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PREDICTIVE AND PROACTIVE MAINTENANCE PROGRAM FOR MONITORING FACILITY ASSETS

AGENDA

- Introductions / Maryland Heights Facility
- Maintenance types
- Systems used at Maryland Heights
- Predictive tools overview and deployment
- Program impact and roadmap.

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INTRODUCTIONS

Christopher M. Troutt

- Maintenance Reliability Engineer
- Certified in multiple PdM Disciplines
- Certified Lean leader
- Consulted in many industrial markets including pharma, mining, power generation and paper
- Multiple global site support as Maintenance and Reliability subject matter expert
- Experience with implementation from new programs to refinement and resurrection of failed or stalling programs

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MARYLAND HEIGHTS FACILITY

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MARYLAND HEIGHTS FACILITY

- FDA-registered radiopharmaceutical site since 1964.
- 364,000 ft^2 facility on a 19 acre campus
  - 189,480 sq ft is production related
- 325 employees in North American Operations team
- Regulatory oversight: FDA, NRC, DOT, EPA, EU, etc.
  - Largest broad-scope NRC licensee in the U.S.
- Just in time manufacturing
  - 24/7 plant operations

SITE'S MANUFACTURING CAPABILITIES

- Aseptic filling
- Cyclotron production of radioactive isotopes
- Isolator clean room technology
- Lyophilization capabilities
- Processing of Cyclotron and Reactor – based radiopharmaceuticals
- Terminal sterilization capabilities
- Finished goods packaging, logistics and distribution

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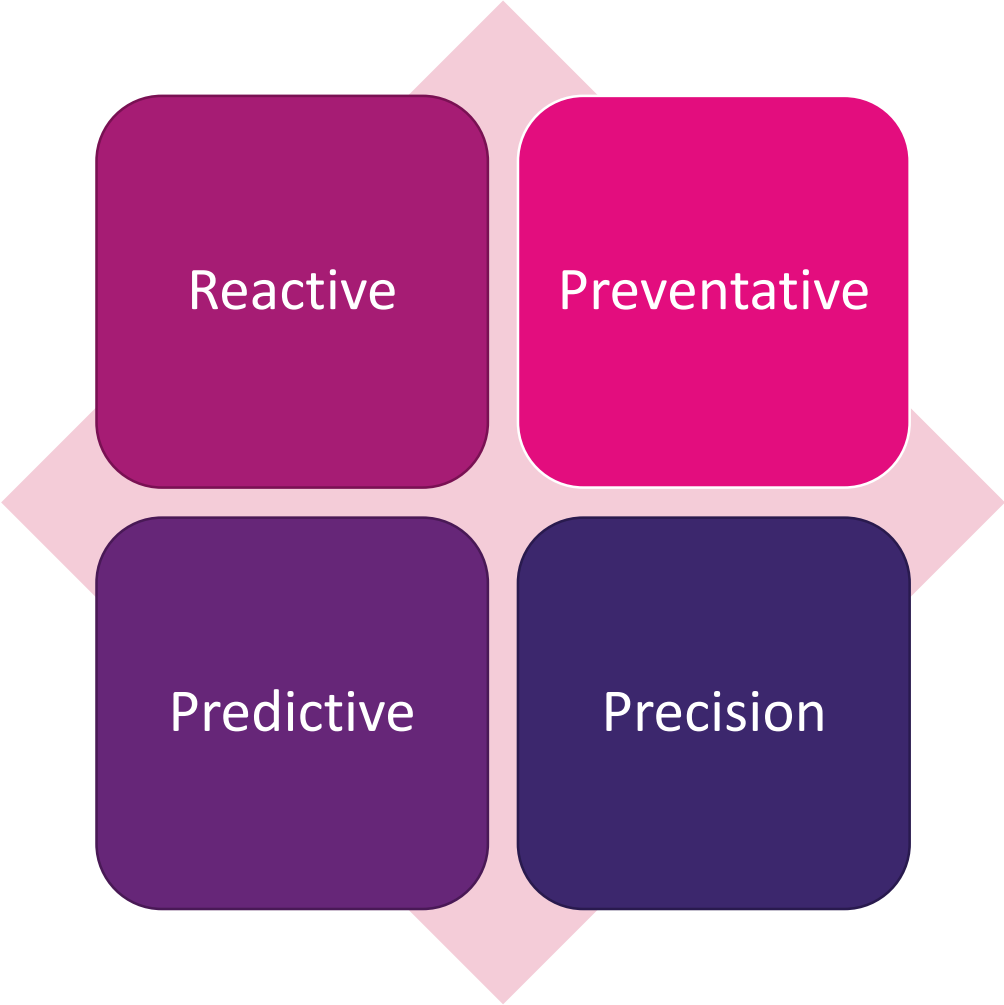
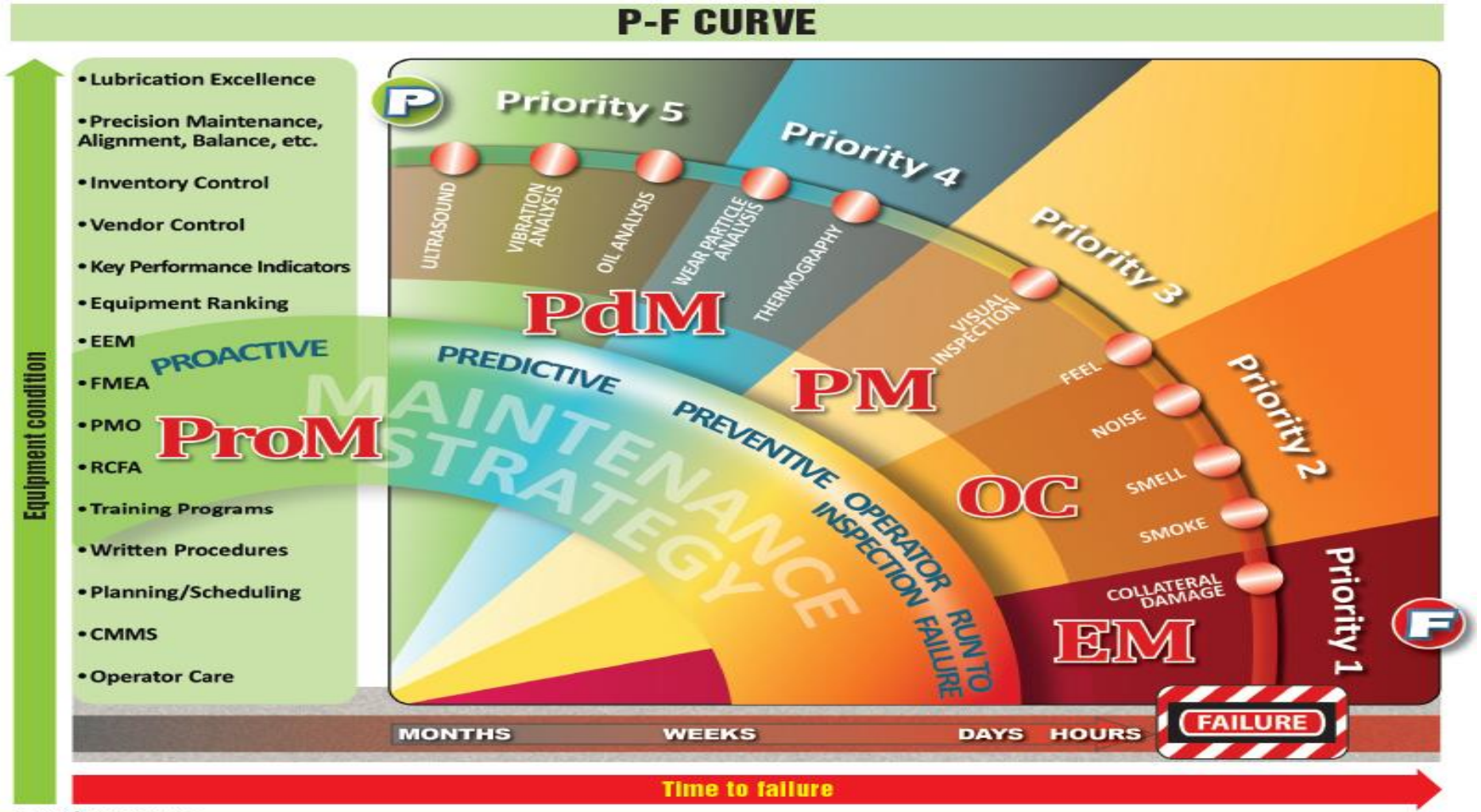
MARYLAND HEIGHTS' PREDICTIVE AND PROACTIVE MAINTENANCE PROGRAM

- Predictive Maintenance (PdM) Program in its 7th year
- Specific benefits realized at Maryland Heights include:
  - Lower total cost of maintenance
  - Equipment failure exceptions decreased by 81%
  - 130 critical assets monitored via vibration analysis
  - 39% reduction in Maintenance and Engineering staff with no impact to service levels
- Program next steps include further development into production areas
  - Reactor Hot Products/V4
  - Cold Products
  - Cyclotron Hot Products
- 2015/16 infrared inspection resulted in major electrical distribution upgrades

FOUR TYPES OF MAINTENANCE



P-F CURVE



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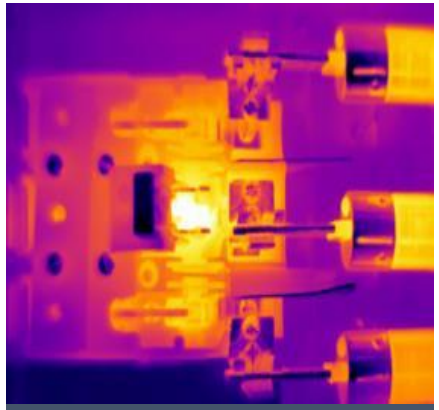
ADVANCED MAINTENANCE SYSTEMS AND TECHNIQUES RESULT IN WORLD-CLASS RELIABILITY OF SUPPLY

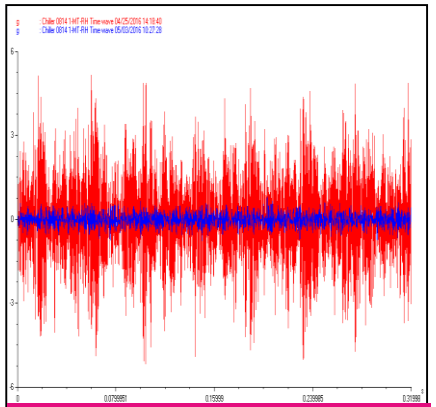
Proactive Maintenance

- **Active monitoring** program deployed across the plant's critical equipment
- **Non Intrusive techniques** used to provide information on machinery health
- **Data Driven** program to allocate resources for critical tasks
- **Proactive approach** allows timely decisions to be made prior to production impact



Infrared Thermography

- **Infrared Imaging** is used to look for temperature differences in equipment to indicate location and severity of potential problems

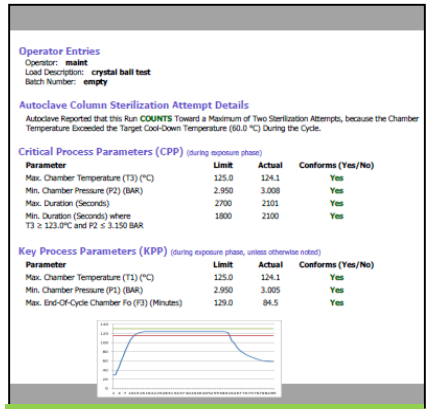


Vibration Analysis

- **Vibration Analysis** is used to measure and analyze specific frequencies to identify developing problems

Ultrasonic Detection

- **Ultrasonic Detection** is used to monitor and analyze "sound" for anomalies



Operator Entries
Operator: maint
Load Description: crystal ball test
Batch Number: empty

Autoclave Column Sterilization Attempt Details
Autoclave Reported that this Run COUNTS Toward a Maximum of Two Sterilization Attempts, because the Chamber Temperature Exceeded the Target Cool-Down Temperature (60.0 °C) During the Cycle.

Critical Process Parameters (CPP) (during exposure phase)

Parameter	Limit	Actual	Conforms (Yes/No)
Max. Chamber Temperature (T3) (°C)	125.0	124.1	Yes
Min. Chamber Pressure (P2) (BAR)	2.950	3.008	Yes
Max. Duration (Seconds)	2700	2101	Yes
Min. Duration (Seconds) where T3 ≥ 123.0°C and P2 ≤ 3.150 BAR	1800	2100	Yes

Key Process Parameters (KPP) (during exposure phase, unless otherwise noted)

Parameter	Limit	Actual	Conforms (Yes/No)
Max. Chamber Temperature (T1) (°C)	125.0	124.1	Yes
Min. Chamber Pressure (P1) (BAR)	2.950	3.005	Yes
Max. End-Of-Cycle Chamber Fo (F3) (Minutes)	129.0	84.5	Yes

Process Monitoring

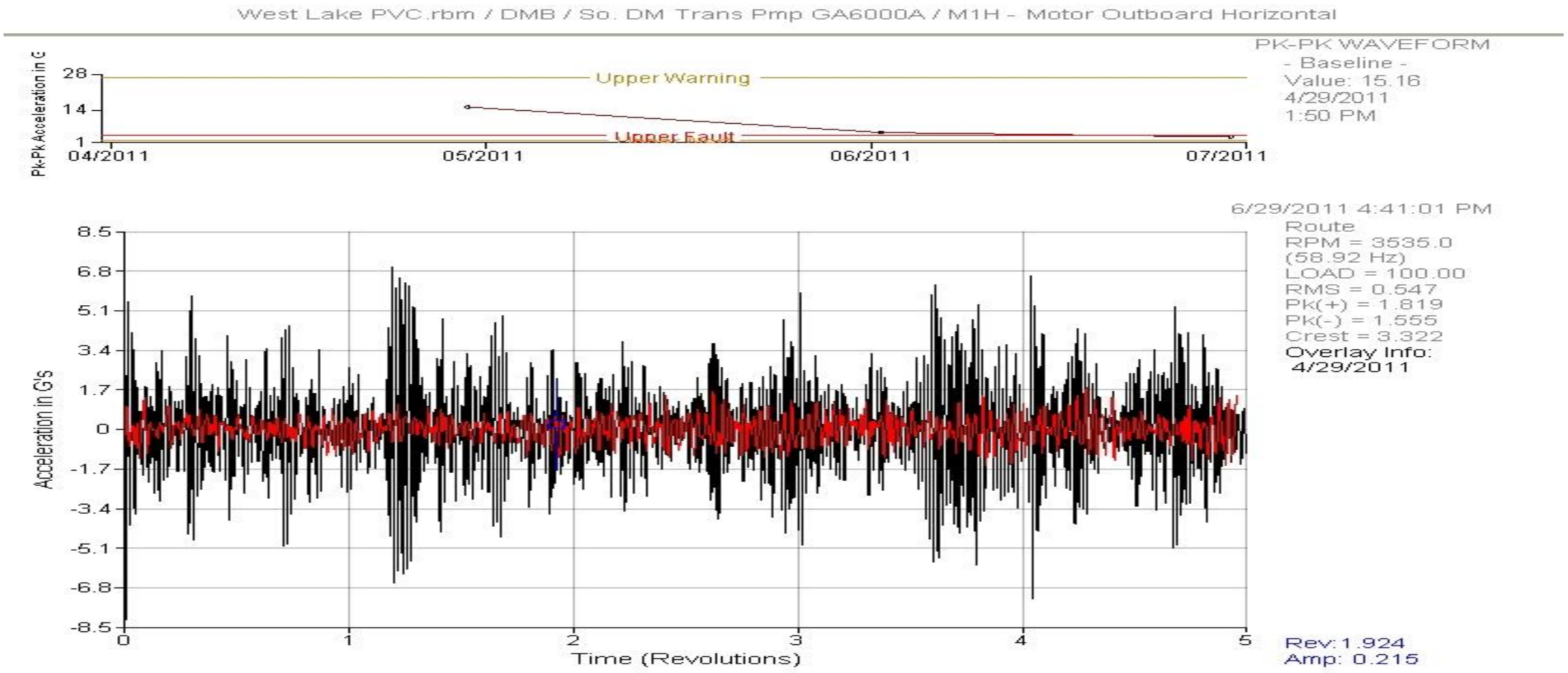
- **Process Monitoring** is used to monitor Critical Process Parameters and Key Performance Indicators to identify items trending away from standard

VIBRATION ANALYSIS- PREDICTIVE

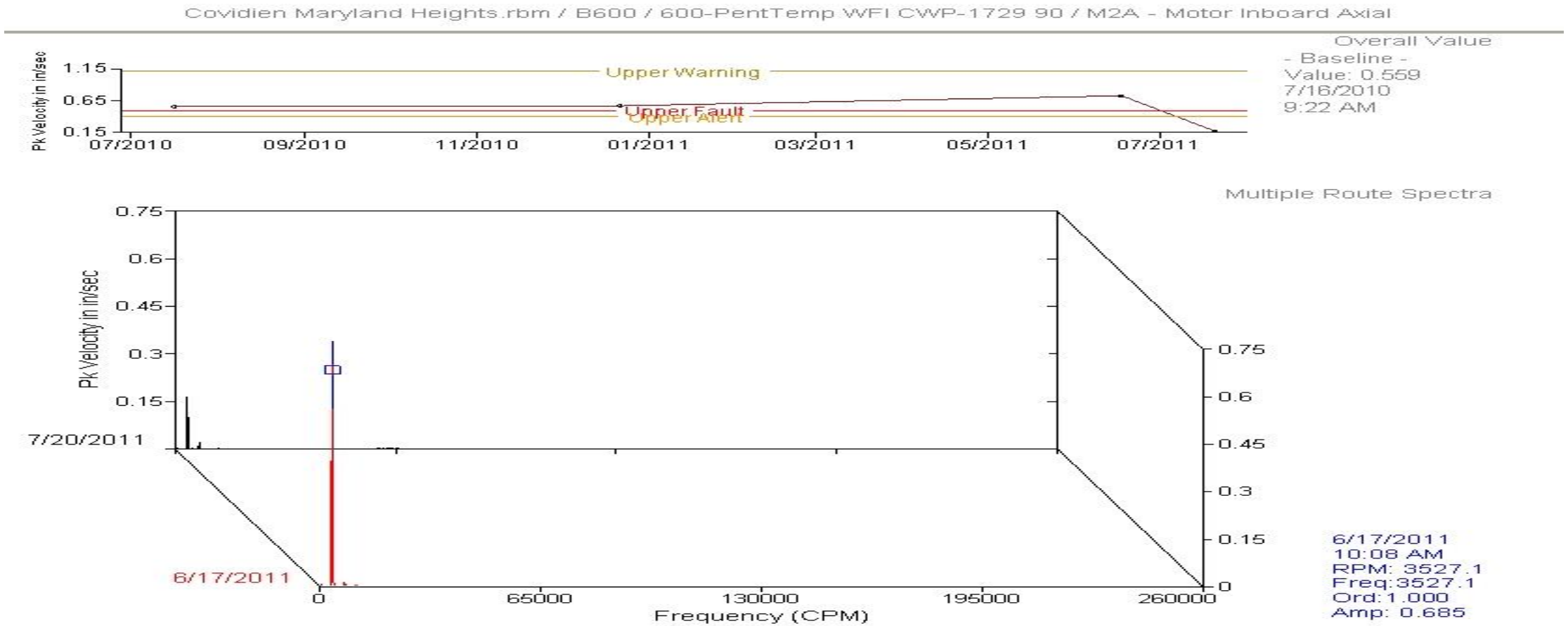
Typical issues found with vibration analysis:

- Bad bearings / lack of lubrication
- Misalignment (belt/coupling)
- Imbalance
- Looseness (structural/mechanical)
- Flow turbulence
- Gear wear and tooth issues

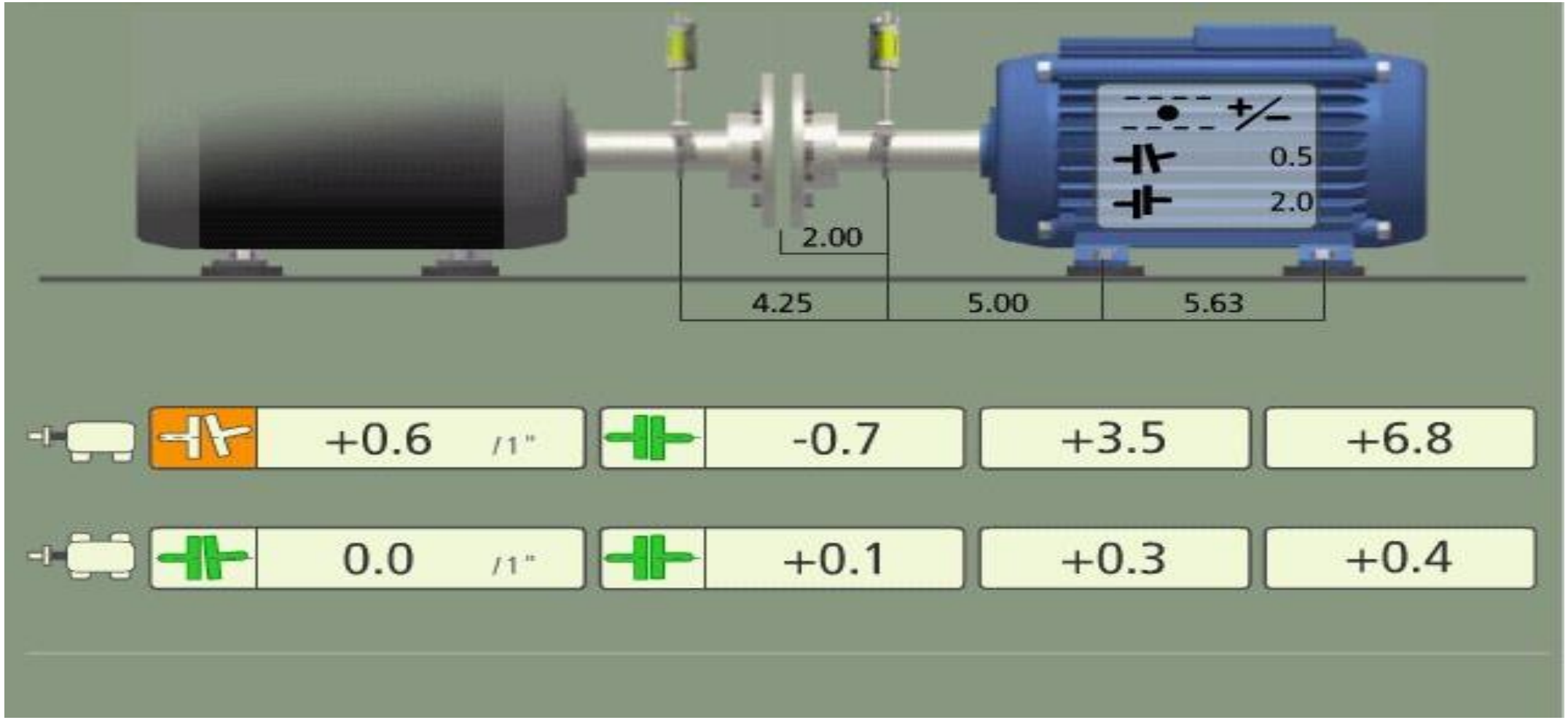
VIBRATION ANALYSIS- PREDICTIVE- BEARING



VIBRATION ANALYSIS- PREDICTIVE-MISALIGNMENT



VIBRATION ANALYSIS- PREDICTIVE-MISALIGNMENT



VIBRATION ANALYSIS- PREDICTIVE

PRO'S

- Allows for storage and trending of past data sets
- Applies to essentially any rotating asset
- No impact to operation
- High degree of accuracy

CON'S

- High cost for tool and software
- Steep learning curve

INFRARED THERMOGRAPHY-PREDICTIVE

Typical issues found with infrared thermography:

- Loose wires or connections
- Dirty or loose Fuse clips
- Imbalanced load (electrical)
- Bad bearings or bearings with improper lubrication

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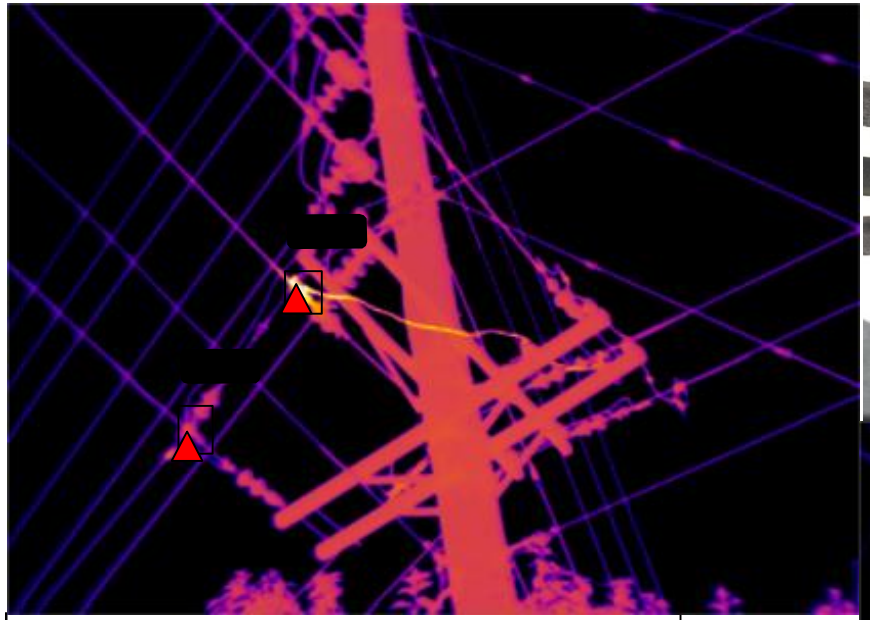
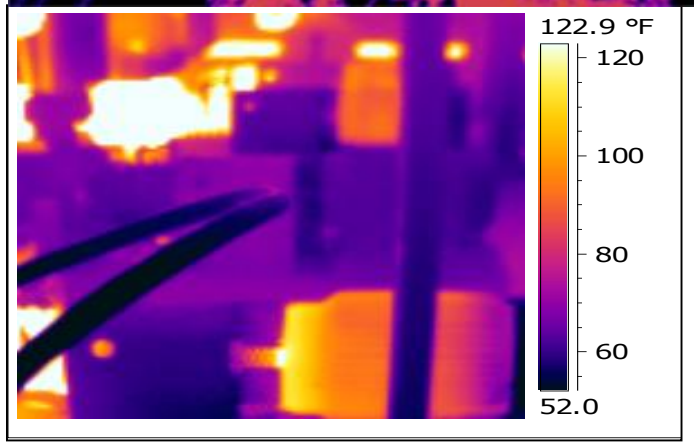
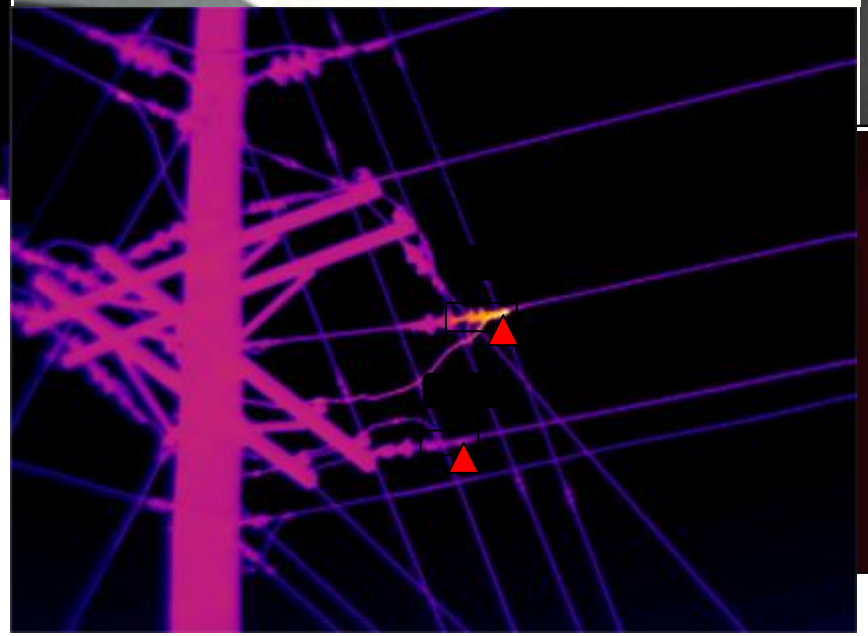
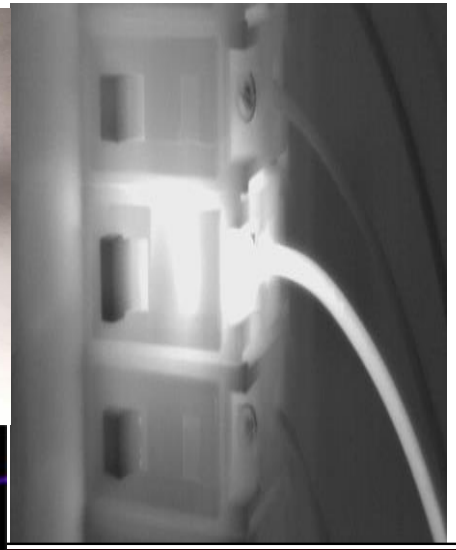
INFRARED THERMOGRAPHY-PREDICTIVE









INFRARED THERMOGRAPHY-PREDICTIVE

PRO'S

- With basic training good success can be had quickly
- Non-contact
- No impact to production
- Applications across mechanical and electrical systems

CON'S

- More training needed for advanced applications
- Not all brands/model have adequate image quality and/or reporting software
- Some mechanical applications will not provide level of detail about fault like vibration. Should be paired together

ULTRASOUND-PREDICTIVE

Typical issues found with ultrasound:

Arcing	Tracking	Corona
Bad bearings or bearings with improper lubrication	Compressed air, gas, or steam leaks	Failing steam Traps

ULTRASOUND-PREDICTIVE

GOOD BEARING

BAD BEARING

BAD BEARING (BEING LUBED)

BAD BEARING 3 MINS AFTER GREASING

ELECTRICAL ARCING

TRACKING

ULTRASOUND-PREDICTIVE

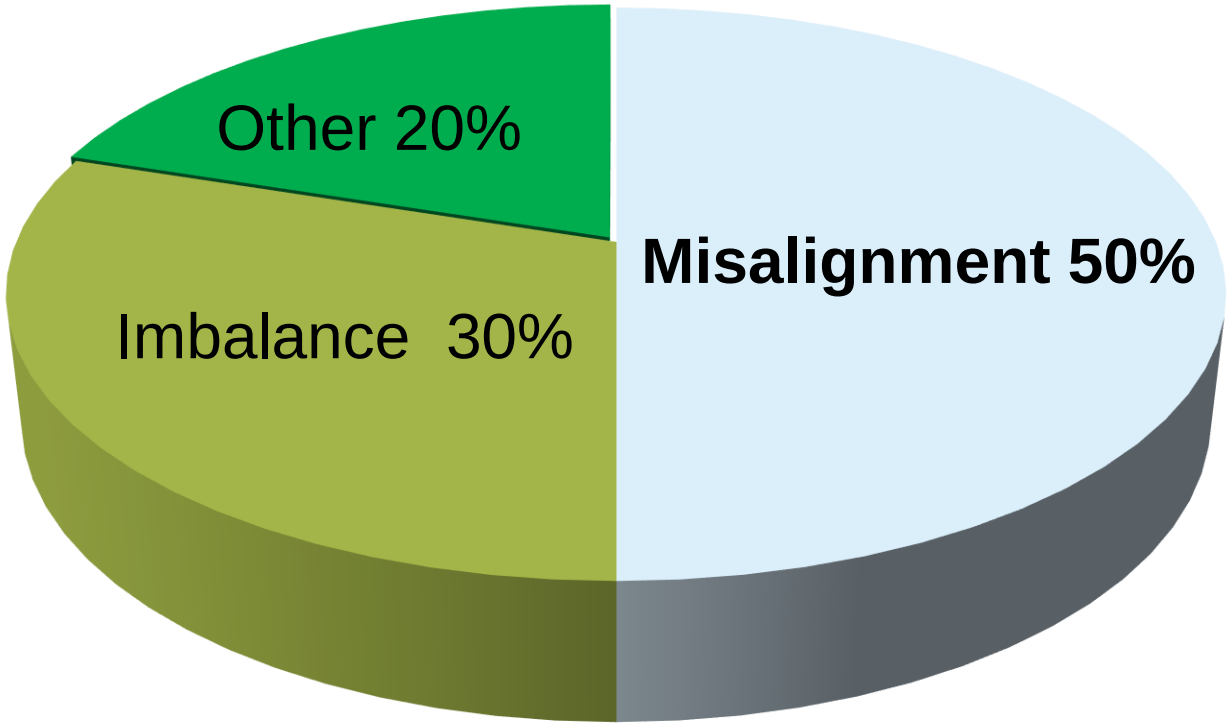
PRO'S

- With basic training good success can be had quickly
- Applications in mechanical and electrical
- Non-destructive
- can make sweeping views to look at many machines at one time
- Additionally are non-contact so they are great for those hard to reach places (conveyors, high lines, etc).

CON'S

- Not as accurate as IR and Vibration, should be paired or followed up on

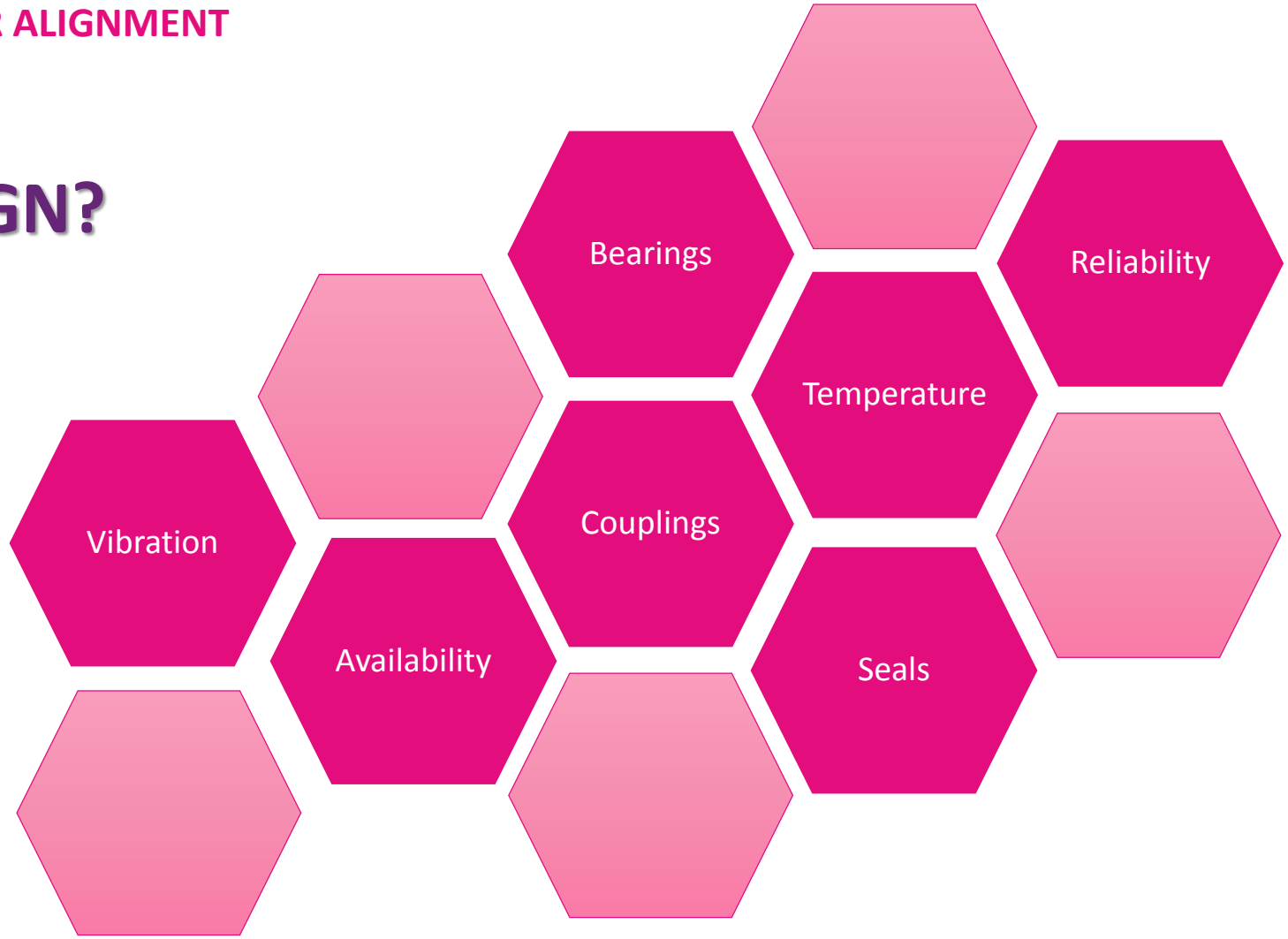
PROACTIVE-LASER ALIGNMENT



Causes of Excessive Vibration

PROACTIVE-LASER ALIGNMENT

WHY ALIGN?



PROACTIVE-LASER ALIGNMENT

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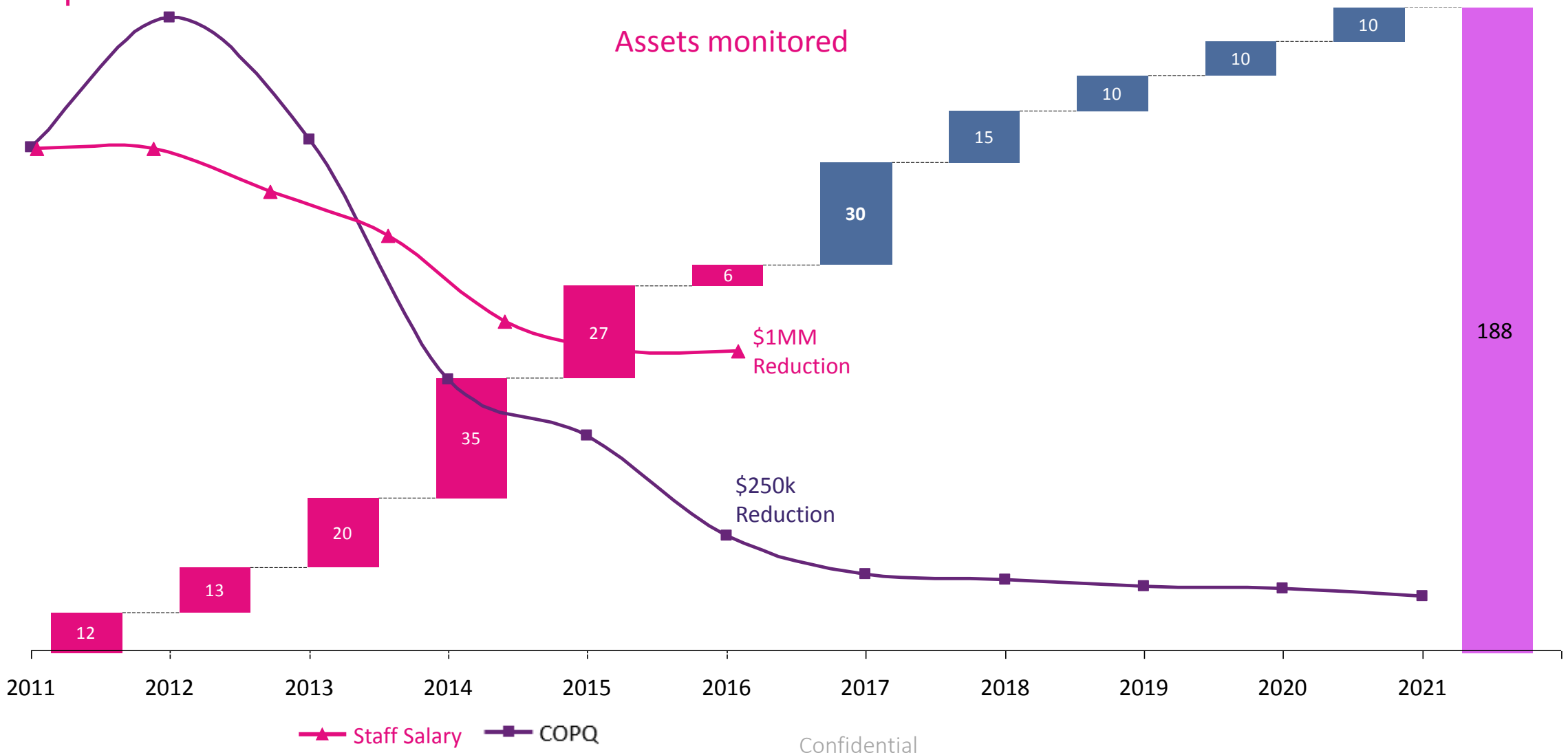
CURRENT STATE

- 130 Assets monitored monthly and bi-monthly by Vibration Analysis, 79% Critical rotating assets
- 100% of V4 utilities rotating assets are monitored by a PdM tool
- 350+ Assets and locations monitored semi-annually by Infrared Thermography and Ultrasound
- Data collected and analyzed by Reliability Engineer and Maintenance Technicians
- 2 Certified Vibration Analysts, 4 Certified Thermographers, 2 Certified in Ultrasound, 2 Certified in Lubrication
- Reduction in complexity and time need to complete yearly electrical distribution PM.
  - >200 Hours to 16 Hours
  - Reduce probability of iatrogenic failure by only working on items identified by PdM.
- MTBF average increased 48% in monitored assets across the site.
- Shift in the fundamental outlook on Maintenance across the site from a Reactive to a Predictive/Precision mindset.
- Provided program development/support at Raleigh, St. Louis, Hobart and BioVectra. Maryland Heights was the standard for PdM in Mallinckrodt.

PROGRAM DEVELOPMENT ROADMAP



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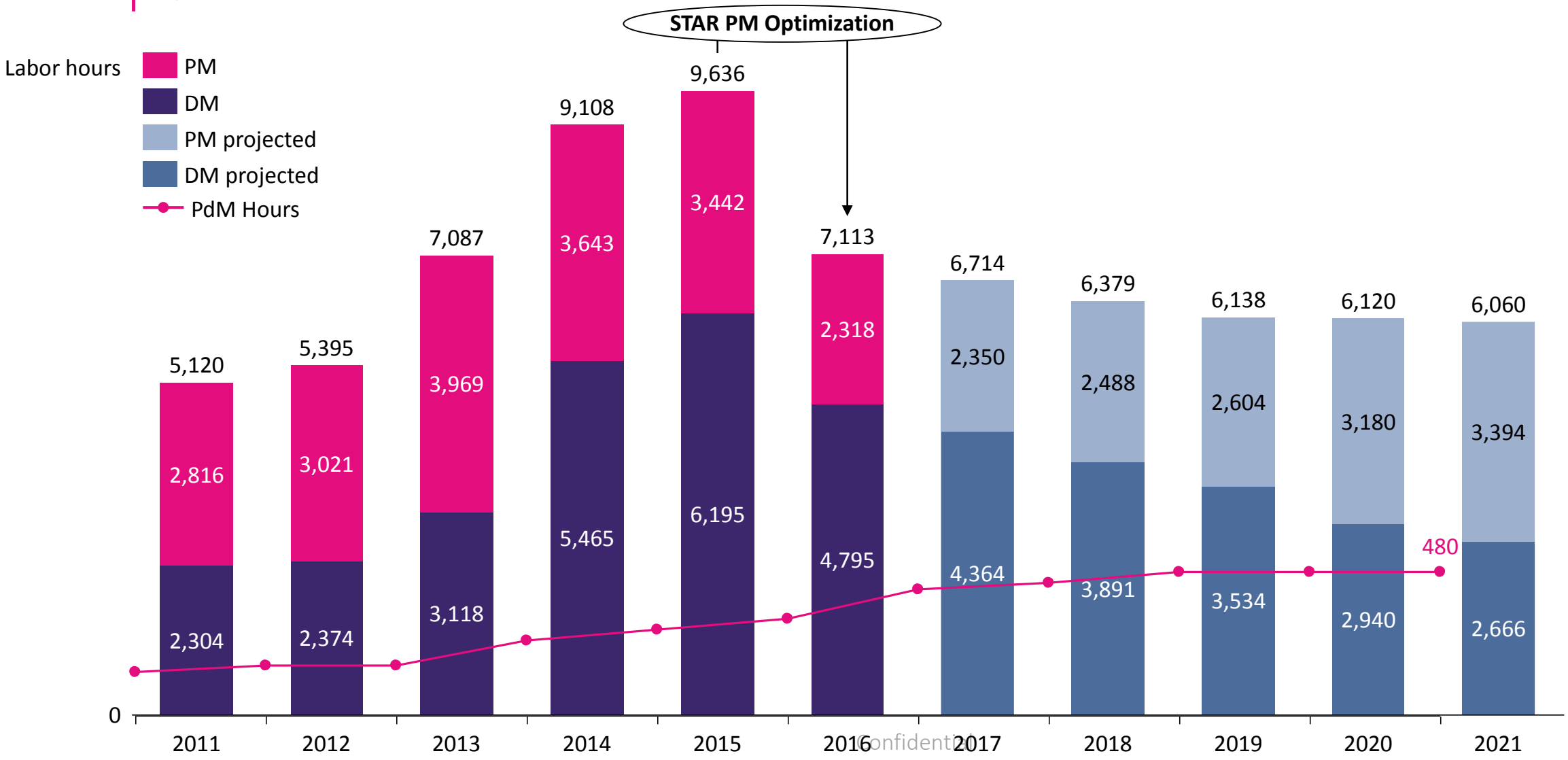
QUANTIFIABLE RESULTS



CASE STUDY DTE V4 AIR HANDLER 1821

- Baseline testing was performed on critical rotating assets during commissioning of the V4 line.
- Large AHU was found unable to be effectively monitored without shutting down the unit. Remote sensors were installed to allow for monitoring.
- First sets of data revealed excessive vibration amplitudes at 1xRPM of the fan with amplitudes averaging 0.7 ips. Amplitudes in this range can fatigue and eventually cause catastrophic failure of structural and rotating components. Closer inspections revealed even higher amplitude readings on structural supports of entire unit. Further analysis showed the fault to be a resonant condition of the unit structural supports.
- Based on the analysis the best option was the installation of a Fan Array (image1). The fan array is 6 smaller direct drive fans in place of one large belt driven fan.
- Had base line testing not discovered this resonance issue prior to V4 start up this unit would have failed catastrophically sometime after V4 went into full operation. Likely failure mode would have been broken structural steel and loss of ability to restrain the rotor including heavy damage to the housing and AHU itself.