|| Volume 2 || Issue 3 || October 2017 || ISSN (Online) 2456-0774

INTERNATIONAL JOURNAL OF ADVANCE SCIENTIFIC RESEARCH AND ENGINEERING TRENDS

Enhancing Patient Safety and Mobility: The Vital Role of Patient Transferring Devices Developed Through Scientific Analysis

Abhijit Dandavate[1], Bhushan Karamkar[2], Sandip A Kale[3], Vikram Avhad[4]
Asst. Prof., Mech. Engg. Dept, Dhole Patil College of Engineering, Pune [1,2,3,4]
abhidandavate@gmail.com, bhushankar22@gmail.com, mech.sandipkale@gmail.com,vikram03.avhad@gmail.com

Abstract: The Patient Transferring Device (PTD) assumes a pivotal role in ensuring optimal safety and seamless patient transfers between critical points, such as the movement to the Intensive Care Unit (ICU) and other vital treatment and hygiene locations within healthcare facilities. With patient well-being being the utmost priority, a systematic and scientific approach is adopted in the development of PTDs, leveraging sophisticated methodologies like Failure Mode and Effects Analysis (FMEA). FMEA enables meticulous risk assessment and identification of potential failure points, thereby ensuring the highest standards of safety and efficacy. By employing this rigorous analytical tool during the PTD design process, healthcare providers can mitigate potential hazards and enhance patient care, solidifying the device's critical role in modern healthcare settings. Various PTDs are compared and observed that the "Air Cushion" patient transfer device scored highest overall weightage of 7.8 out of 10, indicating its superior performance across the selected criteria. The analysis results show that the induced maximum stress is 1.5 MPa which is less than the permissible stress and hence the components are within the safe limits as per the analysis.

Keywords: *Patient Transferring Device, Safety, Safety, FMEA, Risk Priority Number.*

Introductions:

Failure Modes and Effects Analysis (FEMA)

The Failure Mode and Effects Analysis (FMEA) is a structured and systematic methodology designed to proactively identify, evaluate, and manage potential failures within systems orprocesses and their potential impact on operations. By scrutinizing each failure mode, FMEA aims to quantify the likelihood and severity of possible consequences, thus aiding organizations in risk management endeavors. The implementation of FMEA offers substantial advantages in risk reduction and control. Organizations can preemptively address weaknesses and vulnerabilities in their systems, leading to an overall improvement in safety, quality, and reliability of their products and services. Moreover, FMEA promotes a culture of continuous improvement, encouraging teams to be vigilant in identifying and addressing potential failure points. Through the application of FMEA, companies can optimize resource allocation, reduce downtime, and prevent costly errors, ultimately enhancing customer satisfaction and loyalty. Thecomprehensive understanding of potential risks gained from FMEA empowers decision-makers to make informed choices, fortifying the foundation of successful and resilient operations in an ever-changing business landscape.

FMEA Procedure:

The evaluation of failure probability through the FMEA process occurs in two distinct stages, each contributing crucially to risk assessment and management. In the initial stage, potential failures within a system are methodically identified, with a keen focus on comprehending the potential severity of their effects on overall performance. This meticulous study allows teams to prioritize risks and allocate resources effectively to mitigate high-impact failure modes. The second stage involves the Failure Mode and Effects Criticality Analysis (FMECA), which builds upon the insights gained from the FMEA. FMECA delves further into the quantification of risks associated with each identified failure mode. Through systematic measurement of both severity and the probability of failure effects, FMECA provides a more detailed and nuanced understanding of the overall risk landscape. Together, these two analytical methods offer invaluable insights for informed risk management decisions. By understanding the critical failure modes and their respective probabilities, organizations can develop targeted mitigation strategies and optimize resources for the most significant risks, ultimately enhancing the reliability, safety, and performance of complex systems and processes.

1. Identify the system or process to be analyzed.
2. Identify the potential failure modes of the system or process.
3. Estimate the severity of each failure mode.
4. Estimate the occurrence of each failure mode.
5. Estimate the detection of each failure mode.
6. Calculate the risk priority number (RPN) for each failure mode.
7. Take corrective action to reduce the risk of each failure mode.
8. Repeat steps 2-7 for each failure mode.
9. Review and update the FMEA as needed.

Here is a more detailed explanation of each step:

1. Identify the system or process to be analyzed. This could be a new product, a manufacturingprocess, or a healthcare procedure.
2. Identify the potential failure modes of the system or process. A failure mode is any way that the system or process could fail to meet its desired outcome.
3. Estimate the severity of each failure mode. The severity of a failure mode is the likelihood of it causing harm to the patient, the caregiver, or the environment.
4. Estimate the occurrence of each failure mode. The occurrence of a failure mode is the likelihoodof it happening.
5. Estimate the detection of each failure mode. The detection of a failure mode is the likelihood ofit being detected before it causes harm.
6. Calculate the risk priority number (RPN) for each failure mode. The RPN is a measure of the overall risk of each failure mode. It is calculated by multiplying the severity, occurrence, anddetection ratings.
7. Take corrective action to reduce the risk of each failure mode. The corrective action should beaimed at reducing the severity, occurrence, or detection of the failure mode.
8. Repeat steps 2-7 for each failure mode. The FMEA process should be repeated for all of thefailure

modes in the system or process.

9. Review and update the FMEA as needed. The FMEA should be reviewed and updated regularlyto ensure that it is still accurate and up-to-date.

Risk Priority Number (RPN)

Risk prioritization of potential failures is accomplished through the utilization of the Risk Priority Number (RPN) methodology. This involves a comprehensive assessment of three critical factors: occurrence, severity, and detection, each rated on a scale from 1 to 10. By multiplying these ratings, the RPN value for each failure mode is determined, enabling the identification of higher-priority failure modes with elevated RPN values. Subsequent to the identification process, appropriate preventive measures, also known as solutions, are devised and implemented to address the recognized failures. The RPN calculation is diligently performed for all potential failure causes, facilitating the systematic ranking of causes and guiding the formulation of effective corrective actions. Notably, RPN values exceeding 125 signify the need for special attention, as these failure modes present significant risks that require immediate action. Additionally, any failure mode with severity rankings ranging from 9 to 10 always demands meticulous consideration, ensuring that robust mitigation strategies are put in place to safeguard against adverse consequences. By diligently following this risk assessment and management process, organizations can proactively address vulnerabilities, optimize system reliability, and maintain the highest levels of quality and safety in their operations.

Occurrence:

The initial assessment of the "Occurrence" ranking involves a subjective estimation of the likelihood of the cause of failure occurring and resulting in the potential failure mode experienced by the end user or customer. To adjust the Occurrence ranking at a specific design level, two actions can be taken: Implement design changes to minimize the likelihood of the cause of failure leading to the specific failure mode. Enhance production methods and control systems to prevent the occurrence of the cause of failure. By implementing these actions, the Occurrence ranking can be adjusted to reduce the possibility of failure modes arising from the identified causes. To quantify the probability of failure, historical data is essential for a more accurate ranking. If historical data is unavailable, similar systems and working conditions can be used to estimate the ranking. The "Effect" can be determined based on operating hours, days, cycles, or other components that allow for a consistent calculation approach. The "Comment" can consider local conditions. For example, in a specific project, the industry modified the statistical method for ranking 1 through 5 to better reflect the number of cycles of the analyzed system (Refer Appendix VI).

Severity / Criticality Assessment:

In FMEA, severity evaluation is typically conducted using a numeric rating scale, often ranging from 1 to 10, where lower ratings indicate minimal severity, and higher ratings signify significant severity. The assigned rating reflects the potential impact of the failure mode on the process or product, taking into account factors such as safety, regulatory compliance, customer satisfaction, and financial consequences. Expert teams with in-depth knowledge of the analyzed process or product usually perform the severity assessment. Their expertise enables a comprehensive evaluation of the potential ramifications associated with each failure mode. Each failure mode is evaluated based on its potential severity, and a numerical rating is assigned. The team also considers the likelihood of the failure mode occurring and its detectability before becoming a problem. After completing the severity assessment, the FMEA team prioritizes potential failure modes based on their severity ratings and takes necessary steps to mitigate risks associated with the highest-priority failure modes. Actions to address failures may include processor product redesign, implementation of additional controls or safeguards, or development of contingency plans for effective management of potential failures. The criticality assessment aims to evaluate the importance or criticality of items or components within a system or process. This assessment helps identify which items or components play the most crucial role in the overall performance and reliability ofthe system, allowing organizations to focus their efforts on key areas to ensure optimal system functionality and safety.

Detection

The evaluation of the likelihood of early detection of failure causes or failure modes before product release is conducted using a rating scale from 1 to 10. This assessment assumes that the failure cause has already occurred and focuses on the effectiveness of existing controls in detecting the failure promptly. It is crucial to recognize that sporadic quality checks may not be sufficient to identify individual failures andmay not heavily influence decision ranking. However, statistical sampling can be beneficial in detecting failures related to the overall process. By utilizing the rating scale, the FMEA team can gauge how well the current detection mechanisms can identify potential failures before they escalate into critical issues. This allows organizations to identify areas where detection controls are weak and implement improvements to enhance early failure detection, thus reducing the likelihood of failures reaching customers and causing adverse impacts. The goal of this assessment is to bolster the overall risk management process and ensure that potential failure modes are adequately addressed and detected in a timely manner. By doing so, organizations can enhance product quality, customer satisfaction, and overallreliability, ultimately leading to improved business performance and reputation.

Recommended Action

Positive and separately identified actions A design change to the component.

A change of process.
Increased quality control.
Ranking index scales

The following ranking index scales are used to evaluate the RPN of elements:

Severity:

1: No significant effect.

2: Minor effect, no safety hazard.

3: Moderate effect, potential safety hazard. 4:
Major effect, significant safety hazard. 5:
Catastrophic effect, severe safety hazard.

Occurrence:

1: Very unlikely to occur.
2: Unlikely to occur. 3:
Possible to occur. 4:
Likely to occur.
5: Very likely to occur.

Detection:

1: Very easy to detect.

2: Easy to detect.

3: Moderately easy to detect.

4: Difficult to detect.

5: Very difficult to detect.

The RPN is calculated by multiplying the severity, occurrence, and detection ratings. For example, a failure mode with a severity rating of 3, an occurrence rating of 4, and a detection rating of 3 would have an RPN of 36.

The higher the RPN, the greater the risk. The FMEA team should focus on the failure modes with the highest RPNs.

The FMEA team can take a number of actions to reduce the risk of failure, such as:Design changes

Process changes Increased
quality controlTraining

Preventive maintenance
The FMEA team should also track the effectiveness of the corrective actions taken. The FMEAshould be reviewed and updated regularly to ensure that it is still accurate and up-to-date.

Tables 1: FMEA for RPN of various subassemblies are given on sheet next page

FMEA SHEET

PROJECT : PATIENT TRANSFERRING DEVICES

FAILURE MODE	EFFECT OF FAILURE	SEVERITY	CAUSES OF FAILURE	CURRENT DESIGN CONTROL/SPEC	PROBABILITY OF OCCURRENCE	DETECT-ABILITY
Column Breaks and falls	Patient hurt/injured	9	Column Weak	Design for 4x load	2	5
		9	Column mounted wrong	None	7	8
		9	Double fault not done	None	4	8
Imbalance causes fall C Breaks and falls	Patient hurt/injured	9	Rotating Device support mounted wrong	None	7	6
		9	Wrong usage	None	8	8
		9	Overweight use	None	4	8
		9	Wrong CG position by design	Current design fine for sling but wrong in others	7	7
	Patient hurt/injured	9	Bending process causes C to develop hidden defects	None	5	8
		9	C Weak	FOS = 4	2	5
		9	Overload	Designed for 95% weight	3	8
Sling : Patient swings when moved	Patient insecure	4	long suspensions	4 point support helps provide rigidity	3	3
		4	Creep in Sling over time	None	6	8
Sling : breaks/tears	Patient hurt/injured	9	Fatigue	None	7	7
		9	Misuse	None	7	7
Air Cushion: Air does not fill	Patient Discomfort/slightly hurt	6	Pump Failure	Proven/ Reliable company off the shelf pump to be chosen	4	2
		6	Leakage	Minor leakages can be tackled by leaving pump on	7	2
		6	Air path choked	None	8	7
Vertical lift does not work	Patient stranded	7	Power failure	None	8	8
		7	Overload	Designed for 95% weight	3	8
Indian Toilets not accessible	Utility lost	7	Not designed	Not designed	9	7

Inter room transfer not possible	Utility lowered/lost	7	Width of base high	Designed fro 2.5 feet doors	3	8
		7	Step between rooms	Designed fro 25mm obstacles	3	8
Roll Over : Patient rolls out !	Patient injured	9	Support handle not moved in (misuse)	None	5	5
Support frame unlocks	Patient injured /hassled	8	Lock joint fails	Interlock by interference and not links	3	7

Images of The Models Designed using FMEA

The following models have been developed based on the sub-system flow down.

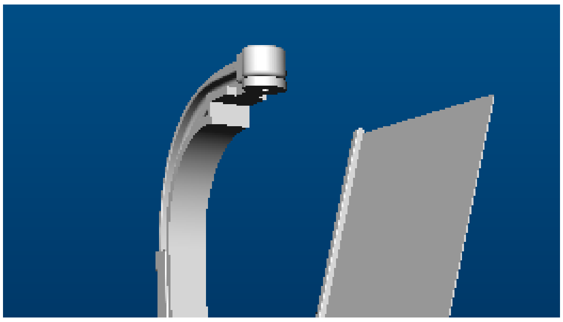


Figure 2: Rollover.

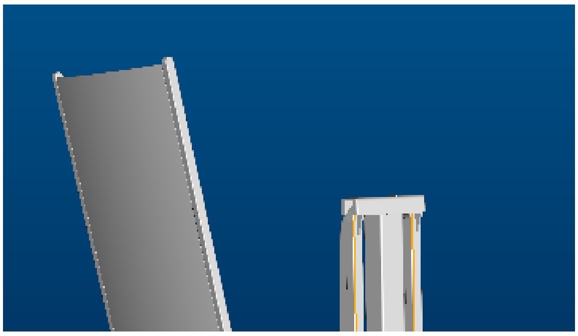


Figure 3: Semi Rigid

Figure 4: Sling

Figure 5: Air Cushion

Concept Generation

a) The following concepts were generated through a brainstorming session:
Roll Over (Hard bottom Convertible) Concept. (Refer fig. 2)

The roll-over concept, known as Hard Bottom Convertible, offers a versatile solution for patienttransfers. This innovative concept can be converted into a stretcher format, facilitating seamless movement of patients between locations. It is particularly preferable for class-II or class-III patients, addressing their specific needs during transfers.

The roll-over concept incorporates a rigid frame with a hard board support that can be lowered onto a bed. This enables the patient to rollover and position themselves onto the hard board support, streamlining the transfer process. Moreover, the hard board is specially designed to allow toileting and is made of waterproof material to support bathing, ensuring patient comfort and hygiene.
Another notable feature of the concept is the 180-degree swivel capability of the rigid frame around the vertical axis. This allows for easy repositioning with respect to a toilet chair, bed, or other surfaces, enhancing flexibility during patient transfers.

Overall, the Hard Bottom Convertible concept provides a comprehensive and efficient solution for patient transfers, optimizing safety, comfort, and convenience for both patients and healthcare professionals.

b. Semi Rigid Concept. (Refer fig. 3)

The semi-rigid concept introduces a detachable flexi support system that can be easily attached with pre-tension to the rigid frame, enhancing versatility and patient comfort. The flexi support,designed like soft cloth, mimics the feel of bed linen and can be permanently placed below the patient on the bed for added convenience.

To ensure patient safety and comfort, the flexi support is attachable on the side edges to the rigidframe, holding it in tension to provide a sense of rigid support while offering flexibility to conform around the patient, minimizing stress concentration.

The flexi support is designed to be autoclavable or washable at the patient's end, promotinghygiene and easy maintenance. Moreover, the semi-rigid concept can be converted into a stretcher format, facilitating smooth patient transfers.

To accommodate toileting and bathing needs, the flexi support is specially designed, and a separate support part may be devised. Furthermore, the rigid frame can be folded into a chair,providing enhanced transfer dignity to the patient.

For added flexibility, the rigid frame swivels 180 degrees about the vertical axis, allowing easy repositioning with respect to toilet, chair, and bed. The concept offers both powered and manual motion options, except in the case of vertical lift, where powered motion is essential for patientsafety.

In stretcher position, the concept allows X-Ray procedures to be performed without requiring patient transfer, further streamlining the medical process. This comprehensive semi-rigid conceptcombines functionality, comfort, and patient dignity, significantly improving patient transfer experiences in healthcare settings.

(c) Air Cushion concept (Fig. 4)

The air cushion concept operates on a similar principle to the flexi support but with the distinct advantage of offering superior pressure distribution on the human body. As such, it proves especially beneficial for patients with burns and multiple injuries, ensuring optimized comfort and support.

The design of the air cushion is intended to keep it securely positioned below the patient, promoting a better resting posture and effectively distributing forces while the patient is on the bed. This feature enhances patient comfort and minimizes the risk of pressure sores, a crucial consideration in healthcare settings.

An essential aspect of the air cushion's functionality is its rapid rate of inflation and deflation, which should not exceed 30 seconds. This quick inflation and deflation process enables efficient and timely adjustments to the cushion's support level, allowing healthcare professionals to cater to the specific needs of each patient swiftly and effectively.

The air cushion concept represents a significant advancement in patient care, offering enhanced pressure distribution and rapid adjustability to promote optimal comfort and support for patients with burns or multiple injuries. By utilizing this concept, healthcare facilities can improve patientoutcomes, reduce the risk of complications, and provide a higher standard of care for those in need of specialized support during their recovery.

(D)Roller Concept. (Fig 5)

The Roller Concept operates similarly to the hard bottom, but with the notable difference of using rollers to achieve improved pressure distribution on the human body. These rollers can be effortlessly placed under the patient by twisting and rotation, securely supporting them when locked onto the rigid frame.

An important advantage of this concept is the ease of removing the rollers from under the patientduring toileting and bathing, enhancing patient comfort and convenience.

The Roller Concept proves particularly advantageous for patients with multiple injuries as it allows for precise positioning of the rollers, avoiding contact with sensitive or injured areas of the body. To ensure patient comfort and safety, the rollers are manufactured with a high degree of surface finish and ideally should not have protrusions, providing a smooth and gentle support surface.

By leveraging the Roller Concept, healthcare facilities can enhance patient care and comfort during transfers, reducing the risk of pressure sores and ensuring optimal support for patientswith injuries or specific medical needs. The smooth and adjustable nature of the rollers makes this concept a valuable addition to the range of patient transfer solutions available, offering greater flexibility and improved outcomes for patients and healthcare professionals alike.

e)Sling concepts (Fig. 4)
Key features of the sling concept for patient transfers presented.

Additional Locking Loop: Incorporates an additional locking loop as a safety device to ensurecontinuous support even in case of sling failure during patient transfers.

Autoclavable Material: The sling material is designed to be autoclavable, enabling easysterilization and maintenance to maintain high hygiene standards.

Pressure Distribution: Avoids concentration of load on the patient's body to minimize the risk ofpressure sores and discomfort during transfers.

Permanently Positioned Below Patient: The sling is spread out below the patient while on thebed, allowing it to be kept in place permanently for swift transfer readiness.

Texture and Smoothness: Ideally, the sling's texture and smoothness closely resemble that of abedspread, providing a comfortable experience for the patient.

Protrusion-Free Design: Meticulously crafted without protrusions at the edges or betweenattachment points to ensure a smooth and gentle support surface, preventing patient discomfort. Hydraulic/Gas Spring Powered Concept: The sling may utilize either hydraulic or gas springpowered systems for support, optimizing functionality during patient transfers.

By implementing these features, the sling concept aims to enhance patient care, improve transferefficiency, and prioritize patient safety and comfort in healthcare settings.

e) Compare various types of patient transfer devices:

Rollover, semi rigid, sling, and air cushion – based on certain criteria and assign weightages to each criterion out of a maximum weightage of 10. We'll consider five criteria for comparison: ease of use, patient comfort, versatility, safety, and cost.

Table 2: Comparative analysis:

Criteria	Rollover	Semirigid	Sling	Air Cushion
Ease of Use	7	8	6	9
Patient Comfort	8	7	9	6
Versatility	6	7	5	8
Safety	9	8	7	7
Cost	6	6	7	9
Weightage	7.4	7.6	7.4	7.8

Criteria and provide a rationale for the weightage:

Ease of Use: This criterion assesses how easy it is for healthcare providers to operate the transfer device efficiently and without undue effort. Devices like the air cushion, which require minimal physical exertion from the caregiver, receive a higher weightage.

Patient Comfort: This criterion evaluates the level of comfort experienced by the patient during the transfer process. Devices like the sling, which provide good support and distribute pressure evenly, score higher in this aspect.

Versatility: Versatility considers how adaptable the transfer device is to accommodate a wide range of patient conditions and transfer scenarios. Devices like the semi rigid type, which can be used for various transfer tasks, receive a higher weightage.

Safety: Safety is a critical aspect, and devices that prioritize patient safety, such as the rollover and semi rigid types, earn a higher weightage.

Cost: The cost factor evaluates the financial affordability of the transfer devices. Typically, simpler devices like the air cushion tend to be more cost-effective, receiving a higher weightage.

After evaluating the devices based on these criteria, we provide weightages (out of 10) to each type, where 10 indicates the best possible performance:

Rollover: 7.4 (Ease of Use: 7 + Patient Comfort: 8 + Versatility: 6 + Safety: 9 + Cost: 6) / 5

Semi rigid: 7.6 (Ease of Use: 8 + Patient Comfort: 7 + Versatility: 7 + Safety: 8 + Cost: 6) / 5

Sling: 7.4 (Ease of Use: 6 + Patient Comfort: 9 + Versatility: 5 + Safety: 7 + Cost: 7) / 5

Air Cushion: 7.8 (Ease of Use: 9 + Patient Comfort: 6 + Versatility: 8 + Safety: 7 + Cost: 9) / 5

Keep in mind that these weightages are subjective and based on hypothetical evaluations. The actual weightages may vary based on individual needs, preferences, and specific use cases. It's essential to consider other factors such as patient-specific requirements, caregiver training, and institutional guidelines when choosing the most suitable patient transfer device.

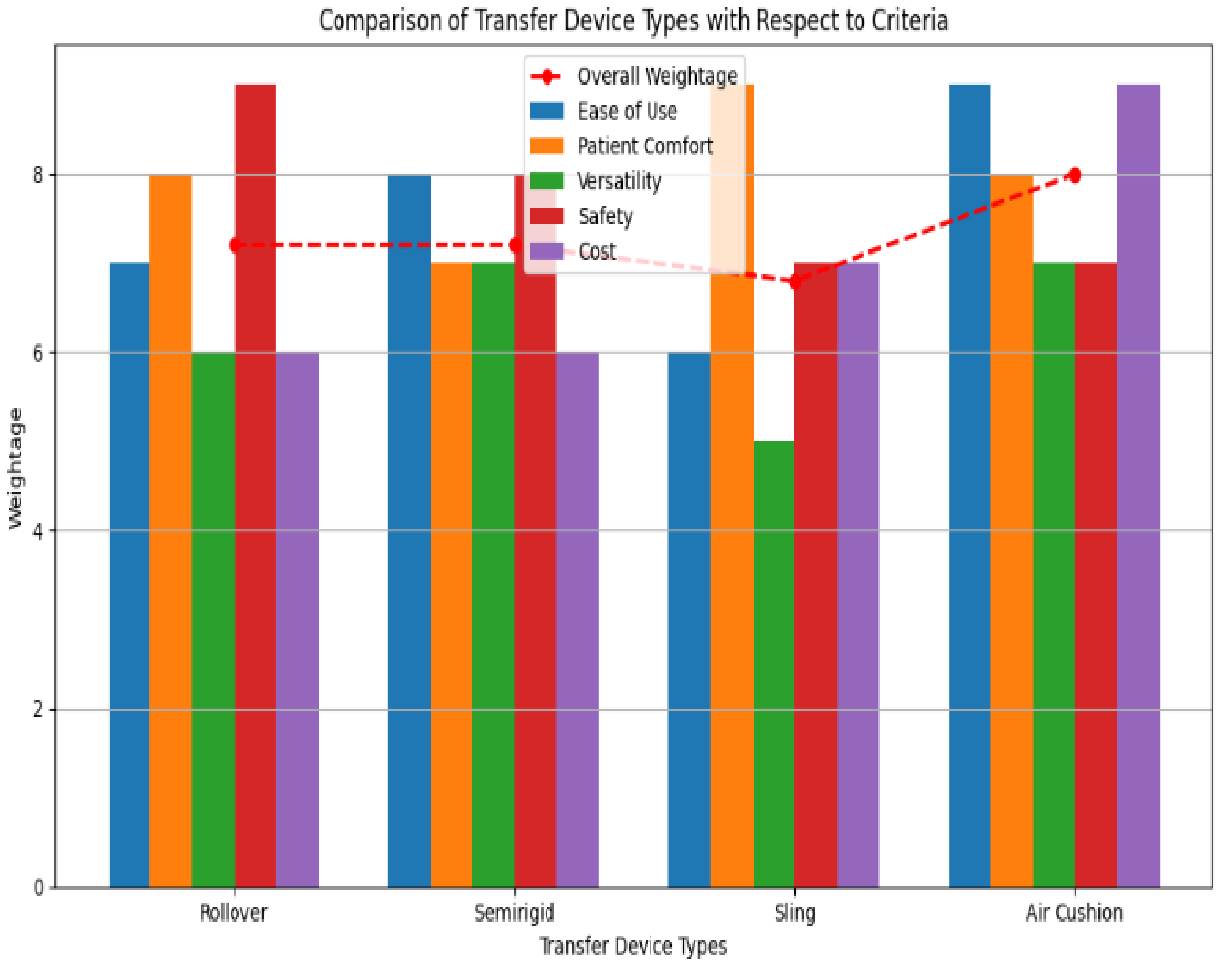


Fig 6: Comparison of transfer devices with respect to criteria

Based on the results of the comparison table, we observed that the "Air Cushion" patient transfer device scored the highest overall weightage of 7.8 out of 10, indicating its superior performance across the selected criteria. The "Rollover" and "Sling" types obtained similar weightages of 7.4, while the "Semi rigid" type achieved a slightly higher score of 7.6. The evaluation revealed that the "Air Cushion" device excelled in factors such as ease of use, patient comfort, and cost-effectiveness. However, individual preferences and specific requirements must be considered when selecting the most suitable patient transfer device, as each type offers unique advantages and may cater to different scenarios.

b) Finite Element Analysis of basic model:

A PTD has certain basic elements which are defined in this section so that you can have clarity on various aspects of the machine and how you can suitably customize it for your use Please refer fig 7 which clearly marks the key elements in the PTD.

This is present in the Nirmal 2000 series of the product. This is a special four bar mechanism design which always keeps the sling bar holder rigidly vertical. Hence patient swing/shake is much lower (unlike plain pivoted as shown in where sling bar holder can swing). depict the same in the actual machine.

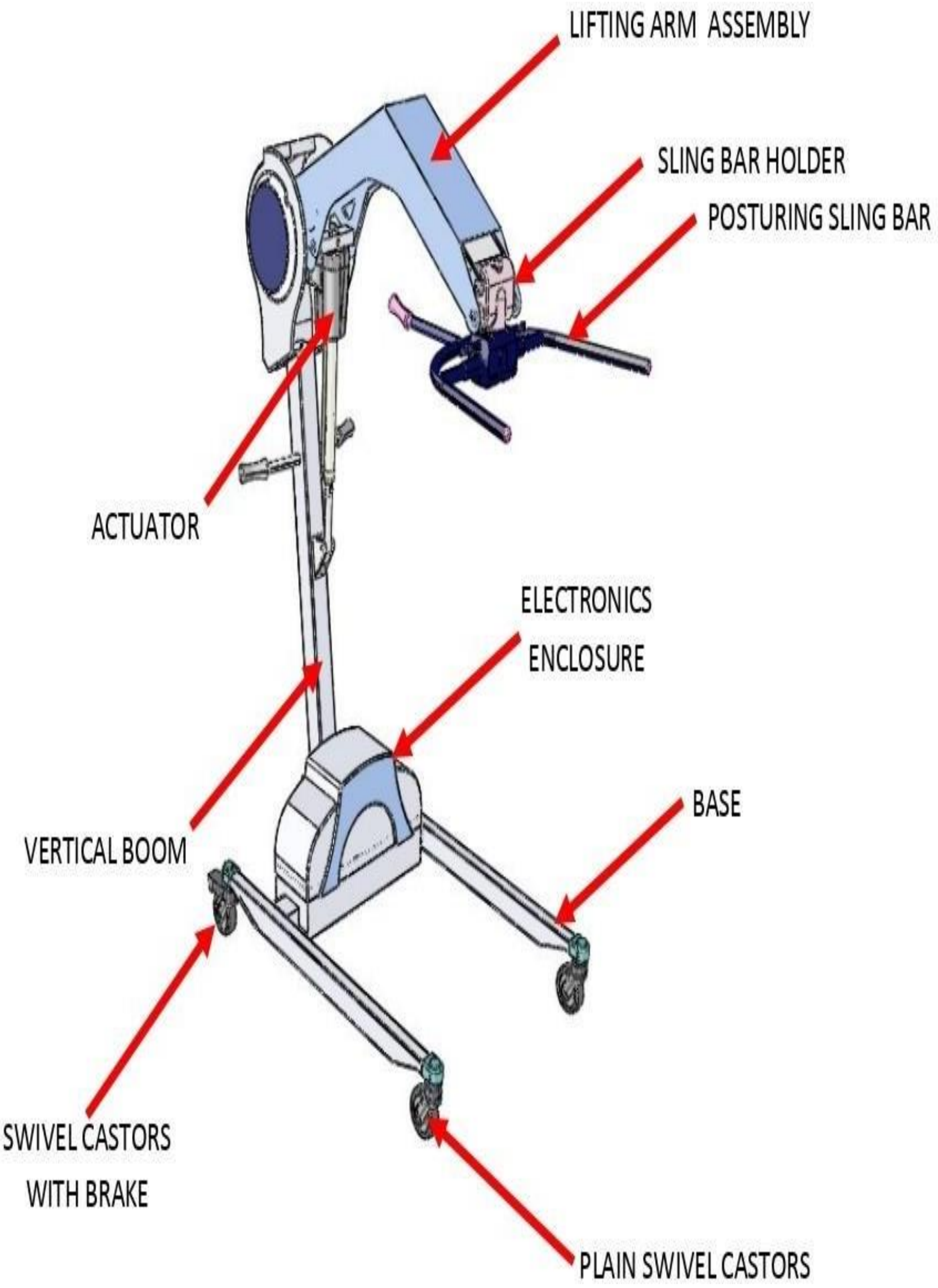


Fig 6 basic model of PTD - Nirmal 2000

The lifting arm assembly with stabilizing bar (fig 7) is a unique feature to keep the patient being always transferred in stable position. As a result, the patient does not swing excessively while lifting. The lifting arm assembly with stabilizing bar has added advantage that it allows posturing of the patient through ratchet lock mechanism.

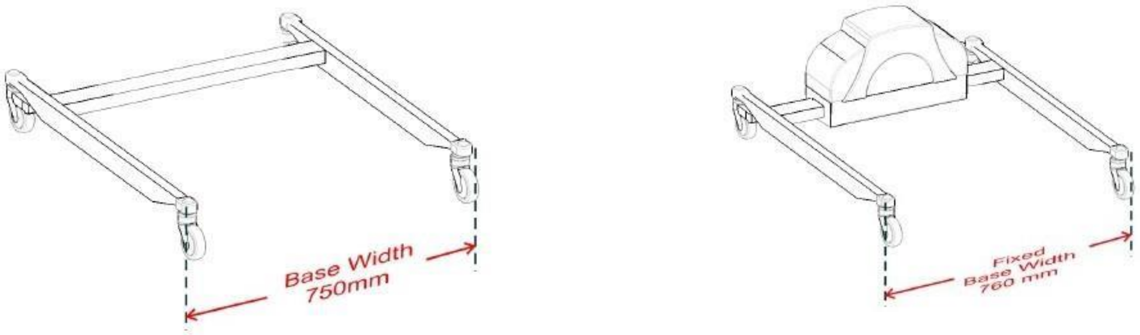


Fig 7: Lifting arm assembly with stabilizing bar

General dimensions of Nirmal 1000 series machine: they are highlighted in fig 8 with the detailed dimension.

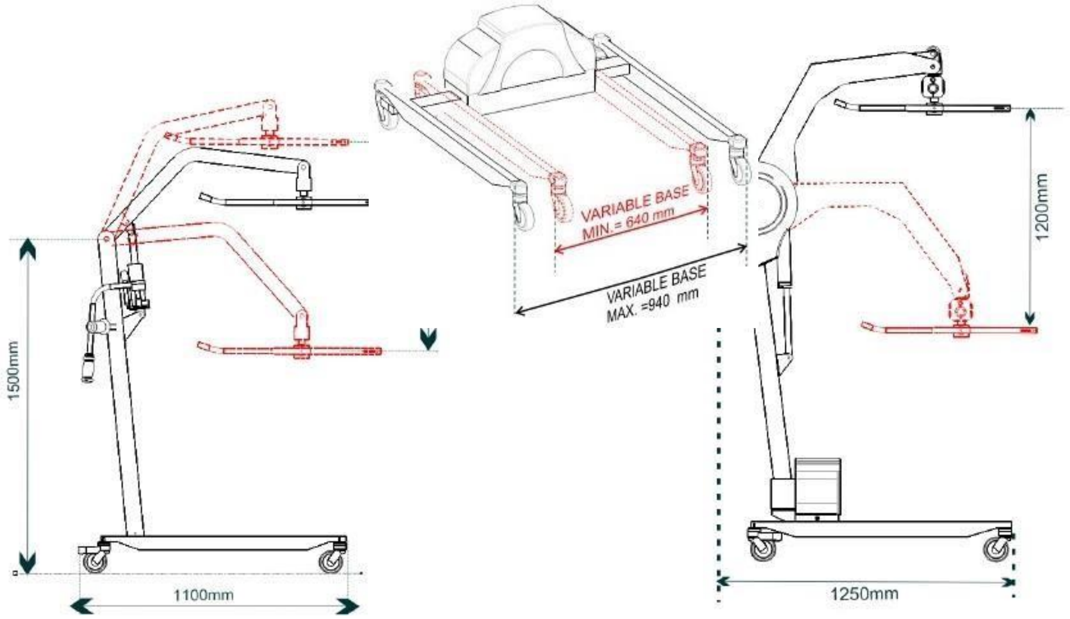


Fig 8: Dimensions of Nirmal 1000 series machine

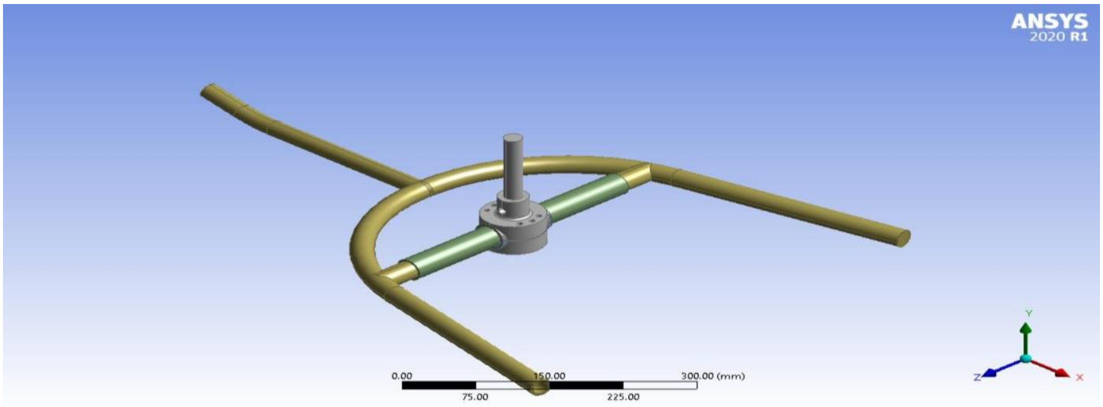
Material properties of Nirmal 1000 series machine components are in the table 3 are detailed below.

Properties of Material	Structural Steel
Young’s modulus	2e+11Pa
Poisson's ratio	0.3
Ultimate strength	4.6e+08Pa
Compressive strength	2.5e+08Pa
Tensile strength	2.5e+08Pa

Design Concepts

The equipment is designed to bear a load of 100 kg capacity. Geometric model is found in fig 9.

Fig 9. Geometric model



Meshed model after discretization is shown in fig 10 below.

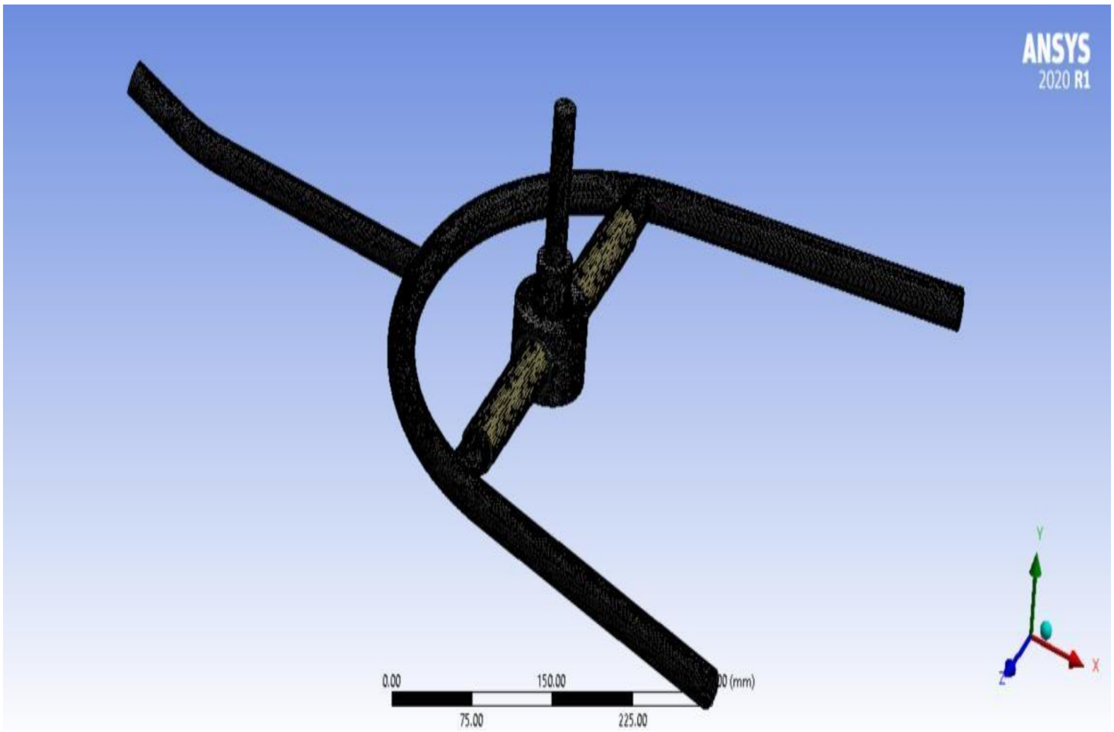


Fig 10: Meshed model

Finite element model with the boundry conditions applied is shown in fig 11 below.

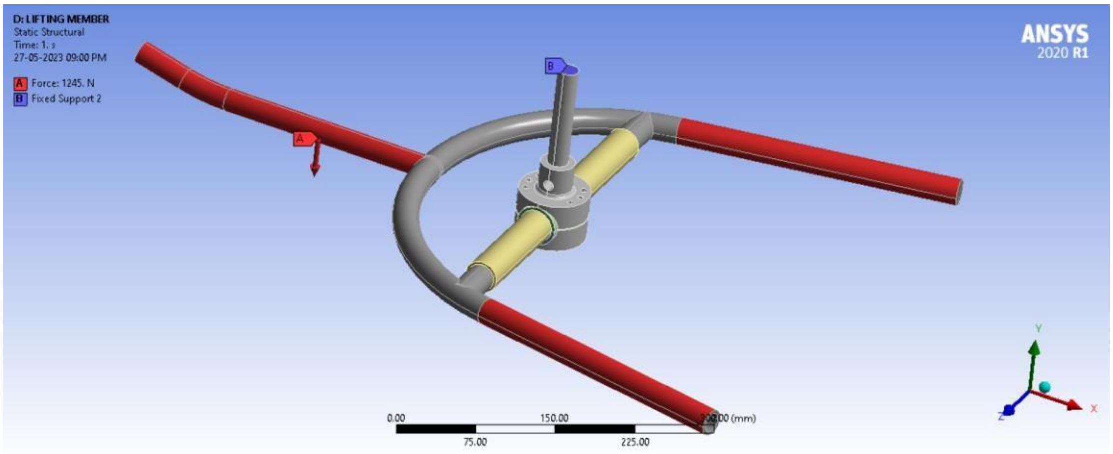
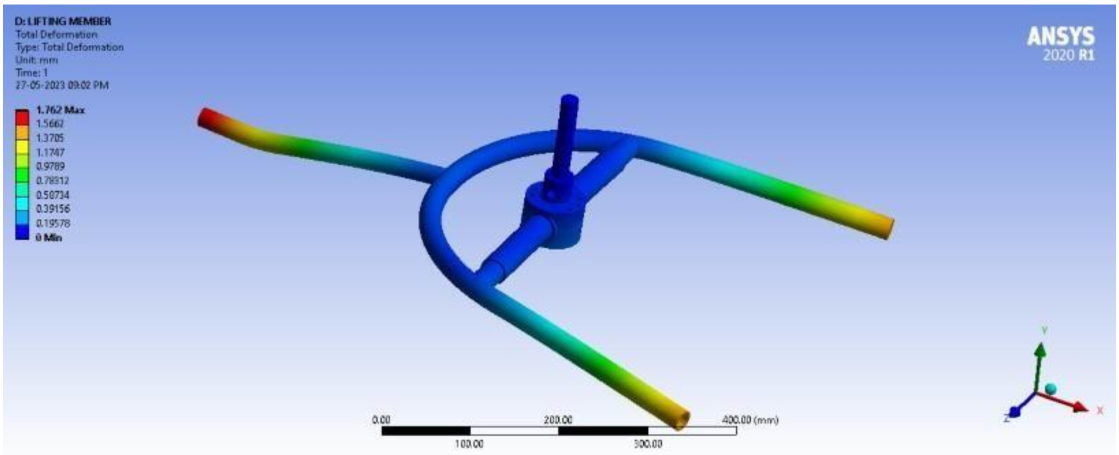


Fig 11: Finite element model with the boundry conditions

Finite element model is subjected to boundary conditions and solution results are shown in fig 12 below.

Fig 12: Results on the meshed model



The results show that the induced maximum stress is 1.5 MPa which is far less than the permissible stress and hence the components are within the safe limits as per the analysis.

Conclusion:

The study/survey findings indicate that patient transfers present significant challenges and discomfort to patients while also causing repetitive stress injuries for nursing personnel. To address these issues, a comprehensive analysis was conducted, involving literature review, interviews with disabled individuals and nursing staff, and examination of actual transfer tasks. The insights gathered from these end-users' requirements have been instrumental in addressing deficiencies in the transfer process.

The application of Failure Mode and Effects Analysis (FMEA) has been crucial in anticipating and identifying potential failure modes, enabling necessary design modifications based on their criticality. FMEA is systematically applied to each system, sub-system, and component to ensurea thorough risk assessment and implementation of effective preventive measures.

From a manufacturing perspective, these designed assemblies and sub-assemblies provide valuable insights into resource requirements, including manufacturing process planning and material needs. Moreover, they aid in cost estimation and facilitate decision-making regarding make or buy policies.

By integrating FMEA into the development process, healthcare facilities can optimize patient transfer protocols, minimize risks, and enhance the overall patient experience. Simultaneously, manufacturing processes are streamlined, resource allocation is optimized, and cost-effectiveness is improved. Ultimately, these efforts contribute to improved patient care and staff well-being in healthcare settings.

Based on the results shown in the comparison table, it is observed that "Air Cushion" patient transfer device scored the highest overall weightage of 7.8 out of 10, indicating its superior performance across the selected criteria.

The results show that the induced maximum stress is 1.5 MPa which is far less than the permissible stress as per the analysis.

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