Characterizing an automation level-based safety assessment tool to improve fluency in safe human cobot interaction

by

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ABSTRACT

In the current manufacturing era of advanced automation, cobots, and robots play an integral role in any manufacturing operation. Collaborative robots can share a workspace with humans to carry out day to day operations with safety. Although there are a lot of studies in the field of industrial-size robots and cobots and their programs or algorithms to make them safer, faster, efficient, the number of OSHA reported accidents due to cobots and robots has not decreased. Even though these cobots are considered inherently safe, they open more probability for accidents because they are not caged. Therefore, it is necessary for the manufacturing industries using cobots to consider the risk involved in human cobot interaction and the ways to attain safety and lower the risk of injury before installing cobots on assembly lines.

This study has developed a lightweight cobot and a user-centric tool to perform a physical and psychological risk assessment using process- failure mode effect analysis (PFMEA) for different automation levels in human cobot interaction. A detailed analysis involving stratification of potential failure modes, their types, causes and effects are discussed, and the failure modes or safety incidents are then ranked based on severity, occurrence and detection. The study also tries to correlate the respiratory rate or heart rate and stress involved in human cobot interaction to improve fluency in assembly operation.

The developed assessment tool generates a quantitative as well as qualitative assessment consisting of RPN and CN scores. It suggests recommended actions and various CAPA options to curtail physical injury. The tool also offers different training modules for the operators based on their perception of safety and the stress level involved in the assembly operation to reduce behavioral risks. Thus, the generated results provide insights about safety analysis that can be used by manufacturers to improve safe human cobot interaction.

CHAPTER 1. INTRODUCTION

In industry 4.0 and lean manufacturing, the priority is given to safety, automation, and cost reduction concepts to be used in a manufacturing environment or assembly lines to create a smarter and safer workplace environment. Most of the manufacturers are adopting lean manufacturing and automated technology in their manufacturing plants. One of the advanced manufacturing solutions for this is collaborative robots. These automated manufacturing practices are considered as an integral part of the manufacturing operations that attempts for minimum human errors with maximum productivity. The collaborative robot is one of the best solutions which can be used to perform repetitive tasks to reduce MSDs (musculoskeletal disorders) and unsafe working conditions.

Robots vs Cobots

The manufacturing automation solutions have two types that are, hard automation and flexible automation. Hard automation is where the robots are used on manufacturing assembly lines. This type of automation is suitable for high volume products with very little to no changeovers. For example, robots are used in metal sheet press applications for appliances or car structures to pick the colossal metal sheet. The metal sheet is then fed to the press robot, which punches it, and passes it to the next workstation. The programming and the mechanical movements used behind this operation are difficult to change, and hence, these robots are usually selected for operations where no change over is required. The higher production rates typically come along with high initial installment cost. In contrast to hard automation, flexible automation, as its name suggests, can be used for repetitive tasks. Cobots can be considered as flexible automation. According to Malik et al. (Malik & Bilberg, 2017) cobots interact with humans by sharing the workplace on the manufacturing assembly line. The changeovers can also be performed speedily. This type of automation comes with a low installment cost as compared to hard automation. Even though cobots have the flexibility to run the changeovers, speed and productivity are slowed down. For example, a cobot is picking a wooden frame from the ground and placing it on the workstation. The program used to perform mechanical movements of a cobot can be changed easily, and now it can be used to pick up small and delicate objects like glass test-tubes. The downtime for this application is not wasted because it is providing the ability to continue manufacturing in small batches (Villani, Pini, Leali, & Secchi, 2018). Therefore, cobots are considered an integral part of new manufacturing facilities.

Cobots – Application, Advantages, and Disadvantages

In the new industrial robotic paradigm, the cobots are not enclosed in cages, but they are designed to collaborate with the human workers. A collaborative robot can share its workspace with human employees to carry out an operation that requires physical efforts such as excessive bending or repetitive body motion. By doing so, the workplace is considered more technology-centric, efficient, and safer without eliminating human jobs on the assembly line. This makes human operators work on tasks that require a more cognitive application.

The research in the last few years about cobots has been remarkable as it has made cobot the face of the new automation industry. They come in all sizes and all requirements with customized programs to carry out both simple and complex tasks around it. The actions can be autonomous or semi-autonomous, depending on the task assigned to the cobot. The installation of cobots should be done on the assembly line where the human operators have to use a lot of dexterity to carry out tasks that include constant bending, frequent kneeling, lifting objects from the ground and repetitive tasks causing wrist and spine injuries, etc. Cobots should be utilized in extreme working conditions where they can withstand fluctuations in temperatures or poisonous, toxic, or sticky glueing items. For example, cobots can be used in the food manufacturing or glass manufacturing facility where the temperature is an unavoidable yet essential factor. Some manufacturing industries are involving cobots in spot welding operation to reduce human contact with flames/ fire and risky, dangerous tasks for the betterment of safety approach.

The flexibility, the cost, and the ability to coexist with human employees have proved cobot an excellent investment option in any manufacturing facility, according to Wang et al. (Wang, Kemény, Váncza, & Wang, 2017). Additionally, they can be easily moved to the other workstation if the tasks they were initially assigned to is changed. In most cases, cobots are not considered to have a safety cell around themselves. In short, cobots can be used where industrial robots cannot be fit to carry out a variety of operations with low installation costs.

Although there are a lot of studies in the field of the industrial size robots and cobots to make them safer, according to OSHA (LABOR, 2020) reports, the fatal accidents caused due to cobots and robots are reduced over the period but not fully diminished. Therefore, we have forecasted the number of accidents and proposed a safety /risk assessment approach for fluent human cobot interaction. Figure 1 shows the trend of accidents from 1984 when the robots and cobots were introduced on the manufacturing front. Based on this data available with OSHA, this study attempts to calculate and analyze risks and suggest required pieces of training for the operators when the cobots are newly installed on the assembly.

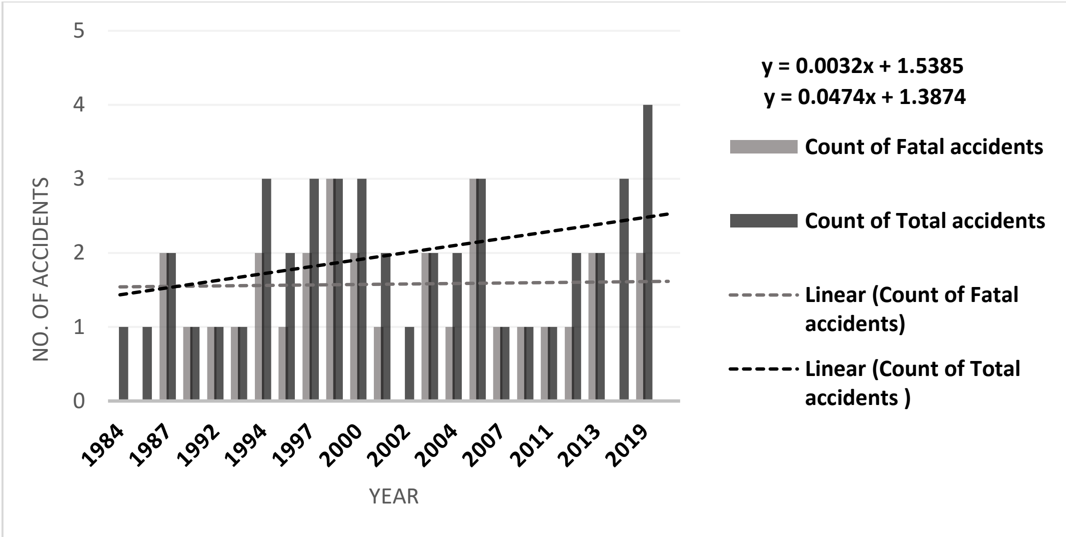


Figure 1: Count of total and fatal accidents over the years

The proposed methodology will be validated in the future by performing experiments with human subjects to observe the safety and efficiency of the common assembly practices because the applications like pick and place operations can be applied for novice operators (Pieskä, Kaarela, & Mäkelä, 2018). The process of this study also includes reviewing safety components, systems, and subsystems their effects and potential failure modes, creating FMEA based on the level of automation. It also takes human body changes such as heart rate, respiratory rate, heart variability rate into consideration to measure stress level. Hence, it will be a great systematic safety assessment tool where costly injuries are averted with a proactive and prevention-focused approach that guides the operator and manufacturer for safe production practices.

CHAPTER 2. METHODOLOGY

There is no systematic development of safety and risk assessment tools when human cobot interaction is considered. To understand the trend of accidents for upcoming years, the predictive analysis has been performed on the dataset available with OSHA. The forecasted rate of accidents is calculated by the Naïve forecast method, which shows that the number of casualties is continuously increasing over the years, as shown in Figure 2. Naïve forecast is calculated by the following formula

$$\hat{y}_{T+h|T} = yT$$

where yT is the past data available with OSHA and $h|T$ is the forecast horizon (total time in the future for which the data is forecasted).

Figure 2 displays mean absolute scaled error (MASE) as 0.64 which interprets that the forecast accuracy is good and close to the prediction which is calculated by

$$MASE = \frac{\sum_{t=1}^{N} \left| \frac{E_t}{\frac{1}{N-m} \sum_{t-m+1}^{N} |y_t - y_{t-m|}} \right|}{N}$$

The mean absolute percentage value (MAPE) is 1.44, which describes the accuracy of the forecasting model.

$$MAPE = 100 * \frac{\sum_{t=1}^{N} \left| \frac{E_t}{Y_t} \right|}{N}$$

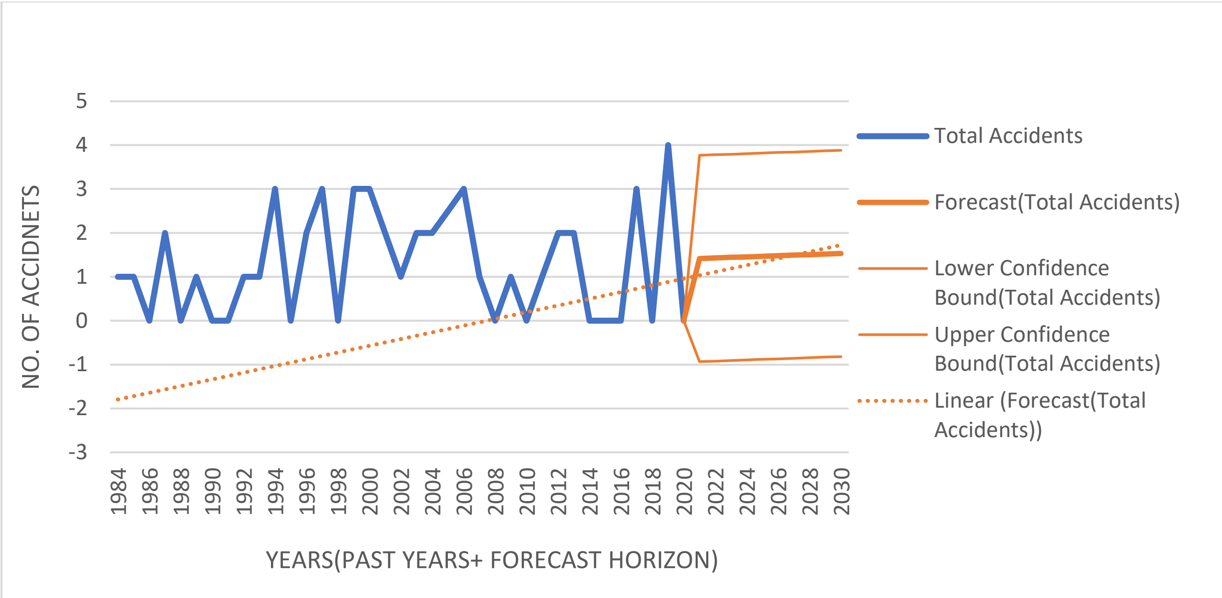


Figure 2: Forecasted fatal accidents vs years

Figure 2 depicts the requirement for understanding the justification of human cobot interaction and observing the resulting increase in accidents due to collaborative activities carried out along with the human operators. These risks or hazards are not newly created but are always exposed to the operators, according to Jocelyn et al. (Jocelyn, Burlet-Vienney, & Giraud, 2017). Therefore, it is necessary to develop a systematic approach that can be utilized to analyze the safety according to the level of automation used in the human cobot interaction. Additionally, the risk and safety assessment platform provides insight into the requirements of the manufacturing assembly lines. Thus, the proposed tool might help manufacturing industries to decide whether to incorporate expensive tooling and equipment like cobots.

To understand and address safety when introducing cobots to the workplace, the following criteria have to be satisfied.

1. Choosing operation for the cobot – Most of the time, cobots are used for repetitive tasks. They can withstand high/ low temperatures, toxic fumes, etc.

   Tasks- Pick and place objects, application of adhesive glue material, Spot Welding, clamping objects in extreme conditions.
2. Set up of cobot workplace – After assigning a specific task to the cobot, understand the area covered by its arms, safety requirements, safety cell needs. Fix a place on the assembly line for a cobot to perform the operation. Consider additional safety and signboards around it. Decide a suitable number of people interacting with the cobot. Check if a safety cell is needed; if yes, design and plan the setup of a cell, type of cell, the height of the cell, etc.
3. Risk assessments for creating safer environments - It is essential to understand whether the cobot cells need to be certified for safety. In the US, according to OSHA, employers are required to provide a workplace with zero recognized hazards and safety standards within the industry. And to provide such data, safety, and risk assessment is required to be done to identify potential failures and their types.
4. Implement safety to protect humans physically and psychologically – Investigate the takt time of the operation, check the operation or task time involving human cobot interaction. Find out potential risk factors. Perform risk analysis by understanding risk patterns and try to mitigate the risk to have a safe manufacturing operation (LABOR, 2020).

There is a lack of safety assessment and training practices required considering behavioral aspects of operators while working with cobots. There is no systematic and straightforward approach to identify and evaluate these safety concerns quantitatively or qualitatively. Hence, the safety assessment tool is developed for easy use if manufacturers to adhere to safe production practices.

Safety Analysis – Safety Zones

When a collaborative robot performs a task or a specific operation within its safety limits, it is usually considered that the entire workspace around it is safe. But if the task requires different safety limits around the cobot, it is crucial to understand the safety needs, according to Franklin et al. (Franklin, Dominguez, Fryman, & Lewandowski, 2020). The area around the cobot can be split into five distinct zones as follows

1. Maximum space – The space where the collaborative robot is capable of moving. It may be called a cobot workspace.
2. Restricted space – The space which is not used by collaborative robot due to hard limit switches and or sensors or safety-related axis limits in the workplace.
3. Operating space – The space in the restricted zone, which is used in a particular task or program, is called an operating space. It is usually based on tasks and not the safety aspects.
4. Safeguarded space – The space which falls under safety fencing can be called a safeguarded space. The fencing can be the actual physical territory or the invisible one. This includes safety mats and safety strips drawn around cobots. This space may be bigger than the maximum space utilized by cobot to ensure the utmost safety and wellbeing of all the operators.

5. Collaborative space – The space where collaboration takes place is primarily known as a collaborative space. It is the space where the human and cobot coexist and work together on the task at the same time. This space is a portion of the operating space. When the cobot operates in a collaborative space, it is always operated in a restricted way with the help of advanced remote sensing technologies.

To avoid any safety incidents in collaborative space, manufacturers should list and map out all additional equipment in the complete collaborative automation projects and evaluate each device for potential hazards, failure modes, and safety sensors to prevent human and equipment damage. Thus, this report focuses on four levels of automation safety by which cobots could be classified for different manufacturers' operations and environments by building a lightweight cobot. The study includes building an industrial-sized lightweight cobot with 3 to 4 degrees of freedom depending upon the application. The typical degree of freedom is the shoulder, elbow, wrist roll, wrist pitch, and gripper depending upon the operation to be performed. These parts relate to each other with the help of servo motors and their horns to have 180degrees + of rotation. The lightweight cobot is programmed on Arduino to perform basic operations like pick and place or glueing in a continuous loop. The research also tries to identify potential safety concerns and assess the risk of those safety issues quantitatively and qualitatively by using the following parameters.

1. A number of times, humans were struck by a cobot.
2. Productivity, i.e., how many units were made and how many were targeted.
3. Number of near misses while carrying out any operation with cobot
4. Slack time, i.e., the amount of time invested by human operators to work around/on/with cobots.

The task distribution between human operators and cobots should be analyzed according to Krüger et al. (Krüger, Lien, & Verl, 2009). Hence, the proposed safety and risk assessment tool can be used to validate lightweight cobots and human interaction.

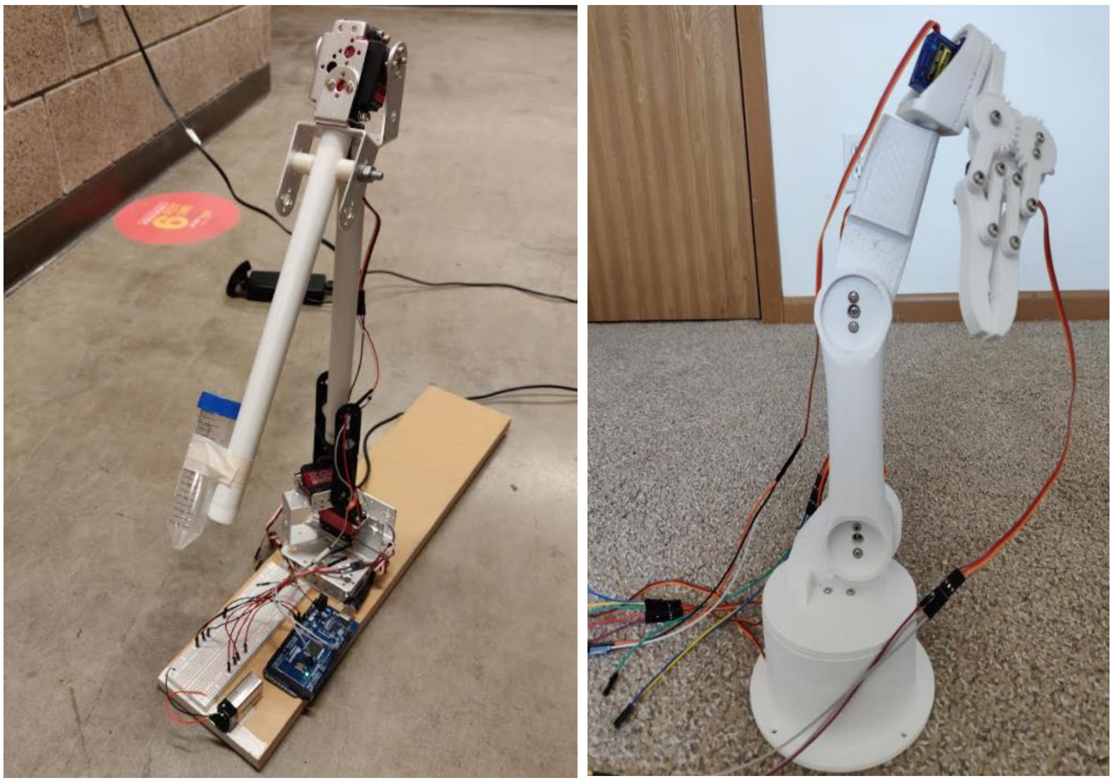


Figure 3: Lightweight cobot for glueing operation (left side) and lightweight cobot for pick and place operation (Right side)

This approach compares the different levels of automation incorporated for human cobot interaction to compare themselves in terms of physical and psychological risks and safety. The risk assessment tool focusing on FMEA (Failure Mode Effect Analysis) has been created that generates risk assessment scores based on risks involved in human cobot interaction.

Table 1: Level of automation

Level	Presence of Human	Presence of Cobot	Caged/barricades
L-1	Yes	No	No
L-2	Yes	Yes	Yes
L-3	Yes	Yes	No
L-4	No	Yes	No

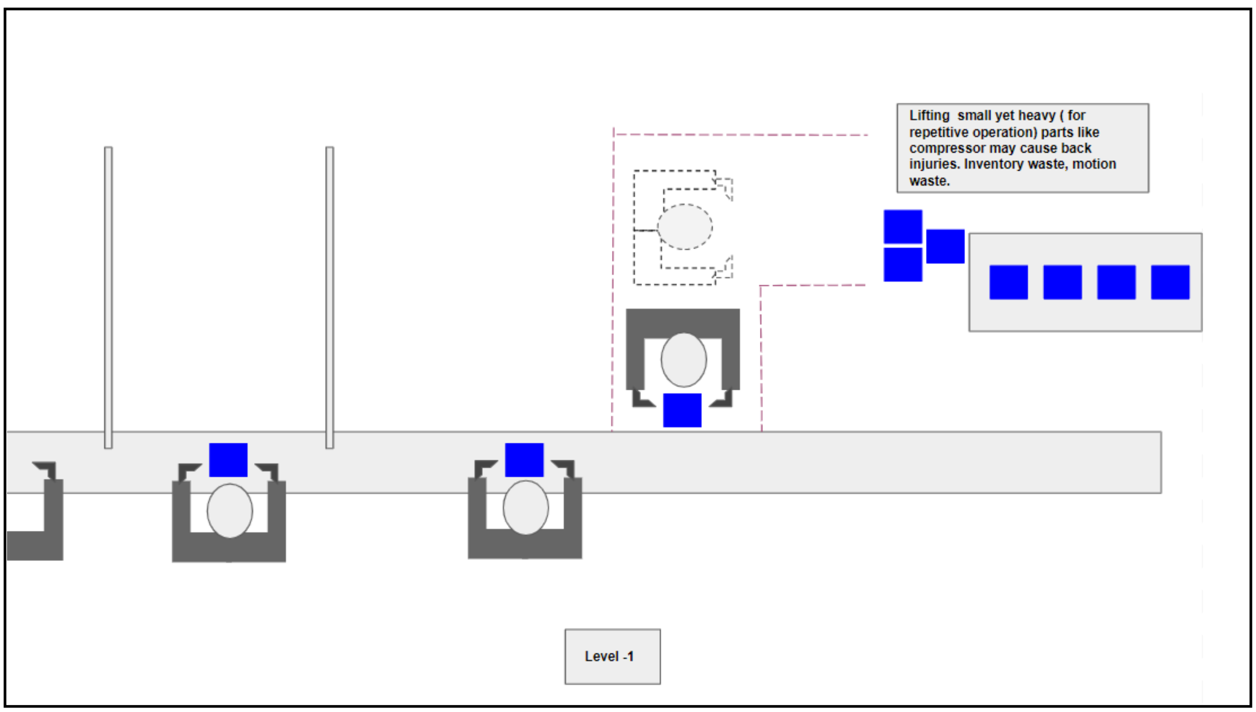
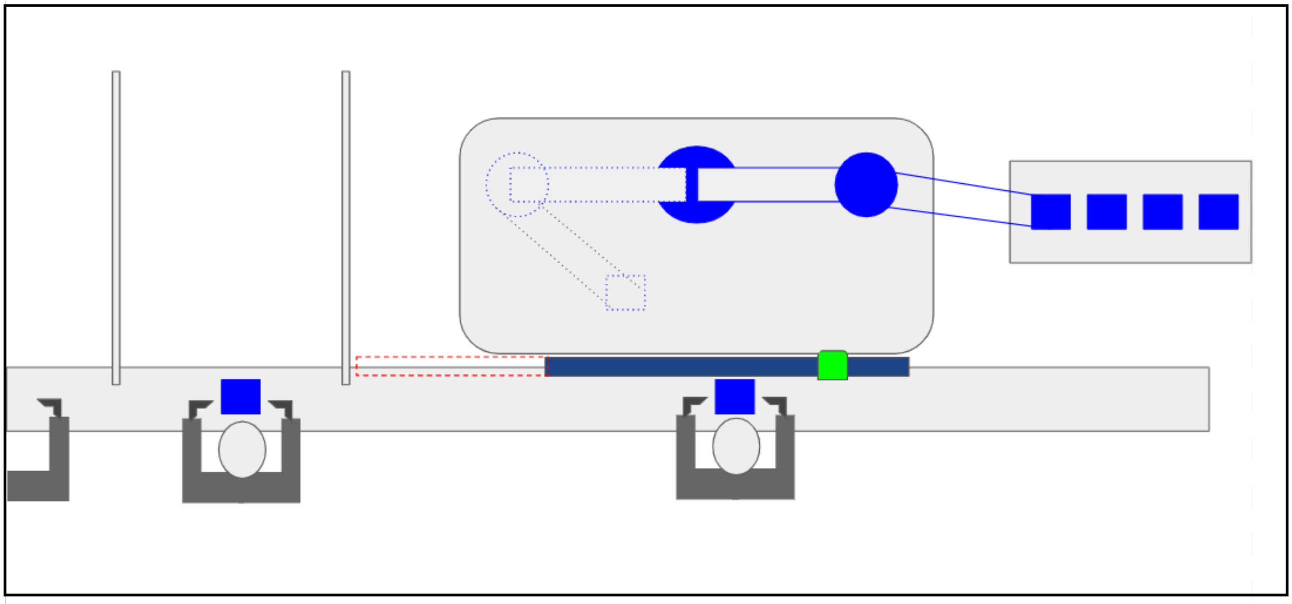
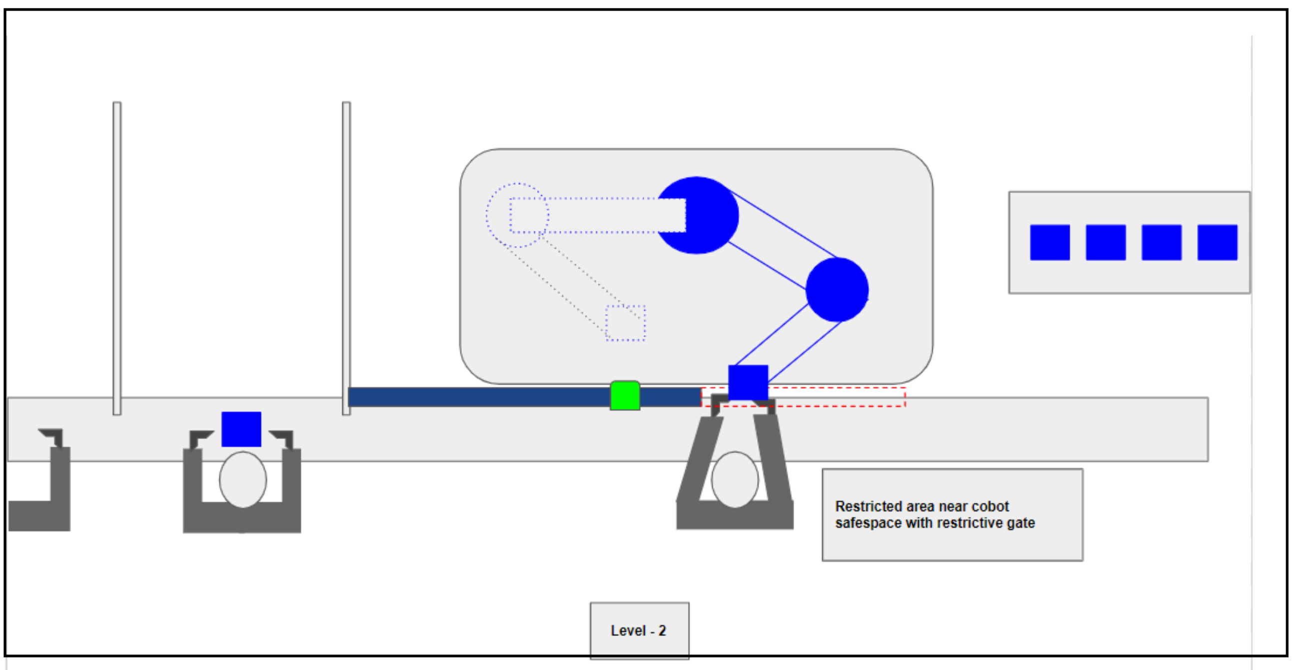


Figure 4: L1- manual assembly



(a)



(b)

Figure 5: L2- human cobot interaction with restrictive gate. Image (a)- cobot picking an object. Image(b) – Cobot placing an object

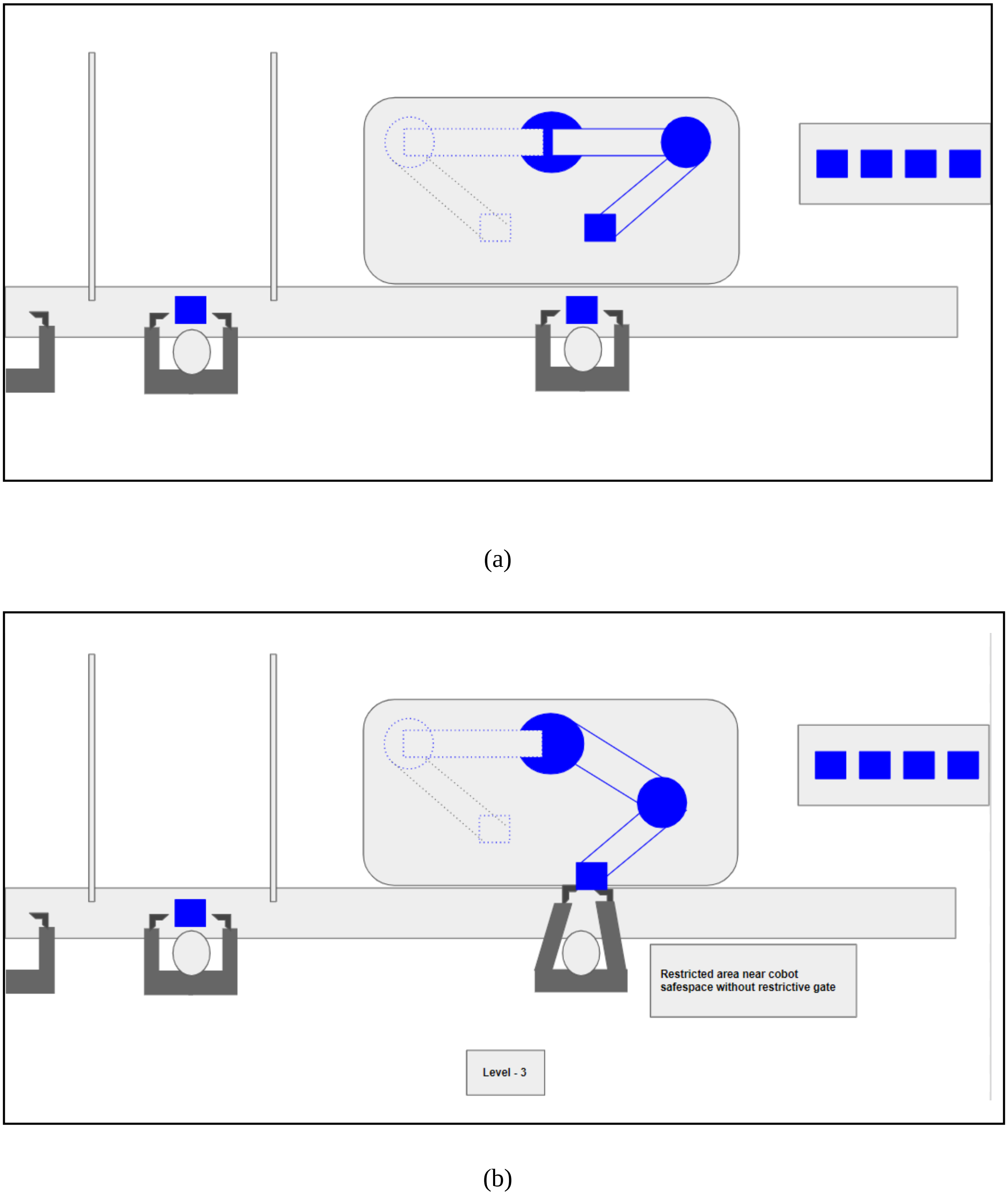


Figure 6: L3- human cobot interaction without restrictive gate. Image (a)- cobot picking an object. Image(b) – Cobot placing an object

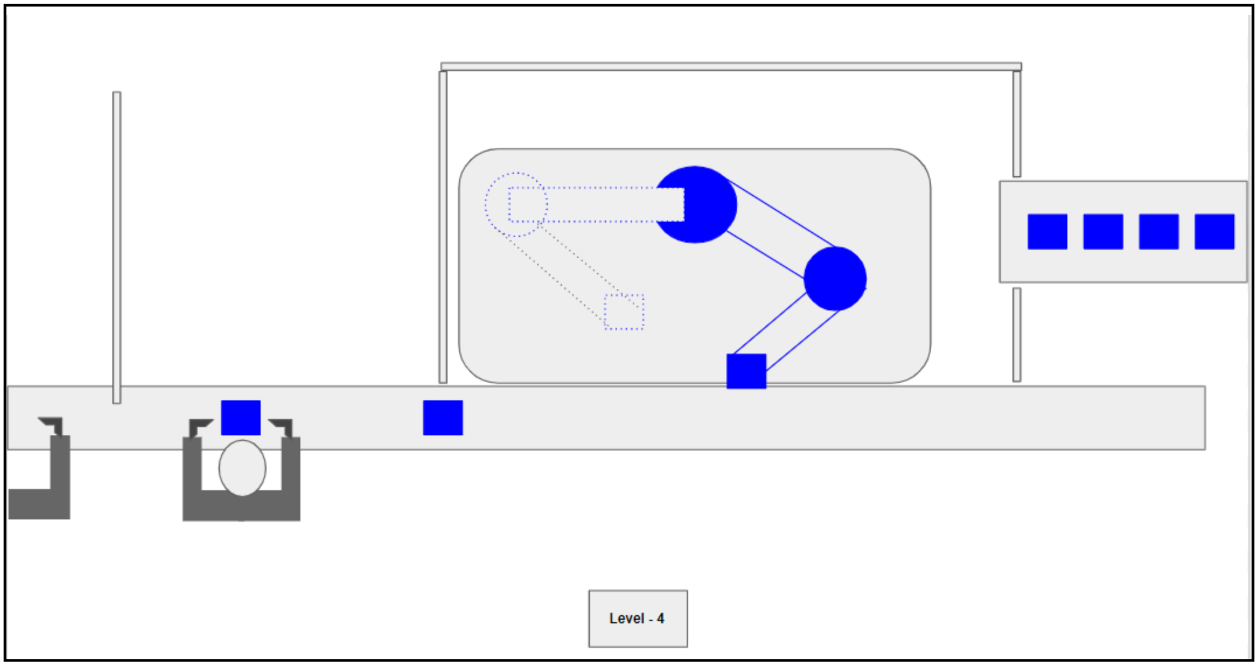


Figure 7: L4- no human cobot interaction. (automatic assembly)

FMEA is a very commonly utilized technique in the manufacturing industry. It stands for Failure mode effect analysis and has two types predominantly. 1. PFMEA (Process FMEA) and 2. DFMEA (Design FMEA). In this experiment, PFMEA - a powerful tool, is used to help identify and analyze potential risk causing various failures in the process (Franklin, Dominguez, Fryman, & Lewandowski, 2020). The analysis is done by the qualitative or quantitative approach to have an understanding of what might go wrong within the system, types of failures, depth of failure, and potential area or machine or human operators getting affected. It is widely used in six sigma standards and hence can be utilized to develop a systematic approach while developing fluency between humans and cobot interaction. It suggests changes in process, subprocesses, designs, and product validation adhering to ISO 9000 standards.

This research focuses explicitly on potential problems that could cause unsafe working condition due to abnormal cobot operation or hazardous environments for the different levels of automation. The developed automated tool gives out potential risk priority number (RPN) based on causes of failures, their severity, frequency by which they are occurring, and likelihood to detect their frequency. The generated tool uses FMEA as a base to suggest corrective and preventive action (CAPA) to the manufacturing teams in order to mitigate failures by taking quick actions in the very early stages of installing a collaborative robot.

In this experiment, three basic criteria of FMEA are used, that are severity, occurrences, and detection of the system to calculate the level of risk. The severity number counts the effect of the potential failure on the customer or machine and assembly operation and human operator. The occurrence ranking is determined by the frequency or the number of times the incident is probable to occur. The detection count is purely based on the systems used in manufacturing operation, which are certainly capable of detecting incident before or after it happens. The ranking is assigned between 1 and 10 for all types of failure based on the depth of the above-mentioned criterion (1 = low, 5 = Moderate, 10 = high). This study has generated PFMEAs as per the levels depending on cobot and human interaction. To make the tool even simpler and user-focused, all the potential problems, along with severity ranking, have been suggested. The detection systems are discussed from the general manufacturing plant floor condition study. The occurrence ranking can be selected by calculating the probability of safety incidents based on historical data available at the manufacturing facility. This method can be used by manufacturers planning to implement new cobot in their assembly.

On the other hand, manufacturers already having cobot set up and evaluating safety or risk assessment can use historical data to calculate severity, occurrence, and detection. The parameters used for the calculations are the total number of products made daily, reported near misses, safety incidents, etc. The following figures are showing sample calculations of near misses and safety incidents occurrence for various levels of automation. For example, the recorded data for near misses (sensor detected information) and data of production for ten days are used to calculate near-miss occurrences per 1000 products. Similarly, the occurrence incidents are calculated by using recorded safety events. These tables are only suitable to use if the cobots were installed on the assembly line and the risk assessments were to be done. The user will enter the first four columns as input in the tool. In level 1, there is no record of near misses as this level shows manual assembly. But safety incidents are noted for ten days of production and converted to the number of occurrences per 1000 products.

Level	Near misses (Sensor- decides detection) per 10	Safety Incidents (decides	No. Of products / 10 day	Near miss occurrence /1000	Occurrence/1 000	Operation
L-1	0	1	6000	0	0	No Picking / Placing
L-1	3	1	7500	0	0	Late Picking/ Placing
L-1	0	3	8500	0	0	Damaged materials/ previous products
L-1	0	1	10000	0	0	Directly hitting other objects/ Operators
L-1	0	1	10000	0	0	Improper mechanical movements
L-1	0	1	10000	0	0	Undesireable action or disrupted operations
L-1	0	1	10000	0	0	Failure to start the process

Figure 8: Level 1- sample calculations of near misses and safety incidents occurrence

In Figure 9: Level 2- , there are 50 near misses recorded by the sensors along with 20 safety events per 6000 products. The tool is merely calculating these events per 1000 products in order to ease the operation of risk assessment. Similarly, some example scenarios are used in the following tables to illustrate the number of accidents occurring for different levels of automation.

Level	Near misses (Sensor- decides detection) per 10 days	Safety Incidents (decides occurrence) per 10 days	No. Of products / 10 day	Near miss occurrence /1000	Occurrence/1000	Operation
L-2	50	20	6000	8	3.33	No Picking / Placing
L-2	30	1	6000	5	0.17	Late Picking/ Placing
L-2	200	3	6000	33	0.50	Damaged materials/ previous products
L-2	5	1	6000	1	0.17	Directly hitting other objects/ Operators
L-2	0	5	6000	0	0.83	Improper mechanical movements
L-2	0	1	6000	0	0.17	Undesireable action or disrupted operations
L-2	5	60	6000	1	10.00	Failure to start the process

Figure 9: Level 2- sample calculations of near misses and safety incidents occurrence

Level	Near misses (Sensor- decides detection) per 10 days	Safety Incidents (decides occurrence)	No. Of products / 10 day	Near miss occurrence /1000	Occurrence/1000	Operation
L-3	22	3	6000	4	1	No Picking / Placing
L-3	53	10	6000	9	2	Late Picking/ Placing
L-3	0	32	6000	0	5	Damaged materials/ previous products
L-3	0	6	6000	0	1	Directly hitting other objects/ Operators
L-3	0	10	6000	0	2	Improper mechanical movements
L-3	0	23	6000	0	4	Undesireable action or disrupted operations
L-3	0	2	6000	0	0	Failure to start the process

Figure 10: Level 3- sample calculations of near misses and safety incidents occurrence

Level	Near misses (Sensor- decides detection) per 10 days	Safety Incidents (decides occurrence) per 10 days	No. Of products / 10 day	Near miss occurrence /1000	Occurrence/1000	Operation
L-4	0	1	6000	0	0	No Picking / Placing
L-4	3	1	7500	0	0	Late Picking/ Placing
L-4	0	3	8500	0	0	Damaged materials/ previous products
L-4	0	1	10000	0	0	Directly hitting other objects/ Operators
L-4	0	1	10000	0	0	Improper mechanical movements
L-4	0	1	10000	0	0	Undesireable action or disrupted operations
L-4	0	1	10000	0	0	Failure to start the process

Figure 11: Level 4- sample calculations of near misses and safety incidents occurrence

Severity Ranking Sheet

Severity ranking focuses on what is important to the industry, and manufacturing set up and the clients (for example, safety standards, production percentage, scrap, quality hardware).

Table 2: Severity ranking

Ranking	Effect	FMEA
10	Very severe Hazardous- No warning	May cause high risk /failure to the machine or the operator without any warning
9	Very severe Hazardous- with warning	May cause high risk /failure to the machine or the operator without any warning
8	High	A major disruption in operation causing scrap/rework. (directly affecting client)
7	High	Minor disruption in operations causing scrap. (directly affecting client)
6	Moderate	Minor disruption in the operations causing rework not directly affecting client
5	Low	Minor disruption in the operations causing no direct effects to the client
4	Very Low	Very minor disruptions involving client directly
3	Minor	Very minor disruptions
2	Very Minor	No disruption on assembly lines
1	None	No effect

Severity Ranking calculations can also be done by using the following formulae-

Severity Rate can be calculated as the number of lost days as compared to the number of incidents experienced by human operators while interacting with robots on the assembly line.

$$\textbf{Severity Rate} = \frac{\textbf{Tot. number lost workdays (due to cobot accident/injury)}}{\textbf{Tot. number of recordable incidents}}$$

Apart from severity rate, OSHA uses TCIR, LTIR, and LWDR to monitor and collect data in high-risk industries to allow operations and safety managers to track accidents, injury incidents, and frequency to find out the root cause of the incident.

Total Case Incident Rate (TCIR) gives the total number of events involving injuries reported to OSHA in total man-hours.

$$\textbf{TCIR} = \frac{\textbf{Number of reported OSHA cases * 200000}}{\textbf{Man-hours}}$$

Lost Time case rate (LTIR) gives the number of cases that causes time loss per 100 full-time employees.

$$\textbf{LTIR} = \frac{\textbf{Tot. number of Lost time cases * 200,000}}{\textbf{Man-hours}}$$

Where LWDR is the number of lost workdays per 100 employees. The lost workday rate can also be calculated by finding the rate of time loss in injury

$$\textbf{LWDR} = \frac{\textbf{Tot. number of Lost workdays * 200,000}}{\textbf{Man-hours}}$$

Above mentioned calculations are beneficial when the new cobot is to be installed. The manufacturers can study the pattern and perform PFMEA accordingly.

Occurrence Ranking Sheet

The ranking is done by finding out the probability of a failure that occurred during the time when the system was running on assembly. Table 3 explains the occurrence ranking sheet.

Table 3: Occurrence ranking

Ranking	Effect	FMEA
10	Hazardous- No warning	1 in 10 (100 per 1000)
9	Hazardous- with warning	1 in 20 (50 per 1000)
8	High	1 in 50 (20 per 1000)
7	High	1 in 100 (10 in 1000)
6	Moderate	1 in 500 (2 per 1000)
5	Low	1 in 2000 (0.5 in 1000)
4	Very Low	1 in 10,000
3	Minor	1 in 100,000
2	Very Minor	1 in 1,000,000
1	None	Failure is eliminated through preventive measures or control

Below mentioned calculations are instrumental when the new cobot is to be installed on a new assembly line. The manufacturers can study the pattern by checking their history records to calculate the probability by poisons distribution and perform PFMEA accordingly.

Poisson's distribution is typically used to calculate the possibility of the occurrence of an event (accidents involving cobots) over a finite interval of time. To model a system using Poisson's distribution, the following conditions should be satisfied.

1. The occurrence of accidents should be independent of each other.
2. The interval for which the accident probability is calculated should be the same for all intervals.

$$\mathbf{p(x)} = \frac{e^{-\lambda}\lambda^{x}}{X!}$$

Where λ is the mean of the number of accidents;

P describes the probability of X;

X is the counts of the accident in a particular interval.

This equation can be used to forecast safety events throughout the year if recorded data is only available for a few months.

Detection Ranking Sheet

The ranking is done by finding out the capacity of the system to detect problems. The ranking scale is in between very likely to detect to impossible to detect (low to high) as explained in Table 4.

Table 4: Detection ranking

Ranking	Effect	FMEA
10	Very Low	Currently out of detection capacity
9	Very Low	Failures that are not easily detected
8	Low	Failure detection by the operator using basic sensory organs (vision, audible)
7	Low	Failure detection by a human operator using primary tools such as a manual wrench
6	Moderate - Low	Failure detection by quality control gate/operator using go no go gages post-processing
5	Moderate	Detection of failure by quality control gate and operator using light and buzzer at the source
4	High	Failure is detected post-processing, and further processing is avoided
3	High	Failure is detected at the same workstation & further processing is avoided
2	Very High	Detection by process /automation control, preventive action is also taken by the manufacturer.
1	Almost certain	Detection not applicable; operation is mistake-proof

These ranking are used while assessing risk quantitatively as well as qualitatively.

Qualitative and quantitative analysis

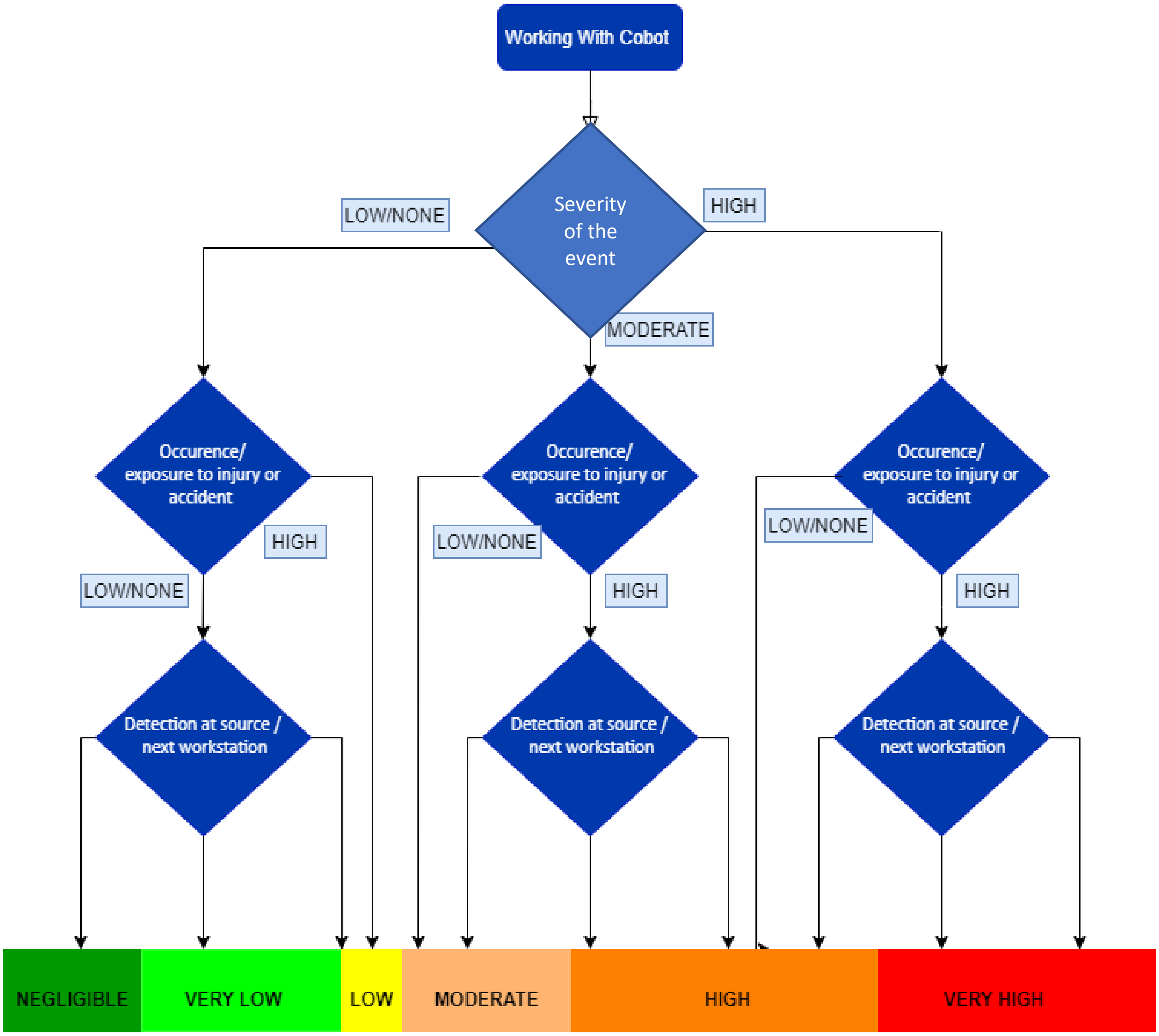


Figure 12: Risk analysis flowchart

Figure 12 presents a flowchart that can be used to detect the ranking of risk. This is a qualitative technique to predict the type of risks human cobot interaction/operation involves. The more sophisticated approach, i.e., a quantitative approach, is used to calculate the amount of risk involved. It can be calculated as RPN (risk priority number) as given below:

$$\mathbf{RPN = Severity\ of\ the\ accident * Occurence\ of\ the\ event * Detection}$$

Where RPN is a score generated by a quantitative method of risk assessment to determine the priority of the risk and potential failure modes in an FMEA caused in assembly lines due to failures of cobots, the generated score helps the manufacturing team to prioritize risks to decide immediate corrective and preventive action. The RPN number does not usually have USL or LSL (upper specific limit or lower specific limit), but as the number goes above 100, the priority is to reduce it by changing the process involving human cobot interaction using recommended corrective actions. Usually, the RPN is higher due to the absence of advanced detection systems for process control to investigate the problems at the workstation itself. Hence, it is very necessary to understand the CN (Critical number) when the RPNs of the two failure modes are the same where CN is a critical number in risk analysis which is obtained by multiplying severity and occurrence.

$$\mathbf{CN = Severity\ of\ the\ accdient * Occurence\ of\ the\ event}$$

For example, in Table 5: RPN and CN calculation, the two different failure modes have the same RPN, that is. 48. Hence, the failure mode having the highest CN will be given a priority. The CN score is calculated as explained in Figure 13.

Table 5: RPN and CN calculation

Failure no.	**Severity**	**Occurrence**	**Detection**	**RPN**	**CN**
1.	6	4	2	48	24
2.	4	4	3	48	16

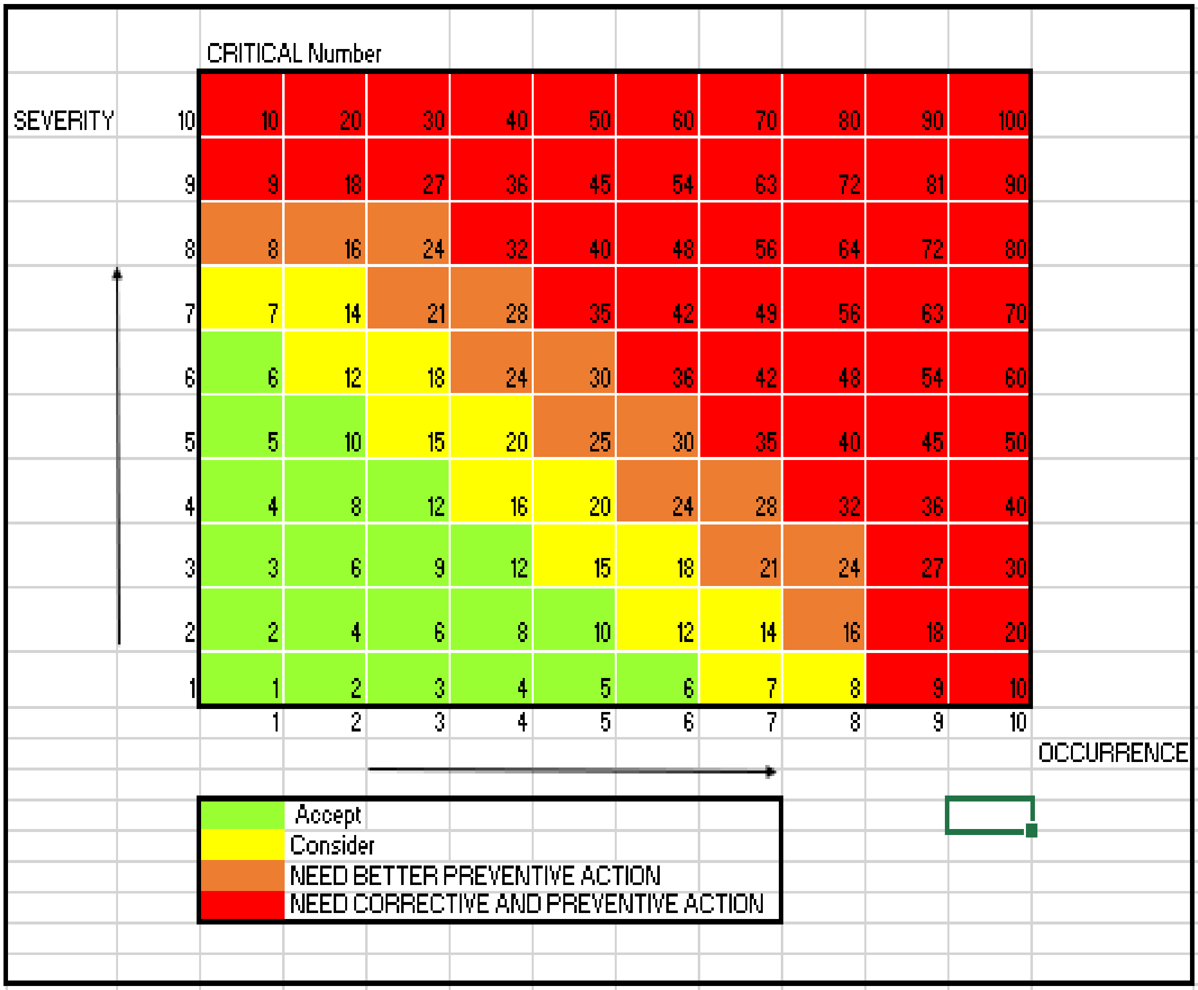


Figure 13: CN matrix

For PFMEA, failure modes for all levels are listed along with the type and effect of failure. These events are then ranked based on their severity, frequency by which they occur and if these failures were detected as explained in figures below.

For level 1, the PFMEA will not have a variety of failures and potential causes for the same but will have a high number of occurrences and detection as level 1 is complete manual assembly. It may cause future problems associated with back injuries for the operators. This level will have a very high ranking under the detection column as the assembly does not include any automatic or camera-based inspection systems, as shown in Figure 14.

Process Step/Input	Potential Failure Mode	Potential Failure Effects		SEVERITY (1 - 10)	Potential Causes	OCCURRENCE (1 - 10)	Current Controls	DETECTION (1 - 10)	RPN	Recommended Detection System
What is the process step, change	In what ways could the step,	What is the impact on the customer/ employee if	Type of Failure		What causes the step, change or feature to go wrong? (how		What controls exist that either prevent or detect the failure?			What are the recommended actions for reducing the occurrence of the cause or improving
Pick and Place Object	No Picking	NA -customer ; Lost Takt Time for the Operations	Operation Failure / Back injury /excess motion	3	Not enough takt time / backpain /excess motion	7	Human Vision	8	168	Vision System on assembly line equipped with alarms and ability to stop the line.
	No Placing	NA -customer ; Lost Takt Time for the Operations	Operation Failure / Back injury / excess motion	3	Not enough takt time / backpain /excess motion	7	Human Vision	8	168	Vision System on assembly line equipped with alarms and ability to stop the line.
	Late Picking/ Placing	NA -customer ; Lost Takt Time for the Operations	Fail to match operating speed / excess motion	3	Not enough takt time / backpain /excess motion	8	Human Vision	8	192	NO
	Damaged materials	Might get damaged/ bad product	No proper Checking	5	Rough handeling by operators	6	Quality Inspection gate/ visual inspection	8	240	Vision System on assembly line equipped with alarms and ability to stop the line.

Figure 14:FMEA – level 1 (manual)

For level 2, the process FMEA will have a variety of failures and potential causes for the same and will have less RPN and CN since safety gate with the sensor is incorporated from the human cobot interaction perspective as explained in Figure 15.

Process Step/Input What is the process step, change or feature under investigation?	Potential Failure Mode In what ways could the step, change or feature go wrong?	Potential Failure Effects What is the impact on the customer/ employee if this failure is not prevented or corrected?	Type of Failure	SEVERITY (1 - 10)	Potential Causes What causes the step, change or feature to go wrong? (how could it occur?)	OCCURRENCE (1 - 10)	Current Controls What controls exist that either prevent or detect the failure?	DETECTION (1 - 10)	RPN	Recommended Detection System What are the recommended actions for reducing the occurrence of the cause or improving detection?
Pick and Place Object	No Picking / Placing	NA -customer ; Lost Takt Time for the Operations	Operation Failure	3	Control failure / Human error while programmimg the cobot	5	Human Vision	8	120	Vision System on assembly line equipped with alarms and ability to stop the line.
	Late Picking/ Placing	NA -customer ; Lost Takt Time for the Operations	Electronic / Control Failure	3	Communication lag or programming error / worn out sensors	5	No detection	10	150	NO
	Damaged materials/ previous products	Might get damaged/ bad product	Operation Failure	5	Rough handeling by cobot arms / damaged sensors	6	Quality Inspection gate/ Operator	6	180	Vision System on assembly line equipped with alarms and ability to stop the line.
	Directly hitting other objects/ Operators	Very unsafe work condition for the operators	Control and Safety Failure or improper installation	10	Control Failure or No safe space calculation whilw installation	5	Safety Gate sensor	3	150	Beeping sensor/ warning if cobot is too close to human operator
	Improper mechanical movements	Might hurt Operators/ restrictive gate. Disrupt proper assembly operation	Mechanical Failure	8	Lack of mechanical maintainance or mechanical failure	1	Restrictive gate and Safety sensors	3	24	NO
	Undesireable action or disrupted operations	Damaged product or Hazardous behaviour towards operator/ restrictive gate	Control and Safety Failure	9	Power system failure, Communication failure	1	No detection	10	90	NA
	Failure to start the process	NA -customer ; Lost Takt Time for the Operations	Electronic / Control Failure	4	Servo Motor/ electronic Failure	2	No detection	10	80	Motion sensing or photography based inspection techniques

Figure 15:FMEA – level 2 (human and cobot with safety gate)

Process Step/Input What is the process step, change or feature under investigation?	Potential Failure Mode In what ways could the step, change or feature go wrong?	Potential Failure Effects What is the impact on the customer/ employee if this failure is not prevented or corrected?	Type of Failure	SEVERITY (1 - 10)	Potential Causes What causes the step, change or feature to go wrong? (how could it occur?)	OCCURRENCE (1 - 10)	Current Controls What controls exist that either prevent or detect the failure?	DETECTION (1 - 10)	RPN	Recommended Detection System What are the recommended actions for reducing the occurrence of the cause or improving detection?
Pick and Place Object	No Picking / Placing	NA -customer ; Lost Takt Time for the Operations	Operation Failure	3	Control failure / Human error while programmimg the cobot	1	Human Vision	8	24	Vision System on assembly line equipped with alarms and ability to stop the line.
	Late Picking/ Placing	NA -customer ; Lost Takt Time for the Operations	Electronic / Control Failure	3	Communication lag or programming error / worn out sensors	2	Human Vision	8	48	NO
	Damaged materials/ previous products	Might get damaged/ bad product	Operation Failure	5	Rough handeling by cobot arms / damaged sensors	5	Quality Inspection gate/ Operator	6	150	Vision System on assembly line equipped with alarms and ability to stop the line.
	Directly hitting other objects/ Operators	Very unsafe work condition for the operators	Control and Safety Failure or improper installation	10	Control Failure or No safe space calculation whilw installation	1	No Sensor	10	100	Beeping sensor/ warning if cobot is too close to human operator
	Improper mechanical movements	Might hurt Operators/ restrictive gate. Disrupt proper assembly operation	Mechanical Failure	8	Lack of mechanical maintainance or mechanical failure	2	No detection	10	160	NO
	Undesireable action or disrupted operations	Damaged product or Hazardous behaviour towards operator/ restrictive gate	Control and Safety Failure	9	Power system failure, Communication failure	4	No detection	10	360	NA
	Failure to start the process	NA -customer ; Lost Takt Time for the Operations	Electronic / Control Failure	4	Servo Motor/ electronic Failure	0	No detection	10		NA

Figure 16: FMEA- level 3 (human and cobot)

For level 3, the process FMEA will have a variety of failures and potential causes for the same and will have max RPN and CN as compared to other levels since there is an absence of restrictive gate (additional safety), as shown in

Figure 16.

For level 4, the process FMEA will have a variety of failures and potential causes for the same but will have a low number of safety incidents and accidents since it is a completely automatic assembly as explained in Figure 17.

Process Step/Input	Potential Failure Mode	Potential Failure Effects	Type of Failure	SEVERITY (1 - 10)	Potential Causes	OCCURRENCE (1 - 10)	Current Controls	DETECTION (1 - 10)	RPN	Recommended Detection System
What is the process step, change or feature under investigation?	In what ways could the step, change or feature go wrong?	What is the impact on the customer/ employee if this failure is not prevented or corrected?			What causes the step, change or feature to go wrong? (how could it occur?)		What controls exist that either prevent or detect the failure?			What are the recommended actions for reducing the occurrence of the cause or improving detection?
Pick and Place Object	No Picking / Placing	NA -customer ; Lost Takt Time for the Operations	Operation Failure	3	Control failure / Human error while programmimg the cobot	5	No detection	10	150	Vision System on assembly line equipped with alarms and ability to stop the line.
	Late Picking/ Placing	NA -customer ; Lost Takt Time for the Operations	Electronic / Control Failure	3	Communication lag or programming error / worn out sensors	5	No detection	10	150	NO
	Damaged materials/ previous products	Might get damaged/ bad product	Operation Failure	5	Rough handeling by cobot arms / damaged sensors	6	Post processing inpsection	9	270	Vision System on assembly line equipped with alarms and ability to stop the line.
	Directly hitting other objects/ Operators	Very unsafe work condition for the operators	Control and Safety Failure or improper installation	10	Control Failure or No safe space calculation whilw installation	4	Safety Gate sensor	3	120	Establishment of more safety sensors
	Improper mechanical movements	Might hurt Operators/ restrictive gate. Disrupt proper assembly operation	Mechanical Failure	8	Lack of mechanical maintainance or mechanical failure	1	Safety Sensors (but not easily detectable)	9	72	NO
	Undesireable action or disrupted operations	Damaged product or Hazardous behaviour towards operator/ restrictive gate	Control and Safety Failure	9	Power system failure, Communication failure	1	No detection	10	90	NA
	Failure to start the process	NA -customer ; Lost Takt Time for the Operations	Electronic / Control Failure	4	Servo Motor/ electronic Failure	2	No detection	10	80	NA

Figure 17: FMEA – level 4 (no humans involved)

Above generated FMEA for different level by this study lets user know the following

- Potential Cobot related failure concerns

- Operator Safety
- The level safety to be followed assembly line in the near future
- Process deficiency to keep the operator safe in the manufacturing environment
- Detects Risk Priority of the failure mode and helps manufacturers to take corrective action

Behavioral Risk Analysis

This section focuses on behavioral risk patterns when human operators are working around cobots. Although PFMEA detects and helps manufacturers to work on corrective actions to create an accident-free and safe environment for fluent human cobot interaction, there are a few human behavior aspects that are usually ignored while working on the floor.

Perception of safety depends on various factors, and it varies from person to person. It is difficult to find out the root cause of any given unsafe behaviors or unsafe act that contains high-risk behaviors. And hence, this study also focuses on those aspects to recommend condition-specific training for the operators. For working with an industrial collaborative robot's environment, the following elements are the most concerning human behavioral characteristics for any given manufacturing environment set up containing industrial cobots.

1. Absence of anticipating significantly harmful or dangerous consequences – According to the researchers, it is common to find out the heightened perception of any potential hazard in the users who have experienced some incident within last two years than those who have not. They cannot foresee the potential hazards, and this is called a lack of anticipating, significantly unsafe working conditions or situations containing high severity risk index.

2. Perception heightened or hyped sense of safety – People tend to be more careless when they know they are well protected or they percept that they are within the safety range. In short, they feel comfortable taking risks when their perception of security is heightened. In the manufacturing system, a machine that is considered safe and is equipped with safety interlocks should not encourage the operator to repair or clean the machine when it is running. Cobot manufacturers strive to give maximum safety protection; they try to make the system smart, which often makes people very comfortable around cobots where the risks are precepted less risky.

3. Daily routine or habitual working conditions are precepted less risky than the value of risk index they carry- Every time operator or user performs something risky or creates an unsafe working condition and does not hurt themselves, their perception about the cobots and risk associated with it, changes completely. The risk is the same or maybe more every time, but it is underestimated due to the human nature aspect. Similarly, when an operator continuously works with cobot for years, it becomes his/ her daily routine, and the perception of risky is impacted on a vast level. The cobots, machines, robots seem risk-free to these people.

Hence to target these aspects and to have a safer workplace environment for operators, this study proposes to observe heart rate or HRV, breathing rate to calculate the level of stress and to relate it to CN to determine the training needed for the manufacturers or the operators. "The breathing rates could be higher during the stressed session than that of normal or rest sessions," according to Moses et al. (Moses, Luecken, & Eason, 2007). Similarly, increased Heart Rate also increases stress for 95% of the population, which then causes other heart and blood pressure conditions. The manufacturing industry is one of the top sectors where people have high-stress levels due to long working hours, high demands, job control, and ergonomics. Thus, this study helps manufacturers to design training programs for the operators based on the level of stress and severity of the job while working around cobot to eliminate additional stress. The proposed method asks the manufacturer to have daily HR (heart rate) and RR (respiratory /breathing rate) checkup for the operators (working with cobot) when the cobot is newly installed or cobot-human training is to be given. The developed safety assessment tool generates the required training type automatically once the values are entered, and the severity of the assigned task is determined, depending on the operator's stress level and the level of automation.

CHAPTER 3. RESULT

This safety assessment tool can help manufacturers to evaluate risk quantitatively as well as qualitatively when using lightweight cobot. Additionally, this theoretical approach proposes human interaction with a lightweight cobot equipped with a safety sensor and detection system to evaluate risk and its effect on productivity.

The developed tool generates the following results for different levels of automation based on RPN and CN. The action column suggests if the score generated by the tool is acceptable or not. The changes in corrective and preventive action are suggested based on CN scores.

Severity -CRITICAL	Severity	CRITICAL NUMBER	ACTION	RPN
3-21	3	21	NEED BETTER PREVENTIVE ACTION	168
3-21	3	21	NEED BETTER PREVENTIVE ACTION	168
3-24	3	24	NEED BETTER PREVENTIVE ACTION	192
5-30	5	30	NEED BETTER PREVENTIVE ACTION	240

Figure 18:Recommended action and CN – level 1(manual)

Severity - CRITICAL NUMBER	Severity	CRITICAL NUMBER	ACTION	RPN
3-15	3	15	Consider	120
3-15	3	15	Consider	150
5-30	5	30	NEED BETTER PREVENTIVE ACTION	180
10-50	10	50	NEED CORRECTIVE AND PREVENTIVE ACTION	150
8-8	8	8	NEED BETTER PREVENTIVE ACTION	24
9-9	9	9	NEED CORRECTIVE AND PREVENTIVE ACTION	90
4-8	4	8	Accept	80

Figure 19: Recommended action and CN – level 2 (human and cobot with safety gate)

Severity - CRITICAL NUMBER	Severity	CRITICAL NUMBER	ACTION	RPN
3-15	3	15	Consider	120
3-15	3	15	Consider	120
5-30	5	30	NEED BETTER PREVENTIVE ACTION	180
10-50	10	50	NEED CORRECTIVE AND PREVENTIVE ACTION	500
8-8	8	8	NEED BETTER PREVENTIVE ACTION	80
9-9	9	9	NEED CORRECTIVE AND PREVENTIVE ACTION	90
4-8	4	8	Accept	80

Figure 20: Recommended action and CN – level 3 (human and cobot)

Severity - CRITICAL NUMBER	Severity	CRITICAL NUMBER	ACTION	RPN
3-15	3	15	Consider	150
3-15	3	15	Consider	150
5-30	5	30	NEED BETTER PREVENTIVE ACTION	270
10-40	10	40	NEED CORRECTIVE AND PREVENTIVE ACTION	120
8-8	8	8	NEED BETTER PREVENTIVE ACTION	72
9-9	9	9	NEED CORRECTIVE AND PREVENTIVE ACTION	90
4-8	4	8	Accept	80

Figure 21:Recommended action and CN – level 4 (no humans involved)

From Figure 22, it is clearly understood that the most optimal and safe solution to implement in any assembly is level-2 of human-cobot interaction. It has an additional safety feature, and which can help protect employees with catastrophic safety accidents and thus improving fluency in human cobot collaboration.

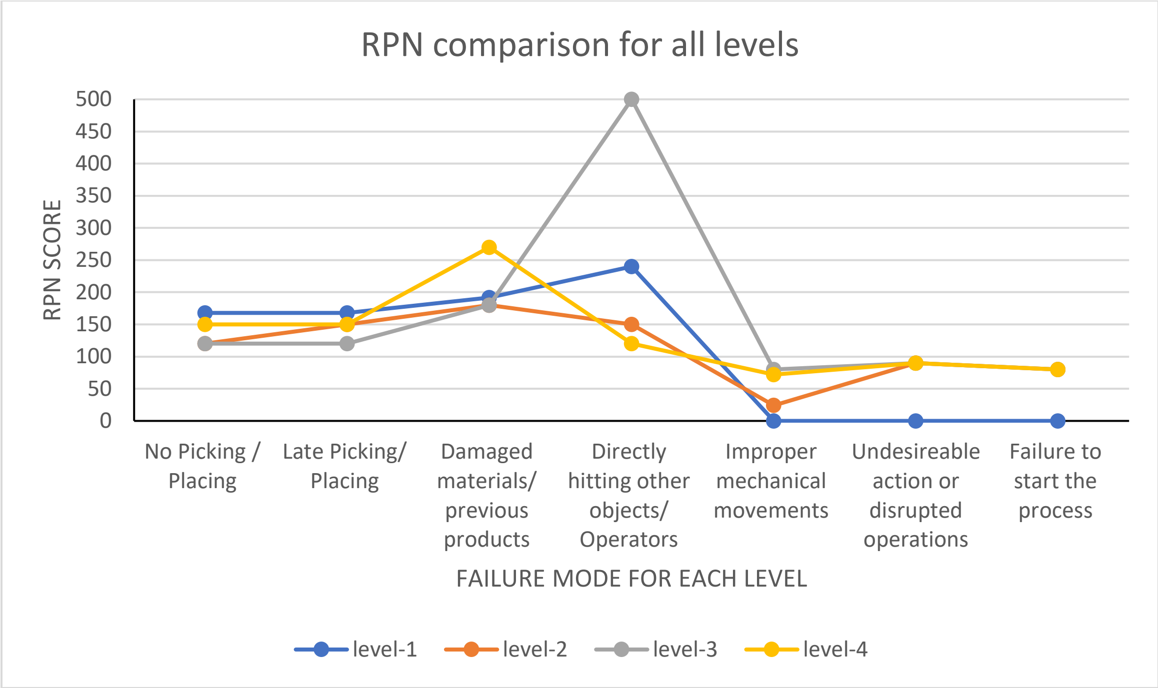


Figure 22: Comparison of level-1, level-2, level-3, and level-4

This study can be useful for the manufacturers and EHS managers to evaluate risk before installing cobots on the assembly line. This safety and risk evaluation can be used to make decisions about which risks need to be addressed while using lightweight cobot based on the estimate of metrics identified in risk analysis. This evaluation may be quantitative, qualitative, or both. Once quantitative estimates of the metrics (for example, RPNs in an FMEA) have been computed, they should be compared with the level of risk or risk criteria already in place or critical number. This tool can be used to determine whether the level of risk is acceptable. Qualitative assessment of risk can include determining the level of severity of potential harm (for example, catastrophic, critical, or minimal) as in a risk matrix.

Minimizing and reducing risk can be attained by implementing actions that minimize the likelihood of the risk occurring. Furthermore, to control the risk, human operators and their comfort around cobots have to be taken into consideration. The understanding behavioral aspect of human operators working around cobots can be studied in depth to further reduce cognitive load.

Level	Heart rate	Heart rate	Respiration Rate	Stress
L-3	60	60	12	Normal
L-3	50	50	10	Normal
L-3	120	120	24	HIGH / VERY HIGH
L-3	80	80	16	Normal
L-3	100	100	20	HIGH / VERY HIGH
L-3	60	60	12	Normal
L-3	70	70	14	Normal

Figure 23:HR and RR calculating stress

This study tries to connect different heart rate patterns based on their behaviors to stress in the workplace, which is later used to suggest operator training based on the actual Severity and critical Number as explained in Figure 23. The suggested Corrective actions/training suggested are as follows.

1. Situation Awareness training
2. Trust in Automation training
3. Operator being overutilized
4. Safety Zone Reassessment
5. Safety cell requirement
6. The necessity to change Takt/ operation time

7. Need to have CAPA (corrective action and preventive actions both)

Level-Stress-severity	Level	Stress	severity	Training Required
L-3- Normal -3	L-3	Normal	3	Accept
L-3- Normal -9	L-3	Normal	9	Situational Awareness Training required + CAPA
L-3- HIGH / VERY HIGH -5	L-3	HIGH / VERY HIGH	5	Safety Zone Reassessment required + CAPA
L-3- Normal -10	L-3	Normal	10	Situational Awareness Training required + CAPA
L-3- HIGH / VERY HIGH -8	L-3	HIGH / VERY HIGH	8	Safety Cage/ gate/ cell required
L-3- Normal -10	L-3	Normal	10	Situational Awareness Training required + CAPA
L-3- Normal -4	L-3	Normal	4	Need better Preventive Action

Figure 24: Safety training suggestions

Figure 24 shows an example of training suggested for operated based on the level of automation and stress involved in the assembly operation. The pieces of training suggested are not only for the operators but also manufacturers when the operation takt times are to be changed by rearranging assembly operations and to know if the operators were over-utilized while working with a cobot. These suggestions will help manufacturers and operators to take preventive actions and precautions in order to prevent similar accidents or causalities from happening in the future.

CHAPTER 4. CONCLUSION AND DISCUSSION

The overall goal of focusing on a systematic approach to perform safety and risk analysis is to evaluate risks by easy methods and suggest methods to curtail them. This approach is useful to minimize and ultimately eliminate risk by controlling and monitoring it using CAPA quality techniques. This tool is made by keeping users' convenience and accessibility in mind and can be used to perform FMEAs for human-cobot operations for different levels of automation to identify and evaluate risk.

It is better to include the user or the person who is going to use the system while doing a risk assessment to understand a broader perspective about the situation-based safety according to the safety standard. On any assembly or operation lines in any manufacturing industry, the system owner or user can be inspectors, operators, quality police, assembly and operation managers, manufacturing engineers. They may or may not have the aptitude and ability to recognize the risks or unsafe working conditions with or without knowing the solution to resolve it based on knowledge, rules, or experience. Therefore, proactive measures may or may not be provided to avoid potential hazards. Hence, this study tries to suggest training based on operator behavioral aspects to have additional safety before there is the scope of injury or workplace involving safety hazard.

On the other hand, trying to create safety at the cost of productivity is equally destructive. Implementing additional layers of safety can slow down productivity, for example, the level-2 safety can have 10 sec (opening and closing of the restrictive gate) of additional time per unit, and that may lead to slower productivity. For level - 4 automatic assembly, the parts will need additional quality check post-processing, and that will lead to lean waste. Level-3 directly imposes a threat to the human operator even though the occurrence rate is very less. Hence, it depends on the product line, assembly type, and manufacturers to choose the level of safety without having to trade-off with productivity.

When it comes to the cost of lost productivity due to unsafe working conditions, it may cause several additional costs to manufacturing operations. The additional cost includes emergency response team cost, medical cost, union laws, absence of injured workers, morals of other workers, etc.

The cobot opens more probability for accidents because they are not caged or do not usually have a presence of fencing around it. Therefore, it is necessary to take the decisions with a primary focus on safety when the level of automation is to be incorporated. The systematic approach used in the study suggests that the risk assessment if used at an initial stage of process design and development (before process and product validation), allows integrating safety standards or interlocks (ISO TS 15066) that safeguard production quality. To conclude, the automated safety assessment tool proposed in this research urges to analyze risk in the development of a human cobot interaction considering the fact that it is almost impossible to remove inherent risk from the manufacturing industry or in any operation. This trade-off can be settled by creating a safe production environment and choosing suitable methods of human cobot interaction in order to create a safe environment for the workers.

CHAPTER 5. FUTURE WORK

To validate the proposed safety assessment method using lightweight cobot interaction with the human operators, the safety gate (already built) can be equipped with various proximity sensors and can be actuated by every 10 or 20 seconds depending upon the required application. This can also be a part of visual management in the factories by attaching red or green alarms.

For the future scope of the project, proximity sensors can be used to detect the presence of a human being while using operating and collaborative space. The operational range of this IR detector sensor is 10-80 cm. IR distance sensor provides an output in an analog signal form, which can be used as a proximity sensor. It is directly proportional to the distance between sensors.

With the help of Arduino code and the application used to control the cobot, we can have a repetitive motion to study the interaction between humans and lightweight cobots.

In order to avoid injuries in automation level -3, the application of smooth surfaces can be made at the gripper or the cobot body parts which come in contact with human hands while carrying out daily or assembly operations.

To improve safety and fluency in human cobot interaction, more intelligent automation is required, and some of the brands are working towards it. However, the new systematic safety approach should be developed, which covers safety assurance of human cobot interaction to identify the level of hazard and then develop safety standards, particularly for cobots industry.

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APPENDIX A. Demo of working cobot and the safety assessment tool

https://iastate.box.com/s/r1wdsm9vxhzmr2erm87wyiw9f2fqs7dr

This link contains a demo/video of the cobot, codes, images of both the cobots and the automated tool.

APPENDIX B. Example scenario

This shows an example scenario for using the safety assessment tool generated by this study.

Operation- Pick and Place without the restrictive gate.

1. Select the level of automation used or planning to use

Level	Presence of Human	Presence of Cobot	Caged/barricades
L-1	Yes	No	No
L-2	Yes	Yes	Yes
L-3	Yes	Yes	No
L-4	No	Yes	No

2. If using historical data, calculate severity and occurrence

Level	Near misses (Sensor- decides detection) per 10 days	Safety Incidents (decides occurrence)	No. Of products / 10 day	Near miss occurrence /1000	Occurrence/1000	Operation
L-3	22	3	6000	4	1	No Picking / Placing
L-3	53	10	6000	9	2	Late Picking/ Placing
L-3	0	32	6000	0	5	Damaged materials/ previous products
L-3	0	6	6000	0	1	Directly hitting other objects/ Operators
L-3	0	10	6000	0	2	Improper mechanical movements
L-3	0	23	6000	0	4	Undesireable action or disrupted operations
L-3	0	2	6000	0	0	Failure to start the process

3. Generate FMEA sheet with entered figures.

What is the process step, change or feature under investigation	In what ways could the step, change or feature go wrong?	What is the impact on the customer/ employee if this failure is not prevented or corrected?	Type of Failure	SEVERITY (1	What causes the step, change or feature to go wrong? (how could it occur?)	OCCURRENC 10)	What controls exist that either prevent or detect the failure?	DETECTION (	RPN	What are the recommended actions for reducing the occurrence of the cause or improving detection?
Pick and Place Object	No Picking / Placing	NA -customer ; Lost Takt Time for the Operations	Operation Failure	3	Control failure / Human error while programmimg the cobot	1	Human Vision	8	24	Vision System on assembly line equipped with alarms and ability to stop the line.
	Late Picking/ Placing	NA -customer ; Lost Takt Time for the Operations	Electronic / Control Failure	3	Communication lag or programming error / worn out sensors	2	Human Vision	8	48	NO
	Damaged materials/ previous products	Might get damaged/ bad product	Operation Failure	5	Rough handeling by cobot arms / damaged sensors	5	Quality Inspection gate/ Operator inspection	6	150	Vision System on assembly line equipped with alarms and ability to stop the line.
	Directly hitting other objects/ Operators	Very unsafe work condition for the operators	Control and Safety Failure or improper installation	10	Control Failure or No safe space calculation whilw installation	1	No Sensor	10	100	Beeping sensor/ warning if cobot is too close to human operator A safety gate opening and closing time to time.
	Improper mechanical movements	Might hurt Operators/ restrictive gate. Disrupt proper assembly operation	Mechanical Failure	8	Lack of mechanical maintainance or mechanical failure	2	No detection	10	160	NO
	Undesireable action or disrupted operations	Damaged product or Hazardous behaviour towards operator/ restrictive gate	Control and Safety Failure	9	Power system failure, Communication failure	4	No detection	10	360	NA
	Failure to start the process	NA -customer ; Lost Takt Time for the Operations	Electronic / Control Failure	4	Servo Motor/ electronic Failure	0	No detection	10		NA

Or use a sample FMEA sheet used for the appropriate level.

Process Step/Input What is the process step, change or feature	Potential Failure Mode In what ways could the step, change or feature go wrong?	Potential Failure Effects What is the impact on the customer/ employee if this failure is not prevented or corrected?	Type of Failure	SEVERITY (1 - 10)	Potential Causes What causes the step, change or feature to go wrong? (how could it occur?)	OCCURRENCE (1 - 10)	Current Controls What controls exist that either prevent or	DETECTION (1 - 10)	RPN	Recommended Detection System What are the recommended actions for reducing the occurrence of the cause or improving detection?
Pick and Place Object	No Picking / Placing	NA -customer ; Lost Takt Time for the Operations	Operation Failure	3	Control failure / Human error while programmimg the cobot	5	Human Vision	8	120	Vision System on assembly line equipped with alarms and ability to stop the line.
	Late Picking/ Placing	NA -customer ; Lost Takt Time for the Operations	Electronic / Control Failure	3	Communication lag or programming error / worn out sensors	5	Human Vision	8	120	NO
	Damaged materials/ previous products	Might get damaged/ bad product	Operation Failure	5	Rough handeling by cobot arms / damaged sensors	6	Quality Inspection gate/ Operator	6	180	Vision System on assembly line equipped with alarms and ability to stop the line.
	Directly hitting other objects/ Operators	Very unsafe work condition for the operators	Control and Safety Failure or improper	10	Control Failure or No safe space calculation whilw installation	5	No Sensor	10	500	Beeping sensor/ warning if cobot is too close to human operator A safety gate opening and
	Improper mechanical movements	Might hurt Operators/ restrictive gate. Disrupt proper assembly operation	Mechanical Failure	8	Lack of mechanical maintainance or mechanical failure	1	No detection	10	80	NO
	Undesireable action or disrupted operations	Damaged product or Hazardous behaviour towards operator/ restrictive gate	Control and Safety Failure	9	Power system failure, Communication failure	1	No detection	10	90	NA
	Failure to start the process	NA -customer ; Lost Takt Time for the Operations	Electronic / Control Failure	4	Servo Motor/ electronic Failure	2	No detection	10	80	NA

4. Enter HR or RR to detect stress level

Level	Heart rate	Heart rate	Respiration Rate	Stress		Normal
L-3	60	60	12	Normal		HIGH / VERY HIGH
L-3	50	50	10	Normal		Low
L-3	120	120	24	HIGH / VERY HIGH		
L-3	80	80	16	Normal		
L-3	100	100	20	HIGH / VERY HIGH		
L-3	60	60	12	Normal		
L-3	70	70	14	Normal		

5. Suggested CAPA actions

Severity - CRITICAL NUMBER	Severity	CRITICAL NUMBER	ACTION	RPN
3-15	3	15	Consider	120
3-15	3	15	Consider	120
5-30	5	30	NEED BETTER PREVENTIVE ACTION	180
10-50	10	50	NEED CORRECTIVE AND PREVENTIVE ACTION	500
8-8	8	8	NEED BETTER PREVENTIVE ACTION	80
9-9	9	9	NEED CORRECTIVE AND PREVENTIVE ACTION	90
4-8	4	8	Accept	80

6. Suggested Operator training based on severity and stress level

Level-Stress-severity	Level	Stress	severity	Training Required
L-3- Normal -3	L-3	Normal	3	Accept
L-3- Normal -9	L-3	Normal	9	Situational Awareness Training required + CAPA
L-3- HIGH / VERY HIGH -5	L-3	HIGH / VERY HIGH	5	Safety Zone Reassessment required + CAPA
L-3- Normal -10	L-3	Normal	10	Situational Awareness Training required + CAPA
L-3- HIGH / VERY HIGH -8	L-3	HIGH / VERY HIGH	8	Safety Cage/ gate/ cell required
L-3- Normal -10	L-3	Normal	10	Situational Awareness Training required + CAPA
L-3- Normal -4	L-3	Normal	4	Need better Preventive Action