[[1]](#footnote-2)

Full Analysis on Machinery Design Standard to Improve the Performance of DoctoSight Robot

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***Abstract -* In this project, the design of DoctoSight robot in part of mechanical structure of robot has been complied with international standards. These standards included ISO 12100-2 Safety of machinery – General principles for design, IEC 60601-1 Medical electrical equipment, and Building regulation for wheelchair access B.E. 2548. These improve performance and reliability of DoctoSight robot for continuous operation.**

***Index Term –* Tele-medicine / Personal care robot / Remote diagnosis / International standard.**

I. INTRODUCTION

I

n Thailand, Hospitals have to reserve a large number of patients almost every day and increasing in number of patients causes a long queue of patients to access the medical service[ref]. Hence, the result is the problem that physician may need to work continuously for a long period of time to take care a large number of patients at limited amount of time. Due to the problem, the lower efficiency of medical service is then occur [ref].

According to physician distribution statistics in Thailand (1999-2014)[ref], the statistics show that the physician shortage problem is now the major problem in rural region of Thailand. Which mean, people who live in rural regions will be unable to access to expert medical specialists and quality medical service that always only accessible in metropolis [ref].

The tele-medicine system is the system that can help patient to remotely access to medical service and help physician to interact with their patient remotely. The system is one of the best choices for health organization to solve the problem. Because the system will provide a new way of diagnosis that allow physician to access to their patient remotely from their place, instead of meet with their patient directly. Additionally, the system will solve accessibility problem for patient who need to access to medical specialist from far different places.

In the BART LAB, research and development about in-door mobile robot and tele-presence robot are now on progression with several iterations. The DoctoSight project is the project that has been progress with the main goal to solve the accessibility problem of medical service, as to develop the mobile tele-diagnosis robot that has capability to help expert medical specialist and their patient to access to each other remotely. Additionally, to allow the robot to operate in real situation, the robot must be reliable and can work continuously for the significant amount of time to operate in real situation.

For capabilities to operate in the real situation, the tele-presence robot is required to research to be complied with standard and regulation as to improve reliability and capabilities of the robot. There are several standards and regulations

IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, is the standard that published by International Electrotechnical Commission. The object of this standard is to specify general requirements and to serve as the basis for particular standards. The standard consists of detail about basic safety and essential performance for medical electrical equipment or medical electrical system to comply. The topics about physiological malfunction, in vitro diagnostic equipment, active implantable medical device, and medical gas pipeline systems are excluded from this standard.

ISO 12100-1 Safety of machinery – Basic concepts, general principles for design, is the standard that published by International Organization of Standardization. The primary purpose of the standard is to provide designers with an overall framework and guidance to enable them to produce machines that are safe for their intended use. It also provides a strategy for standard makers. The standard is giving basic concepts, principles for design, and general aspects that can be applied to all machinery.

Ministerial regulation for building accessibility of disabled person and old people, B.E. 2548, this regulation is referenced by The Act: Person with Disabilities Empowerment Act, B.E. 2550 (2007). The regulation provides information about interior structure for building that must be access by disabled person and old people. The regulation specifies size and dimension of elevator, ramp, stairs, door, entry way, toilet, different level area, entertaining hall, meeting hall, and hotel.

II. METHOD

*A. Standards and Regulation Analysis*

Because there are various standard and regulation presently available on international organization, the method to choose and comply standard and regulation to the right product, service, or system shall be included at first. The product standards themselves have their priority. The specified standard will be complied by specific product before other standards. Alternatively, if there is none of any specific standard available, the lower priority standard will come to account instead. For example, there are defibrillator device developed and ready to comply with standard and regulation. At first, the standard for defibrillator will come at first place if it available. If none of any specific standard available, the product family standard for emergency medical devices will be used instead of the first one. However, if there is none of any product family standard available for comply with, the generic standards for medical equipment will come to account instead. At last, if the product (defibrillator) is not included in the generic standards, the basic standards for electrical equipment will be used by the product to comply with.

For DoctoSight robot that is a tele-medicine robot consist of mechanical machine part, medical electrical equipment part, and software part, the robot is included in both standards and regulations about machinery design and medical electrical equipment design (which included control software for robot). The standard that included information and guidelines about machinery design and evaluation is ISO 12100 -2 Safety of machinery – Basic concepts, general principles for design – Part 2: Technical principles. The standard that included information and guidelines about medical electrical equipment design and evaluation is IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. And as BART LAB is the organization that research and develop medical equipment so, the ISO 13485 standard should come to account. Additionally, as the robot needs to be used in hospital, the standards and regulations for building of hospital must be included in robot design. In recent year (2014), there was new standard published by ISO called “ISO 13482: Standard for personal care robot”. This standard can be referenced directly by the design of DoctoSight robot but, there is none of any source of this standard available to public. This result as the project developer of this project can only be able to use relate standards and regulations for the design of robot instead of direct standard for personal care robot.

The standard consists of three major parts (as called in standard as “clause”) that give an information and guideline for machine design. The first part is about inherently safe design measures. The second is about safeguarding and complementary protective measures. The last one is about how to provide information for use to user. The second part and the last part are about post design regulation so; these parts are excluded from this project.

These are how the design must be, to comply with ISO 12100-2 standard; a gap on machine must be suit with maintainability for machine. For an area that should not be accessible, these areas must be sealed off. Alternatively, for an area that might need accessible for maintenance, these areas should be large enough for accessibility. The machine outer shape must be in circular shape. Because this will reduce risk for accident that maybe occur during collision between machine, obstacle, and user. It also reduces injury in case that accident occurs in unpredictable situation. The center of mass position of machine must be controlled to stay at the least height of machine as to maximize stability of machine. The machine must be able to resist disturbance force (i.e. the force that occurs from a young kid who runs to hug the machine). This can be done by apply suspension system to the machine platform. Internal structure and component should be allowed for maintainability. In the case that an unsafe behavior of machine design is unavoidable, this must be substitute by suitable signal or alarm that can warn the user about danger. The maximum velocity of machine movement must be limit at the point that not causes injury to person who collides with the machine. Materials and components that used on machine must be reliable and suitable with environment in operate area.

Information and guidelines that included in IEC 60601-1 are related to design of medical electrical equipment as intend to improve safety and reliability of product. The object of this standard is to specify general requirements and to serve as the basis for particular standards of medical electrical equipment.

Clause 9, Protection against mechanical hazards of medical electrical equipment and its system, is the part of the standard that relate to mechanical structure of robot design. This section is about information and guidelines of protection against mechanical hazards of medical electrical equipment and medical electrical systems. These included: mechanical hazards of equipment, hazards associated with moving parts, hazards associated with surfaces, corners and edges, instability hazards, expelled parts hazard, acoustic energy, pressure vessels and parts subject to pneumatic and hydraulic pressure, and hazards associated with support systems. These can be summarize to major topics as hazards associated with moving parts, gaps for accessibility, instability and balance of device, handle, noise and vibration, and mechanical strength.

Gap is one of major hazard area associated with medical electrical equipment. Acceptable gaps value for adult is commonly used for comply with but, if an equipment was specified to use with children then acceptable gaps value for children will be used for comply with instead.

In transport position, equipment must remain stable on a ramp with 10 degree referenced to horizontal line. When excluding from transport, equipment must remain stable on a ramp with 5 degree referenced to horizontal line. If equipment will become unstable on a ramp with 10 degree referenced to horizontal line while exclude from transport, it must has warning sign for user provided on the equipment.

Other than stability of equipment itself, instability caused by horizontal and vertical forces also is a major factor that must be accounted. Equipment with mass more than 25 kg that have not fixed in place and was design as intend to use on the ground, must remain stable when applied by force less than ¼ of its weight according to horizontal line (at highest point of its height). The equipment must remain stable when applied by force according to vertical line.

If equipment was design to be mobile platform, it must be able to manually move by user using less than 200 N of force except it was defined as it require more than one person to move the equipment. Equipment must be move by apply force at the position of 1 meter of equipment height or at the top of equipment in case that the equipment is shorter than 1 meter. It must be able to move pass 20 mm tall of a threshold (the threshold is 80 mm width), especially for equipment with weight more than 45 kg. It is unacceptable if equipment can’t pass over a door threshold or showing any unacceptable risk of instability to pass.

For instability in transport, brake of equipment that can be move by power driven must be design to function normally and can be release only by continuously stimulate the control unit. Mobile equipment must consist of component that provided to inhibit the movement of platform as intend to prevent any unwanted movement of equipment. When the equipment is moving on a ramp and then suddenly stopped, unwanted movement that aligned to normal movement must not more than 50 mm.

For instability excluding transport, mobile equipment must consist of suitable wheel lock or brake mechanism that prevents unwanted movement while the equipment stopped on a ramp. Mobile equipment must not provide unacceptable risk that cause by unwanted lateral movement.

Equipment that weight more than 20 kg that require to lift up in normal usage or relocation, must consist of suitable handle or specified position that can be used to lift the equipment up safely. It’s acceptable if safely lifting method is well knows among user without proper handle. In case that it is handle that used to lift up the equipment, the handle must be handed by two or more users at the same time.

For noise that emit from equipment, maximum acceptable noise is 80 dBA accumulative 24 hour for 24 hour (allowed +3 dBA for each half value of accumulative). Maximum acceptable noise is 140 dB un-weighted for impulse. For vibration transmit to handle of equipment and any parts that need to contact with human, maximum acceptable vibration is 2.5 m/s2 cumulative 8 hour for 24 hour.

Equipment must not have a risk of hazard from pressure lost or vacuum lost of component, and must not have a risk of hazard due to leakage of component. Component of equipment must be preventing from damage that may cause unacceptable risk in usage, especially, liquid or gas tube. Reservoir of pneumatic or hydraulic component that may cause unacceptable risk must have fail safe system installed or safe method to remove the component from equipment. It must have a sign that warn about how necessary to take care of these components.

Strength of component must be able to support a load times by its safety factor from the value of 2.5.

Directed from Ministerial regulation for building accessibility of disabled person and old people, B.E. 2548, it consists of two major parts that affect the robot design. The first is the regulation for doorway that limited the size of doorway and accessible gap of the door. This allows an accessibility of wheelchair.

The second is the regulation for ramp in public building that limited the size of ramp. This also allows an accessibility of wheelchair as well as doorway regulation.

Other than doorway and ramp, the regulation has declared maximum height for a threshold of doorway as it must not more than 20 mm. This size of threshold will allow wheelchair and most of medical mobile equipment to pass over.

*B. Implementation and Design*

Before the design of robot structure and mechanism can begin, weight of devices must be estimated first. Total weight of the robot can be estimate by summation weight of every device in upper part of the robot (devices relate to tele-presence operation) plus estimated weight of every component of the robot and safety factor of 1.3 (weight of the robot is important consideration). This estimate value can be re-estimated according to real component of the design that has been revealed in later state of design process.

Accessible gap on robot mainly used for maintenance and adjust component inside the robot which should be accessible using fingers, hand, or arm. So, a gap must larger than 120 mm. according to IEC 60601-1 standard.

As the robot must be able to stand still on a ramp with 10 degree according to IEC 60601-1, the design need to concentrate mass to lower part of the platform for maintain center of gravity at minimum height of the robot. The lower height of center of gravity, mean the more stability of the robot. Additionally, the robot must be able to run over ramp with 5 degree without fall down as follow IEC 60601-1 standard.

For stability of the robot in term of resistant to disturbance force, the robot must be able to resist force with amount equal to ¼ of its weight. This is according to IEC 60601-1 standard.

According to ISO 12100-2, the machine must not give a risk to cause injury to user during usage or during the time that intend to move the machine. From limitation of previous work that worm gear mechanism not allow the robot to move freely while power off, this force user to lift the robot up if they want to move the robot when it switched off. This gives a risk for injury to user because of heavy weight of the robot that they must lift up. Other than that, following to IEC 60601-1, the robot must be able to manually move by user using push force about less than 200 N. These lead to introduction of clutch mechanism as to be use with the robot. The mechanism provides capability to allow the robot to move freely while power off depending on user to choose when robot wheels will release from worm gear mechanism. Then user can gain benefit from its wheel when power off as they can move the robot platform by pushing like a cart.

At first, the developer was seeking for suitable readymade clutch mechanism that available in the market. We found that readymade clutch mechanism in the market was built to be used in automotive industry. There is none of any suitable readymade clutch mechanism available in the market so, we design the new custom clutch mechanism to use with the robot. The mechanism composed of four spur gears, shaft, and spring. One gear attached to the shaft that link to worm gear mechanism which linked to motor (as actuator). The second one attached to the shaft that will transmit rotation force to wheels. The last two gears attached to the same shaft and act as bridge that will transmit rotation from actuator to wheels. This bridge shaft attached to lever that will become the main controller of clutch mechanism. The bridge will join two shafts together when it pushed inside, alternatively, the bridge will release from drive shaft when it pulled back. Additionally for mechanism as to prevent the error when spur gear of the bridge can’t attach to that spur gear of drive shaft due to its teeth stuck with each other, a tension spring then attached between the lever and robot platform as intend to pull the bridge to attach with spur gears of drive shaft. This will solve the error as it requires only some movement of actuator to fully attach the bridge to spur gears of drive shaft because tension spring will keep it intend to attach to each other.

At first to avoid error due to limit of space inside robot, spur gear ratio was chose to be 1:1. It is according to limit available of motor specification in BART LAB and limit available of readymade worm gear mechanism in the market so, ratio of spur gear needs to be adapted to 1:3. This ratio of spur gear will maintain maximum velocity of the robot at close to 1 m/s. Size of spur gear need to calculated with precision as it may result in error when spur gear not match to each others. The lever that used to attach with bridge spur gear need to design as custom shape to allow attachment of tension spring, the bridge shaft, bearing for shaft, lock, and necessary component to attach the lever to the platform. Specification of tension spring that used for the mechanism must not too rigid for user to pull mechanism out while it must not too soft to pull the bridge and spur gears to attach to each others.

The robot must be able to run pass over 2 cm. height threshold and should not have any misdirection behavior occur while the robot move passes the threshold. This is according to IEC 60601-1 standard as well as building regulation for wheel chair access. The first solution for this topic is size of castor wheels as it must have large enough diameter to pass over the threshold (half of diameter of castor wheel must larger than height of threshold). This will allow the robot to run pass over threshold. The second solution that analyzed from previous work of DoctoSight is that the drive wheels of the robot not have suspension mechanism installed. This cause misdirection movement of the robot after it passed a threshold that may result as error of navigation system later. This is one of the reasons that it necessary to improve drives wheels with suspension mechanism as it will reduce misdirection of movement.

As addition to stability in movement of the robot, unwanted movement is also a major factor that affects stability in movement of the robot and it defined in IEC 60601-1. This unwanted movement can be defining in two directions. The first is unwanted movement in lateral side of the robot. This unwanted movement can be limit by weight of the robot and position of wheels. When robot wheels places in the position near an edge of robot size, it require applied force from lateral side of the robot to be at the amount of robot weight. The second is unwanted movement in the direction align to robot movement. This mainly causes by a wheels that not have lock mechanism which will inhibit it from freely rotate when it released from actuator control. This lead to the solution that will allow wheels to move under actuator control while it does not require any interaction from user, at the same time, it will not allow wheels to move freely when out of actuator control. Worm gear mechanism is a component for this solution. It is a mechanism that allow one way actuation from motor while inhibit rotation that came from opposite direction. With an addition of worm gear mechanism in drive system, unwanted movement in direction align to robot movement will be limited.

From an analysis of previous work, it show a significant amount of vibration transmit across the whole robot platform. This may reduce durability of electrical and mechanical components for long-term usage which will increase risk of error during the time of usage. The main source of vibration is drive system as the robot move over rough terrain or pass over door threshold, it will generate vibration that transmit to upper part. This mean, the solution for this situation is it must have vibration damping mechanism include in drive system. In previous work, suspension mechanism was introduced for support wheels as vibration damping mechanism and provides flexibility of robot movement. From an analysis, it show that suspension mechanism must be applied to drive wheels as well as support wheels to gain benefit from suspension mechanism as it should be.

For design of suspension mechanism, the design was inspired by suspension mechanism of automotive. The mechanism composed of drive shaft which attached to engine (actuator), C.V. Joint which allow vertical movement drive wheel while transmit rotation to drive shaft, drive shaft which attached to wheels, support shaft which limit horizontal movement of wheels, and shock absorber that act as vibration damper of the system. By adapt the mechanism to use on the robot, C.V. Joint can be substituted by universal joint which available in the market. Other parts of mechanism can be shrinking down to the size that compatible with robot. One shaft will attach to actuator while other end of the shaft will attach to universal joint. Second shaft will attach to wheel while other end of the shaft will attach to universal joint as well. As intend to attach shock absorber to the mechanism, custom shape machine part need to be fabricated. The first part is a joint that will allow wheel shaft to link to shock absorber. The second part is support shaft that will limit horizontal movement of wheel. The third is housing for shock absorber which link shock absorber to the joint from drive shaft as well as link it to the robot platform. Custom housing for shock absorber need to be fabricated due to specification of shock absorber which adapted from industrial shock absorber with none of any available accessories to allow attachment of shock absorber to the mechanism. As a result, shock absorber will absorb every impact force and vibrations generated from wheels when impact force or vibration applied to robot wheels instead of transmit the force to upper part of the robot.

According to building regulation for wheelchair access, size in horizontal axis of the robot must be limited at 80 cm. plus with safety factor. From previous work analysis, it show that square shape of DoctoSight No.1 cause some limitation to robot movement. As improvement of robot platform, size in horizontal axis can be reduce and change to circular shape by rearrange position of component inside the robot. This will provide an improvement in mobility of the robot as a result.

Robot height must be limited at 150 cm. According to research that related to personal care robot, it shows that 150 cm. robot affect friendly feeling of user about the robot. The robot may scare some user if it taller than 150 cm. while it may affect quality of usage if it shorter than 150 cm.

Maximum velocity of the robot must be limited at 2 m/s as it will not cause injury to person in case that accident happens. In term of friendliness to user, maximum velocity of the robot must be limited at 1 m/s as it has research related to personal care robot which shows that velocity more than 1 m/s may scare user off.

III.RESULT

For accessible gap inside the robot, this have been done by adjust size of gaps inside the robot as to allow accessibility of fingers, hand, and arm for maintainability of the robot.

To maintain stability of the robot, this have been done by keep center of mass of the robot at minimum height as to maintain stability of the robot on ramp and resistant to disturbance force. Additionally, suspension mechanisms have provided capabilities to maintain stability of the robot while passing ramp or affect by disturbance force.

To provide mobility of the robot, this have been done by include clutch mechanism into drive system which will allow wheels to move freely depend on user.

To maintain stability in movement of the robot, these have been done by using castor wheels with diameter larger than 40 mm. and addition of suspension mechanism. As intend to inhibit unwanted lateral movement of the robot, worm gear mechanism has been included in drive system.

For a risk of error that may occur from mechanical structure of the robot is effect of vibration that may cause damage to other component inside the robot and lead to system error or system malfunction, this have been solve by included suspension mechanism to drive system.

For accessibility of the robot to operating area, this have been done by adjust size of the robot to circular shape which reduce risk to cause injury and easier to design control algorithm while robot size in horizontal axis have been minimized as small as possible.

Maximum velocity of the robot limited at 1 m/s as to maintain friendliness to user by specified motor specification that has maximum capabilities to operate at 1 m/s.

IV. DISCUSSION

Because of limit available of ISO 13482:2014 Robot and robotic devices – Safety requirements for personal care robots that none of its copies available in public source so, we can’t gain access to information of this standard. The suggestion is that the government should have purchase this standard to be used in Thailand which will help researchers to gain access to essential standard for development of their product. This will help accelerate development of Thai products to the level of international in shorter time with shorter cost.

V. CONCLUSION

As this project focus to study on international standards and regulations as to improve performance and reliability of DoctoSight robot, the mechanical structure of the new robot now complied with standards and regulations. This structure provides flexibility in usage of the robot and reduces risk of injury to user. By addition of clutch mechanism and suspension mechanism, this improves reliability of the robot to next step. Clutch mechanism provide capabilities of usage as user now can push the robot to move it while power off instead of lift it up which may cause injury to user such as long-term back pain. Suspension mechanism provides vibration damp function for robot platform and help robot access to wider variation of places. This also prolongs the durability of electrical components inside the robot which improve reliability of the whole system of the robot.

The major problem we encountered in this project is availability of component for additional mechanism that we included to the system. It requires many custom parts that not available in market so, many progress of the project has been delayed for long time. Additionally, this pause the process of the project at design phases for long time and cannot gain access to real platform of the robot.

For next step of the development of DoctoSight robot, it should study on standard in term of electrical component, electromagnetic compatibility, and ergonomic principles. This will lead the development of DoctoSight robot to fully comply with standards and regulations. After that, it will result as new robot with high reliability and performance while get closer to become real commercial product that can be used widely in real situation.

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