Human Factors Based TEE Probe Positioning Control System Design

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Abstract: - Transesophageal Echocardiography is a portable, relatively non-invasive modality of the heart. It is intensively used in operating theaters as a surgical monitoring device. Moreover, it is applied as a diagnostic tool before cardiac surgeries are performed. The procedures utilizing TEE require wide ranges of duration, which highly depends on the operators' experiences as well as other human factors. It is sometimes performed under exposure of fluoroscopy like X-Rays. This results in health risks caused by radiation to the operator. In order to decrease health related hazards, this paper proposes a remote control of the TEE probe position based on radiofrequency with considering the human factors. We analysed the performance of 433 MHz radiofrequency in different indoor environments. Furthermore, the developed remote control was evaluated and showed in all cases successfully positioned the probe positions.

Key-Words: - Transesophageal Echocardiography; human factors; remote control; radiofrequency; medical device; interference; clinical applications

1 Introduction

Transesphageal echocardiography or the TEE is an alternative procedure for further cardiac examination and a complementary technique to the conventional transthoracic echocardiography (TTE) [1-4]. TEE is a semi-invasive procedure, used to evaluate, diagnose, and monitor the cardiac conditions of patients during perioperative and intraoperative period of cardiac surgeries. It is also used in non-cardiac surgery for patients with hemodynamic instability, hypoxemia, to evaluate chest trauma, and pre-incision cardiac evaluation prior to emergent surgery [5, 6]. The cardiac data and images provided by the TEE are clearer compared to TTE and are also less affected by the interference originating from ribs and lungs [7-9]. Fig. 1 shows a conventional TEE probe that is used in most hospitals currently [10]. A TEE probe consists of a modified gastroscope, being approximately one meter long, with an ultrasound transducer mounted at its tip. The tip gets advanced into the esophagus, positioned posterior to the heart. The transducer consists of a rotating part that enables the scanning of the heart at various cross sectional positions. In order to flex the probe tip, knobs are provided as shown in Fig. 1. The knobs are being manually adjusted [11-14]. TEE has the capability to visualize dynamic cardiac information and is helpful in the process of decision making during surgical [15-18] as well as interventional procedures with radiation exposure. Prolonged radiation exposure may be brought to development of cataracts, impaired fertility and cancer. Several studies were performed on radiation effects and safety measures [19, 20].

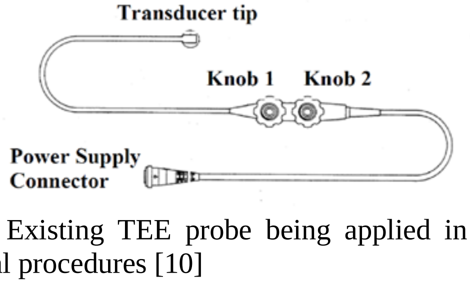

Fig. 1 Existing TEE probe being applied in most surgical procedures [10]

The aim this paper is the development of a remote control in order to adjust the position and orientation of a TEE probe controller towards required angles and directions via wireless communication. This developed system is expected to support clinical staff to monitor patients with cardiac problems. It is an essential tool in order to minimize harmful radiation. Moreover, it is expected to increase the efficiency in diagnostic TEE procedures. This research does not include the scope of a control for the TEE probe controller.

The application of TEE in clinical procedures can be traced back for more than a decade. It was first applied in 1976 and was introduced to cardiac operating rooms and clinical practice in the early 1980s [21, 22]. The first TEE instrument was a rigid, mechanically sectored scanning device that caused discomfort during intubation [23-25]. The examiner had limited control over the transducer position as the transducer was connected only by the cable to the ultrasonic apparatus [7]. In the U.S. Pat. No. 4,543,960 to Harui et al had made improvement to the ultrasound probe having a rotatable array, hence allowed images to be scanned in 2D manner. Improvement to Harui et al. probe are described in U.S. Pat. No. 5,226,422 to Mckeighen et al., where a circular array transducer was employed with new grounding technique as well as bell-shaped housing for the transducer [26]. TEE has been improved by using an electrically powered motor that was coupled to the flexible endoscope shaft to minimize overtorque situations [27]. Later, articulation mechanism was added to the gastroscope tube to provide high torsional stability to the probe [8]. None of the study regarding the remote control for controlling the TEE is considered up to date.

In this study, a state-of-the-art remote control designed forseen to adjust the position and orientation of the TEE probe tip via radiofrequency is presented. The human factors to optimize the remote control designed are explained in section 2. The modelling of the remote control hardware and derived algorithm are presented in section 3. Section 4 analysed the performance of 433 MHz radiofrequency in different indoor environments, and the last section presented the conclusion.

2 Medical Device Design Cycle Compliances to Human Factors Engineering

Designing and introducing a new device into medical applications requires tasks to identify and address the potential user-related hazards during the device development. One should identify the proposed usage of the device designed, who would be device end users and how the users interact with the device as well as the characteristics of the environment, wherein the device will be used. Human factors engineering (HFE) [28] shall be performed parallel to the designing development cycle in order to validate the device usage. This shall be safe and not inherit hazards to the target group in the intended use environment. To control the overall risks, design-related use problems should be reduced or eliminated. Some important safety features were included in a similar research [37, 38].

The use-related hazards can be investigated through the device usage analysis and testing. Applying HFE approaches incorporated into the design and risk management processes include to identify use-related hazards analytically or empirically.

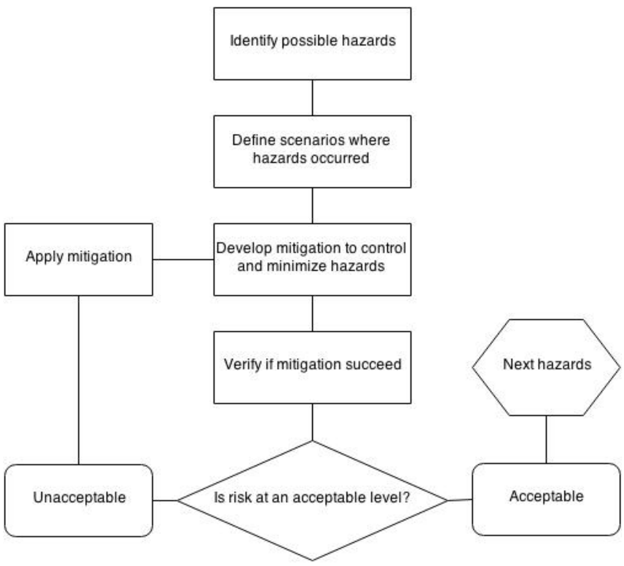

Fig. 2 Essential steps addressing the use-related hazards in risk management

In the analytic approach, the use-related hazards were identified by function and task analysis, heuristic analysis and expert review. Function and task analysis identify possible hazards associated with the device use. Heuristic analysis evaluates the interaction of the users with the device user interface. Expert reviews involved human factors experts to analyse the usage of the device, identify problems that may occurred and addressing recommendations for them. While empirical approach, the hazards are identified during the early stage of design. Moreover, a description of use-related scenarios where hazards occur was developed. Once, use-related hazards are identified, mitigations are developed and the hazards got controlled to an acceptable level by modifying the device user interface. For example screen display characteristics, control wheels, size of knobs, labelling or even to provide training to users. Effectiveness of the mitigations are tested to validate that the design have met the specific requirements. Fig. 2 shows the essential steps addressing the use-related hazards in risk management.

Medical devices designed, follow the HFE methods and guidelines. This comes with increased safety, reduced use error, reduced risks, ease of use, enhanced user satisfactory and improved patient outcomes.

In the current study, the designed device is used to control the TEE probe position by a remote control unit via the wireless communication technology. Table 1 summarizes the human factors considerations for the device-user system.

Table 1 Human factors considerations for the device-user system

Human Factors		Requirements	Specifications of the device designed
Environment	Room dimension	A room of 4 m x 4 m dimensions, therefore need to be controllable in a diameter of 6 m	Minimum distance for controlling is 6 meters
	Lighting intensity	Position of the probe to be adjustable from low lighting environment to high intensity lighting	Install a monitor that display the simulator with adjustable brightness
	Radio communication devices in used	To be operational and functional with Bluetooth devices, Wi-Fi networks, walkie-talkie, pagers, mobile phones	considerations on other frequencies might encounter interferences 433 MHz will be used
	Radiation	Do not brings radiation	No radiation
	Sound from the speakers and other entertainment devices	Emergency alarms, sounds from the speakers and other entertainment devices	No microphones, speakers installed. Error will be warned through the simulator
	Surrounding temperature	To be able to use in wide range of temperature between 10°C to 40°C	Operational temperature between 10°C to 40°C
Users	Cardiologists	User friendly user interface	Simple calibration procedures to bring probe position to neutral
	Experienced clinical staff	To provide training on the TEE procedures They must obtained license to do diagnosis using TEE	Implement position simulator to indicate the position status Adding START button to start the procedures Adding STOP button to return probe to neutral position Adding PAUSE button to hold the probe position or when probe is not in use

	Other visitors such as family members and children may touch TEE Probe during visit.	To prevent other individual from manipulating the probe	Password for operation of the remote control system. Combination of few button to avoid undesired movement.
Device	Probe movement Probe temperature for long use Probe size Probe position monitoring To be able to be used by user for more than 8 ours Comply with operating theatre (OT) equipments	To be able to move in six directions Low heat dissipation The size of the transducer tip To be able to inform the coordinates of probe. Ergonomic design Not produce radio frequency used in OT	Six motors implemented to enable various position movement conveniently To select motors with low power output and wireless technology with low transmission power To provide probe position sensor Ergonomic design according to game joystick Use 433 MHz frequency
Safety	Mechanical hazard Electrical hazard Chemical hazard Biological hazard Temperature hazard Radiation hazard	Not effected by vibration and unexpected movement No electricity connection to probe No chemical solution in the remote control system Not easy contaminated by biological agent Not produce excessive temperature during use Not use radioactive or frequency above UV	Have mechanism to sense the vibration and unexpected movement, and give signal or mitigation action to reduce the risk Battery operated wireless remote control system Electronically controlled / not using any liquid Easy for decontamination process and material not absorb biological agent Not using material that produce excessive heat Using temperature sensor to monitor the temperature Use frequency 433 MHz

2.1 Use environment

The use environment is defined by the type and functionality of the medical devices used nearby. It can have major impacts on the usability and use-related hazards. The designed control unit is required to function within a radius of 6 m under different intensities of lighting and different temperatures. Moreover it is supposed to be free of interferences, radiation and surrounding noises.

Advances in wireless technology provide a revolution. On this basis medical services and information can be delivered unrestrained from time and space limits [29, 30]. Wireless communication and compatible technologies were considered. Considerations should include the coexistence of wireless technologies, data security and electromagnetic compatibility (EMC). This is especially important for critically functioning medical devices like those for life-supporting and life-sustaining [31]. Some examples of potentially wireless-related hazards in medical environment include:

1. Signal or data lost, data corruption and

noise.

2. Delayed or degradation in the signal transmissions caused by coexistence with other wireless technologies.
3. Insecure wireless networks or hacking.
4. Silent malfunction of the medical devices.

The selected frequency should not other medical devices at risks and therefore be free of interferences. The preferred characteristics of the wireless technology are of high frequency and low transmission power. According to Wallin et al. and Tan et al. [32, 33], wireless technology which has a relatively high frequency and low transmission power is believed to have less chances to interfere with other medical devices in proximity.

In this study, 433MHz RF transmitter-receiver module was chosen based on the preferences of its lower transmission power. Although there are other wireless technologies with higher frequency and lower transmission power available such as Bluetooth (IEEE 802.15.1), and Zigbee (IEEE 802.15.4). However, these technologies are highly interfered by other wireless devices in proximity [34]. Wireless local area networks (WLANs – IEEE 802.11) is suitable for indoor applications such as hospitals [35]. However, due to its higher transmission power approximately 100 mW, it tends to interfere other wireless devices of lower transmission power in proximity [34]. 433 MHz RF was also chosen because of the frequency is located distant from the unlicensed Industrial, Scientific and Medical (ISM) band. Frequencies located in the ISM band are not entitled to interference protection. Therefore, there is possibility to be interfered in this frequency band as it is heavily used by many devices. In addition, the frequencies that range from 500 kHz and above are capable of transferring data [38].

Experiment were setup as enclosed in section 4 to validate the performance of the 433 MHz in different environment.

2.2 Intended users

The users who are likely to be involved in using the remote positioning control are the cardiologists who are already familiar with the use of the current existing TEE probe. Therefore, the user interface designed for the remote control should mimicking the existing control panel of the TEE probe. For example, by rotating the knob clockwise will move the probe to the right vice versa. The designed control system should include simple calibration procedures to bring the probe back to neutral position and a simulator to display the position status of the probe.

There will be users with inadequate experience with the usage of the TEE probe remote control. Therefore, to provide training to the users is appropriate. The users should pass the training and obtained licensed to perform TEE procedures.

To prevent individuals from accidentally misconfigured the operation of the TEE, some operational buttons will be added to the user interface. For examples, START button to activate the TEE remote control system, STOP button to return the position of the probe to neutral and exit procedure and PAUSE button to hold the current position of the probe.

2.3 Device use

In the designed remote control, the device is required to be able to move freely in six directions. The probe should be able to reach all the directions like the current existing TEE. It is also required that the dissipation heat is low to minimize sensation on the patients. The size of the transducer tip should designed to be in small dimension to avoid complication during insertion of the tip into esophagus of patients.

2.4 Device safety

The device designed should be free of chemical hazards. The disinfections of the transducer tip should be easily done and cleanse with mild chemical cleanser. Device should also be free of mechanical and biological hazards. The device should be easily to reconfigure so that the firmware is able to be upgraded from time to time. Outdated firmware may cause systems not being able to detect new faults that has been updated to the systems.

In addition, the remote positioning control system should always be free of electrical hazards. Every parts of the device should insulated with proper insulator to avoid unwanted electric shocks that may cause to death.

Moreover, thermal hazards should be controlled as to avoid sensation to both cardiologists and patients. Joystick that consume a lot of current during usage should not be used as it will cause discomfort to cardiologists. Lastly, it is important that the remote control designed is free of radiation hazards.

3 The TEE probe positioning control system design

The proposed system sends and receives position commands. The signal is transferred to the TEE probe via a RF transmitter-receiver module. The conventional TEE is divided to two parts. The first part is the remote control unit, which sends the position signal. The other part is the TEE probe. Subsequently, the TEE probe tip will move and can be adjusted according to the received position signal. Both parts are placed in two different rooms separated by transparent glass. Ultrasound signal of the TEE are to be viewed on the imaging system for transesophageal diagnosis. However, the imaging system is not included in this field of study.

With the developed system, real-time remote monitoring and diagnosis of patient's heart information and parameters can get achieved. In this way, medical doctors will be supported in monitoring more patients out of different surgical theatres with increased efficiency. The architecture design of the proposed approach is provided in Fig. 3.

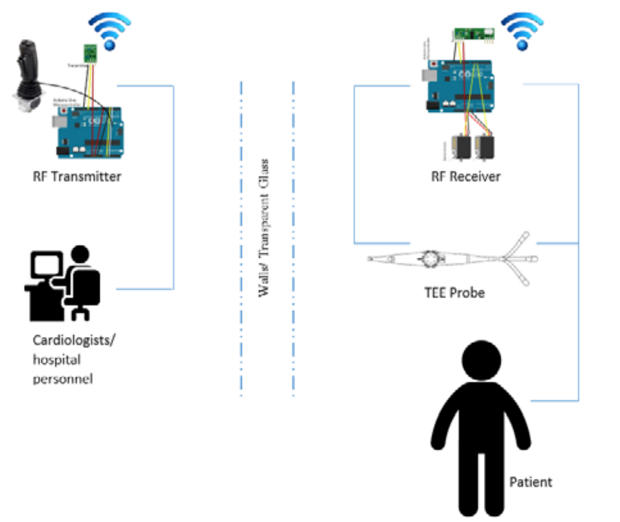

Fig. 3 Architecture design of the proposed remote control

3.1 Remote positioning control setup

For the setup of the wireless communication system, a pair of 433 MHz RF wireless transmitter-receiver modules is used. The signal is generated in order to be transferred by the transmitter. The position signal generated is received by the corresponding receiver. A parallax joystick is connected to the transmitter and used to provide the position signal. A prototype of the TEE probe is connected with the receiver and is configured in order to move simultaneously a joystick. There are two units. One is the servo motor unit that will be remotely controlled by the joystick and positioned the probe. Here, Arduino Uno is used as the microcontroller to encode and decode the analog data to serial data and vice versa. The block diagram of the complete setup is given in Fig. 4. The setup of the remote positioning control unit is a test unit developed.

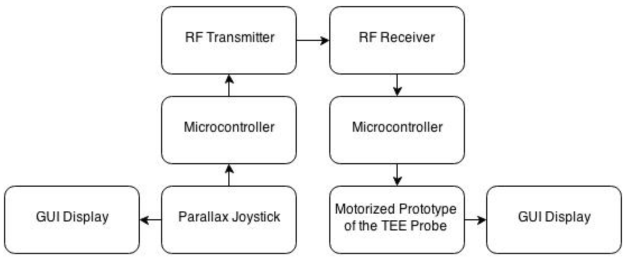

Fig. 4 Block diagram of the remote positioning control unit

3.2 Position signal detection algorithm

The following steps are the designed algorithm for the position signal detection using the microcontroller:

1) Read any value from the analog pin if available.
2) If there is any value from 0 to 1023, map the value to degree, which is in the form from 0° to 180°.
3) Write the mapped value onto serial monitor and GUI of the transmitter side.
4) Send the corresponding value to the receiver.
5) Any data received by the receiver will be sent to the microcontroller and then to the servo motors.
6) Servo motors will be triggered to actuate in accordance to the degree received.
7) The degree of movement of the motor will be written onto a new serial monitor and also GUI of the receiver side.

Fig. 5 shows the flowchart in developing the algorithm of the remote positioning control system.

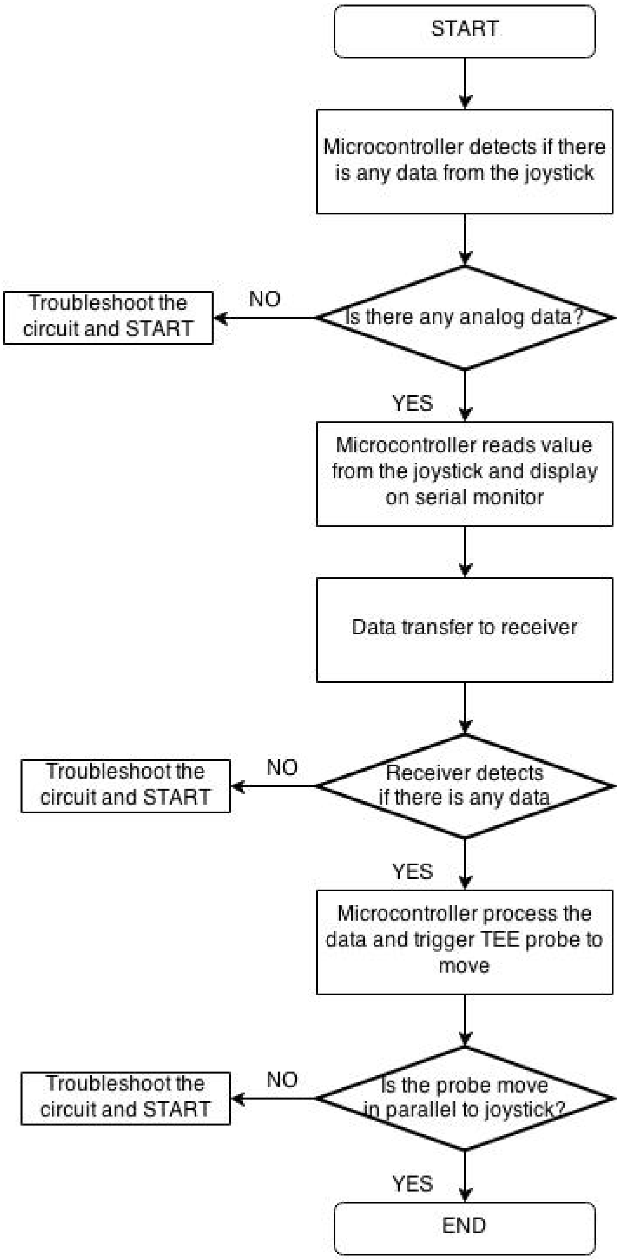

Fig. 5 Flowchart of the remote control system

3.3 Software architecture

The complete operation of the proposed remote positioning control setup is programmable, thus the software can be reprogrammed without any requirement of major changes on the hardware designed.

During the remote positioning control runtime, a connection between the transmitter and the receiver is established when the baud rate and bit rate of the signal transmission was configured at the same rate. After connection was established, transmitter will keep updating the receiver with the latest position data.

The software architecture design includes the programming of the Arduino Uno to read data from its analog input pin, blinks the LEDs to indicate transmit and receive data, and to move the motors as the end results. Arduino Uno is programmed using Arduino IDE ver.1.0.5-r2.

4 Experimental setup to observe the functionality of the 433 MHz receiver

The following experiment was setup to observe if there is any interference that is occurring by the use of wireless technology that coexists with the 433 MHz transmitter-receiver module used. The pattern of the signal received by the 433 MHz RF receiver was observed. If there occured any interference by the adjacent wireless network, a possible signal degradation was expected. The experiment was done in three different environments. Signal observation was performed at a range of distances between 0.2 m to 10 m for all three environment. Both, the 433 MHz RF transmitter and receiver were in ON mode throughout the observations.

4.1 Environment 1: In an empty room with no wireless network and mobile phone turned off

In this experiment, both the transmitter and receiver were placed in the same room. There was no wireless network detected and all mobile phones were switched off. The receiver was placed static at a constant position while the transmitter was manipulated in order to move away from the receiver up to 10 m. Fig. 6 shows the received signal by the receiver.

As observed, the signal received was approximately -66 dBm when the transmitter was in very close proximity with the receiver at 0.2 m. As the transmitter moved away from the receiver, a drastic drop in the signal was observed at 0.5 m at rate approximately -13.75 dBm/m. The signal received was almost constant from 1 m to 9 m. A slight drop was observed at 9 m onwards. The remote control was able to manipulate the movement of the motor up to 10 m.

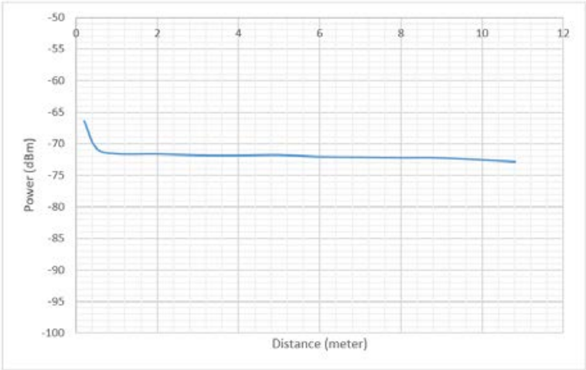

Fig. 6 Signal degradation of the 433 MHz receiver in an empty room environment

4.2 Environment 2: In a real-time environment where wireless network coexist with the 433 MHz RF

In this experiment, both the transmitter and receiver were placed in the same room. There was a wireless network detected in the room. The receiver was placed static at a constant position while the transmitter was manipulated to move away from the receiver up to 10 m. Fig. 7 shows the received signal by the receiver.

As observed, the signal received was approximately -67.5 dBm when the transmitter was in very close proximity with the receiver at 0.2 m. As the transmitter moving away from the receiver, the signal degraded exponentially until a distance at 8 m. A bump on the signal received was observed at 9 m onwards. The remote control was able to manipulate the movement of the motor up to 10 m.

4.3 Environment 3: Both the 433 MHz transmitter and receiver were wrapped with aluminum foils

In this experiment, both the transmitter and receiver were wrapped with aluminium foils and were placed in the same room. The receiver was placed static at a constant position while the transmitter was manipulated to move away from the receiver up to 10 m. Fig. 8 shows the received signal by the receiver.

As observed, the signal received was approximately -68 dBm when the transmitter was in very close proximity with the receiver at 0.2 m. As the transmitter was moved away from the receiver, the signal degraded exponentially at a dramatic rate compared with that in Environment 2. A bump on the signal received was observed at 9 m onwards. The remote control was able to manipulate the movement of the motor up to 6 m only. At 6 m onwards, the receiver showed a signal delay as the movement of the motor was delayed. Motors were not able to be controlled at 7 m onwards.

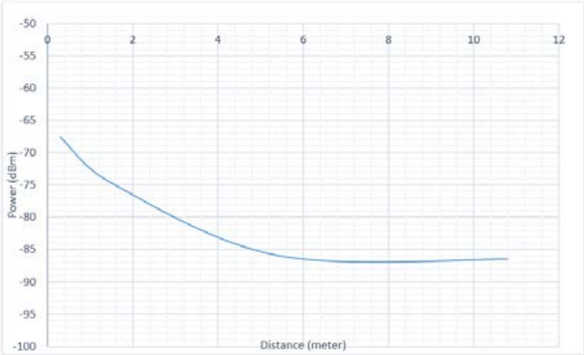

Fig. 7 Signal degradation of the 433 MHz receiver in a real-time environment

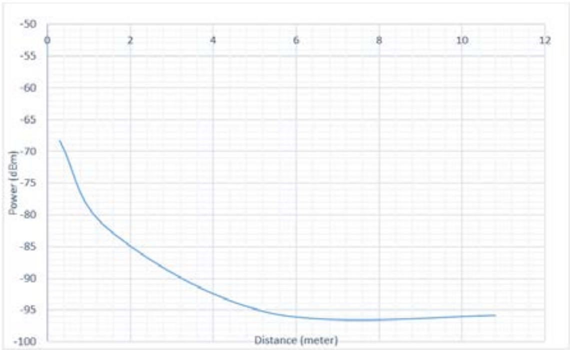

Fig. 8 Signal degradation of the 433 MHz receiver with the transmitter and receiver wrapped with aluminum foils

From the observation, the signal received by the 433 MHz receiver in a room without any network distraction was approximately -66 dBm. There was a slight decrease in the signal to approximately -67.5 dBm when the experiment moved to a room where wireless network coexisted. In the experiment where both, the transmitter and receiver were wrapped with aluminum foils, the signal dropped 0.5 dBm to approximately -68 dBm. The movement of the motors shown was positive in both experiments 1 and 2. There were no delays in the transmission of the signal sent from the transmitters up to 10 m. However, in experiment 3, the signal dropped at a faster rate compared to that in experiment 2. There were signal delays at 6 m and signal lost started to occur at 7 m.

5 Conclusion

From the experiment tested, 433 MHz RF wireless module is capable to transfer signal as far as 10 m and without serious interference when it was functioned coexist with the Wi-Fi networks. 433 MHz RF has met the requirement to be used as the communication interface in the remote positioning control system. The used frequency is able to comply the human factors requirement including user, environment, device and safety factors. Further investigation needed in order to fully support that the designed device is suitable to be applied to the real-time TEE procedures.

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