create a battery-operated pacemaker. Within four weeks, Bakken did just that, and the revolutionary device began saving lives. Hermundslie, an accomplished pilot, flew all over the United States delivering pacemakers to customers. Soon, the "wearable" Medtronic pacemaker was being shipped around the world. One year later, Medtronic produced the first implantable pacemaker.

Medtronic

Written in 1960, our Mission drives everything we do

1. To contribute to human welfare by application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that **alleviate pain, restore health, and extend life**.
2. To direct our growth in the areas of biomedical engineering.
3. To strive without reserve for the greatest possible reliability and quality in our products.
4. To make a fair profit.
5. To recognize the personal worth of all employees.
6. Maintain good citizenship.

Medtronic


Medtronic Micra
Leadless CRM
Transcatheter Mitral Valves
LVAD Systems
Reveal LINQ
Stroke Therapies
Neuro-stimulation Advancements
PillCam
120
118
133
Advanced Surgical Tools and Robotics
Capsule Endoscopy Solutions
Closed Looped System for Diabetes Management
CGM in Standard Use

Site Overview

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Medtronic

Manufacturing Regions

★ Medtronic Global Model Sites
Medtronic Technology Centers
Medtronic Mfg. & Development Centers

WEST/Mexico

Manufacturing Plants:

1. Boulder
2. Parker
3. Louisville
4. Juncos* ★
5. Northridge
6. Tempe* ★
7. San Diego
8. Irvine
9. Santa Ana
10. San Juan
11. Menlo Park
12. Nellcor* ★
13. El Lago* ★
14. Empalme
15. Juarez

CENTRAL

Manufacturing Plants:

1. Brooklyn Center MECC * ★
2. Plymouth NL
3. Rice Creek
4. Plymouth ATS
5. Plymouth SuperD
6. Brooklyn Park
7. Grand Rapids
8. Milwaukee
9. Memphis Medicrea
10. Fort Worth

EAST

Manufacturing Plants:

1. North Haven* ★
2. Danvers
3. Montreal
4. Eatontown
5. Mystic
6. Jacksonville
7. Bedford
8. Billerica

CARIBBEAN

Manufacturing Plants:

1. San Isidro* ★
2. Humacao
3. Warsaw
4. Costa Rica
5. Villalba
6. Ponce
7. Ribeirao Preto
8. Sao Sebastiao

EMEA

Manufacturing Plants:

1. Parkmore* ★
2. Athlone
3. Mervue
4. Tolochenaz
5. Yokneam
6. Trevoux
7. Grenoble
8. Lyon
9. Kerkrade
10. Fourmies
11. Deggendorf
12. Jerusalem
13. Mirandola

Contract Manufacturing & Asia/China

Manufacturing Plants:

1. Shanghai
2. Chengdu - DIA
3. Changzhou
4. Kanghui
5. Kangdi *(reports commercially)*
6. *Myancor*
7. Ho Chi Minh
8. Singapore

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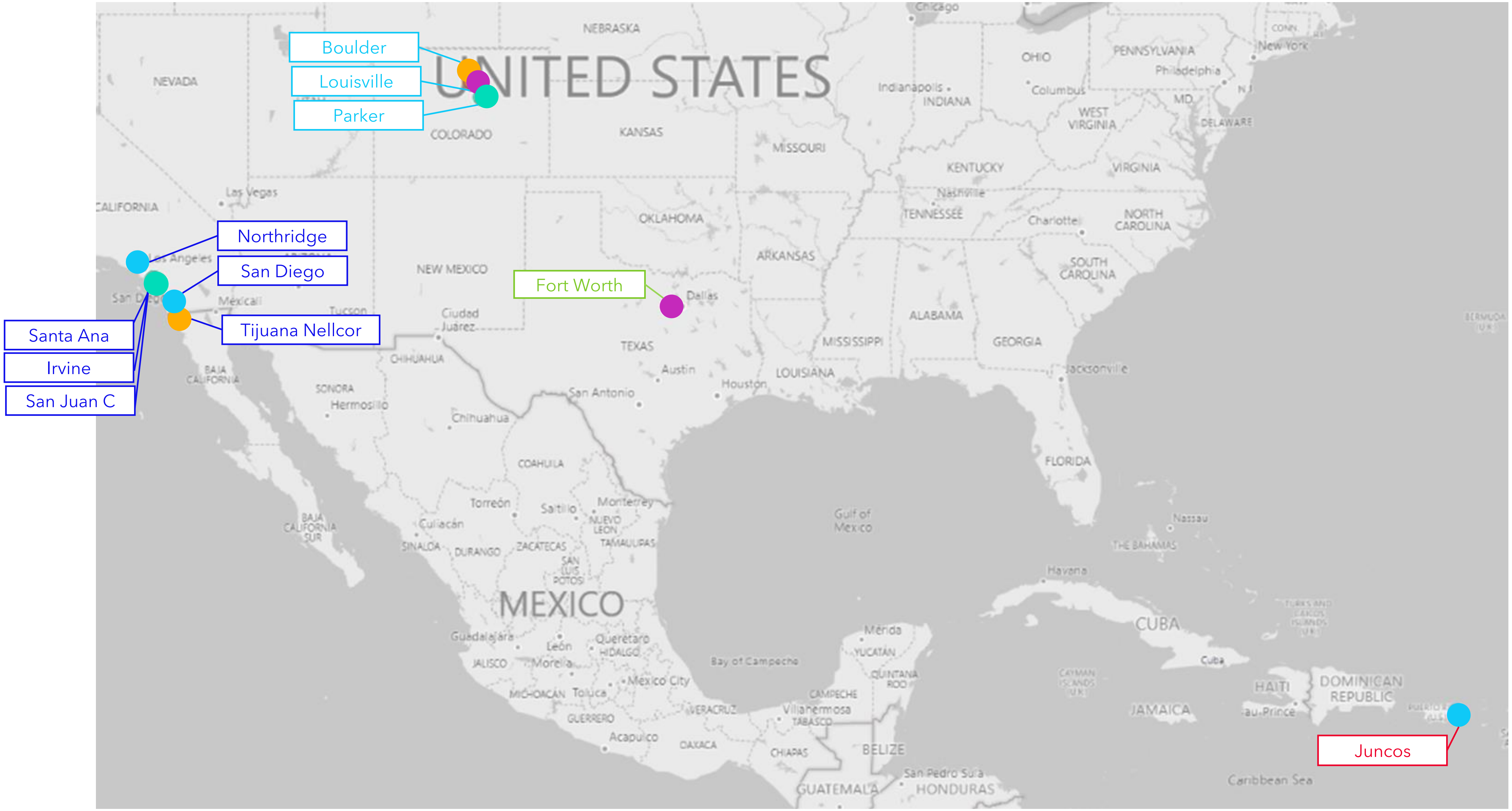
West Americas Platform

Our Sites



Span Breakers

None

Legacy Platforms

- VT&I
- ET&C
- MAP
- CE

Time Zones | GMT

- 06:00am (-8h)
- 07:00am (-7h)
- 08:00am (-6h)
- 04:00pm (+2h)

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MEDTRONIC IN PUERTO RICO

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Puerto Rico Manufacturing & Process Development Centers

Key Facts

- It will be 50 years manufacturing presence in PR by 2024
- One of the largest employers in PR, >38% Female Leaders
- Significant Global Revenue comes from Puerto Rico
- Multiple products for ALL (4) Portfolio Groups :
  - CV
  - Diabetes
  - Medical Surgical
  - Neuroscience
- 900,000+ sq ft footprint
- Technical capabilities (3/4 Process Development Centers)
- Strong Quality and Continuous Improvement Culture

Core Competencies

- Laser Processing: welding, soldering and marking/etching
- Automation, Mech Assy, Process Controls/Vision Systems
- MES, Controls, Data Automation & Digitalization, Electrical Testing
- Metals + Plastics Machining / Grinding and Metrology
- Metal and Polymer Micro Joining, Electro-Chemistry

Leverage Beyond GOSC Common Systems

- Quality System (except Ponce)
- MES System (Except Ponce)
- BCP System & Crisis Recovery
- Warehouse & Incoming Inspection
- Talent Development
- Employee Resource Groups (ERG)
- Government Affairs

MEDTRONIC MISSION

CLUSTER OF SHARED SITES

Humacao
(Cranial & Spinal)

Juncos
(Diabetes, NM, PH)

Villalba
(CRM, CAS, NM, PH)

Ponce
(Surgical Innovations)

SITE PROFILE
MJC

Address: 50 Road 31, Ceiba Norte Ind. Park, Juncos PR
DOB: 2003 (coming from Humacao-1978)
Platform: West
Op. Units: Neuromodulation, Pelvic Health, Diabetes

FY24 LBE COGM: $538M DIB-70% & Neuro/PH-30%
Labor: $56M (10%) – DIB-15% & Neuro/PH-4%
Burden: $100M (19%) – DIB-21% & Neuro/PH-15%
Material: $382M (71%) – DIB- 64% & Neuro/PH-81%

FY24 LBE FG Volume, SKUs, Space:
DBT: 71M/ 225 SKUs (RSV: 52M, SNS: 18M, EP: 216K)
NS: 219K/149 SKUs (SMII: 30K, Ascenda/Catheter/Kits: 77K, Devices: 112K)
Space: 250K Ft^2 (CEA = 87K Ft^2 ,Mfg. Non-CEA = 42K Ft^2)

Quality System: Legacy CVG
Regulatory: PMA, 510K Products

Work & Shift Configuration: Monday-Sunday
- **Neuromodulation Pumps:** 1 Shift
- **Neuromodulation/Pelvic Health Devices/Kits:** 2-3 Shifts
- **DBT:** 3 Shifts (24/5), Sensor Assy. & Fab. (24/7)

Employees: 2,854
IDL: 706 (Regular = 605, Temp = 101)
DL: 2,148 (Regular = 1,306, Temp = 842)
DL / IDL Ratio: 3.0 to 1

Women: 49% **Women in Leadership:** 37%

Active ERGs: MWN/MAE, HLN, PRIDE, CERG

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MEDTRONIC JUNCOS CAMPUS

CORE PRODUCTS & COMPETENCIES

Core Products

Diabetes
- External Insulin Delivery Infusion Pumps
- Fabricated Sensors for Continuous Glucose Monitoring
- Continuous Glucose Monitoring (CGM) Sensors
- Reservoirs for Insulin Delivery Infusion Pumps

Neuromodulation & Pelvic Health
- Implantable Drug Delivery Infusion Pumps for pain management
- Implantable Neuromodulation Devices for Deep Brain, Sacral and other stimulation therapies (Tibial, Spinal)

Core Competencies

Manual →	Mechanized →	High Vol Automation
Implantable Devices (Neuro, Pelvic)		
Implantable (Neuro) & Ext'l Pumps (Diabetes)		
CGM Sensors (Diabetes)		
		Reservoirs (Diabetes)

Electrical Testing
- Electrical Testing

Laser
- Laser Welding
- Laser Soldering
- Laser Ribbon Bond
- Laser Marking
- Laser Cutting

Chemical (New in-development)
- Electrochemistry
- Rinse, AP/CVD Crosslink, Plasma
- UV Curing (Flood, Lithography)
- Polymer Synthesis
- Coating (Slot, Spin, Spray, Parylene)
- Dadet

High Volume Automation
- Mechanical Assembly
- Automated Controls
- Vision Systems
- Adhesive Dispensing
- Packaging

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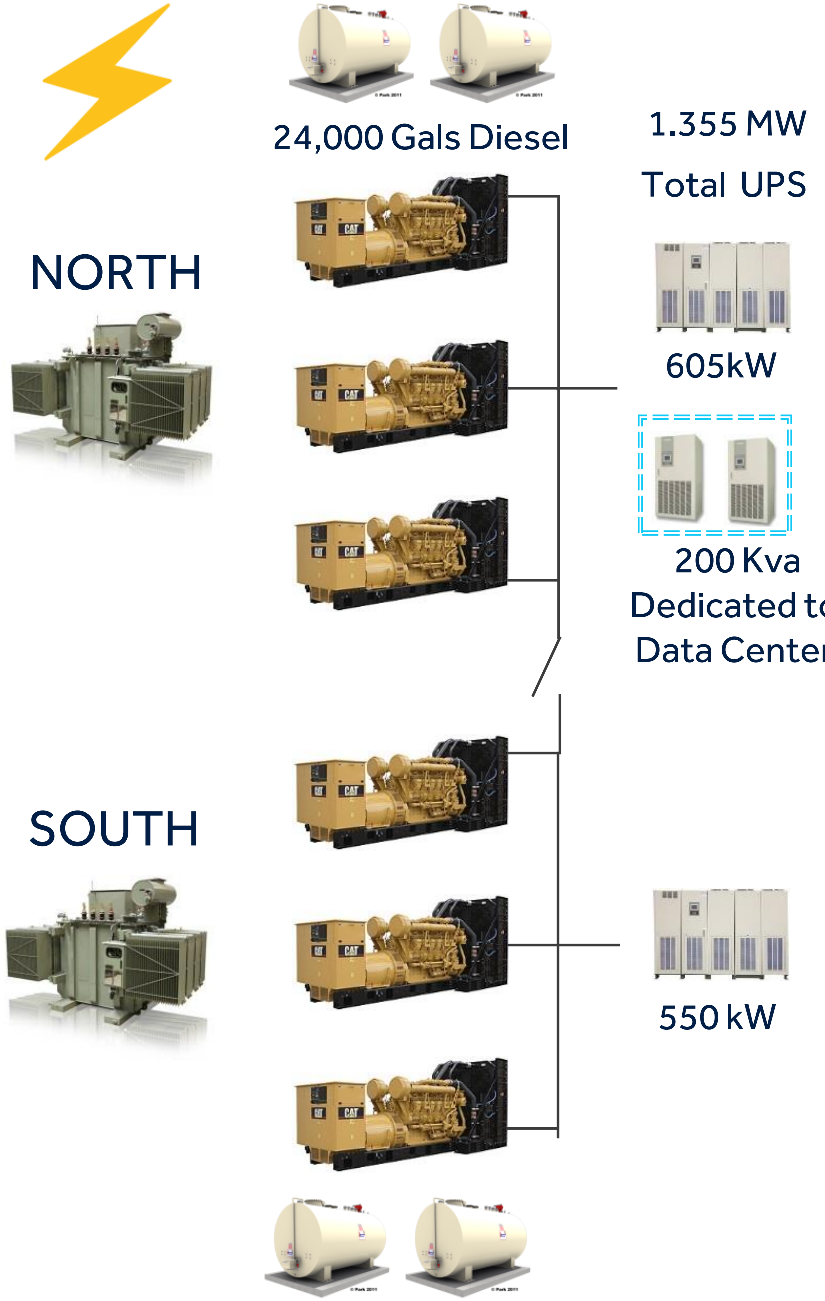
Juncos BCP Infrastructure

Natural Gas Cogen.

Solar Farm

= 66% Energy Needs

9MW TOTAL EMERGENCY GENERATION



Water Wells
- 2 Wells
- For Utilities Water
- 78.4k gallons per day

Potable Water Reserves:
- 200K Gals Potable
- 2 days of supply

Utilities Water Reserves:
- 280K Gals Fire Suppression
- 120K Gals Cooling Reserve, 4 days of supply, replenished from well water

NITROGEN
- Storage: 397.5k cubic feet
- 20 days of supply
- In-House Nitrogen Generation
  - ✓ 85 SCFM @ 99.998% Purity
  - ✓ 100% of current demand

ARGON
- Storage: 289.5K cubic feet
- 15 days of supply

HELIUM
- Storage: 2300 lb
- 23 days of supply

Redundant HVAC Technologies

Water Cooled 1700T

Air Cooled 800T (Backup)

Total of 2500 Tons

ATT / CLARO (Fiber)
OSNET (Microwave)

MAN (Local Ring)

CLARO / ATT (Fiber)
VERIZON (Satellite)

WAN (PR to US)

Juncos New Product Introductions Outlook

Launched

- InterStim-X INS — PH
- G4 / Zeus Sensor — DIA
- NGP 700G @MDCL Principal Structure — DIA
- NGP PRIME 780G — DIA
- NGP 720G @MDCL Principal Structure — DIA

Ramp-up

- Inceptiv & Percept RC INS — NMD
- SMII Pump Cortex — NMD
- Synergy COS — DIA
- GS3 + G4S Sensor Fabrication — DIA (Sensors Fabrication)

In-Flight

- Tibial NM — PH
- Mojave INS — PH
- Synergy Auto & Celestica CM — DIA
- Synergy Sensor Fabrication — DIA (Sensors Fabrication)
- Synergy DEX — DIA

Pipeline

- Deep Blue INS — NMD
- Unity — DIA
- T-Entry — PH
- Deep Blue PC — NMD

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Product Lifecycle Process & NPIs

Luis Torres & Juan Merced

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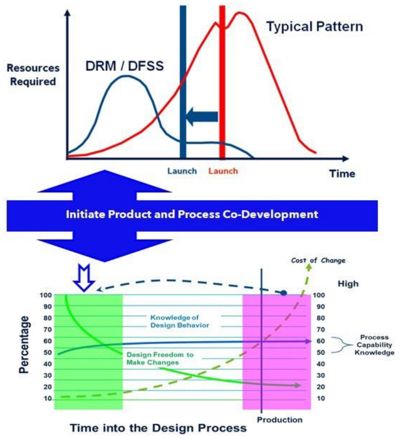
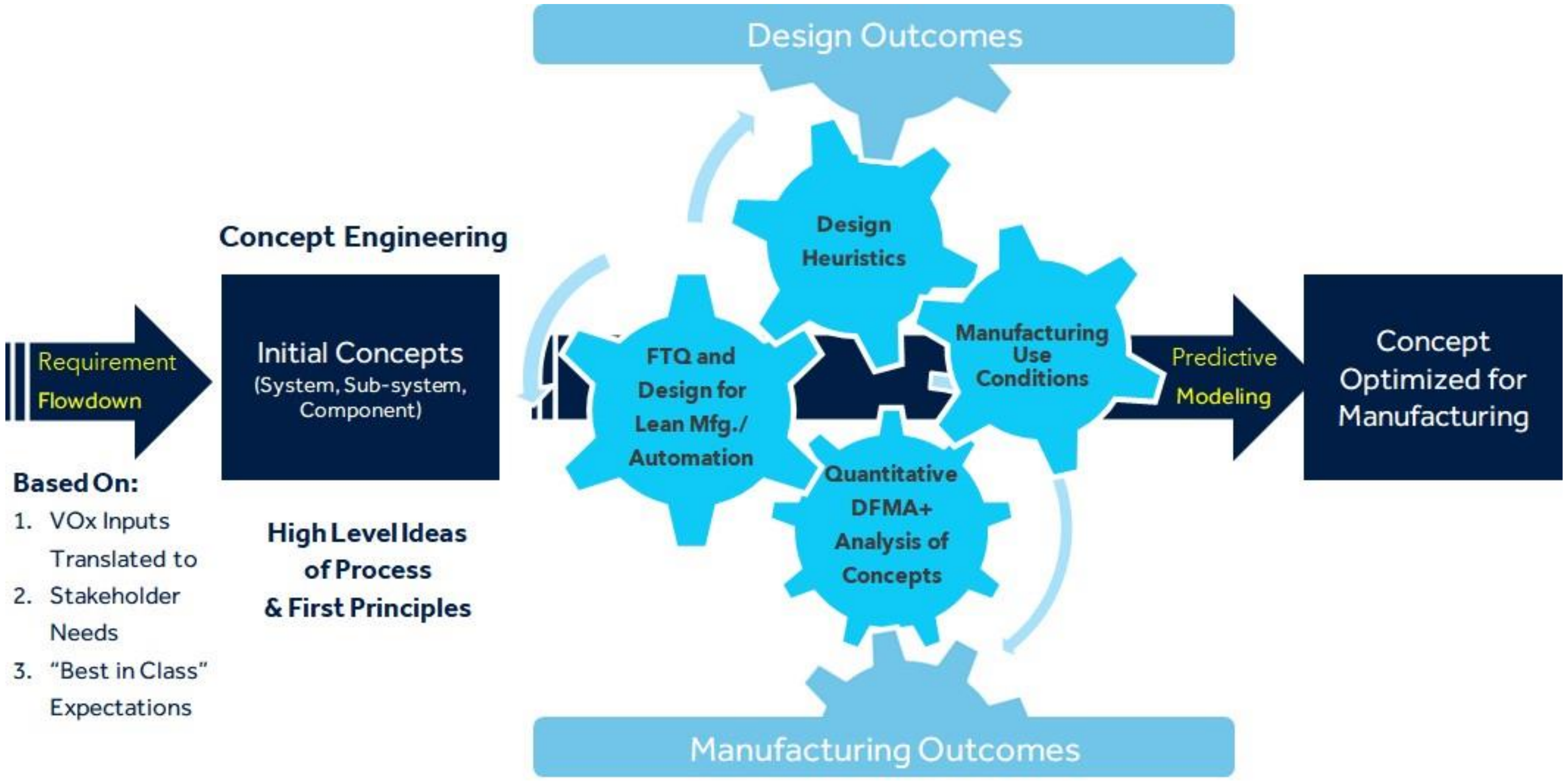
Innovation Excellence

Medtronic Performance System (MPS)

Robust Product and Process Co-Development



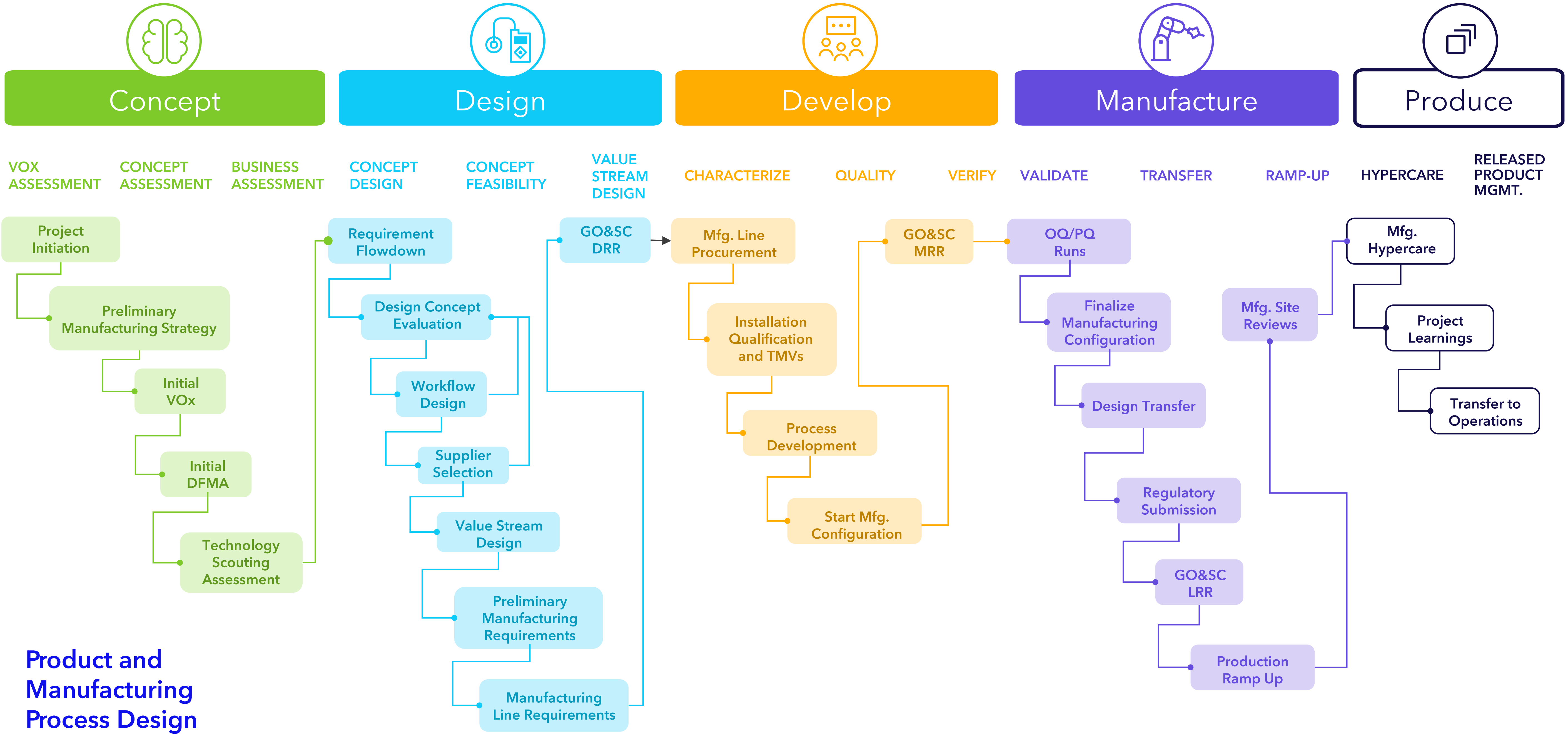


Use MPS Best Practices to achieve the most Optimum Product and Process Design that meets the Stakeholder Needs and minimizes Time to Achieve Launch Stability.

- Design for First Time Quality (FTQ)
- Design for Lean Manufacturing and/or Design for Automation
- Utilize DRM Practices
  - Voice of Customer (VOx)
  - Use Conditions (UC)
  - Requirements Flow (RF)
  - Concept Engineering (CE)
  - Design for Manufacturability (DFM) and Design for Assembly (DFA)
  - Robust Design (RD)
  - Design for Reliability (DfR)
  - Capability (%Ppk)
  - Control (C)
- Other Applicable Frameworks

Innovation Excellence

Medtronic Performance System (MPS)



Product and Manufacturing Process Design

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Innovation Excellence

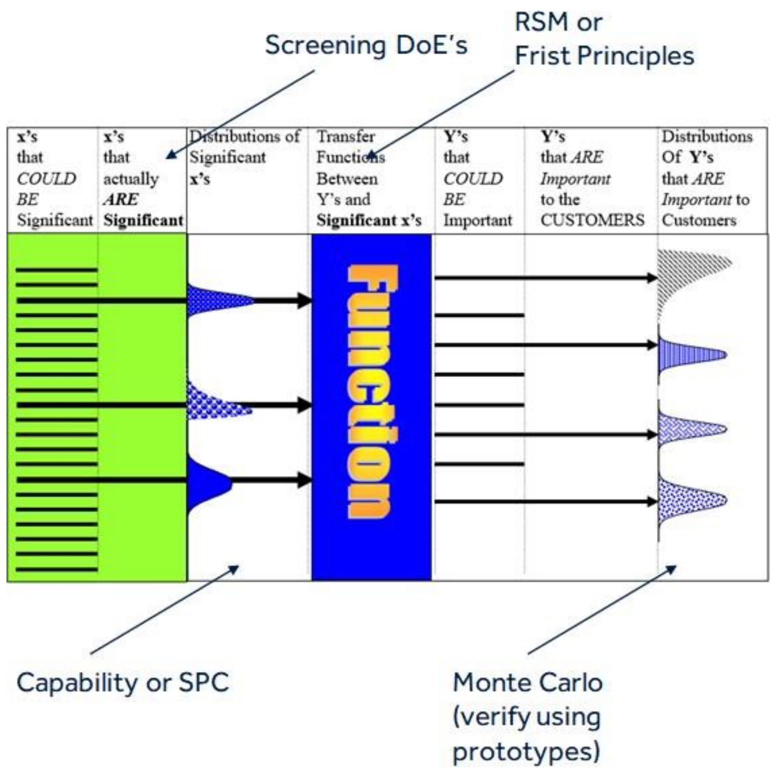
Medtronic Performance System (MPS)

Predictive Modeling to Increase NPI Launch Confidence

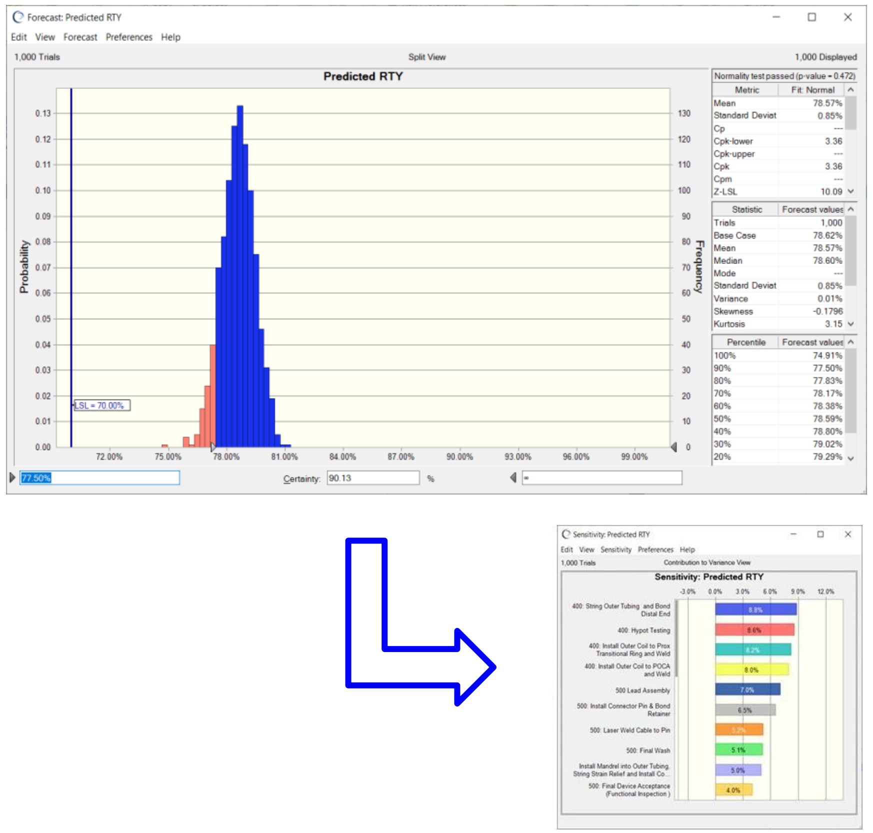
Enhance Existing and Develop New Predictive Models

- Utilize DRM Practices to establish Product/Process Output Transfer Functions and Monte Carlo Simulations
- Utilize Bayesian Networks to establish initial Performance/Reliability/Project Estimates
- Support Development of Value Stream Models to predict Capacity and optimize Planning

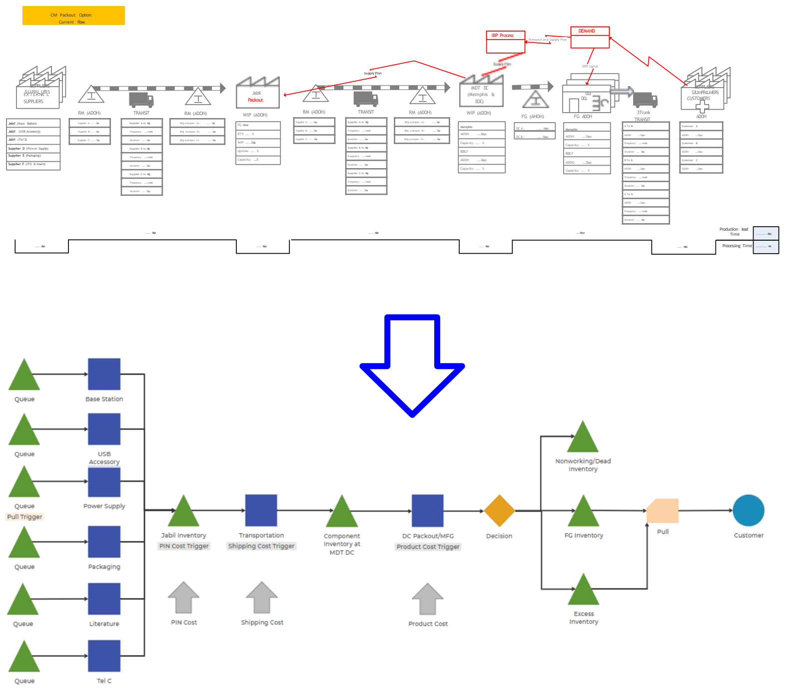
Transfer Function



Monte Carlo Simulation and Sensitivity Analysis



Value Stream Modeling



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DRM Process

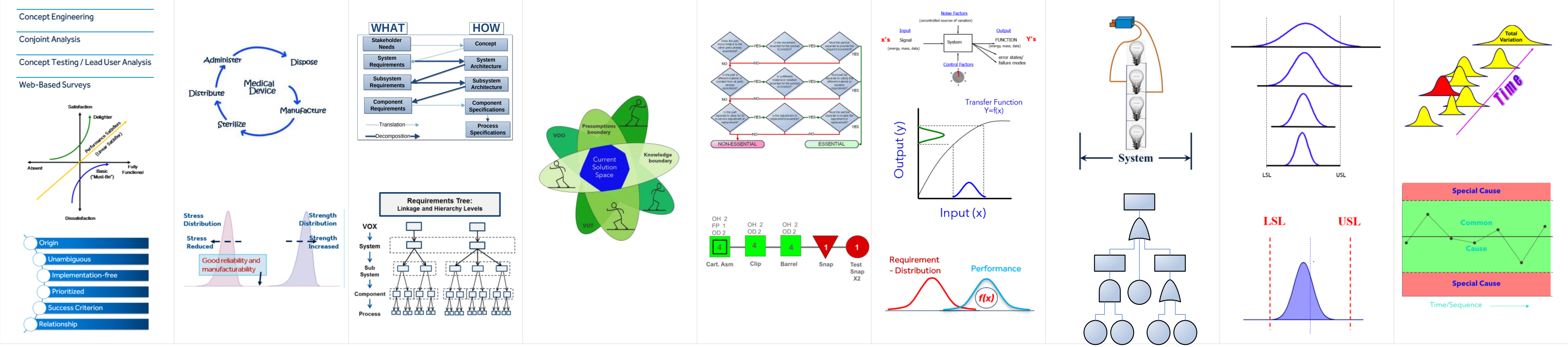
Juan Merced

Medtronic

Design, Reliability and Manufacturability (DRM)

DRM Practices

Voice of the customer	Use Condition	Requirements Flow	Concept Engineering	Design for Manufacturability and Assembly	Robust Design	Design for Reliability (DFR)	Capability	Control
VOX helps project teams to focus their development efforts on what matters most to customers, and this helps accelerate time to market and earns us customer preference.	Understanding the Use Conditions up front helps teams identify applicable requirements and develop robust designs.	Requirement Flow gives teams a sense of purpose by tracing requirements back to the underlying customer needs and supports design effort prioritization by making critical requirements visible.	Concept Engineering helps teams think broadly about solution concepts, compare options and develop optimal solutions.	Design for Manufacturing and Assembly helps teams simplify product designs and optimize manufacturing process designs.	Robust Design helps teams develop reliable products by optimizing input factors and reducing the impact of factors beyond their control.	Design for Reliability helps teams design products that perform consistently over time.	Capability helps teams predict the performance of the system and fix subsystem and component issues even before the system is built.	Good Control plans ensure we consistently produce products of the highest quality over time.



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Process Development - 1

Manufacturing Equipment Integration to an MES

Jose Guzman

Medtronic

Basic Concepts

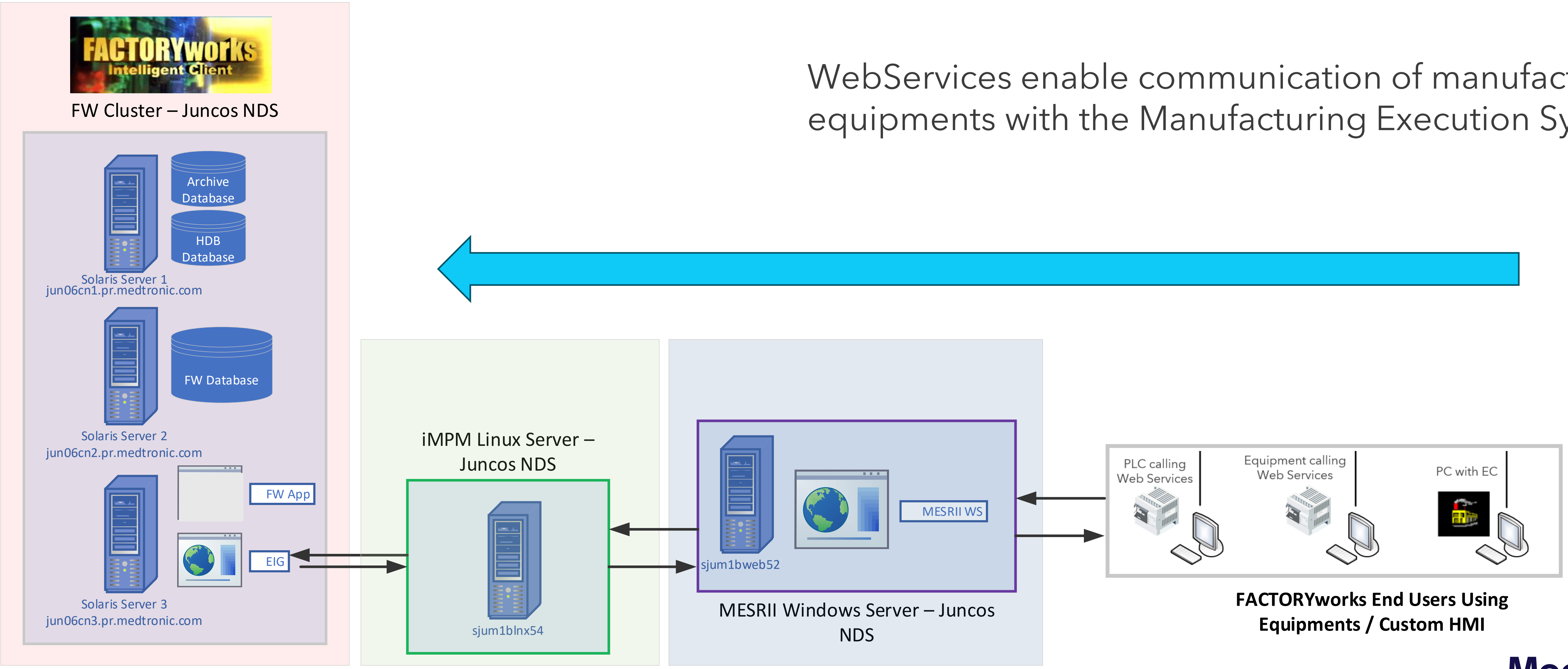
Manufacturing Execution System (MES) – a comprehensive, dynamic software system that monitors, tracks, documents, and controls the process of manufacturing goods from raw materials to finished products.

Web Services - a type of internet software that use standardized messaging protocols and are made available from an application service provider's web server for use by a client or other web-based programs.

Web Libraries - a collection of precompiled code modules or functions that developers can use to add specific functionality to their applications. Unlike frameworks, libraries do not dictate the overall structure or design of an application.

High Level Architectural Diagram

WebServices enable communication of manufacturing equipments with the Manufacturing Execution System



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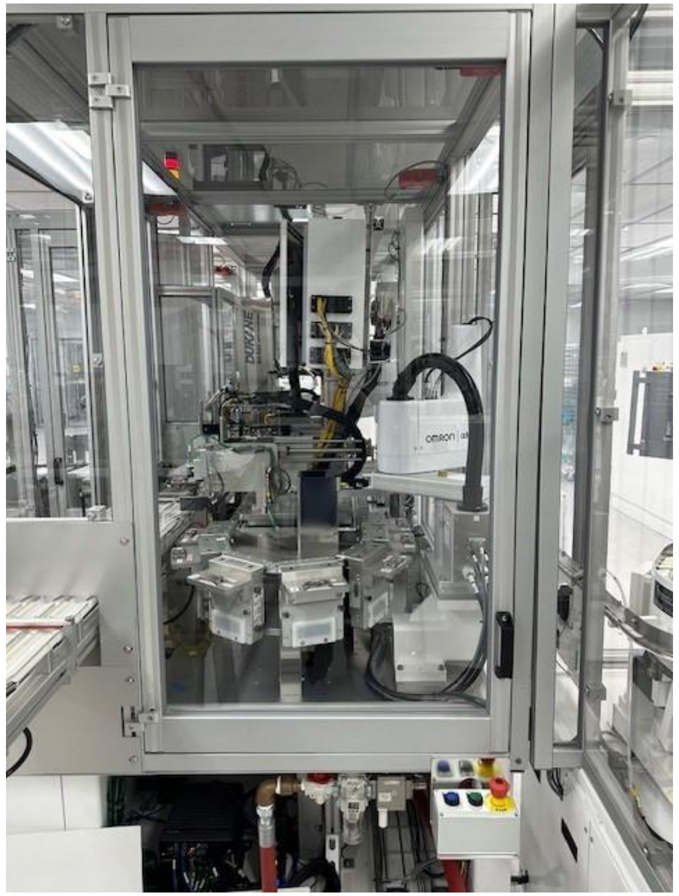
Uses

Control of high-volume automated Equipment

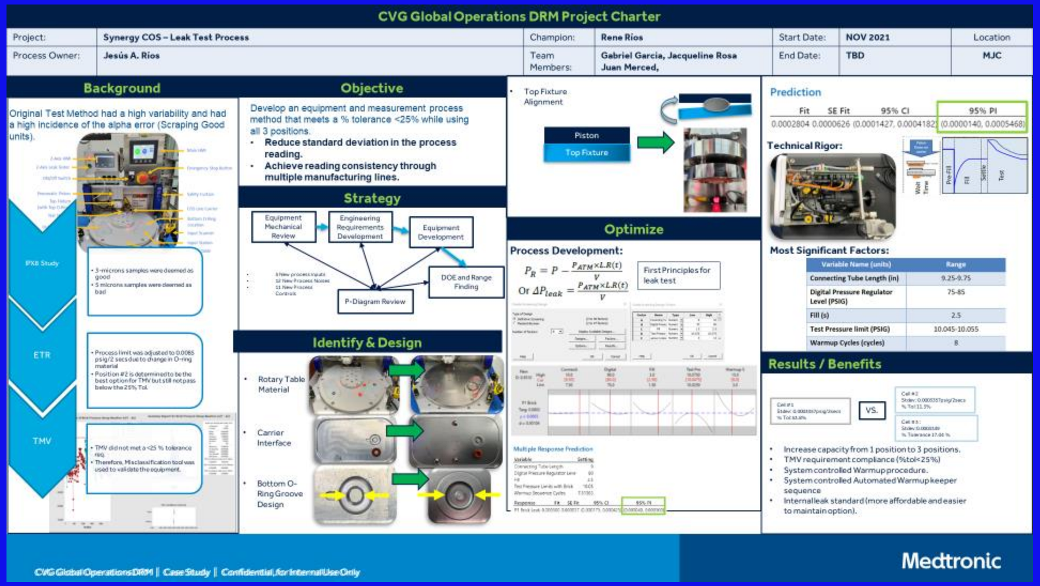


Interconnection of multiple manufacturing equipment within a production line

Reporting of manufacturing data for quality/operations decision-making

Process Development - 2

Synergy COS – Leak Test Process



Rene Rios

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Synergy COS – Leak Test Process

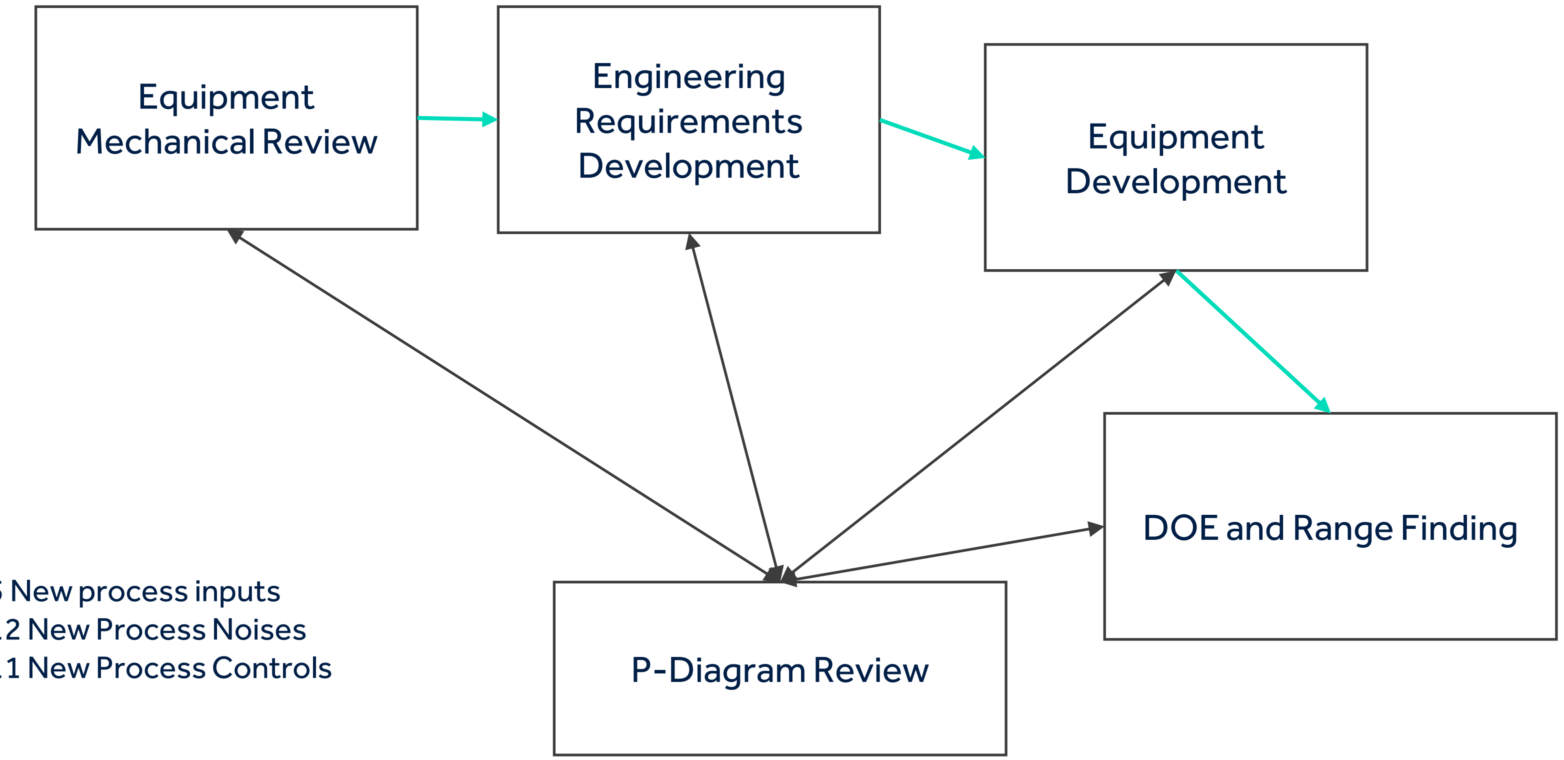
Objective & Strategy

Objective

Develop an equipment and measurement process method that meets a % tolerance <25% while using all 3 positions.

- Reduce standard deviation in the process reading.
- Achieve reading consistency through multiple manufacturing lines.

Strategy



- 5 New process inputs
- 12 New Process Noises
- 11 New Process Controls

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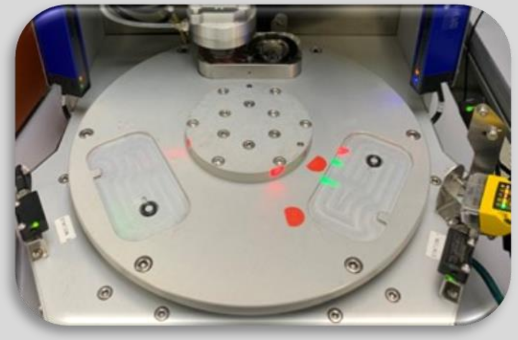
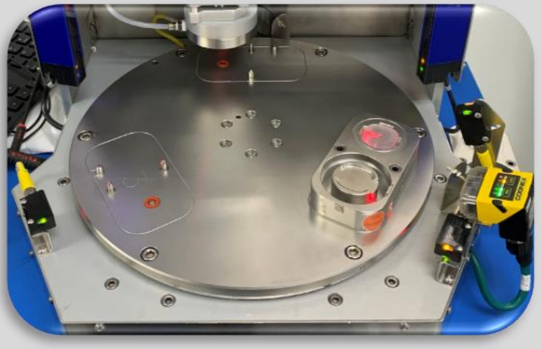
Synergy COS – Leak Test Process

Identify & Design

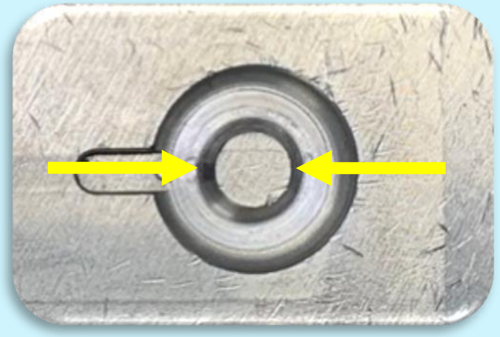
Rotary Table Material

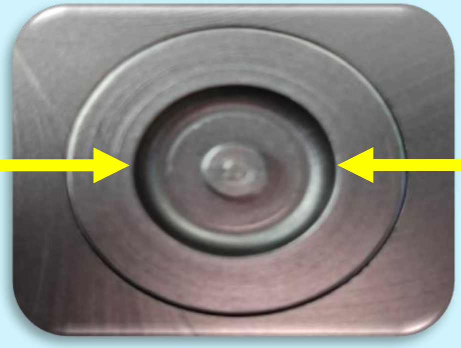




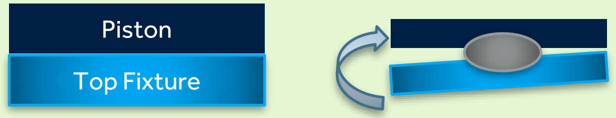
Carrier Interface

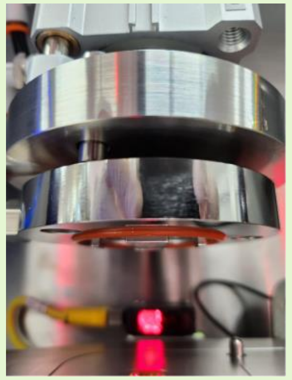
Bottom O-Ring Groove Design





Top Fixture Alignment





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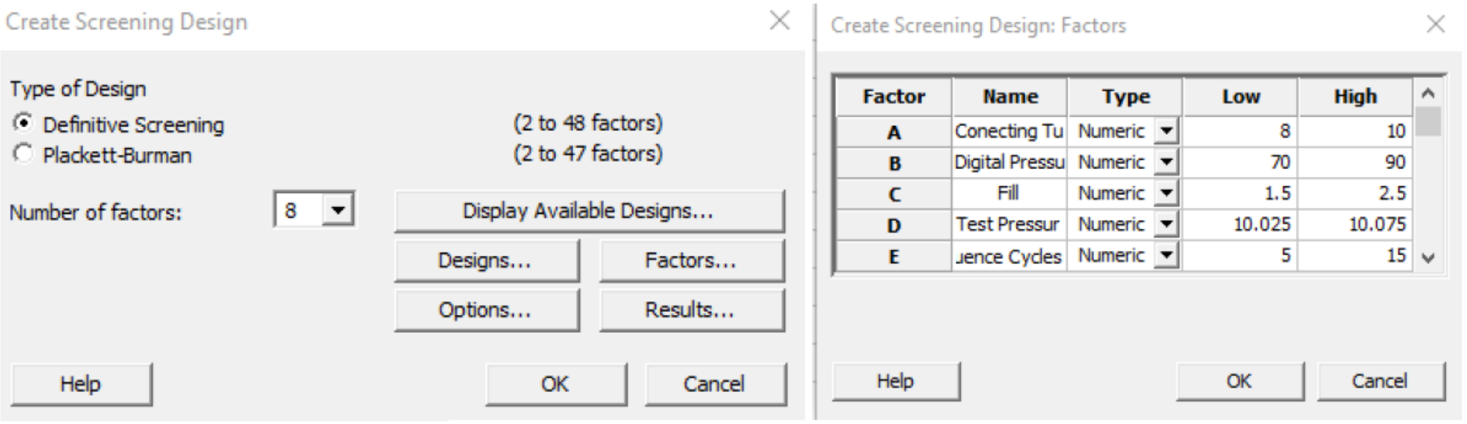
Synergy COS – Leak Test Process

Process Development

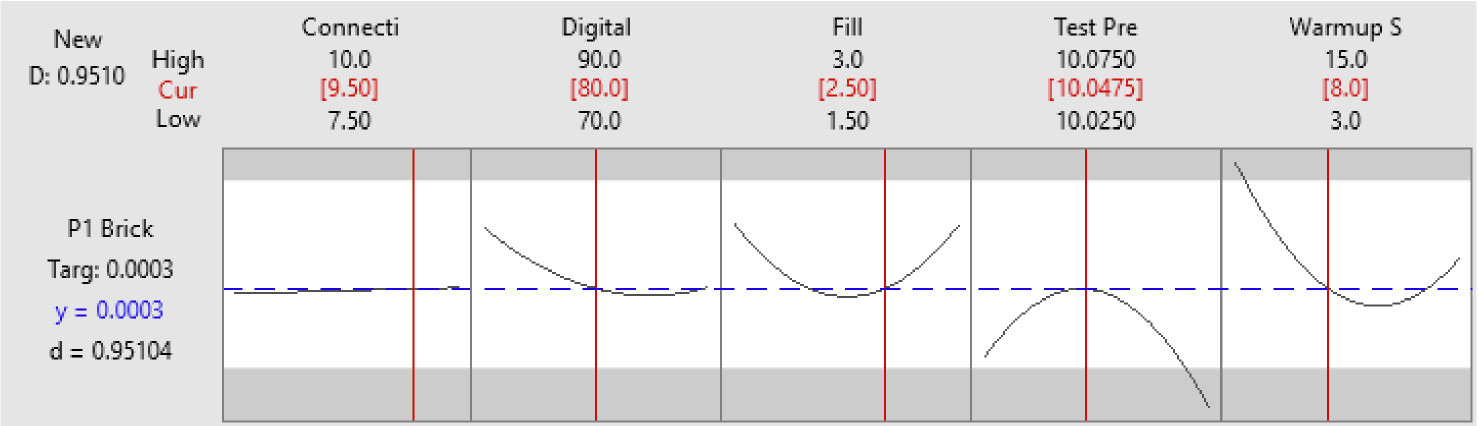
First Principles for leak test

$$P_R = P - \frac{P_{ATM} \times L.R(t)}{V}$$

$$\text{Or } \Delta P_{leak} = \frac{P_{ATM} \times L.R(t)}{V}$$



Factor	Name	Type	Low	High
A	Conecting Tu	Numeric	8	10
B	Digital Pressu	Numeric	70	90
C	Fill	Numeric	1.5	2.5
D	Test Pressur	Numeric	10.025	10.075
E	ɹence Cycles	Numeric	5	15



Multiple Response Prediction

Variable	Setting
Connecting Tube Length	9
Digital Pressure Regulator Leve	80
Fill	2.5
Test Pressure Limits with Brick	10.05
Warmup Sequence Cycles	7.51363

Response	Fit	SE Fit	95% CI	95% PI
P1 Brick Leak	0.000300	0.000057	(0.000175, 0.000425)	(0.000040, 0.000560)

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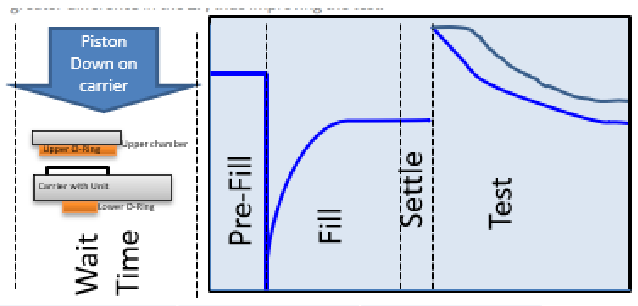
Synergy COS – Leak Test Process

Prediction & Results

Prediction

Fit	SE Fit	95% CI	95% PI
0.0002804	0.0000626	(0.0001427, 0.0004182)	(0.0000140, 0.0005468)



Most Significant Factors:

Variable Name (units)	Range
Connecting Tube Length (in)	9.25-9.75
Digital Pressure Regulator Level (PSIG)	75-85
Fill (s)	2.5
Test Pressure limit (PSIG)	10.045-10.055
Warmup Cycles (cycles)	8

Results

- Increase capacity from 1 position to 3 positions.
- Test Method Validation requirement compliance (%tol<25%).
- System controlled Warmup procedure.
- System controlled Automated Warmup keeper sequence
- Internal leak standard (more affordable and easier to maintain option).

Cell #1
Stdev: 0.0003357psig/2secs
% Tol:53.8%

VS.

Cell #2
Stdev: 0.0003357psig/2secs
% Tol:11.3%

Cell #3 :
Stdev:0.0003349
% Tolerance 17.04 %

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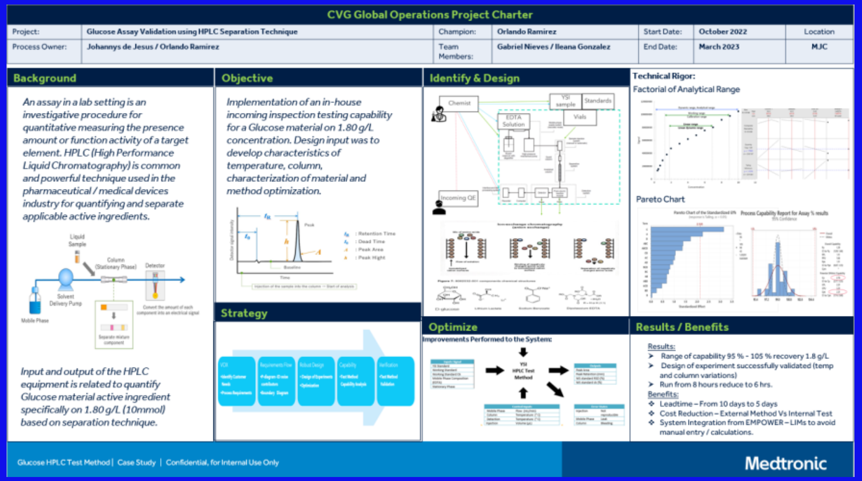
Process Development - 3

D-Glucose Concentration through HPLC Assay



Orlando Ramirez

Medtronic

Project Charter

Determination of D-Glucose Concentration through HPLC Assay

Project Start Date: *07/OCT/2022*

Problem Statement

- *Bicarbonate Test involves the final glucose reading verification of Guardian Sensor 3. YSI Biochemistry Analyzers are used to verify glucose concentrations of the solutions tested. YSI instruments are calibrated with glucose standards.*

- *The Glucose components are being tested externally by SGS Life Science Service Company. Testing and raw material release takes 30 days normally.*

Project Scope

- *This implement the testing capability for two (2) components (both glucose material) with concentrations of 1.80 g/L and 10 mmol; validating the instrumentation and optimizing the test method required in MPROC Laboratory facilities.*

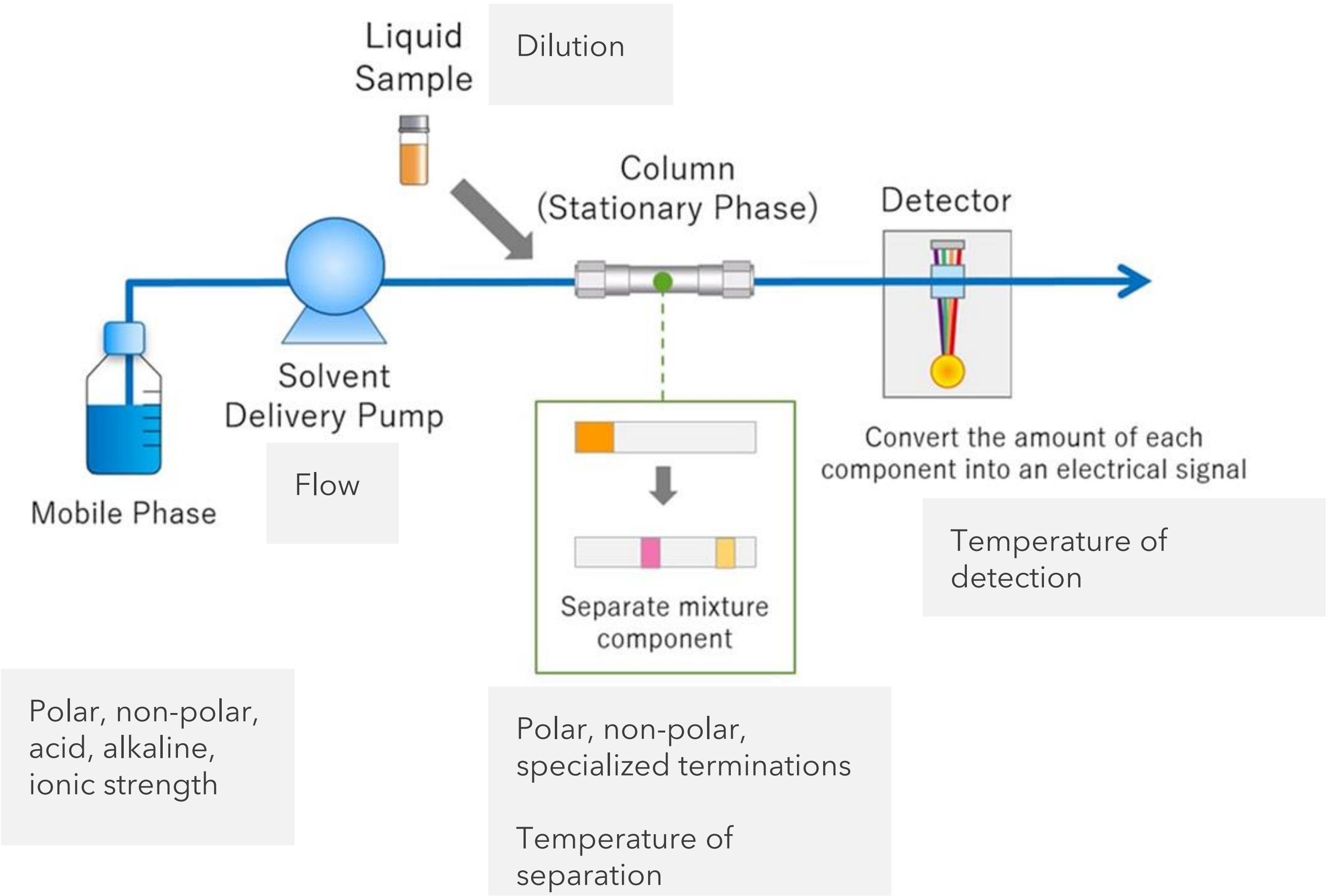
	External Supplier
Testing Lead Time	~30 days
Sample Shipping	1 additional day + Cost
Operational Cost	~ $4000 USD

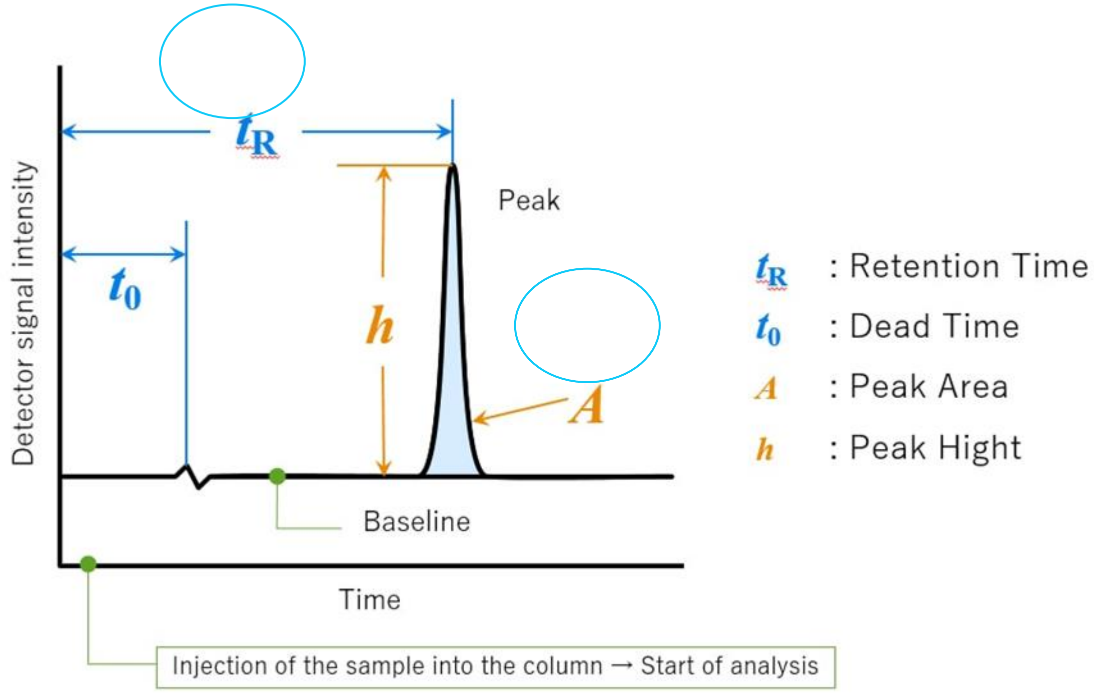
Background

An assay in a lab setting is an investigative procedure for qualitatively or quantitatively measuring the presence, amount, or function activity of a target element.

$$\sigma^2 = \sigma^2_{\text{product}} + \sigma^2_{\text{method}}$$

High-performance liquid chromatography (HPLC) is an analytical technique used to separate the components in a mixture, and to identify and quantify each component.





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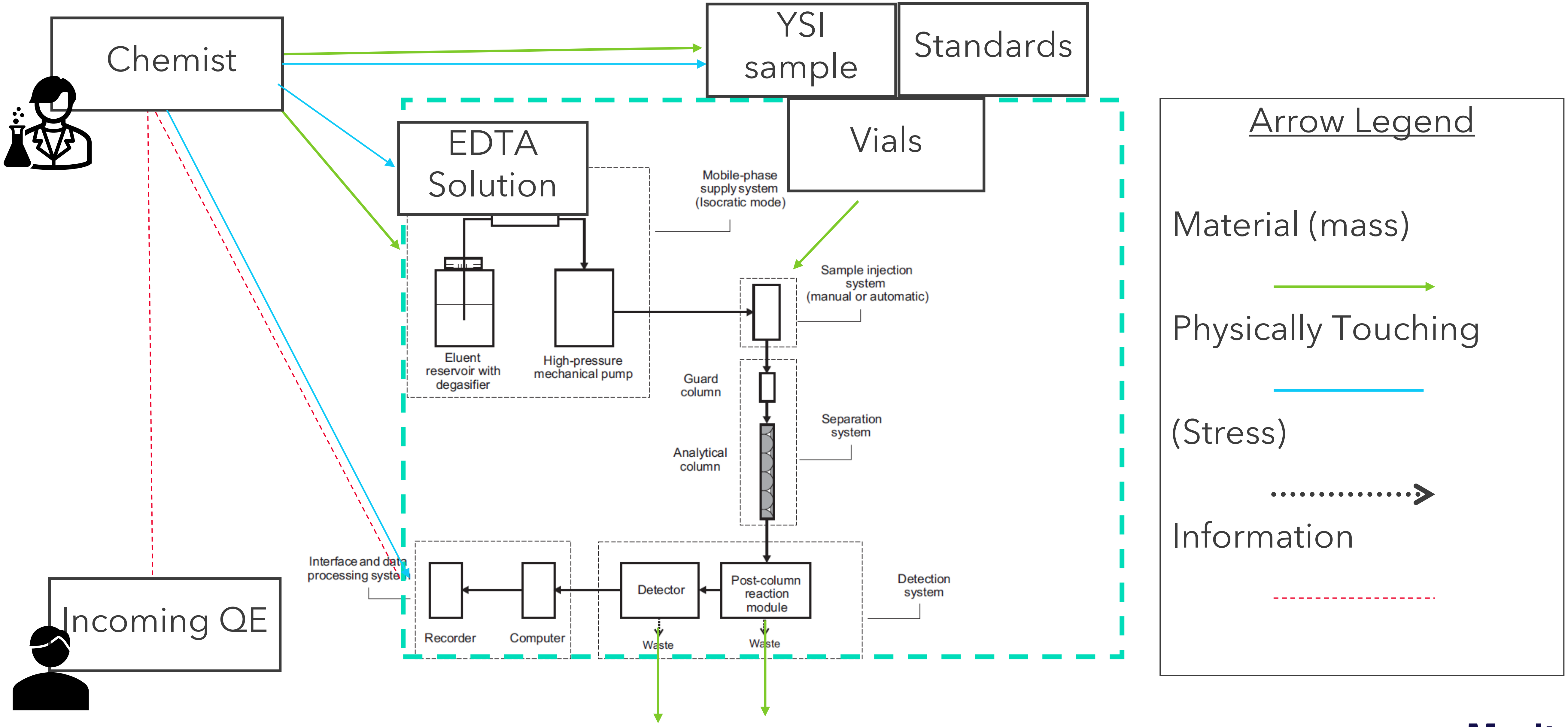
https://www.waters.com/webassets/cms/events/docs/FundamentalsofHPLCWebinar_TRS_102012.pdf

Boundary Diagram: Identify and Design

Key Parameter: Characterization – Boundary Diagram

Desired Outcome: Identify potential noises related HPLC system operation by the chemist.



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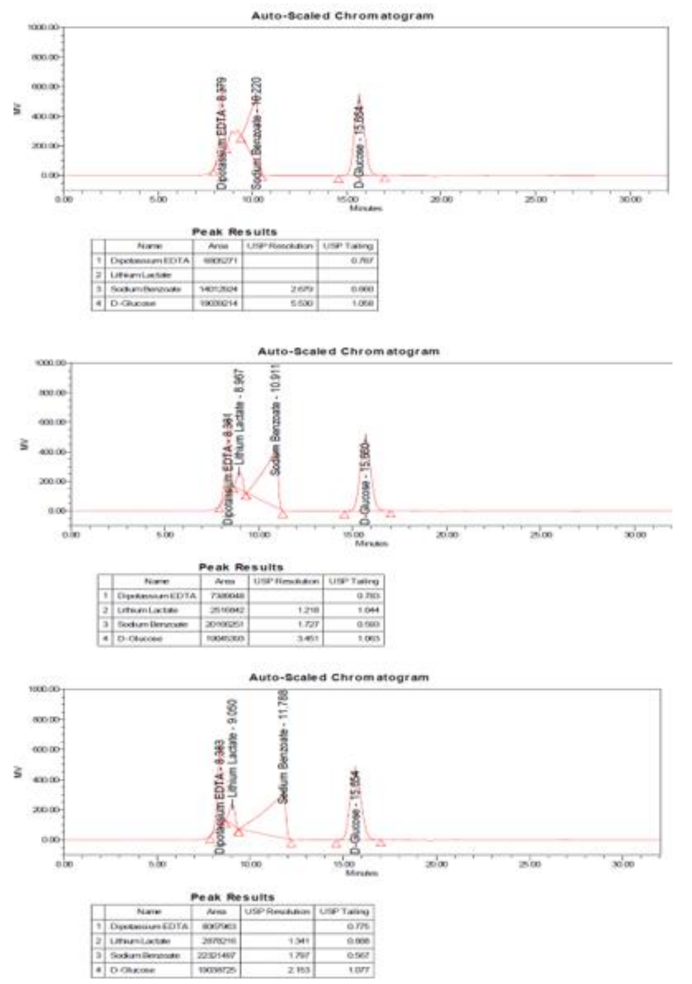
Example of Error State Occurrence Reduction: analytes coelution and column bleeding

Key Parameter: Optimize – P-diagram

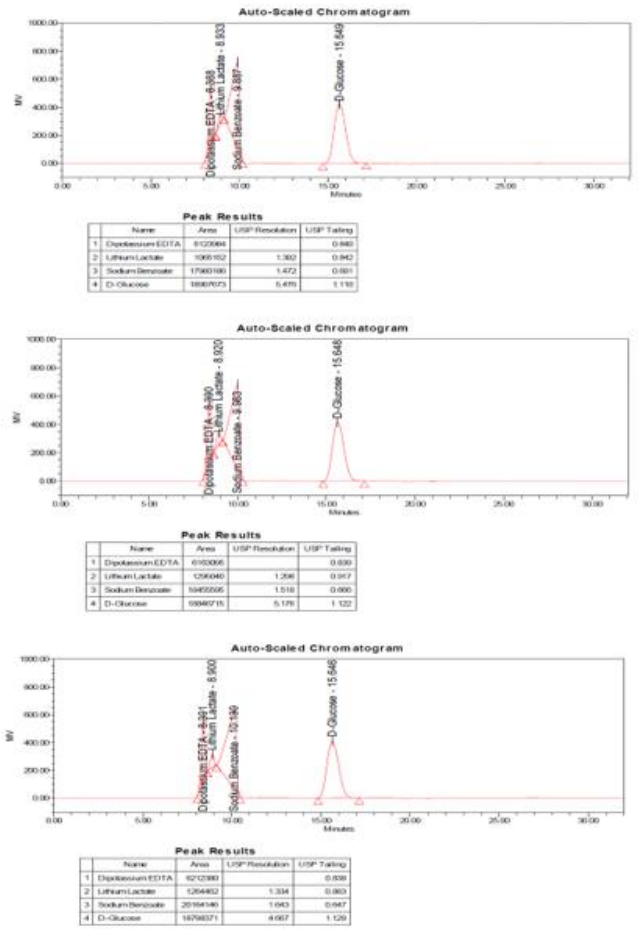
Takeaways: Error state occurrence was reduced.

The life of the column SugarPak1 was extended from 3 to 85 lots. (Cost of each 1,980.00)

DI water



CaEDTA (0.0001 M)



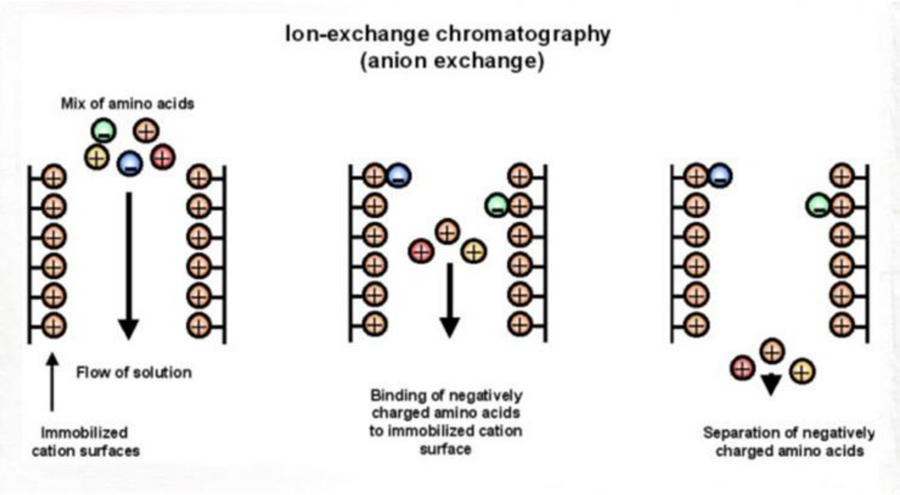
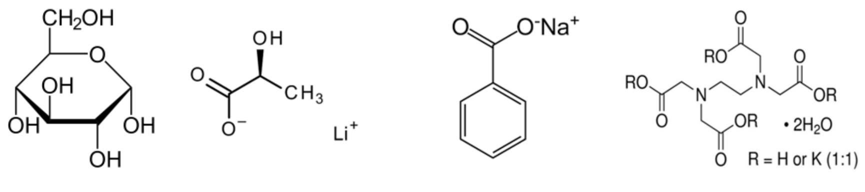


Figure 7: 8082032-001 components chemical structures



D-glucose | Lithium Lactate | Sodium Benzoate | Dipotassium EDTA

Mobile Phase	Glucose Retention time (min)	Sodium Benzoate Initial Retention time (min)	Sodium Benzoate Retention time injection 15 (min)	Injection at which the peaks overlapped	Peak shift per injection (min)
DI Water	15.6	10.2	11.0	32	0.043 min
Calcium EDTA (0.0001 M)	15.6	9.8	9.9	855	0.007 min

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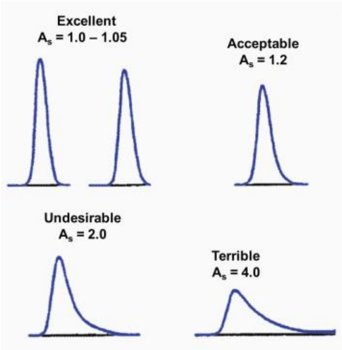
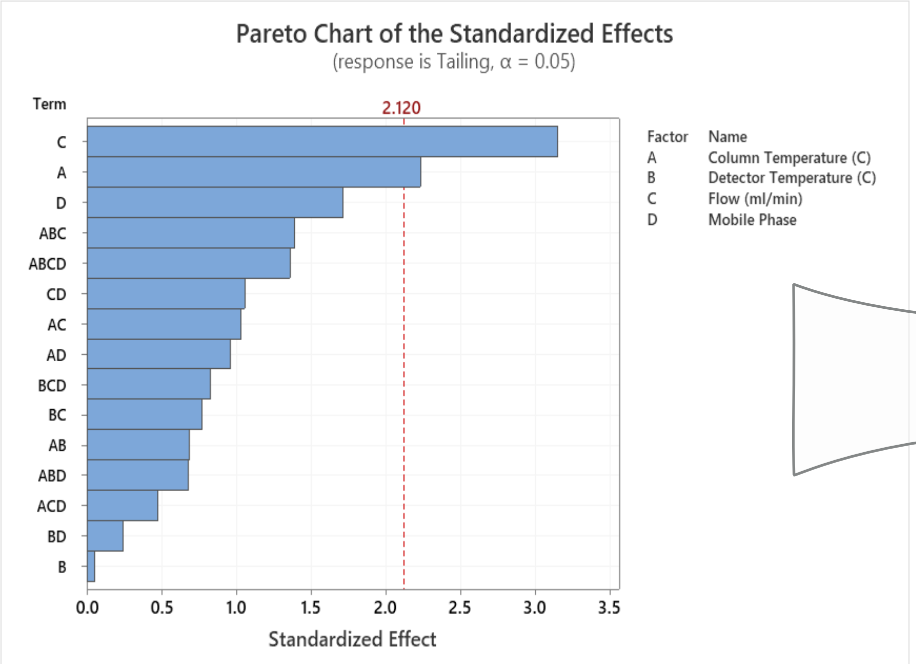
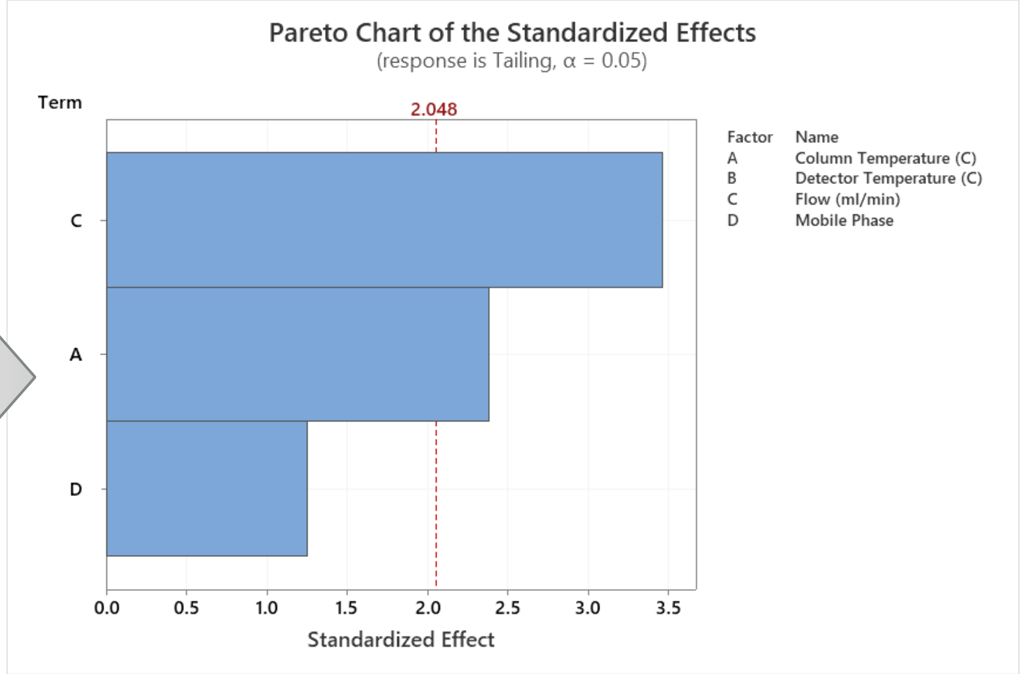
DOE: Pareto Graphs for peak tailing

Scope: Minimize the peak tailing





Complete Factorial Regression

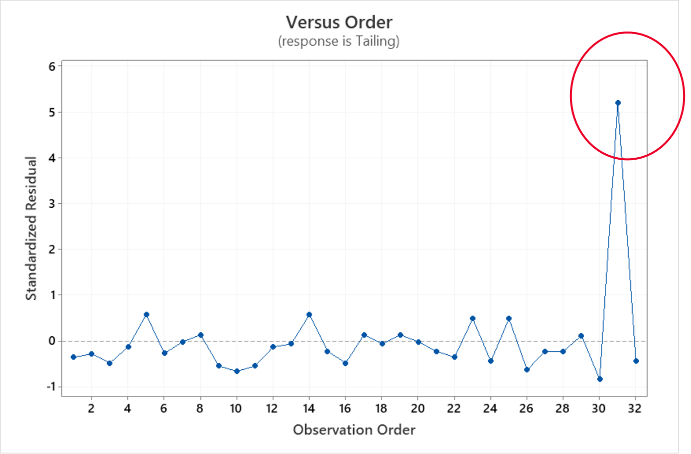


Reduced Factorial Regression

Regression Equation in Uncoded Units

Tailing = 2.272 - 0.02225 Column Temperature (C) + 0.647 Flow (ml/min) - 0.0234 Mobile Phase

The obs 31 resulted in an outlier, upon data verification the chromatography had an atypical tailing. This analysis was removed for the regression analysis execution and repeated. The new tailing factor was 1.18 and 1.19.



Fits and Diagnostics for All Observations

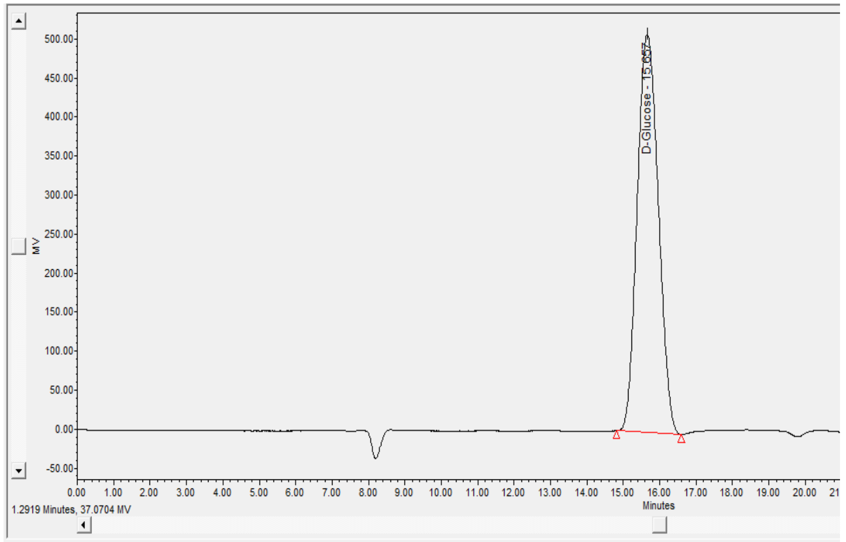
Obs	Tailing	Fit	Resid	Std Resid	
1	1.1810	1.2168	-0.0358	-0.36	
2	1.2350	1.2636	-0.0286	-0.29	
3	1.0860	1.1342	-0.0482	-0.49	
4	1.0740	1.0874	-0.0134	-0.14	
5	1.0550	0.9984	0.0566	0.57	
6	1.2360	1.2636	-0.0276	-0.28	
7	1.0850	1.0874	-0.0024	-0.02	
8	1.0580	1.0452	0.0128	0.13	
9	1.1200	1.1746	-0.0546	-0.55	
10	1.0680	1.1342	-0.0662	-0.67	
11	1.1200	1.1746	-0.0546	-0.55	
12	1.0740	1.0874	-0.0134	-0.14	
13	1.1210	1.1278	-0.0068	-0.07	
14	1.0550	0.9984	0.0566	0.57	
15	1.1050	1.1278	-0.0228	-0.23	
16	1.0860	1.1342	-0.0482	-0.49	
17	1.0580	1.0452	0.0128	0.13	
18	1.1210	1.1278	-0.0068	-0.07	
19	1.0580	1.0452	0.0128	0.13	
20	1.0850	1.0874	-0.0024	-0.02	
21	1.1940	1.2168	-0.0228	-0.23	
22	1.1810	1.2168	-0.0358	-0.36	
23	1.0460	0.9984	0.0476	0.48	
24	1.1300	1.1746	-0.0446	-0.45	
25	1.0460	0.9984	0.0476	0.48	
26	1.0710	1.1342	-0.0632	-0.64	
27	1.1050	1.1278	-0.0228	-0.23	
28	1.1940	1.2168	-0.0228	-0.23	
29	1.0560	1.0452	0.0108	0.11	
30	1.1800	1.2636	-0.0836	-0.85	
31	1.7780	1.2636	0.5144	5.20	R
32	1.1300	1.1746	-0.0446	-0.45	

R Large residual

LIMs Labware / EMPOWER 3

System Integration and Data Management

EMPOWER 3



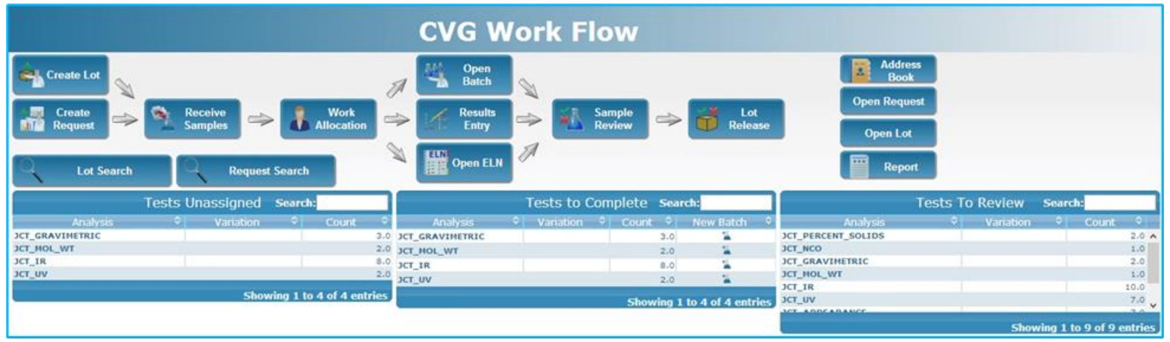
	Name	Retention Time (min)	Area (µV*sec)	% Area	Height (µV)	Int Type	Amount	Units	Dissolved Amount	Dissolved Percent	Peak Type	Peak Codes	Assay_Percent	Percent_Recovery
1	Sodium Benzoate	9.179				Missing					Missing			
2	D-Glucose	15.657	20617415	100.00	510159	BB	1.773	g/L			Found	Q10		98.5

	Name	Field Type	Type	Width	Precision	Minimum	Maximum	Default	Source	Required	Formula	CField Id
1	Assay_Percent	Peak	Real (0.0)	12	2	-1000000000	1000000000		Calculated	☐	(CCompRef1[Amount]/1.80)*100	100
2	Column Name	Sample	Text	32	0	0	0		Keyboard	☐		81
3	Column Serial Number	Sample	Text	32	0	0	0		Keyboard	☐		80
4	Dilution	Sample	Real (0.0)	11	4	0	1000000	1.0	Keyboard	☐		97
5	Level Values	Sample	Enum	32	0	0	0		Keyboard	☐		95
6	Percent_Recovery	Peak	Real (0.0)	12	1	-10000000000	10000000000		Calculated	☐	(CCompRef1[Amount]/Control Value)*100	101
7	Sample Matrix	Sample	Enum	32	0	0	0		Keyboard	☐		79
8	SampleName	Sample	Text	32	0	0	0		Keyboard	☐		99
9	SampleWeight	Sample	Real (0.0)	11	4	0	1000000	1.0	Keyboard	☐		98
10	Solvent	Sample	Text	32	0	0	0		Keyboard	☐		96

LIMs Labware

Data | Edit

JCT_AMINE [Amine Number] / 1		Version 2	Complete
Date Completed		01/30/2024 02:22:41 PM	
Test Date	✓	01/30/2024	
Sample#1 Tare Weight	✓	0.000000	g
Sample Weight #1	✓	10.000045	g
Sample#2 Tare Weight	✓	0.000000	g
Sample Weight #2	✓	10.000020	g
HCL Concentration	✓	0.5007	equivalents/L
Volume of HCL spl#1	✓	15.2	ml
Volume of HCL spl#2	✓	15.0	ml
Amine Value spl#1	✓	0.7610605752	meq/g
Amine Value Spl#2	✓	0.7510484979	meq/g
Final Amine Value [Amine Number]	✓	0.76	meq/g
Range	✓	1	%



System Suitability Run:		
Empower Sample Set Run:	240307_JIG_01 SS: 3341 RS: 3386	
Specifications:	Results:	Status:
Resolution 200,000 - 100,000 g/mol: (Pass: Res. Value ≥ 0.5, Fail: Res. Value < 0.5)	1.4	Pass
Resolution 100,000 - 50,000 g/mol: (Pass: Res. Value ≥ 0.5, Fail: Res. Value < 0.5)	1.1	Pass
Tailing 100,000 g/mol: (Pass: Tailing ≤ 2.0, Fail: Tailing > 2.0)	1.0	Pass

Process Development - 4

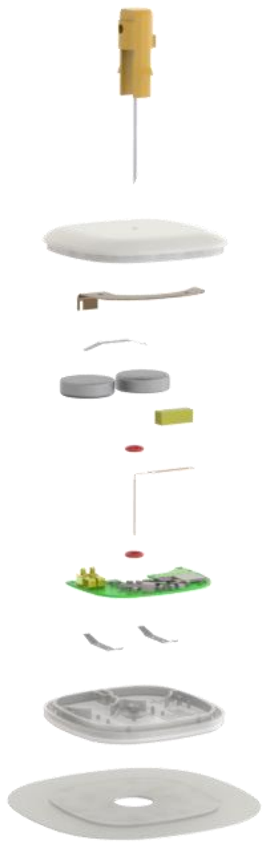
Synergy COS Ultrasonic Welding Process

Rene Rios

Medtronic

SYNERGY COS ULTRASONIC WELDING PROCESS
SYSTEM DESCRIPTION

Synergy Product



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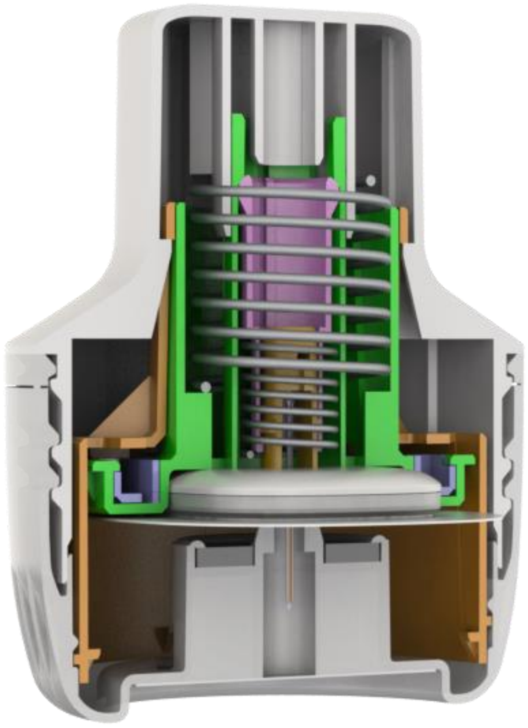

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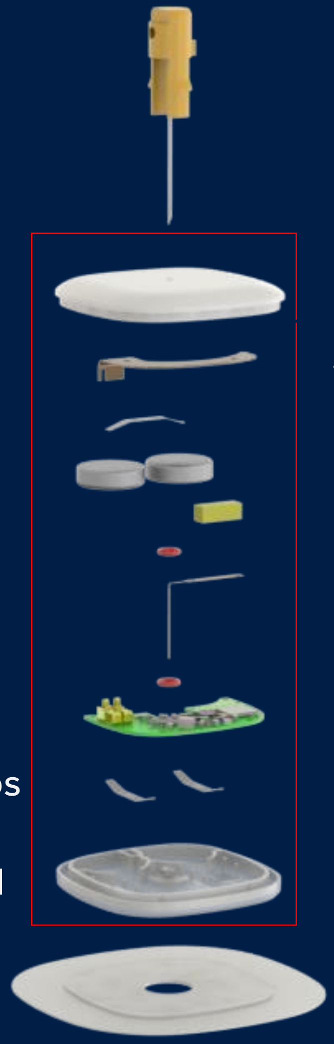
Sensor Assembly

Cap / Serter Assembly

Synergy Final Product

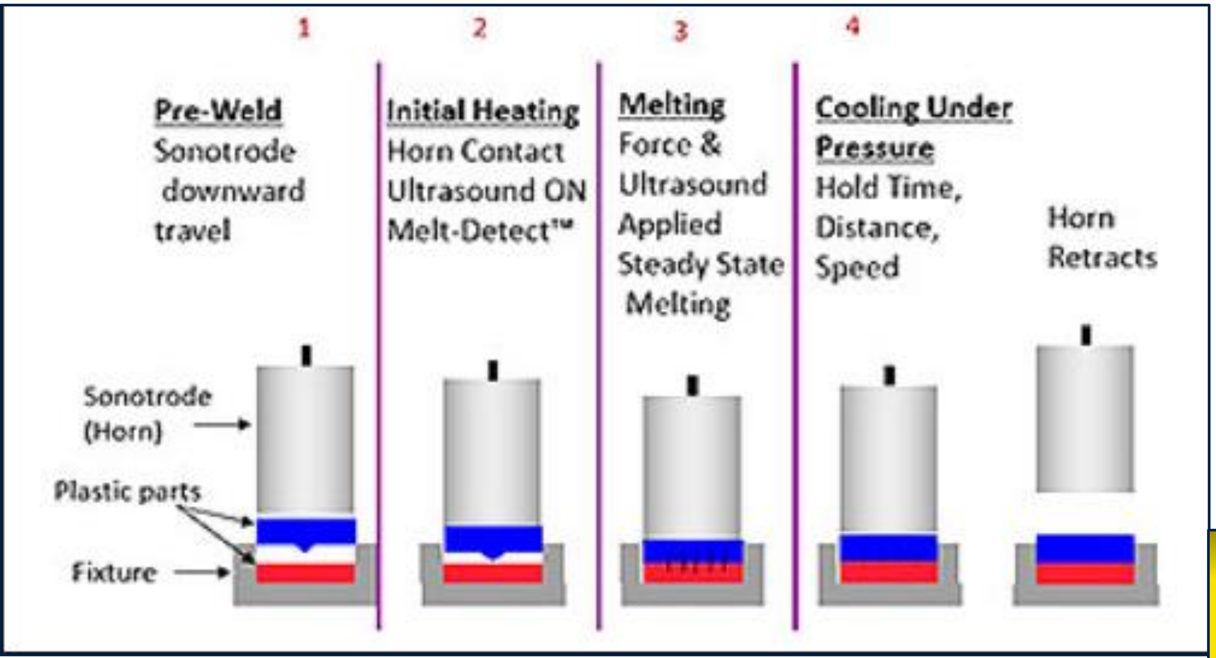
USW Application

USW Scoped Assembly



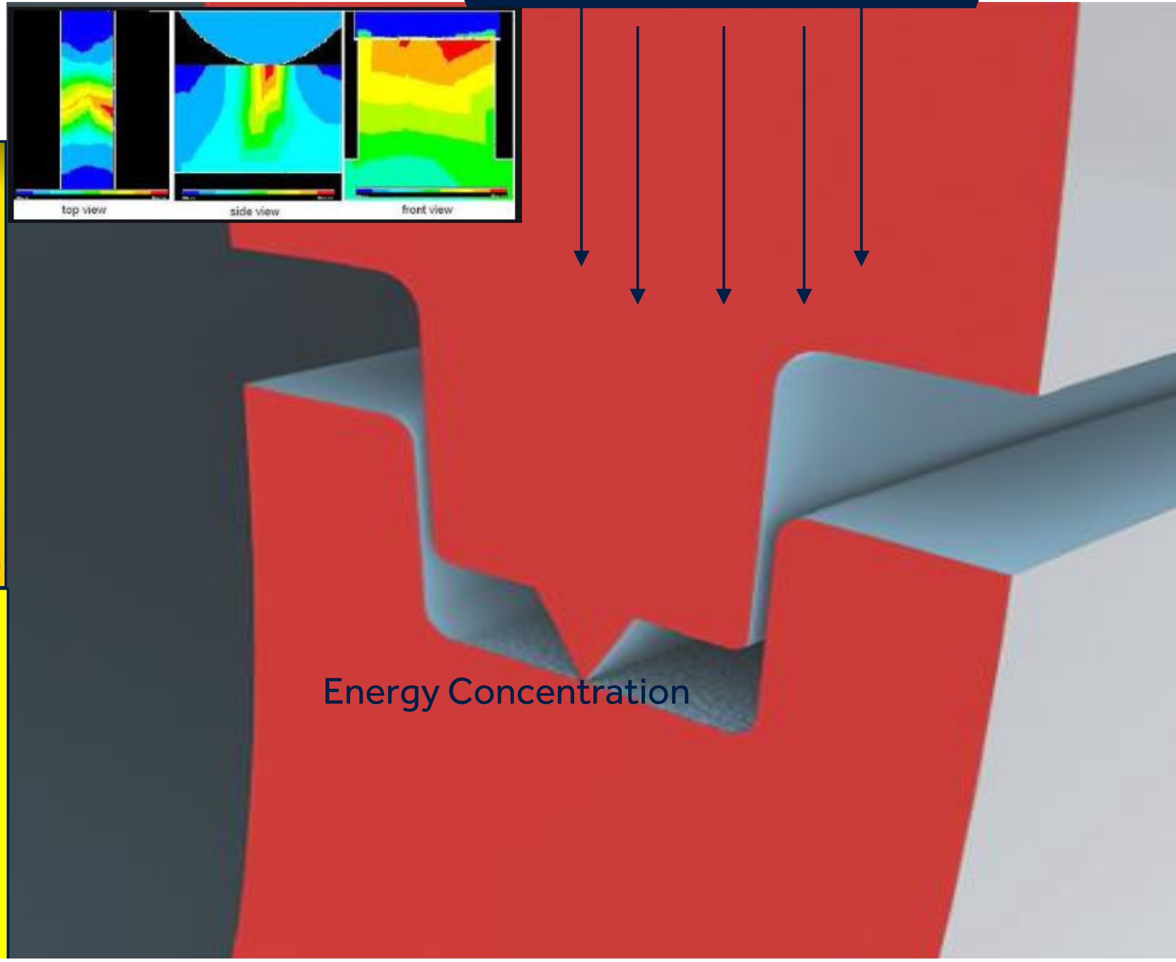
SYNERGY COS ULTRASONIC WELDING PROCESS

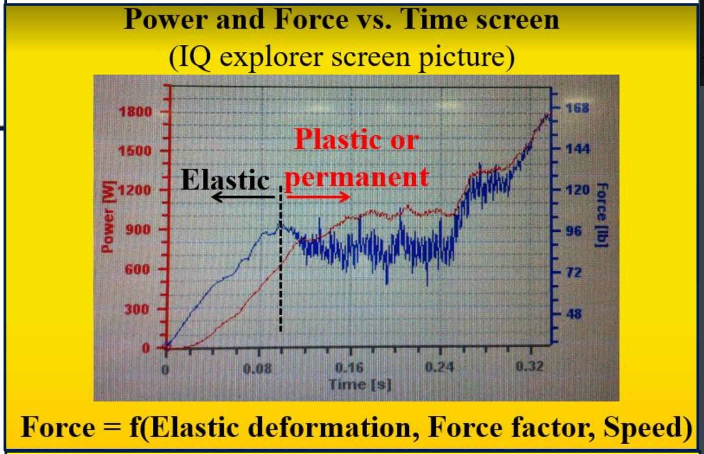
1ST PRINCIPLES

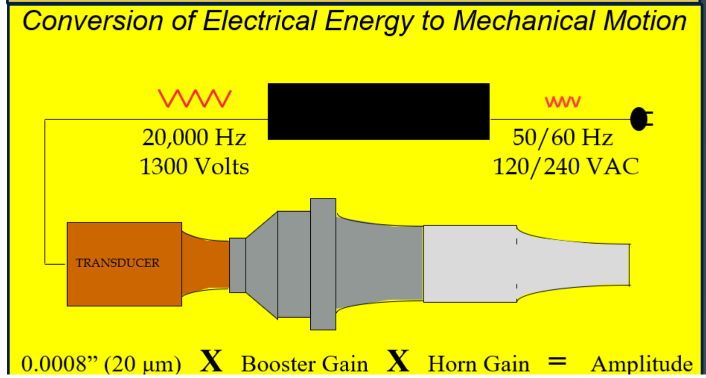


Standard Energy Concentration and heat transfer occurs from the mechanically vibrating part to the part receiving the heated component

Horn







1st Principles Challenge Conditions

Input Parameters	OQ Low (Least Collapse)	OQ High (Most Collapse)
Amplitude	Low	High
Trigger Force	Low	High
Melt Detect	Low	High
Weld Distance	Low	High
Weld Speed	High	Low
Post Weld Force	Low	High
Post Weld Speed	Low	High
Static Hold	Low	High

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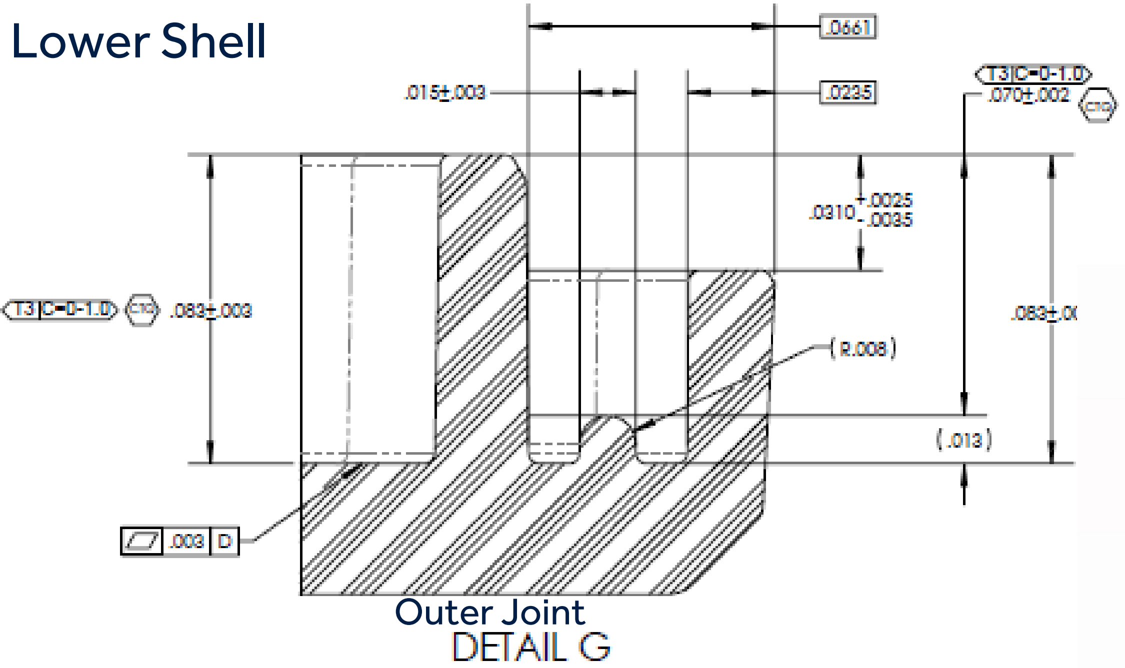
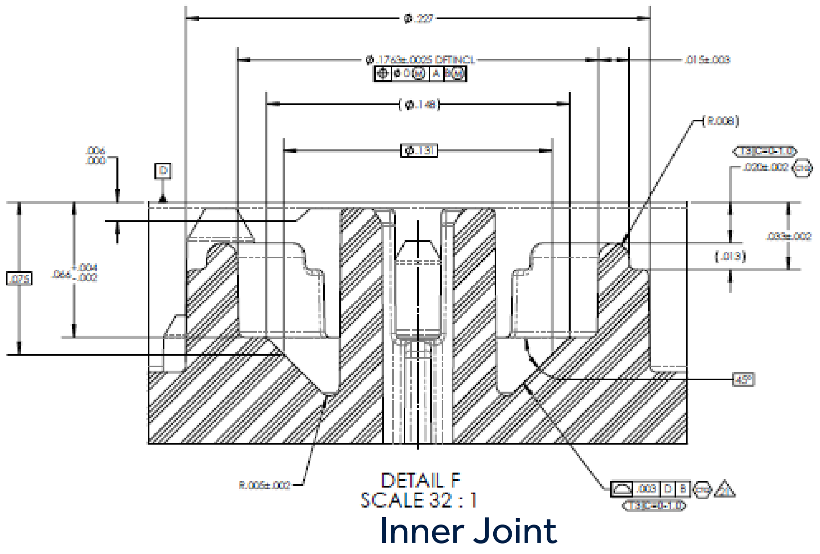
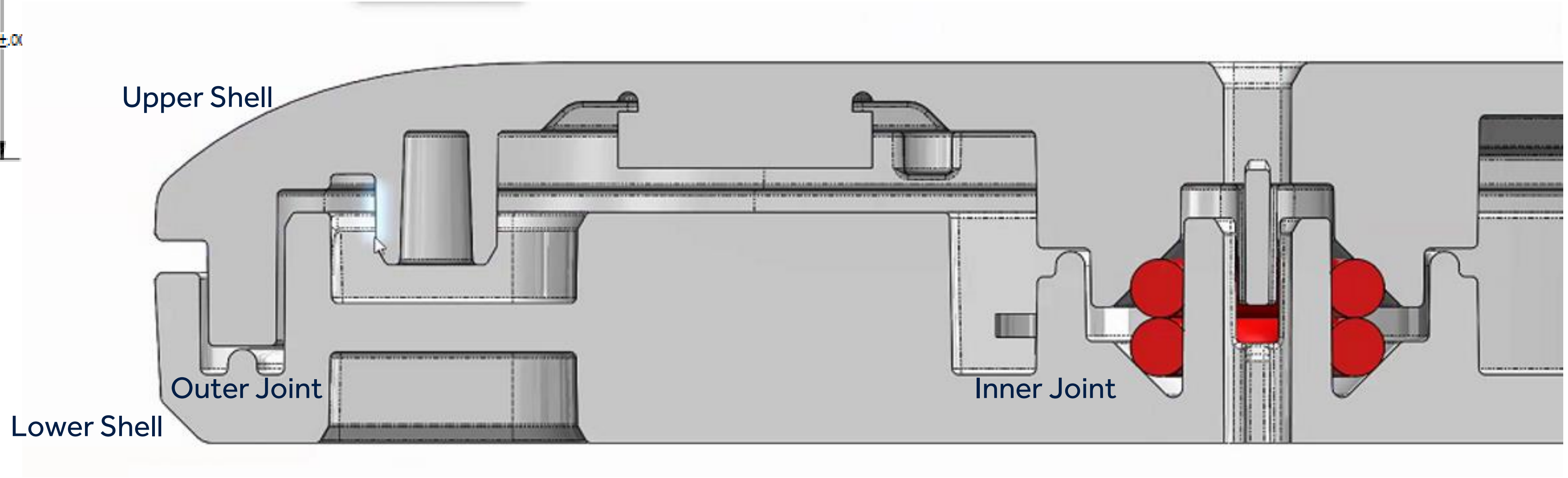
SYNERGY COS ULTRASONIC WELDING PROCESS

1ST PRINCIPLES







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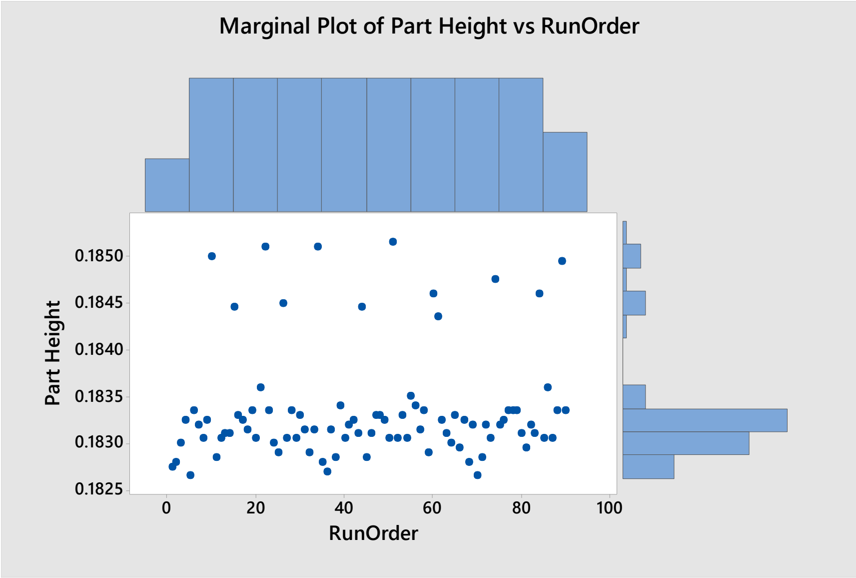
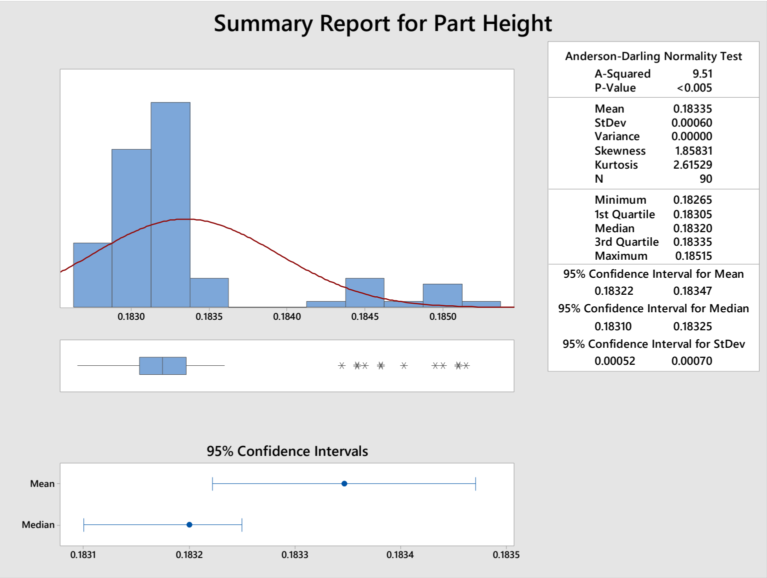
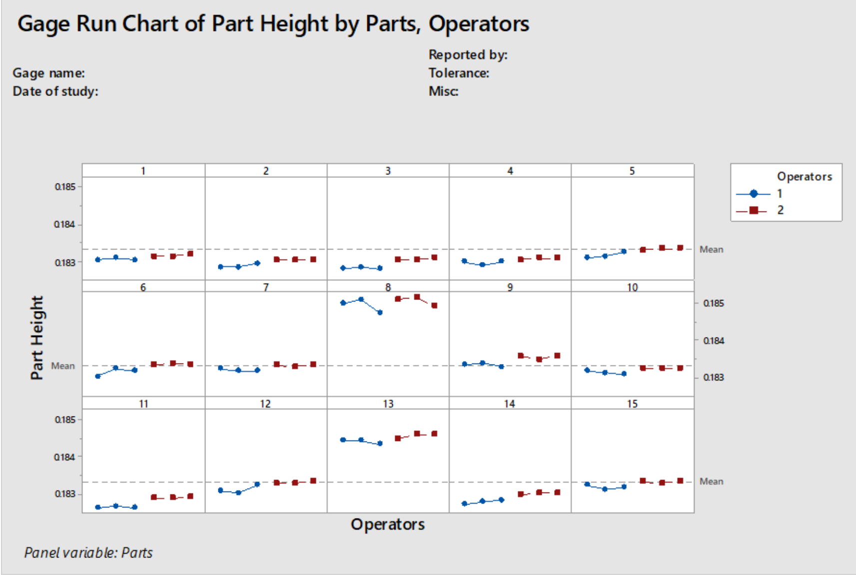
SYNERGY COS ULTRASONIC WELDING PROCESS
PRE DV-PERFORMANCE – PART HEIGHT MSA







Gage R&R

Variance Components

Source	VarComp	%Contribution (of VarComp)
Total Gage R&R	0	4.6
Repeatability	0	0.99
Reproducibility	0	3.62
Operators	0	3.62
Part-To-Part	0.0000004	95.4
Total Variation	0.0000004	100

Gage Evaluation

Source	StdDev (SD)	Study Var (6 × SD)	%Study Var (%SV)
Total Gage R&R	0.0001325	0.0007952	21.45
Repeatability	0.0000613	0.000368	9.93
Reproducibility	0.0001175	0.000705	19.02
Operators	0.0001175	0.000705	19.02
Part-To-Part	0.0006034	0.0036204	97.67
Total Variation	0.0006178	0.0037067	100

Number of Distinct Categories = 6

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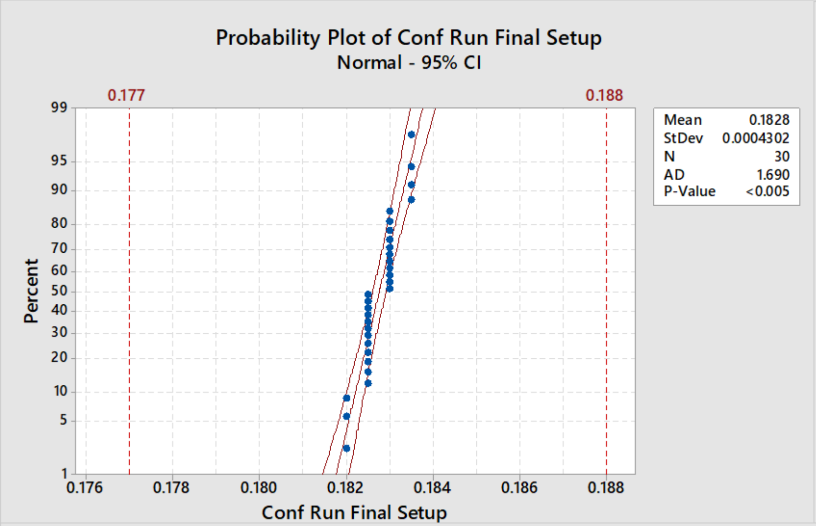
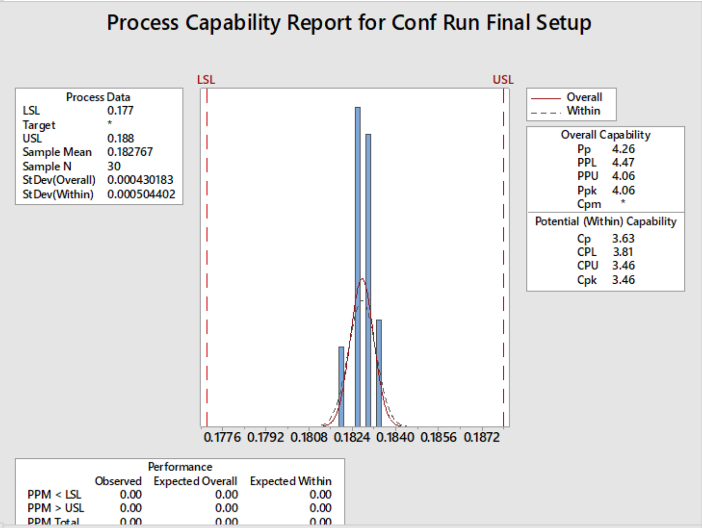
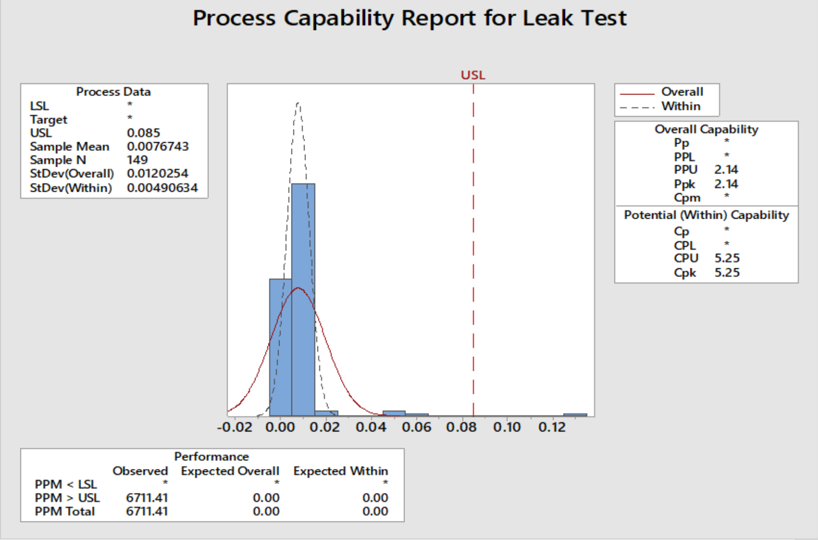
SYNERGY COS ULTRASONIC WELDING PROCESS

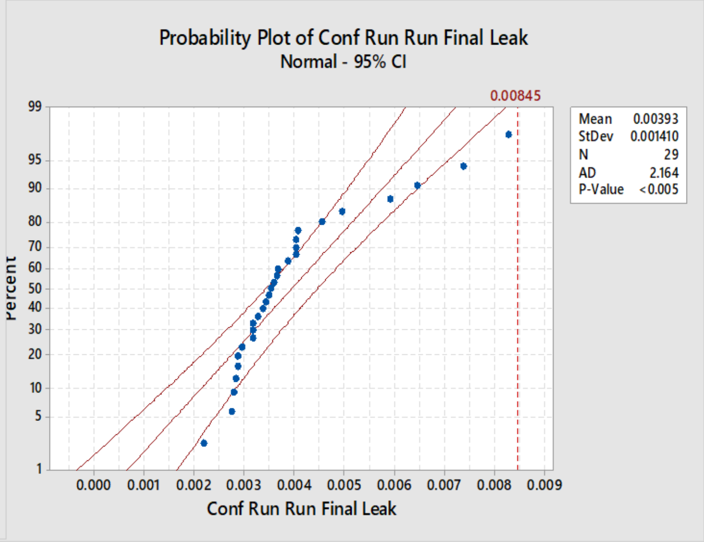
PRE DV-PERFORMANCE – CONF RUNS NOMINAL

Capability









Design Requirements Output

Part Height = 4.06

Leak Test = 2.14
Needle Insertion = 100% Pass

Next Activities:

- **Optimization**
- **Transfer Function Validation**
- **MC Simulation**
- **OQ/PQ Runs**
- **Data Control Analysis**

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SYNERGY COS ULTRASONIC WELDING PROCESS

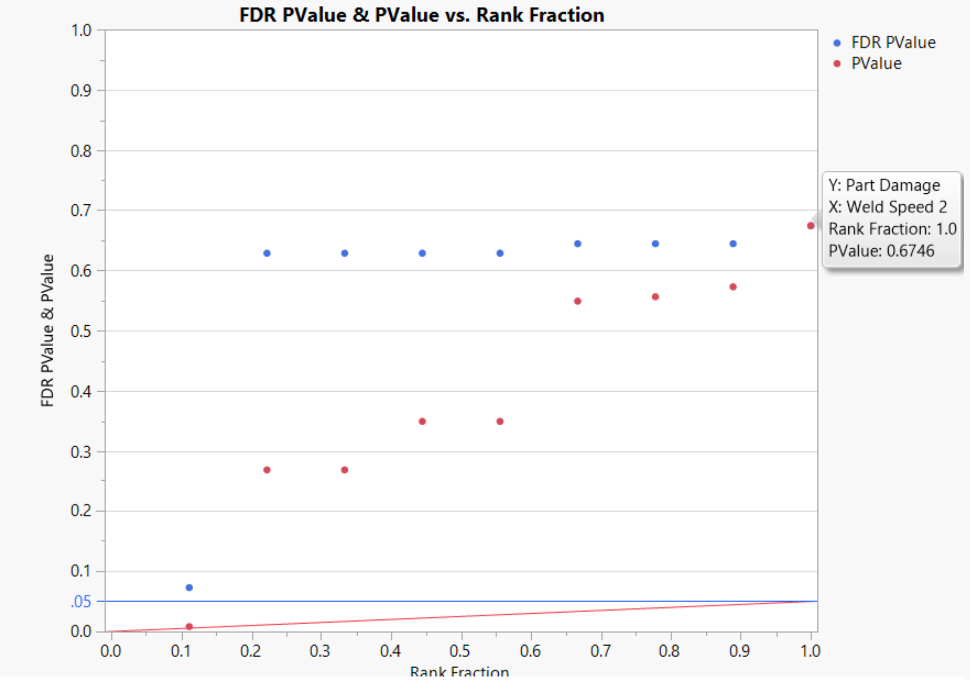
SPEED SEGMENTATION – ORDINAL APPROACH

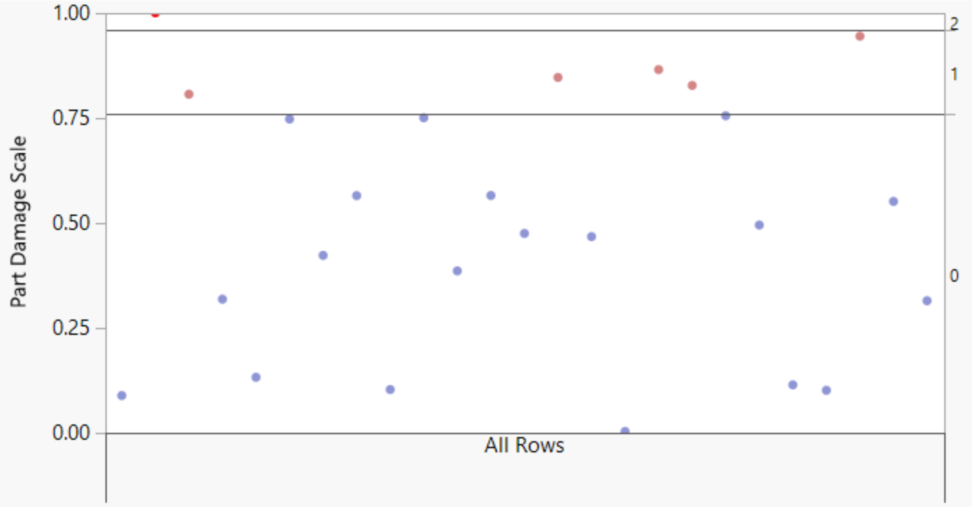
Part Damage

Untitled 4 - Response Screening of Part Damage - JMP

Response Screening

FDR PValue Plot





Split | Prune | Color Points

RSquare	N	Number of Splits
0.000	25	0

All Rows

Count	G^2
25	32.960731

Candidates

Term	Candidate G^2		LogWorth	Cut Point
Amplitude	2.241908786		0.319660263	94
Trigger Force	6.745862260		1.262622642	45
Weld Distance	3.221582397		0.356197008	0.0095
Melt Detect	1.702452803		0.222092792	15
Weld Speed	5.593581494		1.008772163	0.0325
Weld Speed 2	1.912287154		0.259275569	0.07
Post Weld Force	7.363646394	*	1.400752210	85
Post Weld Speed	1.912287154		0.259275569	0.085
Hold Time	1.912287154		0.259275569	0.75

Ordinal Logistic Fit for Part Damage Scale

Effect Summary

Source	LogWorth	PValue
Weld Speed	3.285	0.00052
Weld Speed 2	0.001	0.99792
Hold Time	0.001	0.99827
Melt Detect	0.001	0.99851
Post Weld Force	0.001	0.99856
Post Weld Speed	0.000	0.99935
Weld Distance	.	.
Trigger Force	.	.
Amplitude	.	.

Remove Add Edit ☐ FDR

Whole Model Test

Model	-LogLikelihood	DF	ChiSquare	Prob>ChiSq
Difference	16.480365	9	32.96073	0.0001*
Full	3.38761e-7			
Reduced	16.480365			

RSquare (U)	1.0000
AICc	42.3077
BIC	35.4076
Observations (or Sum Wgts)	25

Fit Details

Lack Of Fit

Source	DF	-LogLikelihood	ChiSquare
Lack Of Fit	37	3.38761e-7	6.775e-7
Saturated	46	0	Prob>ChiSq
Fitted	9	3.38761e-7	1.0000

Parameter Estimates

Term	Estimate	Std Error	ChiSquare	Prob>ChiSq
Intercept[0]	422.093043	63165.971	0.00	0.9947
Intercept[1]	474.774913	67015.292	0.00	0.9943
Amplitude	3.95823463	707.01998	0.00	0.9955
Trigger Force	-8.1273847	643.63039	0.00	0.9899
Weld Distance	-57201.317	0	100000	<.0001*
Melt Detect	-1.9733389	650.0383	0.00	0.9976
Weld Speed	4132.58288	583969.96	0.00	0.9944
Weld Speed 2	2551.49666	190905.55	0.00	0.9893
Post Weld Force	-2.930335	457.15843	0.00	0.9949
Post Weld Speed	1016.23068	180727.97	0.00	0.9955
Hold Time	-68.973083	11513.477	0.00	0.9952

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Closing Remarks

Manuel Mellado

Medtronic