Optimization of Patient Bed Component Design Using Modeling of Motion Mechanisms on Lifting Elements Electric Patient Bed Manufacturing Case As Per ISO 13485

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ABSTRACT

Tempat tidur pasien elektrik adalah perangkat medis penting yang digunakan di rumah sakit untuk meningkatkan kenyamanan pasien dan mempermudah tenaga medis dalam perawatan. Salah satu komponen utama yang mendukung fungsinya adalah mekanisme pengangkat, yang memungkinkan penyesuaian posisi dan ketinggian tempat tidur sesuai kebutuhan. Tantangan utama dalam pengembangannya adalah memastikan desain yang aman, stabil, efisien, dan sesuai dengan standar internasional seperti ISO 13485:2016. Penelitian ini bertujuan mengoptimalkan mekanisme pengangkat melalui pendekatan pemodelan gerak. Pemodelan ini digunakan untuk menganalisis kinematika gerakan, menurunkan Persamaan gerak, dan menentukan parameter desain yang optimal. Untuk mendukung proses ini, aplikasi simulasi berbasis perangkat lunak dikembangkan, yang mempermudah visualisasi gerak dan perhitungan parameter seperti sudut engkol, panjang link, dan gaya aktuator. Pengujian dilakukan untuk memastikan mekanisme berfungsi sesuai standar, termasuk pengujian beban hingga 250 kg dan simulasi siklus hidup hingga 3000 pengoperasian. Hasilnya menunjukkan bahwa desain mekanisme yang telah dioptimalkan mampu memenuhi persyaratan keselamatan, efisiensi, dan keandalan. Penelitian ini memberikan kontribusi dalam pengembangan tempat tidur pasien elektrik dengan mekanisme pengangkat yang lebih presisi, aman, dan sesuai standar internasional.

Keywords: Electric Patient Bed, ISO 13485, Mechanism Modeling, Design Optimization, Simulation Application

ABSTRACT

Electric patient beds are a vital medical device used in hospitals to enhance patient comfort and facilitate easier treatment for medical personnel. One of the main components that supports its function is the lifting mechanism, which allows the bed's position and height to be adjusted as needed. The primary challenge in its development is to ensure a safe, stable, efficient, and compliant design that meets international standards, such as ISO 13485:2016. This research aims to optimize the lifting mechanism through a motion modelling approach. This modelling is used to analyze motion kinematics, derive motion equations, and determine optimal design parameters. To support this process, a software-based simulation application was developed, which facilitates the visualization of motion and the calculation of parameters such as crank angle, link length, and actuator force. Testing is conducted to ensure the mechanism operates as intended, including load testing of up to 250 kg and life cycle simulation of up to 3,000 operations. The results demonstrate that the optimized design of the mechanism is capable of meeting the requirements of safety, efficiency, and reliability. This research contributes to the development of electric patient beds with a lifting mechanism that is more precise, safer, and compliant with international standards.

Keywords: Electric Hospital Bed, ISO 13485, Motion Modeling, Design Optimization, Simulation Application

INTRODUCTION

Technological advancements in the healthcare sector have brought about numerous changes that improve patient comfort and care. One of the innovations widely used in hospitals is electric patient beds, which enable easy adjustment of the patient's position with minimal assistance from medical personnel. This bed is ideal for patients with limited mobility or those requiring long-term care. With the automation feature, medical personnel can focus more on other aspects of the treatment [1] while the bed position can be adjusted easily and quickly.

Behind the automatic function of this patient bed lies a lifting mechanism that allows for position adjustments, such as the backrest and legs. This mechanism is crucial to ensure the bed operates properly and safely. Although it may seem simple, the design of lifting components requires high precision to function optimally, especially in hospital environments that demand a high level of safety and reliability.

As the use of electric patient beds increases, the challenges in designing lifting mechanisms are increasing. One of the primary challenges is ensuring that these designs meet international standards, specifically ISO 13485:2016[2], which governs the quality and safety standards for medical devices. This standard ensures that every medical device product, including electric patient beds, is designed with risk and safe performance in mind.

This study aims to optimize the design of the electric patient bed lift mechanism using motion modelling [3]. From the model, the motion equation for the lifting component will be derived, and the application will be used to determine the optimal motion parameters [4]. With this approach, more efficient and reliable designs can be produced [5] in accordance with the ISO 13485 standard.

Although the primary focus of this research is design optimization through motion analysis, the manufacturing process will also be briefly discussed as part of the theoretical foundation. This research is expected to contribute to improving the quality of electric patient beds, making them safer and more reliable in their use.
The study "Synthesis of a Hospital Bed Lifting and Tilting Mechanism Using Advanced Simulation Techniques" highlights the significance of simulation in designing lifting mechanisms. They found that the use of software such as SolidWorks Motion can improve design accuracy and reduce production errors [6]. Prototype testing can optimise the angle of the actuator to reduce the initial force required in the lifting system [7]. Additionally, the bed's design with this tilting mechanism enables patients to change positions more easily, reduces friction, and alleviates the workload of medical personnel [8]. In contrast, the development of medical devices must apply risk management from the early stages of design to ensure the safety and reliability of the device [9].

Overall, previous research highlighted the importance of implementing the ISO 13485 standard in the design of electric patient bed lift mechanisms. Although many advances have been made, there is still room for further research in design optimization, particularly in areas such as mathematical modelling and motion simulation.

This research will focus on optimizing the lifting mechanism using simulation and motion modelling approaches to determine the optimal parameters. Thus, a more efficient, reliable, and compliant design can be produced by the requirements of ISO 13485 and SNI IEC 60601-2-52 [10], thereby improving the quality of medical devices in the global market.

This study is limited in scope and focuses on aspects that support the primary goal, namely the optimization of the design of the lifting mechanism in the beds of electric patients, incorporating motion modelling and risk management. These limitations are intended to allow research to be conducted in a directed and in-depth manner, without expanding the scope to include irrelevant matters. The problem limitations set includes two main aspects: optimising the lifting mechanism and addressing design-related safety aspects.
Optimization of Lifting Mechanism Design

This research will focus on optimizing the design of the electric patient bed lift mechanism. Motion modelling will be used to calculate and analyse kinematics and its static mechanisms, to find optimal motion parameters that ensure the lifting mechanism can work safely, efficiently, and sustainably [11]. This analysis will aid in designing components that can withstand loads according to the specifications required in a medical environment. This calculation, based on mechanical principles, will incorporate the simulation of forces and loads to enhance the reliability and performance of the lifting mechanism [12].

Focus on Safety and Design Quality
In addition to design optimisation, this research will prioritise safety aspects by the ISO 13485 standard [13]. This limitation includes an analysis of the potential risk of mechanical failure that could pose a threat to the patient's safety. The research will not cover the manufacturing aspects in detail or the optimisation of the production process in depth. The primary focus is to ensure that the resulting design meets safety and quality requirements by implementing Risk management at every stage of the design.

RESEARCH METHODS

In this study, the research methodology employed is a combination of theoretical and experimental studies. The theoretical study is built through the modelling of bed mechanisms and mathematical equations of motion. Through this model, the mechanical movement of the bed and its elements can be simulated, and the force on the mechanism and the movement of the setting can be defined.

Experiments were conducted offline and online. The offline experiment using the Taguchi method is currently online, utilising a sample of one of PT Mega Andalan Kalasan's products, which was tested in a test laboratory. The data obtained from this study were analysed using *statistical methods and an analysis of variants [21]. The results obtained from this test will be used to optimise the design of the lifting mechanism of the company's product beds.*

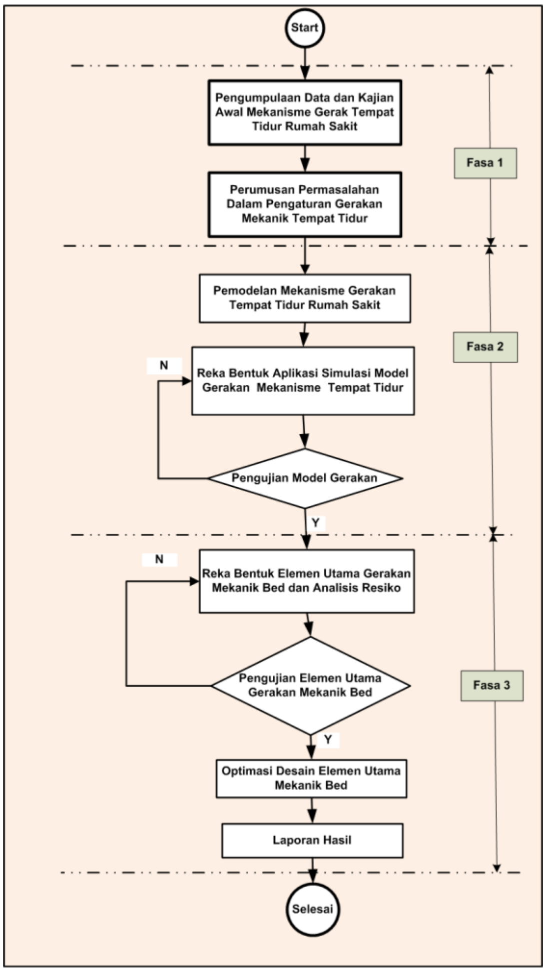

Figure 1 Research Flow Diagram

Modeling of Hospital Bed Movement Mechanism

Mechanical movements in machine tools, as used in mechanical engineering, fall within the scope of machining kinematics [22]. These movements are widely used, ranging from steel wire cutting pliers to robots used in space and medical devices. For hospital beds, the mechanism for bed drive generally uses a 4-rod mechanism as the basis of movement. In this study, two models of the movement mechanism will be made, namely the base of the rod mechanism and the modified 4-rod mechanism.

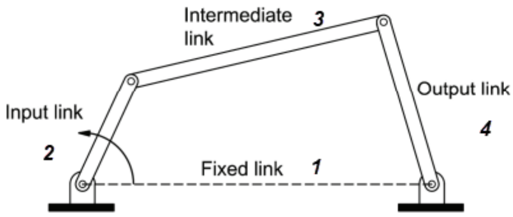

Figure 2. 4 Rod Basic Mechanism Model

Mechanism 4 Modified Rods

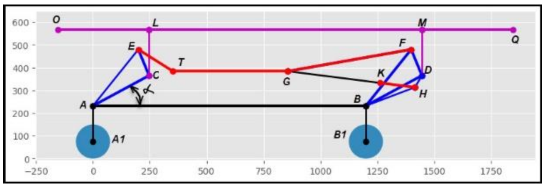

Figure 3. Modified 4 Rod Mechanism Model

The modified model of this 4-bar mechanism is that the fixed link AB represents link 1, the BHDF crank represents link 2, the ETGF link represents link 3, and the ACE crank represents link 4. This mechanism is connected via the CLOQMD link, which represents the mat platform. To operate this mechanism, a GKH actuator is placed, which is connected to links 2 and 3. To complete the model, a fixed link is attached to the frame, to which the wheels are positioned.

Experimental Results

Table 1. Test Result 1

Faktor		RESPON MEKANISME						
δ	ε	Tinggi Minimum (mm)	Tinggi Maksimum (mm)	Gaya Minimum (N)	Gaya Maksim (N)	Stroke Maksim (mm)	β minimum	β maksimum
90	25	292	630	3582	5816	211	-0.88	-6.76
90	32	292	630	3545	5335	218	-1.84	-7.29
90	39	292	630	3535	4933	226	-2.87	-7.77
96	25	292	630	3378	6372	202	-0.08	-7.22
96	32	292	630	3351	5784	209	-0.89	-7.68
96	39	292	630	3341	5300	217	-1.96	-8.16
102	25	292	630	3210	7214	193	1.26	-7.66
102	32	292	630	3187	6449	199	2.52	-8.09
102	39	292	630	3180	5837	207	-0.84	-8.45

Table 2. Test Results 2

Faktor		RESPON MEKANISME						
BD	DH	Tinggi Minimum (mm)	Tinggi Maksimum (mm)	Gaya Minimum (N)	Gaya Maksim (N)	Stroke Maksim (mm)	β minimum	β maksimum
260	55	302	615	3205	5388	210	-1.00	-5.20
260	60	302	615	3112	5371	209	-1.00	-5.60
260	65	302	615	3023	5353	208	-1.00	-6.10
280	55	292	630	3451	5802	210	-1.00	-5.20
280	60	292	630	3351	5784	209	-1.00	-5.60
280	65	292	630	3256	5764	208	-1.00	-6.10
300	55	282	644	3698	6217	210	-1.00	-5.20
300	60	282	644	3590	6197	209	-1.00	-5.60
300	65	282	644	3488	6176	208	-1.00	-6.10

Test Parameters

Table 3. Test Parameters

Parameter	Description	Measuring Instruments
Number of Cycles	3000 cycles (1 cycle = up & down)	Automatic counter
Test Load	250 kg static load	Standard test load
Tinggi Minimum	Lowest sat height	Sensor displacement
Maximum Height	Height sat highest position	Sensor displacement
Deformation	Changes in height after 3000 cycles	Digital caliper
Status Motor	OK or Fail	Visual monitoring

Test and Measurement Equipment

This test uses the following tools:

1) Bed Lift System: Celebes *Bed* 3 Motors.
2) *Automatic* Cycle Counter: Used to calculate the number of cycles of altitude setting.
3) Test Load 250 kg: Used to simulate the maximum load of patients and auxiliary equipment.
4) *Displacement Sensor*: Measures maximum and minimum height.
5) Digital *Caliper*: Measures the deformation of the lifting mechanism.

Data Processing and Analytics

The test data will be processed and analyzed in the following ways:

1) Recording of Test Data
2) Altitude data (minimum and maximum).
3) All data will be recorded and compared to the initial value (pre-test conditions).
4) Deformation Analysis
5) The calculation of the total deformation is calculated as follows: Deformation = Initial Height−Final Height
6) Failure Analysis
7) If there is a motor failure (e.g., motor damage), then the motor will be replaced, and an analysis will be carried out on the cause of the failure.

Test Success Criteria

A test will be considered successful if it meets the following criteria:

1) The motor and lifting system do not suffer from total failure.
2) The maximum height and minimum height remained consistent within the tolerance of ±5 mm during the test.
3) There is no significant deformation in the frame or lifter.
4) There is no physical damage, wear and tear, or fatigue that interferes with functionality.

DISCUSSION RESULTS

Analyze Offline Test Results Using the Anova Method

Evaluation of Test Results 1

Evaluation of the results of the experiment was carried out by analyzing the results of test 1 as shown in Table 1, using the crank angle factors delta and eta, by developing the hypothesis H0:

A. Using the Variance analysis method (anova) to test the significance of the test factor to the test output

1) H011 Large minimum height setting achieved unchanged
2) H012 Large maximum height setting achieved unchanged
3) H013 Large minimum force actuator for unchanged setting
4) H014 Large maximum force actuator for unchanged setting
5) H015 Large step actuator to reach the highest position unchanged
6) H016 The position of the actuator along the motion remains straight $\beta=0$

B. Using the student test to compare the output results to the target

1) Target bed bottom position = 300 mm, H017 = 300 mm
2) Target maximum position of bed = 630 mm, H018 = 630 mm
3) Actuator maximum force target = 6000 N, H019 = 6000 N
4) Actuator straightness target $\beta = 0$, H0110 = 0

As an illustration of the ANOVA calculation, a case is presented for the minimum and maximum forces of the actuator, along with the analysis results as shown in Tables 4 and 5.

Table 4. Effect of *Crank* Angle Factor on Minimum Actuator Force Achievement

	Sumber	Sum Square	df	Mean Square	F	P Value
1	Sudut Crank Delta	4732	2	2366	Inf	0
2	Sudut Crank Motor Eta	3.9350e+05	2	1.9675e+05	Inf	0
3	Sudut Crank Delta:Sudut Crank Motor Eta	170.6667	4	42.6667	Inf	0
4	Error	-2.3283e-10	9	-2.5870e-11		
5	Total	3.9840e+05	17			

Table 5. Effect of *the crank* angle factor on the achievement of maximum actuator force

	Sumber	Sum Square	df	Mean Square	F	P Value
1	Sudut Crank Delta	3.7133e+06	2	1.8566e+06	8.9710e+15	1.4180e-69
2	Sudut Crank Motor Eta	3.9399e+06	2	1.9699e+06	9.5184e+15	1.0862e-69
3	Sudut Crank Delta:Sudut Crank Motor Eta	1.2521e+05	4	3.1301e+04	1.5124e+14	3.2858e-62
4	Error	1.8626e-09	9	2.0696e-10		
5	Total	7.7784e+06	17			

Evaluation of Test Results 2

The evaluation of the results of the experiment was carried out by analyzing the results of test 2, namely the test using the crank radius factors BD and DH shown in Table 2, in this case the H0 hypothesis is used, namely:

A. Using the Variance analysis method (anova) to test the significance of the test factor to the test output
1) H021 The minimum height of the setting reached does not change
2) H022 The maximum height of the setting is achieved unchanged
3) H023 Large minimum force actuator for unchanged setting
4) H024 Maximum force size actuator for unchanged setting
5) H025 Large Actuator step to reach the highest position unchanged
6) H026 The position of the actuator along the motion remains straight β=0

B. Using the student test to compare the output results to the target, namely:
1) Target bed lowest position = 300 mm, H027 = 300 mm
2) Target highest position of bed = 630 mm, H028 = 630 mm
3) Actuator Maximum Force Target = 6000 N, H029 = 6000 N
4) Actuator straightness target β = 0, H0210 = 0

The results of the above experiment are presented in the form of tables, specifically in Table 6 for variant analysis and Table 7 for the student test.

From the results of Experiment 2 for various motion adjustment effects of the experimental factors according to the statistical criteria in the analysis of variance or student test, as stated in the Equation.

- Lowest position = 432 - 0.5 BD (mm), DH has no effect
- High position = 426.66667 + 0.725 BD (mm), DH has no effect
- Initial motor force = 1.5555556 + 20.65 BD(N), DH has no effect
- End motor force = 2 + 11.966667 BD(N), DH has no effect
- Motor stroke ==221 - 0.2 DH (mm)), BD has no effect
- Motor Orientation Angle β = -0.233333 - 0.09DH (degree), BD has no effect

Table 6. Crank length effect in experiment 2 using two variant analysis

Elemen Uji Statistik	Respon Parameter Berdasar ANOVA Untuk Factor BD dan DH						
	Posisi Terendah (mm)	Posisi Tertinggi (mm)	Gaya Motor Awal (N)	Gaya Motor Akhir (N)	Langkah Motor (mm)	β minim	β maksi
Hipotesis Pengaruh Faktor uji	Tidak mempengaruhi posisi	Tidak mempengaruhi posisi	Tidak mempengaruhi gaya Motor	Tidak mempengaruhi gaya motor	Tidak mempengaruhi langkah	Tidak mempengaruhi β	Tidak mempengaruhi β
P Value	0	0	0	0	1	1	0
Hipotesis 0	tertolak	tertolak	tertolak	tertolak	diterima	diterima	tertolak
Efek faktor BD	432 - 0.5BD	426.66667 + 0.725BD	= 1.5555556 + 20.65BD	= 2 + 11.966667*BD	209 + 0*BD	0	= -5.633333 + 0 BD
RSquare	1	0.999604	0.997878	0.856381	0	0	0
P Value Linieritas BD	0	0.0001	0001	0.0003	1	0	1
Efek faktor DH	292 + 0DH	629.66667 + 0DH	6011.5556 - 3.8DH	4526.6667 - 19.566667DH	= 221 - 0.2DH	0	-0.233333 - 0.09DH
RSquare	0	3.69e-13	0.002112	0.143098	1	0	0.995902
P Value Linieritas DH	1	1	0.9065	0.3154	0	0	0.0001

Table 7. Crank length effect in experiment 2 using student test

Elemen Uji Statistik	Respon Parameter Berdasar *Student Test* Untuk Faktor BD dan DH						
	Posisi Terendah (mm)	Posisi Tertinggi (mm)	Gaya Motor Gerak awal (N)	Gaya Motor Gerak Akhir (N)	Langkah Motor (mm)	β minim	β maksi
Mean	292	629.6666	5783.5556	3352.6667	209	-1	-5.6333
Std Dev	8.6602	12.5598	358.0485	223.9754	0.8660	0	0.3905
Std Err	2.8867	4.1866	119.3495	74.6584	0.2886	0	0.1301
Upper 95% Mean	298.6560	639.3210	6058.7760	3524.8294	209.6656	-1	-5.3331
Lower 95% Mean	285.3431	620.0123	5508.3351	3180.50390	208.3343	-1	-5.9335
Harga Hipotesis	300	630	6000	6000	200	0	0
P Value	0.0242	0.9385	0.1073	0	0	1	0
Hipotesis 0	tertolak	diterima	diterima	tertolak	tertolak	diterima	tertolak

Results of Crank Angle Influence.

The purpose of this test was to evaluate the influence of crank angles (δ and ε) on height, actuator driving force, and actuator stroke. The parameters of the crank angle are tested with 3 levels, namely:

- δ angles: 90°, 96°, and 102°
- ε angles: 25°, 32°, and 39°

Key Results

a) Height Height:
   - o The height of the height remains stable at 290 mm to 630 mm in all crankshaft angle settings (P-value > 0.05).
   - o This means that changes in crank angle do not affect the minimum height and maximum height of the lifter.

b) Force Actuator:
   - o The minimum driving force ranges from 3180 N to 3582 N.
   - o The maximum driving force ranges from 4933 N to 7214 N.

c) ANOVA shows that the crank angle has a significant effect on the actuator force (P-value < 0.05).

d) Optimal crank angle can reduce the driving force required by the actuator.

From the test of the influence of the crank angle, it can be concluded that:

- o The angle of the crank does not affect the height of the bed, but it does affect the force of the actuator significantly.

The result of the Influence of Crank Length BD and DH.

The purpose of this test was to evaluate the effect of BD and DH crank length on height, actuator stroke, and driving force. The length parameters of BD and DH are tested with 3 levels, namely:

a) BD: 260 mm, 280 mm, and 300 mm
b) DH: 55mm, 60mm, and 65mm

Key Results

- Height Height:
  - Height varies from 282 mm to 644 mm, depending on the length setting of the BD and DH.
  - Optimal BD and DH length settings allow for more flexible height adjustments.
- Gaya Actuator:
  - The minimum driving force ranges from 3023 N to 3698 N.
  - The maximum driving force ranges from 5353 N to 6217 N.
  - ANOVA showed that the length of BD and DH had a significant influence on height, height, and actuator force ($P\text{-value} < 0.05$)
- From the influence of the crank length test of BD and DH, it can be concluded that:
  - The length of BD and DH significantly affects the height, height and driving force.
  - Optimal BD and DH lengths allow for more stable height adjustment and reduced driving force.
  - The optimal combination of BD and DH allows for a reduction in the required force, which ultimately increases the efficiency of the lifting system.

The optimal values that can be used from this study to obtain the required lowest and highest height positions and the maximum motor force not exceeding 6000 N are, BD = 280 mm, DH = 65 mm, $\delta = 960$, $\varepsilon = 320$ and the motor PCD setting = -412 mm, the initial $\alpha = -280$ will result in an optimal thrust force of 5764 N.

Laboratory Test Results.

Based on the results of the laboratory tests (see attachment 3) carried out, it can be concluded that the height adjustment mechanism on the Celebes 3 Motor 74005 patient bed has met all the requirements of the SNI IEC 60601-2-52:2014 standard. Some key points of this conclusion include:

1) Load Ability: The drive system is capable of lifting a maximum load of up to 250 kg without interruption or deceleration.
2) Cycle Durability: There is no significant wear after 3000 operating cycles, proving the long-term reliability of the system.
3) Operational Noise: With a noise level of only 52 dB, the system provides acoustic comfort for patients and medical staff.
4) System Reliability: All drive components and connectors remain in good condition after intensive testing, indicating that the system has excellent operational endurance.

Risk Management Results

After Risk control is applied, Residual risk (residue) is evaluated, shown in Table 8. All previously high risks, such as motor failure and *linkage jams, have been downgraded to a medium risk level. The risk of noise and power failure has also been minimized to a low level.*

Tabel 8. FMEA Evaluated

Yes	Failure Mode	Initial RPN	RPN After Control	Status
1	Motor Failure to Function	216	108	Keep
2	Jammed Linkage *Mechanism*	168	84	Keep
3	Electrical Power Failure	84	42	Low
4	Excessive Noise	180	72	Low

Based on the Risk management process carried out using the FMEA method, it can be concluded that all Risks have been managed properly. Some of the key points of this Risk management outcome include:

1) Effective Risk Control: The control measures implemented successfully reduce the Risk from high to medium or low levels.
2) Improved System Reliability: The risk of motor and *linkage failures has been minimized through design reinforcement and long-term testing.*
3) Patient and Operator Safety Is Maintained: The risk of power failure and noise has been addressed with a power backup system (UPS) and the use of a motor with low noise levels.
4) Compliance with Standards: This Risk management process meets the requirements set out in ISO 14971 and SNI IEC 60601-2-52.

CONCLUSION

This research succeeded in achieving the objectives by providing the following results:

1) The Success of Kinematics Modelling.
   Kinematic modelling of lifting systems accurately predicts performance. The simulation showed stable movement without harmful oscillations, and the results were validated through laboratory tests over 3000 cycles. This modelling allows for design refinement without requiring many physical prototypes.
2) The Influence of Crank Angles.
   The adjustment of the crank angle has a significant impact on the actuator's driving force, although it does not affect the system's height. Optimal settings reduce the energy required for lifting, thereby improving system efficiency.
3) The Influence of Crank Length BD and DH.
   Crank length affects height (282 mm to 644 mm) and drive force (3023 N to 6217 N). The optimal setting provides flexibility in height adjustment and improves the efficiency of the lifting system.
4) The optimal values for achieving the required lowest and highest altitude positions, with the maximum motor force not exceeding 6000 N, are as follows:
   - BD = 280 mm,
   - DH = 65 mm,
   - δ = 960,
   - ε = 320,
   - Motor PCD setting = -412 mm, and
   - Sudut awal α = -28°

   With such configurations, the optimum thrust generated is **5764 N**, ensuring safe and efficient performance.
5) The results of the Laboratory Test show that the height adjustment system meets the criteria of safety, reliability, and performance according to the SNI IEC 60601-2-52:2014 standard. The system performs well under normal conditions and at maximum load, and produces noise within safe limits.
6) Risk Management Results.
   All risk mechanisms have been identified, analysed, and controlled by ISO 14971:2019 and SNI IEC 60601-2-52:2014 standards using the FMEA method. The identified risks have been successfully mitigated to an acceptable level.

Thus, this research successfully produced a safe, efficient, and standardised lifting system motion model, as well as supporting the development of a more reliable electric patient bed design.

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