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Development of Data Communication System with Ultra High Frequency Radio Wave for Implantable Artificial Hearts

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***Abstract*—In order to minimize infection risks of patients with artificial hearts, wireless data transmission methods with electromagnetic induction or light have been developed. However, these methods tend to become difficult to transmit data if the external data transmission unit moves from its proper position. To resolve this serious problem, the purpose of this study is to develop a prototype wireless data communication system with ultra high frequency radio wave and confirm its performance.**

Due to its high-speed communication rate, low power consumption, high tolerance to electromagnetic disturbances, and secure wireless communication, we adopted Bluetooth radio wave technology for our system. The system consists of an internal data transmission unit and an external data transmission unit (53 by 64 by 16 mm, each), and each has a Bluetooth module (radio field intensity: 4 dBm, receiver sensitivity: -80 dBm). The internal unit also has a micro controller with an 8-channel 10-bit A/D converter, and the external unit also has a RS-232C converter. We experimented with the internal unit implanted into pig meat, and carried out data transmission tests to evaluate the performance of this system in tissue thickness of up to 3 mm.

As a result, data transfer speeds of about 20 kbps were achieved within the communication distance of 10 m.

In conclusion, we confirmed that the system can wirelessly transmit the data from the inside of the body to the outside, and it promises to resolve unstable data transmission due to accidental movements of an external data transmission unit.

Keywords—**Wireless data communication system, ultra high frequency radio wave, Bluetooth, and implantable artificial heart.**

I. Introduction

In order to assist and substitute for the cardiac functions of heart failure patients, artificial hearts have made great strides in their performance [1]–[5]. To realize long-term effective medical treatment, it is essential to manage not only the driving condition of an artificial heart but also the physiological condition of a patient with the artificial heart. However, the method of measurement used in intensive care unit (ICU) is invasive and cannot be applied to the implanted artificial heart.

In our project, we have developed an intelligent artificial heart with noninvasive sensor systems—called Smart Artificial Heart (SAH) [6], [7]—and a remote monitoring system [6], [8]. SAH can measure not only the driving data of the artificial heart but also the physiological data of the patient via small-sized, accurate, and non-invasive sensors as if they were in an ICU. The remote monitoring system enables medical staff to manage the physiological condition of patients and the driving condition of the artificial heart based on the data measured by SAH. To implant SAH in the living body and transfer the data to the monitoring system with the minimum risk of infection, it is essential to develop a wireless data communication system to transfer the data from the inside of the body to the outside.

Researchers have developed transcutaneous energy transfer (TET) systems with electromagnetic induction, and wireless data communication systems with electromagnetic induction or light [9]–[12]. Such wireless systems also have been used in commercial products [13]. Although electromagnetic induction is one of the best approaches to transmit the power of more than 10 W in TET systems, the wireless data communication systems have not only low transmission speed for SAH but also a general critical problem that the transmission of the data can become difficult if the external data transmission unit shifts from its proper position.

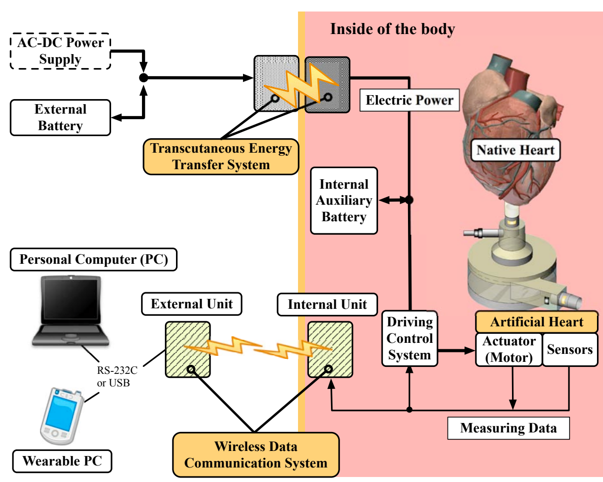

Fig. 1. Concept of wireless data communication system for implantable artificial heart. The wireless data communication system continuously transmits the data from the inside of the body to a remote personal computer (PC) or a wearable PC. The transcutaneous energy transfer (TET) system can stably supply electric power to the implanted artificial heart and the wireless data communication system by using the internal auxiliary battery even if the external energy transmission coil shifts from its proper position and its energy transmission becomes difficult.

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TABLE I
REQUIRED SPECIFICATIONS FOR
WIRELESS DATA COMMUNICATION SYSTEM

Item	Requirement
Size	70 x 100 x 10 mm
System Configuration	Simple
Measurement function	A/D converter has 10-bit resolution and 6 channels.
Transmission function	Transmission speed is more than 9.6 kbps. Communication distance is more than 3 m. Correct data transmission is available under the various radio waves. There are negligible effects on the other medical devices. Secure data transmission is available.
Power consumption	Very low compared with implantable artificial heart's powers consumption
Cost and availability	Low cost and easy availability

In order to resolve this problem, the purpose of this study is to develop a prototype wireless data communication system with ultra high frequency radio wave and confirm its performance. Fig. 1 shows a concept of the wireless data communication system for a patient with an implantable artificial heart. By using ultra high frequency radio waves, it is possible to continuously transmit the data from the inside of the body to a personal computer (PC) or a wearable PC without an external data transmission unit approaching an internal unit like the existing methods.

II. MATERIALS & METHODS

Firstly, we defined the design specifications for the data communication system. Secondly, based on the specifications, we considered wireless technologies with ultra high frequency radio wave and decided to adopt Bluetooth technology [14]. Thirdly, we developed a wireless data communication system based on the design specifications by using Bluetooth technology. Finally, we carried out data transmission tests to evaluate the performance of this system.

A. Required specifications for a wireless data communication system

To develop this system, we defined required specifications shown in Table 1. The size of the internal data transmission unit was limited to 70 mm by 100 mm by 10 mm since this size enables the system to physically be implanted. The desired communication distance was more than 3 m. If this distance is achieved, a patient with an artificial heart could be free from restraint. For example, since the patient wouldn't have to wear a short-ranged external data transmission unit, they could take a shower while the data communication establishes.

The communication speed was determined to be more than 9.6 kbps. This speed was decided as follows:

1) The SAH has six sensors: a flow meter, a temperature sensor, two pressure sensors, a current sensor, and a pump speed sensor [7].
2) Since data of 10-bit resolution are transmitted in two bytes, the data are treated as 16 bit.
3) The sampling frequency of each sensor is 100 Hz.
4) 6 channels x 16-bit x 100 Hz = 9600 bps = 9.6 kbps.

For safe transmission, the influence on other medical devices must be negligible, and correct data communication must be achieved despite electromagnetic noise. Furthermore, low power consumption is also important requirement.

B. Wireless technologies with ultra high frequency radio wave

To transfer physiological data of the human body from the inside of the body to the outside wirelessly and continuously, several researches have indicated the possibility of the use of ultra high frequency radio waves [15]–[18]. The industrial, scientific, and medical band of 2.45 GHz particularly has to be carefully considered because this frequency resonates water molecules in the human body and may cause fever. However, it can easily transmit high data rate. At 2.45 GHz band, several wireless technologies such as wireless LAN, ZigBee, or Bluetooth are available. In this study, we adopted Bluetooth technology considering its specification described in the next subsection.

C. Specification of Bluetooth communication

The latest available Bluetooth technology has the following specifications [14].

1) Bluetooth wireless technology operates in the unlicensed 2.4 GHz spectrum.
2) Bluetooth wireless technology can operate over a distance of 10 meters or 100 meters depending on the Bluetooth device class.
3) The peak data rate with Enhanced Data Rate (EDR) is 3 Mbps.
4) Bluetooth wireless technology is able to penetrate solid objects.
5) Bluetooth technology is omni-directional and does not require line-of-sight positioning of connected devices.
6) The Bluetooth specification allows for three modes of security.
7) The cost of a Bluetooth chip is under $3.

In addition, Bluetooth technology employs a frequency hop transceiver to combat interference and fading, and have security protocols such as device authentication, parity checking, and password checking in order to reduce the possibility of communication errors. Therefore we believe that the above specifications satisfy the requirements for our wireless data communication system.

By April 2009, the Bluetooth Special Interest Group notified Bluetooth 3.0 (Bluetooth Core Specification Version 3.0 High Speed) achieving data transfers at the approximate rate of 24 Mbps, and Bluetooth Low Energy realizing low power consumption [14]. The capability of Bluetooth technology can be anticipated.

D. Development of a prototype wireless data communication system

The developed prototype data communication system consisted of an internal data transmission unit and an external data transmission unit. The internal unit is shown in Fig. 2. This internal unit mainly consists of a peripheral interface controller with an 8-channel 10-bit A/D converter and a Bluetooth module in order to transmit measured data to the external unit. The Bluetooth chip used in this Bluetooth module is version 1.1, class 2 [13]. Its radio field intensity is 4 dBm, and its receiver sensitivity is -80 dBm. This internal unit was 53 mm by 64 mm by 16 mm. The total power consumption of this internal unit was less than 220 mW (The power consumption of Bluetooth module was less than 120 mW). In practice, a TET system or an internal auxiliary battery supplies electric power to an implantable artificial heart and an internal data transmission unit. Compared with the power consumption of an implantable artificial heart, since the power consumption of the internal unit is low enough, it doesn't interrupt the artificial heart.

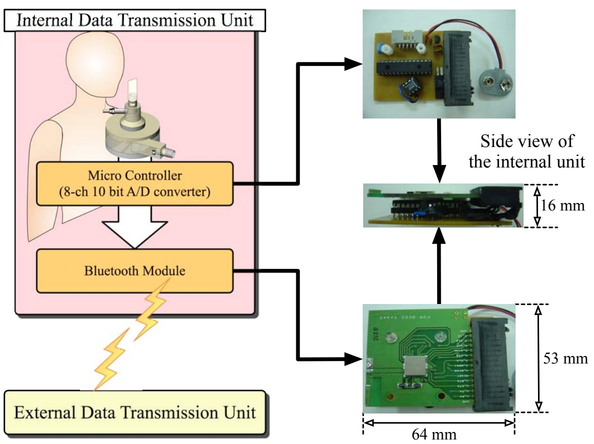

Fig. 2. Internal data transmission unit of developed prototype wireless data communication system.

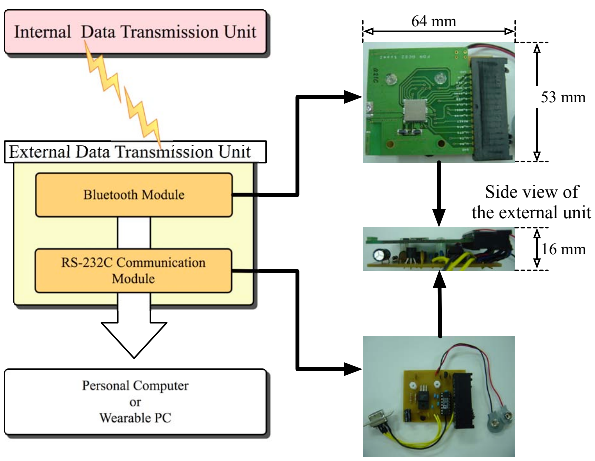

Fig. 3. External data transmission unit of developed prototype wireless data communication system.

The external unit is shown in Fig. 3. The external unit consisted of the same Bluetooth module to receive the data from the internal unit and an RS-232C communication module connected to a personal computer (PC). The external unit also measured 53 mm by 64 mm by 16 mm, and the total power consumption was less than 170 mW. In practice, a PC, a wearable PC, and a personal digital assistance which have a built-in Bluetooth chipset are available instead of this external unit.

The internal and external units start data communication after they establish a connection with each other.

E. Performance test of the data communication system

In order to confirm the performance of the developed wireless data communication system, we carried out the performance test shown in Fig. 4. In order to reproduce the conditions of the internal unit implanted in the body, we wrapped the unit with fresh pig meat during the test. In addition to an absence of the pig meat altogether, two different thicknesses (1.5 mm, and 3 mm) were tested. After wrapping the internal unit, it was strapped to the abdomen of the tester and the relationship between communication distance and speed was investigated.

Moreover, considering the attenuation of the radio field intensity by radio wave absorption in body tissues, we carried out this test in two cases. In the first case, the internal unit faced the external unit directly as shown in Fig. 4(a). In the second case, the internal unit faced the external unit indirectly as shown in Fig. 4(b). In the case of Fig. 4(b), since there was a human body on the shortest path between the internal unit and the external unit, we anticipated the strongest attenuation of radio field intensity.

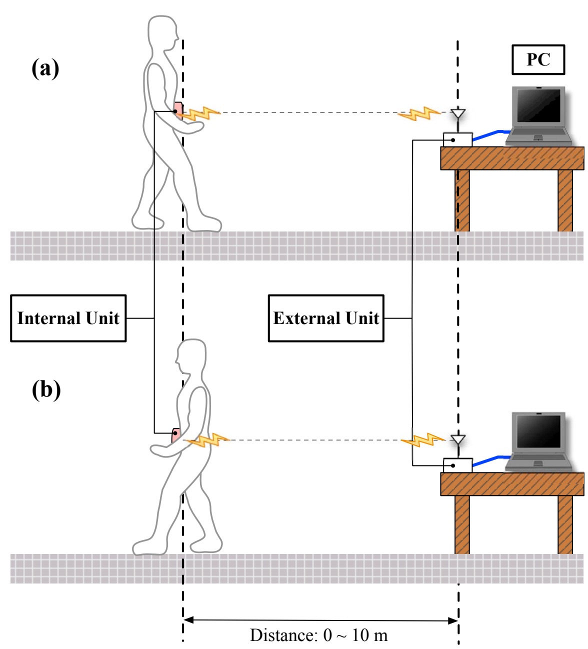

Fig. 4. Performance test for developed prototype wireless communication system. (a) The internal data transmission unit faced the external unit directly. (b) The internal data transmission unit faced the external unit indirectly.

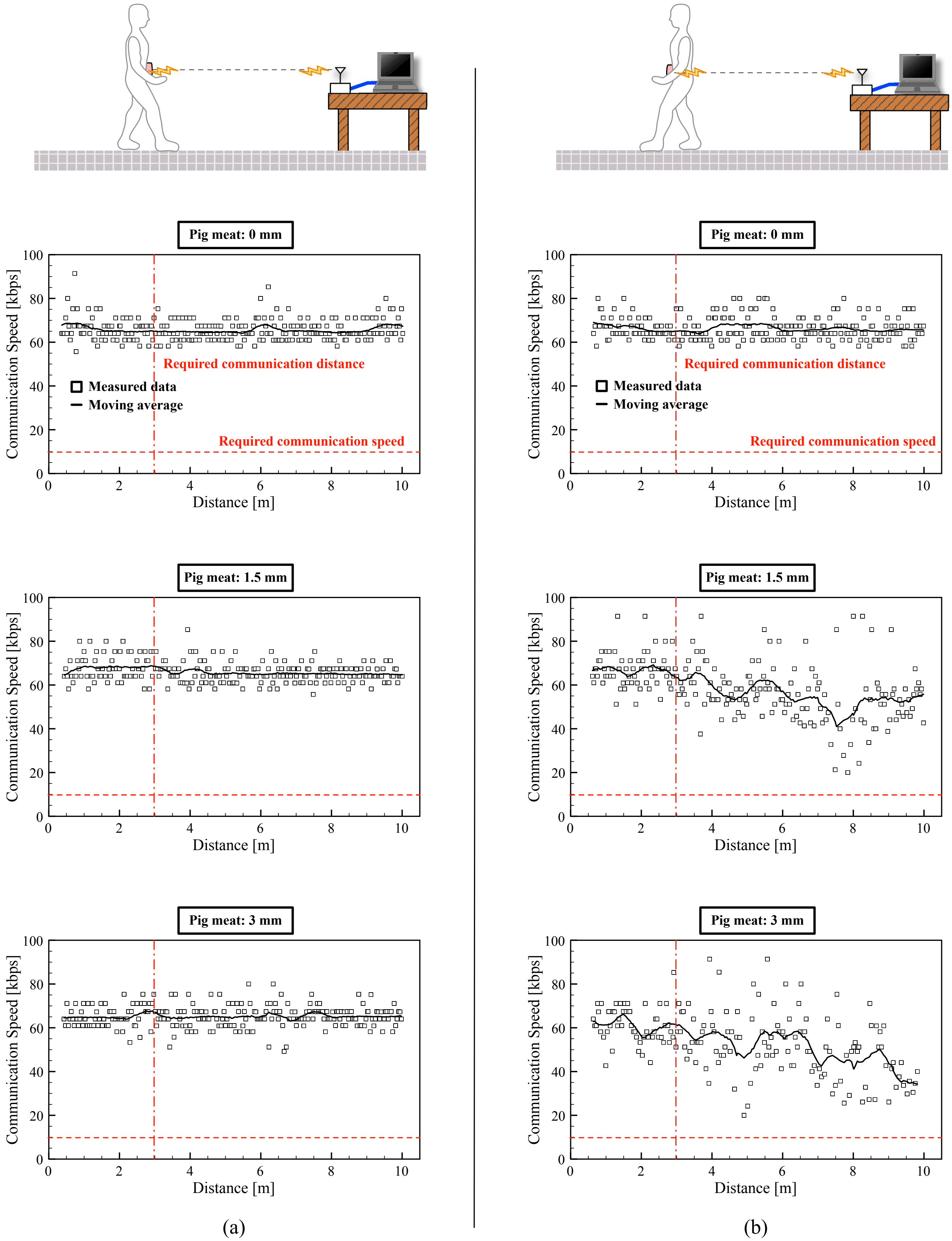

Fig. 5. Results of performance test in three different conditions (thickness of pig meat: 0 mm, 1.5 mm, and 3 mm). (a) The internal unit faced the external unit directly. (b) The internal unit faced the external unit indirectly.

III. Results

Fig. 5 shows the relationship between the communication distance and the communication speed in the two cases [Fig. 4(a) and Fig. 4(b)]. In the case of Fig. 4(a), communication speed measured under two conditions (meat thickness: 0 mm and 1.5 mm) was continuously more than 55 kbps within the distance of 0 m to 10 m. Communication speed measured under the third condition (meat thickness: 3 mm) experienced a slight decrease in speed, but was more than 45 kbps. Furthermore, the average speed was continuously more than 60 kbps under the three conditions [Fig. 5(a)].

In the case of Fig. 4(b), communication speed measured without pig meat was continuously more than 55 kbps within the distance of 0 m to 10 m and its average speed was continuously more than 60 kbps. Communication speed measured under two conditions (meat thickness: 1.5 mm and 3 mm) was about 20 kbps and this speed decreased according to the distance. Moreover, the condition (meat thickness: 3 mm) showed a stronger decrease with distance than the condition (meat thickness: 1.5 mm) [Fig. 5(b)]. As a result, data transfer speeds of about 20 kbps were achieved within the communication distance of 10 m through all conditions.

IV. Discussion

A wireless data communication system is essential for ensuring the safety of a patient with an implantable artificial heart because the data measured by the implantable artificial heart can be transferred to an external wearable personal computer by using the communication system with the minimum risk of infection and be monitored via the Internet by medical staff from a remote location.

The Bluetooth technology that we applied to our data communication system is suitable in communication speed, security, cost, and availability. Compared with existing data communication systems using electromagnetic induction or light [9]–[12], it is possible to continuously transmit the data from the inside of the body to a remote location without the need of an external intermediary data transmission unit approaching an internal data transmission unit.

When the internal unit communicated with the external unit over a clear path [Fig. 5(a)], the communication speed was sufficiently fast, stable, and unaffected by the communication distance or the thickness of the pig meat. Furthermore, even when the wearer's body was positioned to block the communication path [Fig. 5(b)], it satisfied the required communication speed and distance. From the variability of the communication speed in the conditions (meat thickness: 1.5 mm and 3 mm) in Fig. 5(b), we found that the body position strongly affected stable communication as compared with the effect of tissue thickness of up to 3 mm. Thereby, we will have to conduct another study about the relationship between stable communication and body positions or movements.

As for the developed communication system, since the size doesn't satisfy the desired specification, we are developing a smaller size system by replacing all electronic components with surface-mount equivalents. Moreover, we should confirm a maximum thickness of body tissue at which the required communication speed can be realized because 3 mm thick fresh tissue restricts anatomical positions of the internal unit if the antenna is not separated from the Bluetooth module generally including the antenna. Since we didn't deal with biocompatibility about 2.45 GHz band in this study, we should also confirm specific absorption rate [19] satisfies relevant regulatory requirement in our data communication system. During the performance test, although the communication connection was not lost, in practice, we have to consider self-recovery from connection failure in our system.

V. Conclusion

In this research, we have developed a prototype wireless data communication system with Bluetooth as ultra high frequency radio wave technology in order to continuously transmit the data from the inside of the body to a remote place without an external data transmission unit approaching an internal data transmission unit like the existing methods. When the internal unit communicated with the external unit over a clear path, the communication speed was sufficiently fast, stable, and unaffected by the communication distance or the thickness of the pig meat. Furthermore, even when the wearer's body was positioned to block the communication path, it satisfied the required communication speed and distance. Therefore we confirmed that this system has the capability to wirelessly transmit the data from the inside of the body to the outside, and it promises to resolve unstable data transmission due to accidental movements of an external data transmission unit. Moreover, by using Bluetooth 3.0 module in our wireless communication system in the near future, we will apply functions for detecting abnormal conditions [20], [21] to SAH, which need faster data communication speed, and be able to dramatically improve SAH.

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References

[1] K. Yamazaki, S. Kihara, T. Akimoto, *et al*., "EVAHEART: an implantable centrifugal blood pump for long-term circulatory support," *Jpn J Thorac Cardiovasc Surg*., vol. 50, pp. 461–465, 2002.

[2] R. D. Dowling, L. A. Jr. Gray, S. W. Etoch, *et al*., "Initial experience with the AbioCor implantable replacement heart system," *J. Thorac Cardiovasc Surg.,* vol. 127, pp. 131–141, 2004.

[3] Y. Nosé and K. Furukawa, "Current status of the Gyro Centrifugal Blood Pump — Development of the permanently implantable centrifugal blood pump as a biventricular assist device (NEDO Project)," *Artif. Organs,* vol. 28, pp. 953–958, 2004.

[4] T. Nishinaka, H. Schima, W. Roethy, *et al*., “The DuraHeart VAD, a magnetically levitated centrifugal pump: the University of Vienna bridge-to-transplant experience,” *Circ. J.*, vol. 70, pp. 1421–1425, November 2006.

[5] D. S. Esmore, D. Kaye, R. Salamonsen, *et al*., “Initial clinical experience with the VentrAssist Left Ventricular Asssit Device: The Pilot Trial,” *Journal of Heart Lung Transplant*, vol. 27, pp. 479–485, 2008.

[6] Y. Sankai, H. Koguchi, R. Takiya, *et al*., “Bio-telemetry system and non-invasive sensors for smart artificial heart (SAH)” (Abstract). *ASAIO J.*, vol. 46, pp. 205, 2000.

[7] H. Yamagishi, Y. Sankai, T. Yamane, T. Jikuya, and T. Tsutsui, “Development of built-in type and noninvasive sensor systems for smart artificial heart,” *ASAIO J.*, vol. 49, pp. 265–270, 2003.

[8] R. Kosaka, Y. Sankai, R. Takiya, *et al.*, “Tsukuba remote monitoring system for continuous-flow artificial heart,” *Artif. Organs*, vol. 27, pp. 897–906, 2003.

[9] E. Tatsumi, Y. Taenaka, K. Uesho, *et al*., “Long-term in vivo testing of the National Cardio- vascular Center electrohydraulic total artificial heart,” *J. Congest Heart Fail Circ. Support*, vol. 1, no. 4, pp. 153–160, 2001.

[10] T. Mussivand, P. J. Hendry, R. G. Masters, and W. J. Keon, “A totally implantable VAD with remote patient monitoring and control”, *J. Congest Heart Fail Circ. Support*, vol. 1(4), pp. 371–377, 2001.

[11] E. Okamoto, E. Iwazawa, S. Suzuki, S. Fukuoka, and Y. Mitamura, “Feasibility of a remote monitoring system for implantable LVAD patients using PHS telecommucation technology,” *J. Artif. Organs*, vol. 4, no. 3, pp. 205–213, 2001.

[12] A. Snyder, W. Pae, J. Boehmer, *et al*, “First clinical trials of a totally implantable destination therapy ventricular assist system,” *J Congest Heart Fail Circ Support*, vol. 1, no. 4, pp. 185–192, 2001.

[13] J. Choi, J.W. Park, J. Chung, and B.G. Min, “An intelligent remote monitoring system for artificial heart,” *IEEE Trans. Inf Technol Biomed.*, vol. 9, no. 4, pp. 564–573, 2005.

[14] Bluetooth SIG, Inc., “BLUETOOTH SPECIFICATION,” [Online] Available: http://www.bluetooth.com/Bluetooth/. Accessed May 5, 2009.

[15] Y. Chan, H.M. Max, K.L. Wu, and X. Wang, “Experimental study of radiation efficiency from an ingested source inside a human body model,” in *Proc. IEEE Eng. Med. Biol. Soc 27th Annu. Int. Conf.*, Sept. 2005, pp. 7754–7757.

[16] X. Lisheng, M.Q.H. Meng, and R. Hongliang, “Effect of subject size on electromagnetic radiation from source in human body following 2450MHz radio frequency exposure,” in *Proc. IEEE Integratio Technology Int. Conf.*, Mar. 2007, pp. 326–329.

[17] U. Kawoos, M.R. Tofighi, R. Warty, F.A. Kralick, and A. Rosen, “In-vitro and in-vivo trans-scalp evaluation of an intracranial pressure implant at 2.4 GHz,” *IEEE Trans. Microw. Theory Tech.*, vol. 56, no. 10, pp. 2356–2365, 2008.

[18] A. Alomainy and Y. Hao, “Modeling and characterization of biotelemetric radio channel from ingested implants considering organ contents,” *IEEE Trans. Antenna Propag.*, vol. 57, no. 4, pp. 999–1005, 2009.

[19] International Commission on Non-Ionizing Radiation Protection, “Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz)” *Health Phys.*, vol. 74, no. 4, pp. 494–522, Apr. 1998.

[20] S. Tsujimura, T. Kuwabara, H. Koguchi, *et al.*, “Development of failure detection system based on vibration signal for smart artificial heart: In vitro study”, in *Proc. IEEE Eng. Med. Biol. Soc 30th Annu. Int. Conf.*, Aug. 2008, pp. 697–702.

[21] S. Tsujimura, H. Koguchi, T. Yamane, T. Tsutsui, and Y. Sankai, “Development of noninvasive thrombus detection system with near-infrared laser and photomultiplier for artificial hearts”, *in Proc. 13th Int. Conf. Biomed. Eng.,* Dec. 2008, pp. 635–638