Capacity Utilization and Lean Manufacturing at a Plastic Medical Device Components Manufacturer

by

Stephen Edward Laskowski

Submitted to the Department of Mechanical Engineering and the MIT Sloan School of Management in partial fulfillment of the requirements for the degrees of

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and

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Abstract

An understanding of capacity utilization within any manufacturing system is critical in setting operational strategy. Production lines and machines must have their performance accurately tracked and available for reporting if a business is to continually improve their performance. With capacity utilization and manufacturing performance known, a business can provide short-term corrections and also adapt its manufacturing capabilities to meet long-term market requirements.

Boston Scientific is a manufacturer of medical devices and is known for its ability to scale up new technologies through the use of an applied Lean Manufacturing framework in its final product assembly. The company also internally houses several component manufacturing groups that supply its assembly operations. While the company has a defined strategy for its assembly operations, strategy for its internal components suppliers is less clear. This thesis discusses building the foundation to transform the Spencer Components manufacturing group into a world class plastics operation. In particular, the ability to utilize manufacturing data to inform short and long term decisions is a critical foundation for any organization in its quest to become World Class.

This thesis studies how Spencer Components, a Boston Scientific internal component manufacturer, utilizes newly acquired manufacturing data to improve its operations and begin its transformation into a world class high-mix low-volume plastic components manufacturer. Prior to this research internship, no electronic performance data systems were in use, and Boston Scientific was blind to the operational performance of Spencer Components. While the technology of the new data system is several decades old, a considerable amount of effort was required to successfully implement it within the well-established manufacturing system.

Upon implementation equipment utilization improved and inventory targets that previously appeared unattainable were achieved. In addition, a continuous improvement environment was created and allowed Lean Manufacturing techniques such as Single Minute Exchange of Die (SMED) and operational improvements such as Economic Order Quantities (EOQ) to be implemented, tracked, and iteratively improved. A new capacity planning tool was created to identify long-term capital requirements associated with component demand. While Spencer Components is not yet a World Class manufacturer, it now has the tools to achieve its goal of becoming one.

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Chapter 1

Introduction

Optimization of capacity utilization is an important aspect of any manufacturing system. Without a clear utilization strategy a business risks being less efficient with shareholder assets and less flexible to customer needs. Many manufacturing companies have implemented technology systems to track utilization and integrate them into day-to-day business processes. However, as with many new technology initiatives, implementation of these systems is not always smooth. This thesis serves as a case study of the challenges and successes that a high-mix low-volume plastics manufacturer within a large company encountered when implementing a new technology to track capacity utilization.

Boston Scientific is a worldwide manufacturer of medical devices that helps improve the quality of patient care across the world. Its supply chain includes both internal and external suppliers for its medical devices, and it is determining how to position itself to optimize the total value its suppliers bring to the greater Boston Scientific business. This thesis focuses on the plastic components manufacturing group, Spencer Components Department (SCD), that serves the finished assembly group in Spencer as well as four other assembly sites. In addition to managing short term goals such as annual cost reduction and increased quality, the department must determine how best to utilize its footprint in Boston Scientific's land-locked Spencer Facility. This thesis will provide an examination of the department's current state and identify a pathway that will lead to greater utilization of SCD's assets.

1.1 Company History

Boston Scientific is a publicly-traded global provider of medical devices to the health care market.[1] Their products are well-known in fields such as endoscopy, urology, neurology, and cardiology. Boston Scientific was formed in 1979 when John Abele purchased Medi-Tech, a manufacturer of steerable catheters. An early company success was the development of "the first percutaneous transluminal coronary angioplasty."[2] Since the 1980's Boston Scientific has absorbed many other medical device companies such as Van-Tech, Endo-Tech, and Guidant. Today, the company serves 22 million patients per year with a selection of over 13,000 different medical devices.

Boston Scientific has experienced near double-digit growth over the last few years in nearly all of its product categories due to a mixture of timely product acquisitions and extraordinary quality in its current product portfolio.

1.2 Federally Regulated Industry

The medical devices and components that are manufactured at Spencer fall under the regulatory authority of the Food and Drug Administration (FDA) of the Federal Government of the United States of America:

> The FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation′s food supply, cosmetics, and products that emit radiation.[3]

The regulation by the FDA manifests itself within the business as a quality system ensuring that the safety and quality of the device is maintained. For medical devices, the FDA's regulation is most noticeable in the design and testing phase within the product life cycle. Extensive product and verification, along with patient trials are required in

[1] Basic Product Knowledge Booklet, provided during New Employee Orientation
[2] www.bostonscientific.com/about/history
[3] http://www.fda.gov/AboutFDA/WhatWeDo/default

order to prove a given product is safe for use within the human body. The introduction of new devices can take years before being released to market.

In manufacturing the quality system is most noticeable during initial runs of a new product or when the location of manufacture of a certain component is changed. All medical device regulations mandate the presence of a quality system in the manufacturing and distribution process. Product traceability, process validation and verification, corrective and preventative action plans are some of the required programs.

Of the quality systems in place at Boston Scientific, process validation and verification have one of the largest impacts on component manufacturing strategy. Process Validation and Verification (PV) is the process by which Boston Scientific ensures that all of its components and finished products will perform according to their design intent and engineering specification. The PV process is required any time there is a change to the process or location of manufacture. The implications of this requirement are that each production line or machine that may run a given product must undergo the PV process. There is a large cost associated with PV as it requires rigorous testing to ensure product quality and safety.

One of the outputs of the Process Validation process is the testing protocol that is executed on every manufacturing lot of components. Highly reliable processes will generate light testing plans while a variable process will result in a higher testing rate.

In order to ensure Boston Scientific is compliant with all FDA regulations, many third party certification groups are contracted to audit each facility multiple times per year. During these audits all manufacturing processes, test plans, test results, and physical manufacturing locations are examined to ensure they meet or exceed any regulatory body governing the site.

1.3 Boston Scientific: Spencer Facility

Boston Scientific's internal manufacturing supply chain specializes in the final assembly of its finished medical devices. Every manufacturing site's core focus is the manual assembly of its complex medical devices. In addition to finished assembly operations, many sites have smaller manufacturing groups that specialize in metalworking, plastic extrusion, injection molding, and plastic tipping. Boston Scientific operates a Center of Excellence (CoE) Model to handle these non-core activities. Each site will specialize in a certain manufacturing technique and be considered an expert in that particular subject. SCD has been named the Center of Excellence for plastic injection molding within the Boston Scientific network.

In the 1980's the Spencer Manufacturing Facility was founded by a company called Van-Tec, which "Developed, produced and sold urological devices."[4] The company was purchased in 1988 by Boston Scientific, and has since grown to manufacture products in "Endoscopy,... Women's Health, and Peripheral Interventions."[5].

In total, about 1,400 finished products are assembled and packaged in the Spencer facility. These products are shipped to Boston Scientific's warehouse where they are sent to other distribution sites, hospitals and physicians throughout the world. Boston Scientific classifies the Spencer Facility as a "high mix, medium volume" site[6] however for the purposes of this thesis its product mix is considered high mix, low volume.

During the duration of the internship the site instituted a strategy initiative called Spencer 2020 in an effort to re-align the site's goals with Boston Scientific's long term manufacturing strategy. The research for this thesis was conducted in response to the Spencer 2020 initiative. Leadership at the site has prioritized being the manufacturing site of choice for new product launches by ensuring production flexibility to the rest of the organization. While the building itself is landlocked, available floor space for additional

[4] Basic Product Knowledge Booklet, provided during New Employee Orientation
[5] Boston Scientific Co-op Handbook, provided during New Employee Orientation
[6] Ibid

assembly lines still exists. The Spencer facility is the manufacturing site closest to Boston Scientific's distribution center in Massachusetts, which gives it a distinct advantage in the company's supply chain.

1.4 Problem Statement and Objective

Boston Scientific has a strong Lean Manufacturing culture within its Final Assembly operations and does an excellent job of matching resources and line speed to customer demand. However, this same Lean culture is not present in its SCD department. This research study was conducted to understand how to apply the same continuous improvement mindset seen in its assembly business to SCD and maximize the return on the investment that Boston Scientific has made in the department to date. Boston Scientific's long term objective is to transform SCD into a World Class organization. While this was not realized during the term of this study, the foundation for the path forward has been laid.

1.5 Spencer Components Department

The Spencer Components Department (SCD) is a plastic medical device component manufacturer located in the same building as the Spencer Assembly department. It started as a collection of machines to support Spencer Assembly years ago and has grown considerably over the past decade to include a variety of injection molding and extruding capabilities. Spencer Component's largest customer is Spencer Assembly, and it also serves several other Boston Scientific assembly plants.

Over 550 different components are manufactured in the department using over 30 different manufacturing cells. SCD is not the only injection molding supplier for its customers. The department is in competition with a variety of external molders for new products.

1.5.1 Plastic Components Sourcing at Boston Scientific

Every manufacturing company must determine whether or not to manufacture its products within its own facilities or utilize an outside vendor. This decision occurs at all levels: raw materials, components, sub-assemblies, and finished products. A given medical device may be assembled internally; however that product's raw materials, components, and sub-assemblies could be partially or completely sourced externally. The decisions to vertically integrate or outsource a supply chain is a difficult and important strategy issue that is often based on the following factors shown in Figure 1-1[16].

Table 1
Drivers of outsourcing

Drivers	References
Reduction of cost	Barthélemy & Geyer (2000), Drauz (2014), Kremic et al. (2006), Lonsdale & Cox (2000), McFarlan & Nolan (1995), Sharma & Loh (2009)
Focus on core competences	Arnold (2000), Kakabadse and Kakabadse (2002), Lonsdale & Cox (2000), McIvor (2009), Saunders et al. (1997), Quinn & Hilmer (1994),
Reduced capital investments	McFarlan & Nolan (1995), Kakabadse & Kakabadse (2002)
Access to external competences and quality	Drauz (2014), Kakabadse & Kakabadse (2002), McFarlan & Nolan (1995), Quinn & Hilmer (1994),
Transform fixed cost to variable cost	Alexander & Young (1996), Lonsdale & Cox (2000)
Regain control over internal departments	Alexander & Young (1996)
Improved cost measuring and control	Barthélemy & Geyer (2000)
Improve time to market	Lonsdale & Cox (2000)
Capacity use	Drauz (2014)

Source: Adapted from Quélin & Duhamel (2003) and Drauz (2014).

Table 2
Drivers of insourcing

Motives	References
Use capacity, scale advantages	Drauz (2014)
Loss of know-how, vital knowledge	Drauz (2014), Hoecht & Trott (2006), Kakabadse & Kakabadse (2000), Lonsdale & Cox (1998),
Unexpected cost through outsourcing	Bergin et al. (2011), Drauz (2014), Jennings (2002), Kremic et al. (2006),
Changes in strategy	Richardson (1996)

Figure 1-1: Drivers for the Make or Buy Decision

Since the late 90's the molding business has seen increased pressure to reduce the cost of the complete manufacturing package [8]; it is not enough to compete on quality or cost alone. With many companies embracing Lean and Six Sigma methodologies molding suppliers must continually deliver on cost, quality, and lead time while simultaneously finding ways to continually improve each metric. For a molding shop, continuous improvement can be measured through reductions in cycle time, non-compliant parts, and lead time. SCD is no exception to this trend, and in order to remain competitive it must focus on continual improvements of cost, quality, and so on. SCD's costs, quality, and lead time are currently being measured by Boston Scientific's Global Sourcing Group and are compared to other suppliers.

The assets at SCD are underutilized. Some of the underutilization is planned for the end-of-life of some of the department's machinery; however the grand majority of free machine hours is due to the low volume of many of its components. In achieving the project objective of utilizing existing capacity, there are two sources of work the department can utilize to fill up machine time: new components or in-sourced components. Boston Scientific has many new products in its development pipeline; however the number of products is small compared to the available capacity at SCD. Finding components to in-source is an easier task for SCD to achieve in order to increase its capacity utilization.

The next question is what type of in-sourcing opportunities exist and which would be most compatible with the current SCD product mix. A look at the currently out-sourced components used in Spencer Assembly provides insight into the types of opportunities SCD could in-source. Ignoring technological constraints, Figure 1-2 below illustrates the distribution of annual demand for products used in Spencer Assembly that are not manufactured in SCD.

Most out-sourced components fall below BSC's threshold for "high demand" of 300,000 units per year, and therefore the majority of work that SCD could in-source is medium to low volume components. This is important to understand from a strategic stand-point; if most of the work is low volume then it fits well at the SCD site, which operates a high mix low volume product strategy.

If Spencer were to in-source, it would run into a large financial barrier. The costs associated with performing the required Process Verification to in-source low volume components often overshadow its potential benefit. Due to these costs, a low volume

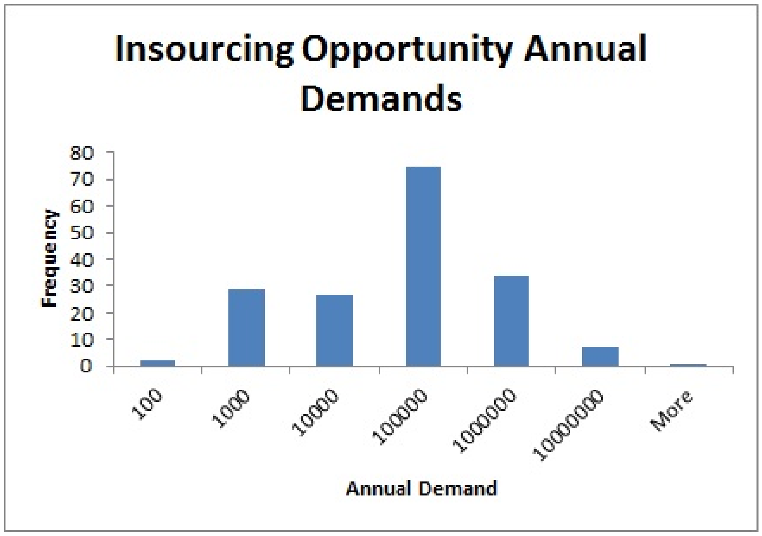

Figure 1-2: History of Annual Demand for Out-Sourced Components at Spencer Assembly

component will remain sourced from its original vendor even if cost targets are not being met. A good analogy is the activation energy needed for a chemical reaction to occur. In order to make the in-sourcing of low volume components appealing either the cost savings from the in-sourcing must overcome the Process Validation costs, or Boston Scientific must fundamentally changes its component sourcing strategy.

As of Q3 of 2016, BSC had nearly 900 suppliers [7]. The spend for this supplier group follows the Pareto rule: 80% of the spend is concentrated on 20% of the suppliers. In recognizing this trend, the company has started an initiative consolidating suppliers to command higher purchasing leverage and achieve reductions in both work flow and risks due to a complex supply chain. This initiative provides a one time opportunity for SCD to in-source.

A question that Boston Scientific must answer is what capabilities it should keep in-house and what can be produced more efficiently through an outside vendor[17] Most injection molded components are considered commodities and can be produced by any company with an injection molder. However, aspects such as quality, lead time, and

[7] *Get to know Global Sourcing Presentation*, internal Boston Scientific documentation

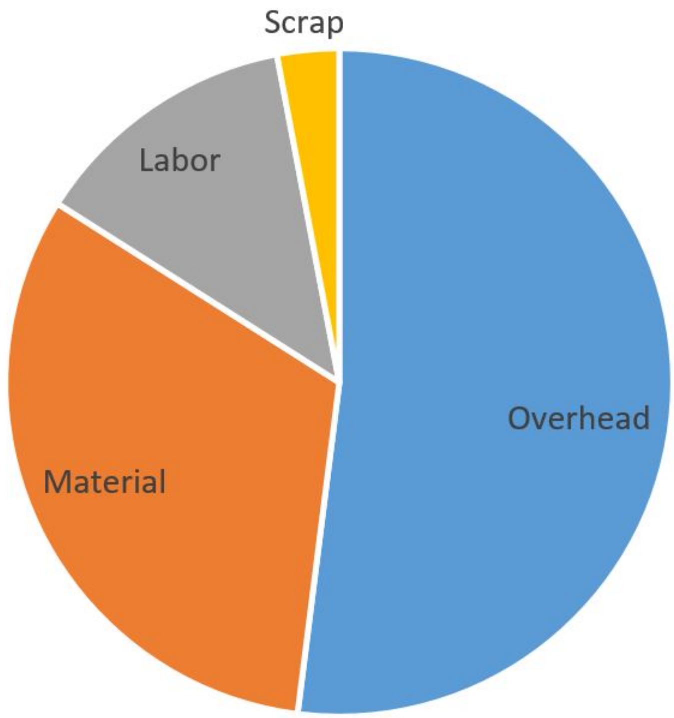

Figure 1-3: Cost breakdown of SCD

flexibility can be difficult to manage with an outside vendor. In general it is a good idea to out-source easy to produce, high volume components and in-source difficult to manufacture and critical components.

Boston Scientific claims it uses a Total Cost of Operation point of view in its sourcing. Not only will it consider price per piece but also the cost to transport materials to and from its component suppliers. Since SCD resides in the same building as Spencer Finished Product Assembly it has transportation cost and inventory flexibility advantages over other suppliers.

The main disadvantages for SCD are high labor/overhead rates and high resin costs (See Figure 1-3). The costs for the department are dominated by overhead and material rates. Since material costs are dependent on component design, the biggest lever that SCD can pull to improve cost performance is overhead. Overhead is the summation of indirect manufacturing costs such as engineering, utilities, capital depreciation, etc. divided by the number of earned machine hours. SCD has set a target to lower its overhead rate to $70 per earned hour from its current value which is significantly higher.

1.5.2 Flow of Operations

Demand forecasts for each medical device are published by Boston Scientific's Sales group on a monthly basis. This demand information is fed into Spencer's Planning team which creates production orders for its suppliers. From these orders, raw resin is purchased and production orders are created. In SCD, the Components Scheduler will prioritize the production orders for each machine. When a production order is ready to be run, the Components Scheduler will print tags that list all required production information and place it on the magnetic production board. Each machine has a spot for the current running work order and the runner up. Only the Components Scheduler and Lead Operators have any visibility into the entire machine schedule past those listed on the magnetic board. Most machines have over ten scheduled work orders at any given time; however these are not known or displayed to the operations team until the printer work tag is placed on the board.

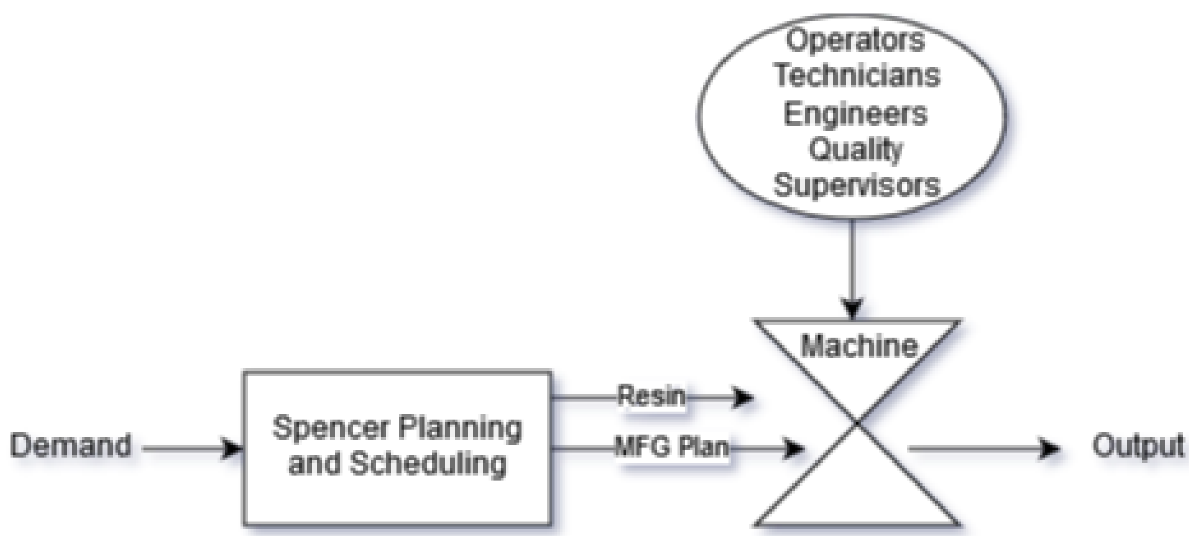

Figure 1-4: Model of Spencer Operations

When a machine completes its work order, the machine operator will perform quality inspections in accordance with BSC's Quality System. If the next work order requires a machine adjustment such as a mold parameter change the operator will alert a machine technician to conduct the change. While the operator completes his or her inspections the machine technician will execute the machine changeover and prepare for the next run. Once both the operator and the technician complete their tasks, the machine is started and the first good parts are set aside and labeled as "first shots." These will be retained in storage in case further product investigation is required. From this point the technician moves on to the next machine while the operator performs whatever tasks are necessary to keep the machine cycling.

Molding machines require raw polymer resin in order to make parts, and a material handler ensures the department's machines have a steady supply of resin. As the machines create parts operators place them into corrugate boxes or plastic bags in predetermined quantities. Once a work order is complete, finished components are transferred to the warehouse team. If the components are to be used in Spencer Assembly, they are stored in Spencer's warehouse. If they are to be sent to external assembly sites then they are immediately packaged and staged for shipment.

Notice in Figure 1-4 that no feedback loop exists between the output of the manufacturing system and any other group. This graphic highlights the fact that there is no formal or timely feedback mechanism should there be an issue at SCD.

1.5.3 Injection Molding

Process Theory

Below is a brief overview of the basics of injection molding to illustrate the operations of Spencer's Components Department. The following succinctly describes injection molding with thermoplastics:

> "Injection molding is a process in which a polymer is heated to a highly

plastic state and forced to flow under high pressure into a mold cavity, where is solidifies."[4]

In injection molding the mold cavity is the primary driver in finished part geometry. Many molds have pins, pinchoffs, and mold inserts that can change the geometry of the cavity and allow for a single mold to produce multiple components of varying geometry (diameters or labels).

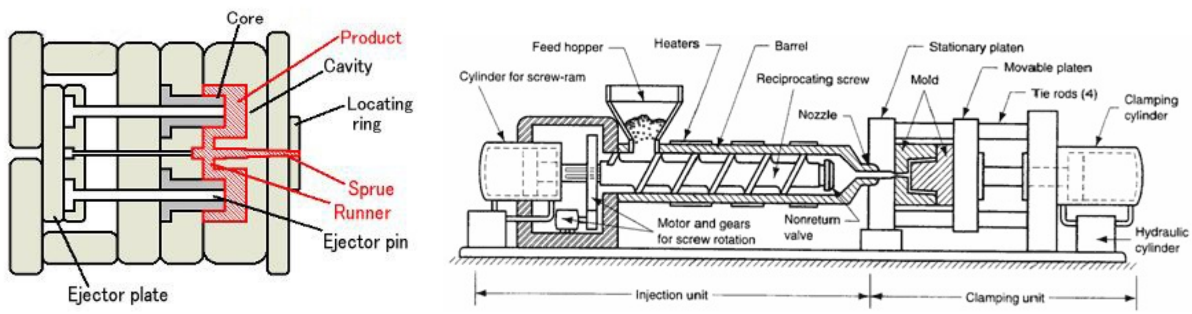

Figure 1-5: Diagram of Mold Cavity (Left,http://injectionmolding.blog.quickparts.com) and Injection Molder (Right,https://www.xcentricmold.com)

Raw thermoplastic resin in the form of pellets is placed into a feed hopper above the injection screw. The screw can be over three feet in length and mixes the resin as it heats into a highly plastic state. The heat required to melt the resin is generated from the shearing action of the mixing screw and thermal output from heater bands attached to the screw barrel.

The machine cycle for injection molding is an indexed sequence of events: Mold close, plastic injection, plastic static retention, screw retraction, and finally mold open with part ejection. In mold close the machine uses a hydraulic press or toggle clamping system to push the two halves of the mold together. The pressure generated between the two halves is important in preventing flash, or the leakage of resin outside of the mold cavity . After the mold has been closed plastic injection begins.

The injection screw mixes the molten thermoplastic when not injecting. During injection, the screw stops rotating and moves forward relative to the screw barrel, pressurizing the plastic in front of the screw and pushing it through the nozzle tip into the mold. It is important that the volume of plastic pushed into the mold equals the volume of the mold cavity. If the injected volume is less than the cavity volume, the part will be "short shot" and defective.

Once the mold cavity is full the static retention stage begins. During this stage the plastic inside the mold cavity is cooling and hardening. Water is used to thermally regulate the mold. The injection screw maintains a static pressure as the mold cools to prevent part shrinkage.

Once the mold has cooled to a point where geometric shrinkage is no longer a concern, the mold opens. Each mold is equipped with a pair of ejection pins that run parallel with the mold halves. The pin's purpose is to push the part out of the mold during part ejection. Evidence of ejection pins can be seen on most injection molded parts.

Depending on the manufacturing setup, the ejection pins will either push the part out of the mold and into a collection bin or into the end effector of a multi-axis robot. From here the parts are inspected and packaged into kanban kits for use in assembly.

Silicon molding is a nearly identical manufacturing process to thermoplastic plastic molding. The primary difference is that raw silicon flows below room temperatures and cures into an elastic solid over time. Curing is hastened with higher temperatures, and as such silicon in the mixing screw is maintained below 60F to inhibit the materials solidifying in the barrel. The silicon mold is heated up to 400F to facilitate rapid curing.

1.5.4 Spencer Molding Capabilities

Within the Boston Scientific manufacturing network there are five injection molding manufacturing sites. Each is unique in its product mix and manufacturing technology and is graded in six areas: automatic molding, insert molding, silicon molding, two-shot molding, engineering materials, and micro-molding[8].

[8] BSCI Molding Capability Matrix

Technology/Capability	Capability Scale				
	1	2	3	4	5
Automatic Injection Molding					✓
Insert Molding				✓	
Over Molding/2-Shot Molding				✓	
Micro Molding		✓			
High Temp/Engineering Materials Molding		✓			
Silicone Molding					✓

Figure 1-6: Capability Matrix of SCD. Scale rating 5 means highest proficiency; Scale rating 1 is lowest

Spencer rates itself as being proficient in four of these six categories: automatic, insert, silicon, and two-shot molding. Over 30 million individual parts representing 550 component part numbers are manufactured each year in SCD. Most machines operate on a 24/5 schedule, and a skeleton weekend shift is used for high volume production.

The department has injection molding machines from four different Original Equipment Manufacturers (OEM). Most are designed for thermoplastic injection while some are designed for the thermoset molding of liquid silicon. In total there are 155 unique molds that produce over 350 component parts. The following sections will discuss each proficiency at SCD.

Insert Molding

Insert molding refers to any injection molded component where a sub-component is placed between the mold halves during the injection molding process. When the machine cycles, a new geometry is over-molded onto the sub-component, referred to as an insert. This insert becomes part of the finished molded component. A machine that is performing an insert molding operation requires either an operator or a robot to place the insert between machine cycles. Many of the plastic extrusions produced in the Components department are used as inserts on manual machines within the department. Any of the department's molding machines can be setup to do insert molding.

The majority of the department's insert molding requires an operator fully dedicated to the machine during production. In order to facilitate an ergonomic work process, hand load fixtures are used for the operator to place the insert into the mold. There are at least two identical fixtures for each product: one fixture will be in the mold during the mold cycle, and the other will be prepared by the operator for the next cycle. While a machine is molding, the operator will remove the completed molded components from the second fixture. Some components are easier to remove than others. Most can be pulled off the fixture and inspected. Some components have threaded features that require the operator to unthread the component from the fixture. Once the completed component is removed, new inserts will be secured to the fixture, and the operator will replace the molded fixture with the newly prepared one.

In manual molding the operator is in control of the machine's cycle time. If the fixture preparation is not completed in a consistent and timely manner the machine will complete a mold cycle and sit idle. Cycle times for manual insert molding can be highly variable depending on the complexity of the insert. One of the challenges with manual molding is ergonomics. Most fixtures are designed for molding and not designed for operator safety. To combat long term ergonomic fatigue and injury, operators must run different machines every week. This further adds to the variability in machine cycle times, as some employees can operate a machine faster and with more consistency than others.

Automatic Molding

As the name suggests, a molding process is considered automatic when the molding machine does not require human intervention between work cycles. In this work stream an operator is only required to conduct quality inspections and administrative tasks at intervals specified in the part's manufacturing plan; as long as raw resin is available in the machine's hopper, the machine will continue to mold. The finished parts either fall from the mold directly into a product bin or are removed by a 3-axis robot. 80% of the injection molding machines in the department are capable of automatic molding, though many run both automatic and manual components. While the work load varies from component to component, the current assumption of required manual labor for automatic machines is 15 minutes per hour.

Most automatic molding processes are components without inserts. However, the department does have automatic insert molding capability. This means that robots are responsible for removing freshly molded components from the mold and placing the new inserts within the mold for each cycle. Automation of these tasks provides the benefits of more stable cycle times and more consistent placement of the inserts. SCD has had varying degrees of success in implementing automatic insert molding.

The majority of the department's automation assets are for the removal of a completed component from the machine. A 3-axis robot is used to travel into the machine upon the opening of the mold, remove the components and sprue, dispose of the sprue, and place the components on a conveyor that drops them into the correct product bin. Due to the fact that the 3-axis robots have been standardized across the majority of the machines, there is plenty of expertise and documentation on how to operate them. The robots have the capability to make automated quality decisions based on input from the machine, yet this feature is not currently used.

Silicon

The Components department has four molding machines dedicated to thermoset injection molding of liquid silicon parts. The silicon injection molding machines differ fundamentally from thermoplastic molding machines, and thus require separate expertise. The department's utilization of its silicon equipment is low despite the fact that silicon machines consume about 15% of the department's available floor space. While the manufacturing process is very similar to molding thermoplastic resins, there remain many differences that necessitate a separate set of technical skills and physical assets. SCD is in the midst of bolstering its silicon expertise to be able to handle in-sourcing more silicon products.

Extrusion

There are four extruders producing over 157 plastic extrusions in SCD. Many of these extrusions require additional manual molding operations before they are delivered to an assembly line. The department is in the midst of conducting end-of-life product transfers from the older machines to newer ones through the Boston Scientific Validation Process.

1.6 Approach

1.6.1 Literature Review

There have been many previous research studies on manufacturing systems regarding the usage of capacity at a High Mix Low Volume manufacturer, as it is a problem increasingly faced by companies in most sectors. An extensive amount of research has been conducted through the *Leaders for Global Operations*[9] at MIT.

Kevin McKenney [10], LFM '05 alum, completed an analysis on a United Technologies facility faced with similar challenges and created an inventory control model for a High Mix, Low Volume manufacturing site. Many of the manufacturing and operational processes are similar to those at SCD. Jon Frommelt [3], LFM '01, implemented a new automated data acquisition for Intel's CAPS program, which was designed to determine optimal capacity for new chip lines based on real time machine performance. His work highlighted the benefits of systems that automatically collect and interpret manufacturing data. David Campos [1] LFM '01 documented metrics systems on performance at Boeing. Roberta Roberts [14] LFM '96 discussed the impact of Overall Equipment Effectiveness in an Intel manufacturing system.

[9] The Leaders for Global Operations Program (LGO) was called Leaders for Manufacturing (LFM) program prior to 2008. LGO is a dual engineering and business masters degree program with a special focus on manufacturing and supply chain operations

Several Lean Maufacturing techniques are also discussed in this thesis. *The Machine that Changed the World* by Roos, Jones, and Womack introduced the Toyota Production System and Lean Manufacturing to the world. Jones and Womack later released *Lean Thinking* to further explain the Lean Manufacturing mindset.

1.6.2 New Technology Introduction

This thesis also discusses the introduction of new technology in the workplace. New technologies of all types in both industrial and office settings are often met with numerous roadblocks during implementation that lead to less than ideal outcomes; in fact as many as 50-75% new technology implementations end in failure[2]. A lot of research in the early 1990's targeted the subject of implementing Advanced Manufacturing Technologies (AMT) in the workplace. AMT can be defined as "an automated production system of people, machines, and tools for the planning and control of the production process, including the procurement of raw materials, parts, and components, and the shipment and service of finished products" [9].

McDermott and Stock[9] among many others have studied the effects of business culture on AMT implementation. In general, AMT's have the potential to provide four types of outcomes[13][18]:

1. Operational - increased production efficiencies and output
2. Organizational - improved work flows and managerial control
3. Competitive - Improvements that lead to higher sales or gain of market share
4. Satisfaction - How satisfied the management is with implementation leads to greater outcomes

McDermott and Stock's research concluded that company culture significantly affects its satisfaction with AMT. Satisfaction is a crucial metric for AMT implementation because it represents the company's view regarding the success of an AMT system. Cultures that have high satisfaction with AMT are likely to devote resources to continue the development of other AMT solutions. An AMT implementation that provides high competitive and operations benefits but yields low satisfaction is still a failure; management is unlikely to pour resources into developing the AMT's capabilities.

Small and Yasin[15] point out that any new capability a business is pursuing requires both new structure (new processes, both physical and IT) and infra-structure (management, people, procedures). Through research of over 120 different manufacturing sites they concluded that AMT implementations are more successful when infrastructure is developed to a higher degree. They found that firms tend to put fewer resources into the human factor of AMT implementation than is required. This results in a workforce that does not fully understand the capabilities of the new technology, and as such will have a lower satisfaction with its performance.

Hayes and Jaikumar[5] write about the six barriers to successful technology implementation.

1. **Within Manufacturing** - Manufacturing systems are complex, and the maximum capabilities of AMT cannot be realized unless the entire manufacturing system is optimized.

2. **Across Functional Barriers** - Businesses must recognize that new technology has many new capabilities that allow it to interface with more business functions than before. Hayes and Jaikumar use the analogy of selling a car and buying a helicopter. Both are a means of transportation, yet they have vastly different capabilities.

3. **Customers and Suppliers** - If new capabilities are not shard with customers and suppliers, there are fewer stakeholders interested in implementing the new technology.

4. **Financial Justification** - Firms are often too conservative on the financial benefits of new technologies, which leads to a conservative allocation of resources during implementation

5. **Dependence on External Knowledge** Often management is looking for AMT vendors to supply a turnkey operation that requires few resources allocated for learning. However, in order for new projects to reach their full potential, businesses must build internal expertise on the project. This way any issues or hiccups can be solved quickly without reliance on outside help.

6. **Performance Measurement** - New technology's performance cannot be measured in the same manner as their predecessors. Using the analogy of the car and helicopter, measuring the helicopter based on miles per gallon will lead the owner to believe the helicopter is performing poorly.

By understanding and targeting these barriers during new technology implementation, businesses will have more successful new technology implementations, get more out of their investments, and have a high sense of satisfaction.

1.6.3 Current State Analysis

This research project was commissioned with the objective of maximizing Boston Scientific's investment in its internal plastic components capabilities. One way to achieve this is through Lean Manufacturing, a well-studied method of increasing a factory's utilization and performance. One of the staples of Lean is monitoring the impact of initiatives to enable continuous improvement[6]. At its current state, SCD does not have a convenient manner by which to monitor production performance. Thus the success of any Lean implementation would be unknown unless manually monitored by the department's employees. To facilitate the continuous improvement mindset, an automated data collection system, which can be considered an AMT, was utilized to provide a new source of information to aid in decision making. This system suffered through many of the barriers discussed by Hayes and Jaikumar. Despite these barriers, the impact of the system has led to a high satisfaction not only from management but from suppliers and customers as well.

1.6.4 Lean Implementations

The most impactful capability realized from the implementation of the production performance system was the ability to easily track production performance. With this new capability, Lean Manufacturing techniques were implemented and their progress was able to be monitored, thus facilitating continuous improvement. Management, now able to easily track its Lean improvements, can now drive them further than ever before. Projects including Single Minute Exchange of Die (SMED), Economic Order Quantities (EOQ), and a Sales & Operating Plan (S&OP), which were once failed initiatives, are now sustained. The implementations of these lean initiatives is discussed later in this thesis.

1.6.5 Future Opportunities

Many other opportunities exist that would benefit SCD; there is a large suite of Lean Tools that is not mentioned within the scope of this document that would greatly benefit SCD, such as schedule optimization, and single piece flow. A discussion of how to overcome the AMT barriers proposed by Hayes and Jaikumar will also be included.

1.7 Overview of Sections and Appendices

The many challenges facing the SCD department will be detailed in Chapter 2. The discussion focuses on how each challenge impacts the department's ability to effectively utilize its machine time and extract full value from its assets. Some of these challenges include a high mix low volume product mix, manufacturing metrics that are not aligned with overall department goals, and high overhead rates.

The introduction and implementation of *Intouch*, an automated production monitoring software, comprises the content of Chapter 3. Key discussion points are the challenges associated with change management of a new technology and the benefits of the technology on the performance of the manufacturing system.

Chapter 4 details how SCD uses a reorder point system to schedule the production of over 550 individual components types. Chapter 4 also discusses how technology solutions such as automation and data collection can help Boston Scientific achieve the project goal. Chapter 5 will conclude this thesis with a list of recommendations for SCD to achieve its ultimate goal of World Class production.

Chapter 2

Challenges at SCD

2.1 High-Mix, Low-Volume

The production at SCD is High-Mix Low-Volume and is the most prominent challenge faced in the department. Over 550 different products with annual demands ranging from five to over 1,000 hours of production are manufactured on the department's injection molding machines and extruders.

SCD began as a very small specialty mold shop. As Boston Scientific grew through acquisitions and mergers the Spencer facility in-sourced many new products, and SCD's product mix grew in turn. Because most of Spencer Component's products have been in-sourced from other companies, there is high variability in mold and part geometries, raw material specifications, and required machine capabilities. Because of low volumes and high revalidation costs, there have been few efforts to streamline raw materials or retool molds.

Few standardizations exist between product codes, and much of the operational knowledge of the department lies within the department's machine technicians and operators. Years of training are required for a technician to gain the confidence to perform all required tasks. Much of this training is done through word of mouth between technicians or through trial and error.

Given the large number of molded components from different acquisitions, it is nearly impossible for management to deep dive into which components are the most difficult to manufacture. Difficult components result in machine downtime, operator dependent output, and high material scrap rates. The current level of data collection in the SCD does not provide this level of detail; all individual component performance is aggregated into overall machine performance, so it is difficult for SCD to know where to focus operational improvement efforts.

Little direction is given from Boston Scientific Global Supply Chain or any other internal group as to the long term strategy driving SCD. The department is left to make critical capital decisions by itself without a clear vision of what technology to pursue or what component types to target. Perhaps SCD should focus on manual insert molding and outsource automated components. Another option is for the department to outsource all difficult-to-manufacture components and focus on fully utilizing its automated injection molding machines. Without strategic guidance the department will not be able to transition its fragmented product mix into a more focused grouping.

Another challenge SCD faces is the storage space required for all its different product molds. The current mold racking system is nearly at capacity, and there is little available real estate to accommodate increased racking, let alone additional machines. The walkways behind and between machines are narrow and filled with the different equipment required to run the full product mix. Storage space is also required for the raw resins. The department staffs a full-time material handler to coordinate resins to the correct machine and keep feed hoppers full.

2.2 Process Validation

Before a new component enters its first production run, the manufacturing process must be validated to ensure critical geometries are created at an acceptable quality level. The FDA mandates that medical device manufacturers have a process validation program that verifies a range of acceptable manufacturing setups to produce the appropriate part.[1] Boston Scientific has an extensive validation and verification process that produces a manufacturing plan to which all components, assemblies, and finished products must adhere. This thesis does not delve into the details regarding Boston Scientific's validation and verification program; rather, its implication on the manufacturing floor will be discussed.

Validation is on a per machine basis. For example, two identical molding machines will require separate validations in order for them to produce the same component. Any modifications that could potentially change the process capability of that machine such as physically moving a molding machine or modifying mold cooling water lines will trigger a re-validation. While there are varying degrees of severity, the cost associated with the engineering and direct labor to perform a validation reaches the tens of thousands of dollars and takes many weeks. Over 98% of the codes produced in SCD are only validated on a single machine (i.e.. single sourced), and products will only be validated on multiple machines if there are capacity concerns.

The result is that there is limited product flexibility at SCD. The supply chain has many single points of failure that would halt production until they were resolved. An example would be a machine breakdown on a heavily utilized piece of equipment. BSC would need to resolve the machine issue before inventory of the machine's components was depleted or initiate a process validation on another piece of machinery with free capacity. During the duration of this study, a severe machine breakdown prevented the production of over 40 components for over two weeks due to the failure of an obsolete machine part.

Reduced flexibility creates long-term department challenges. When a new or in-sourced component is brought into SCD, its machine placement is optimized based on the current product mix on each machine. However, inefficiencies arise over time. This challenge is similar to Alexey Pajitnov's arcade game *Tetris*: as the game progresses it becomes more

[1] FDA Guidelines 21 CFR 820.75

difficult to fit the incoming blocks in the wall unless the game was played with careful planning. SCD must manage its product mix to ensure it not only produces high quality components to specification but also ensure there is enough available capacity on its machines to support the ever changing product mix.

Process validation is not the only barrier to machine flexibility. Because Spencer Component's product mix is the result of acquisitions of external medical device companies, many of the machine specifications for each product require different machine settings. Molding machines can have different tonnage or barrel sizes that confer different levels of capabilities. The machine fleet at SCD has many different tonnages and orientations, and these differences limit which molds can run on which machines.

2.3 High Overhead Rate

SCD competes for work just as any external manufacturer does. In order to bring a new product into the department and utilize more machine capacity, a quote must be provided from SCD to Boston Scientific detailing the process steps required to manufacture the component along with its predicted cost. While Boston Scientific uses a total cost of operation model and will not choose vendors on unit cost alone, it is critical for SCD to remain as competitive as possible on cost to win bids on new products and fill idle machine time.

Geography is both an asset and liability for SCD. Because it is located directly underneath Spencer Assembly, it can offer cost savings in terms of inventory reduction and nonexistent transportation costs. This makes SCD an excellent source for any injection molded component that Spencer Assembly uses. Some drawbacks to molding in Indiana are that raw resin in China or Western Europe can be purchased for 70% the cost of the same resin in North America, [2] and the labor rate in the United States is far higher than in other areas of the world.

[2] Boston Scientific Global Sourcing Injection Molding Strategy, June 2016

Spencer Component's overhead rate is not competitive compared to other suppliers for molded components. The overhead rate is the sum of the department's indirect costs (e.g. engineering, quality, human resources, warehousing, and utilities) divided by the quantity of earned labor hours[3]. The overhead value for Spencer Component's business units is calculated annually; should indirect head count increase or decrease during the year the overhead rate will remain the same value until it is next recalculated.

A typical injection molding shop will have an overall overhead of about $70/hr [4], and Spencer Component's overhead significantly exceeds that value. Overhead rates can be reduced by changing either its numerator or denominator. Reducing the indirect costs such as engineering or quality control head counts will lead to reductions in the department's overhead rates.

A second method to decrease the overhead rate is to increase the number of earned hours generated by the department. This is a longer term strategy, as doing so means integrating new or in-sourced components into the product mix of the department. This strategy is one way Boston Scientific can achieve its goal of increasing the return on the assets in SCD. At its current efficiency performance the department utilizes less than 40% of its available machine time. If SCD in-sources new components so that its machine utilization is 85%, the department can easily achieve an overhead close to the industry standard of $70/hr.

The chicken and egg paradigm is now apparent; overhead can be lowered by utilizing more machine hours, yet in order to get more machine hours a competitive overhead may be needed. If Boston Scientific has access to vendors with competitive overhead and labor rates, then the only advantage SCD has is its location and internal expertise. This advantage is not great enough to make SCD the most competitive component supplier. SCD has to prove to the greater BSC business that it is worth the effort to in-source

[3]There are many different ways to allocate overhead. Within SCD overhead is allocated by earned labor hours, however overhead can be allocated based on required machine hours, by machine utilization, etc.

[4]Internal Boston Scientific Research

components because it can deliver on quality, lead time, flexibility, and eventually, cost.

2.4 Nine Panel Metrics & Net Labor Efficiency (NLE)

All Boston Scientific sites' performance is measured using the Nine Panel Metrics system, which is posted at each site. These metrics include inventory, realized cost savings, quality, and safety. Cascading from these metrics is the Core 5, from which every internal manufacturing line in Boston Scientific is measured. The Core 5 metrics differ slightly depending on the department; however on all assembly lines the Core 5 include:

1. **Production Output** - Total units per day
2. **Quality** - Percent of products produced that full conform to all quality system standards
3. **Net Labor Efficiency** - Effectiveness of direct labor (earned hours versus hours worked)
4. **Yield** - Number of finished products divided by total number of products that started the production process (i.e. measure of scrap)
5. **Cycle Time** - Time between successive products at the end of a production line

The metric boards are updated on a weekly basis and reviewed with the Core Manufacturing Team. These two metric strategies unify Boston Scientific's sites as a single company and allows for easy comparison of performance between sites and manufacturing lines. On a daily basis special attention is given to the Net Labor Efficiency (NLE) metric. This metric tracks the efficiency of the direct labor in a particular manufacturing cell. This metric is used universally in all Boston Scientific sites.

In finished product assembly, each production line has its own Core 5 board, yet the performance of all Spencer Component's machinery is placed on a single Core 5 board.

This creates challenges for the team as they are incentivized to meet the metrics board, though they may not necessarily drive the department to the right behaviors. One such example is the Production Output metric. While the total production quantity is correlated with overall department performance, it does not indicate whether the correct components were produced on time or if demand was met. It is conceivable that the scheduler could schedule components with low cycle times to drive this metric up even if the components aren't needed. Line Fill and On-time Delivery is its own panel on the Nine Panel; however it is based on the performance of Spencer Assembly and is not present on the Core 5 board for SCD.

The Net Labor Efficiency of the Core 5 is a highly important metric for each manufacturing group to hit, as it is the measure of effectiveness of the direct labor force. The importance of this metric to Boston Scientific is understandable, given the high manual labor content of its final assembly lines. Very little automation can be found in any Boston Scientific assembly line. Therefore an easy way for the company to measure the performance of each line is to use Net Labor Efficiency (NLE). While this metric works well for final assembly, it is less effective in more automated manufacturing systems like that found in SCD.

SCD struggles to keep its NLE stable from week to week; some weeks they are well above target and others well below. The methodology behind the calculation of NLE is as follows: suppose there is a machine that requires one person to operate with stated capacity of ten completed parts per hour. If the operator completes ten parts in a given hour, that operator is said to have completed one earned hour in one labor hour. However if the operator only completes nine products in the hour, then the operator has completed 0.9 earned hours in the one labor hour, or 90% net labor efficiency. If there is a machine issue and now two operators are required to produce ten pieces, then one earned hour has been generated in two labor hours, and the result is a 50% NLE. Another way to think about NLE is on a per piece basis. In the above example, each piece that the operator completed generates 6 earned minutes. The number of pieces produced over a production shift can be converted to earned hours and divided by the total hours worked by direct labor.

NLE is a useful tool to understand how efficient the direct labor force is, but there are a few factors that can affect NLE. New employees generally need to be accompanied by an experienced employee during the duration of training, therefore employee training will lead to lower efficiencies. One of the drawbacks with NLE is determining the root cause of a change in its value. NLE can be increased by hiring faster operators, improving machine uptime, or automating manual tasks. Since employees are staffed for 8 hour shifts, the NLE trend would match overall equipment efficiency (OEE) trend if they hit target cycle times. Deviations between the two trends indicate a labor gap rather than a machinery problem.

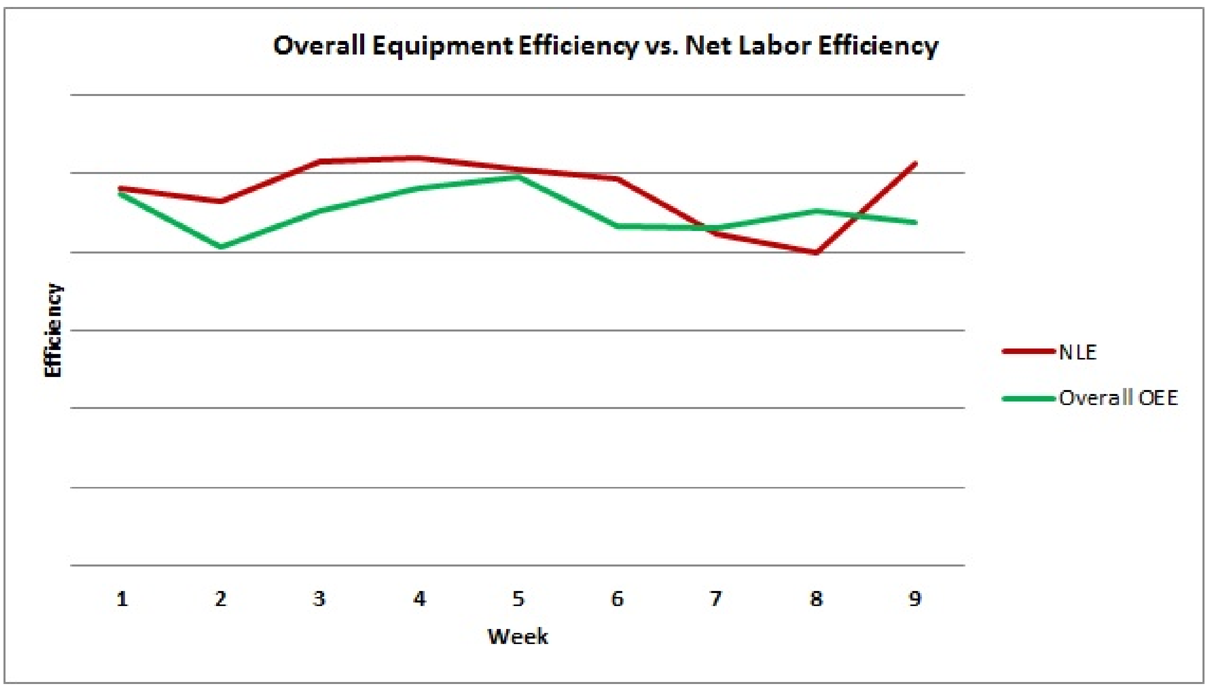

Figure 2-1: Comparison of Net Labor Efficiency and Overall Equipment Efficiency. Values have been normalized to show difference in trending behavior

As seen in Figure 2-1, the variation of the two curves do not match. While initially NLE and Overall Equipment Efficiency (OEE) are directionally aligned, in later weeks OEE rises and NLE falls and vice versa. This is a signal to management that the extraneous events such as employee training, labor shortages, or poor employee performance are causing fluctuations.

One of the nuances with NLE is setting the proper standard for efficiency. Not only must BSC decide the standard time to complete a task but also which labor to include in the efficiency. Labor can be divided into two buckets: direct and indirect. Indirect labor can consist of engineering staff, management, and maintenance; often these resources are allocated to the department's overhead. Direct labor includes the employees directly at the machine. There are some groups of employees who can be put in either classification at the discretion of the management such as material handlers, quality inspectors, and machine technicians.

An increase in indirect labor does not affect NLE because only direct labor hours are used in its calculation. NLE is a highly prioritized metric at Boston Scientific, and as such management works to keep it above target. In the instance where there is insufficient direct labor on the manufacturing floor, it is feasible to hire indirect labor employees such as engineers to complete tasks that could be completed by a direct laborer. In the short term this would provide a boost to NLE: every direct labor hire lowers NLE by a significant amount, thus substituting indirect labor will increase it. This practice does increase the department's overhead rate; however because overhead is reviewed on an annual basis there is no feedback to management that overhead has in fact increased when headcount is increased.

Controlling the direct labor force is one of the primary responsibilities of management. However, when looking at total component cost in Figure 1-3 direct labor is the third largest cost drive behind overhead and raw materials. The major problem caused by the focus on NLE is that management places priority on minimizing its direct labor resource to reduce cost. One could also argue that the department management has just as much ability to control its overhead rate as it does direct labor. Since overhead rate is only calculated on an annual basis, management has no choice but to use NLE as the guide for its decisions.

It is the author's point of view that a different set of performance metrics is required in order to achieve Boston Scientific's objective of optimum return on investment. While NLE is a fine metric to target, NLE and the other Core 5 metrics do not capture the whole picture of Spencer Component's performance.

2.5 Component Scheduling and On-time Delivery

SCD provides products to many different finished product assembly lines both internal and external to the Spencer Facility; each assembly line can be considered a different customer. Most of the components in the department have a steady demand that grows approximately 3-4% year-on-year. The components scheduler is responsible for setting the production schedule and ensuring customers receive their components on time. The components scheduler will also publish a weekly 'hot list' of components that will have zero inventory in the coming week and cause a finished production shortage. This list is constructed with the help of finished product planners, who work together with the components scheduler to determine when shortages will occur, and how many of the shorted components to build. The 'hot list' items are prioritized in the schedule and closely monitoring by supervisors and managers.

The items listed on the 'hot list' receive attention from all levels of management; it is the only real metric by which the schedule is measured. All attention is directed to items on the 'hot list' and rarely on any other production order; there is no sense of urgency regarding machine downtime for non 'hot list' items. The result is that the 'hot list' contains roughly the same amount of component shortages week to week.

Since nearly all components are single sourced, significant downtime or production misses in SCD can cause downstream assembly processes to have part shortages and production misses. Boston Scientific does not track the instances where SCD has caused a part shortage, yet SCD has a poor reputation as a component supplier.

On-time delivery or schedule adherence of SCD is not actively tracked at the component level but at the department level. One of the Core 5 metrics for SCD is output, and this is tracked every week by Spencer's upper management. However, output only ensures that the total number of manufactured components reaches a target level. This metric is independent of component type. Currently SCD does not know at what level they are performing, how they ought to perform, or what needs to be changed to perform well; it only has real visibility into whether or not is makes the correct overall number of components. While the information exists to determine SCD's service level, there does not appear to be any tool in use at Boston Scientific tracking this metric. SCD's service reputation is not based on hard numbers and metrics but rather general feelings from the Spencer Assembly Team.

2.6 Labor Scheduling and Flexibility

A key factor in capacity utilization is labor: when it is scheduled and if it will show up. Most labor schedules are either 24/5 or 24/7. Currently all but three machines within the department run on a 24/5 schedule or less. There are three 8-hour shifts during the work week and a skeleton weekend crew to run high demand components on the weekends. If the department were to bring in more manufacturing hours, it would need to bolster its weekend crew.

The current attendance policy at SCD allows employees to miss their shift as long as they call their supervisor before their shift begins. This action will cause the employee to have an attendance point removed from his or her record, however the number of attendance points are abundant. The attendance flexibility awarded to the workforce is a large challenge for the SCD production team. The current labor market in the Bloomington Metro Area is at a competitive unemployment rate of 4%[5]. Maintaining fully staffed production shifts with full-time employees is difficult, so perks such as a flexible attendance policy are used in an attempt to retain the workforce.

[5]StatsIndiana,http://www.stats.indiana.edu/maptools/laus.asp

The need for a reliable workforce is driven by the need to produce specific components. Boston Scientific's Quality System demands that employees complete a documented training plan for each component they manufacture. Some training plans are easier than others, thus the more complicated components have the lowest number of trained employees. The problem with the attendance policy is that many situations (nearly a weekly occurrence) arise when a critical component is in demand, yet the trained employees required to manufacture them did not show up for work. By the time the employee is noted by management, there is no time to solicit overtime from a trained operator who is leaving for the day, and a production shortage is created.

One of the root causes of this problem is the lack of visible information on which employee is trained on which component. If several highly trained employees do not show up for their shift, the management must individually reference each employee's training plan to figure how out to redistribute the workforce. This kind of decision making is stressful for the leadership team and could easily be alleviated with the help of technology. While training records are already stored and up-to-date in the MES system, a useful training summary for each employee is too cumbersome to use.

Another challenging aspect for the labor force at SCD is the ability to hire more employees for the weekend shift should production volumes increase. SCD is the only department within the Spencer Manufacturing Site that operates more than two shifts. A benefit to running a 24/7 schedule is fully utilizing existing equipment capacity; however there are several challenges to executing this. The department would be forced to manage production every day, and given the fact that the rest of the facility does not operate 24/7, talent resources who favor the work/life balance would likely shy away from employment on the weekend. Engineering hours on machines are more difficult to schedule since the machine hours are already consumed by production components.

2.7 The Need for Production Data

The challenges listed above showcase the reason SCD cannot be managed by human mind alone. Given the high mix low volume nature of the products along with the complications of labor scheduling and overhead rates there is a tremendous opportunity to implement a tool to aggregate data and create relevant performance metrics (such as OEE and on-time delivery) to guide management decisions. The Core 5 metrics have been shown to have weaknesses that can lead to suboptimal business decisions.

It seems clear that what is needed to alleviate the complexity of SCD is the introduction of new tools to simplify production information. The next chapter will discuss how the implementation of a production monitoring software provides a new set of metrics that allow department management to improve its overall performance and create the opportunity for continuous improvement.

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Chapter 3

Automated Manufacturing System Performance Tracker

Given the challenges at SCD, an appropriate next step to address them is to implement systems that aggregate production data into simple performance metrics to make a complicated manufacturing system seem simple. This chapter focuses on the implementation of one such system and how it positively impacted SCD's ability to track and improve production performance.

3.1 Current State Performance Tracking System

3.1.1 Machine Downtime Tracking

Tracking production performance is a vital step in Lean Manufacturing's Continuous Improvement mindset. In order to know how you've progressed you must know where you started. At the start of this project SCD utilized a paper-based tracking system of machine downtime. This system has three significant drawbacks: information inaccuracy, labor intensive data aggregation, and tardiness. In SCD, operators were prompted to record downtime events by making a mental or physical note of the time when their machine stopped. After the event was resolved and machine restarted, he or she would record both the duration and the downtime reason on their daily production sheet.

Data integrity is a concern because it is nearly impossible to prove or disprove the operator-provided information. Downtime that occurred around employee breaks was especially scrutinized. Employees receive a 30-minute lunch and two 15-minute breaks during an 8-hour shift. An operator was not likely to record time durations exceeding those limits regardless of the actual machine downtime for fear of disciplinary actions.

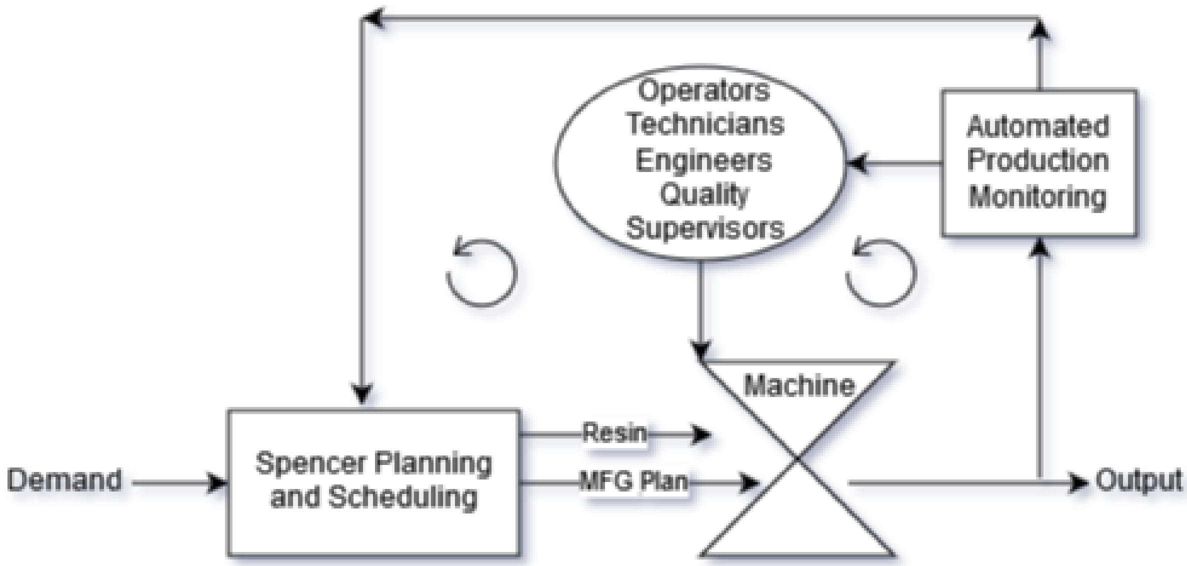

Figure 3-1: Production Monitoring Feedback Loop

Regardless of the data accuracy the manual data was stored on paper and could not be used for live reporting in its current form. At the end of each shift the downtime data was collected by the lead operator and manually entered into an *Excel* spreadsheet. This work content consumed as much as 45 minutes per shift, preventing the lead operator from solving issues on the floor or preparing for the next shift. Because the data was not aggregated until the end of the shift or even a couple days, major downtime trends were not apparent until placed in the tracker.

Access to accurate, real-time data creates two feedback loops for the Components Operations team as shown in Figure 3-1. In the short term, live production data allows the operations team to immediately adjust how it uses its resources based on output. If a machine is not performing well, the team can see that in the data and take action to get output back on track.

Long term planning of capacity and capabilities is also improved through access to accurate data. Data can be aggregated over many months to summarize machine performance per component, month, shift, etc. This information is essential for businesses to know if current capacity and capability will meet future demand. The current manual production tracking method at SCD did not offer these feedback loops.

3.1.2 Production Scheduling

With over 550 components to manufacture SCD must ensure that its machines are producing the right products at the right time. Machine scheduling is completed by the Components Scheduler, who assigns open work orders to machines. The Scheduler's goal is to ensure the components will be available to finished assembly operations and to alert both components and finished assembly when they will not.

Figure 3-2: Magnetic Scheduling board in place prior to *Intouch* system implementation

The Scheduler utilizes Boston Scientific's Manufacturing Excellence System (MES), which is primarily used for recording work order routings for financial records and quality traceability. MES comprises a major portion of Boston Scientific's quality system and only accepts data input from trained employees or other quality system approved applications. Every work order released by the scheduler has a specific pathway it must follow in the MES system in order for Boston Scientific to appropriately assign costs and quality inspections. One of the router steps is assigning the work cell of manufacture, otherwise know as the molding machine. The Components Scheduler will assign each work order to a molding machine and in addition assign a priority number which determines the machine schedule. Priority is largely based on three factors: the due date of the work order, current machine schedule, and raw material availability. Whenever possible, work orders for the same component will be grouped together even if there are different due dates in order to minimize the number of required machine changeovers.

The machine schedule is contained within MES and is only viewable to the scheduler and lead operators from their personal computers. A magnetic production board (Figure 3-2) is used to communicate upcoming machine work orders to the operators and technicians. Every machine has two slots for work orders: the current running work order and the runner up. The production board also has indicators of machine status, such as whether or not the raw resin is available or if the work orders are considered 'hot'. From this board the operators and technicians are able to run the machines and know what the next work order is. The Components scheduler and shift lead operator are responsible for keeping the board up to date and accurate.

There are several advantages to the production board. The major advantage is that the machine schedule is created using the WIP tags that are placed on the finished components container. These tags contain all of the information required for the operations team to complete the job, and it removes the operators responsibility to print the tags. The board minimizes the risk of an operator running the wrong job, since they can only select from the printed tags on the board.

The current system has one major drawback: schedule visibility. As mentioned, full visibility to the work order priority list for each machine resides with the scheduler and lead operators. MES does not contain estimated job completion times, so these must be calculated by hand in order to know if a work order will be completed by its deadline. Without an up-to-date estimate on job completions and end dates, changeover times are not known until the machine has completed its work order. Unplanned downtime events can push changeovers into the evening and night shift when there are fewer technicians on staff. If the Components Scheduler is aware of a changeover delay before it occurs, he or she can adjust the work order size to ensure the changeover happens when there is staffing to support it.

3.2 Automated Performance Tracking - *Intouch*

A solution for the drawbacks of a manual data collection and scheduling process is an electronic production monitoring software package. These server or cloud-based systems can be found in many industrial applications: Oil processing plants utilize *PI Process-Book* to record and analyze production data, and SCD now utilizes a package called *Intouch*, which features tools such as scheduling, live floor status, downtime recording, and historical reporting.

Intouch gives the department a single place to monitor performance at any given moment (Figure 3-3). Each machine is represented by an icon that changes color based on machine status: Green for running, Red for down without a reason, Yellow for down with reason, Orange for machine changeover, and Gray for not scheduled. Timers indicating machine downtime and time remaining on current job are located directly beneath the machine icon. Whereas previously lead operators, technicians, and supervisors had to physically see each machine and inquire about its status, *Intouch* condenses that information into a single window. There are two monitors on the production floor as seen in Figure 3-4; one displaying the floor status page and the other the live machine schedule Gantt chart. There is an additional floor status monitor in the engineering office.

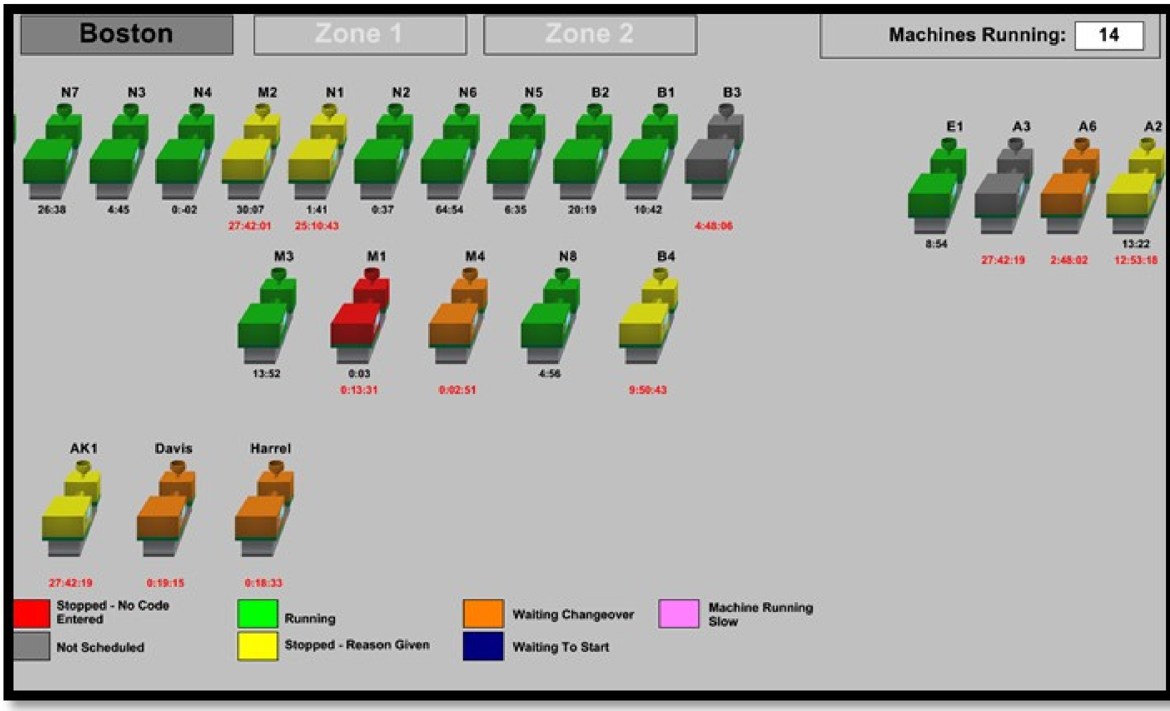

Figure 3-3: Screenshot of *Intouch* Floor Status Module

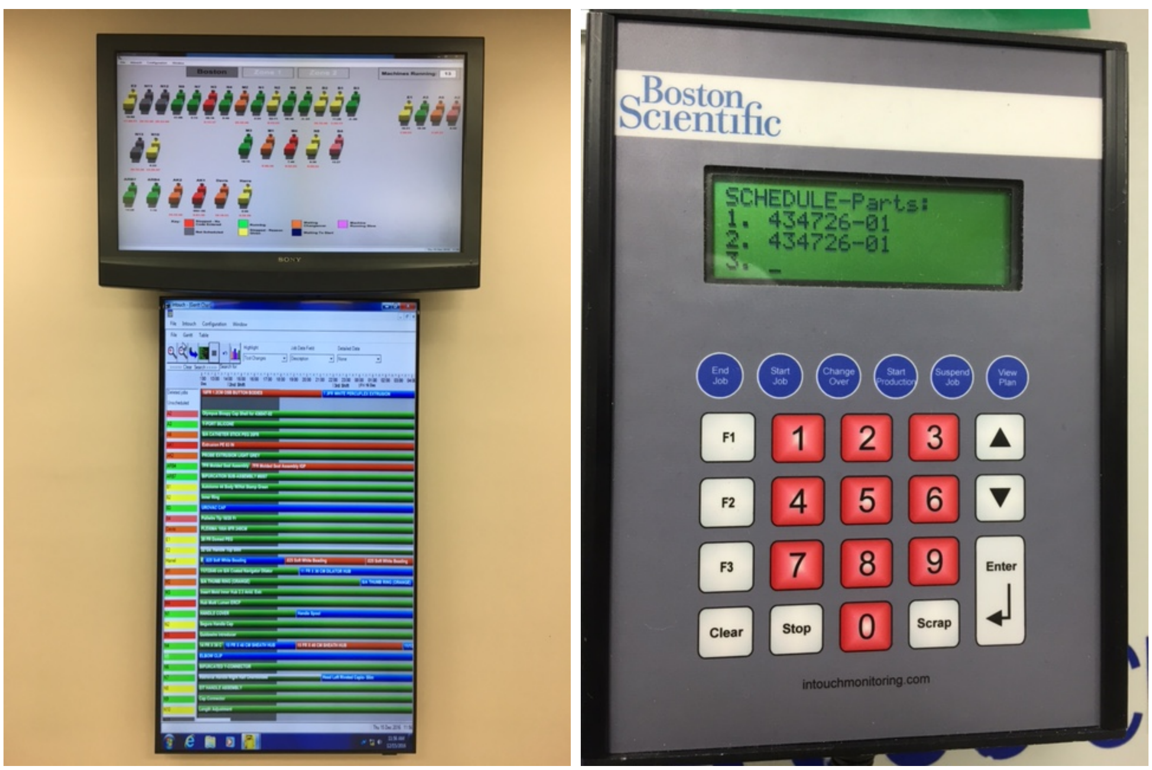

Figure 3-4: Left:*Intouch* Displays on Production Floor, Right: Operator Terminal

The *Intouch* system has been in place at SCD since 2014 and undergone cycles of focused and unfocused implementation. There have been many challenges to its implementation, both technological and cultural. Technologically the system is simple; machine relays are connected to the software server and provide a binary signal to indicate whether a machine is cycling or stopped. Operator terminals on each machine allow workers to input the machine's current work order, quality defect counts, and downtime codes. The machine relays and terminals send data to *Intouch's* server which aggregates it into a database. *Intouch* can be accessed by any personal computer or device connected to its server. From these devices, reports such as downtime Pareto charts or cycle time analysis can be created and used to make informed decisions.

During the duration of the research study, two of *Intouch's* tools were implemented and integrated into business operations: Machine Scheduling and Downtime Reporting.

3.2.1 *Intouch* Scheduling

Intouch comes with a scheduling module that brings a lot of new features to SCD and addresses the current scheduling method's issue with visibility into the machine future schedule. Figure 3-5 is a screenshot of the live machine schedule for SCD.

Figure 3-5: Scheduling module in *Intouch*. Green blocks are the current work order. Orange blocks signify a new work order that does not require a mold change, and Blue blocks represent work orders that require a mold change.

The Gantt Chart uses input from MES, the Components Scheduler, and machine status to provide live estimates of job completion times. Work orders that require a mold change will be highlighted to signal their impending arrival. Because the schedule is updated live it reflects the accurate timings of work order completions and changeovers. In addition to being posted on the plant floor, the schedule is available on any personal computer that is connected to Spencer's network server.

The scheduling module comes with every installation of *Intouch* because the program relies heavily on the machine schedule to provide its maximum value. *Intouch* associates all machine cycles and downtime codes with a work order. In order for *Intouch* to have a functioning schedule, work order details such as quantity, order number, component type, etc. that are stored in the MES system needed to be transferred to the *Intouch* server. When *Intouch* was first installed in 2014 the MES work order list was manually downloaded from MES and uploaded into *Intouch* by the Scheduler. This list only included work orders that had physical WIP tags printed and not those further in the queue without physical printed tags.

There were several issues with this method. First, only work orders with printed WIP tags would be available to choose on the *Intouch* screen, meaning there was no more visibility into the machine schedule than what the magnetic schedule board provided. Also, the Components Scheduler was the only employee trained to perform information transfer; if a machine completed two work orders, and a new work order tag was printed in the middle of the night, *Intouch* would not have the work order in its queue. When operators went to start the job in *Intouch*, it would not be found and no data would be collected during the production run. This scenario resulted in inaccurate data collection and diminished management trust in the system; it is the main reason *Intouch* was not successfully implemented until late 2016.

In order to ensure *Intouch* had the most up-to-date work order list, two hourly automatic reports were created from MES and placed on the *Intouch* server. One report listed work orders with printed tags, the other listed work orders without tags. A Visual Basic script was installed on the server and run every hour using Microsoft's *Task Scheduler* to combine the two MES reports and send the consolidated report to *Intouch*. The creation of the script allows the scheduling module to have all machine work orders without manual input. Data accuracy sky rocketed overnight, and management had a reinvigorated focus on continuing *Intouch's* implementation. The script and automatic reporting, albeit a simple coding solution, were not created in 2014 because SCD did not have the skill set to create them. As with any new technology solution, gaps in required technical skill sets of the employee base lead to less than optimal performance of the solution.

3.2.2 *Intouch* Downtime Reporting

With the scheduling module functioning, focus could be shifted to improving downtime accuracy and using the reporting tools in Intouch to drive business decisions for SCD. *Intouch* uses the Overall Equipment Effectiveness metric as its primary performance indicator.

3.2.3 Overall Equipment Effectiveness (OEE)

Overall Equipment Effectiveness (OEE) is a metric for tracking production performance of individual equipment introduced by Nakajima in the Total Productive Maintenance (TPM)[11] system. Several variants of this metric have been created since Nakajima's work. One variation, Overall Factory Effectiveness (OFE), is an attempt to extend OEE from machines to a factory performance. OFE is now widely used in chip manufacturing where an understanding of overall manufacturing system performance is required[12]. Because the majority of SCD manufacturing is based on single machine cell performance, OEE is an appropriate tool to measure performance and potential.

Nakajima presented OEE as a tool to reduce six losses in manufacturing plants:

1. Equipment Breakdown

2. Set-up and Adjustment Downtime

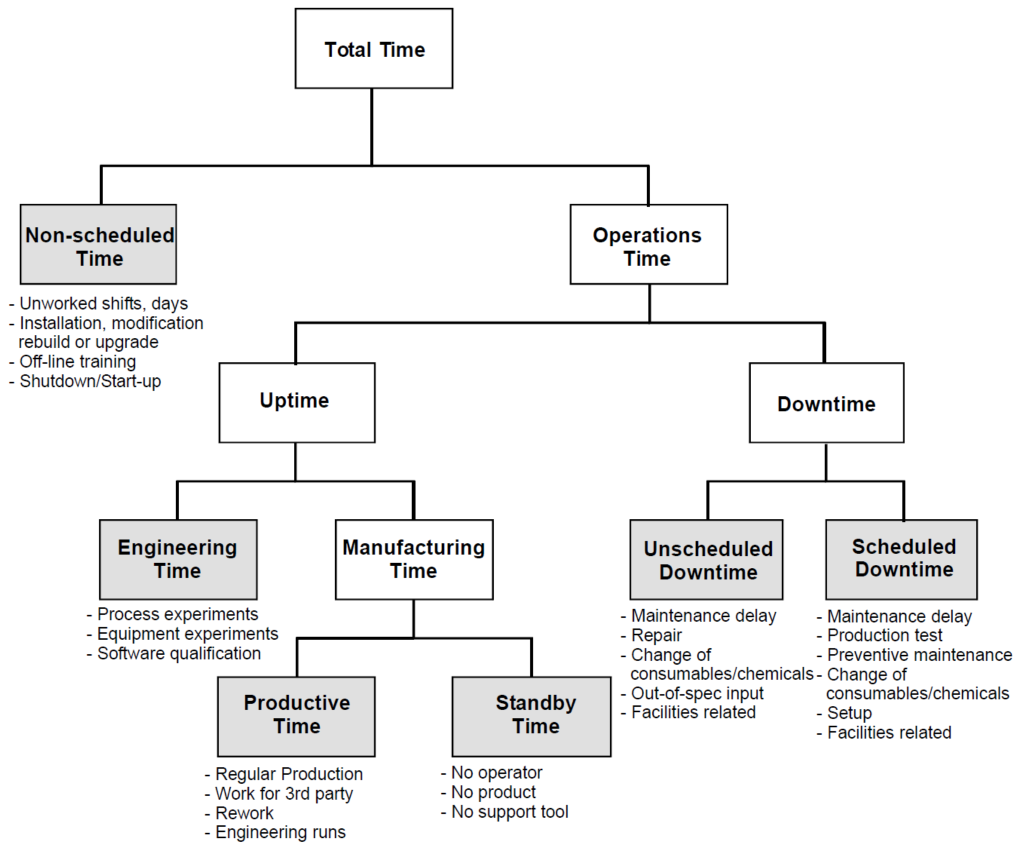

Figure 3-6: OEE Structure according to SEMI E10

3. Minor Stoppage Downtime

4. Reduced Speed Losses

5. Quality Defects and Rework

6. Start-up Losses

While the output of OEE is a single number, it is constructed from not only theoretical utilization but also losses through cycle time variation and quality[14]. OEE can be calculated as follows:

$$OEE = A * P * Q \tag{3.1}$$

Where A is the availability of the machine, P is machine performance (cycle time) while running, and Q is the machine quality.

$$A = \frac{ActualMachineHours}{PlannedMachineHours} \tag{3.2}$$

$$P = \frac{ActualManufacturedParts}{TheoreticalNumberManufactured} \tag{3.3}$$

$$Q = \frac{TotalPassableParts}{TotalPartsManufactured} \tag{3.4}$$

OEE is a powerful metric because the use of its three factors allows the business to determine root causes of production issues. If a machine's availability is 100%, but its quality is at a 78%, then it's easy to conclude that the shortfall in production wasn't due to poor machine performance. It also allows for OEE to adapt with the business. If a machine is only supposed to run a 24/5 schedule, then OEE will not be negatively impacted by an idle weekend. The availability factor does have a vulnerability: an employee must record when each and every machine is scheduled to run. This can be cumbersome at SCD; while most machines are on a stable schedule, there are numerous occasions where machines must run into the weekend even though they were not scheduled to do so. If the OEE isn't updated to reflect the new planned hours, then the extra hours on the weekend will inflate the machine's true OEE. A graphical representation of the machine states used in the OEE calculation is seen in Figure 3-6

Machine	Potential Machine Hours	Planned Down Time (Hrs)	Available Machine Hours	Machine Run Time (Hours)	Unplanned & Setup Hours	Availability %	Standard Hours Earned	Performance %	Quality %	OEE %
N7	632.00	115.58	516.42	263.89	123.91	51.10	263.78	99.96	99.96	51.06
N8	632.00	170.81	461.19	223.98	54.78	48.57	416.86	186.11	100.00	90.39
N9	632.00	203.36	428.64	396.52	15.12	92.51	393.07	99.13	100.00	91.70
Overall:	20,224.00	9,011.06	11,212.94	5,129.55	1,701.84	45.75	5,341.28	104.13	99.97	47.62

Figure 3-7: Example OEE Report from Production Monitoring Software

At SCD, all but three machines are assumed to be on a 24/5 schedule, therefore the OEE can be thought of as the percentage the equipment was utilized during the week. The production monitoring software collects OEE per component code as well. This allows the business to estimate the machine time each component will consume:

$$ConsumedHours = \frac{D * CycleTime(s)}{3600 * OEE} \tag{3.5}$$

where D is the component's annual demand and the cycle time is the machine cycle rate for the given component in seconds per unit. The Sales & Operating Plan (S&OP) tool discussed in Chapter 3 utilizes this equation to estimate the machine hours utilized each month for all of Spencer Component's machines and is the foundation for the long-term feedback loop in Figure 3-1.

3.3 *Intouch*: Implementation and Results

3.3.1 Barriers Encountered during Implementation

Implementation of *Intouch* began mid 2014 and was completed at the end of 2016. According to several employees, implementation occurred in waves. When *Intouch* was first introduced to SCD, training was provided to all employees on the floor, including management. However, it is the opinion of the author that SCD relied too heavily on the knowledge base of the software provider and did not invest in building inhouse capabilities with the *Intouch* system. As technical problems arose they were dealt with slowly or not at all. One such example of this is the Visual Basic script that bridges the information from MES into *Intouch*. The script was not written until late 2016 when the author arrived on site because there was no apparent in-house capability to do so. In fact, only one employee was aware of the *Intouch* scheduling module, the same employee who was initially tasked with its implementation in 2014.

The cost of not investing more in the human factor was the root cause for the failure of the initial implementation in 2014. Every employee who interacts with the molding machines (e.g. operators, machine technicians, engineers) must have working knowledge of the *Intouch* system, and how their actions impact the reporting of the tool. The addage "*garbage in is garbage out*" describes the relationship between operator and system: if employees do not input accurate information into the system then its reports will not be useful. Employees were taught very well how to input data but not why they were doing it or how their inputs would affect the system as a whole.

Inaccurate reporting in *Intouch* has led many stakeholders to mistrust the information in its reports. Training the workforce how to use *Intouch* and making it part of the work content took longer than expected. Since training expectations were not managed properly, managers began using the tool while employees were still learning how to do it correctly. Error rate in data input was high and many of the reports displayed misleading data. Eventually management lost interest and refocused efforts on other initiatives. Operators, who saw that their efforts to use the system were wasted, abandoned their training and fell back on their previous knowledge of life before *Intouch*. Its implementation had become a failure.

The system has undergone several cycles of management focus and mistrust. Over time, employees adopted the attitude that *Intouch* was too inaccurate to trust. An example is a machine technician reviewing the *Intouch* machine status screen in Figure 3-4. One particular machine was marked down for an extended period of time. When asked about why the machine had been down, the technician stated the system was likely wrong and that the machine was running since there was no audible alarm. After further investigation the technicians discovered that the machine and its alarm were both inoperable. By not having full trust in the system, the technician did not respond to a signal that there was a problem. Many instances like this occur every day, and it will take time for the department to begin to place its trust in *Intouch's* data.

The issue of mistrust could have been avoided had enough resources been put in place to fully understand *Intouch* and give employees enough time to master it back in 2014. However, as often happens in AMT implementations, the human factor is not prioritized and the initiative fails.

Another implementation barrier SCD encountered was when it thought *Intouch* would simply replace the manual downtime tracking tasks one-for-one. SCD ignored the scheduling module in Intouch for the first 18 months after installation because the module seemed different than the magnetic board system used currently. Without the schedule module *Intouch* was not operating at its full promised potential, leading to low management satisfaction.

Changing the mindset of SCD to trust and embrace *Intouch* was no easy task. First the author needed to learn the system as well as possible to understand its true capabilities. As there were no instruction manuals or standard operating procedures, most working knowledge of the system came from trial and error and working closely with the software vendors. Actions like this should have been taken by Boston Scientific employees during the program's initial installation. Unfortunately, this trial and error learning period was likely overshadowed by other priorities that arose in the department.

After understanding the system, the task of changing the department's attitude began. All system stakeholders were interviewed about which capabilities they wish the system had. Nearly all requested capabilities such as easy visual identification of machine status, live machine scheduling, and reporting functions which were inherent to *Intouch*. When informed of *Intouch's* capabilities, many stakeholders were stunned and excited. Even though the system had been active for nearly 18 months its capabilities were still widely unknown. From that point the focus was persistent employee training and quick troubleshooting. As employees became more familiar with the system, the persistent issues slowly disappeared and data integrity became more reliable.

3.3.2 Results

Implementation and training of *Intouch* began in late July 2016, and reliable data and reporting wasn't available until mid-September. With the effectiveness of *Intouch's* reporting, new business insights could be discovered and communicated to department leadership. To demonstrate its effectiveness, reporting was completed on one of the department's most troublesome machines, N6. N6 runs 24/7 and is validated to run four component codes; component A consumes over 85% of the N6's run time. According to plant management the inventory of Component A had not reached its target safety stock level in over four years (remains on the 'hot list'). Component A was used in the Costa Rica assembly site, and Spencer was obligated to air ship (versus ocean ship) any component that was on the 'hot list' to Costa Rica. For four years Component A was air shipped rather than ocean shipped.

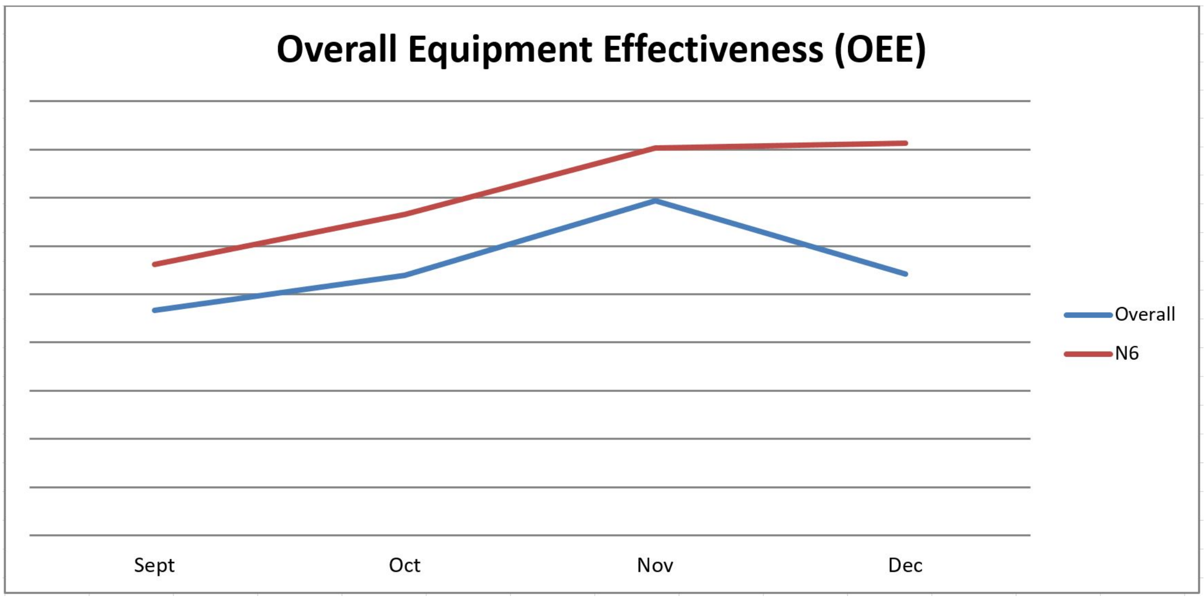

Figure 3-8: OEE performance of N6 compared to overall department

Historically, SCD used a static capacity file that assumes a world class 85% OEE on each machine as a guide for the site's theoretical capacity. According to the static capacity file machine N6 could easily handle demand for Component A manufacturing within a five day work week if it was run at an OEE of 85%. This was in complete contrast to what the manufacturing floor was experiencing, as it seemed impossible to ever achieve production targets. Because there was no live data to help pinpoint why the machine was not performing as theoretically expected, management assumed N6 was operating at an optimum level and began considering capital purchases and machine validations as a way to increase capacity on N6 to finally achieve target inventory levels.

It was at this time that *Intouch* was fully implemented and providing accurate data, and it was determined that N6 historically performed at an OEE of about 60%, far below the assumed world class standard of 85%. Using the system's downtime tracking two conclusions were evident: the machine was not staffed during break times, and there was tremendous variability of production output between operators. These are two items that, without a tracking tool, are difficult to perceive in the midst of a large manufacturing system. Production monitoring systems such as *Intouch* give visibility to individual machine performance that was not otherwise possible.

Management, seeing the data from *Intouch*, immediately focused on assigning the highly effective operators on N6 and ensured the machine was always staffed during breaks. The direct result is that machine performance improved to near world class efficiencies (Figure 3-8). Component A reached its safety stock value and fell off the 'hot list' for the first time in four years, and the additional capital and machine validation plans were canceled.

Boston Scientific has tools other than *Intouch* that could have been used to determine N6's improvement opportunity. The static capacity file used for many years was signaling to management there was a gap between actual production and theoretical capacity. Its manual downtime and production tracking system was showing a tremendous variation in output between operators. Yet no further investigation into N6's performance gap was performed. Perhaps Spencer's information system failed to trigger a management response because information was scattered across resources. With information inputs from machines, department scheduling, and operators, programs like *Intouch* place need-to-know information in one spot, resulting in a simplified decision making process for all stakeholders.

N6 is not the only machine that benefited from the implementation of *Intouch*. As seen in 3-8 the overall department performance also improved before falling again in December. It is important to note that not all machines experienced the same efficiency increase as N6; *Intouch* alone will not improve operations. N6 is a critical machine for

SCD and received a lot of attention as soon as *Intouch* was deemed reliable. It will take some time for the insights that *Intouch* offers on all machines to be utilized and turned into operational improvements

The implementation of *Intouch* has helped to alleviate some of the challenges discussed in Chapter 3. Primarily it has given the department a means to get live feedback on the department's performance and use it to continually improve. SCD has recognized the benefits provided by the use of *Intouch* and has hired a new full time employee to analyze its data and continue to leverage its capabilities. In the next chapter the information from *Intouch* will be used to facilitate lean manufacturing improvements by providing information used for continuous improvement.

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Chapter 4

Manufacturing System & Supply Chain Lean Improvements

4.1 Lean Manufacturing and Continuous Improvement

Lean Manufacturing is a methodology developed by the Toyota Motor Company that focuses on the elimination of *muda*, the Japanese word for "waste", in a manufacturing system[7]. Traditionally there are seven categories of waste:

1. Transport - Movement of goods and people
2. Inventory - Storing of components, finished goods, raw materials, etc.
3. Motion - Movement of employees: bending, rotating, turning, etc.
4. Waiting - Time waiting for materials
5. Over production - Producing more than what is demanded
6. Over processing - Putting more value into product than what the customer wants
7. Defects - Quality issues

Recently a new type of waste has been identified: Talent[1] - not fully utilizing the skills present in the workforce. Companies that embrace the concepts of lean manufacturing strive every day to eliminate these wastes. One of the keys to eliminating waste is the idea of continuous improvement. In order to remove waste in a system, it must first be identified through easily accessible and interpretable information. The *Intouch* automated monitoring system enables continuous improvement and the sustainability of lean initiatives.

During the duration of this research study several lean initiatives were implemented and tracked. These initiatives are in their infancy of implementation; however with *Intouch* SCD is in a position to drive these and many other initiatives to success. This chapter will review the implemented changes and comment on how *Intouch* is enabling their success.

4.2 Single Minute Exchange of Die (SMED)

4.2.1 Background

Single Minute Exchange of Die is a tool created by the Lean Production System at Toyota[6]. In the 1960's there was a need to have increased flexibility in Toyota's manufacturing process to accommodate consumers growing demand for unique features on their automobiles. One area of manufacturing that was not flexible was Toyota's sheet metal formers that produced body panels for their vehicle bodies. Changing the press from one panel to another would take an entire shift to complete and resulted in lost production time. Toyota decided this was unacceptable and systematically modified its presses and procedures so they could be changed in under ten minutes. This process, known as Single Minute Exchange of Die (SMED) is one of the many tools used in the Toyota Production System

[1] MIT LGO Lean Tools Class

Figure 4-1: 7 Step SMED Journey (Graphic from http://www.qualitydigest.com)

Today SMED can be applied to any process with non-valued added time, and mold changeovers on plastic injection molding machines are a perfect candidate. The goal of implementing SMED is to reduce machine downtime and work content for the department's machine technicians. SMED is characterized as a seven step process that is implemented through several continuous improvement cycles (Figure 4-1).

The first step in the SMED process is mapping the work content of a changeover and classifying each work step as either 'internal' or 'external'. An internal task is one that is required to be completed while the machine is down, such as removal of the old mold or the purging of resin from the machine barrel. A external task is one that can be completed before or after the machine is down. Examples of external tasks include finding and staging the incoming mold, collecting all tools, and executing paperwork. An example of a time study conducted at SCD is shown in Figure 4-2. Once the work steps have been classified the operation team must determine how to perform external activities either before or after the machine is taken down for its change.

The next step is to take tasks that are internal and convert them to external tasks. An example of this is installing a second feed hopper that can be filled with the next product's resin while the machine is running, eliminating the need to empty and refill

Station No.	Macro Step	Seq.	Work Element	Time in stop watch	Time Duration	Requir ed Step?	Int (1)/Ext(0)
Tech	Purge Water	1	Water purge on	0:00	0:29	1	1
Tech	Clean previous material from ho|	2	empty resin hopper	0:29	0:11	1	1
Tech	Clean previous material from ho|	3	fill bucket	0:40	0:25	1	1
Tech	Clean previous material from ho|	4	dump first bucket	1:05	0:19	1	1
Tech	Clean previous material from ho|	5	fill second bucket	1:24	0:21	1	1
Tech	Clean previous material from ho|	6	blow out resin hopper	1:45	0:15	1	1
Tech	Clean previous material from ho|	7	dump second bucket	2:00	0:22	1	1
Tech	Purge Water	8	turn purge water off	2:22	0:13	1	1
Tech	Uninstall water lines	9	unhook B1 water lines	2:35	0:14	1	1
Tech	Uninstall water lines	10	Cycle	2:49	0:06	1	1
Tech	Uninstall water lines	11	disengage magnet and manual removal	2:55	0:15	1	1
Tech	Uninstall water lines	12	unhook B2 water	3:10	0:13	1	1
Tech	Uninstall water lines	13	cycle	3:23	0:07	1	1
Tech	Uninstall water lines	14	unhook water b/w molds	3:30	0:13	1	1
Tech	Loosen Clamps	15	Loosen and remove B1 bolts	3:43	0:36	1	1
Tech	Loosen Clamps	16	Loosen and remove B2 bolts	4:19	0:41	1	1
Tech	Misc	17	Move finished product cart out of way	5:00	0:10	1	0
Tech	Misc	18	Move tools from cart to table	5:10	0:05	1	0

Figure 4-2: Example of SMED time study conducted at SCD

the feed hopper during a changeover. By continuously externalizing tasks the goal of eliminating the changeover altogether can eventually be achieved. SCD is beginning this journey, and this section discusses the issues faced and how *Intouch* helps move SMED forward.

4.2.2 Description of Machine Changeover at SCD

The following is a high level overview of a mold changeover on an injection molding machine. The goal of a changeover is to transition a machine that is making component A and replacing molds and adjusting machine settings until the machine is producing component B. A changeover starts when the molding machine is shut down and ends when the machine is producing component B at acceptable quality. At SCD, changeovers are performed by machine technicians who have extensive tacit knowledge of the department's molds and machines. Technicians not only perform changeovers but also help troubleshoot when there are quality issues. They are not staffed evenly across the manufacturing shifts; on day shift there are as many as four technicians, on evenings two, and nights and weekends only one. The production planner plans most changeovers to occur during the day when the most technicians are available, however multiple changeovers inevitably occur during the night shift due to unforeseen material shortages or machine/mold breakdowns.

Machine work orders are for specific component quantities, and once the target quantity is reached, the changeover begins. Therefore they are not scheduled to occur at specific times because their timing depends on machine performance. The technician team must rely on estimates for when changeovers will occur. Because this is difficult to do, machine technicians are often notified of a changeover when the machine has already finished its work order. There are two employees, the Inspection Process (IP) Operator and the Machine Technician, who are active during a changeover, though more can be deployed to decrease downtime. The technician will purge the machine of all remaining resin A from the barrel and feed hopper. Next the cooling water to the mold will be turned off and drained, followed by the removal of water and pressurized hydraulic hoses from the mold. An overhead crane is positioned over the mold and attached to it while the compression clamps that secure the mold to the machine are manually removed. The new mold is placed in the machine and secured. Water lines and pressurized hydraulic hoses are reinstalled from the technician's memory, and new resin is placed into the incoming hopper. Once the feed hopper is full of resin B, the technician will refer to the run procedure to identify the validated machine settings. When the machine is started and making acceptable product, the changeover is considered complete.

While the technician completes the tasks above, the IP operator is busy completing the requirements of BSC's quality inspection procedure. The IP operator's tasks take less time than the technician's on automatic molders, yet often the IP operator is the bottleneck for changeovers on the manual molding machines. Inspection data from the IP operator is logged into BSC's manufacturing system, MES, for financial and quality tracking. It is important to note that IP inspections take place between all batches. Often multiple batches of the same component will be run consecutively. When a batch is completed, the IP operator will stop production, complete the inspection, and start a new batch with no mold change.

4.2.3 Current State

The first step in the SMED process is the separation of internal and external tasks. In order to accomplish this, the changeover process must be understood. As historical changeover data was not available, time studies were conducted to not only understand the average duration of a changeover but also its required steps. The studies were conducted on the most heavily utilized machines, as a reduction in their changeover time would be the most beneficial to the department.

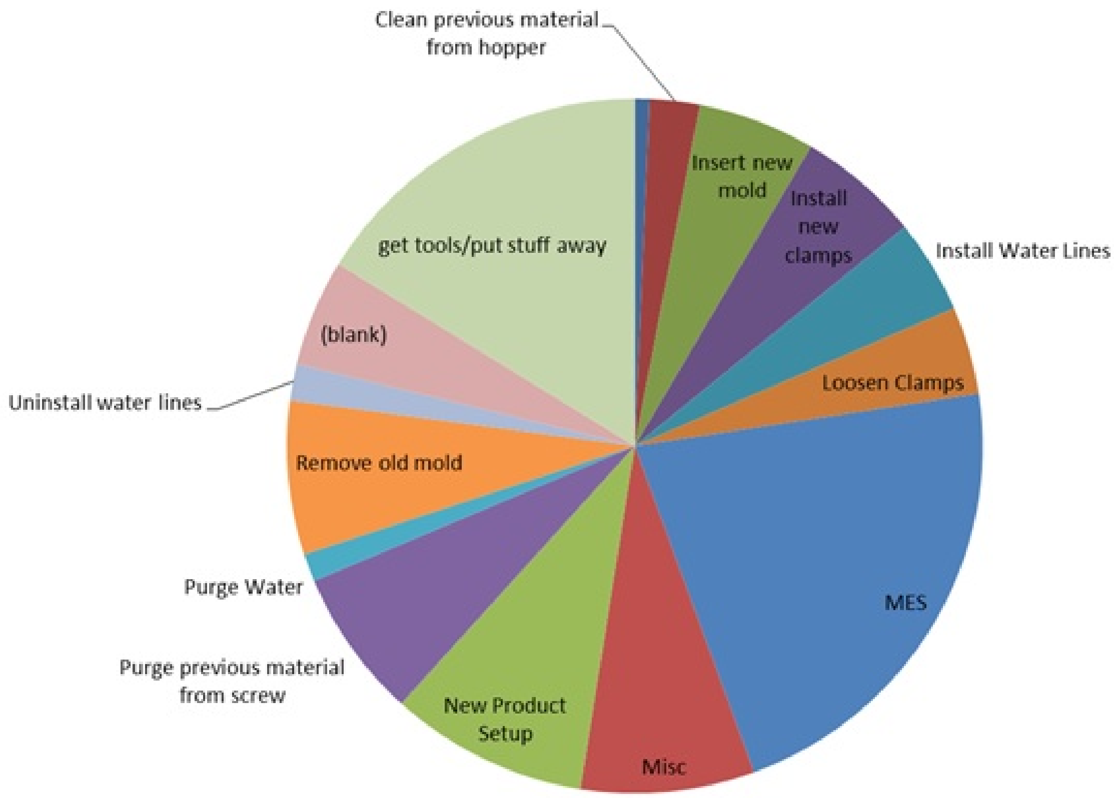


Figure 4-3: Tasks Completed during Changeover

The data from the time studies was analyzed to determine the internal and external tasks present in the current work stream. Figure 4-3 is an example of a typical changeover on a manual molding machine. Over 80 individual work steps were identified for this particular changeover. These tasks were grouped by types of tasks to create the pie chart. Overall 12 changeovers were observed during this phase of SMED.

There are several points of interest in Figure 4-3. The first is the large portion of time devoted to getting/storing tools and miscellaneous activities for the changeover. As these activities provide no value to downstream processes or directly facilitate the changeover, they are prime candidates to be externalized. Another observation is the large amount of time spent performing quality inspections (MES). While MES activities are required by Boston Scientific's quality system, there seems to be a clear opportunity to reduce the amount of time these activities consume.

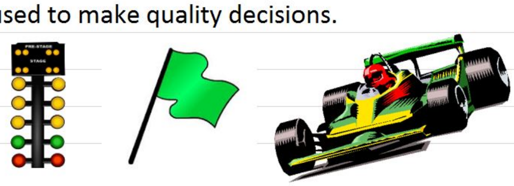
4.2.4 Analysis & Implementation

The time studies uncovered three main opportunities for improvement: preparation of tools and molds prior to the change, communication between operators and technicians when a machine could be shut down, and faster completion of IP tasks (MES). Many of these issues can be seen in Figure 4-3. In working with the department's technicians and leadership team it was discovered that several previous SMED attempts had been started yet failed to move past the analysis phase. Due to these failed attempts, some of the machine technicians came up with the phrase "SMED is dead." It appeared to the author that the previous attempts were abandoned before implementation due to job changes and lack of enthusiasm from employees at all levels. The lack of enthusiasm seemed to stem from the fact that no systems had been put in place to monitor changeover times, thus previous SMED initiatives lost buy-in because progress wasn't tracked.

According to the time studies, about 10-15% of any given changeover was spent finding tools and molds for the changeover. These are external tasks and should be completed before the machine is shut down. In an attempt to ensure each technician was prepared for their changeover, laminated reference cards were created and distributed (See Figure 4-4). The purpose of the card is to help the technician ensure all tools and resources were available and staged before the machine was stopped for the changeover. In addition, a "CYA" List was provided for review to ensure all critical tasks had been completed prior to the machine being restarted.

CYA List
Part(s) look cosmetically correct
Line clearance completed correctly
Mold correct
Inserts correct
Machine parameters match setup sheet
Required tooling at station and working
Water 'on' at wall, thermolator, and manifold
Thermolator on and at correct temperature
Mold watered correctly
Ejector back switch plugged in (if req'd)
Correct Robot program & EOAT (if req'd)
Conveyor setup correctly (if req'd)
Core pack plugged in (if req'd)
Colortronics program correct (if req'd)
Purge bed clear of resin pellets, clamps
eDART on with proper program
InTouch on and proper job pulled

* This document is used as a business tool. It is not used to make quality decisions.



Molder 'Pit-Stop' Checklist
BEFORE SET-UP (to be ready)
Get set-up sheet for new mold
Resin pre-dried
Bring empty mold cart
Bring new mold on different mold cart
Bring Crane close to molding machine
Asaclean and/or -22 cleaner
Water purge container (Check water level)
Torque or Allen Wrenches for mold
Mold Spray Lubricant and Towels
Water hose cart
Air blowoff nozzle
Step Ladder (if req'd)
Clamps
Lift rings
Tags for the mold
Air/hydraulic hoses & extra towels if needed
Pinchoff and inserts (if req'd)
Ejector bars (if req'd)
Core pack (if req'd)
Hot runner controller & cables (if req'd)

* This document is used as a business tool. It is not used to make quality decisions.

Figure 4-4: Changeover Checklist

The checklist did not gain traction with the technicians and was quickly cast aside. Many of the technicians felt the card was a great tool for newer employees, but not experts. Therefore a different solution was required.

Previous SMED attempts had studied the benefits of proper staging of tools and molds and had determined a suitable solution was to replace the technician's individual toolboxes with a standardized set of tools in a SMED toolbox. In the current system, two technicians shared one mobile tool cart and were responsible for determining its contents. As a result, there was dramatic variation in the number, type, and quality of tool in each of the technician's carts. Time studies revealed little to no organization was present in the tool drawers, causing technicians to spend time searching for tools within their drawers. Many technicians had best practices for the use of their tools that were not shared with others.

Figure 4-5: SMED Toolbox Solution Prototype

In the new SMED toolboxes, cut-foam inserts were used to allow easy tool identification and eliminate time wasted searching for tools. Since there was no master list of required tools and often technicians were forced to scavenge for needed tools in other boxes, generating a list of standard tools for the new box was difficult. Soliciting the technicians' help also presented challenges as they felt the SMED initiative was doomed to fail like the previous attempts.

Initially only a few technicians were willing to experiment with the idea of an organized toolbox. With an in-depth knowledge of each machine and mold in the room, and despite the complex product mix of the department they perform changeovers correctly at a very high rate. Rightfully there is a lot of pride in the tacit knowledge they've built during their tenure in the department. One of the most difficult aspects of implementing SMED is talking with all nine technicians and receiving nine different opinions on the correct path to pursue. Because each opinion is based on years of self-taught knowledge, choosing to follow one path over another can lead to hard feelings and increased reluctance to change. This is exacerbated if the path is chosen by an employee with little to no hands-on experience in the matter, such as an MIT graduate student.

With the help of a day shift technician who was passionate about the SMED movement, a prototype SMED toolbox (Figure 4-5) was created. Once he built and tested it, the box was shared with the rest of the technicians, who provided feedback and ideas for improvements. Initially, each technician was reluctant to use the box and tried to ignore its presence. However once the box was used the feedback was positive. A second SMED box was created and placed on the floor, with more planned.

The SMED box externalizes the task of locating tooling for a changeover; the next step was to have the mold, crane, and raw resin properly staged next to the machine prior to the changeover. In order to plan this next phase, the team started a daily technician meeting to review the day's anticipated needs from the technicians. The supervisor, lead operator, all technicians, and engineers attended to plan out the days activities. In this meeting a new communication procedure was created for changeovers: machine operators would notify technicians 30 minutes prior to their machine needing a changeover, allowing the technician time to properly stage his or her toolbox, crane, and mold prior to the machine going down.

The last SMED opportunity was to decrease the time for IP operators to complete their inspections. For certain components, the inspection portion of the changeover took longer than the physical mold change, and between batch changes IP tasks delayed production. Because most IP inspections were proceduralized in Boston Scientific's Quality System, they could not be changed easily. During the newly established technician meeting it was determined that the best way to quicken inspections without altering BSC's inspection plan was have multiple operators complete the inspections in parallel. For some products the inspections could take over an hour for one operator, and a second operator would reduce the time to 30 minutes.

4.2.5 Results

These three solutions - SMED box, 30-minute changeover notification, and IP inspection labor - were implemented throughout September and October 2016. Using data collected with *Intouch*, changeover durations for two of the departments most heavily loaded machines were tracked. The results are shown in Figure 4-6.

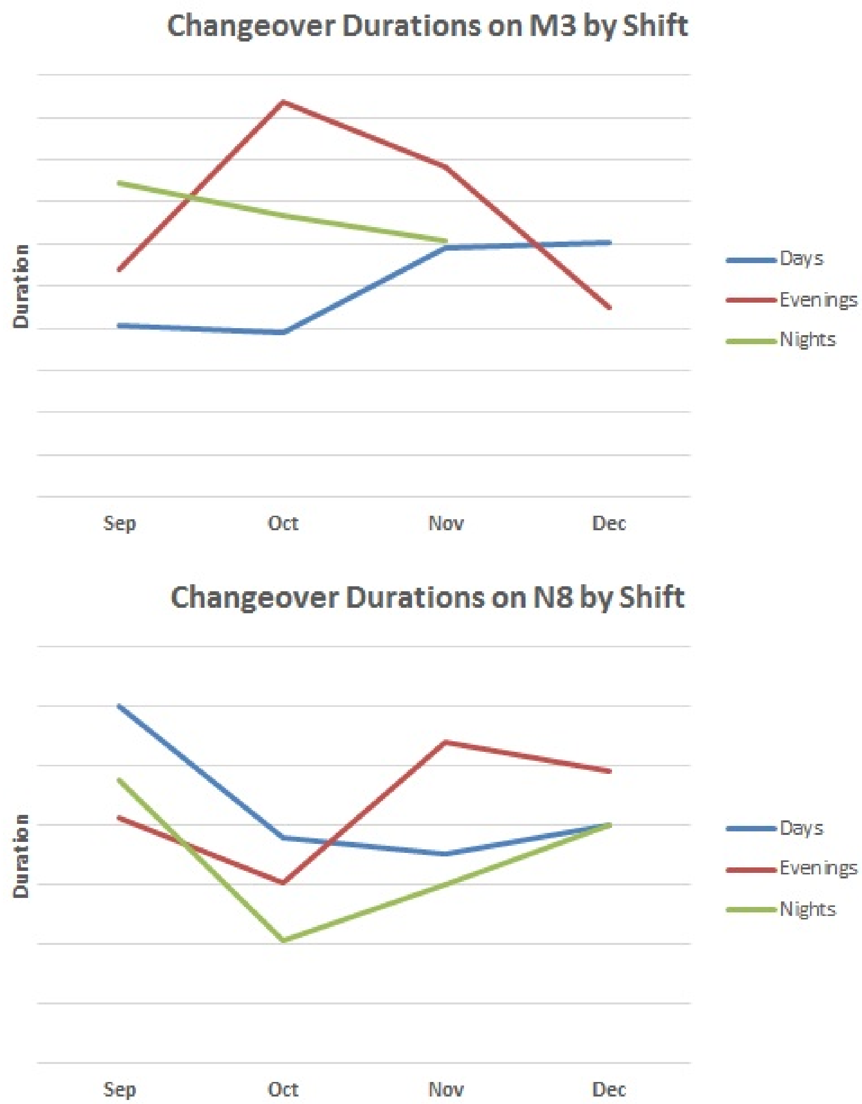


Figure 4-6: Changeover Duration Trending by Shift

The results do not show a clear decrease in changeover time. For M3 there appears to be a negative impact on changeover times, while for N8 there was an immediate benefit followed by rebound. While the expected impact was not realized, there appeared to be an explanation. During the duration of the study, two of the department's technicians left in early October and were not replaced until late December. This resulted in the evening and night shift only having one technician, which likely contributed to the longer changeovers seen in November and December.

Because changeover times were reported on a weekly basis, operators, technicians, and management had a renewed sense of urgency. Changeover times may not have improved, and now management wanted to know why. The previous day's changeovers were reviewed during the daily technician meeting, and corrective actions were put in place to fix any issues that had occurred. The SMED toolboxes have helped train the replacement technicians; whereas before technicians would need to assemble their own tool boxes and learn what tools were required, the SMED box has all required tools and allows trainees to focus on learning how to perform their job.

SCD will have its set of challenges during its SMED journey. Technician turnover, fluctuating customer demand, and new product launches will all draw focus away from SMED. With *Intouch* SCD has progressed further along the SMED journey than ever before. It is likely that without *Intouch*, just like the previous SMED efforts, the department would have lost focus and SMED would in fact be dead.

4.3 Lot Sizing

4.3.1 Re-order Point

SCD serves many customers, and rather than rely on individual production planners to place orders for individual components, a reorder point system is used to streamline the supply chain. Reorder point is a process suppliers use to systematically trigger when products must be manufactured to ensure customer satisfaction. The basic principle in the reorder point system is that a build signal is created when inventory of a specific component falls below the reorder point R. With a build signal the manufacturer will schedule time on a machine to build the product.

At SCD, the reorder point for a given component, R, is the midpoint between the minimum and maximum inventory levels as calculated below:

$$Qmin = ADD(T + tt) + Qsafety \tag{4.1}$$

$$Qmax = ADD(r + T + tt) + Qsafety + L \tag{4.2}$$

$$Qreorder = Average(Qmin, Qmax) \tag{4.3}$$

where ADD is the average daily demand, or $ADD = D/260$, with D equal to the annual demand and 260 the number of weekdays per year. Note that ADD is an average value and does not consider cyclical or stochastic demand signals. L is the manufacturing lot size, T is the manufacturing lead time, tt is the transit lead time, and r is the review period. $Qsafety$, defined as the safety stock inventory, is designed to ensure variations in demand do not deplete inventory. For most components the safety stock is defined using the standard square root law[2]:

$$Qsafety = z\sigma\sqrt{r + T} \tag{4.4}$$

where z is the service level, σ is the standard deviation of the demand, r is the review period, and T is the lead time.

SCD divides its components into three categories based on annual demand: A, B, and C. A codes are high runners with an ADD of 750 units or greater. C codes are low runners with ADD less than 100. B codes are medium runners with ADD between A and C codes. The category dictates the production lot size for each component:

$$L = \begin{cases} \text{Cat A} = & 10ADD \\ \text{Cat B} = & 30ADD \\ \text{Cat C} = & 60ADD \end{cases}$$

In the current system, the ADD of a component is the sole dictator of its manufactur-

[2]Willems, Sean, Analytical Consulting Methods to Solve Supply Chain Problems, 15.762 Supply Chain Planning, MIT Sloan

ing lot size; its unit cost or holding cost is not a factor. This method leads to suboptimal inventory targets and manufacturing lot sizes.

Consider the following example. Component A is a category A component with high demand, and it is also very inexpensive to manufacture. Its manufacturing lot size is equivalent to 10 days of demand; in other words, Component A will be manufactured every ten business days, or 26 times per year. Every time Component A is manufactured, its machine must undergo a 90 minute changeover. Over the course of the year the machine will be down 2,340 minutes (39 hours) for the changeovers. If Component A is on a highly utilized machine, the downtime caused by its changeovers could cause supply shortages. Since Component A is inexpensive to make, its lot size does not have a high inventory value, so it likely makes financial sense to manufacture Component A in larger production runs to reduce machine downtime at the cost of increased inventory holding costs. A different method, Economic Order Quantity (EOQ), alleviates the downside to the current inventory strategy and is considered in the next section.

4.3.2 Economic Order Quantity: Theory

Economic Order Quantity (EOQ) is an idealized tool that optimizes the trade-off between setup tasks and inventory holding costs; its purpose is to find the optimum solution based on the example in the previous section with Component A. The equation is as follows:

$$Q* = \sqrt{\frac{2Dk}{h}} \tag{4.5}$$

where D is the annual demand for a given component. k, the setup cost, is the cost for an incremental machine setup, and h is the inventory holding cost for one unit of a given component. For SCD, the setup cost k occurs when the machine is changed over from one component to the next. Factors such as direct labor rate, cost of lost production, and downtime on other machines due to a machine technician being tied to the changing machine must be considered when determining a value for k. The risks of an incorrect setup or mold damage must also be considered and included in the setup cost. At most the setup cost is equal to the sum of the labor and overhead rate, and at the very least it is only the direct labor rate.

For a given setup cost, EOQ drives a manufacturer to produce larger lot sizes of inexpensive products and smaller lots for those more costly. Lot size is inversely related to quantity of machine changeovers; the larger the lot size, the fewer changeovers are required through the year, resulting in less work content from technicians and machine downtime. For a high mix low volume facility that already has a large number of changeovers, adjusting lot sizes to have fewer changeovers can be an operational advantage.

It must be noted that the EOQ method is a very idealized equation and can sometimes recommend infeasible options. However, it provides guidance for all manufacturing systems on whether or not its lot sizes are close to ideal or way off. The results from this equation are used to move SCD to a more optimum inventory strategy.

4.3.3 EOQ: SCD Analysis

The EOQ equation is based entirely on two cost parameters: setup and holding costs. These quantities are usually not explicitly known and must be estimated. Boston Scientific has an estimate of its holding cost for Spencer, and that value was plugged into the EOQ equation. Estimating the setup costs was more difficult. Some managers believed the setup cost should be equal to the summation of the overhead and direct labor rate of the machine, while others stipulated only the direct labor rate should be used.

Ultimately, a conservative estimate for the setup cost was used: it was set equal to the direct labor rate plus a small amount to account for raw material waste, damage risk, and any overtime required for the additional changeover downtime. Once annual demands and unit costs for each component were determined, the EOQ tool could be applied to each component to calculate a new manufacturing lot size.

EOQ is a idealized equation, and as such some of the newly calculated lot sizes were infeasible. Very inexpensive components yielded lot sizes that equaled multiple years worth of inventory. In order to hold the new lot sizes to a reasonable value, lot sizes were capped at a years worth of inventory, no lot could hold a value greater than a specified value, and no work order could take longer than a week to complete. As a result, the new EOQ lot sizes became feasible and practical.

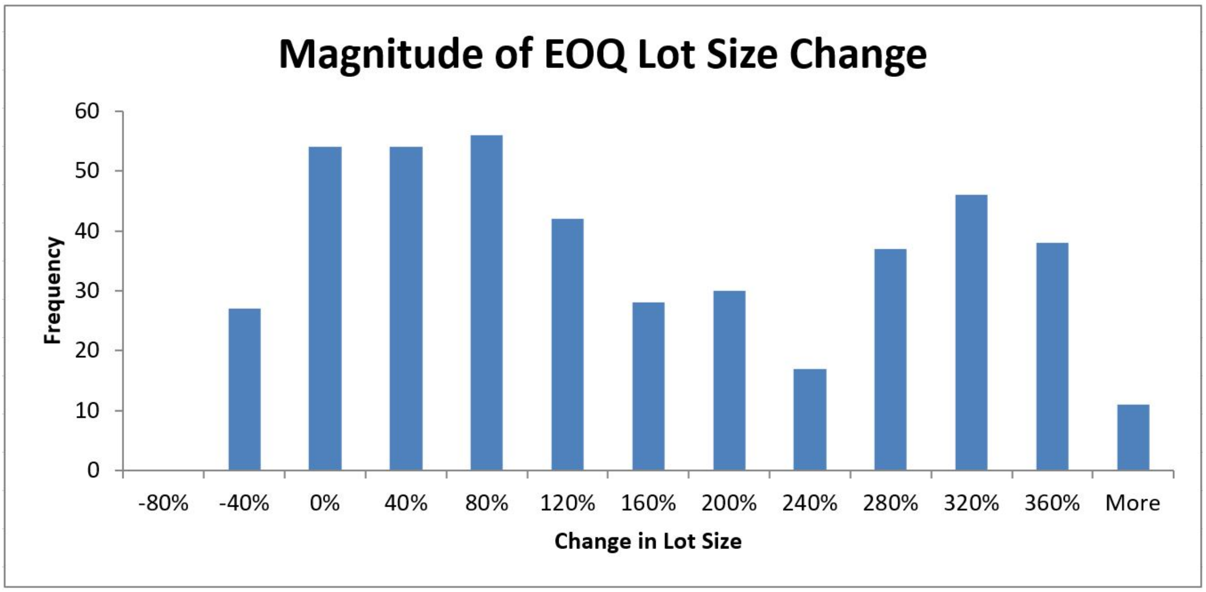


Figure 4-7: Distribution of difference between current lot size and Economic Order Quantity lot size in SCD

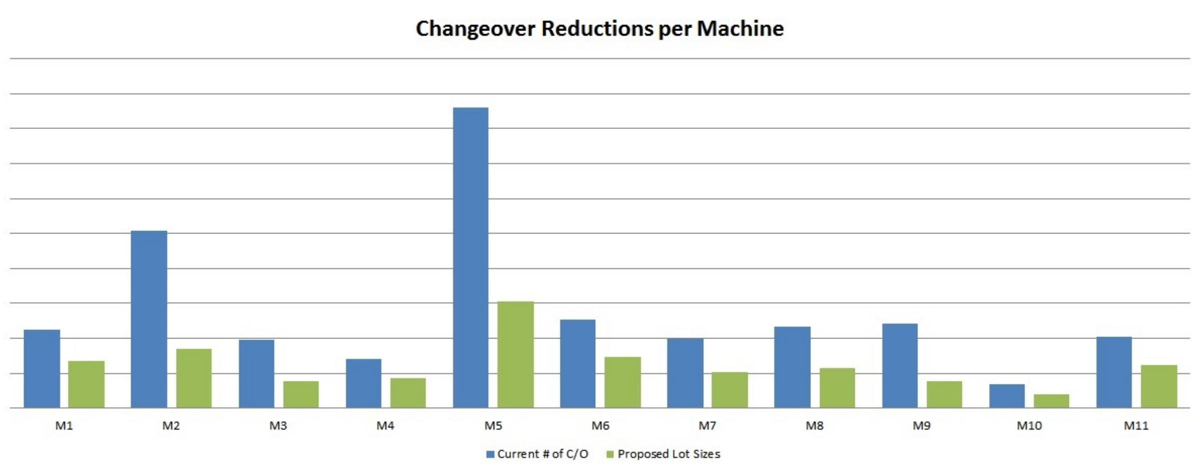


Figure 4-8: Theoretical Changeover Reduction per machine under EOQ Using a Conservative Setup Cost

Figure 4-7 shows that the vast majority of Spencer Component's products should have larger lot sizes than what the current system dictates. Those that show a decrease in lot sizes are the components with the highest unit cost, and thus the highest inventory holding cost. Note that a larger manufacturing lot size necessarily means a reduction in annual changeovers for that particular product. Figure 4-8 shows the changeover reductions of certain machines with EOQ lot sizes.

4.3.4 EOQ: Challenges to Implementation

The machines that benefited the most from the new EOQ lot sizes were automatic molding machines with inexpensive components and the plastic extruders with long changeover times. Implementation of EOQ would be the easiest on these machines because every component code would have an increased lot size.

Implementation of EOQ at the Spencer Facility was unsuccessful. A big problem was uncovered when determining where to physically store the increased inventory. The warehouse at the Spencer facility is fully utilized, and current off-site storage results in complicated component logistics. Site leadership determined that EOQ for components destined for Spencer would not be possible until additional warehouse space was built.

For the components SCD provides to Costa Rica Assembly there was a solution. The Costa Rican warehouse has open capacity, which makes the larger economic lot sizes feasible to produce. This is especially appealing to SCD, which has historically air-shipped (versus ocean-shipped) many manufacturing lots due to poor component availability. Larger manufacturing lot sizes for Costa Rican components will lead to higher inventory at Costa Rica, which results in a higher service level and allows SCD to ocean-ship more. The financial benefit of ocean-shipping versus air-shipping exceeds the reduced setup costs of the EOQ lot sizes.

However, a challenge emerged when the idea was proposed to the Costa Rican team: Boston Scientific's metric structure heavily incentivizes inventory value reduction. While increasing inventory levels for these components results in savings for Boston Scientific, the Costa Rica site itself would only see increased inventory levels, and this would reflect negatively in their site metrics. At first the Costa Rican team was reluctant to accept any additional inventory. SCD stressed the benefit of higher component availability, yet this did not seem to outweigh the Costa Rica team's fear of the increased inventory value. Because the components with very low unit cost were those that experienced the largest increase in manufacturing lot size, the total value of the additional inventory amounted to less than 5% of their current inventory. After realizing the additional inventory burden was small, the Costa Rican team finally decided the overall benefits to Boston Scientific outweighed the inventory issue.

4.3.5 Future Steps

EOQ lot sizing was only considered at SCD, yet its potential to improve inventory levels across the company is substantial. At first glance EOQ lot sizing appears to be in direct opposition to Boston Scientific's goal of reducing inventory. While this is correct at SCD, implementation of EOQ across all business units would lead to a better inventory policy. One of the seven wastes in Lean manufacturing is inventory, yet not all inventory is a waste. For SCD, it is more wasteful to manufacture smaller batches than larger batches for many of their components. In addition, the components SCD produces rarely become obsolete, and demand for medical devices is steady. Therefore, holding inventory presents little risk for Boston Scientific.

The research study concluded prior to the full implementation of EOQ to Costa Rica, and as such there is limited information on how *Intouch* has helped facilitate the continuous improvement of the EOQ project. The implementation of EOQ is a one-time event that causes a step change in the number of changeovers that occur. One of the ways *Intouch* can help monitor the success of EOQ is by merely recording the number of minutes each machine spends in a changeover state. Total scheduled machine downtime will decrease as more components' lot sizes are increased, and management will have immediate feedback regarding the benefits of the project.

4.4 Sales and Operating Plan (S&OP)

4.4.1 Theory & Current Use

In most organizations, Sales and Operations do not have many opportunities to communicate. The salespeople sell, and the operations team produces product. One method that many companies use for the two groups to communicate is through a Sales and Operating plan (S&OP). An S&OP takes the committed sales from the Sales team and gives them to the Operations team to schedule each item's production. With the sales numbers, each manufacturing site will allocate its resources and commit to a manufacturing plan. This plan is then shared with the Sales team to ensure it will satisfy customer expectations. An S&OP can be considered a lean tool because it helps prevent over- and under-production, and generally leads to a level loaded manufacturing plan.

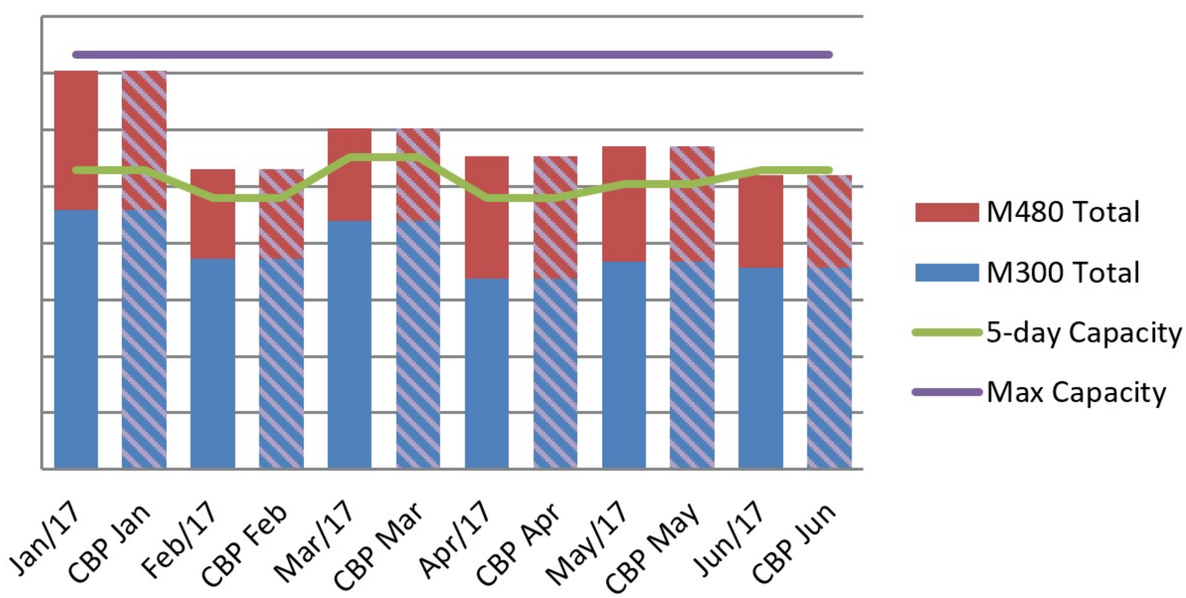


Figure 4-9: S&OP chart for a typical molder. The solid columns are the demand forecast from BSC Sales, and the striped columns are the committed build quantities from SCD. Currently the department is showing commitment to build (CBP) according to monthly demand. M480 and M300 represent two of Spencer Component's customers.

Boston Scientific utilizes a Sales and Operating Plan system for its production planning in finished goods assembly. Every month each production line looks at its demand forecast for the next six months and creates a committed build plan (CBP) that is a contract telling the BSC Sales what it will build. Due to the labor intensive nature of the finished assembly process, all production lines need to be level loaded to fit into the site's shift structure (8-hour shifts with overtime).

The CBP is a handshake between Finished Assembly and Sales that affirms the manufacturing plan for the business. This process does not exist for SCD, and its absence has caused supply issues for Boston Scientific. An S&OP process would not be required if demand was stable, and there were no supplier interruptions. However, machine breakdowns, supplier shortages, and competitor recalls occur and demand a response that is outside of BSC's demand forecast. Without a formal communication between Sales and Operations these anomalies can go unnoticed and cause component shortages for finished assembly.

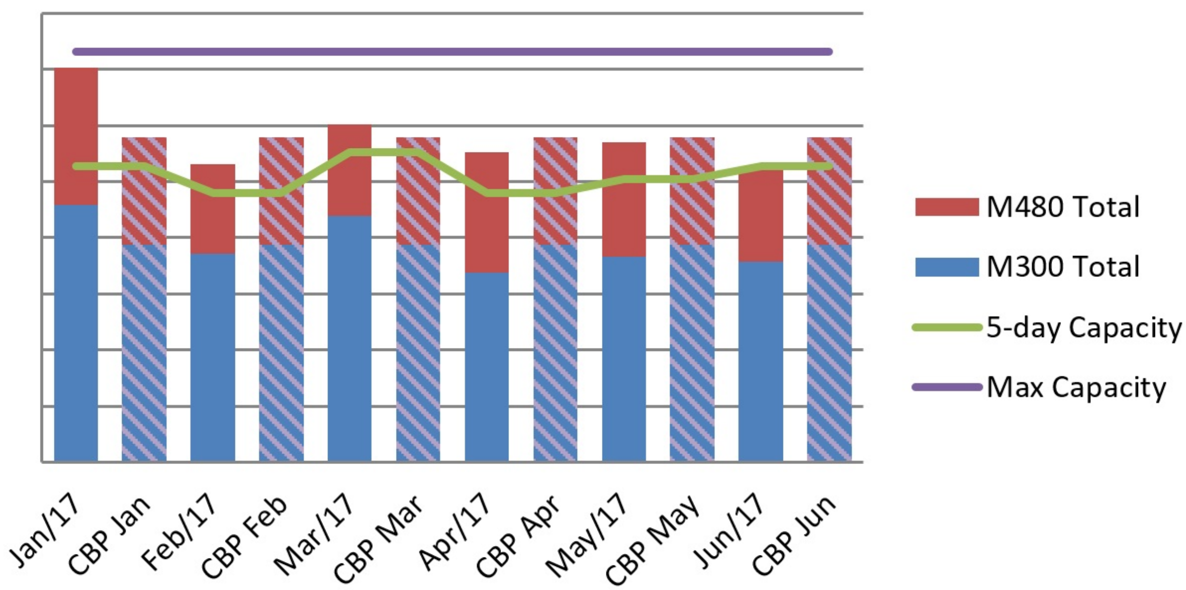


Figure 4-10: Level Loaded Manufacturing Plan

SCD's largest off-site customer, Costa Rica Assembly, is the major reason the S&OP tool was needed since communication between the Spencer and Costa Rica sites was sparse. The need for S&OP in Spencer is less because SCD and the planning teams reside in the same building. Many informal conversations regarding supply concerns spontaneously occur in order to get ahead of any production shortages. These spontaneous communications do not occur with Costa Rica, and this was seemingly the case because Costa Rica assembly was a new facility that was now manufacturing many of the products that Spencer Assembly used to make. This appeared to create tension between the two sites, resulting in strained communication if any occured.

SCD relied on the 'hot list' to signal component shortages for both Spencer Assembly and Costa Rica. The major downside to the 'hot list' is the fact that it only signals component shortages for the following week. This is not as large of a problem for Spencer Assembly because components can be delivered immediately at the end of a production run. Components destined for Costa Rica, on the other hand, must be shipped by either boat or air. Any item that appears on the 'hot list' must be sent via air in order to be available for Costa Rica in time for production. The S&OP tool helps alleviate this issue because it gives both sides the ability to look into the future and agree on what needs to be produced and when.

4.4.2 New Tool: Implementation & Result

In order to provide a method of communication between the production planning department, SCD, and Costa Rica Assembly, an S&OP tool was created. The tool combines the Overall Equipment Effectiveness (OEE) values from *Intouch* and Boston Scientific's demand forecast to predict the capacity utilization of each machine and whether or not it can meet demand.

With forecasted monthly machine hours SCD can communicate to the planning team what it is capable of completing. As an example, Figure 4-9 shows a high demand in Month 1. The machine must run a near 24/7 schedule in order to make demand. In addition to the overtime labor required, any maintenance or raw material supply issue puts the committed production plan at risk. To avoid these risks, the management team will propose to level load the demand on the machine and communicate this plan to the sales and planning teams as shown in Figure 4-10. They will then evaluate whether or not the proposed plan is feasible, or if SCD must in fact run its machine 24/7 in the first month.

The S&OP tool was created to solve a major trust issue between SCD and Costa Rica assembly, and to an extent it achieved this goal. Discussions about supply issues transitioned from what was needed for the following week to what was needed for the following month, and each side had clearer expectations for production.

A side benefit that turned out to be the tool's greatest impact is the understanding it gives to the SCD operations team regarding how loaded each machine will be each month. As mentioned in Chapter 3, one of the greatest impacts of *Intouch* was the increase in performance for N6, such that it reached its production targets for the first time in four years. This success was predicted using a preliminary version of the S&OP tool along with data collected by *Intouch* to demonstrate that a higher OEE for N6 would easily allow it to reach target production. With the S&OP tool, SCD now has clear visibility into upcoming supply issues and can predict the impact of poor machine performance on its committed build plans.

4.5 Implementation of Lean at SCD

The successes of the S&OP tool along with the progress of both SMED and EOQ are demonstrations of how simple technology such as *Intouch* can strongly impact a business if it is implemented correctly. The new potential created by easily accessible data is necessary if SCD is striving to become a fully utilized world class asset to Boston Scientific. These lean initiatives along with the implementation of *Intouch* are only the beginning for SCD's journey of improvement. As SCD incorporates more of *Intouch's* capabilities into its everyday processes the department will continue to improve and innovate its manufacturing processes.

Chapter 5

Conclusion & Future Work

5.1 Spencer Component's Journey to World Class

At the beginning of this research study SCD was a plastic components manufacturer with a wide array of capabilities that was hindered by many challenges. In addition to being a high mix low volume facility, it was responding to business metrics that did not fit the department's business model. Several initiatives such as SMED and *Intouch* had been started yet fizzled out as the department rushed to complete the next component on the 'hot list'. Boston Scientific, recognizing that its assets at SCD were not optimally utilized, sought to find a path toward making the department a world class manufacturer.

Many would agree that lean manufacturing is a clear way to become a world class manufacturer, and one of the core concepts about lean is the idea of continuous improvement. By many objective accounts SCD did not have a robust tool to track production performance to the level needed to facilitate continuous improvement. The successful implementation of *Intouch* was an important first step in Spencer Component's journey. Not only has it led to a step function improvement in one of the department's most critical pieces of machinery, but it has laid the groundwork for the department's lean manufacturing initiatives to be monitored and continuously improved.

Projects like SMED, which had been abandoned, were revitalized, tracked, and continually tweaked to improve performance. They target SCD's challenges with its high mix low volume product mix, high overhead, adherence to the Core 5 metrics, and on time delivery to customers. The creation of an S&OP tool created visibility into the department's ability to meet customer demand on time. SCD is headed in the right direction to achieve its world class aspirations.

5.2 Future Work

SCD is now a manufacturer that has the tools to continue on its journey to world class manufacturing, but that journey is far from complete. There still exist many of the challenges described in Chapter 2 that *Intouch* and the lean initiatives have only begun to address. Below are a few of the next steps the author sees as SCD's highest priorities.

5.2.1 Determine Long Term Strategy

As mentioned in Chapter 2, SCD does not have a long term strategy behind what product mix it wants to have or how it fits into Boston Scientific's Component Supply Chain. The department is merely maintaining the status quo and in-sourcing random components here or there. Given that Boston Scientific is consolidating many of its plastic components supplier there is a tremendous opportunity for SCD to in-source new products and change its product mix into whatever it needs.

The department's strategy decision cannot be made by SCD alone. Multiple business groups from Planning, Global Sourcing, and Operations need to meet and determine the role the department will serve in the Boston Scientific's supply chain. Once this strategy is set, SCD can then focus on the operational improvements required to be successful. This task should be of utmost importance to the department's management.

5.2.2 Focus on Human Factor

One of the barriers to AMT implementation that revealed itself repeatedly in SCD is its inability to prioritize and develop the capabilities of its workforce. This was most prominently noticed during the re-implementation of *Intouch*, but there were several indications elsewhere of its presence. Given the future of injection molding likely involves more automation and newer technology, it is in SCD's best interest to determine the means for it to successfully roll out new technology.

Boston Scientific needs to allocate resources to facilitate employee's education during AMT introductions. These resources include funding for classes and time for employees to test what they've learned on running equipment. As seen with *Intouch's* initial failed implementation, it will likely require more resources than expected to build the workforce capability, yet it's an investment that is paramount to any new technology's success.

5.2.3 Manage Department Using New Metrics

Boston Scientific is unified in its approach to manufacturing through the use of the Nine Panel and Core 5 metric system. Their purpose is to compare production line performance across different product lines and manufacturing locations. The issue with this, as described previously, is that departments such as SCD, which rely less on manual labor and more on automated machinery, are treated the same as a finished production line that is primarily a manual operation.

The implementation of *Intouch* showed that the Overall Equipment Effectiveness (OEE) of a machine is a much better indicator of its performance than the Net Labor Efficiency (NLE) of the department, yet OEE is not found on any Core 5 board in Boston Scientific. On-time delivery is another vitally important metric to Spencer Component's customers but is absent as well. Shifting away from the classic Core 5 metrics to those more appropriate such as on-time delivery and OEE will help the department become a better supplier and better asset to Boston Scientific.

5.3 Conclusion

The Spencer Components Department at Boston Scientific has benefited immensely from the successful implementation of *Intouch*, a production monitoring system that can be considered new technology. This technology has given the department the ability to significantly improve individual machine performance by aggregating and reporting of manufacturing data. In addition to immediate performance improvement, *Intouch* also provides a convenient means to monitor operational improvements such as SMED or EOQ and facilitates the department's ability to engage in continuous improvement.

The foundation of a world class organization has been laid, but there are still many changes and improvements the department must make to optimally utilize its assets. This document has shown that having systems that aggregate and provide useful arrangements of data allow a manufacturing system to perform better and management to make well-informed decisions regarding where to focus resources. In many cases, including SCD, the tools needed to get this data were already available; however due to poor implementation, execution, or other reasons they were forsaken for more immediate concerns. Mishandling of AMT implementation can be avoided through proper preparation and patience while the business adjusts to its new tool.

New technologies often offer more capabilities than the process they are replacing, but they are not always recognized immediately. When new capabilities are utilized it allows the business to accomplish things that have failed in the past. SCD has been able to make great progress on its SMED and S&OP initiatives than ever before with *Intouch*, and there are plenty of other improvements it can make now that it is leveraging *Intouch's* capabilities.

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