DO GEMBA KAIZEN AND 5S REINFORCE MEDICAL EQUIPMENT MANUFACTURING PERFORMANCE?

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Abstract: This study aims to analyze the influence of Gemba Kaizen culture and implementation of 5S (Seiri, Seiton, Seiso, Seiketsu, and Shitsuke) to Medical Equipment manufacturing performance in the Medical Equipment manufacturing industries in Indonesia. This research uses a quantitative approach with Structural Equation Modeling (SEM) using smart PLS software. Data collection methods using online questionnaires and simple random sampling technique, the number of samples to be used as respondents as many as 300 Medical Equipment manufacturing managers. The results of this study indicate that the gemba kaizen has a positive and significant effect on the Medical Equipment manufacturing performance. For 5S also has a positive and significant effect on on Medical Equipment manufacturing performance. The implication of this research is to be a reference that kaizen and 5S can be applied in several manufacturers to improve their performance and can be a reference to be applied in other industries. This novelty of this research is build a new model of the effect of applying new kaizen and 5S to the Medical Equipment manufacturing industries in Indonesia.

Keywords: Gemba Kaizen, 5S, Medical Equipment manufacturing performance

1. INTRODUCTION

KAIZEN is Key to Japan’s Competitive Success (1986), term this is used freely and becomes a connection on Japanese management practices as well as being the real key to the success of Japanese companies around the world. The term (kaizen) itself consists of two words in Kanji Japanese (Ideograms): (kai) which means reform, modify, modify, check, and test; and (zen) which means virtuous noble and kindness (Imai, 1986: Macpherson, 2015). Kaizen can also mean as better change in pursuit perfection in work (Dyer, 2016: 19). This concept makes a lot of attention on kaizen is considered the key to competitiveness Japanese companies in the past three decades twentieth century. In the past 20 years, several companies have applied it the concept through employee participation in the suggestion improvement scheme, while others use it as a group of strategies and
a tool to reduce waste (Imai, 1986: Suarez-Barraza et al, 2011). Japanese companies began to implement kaizen at the end of the 20th century. Since then, some western companies like Catterpillar (Illinois, USA), Harley Davidson (Wisconsin, USA), Husqvarna (Jönköping, Sweden) and GDM Group & Q-West (Wanganui, New Zealand), use kaizen to improve techniques production, systematic operation, and searching more contributions from employees (Macpherson, 2015: 3). The kaizen strategy mainly depends on human endeavors to improve yields, and things it requires process improvement. Process-oriented approach referred to as the "plan-do-check-act" cycle (PDCA) and SDCA "standardize-do-check-act" to improve the improvement process. Cycle this can be called an increase cycle (Imai, 1986: Smadi, 2009). Introduction to concepts main kaizen, as well as the main kaizen system can applied in implementing culture kaizen to the company. That's why understanding about the main concepts and systems of kaizen is essential for the company. The purpose of kaizen is to improve three parameters: quality, cost, and submission or can be called QCD (quality, cost, delivery) (Karas et al., 2016: Imai, 1997). This matter means that kaizen focuses on improvement quality of goods or services, as well as striving to reduce costs at each stage business organizations in order to shorten time work. The goals of the kaizen culture reflect that continuous improvement must have the final goal in its application. In essence, it can be concluded from general explanation above is that the culture of kaizen is a better change (Macpherson, 2015: 3). That's why kaizen gets used in various fields and industrial lines for companies that apply it. Because the main focus of kaizen is the contribution each individual in the company makes continuous change, kaizen too regulate and improve the quality of individuals in the company. Management of resource management humans in this way kaizen form new discipline in change for the better. The main assumption of kaizen is to encourage employees so they can continue to improve the place work / workplace (Shepherd). That matter contribute to independence and self control the big that can be achieved by employees. Duty the main employee in a gemba is to maintain and improve or enhance standards in achieving quality, cost, and submission (QCD) which is accommodating (Imai,1997).

Lean Medical Equipment manufacturing is a production technique that considers the expenditure of resources in the production process. The technique aims to reduce the waste that can be generated during the production process. According to Kilpatrick (2003), one method for implementing lean Medical Equipment manufacturing in companies is the 5S method. 5S method is a work method from Japan that applies work environment management and arrangement. This arrangement aims to create a neat and comfortable work environment so that work effectiveness can be increased. Kumar and Kumar (2012) state that implementing 5S can reduce the number of defective products and maximize the use of space in the work environment. The application of 5S method also instills discipline in workers so that workers have the desire to maintain the tidiness of the work environment. 5S method consists of five methods, namely seiri, seiton, seiso, seiketsu, and shitsuke. Seiri (concise) means that a good work environment is free from excess tools and materials that are not used. Seiton (neat) means that a good layout arrangement for the tools and materials needed in the production process can increase worker effectiveness. Seiso (rehearsal) means that a comfortable work environment can be achieved by maintaining cleanliness. Seiketsu (care) means that a comfortable work environment must be maintained so that the working environment conditions remain comfortable and optimal. Shitsuke (diligent) means that the application of seiri, seiton, and seiso in a company will survive if workers are accustomed to applying it to their daily work. In practice, the first three S values (Seiri, Seiton, and Seiso) are values that are applied on an individual scale, while the last two S values (Seiketsu and
Shitsuke) are values that are applied on a managerial scale. Seiketsu and Shitsuke are needed to maintain and improve the application of Seiri, Seiton and Seiso (Pasale, 2013).

The 5S program (Seiri, Seiton, Seiso, Seiketsu and Shitsuke) is the basis for an employee mentality to make improvements and also to realize quality awareness (Heizer and Render, 2009). 5S is an approach in managing the work environment, which in essence seeks to eliminate waste so as to create an effective, efficient and productive work environment (Osada, 2004). While Hirano (1996) defines 5S as a tool to help express problems and if used appropriately can become a part of the process from a well-planned lean system. 5S itself is an abbreviation of Seiri (Sort), Seiton (Straighten), Seiso (Shine), Seiketsu (Standardize), and Shitsuke (Sustain). In Indonesian it is translated as 5R which means Concise, Neat, Rawat, Diligent. According to Imai (2001) 5S is very important because it is the foundation in making a process as short as possible, reducing production costs, quality output and reducing the incidence of accidents in the presence of better conditions. Seiri (Sort) or Concise, is the stage of distinguishing items that are needed and not needed, take firm decisions and implement stratification management to dispose of unnecessary and store items that are still needed (Osada, 2004). The item differentiation is intended to make the work system become concise. Efforts are made to get rid of goods that are no longer useful, so the company will have a wider workspace. Seiton (Straighten) or Neat, is the stage of storing goods in the right place or in the right layout by emphasizing the aspects of safety, quality and effectiveness, so that it can be used in a sudden situation (Hirano, 1998). This is useful to eliminate time wasted in the process of finding goods and workplaces to be more presentable. Seiso (Shine) or Resik is the third stage in the 5S method. The principle of Seiso or shine is to clean the work place or environment, machinery or equipment and other items so that there is no dust or dirt and rubbish littered. Clean conditions can affect humans psychologically by making themselves feel comfortable and not feeling stressed (Hirano, 1998). The initial steps that can be done at this stage such as throwing trash in place and cleaning the floor in the workspace. Seiketsu (Standardize) or Rawat is an activity where everyone must try to maintain the progress that has been achieved through the Seiri, Seiton and Seiso stages before. At this stage the results achieved have been maintained by standardizing or standardizing (Imai, 2001). The last step in the 5S method is Shitsuke (Sustain) or Diligent. The principle of Shitsuke is the creation of personal habits of employees to maintain and improve what has been achieved. Discipline in the workplace is the development of positive habits in the workplace (Heizer and Render, 2009).

Falkowski and Kitowski (2013) state that the application of Seiri is to remove tools and items that are not used in the operation process. Bhoi et al. (2014) states that tools and items released through the implementation of Seiri will be accommodated in the quarantine area. Reducing tools and materials that are not used can increase the area of work and increase the effectiveness of the movement of workers. Kaluarachchi (2009) states that Castle Street Hospital for Women (CSHW) in Sri Lanka implements seiri by sorting medical devices based on their conditions and making a place for collection and repair of medical devices that do not meet government standards. Zidel (2006) states that the application of seiton means that each tool and material in the work environment has its own place. Michalska and Szewieczek (2007) state that the storage of tools and materials should be labeled (name tags) to make them easier to find. Storage of tools and materials will be adjusted to the operator's range, so that the operator's movements become more effective. Ramesh et al. (2014) states that the preparation of tools and materials is based on the level of use of tools and materials during the production process. Kaluarachchi (2009) states that CSHW in Sri Lanka applies seitons by rearranging sterile fabric storage areas, and also provides direction markers for areas in
hospitals. Pasale and Bagi (2013b) state that the application of SEISO also includes checking engine cleanliness, light sources, and air ducts. The hygiene facilities needed for the application of seiso include bins, brooms, dust cleaners, and floor mats. Korkut et al. (2008) stated that cleaning the work environment should be done at the beginning of a work shift, the end of a work shift, or after a break. Veža et al (2011) states that an example of applying seiso in the work environment is to use transparent plastic bags as trash bins. The use of transparent plastic bags is considered easier for handling garbage and other impurities compared to using plastic or cardboard boxes. Kaluarachchi (2009) stated that CSHW in Sri Lanka implemented a procedure to maintain the cleanliness of floors and toilets in hospitals. Gürel (2013) states that seiri, seiton and seiso must have standards through the application of seiketsu to maintain the continuity of the 5S program. According to Lingareddy et al. (2013), the application of Seiketsu means that everyone must know their respective responsibilities in implementing 5S. One of the things that can be done is to make cleaning the work environment one of the daily work routines. Mallick et al. (2013) states that visual management such as the 5S picket schedule can be used as an effort to implement seiketsu.

The purpose of this study is to determine the influence of gemba kaizen and 5S culture on Medical Equipment manufacturing performance. The benefit of this research is to provide an analysis and explanation of the influence of gemba kaizen and 5S culture on Medical Equipment manufacturing performance. Based on the theoretical review and the results of the empirical findings above, the hypotheses are submitted in this study are:

H1 (hypotheses 1) : It is suspected that gemba kaizen has a positive and significant effect on Medical Equipment manufacturing performance.

H2 (hypotheses 2) : It is suspected that 5S has a positive and significant effect on Medical Equipment manufacturing performance.

2. LITERATURE REVIEW AND HYPOTHESIS DEVELOPMENT

Relationship Gemba Kaizen and Medical Equipment manufacturing Performance

According to Chiarini (2018) many theoretical parallelisms as well as lessons for practitioners, in particular referring to principles such as Jidoka, just-in-time, waste identification and elimination, challenge, Kaizen, Genchi Genbutsu, respect for people and teamwork. According to Kumar et al.(2014) Kaizen reduced processing time has been reduced by 44.4 percent and an amount of Rs. 64,000 has been saved by recovering a total of 80 square feet working area. Improvements in the form of work flow have been achieved. Vo et al.(2019) study utilizes a Kaizen event’s case study data with the help of various waste detection and elimination tools and techniques. Changes in overall productivity along with potential long-term improvements in the delivery process are also analyzed and documented. According to Kumar et al.(2014) Pre- and post-quality measures are provided to demonstrate the results of the event on the production quality and on the performance of the overall Medical Equipment manufacturing processes. According to Chan et al (2018) application of a mix of lean tools resulted in significant productivity improvements of 10-30 percent in the assembly area of the printing company. Based on the outcomes of the lean tools that are applied in various work areas, the best combinations of lean tools are identified and several key considerations are discussed. Al Smadi (2009) if properly implemented, Kaizen model can substantially contribute to continuous improvement and, thus, drive organizations for high competitiveness without a need for major investment. Woong et al (2014) similarities between Quality Circles and Kaizen Events were identified in every component of the logic model. Both mechanisms were effective in driving improvements in
performance and in motivating employees, even though significant differences in the project size, type, and industrial sector existed across the six different projects. Mitra (2019) It was found that the yield was increased from 88.3 to 92.2 percent, which was a significant change, as far as the product line is concerned. The product complaints were reduced to zero with an added increased product quality rating system to 98.2 from the existing rating of 96.7. The product consistency was also improved as an application of Lean in the Medical Equipment manufacturing process. Arya et al (2015) the benefit of kaizen is inventory access time is reduced up to 87 per cent and total distance travelled and total time taken by product is reduced up to 43.75 and 46.08 per cent, respectively. A habit to maintain a clean workplace has been developed in workers

Hypothesis 1: Gemba Kaizen has a positive and significant relationship with Medical Equipment manufacturing performance

Relationship 5S and Medical Equipment manufacturing Performance

Randhwa (2017) 5S is an outstanding Japanese philosophy for the development of any type organization all over the world. This study bring out the concept of 5S, requirements for its holistic implementation, relationship with other lean tools, benefits, success factors and obstacles in 5S implementation. Randhwa (2017) The significant contributions through 5S initiatives in the organization like production, quality, safety and effective utilization of workspace for the sustained organizational improvement have also been highlighted in the study. Enshassi et al (2019) 5S techniques applied to reduce the causes of accidents that were applicable were cleaning the workplace and removing materials and machines that are not required; conducting accident investigation and root cause analysis programmes; and using safety signs and labels on site. Suarez (2012) based on cross analysis findings, a group of reasons was found for applying the 5Ss in the multinational organisations analysed, along with a group of drivers and inhibitors responsible for enhancing or blocking the successful implementation of the 5Ss. Suarez (2012) a conceptual framework was also established, based on the results of comparing theory and fieldwork: this provides a glimpse into the relationship of the 5Ss with other improvement programmes, known as Lean-thinking or Lean-Kaizen, in the organisations analysed. In particular, the framework show the importance between do (way: philosophy) and jyutsu (techniques) during the implantation process of 5Ss. Cheng (2018) study identified the following factors in effective and efficient dissemination of 5S-KAIZEN-TQM activities in the Egyptian health sector: restructuring the quality management structure to establish Quality Improvement Teams and Work Improvement Teams in hospitals, generating strong leadership and commitment among leaders, conducting effective in-house trainings on the 5S-KAIZEN-TQM approach, monitoring and following up on 5S-KAIZEN-TQM activities and introducing the 5S-KAIZEN-TQM approach using non-clinical sections, which could also influence the sustainability of the activities.

Hypothesis 2: 5S has a positive and significant relationship with Medical Equipment manufacturing performance

3. METHOD

The type of this research approach is quantitative research. In this study the type of data used is quantitative data. The sampling technique used in this research method is simple random sampling. The number of respondents used in this study were 300 Medical Equipment
manufacturing company managers in Indonesia. The method used to retrieve data from respondents is to use a questionnaire. For Gemba kaizen variables according to Risma (2008) measured by continuous improvement and improvement while the 5S indicator is 5 indicators namely seiri (concise), seiton (neat), seiso (rehearsal), seiketsu (caring), and shitsuke (diligent). Medical Equipment manufacturing performance variables according to Mangkunegara (2009) are measured by 4 indicators namely quality, quantity, performance of tasks, and responsibilities. The questionnaire was designed closed except for questions or statements about the identity of respondents in the form of a semi-open questionnaire. Each closed question or statement item is given five answer options i.e. strongly agree (SS) score 5, agree (S) score 4, neutral (N) score 3, disagree (TS) score 2, and strongly disagree (STS) score 1. The method for processing data is by PLS and using SmartPLS 3.0 software version as a tool.

Tabel 1. Sample Descriptive Information

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (per April 2020)</td>
<td></td>
</tr>
<tr>
<td>&lt; 30 years</td>
<td>110</td>
</tr>
<tr>
<td>30 - 40 years</td>
<td>105</td>
</tr>
<tr>
<td>&gt; 40 years</td>
<td>85</td>
</tr>
<tr>
<td>Work Period</td>
<td></td>
</tr>
<tr>
<td>&lt; 5 years</td>
<td>95</td>
</tr>
<tr>
<td>5-10 years</td>
<td>100</td>
</tr>
<tr>
<td>&gt; 10 years</td>
<td>105</td>
</tr>
<tr>
<td>Highest Education</td>
<td></td>
</tr>
<tr>
<td>Bachelor degree</td>
<td>170</td>
</tr>
<tr>
<td>Magister degree</td>
<td>130</td>
</tr>
</tbody>
</table>

Distribution of respondents' profiles are 110 respondents below the age of 30, then 105 respondents to 40 years old and 85 respondents above the age of 40. Work periods under 5 years are 95 respondents, between 5 to 10 years are 100 respondents and above 10 years are 105 respondents. The level of education for bachelor degree is 170 respondents. and master degree is 130 respondents.

Figure 1. Research Model
4. RESULT AND DISCUSSION

RESULT
The testing phase of the measurement model includes testing for convergent validity and discriminant validity. Meanwhile, to test the construct reliability, Cronbach's alpha and composite reliability are used. The results of the PLS analysis can be used to test the research hypothesis if all the indicators in the PLS model have met the requirements of convergent validity, discriminant validity and reliability testing. Convergent validity test is done by looking at the loading factor value of each indicator to the construct. For most references, a factor weight of 0.5 or more is considered to have validation that is strong enough to explain latent constructs (Chin, 1998; Ghozali, 2014; Hair et al., 2010).

![Figure 1. Research Model Result](image)

In this research the minimum limit on the size of the loading factor received was 0.5, with the requirement that the AVE value of each construct> 0.5 (Ghozali, 2014). Based on the results of SmartPLS 3.0 processing and after issuing indicators or items that do not meet the requirements, as the results are shown in Figure 2, then now all indicators have a loading factor value above 0.5. Thus, the convergent validity of this research model has fulfilled the requirements. The value of loadings, Cronbach's alpha, composite reliability and AVE for each complete construct can be seen in the following Table 2:

<table>
<thead>
<tr>
<th>Variables</th>
<th>Items</th>
<th>Loadings</th>
<th>Cronbach’s Alpha</th>
<th>Composite Reliability</th>
<th>AVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gemba Kaizen</td>
<td>GK1</td>
<td>0.563</td>
<td>0.876</td>
<td>0.786</td>
<td>0.743</td>
</tr>
<tr>
<td></td>
<td>GK2</td>
<td>0.673</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>GK3</td>
<td>0.562</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>GK4</td>
<td>0.563</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5S</td>
<td>S1</td>
<td>0.732</td>
<td>0.902</td>
<td>0.922</td>
<td>0.511</td>
</tr>
<tr>
<td></td>
<td>S2</td>
<td>0.632</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>S3</td>
<td>0.578</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Discriminant validity testing is carried out to ensure that each concept of each latent variable is different from the other latent variables. The model has good discriminant validity if the AVE squared value of each exogenous construct (the value on the diagonal) exceeds the correlation between the construct and the other construct (values below the diagonal) (Ghozali, 2014). The results of discriminant validity testing using AVE squared values are by looking at the Fornell-Larcker Criterion Value obtained as follows:

Table 3. Discriminant Validity

<table>
<thead>
<tr>
<th>Variables</th>
<th>K</th>
<th>S</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaizen (K)</td>
<td>0.765</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5S (S)</td>
<td>0.753</td>
<td>0.743</td>
<td></td>
</tr>
<tr>
<td>Company Performance (P)</td>
<td>0.754</td>
<td>0.712</td>
<td>0.741</td>
</tr>
</tbody>
</table>

The results of the discriminant validity test in Table 3 above show that all constructs have a AVE square root value above the correlation value with other latent constructs (through the Fornell-Larcker criteria). Similarly, the cross-loading value of all items from one indicator is greater than the other indicator items as mentioned in Table 4, so it can be concluded that the model has met the discriminant validity (Fornell & Larcker, 1981). Next, collinearity evaluation is carried out to find out whether there is collinearity in the model. To find collinearity, VIF calculation is needed for each construct. If the VIF score is higher than 5, then the model has collinearity (Hair et al., 2014). As shown in Table 4, all VIF scores are less than 5, meaning that this model does not have collinearity.

Table 4. Collinearity Statistics (VIF)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Company Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaizen (K)</td>
<td>2.212</td>
</tr>
<tr>
<td>5S (S)</td>
<td>2.124</td>
</tr>
</tbody>
</table>

The results of the discriminant validity test in Table 3 above show that all constructs have a AVE square root value above the correlation value with other latent constructs (through the Fornell-Larcker criteria). Similarly, the cross-loading value of all items from one indicator is greater than the other indicator items as mentioned in Table 4, so it can be concluded that the model has met the discriminant validity (Fornell & Larcker, 1981). Next, collinearity evaluation is carried out to find out whether there is collinearity in the model. To find collinearity, VIF calculation is needed for each construct. If the VIF score is higher than 5, then the model has collinearity (Hair et al., 2014). As shown in Table 4, all VIF scores are less than 5, meaning that this model does not have collinearity.

Construct reliability can be assessed from the value of Cronbach's alpha and composite reliability of each construct. The recommended composite reliability and Cronbach's alpha values are more than 0.7 (Ghozali, 2014). The reliability test results in Table 2 above show that all constructs have composite reliability and Cronbach's alpha values greater than 0.7 (> 0.7). In conclusion, all constructs have met the required reliability.
Hypothesis Testing

Hypothesis testing in PLS is also called the inner model test. The effect test is carried out using the t-statistic test in the partial least squared (PLS) analysis model using the help of SmartPLS 3.0 software. With the bootstrapping technique, R Square values and significance test values are obtained as in the table below:

<table>
<thead>
<tr>
<th>R Square</th>
<th>R Square Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.675</td>
<td>0.687</td>
</tr>
</tbody>
</table>

Based on Table 5 above, the R Square value of Company Performance (P) is 0.675 which means that the variable Company Performance (P) can be explained by the gemba kaizen and 5S at 67.5%, while the remaining 32.5% is explained by other variables not discussed in this research.

Effect of Gemba Kaizen on Company Performance

Based on the test results and summaries in Table 6, for Hypothesis 1 (H1) beta value is 0.231, SE is 0.065, t statistics is 3.124 and p values is 0.001 so this research concludes that Kaizen (K) has a positive and significant effect on Company Performance so H1 is accepted. The results of this study are in line with Chan et al (2018) application of a mix of lean tools resulted in significant productivity improvements of 10-30 percent in the assembly area of the printing company. Based on the outcomes of the lean tools that are applied in various work areas, the best combinations of lean tools are identified and several key considerations are discussed. AL-Hyari et al (2019) the Kaizen approach was economical in terms of both money and time. Also, waste elimination can be achieved through a variety of tools and easily combined with the Kaizen approach. Implementing the Kaizen approach is an effective and reliable system that allows for the tackling of all types of inefficiencies in the caravan repairing project. Santoso (2020) continuous improvement (Kaizen) has a significant and positive effect on employee performance, the application of kaizen can improve employee performance. Asbari (2019) continuous improvement (Kaizen) has a positive effect on company performance, consistent application of kaizen can make company performance improve. Purwanto (2019) continuous improvement (Kaizen) has a significant and positive effect on industry performance, the application of kaizen can improve industry performance. According to Brunet et al (2003) kaizen evolves uniquely within each organisation, following changes to the organisation's business environment. Detailed implementations vary considerably between organisations, but all rely on kaizen to achieve targets as an integral element in the operations management system. This yields insights into kaizen's sustainability, and points to its vulnerability to external economic conditions. Kurmar et al (2014) processing time has been reduced by 44.4 percent and an amount of Rs. 64,000 has
been saved by recovering a total of 80 square feet working area. Improvements in the form of work flow have been achieved.

Al Smadi (2009) if properly implemented, Kaizen model can substantially contribute to continuous improvement and, thus, drive organizations for high competitiveness without a need for major investment. Woong et al (2014) similarities between Quality Circles and Kaizen Events were identified in every component of the logic model. Both mechanisms were effective in driving improvements in performance and in motivating employees, even though significant differences in the project size, type, and industrial sector existed across the six different projects. Mitra (2019) It was found that the yield was increased from 88.3 to 92.2 percent, which was a significant change, as far as the product line is concerned. The product complaints were reduced to zero with an added increased product quality rating system to 98.2 from the existing rating of 96.7. The product consistency was also improved as an application of Lean in the Medical Equipment manufacturing process. Arya et al (2015) the benefit of kaizen is inventory access time is reduced up to 87 per cent and total distance travelled and total time taken by product is reduced up to 43.75 and 46.08 per cent, respectively. A habit to maintain a clean workplace has been developed in workers. Chiarini (2018) many theoretical parallelisms as well as lessons for practitioners, in particular referring to principles such as Jidoka, just-in-time, waste identification and elimination, challenge, Kaizen, Genchi Genbutsu, respect for people and teamwork. According to Kumar et al.(2014) Kaizen reduced processing time has been reduced by 44.4 percent and an amount of Rs. 64,000 has been saved by recovering a total of 80 square feet working area. Improvements in the form of work flow have been achieved. Vo et al.(2019) study utilizes a Kaizen event’s case study data with the help of various waste detection and elimination tools and techniques. Changes in overall productivity along with potential long-term improvements in the delivery process are also analyzed and documented. According to Kumar et al.(2014) Pre- and post-quality measures are provided to demonstrate the results of the event on the production quality and on the performance of the overall Medical Equipment manufacturing processes. According to Chan et al (2018) application of a mix of lean tools resulted in significant productivity improvements of 10-30 percent in the assembly area of the printing company. Based on the outcomes of the lean tools that are applied in various work areas, the best combinations of lean tools are identified and several key considerations are discussed.

Effect of 5S on Company Performance

Based on the test results and summaries in Table 6, for Hypothesis 2 (H2) beta value is 0.3634, SE is 0.076, t statistics is 3.511 and p values is 0.004 so this research concludes that 5S (S) has a positive and significant effect on Company Performance so H1 is accepted. The results of this study are in line with Moriones et al (2020) the existence of a positive relationship between the use of 5S and some contextual factors such as size, the integration of the plant in a multinational group, the type of product manufactured, the technology used and the quality programmes in the plant. Moreover, 5S is positively related to some operational performance measures, especially those referring to quality and productivity. Asbari (2020) the application of 5S has a positive effect on company performance, consistent application of 5S can make company performance increase. Purwanto (2020) the application of 5S consistently has a significant and positive effect on industry performance, the application of 5S can improve industry performance. Santosos (2019) the application of 5S has a significant and positive effect on employee performance, the application of kaizen can improve employee performance. Bayo-. Randhawa et al (2017) association between the significant
nine stimulants for 5S implementation and seven crucial business excellence performance parameters. 5S initiatives can significantly facilitate achievement of business excellence in the Medical Equipment manufacturing organizations. Randhawa et al (2017) 5S is an outstanding Japanese philosophy for the development of any type organization all over the world. the concept of 5S, requirements for its holistic implementation, relationship with other lean tools, benefits, success factors and obstacles in 5S implementation. The significant contributions through 5S initiatives in the organization like production, quality, safety and effective utilization of workspace for the sustained organizational improvement have also been highlighted in the study. Randhawa et al (2018) the empirical results of the study have revealed that effective practice of 5S program brings considerable level of improvements in the quality, production, cost optimizations, employee’s morale values and work culture in the Medical Equipment manufacturing industry. The industry accrued both tangible and non-tangible benefits through the holistic adoption of 5S principals. 5S principals have been envisioned to further support other quality improvement programs like lean Medical Equipment manufacturing initiatives of the organizations.

Randhawa et al (2017) the majority of organizations have shown total commitment toward the implementation and objective realization of 5S quality policy at all levels in the organizations. The implementation of 5S has facilitated Medical Equipment manufacturing organizations to accrue significant benefits such as improvement in overall organizational, productivity, quality, safety, employee morale values, effective workspace utilization, and cost optimizations. The results also show the elimination of serious chronic Medical Equipment manufacturing system problems such as delays, breakdown, demoralized employees, declining profits, and dissatisfied customers through holistic 5S implementation. Randhawa et al (2017) during the implementation of 5S program, leading to attainment of high level of melioration in the BEPP. SEM has been deployed to evaluate the original and modification indices of the model, which further establishes the improvement in SEM’s effectiveness. The model establishes the significant impact of 5S implementation on business excellence of Medical Equipment manufacturing organization. Gupta et al (2015) implementation of “5S” resulted in overall improvement of the organization. With the implementation of “5S”, major benefits in the form of tool searching time have been achieved. Tool searching time from shop floor has been reduced from 30 minutes to 5 minutes. Attri et al (2017) several key barriers which have high driving power and weak dependence power. In this concern, these barriers entail extreme care and handling for successful implementation of 5S. Financial constraints, lack of top management commitment, and no proper vision and mission are found to be the key barriers.

**DISCUSSION**

According to Paul et al.(2003) kaizen evolves uniquely within each organisation, following changes to the organisation's business environment. Detailed implementations vary considerably between organisations, but all rely on kaizen to achieve targets as an integral element in the operations management system. According to Paul et al.(2003) This yields insights into kaizen's sustainability, and points to its vulnerability to external economic conditions. According to Fomseca et al.(2018) a mildly use of Kaizen, Lean and Six Sigma (SS) by Portuguese ISO 9001 certified organizations, which is increase when compared to previous studies. The sample of organizations that are already certified by ISO 9001:2015 have mean and median levels of customer improvement methodologies adoption (Lean, Kaizen, SS) higher than those that are still certified against ISO 9001:2008. According to Fomseca et al.(2018) Checklists, plan-do-check-act cycle and process diagrams, followed by
DMAIC, are the quality tools that are most frequently adopted. Suarez et al (2012) the development, refinement and implementation of a process innovation framework in the context of the Gemba-Kaizen approach has been achieved, working closely with a multinational food company. Consequently, as a result of the application, a conceptual framework was established, based on the results of comparing theory and fieldwork: this provides a glimpse into the relationship of the Gemba-Kaizen approach with other improvement methodologies, known as Process Redesign, in the organisation analysed. Cheser (1998) suggest that kaizen increases job enrichment and employee motivation, and may move employees to higher levels of growth need strength. Implications for Medical Equipment manufacturing management are also discussed. Kumar et al (2018) before and after implementation of value stream map, the data obtained were analyzed and eliminated rework time, reduced inventory level, reduced lead time and cycle time improved productivity and product quality are presented as finding. Cheser (1998) Lean-Kaizen provides a better chance for every individual of the industry to have a hand in achieving organization’s goals to attain continuous progress in productivity and quality of the product. Even good understanding of the concept of lean tools and techniques by SMEs, the employee willingness and motivation to identify and eliminate wastes are found feeble. Doolen et al (2008) even within a single organization, kaizen events may have varied success. Management support was found to be related to human resource outcomes. Positive attitudes at the conclusion of a successful event, however, did not automatically translate to sustained improvements. Additionally, the kaizen event team with a more limited scope was better able to meet targeted business objectives. Bortotti et al (2018) goal clarity, team autonomy, management support, goal difficulty and affective commitment to change (ACC) are the most influential determinants of kaizen capabilities and/or employees’ attitude. Goal clarity, goal difficulty, team autonomy and management support are also found to influence social outcomes directly and/or indirectly through ACC, internal processes and/or an action orientation. Cheng (2018) The results of the Six Sigma system proposed in this paper show that each organization used a unique Kaizen mechanism when initiating a Six Sigma project. A Kaizen event within a Kaizen mechanism can be used to obtain valuable insights about Six Sigma implementations. Firms should be able to achieve better management decisions after conducting self-assessments using the model. Kumar (2004) in Medical Equipment manufacturing, corporate growth and profitability are more challenging than ever before. The company reviewed in this study has been and is currently suffering tremendous growing pains with poor record of profitability. Some of the tasks involved in identifying opportunities for improving operational efficiencies included analysis of current business processes, identification of non-value-added activities including wastes and proposing process changes

5. CONCLUSION

This research concludes that implementation of gemba kaizen has a positive and significant effect on Company Performance and implementation of 5S has a positive and significant effect on Company Performance. The majority of organizations have shown total commitment toward the implementation and objective realization of 5S quality policy at all levels in the organizations. The implementation of 5S has facilitated Medical Equipment manufacturing organizations to accrue significant benefits such as improvement in overall organizational, productivity, quality, safety, employee morale values, effective workspace utilization, and cost optimizations. The results also show the elimination of serious chronic Medical Equipment manufacturing system problems such as delays, breakdown, demoralized
employees, declining profits, and dissatisfied customers through holistic 5S implementation. In the Medical Equipment manufacturing, corporate growth and profitability are more challenging than ever before. The company reviewed in this study has been and is currently suffering tremendous growing pains with poor record of profitability. Some of the tasks involved in identifying opportunities for improving operational efficiencies included analysis of current business processes, identification of non-value-added activities including wastes and proposing process changes. If properly implemented, Kaizen model can substantially contribute to continuous improvement and, thus, drive organizations for high competitiveness without a need for major investment. Woong et al. (2014) similarities between Quality Circles and Kaizen Events were identified in every component of the logic model. Both mechanisms were effective in driving improvements in performance and in motivating employees, even though significant differences in the project size, type, and industrial sector existed across the six different projects. The limitation of this study is the small number of respondents so the results of the study may not be generalized to other places.

6. REFERENCES


