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A Software Upgrade Method for Micro-electronics Medical Implants

Yang Cao, Hongwei Hao, Lin Xue, Luming Li, Bozhi Ma
Engineering Mechanical Department, Tsinghua University, Beijing, P.R.China

Abstract: A software upgrade method for micro-electronics medical implants is designed to enhance the devices' function or renew the software if there are some bugs found, the software updating or some memory units disabled. The implants needn't be replaced by operations if the faults can be corrected through reprogramming, which reduces the patients' pain and improves the safety effectively. This paper introduces the software upgrade method using in-application programming (IAP) and emphasizes how to insure the system, especially the implanted part's reliability and stability while upgrading.

Key words: software upgrade, micro-electronics medical implant, in-application programming (IAP)

I. Introduction

Micro-electronics medical implants, which can work in the human bodies, treat the patients with current pulse therapy chronically. The microelectronics implants available in use mainly contain implantable cardiovascular pacers, neuro-stimulators, ear implants and eye implants. The micro control unit is the core of an implantable device circuit that controls the function of measurement and stimulation, and also manages to exchange parameters with the bidirectional wireless programming apparatus outside body. Once the device is implanted into the patient, the software running on the MCU can't be changed, since it is installed into the memory integrated with the MCU. When needing upgrading the inner software or some unit of the memory disabled, the device should only be replaced by operation. U.S. Food and Drug Administration (FDA) published enforcement reports to recall some implants with faults many times, such as the Guidant recalled more than 50 types of pacemaker implants from 1997 to 2000, in which there were 21,000 implants needing reprogramming because of the memories faults [1].

In addition, the frame of the circuit and hardware has been developed adequately for past years, and the implants' longevities will be improved much with the developments of high-powered batteries and low-power cost technologies. With the comprehensions on the pathologies enhanced, new advanced signal processing arithmetics and therapy methods will emerge ceaselessly. All of these improvements will replace the older generation of products by new ones faster and faster. And most of the replacements are the software upgrade.

A software upgrade method for the implantable medical devices has an active effect on the devices' generation replacements with low cost and no operations. It also can reduce the pain and expenses for the patients when the devices need recalling because of the faults in the software, and is good for reducing the R&D risks too. According to the resources available, the design had better not use new peripheral elements, and insure the reliable upgrade processes, that shouldn't import new problems and faults if unsuccessful. The software controlling the upgrade should have a user-friendly graphical interface, which is easy to use for the doctors.

II. Solution

2.1 System Overview

The software installed in the medical implants, most of which are in use, can't be reprogrammed. Once there are some bugs in the software or some units of memories disabled, the devices can only be exchanged by operations. Nowadays, there are many MCUs' Flash memories supporting In-System programming (ISP) and In-Application programming (IAP) technologies that can be used to upgrade or reprogram the software in the MCUs.

Implantable medical devices usually include two parts, one of which is programming system outside body; the other is the implanted part working in the body. The design bases an implantable neuro-stimulator that developed in Tsinghua Space Center 2005, and reuses its programming system for upgrade, which manages to program and receive telemetry data and also can control the upgrade when necessary. The whole system doesn't need other elements even if the new function is added, and keeps the hardware reliability as before.

A simplified diagram of the whole completely system is represented in Figure 1. The programming and controlling system (PCS) that works outside consists of a bidirectional programming apparatus, hp iPAQ Pocket PC hx 2110 and an external storage card. The implanted part is made up of a MCU, RAM memory, Flash Memory, communication interface, stimulation or measurement circuit and the electrodes or sensors.

When upgrading, the PCS is operated by doctors or other professionals, who run the controlling software installed on the Pocket PC, and communicates with the inner device through electromagnetic coupling [2].

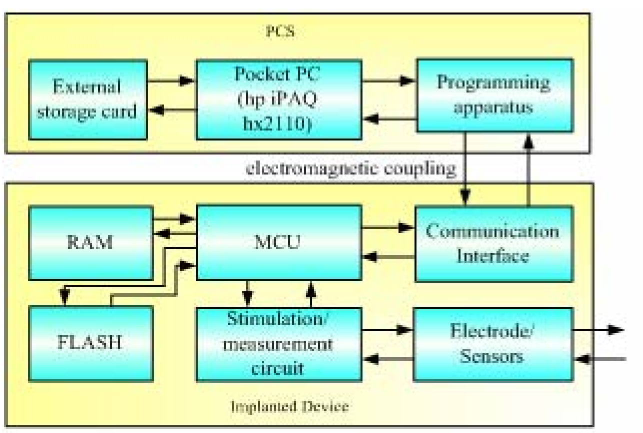

FIGURE I

SIMPLIFIED DIAGRAM OF THE WHOLE SYSTEM

2.2 The Programming and Controlling System (PCS)

The PCS is mainly composed of a Pocket PC and programming apparatus, which is in charge of communicating with the implanted part. The software running on the Pocket PC is developed with Microsoft Embedded Visual C++. To simplify the operation, the upgrade files will be published with SD card. When upgrading, firstly, insert the card into Pocket PC, and run the software that will check whether there are legal upgrade files. Then the Pocket PC indicates the user to reset the implants, sends password and entering orders to get the operating right. The implanted device sends the software's information used in process, such as edition NO. to the Pocket PC to make sure whether needing upgrading or not. The Pocket PC starts to analysis the file and package two types data frames according to the analyse results to send to device if all the conditions above are met. The communication frames definition is shown on Figure 2. One of the frames is the erase frame to erase the Flash, and the other is write frame to write the code at the corresponding addresses in the memory (Flash). During the process, the Pocket PC will wait for the ack from the device after sending each frame to insure the reliability. If something unexpected happens, the process will break off, and preserve the broken point place for the convenience when upgrading next time.

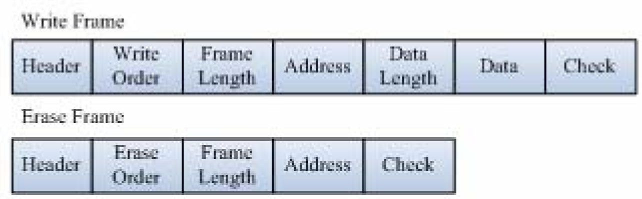

FIGURE II

THE COMMUNICATION FRAME DEFINITION

The software running on the Pocket PC is optimized to suit for the doctors' operating, which aims at as easy to use as possible. Now, the graphics user-interface is simple to use after modifications. Only two pushes on the LCD, choosing the file and starting the process, will accomplish the upgrade automatically. There will be some relevant hints on the upgrade's breaking off.

2.3 The Implanted Device Part

The nerve stimulator Device is the core of the whole system, the MCU of which supports the ISP and IAP technologies, is a product of Texas Instrument, MSP430 [3]. The design doesn't use the ISP with the standard 9600bps baud rate, but uses a user-defined 600bps rate, to avoid mistaken programming and also to ensure the reliability. The IAP mode programming to the memory (Flash) needs another absolute complex code stored in the Flash to analysis the upgrade file commonly that will get the code more and more complex and increase the software invalidation possibility. The method consults IAP thinking, and disposes two types of codes in the Flash memory, one of which is the therapy executing code, that is used to execute the desired therapy program, and the other is the programming service code that manages to reprogram to the Flash when the upgrade mode started. There is a main difference comparing with the common IAP mode, that the MCU only needs to receive the frames and check them, and the complex analysis process is completed by Pocket PC to decrease the codes stored in the Flash and enhance the embedded software's stability and reliability.

The Flash memory is divided into several parts consisting of one information storage area and several code storage areas to make the memory's structure logical and avoid the codes covering with each other. Figure 3 shows the division. As the figure shows, the area for system code stores the programming service code and some constants needing backup, such as the frame header marker and the order markers, which is set to be read only. The other code storage areas store the editions of the therapy executing codes. For the device's safety, the upgrade file is written in the spare area, not covering the original one, and stores the new code when checksum is right. Then renew the therapy program entry pointer in the information storage area. Even if the upgrade is unsuccessful or breaks off, the last edition code is still stored in another area, to which the programming entry can return to point; the device can still work with the original code. And the programming service code set to be read only can also process the data received from the Pocket PC and complete the upgrade again when starting the reset mode.

Flash segment	Content	Mode
System code storage	Programming service code (frame header & order markers)	Read only
Code storage 1	Edition 1	Read/ Write
Code storage 2	Edition 2	
……	……	
Code storage n	Edition n	
Information storage	The available code's entry and edition NO.	

FIGURE III
THE FLASH MEMORY DIVISION DIAGRAM

The implantable medical devices should execute therapy programs highly reliably, and never enter the upgrade mode by external impulse. And when upgraded, the doctors or other professionals should operate the PCS. So the impulse condition for entering the upgrade mode can't be too simple that it is undemanding to enter the mode. Figure 4 shows the upgrade starting process. The MCU in the device should test some special associated conditions and then starts the mode. Firstly, the users should start the MCU's reset mode by a magnet controlling a switch integrated on the circuit and the PCS. On operation, use the magnet to close the switch and then the Pocket PC controls the programming apparatus to send electromagnetic wave at a special frequency, both of the two conditions above are met, the device will enter reset mode, and will return if one of the conditions can't be met.

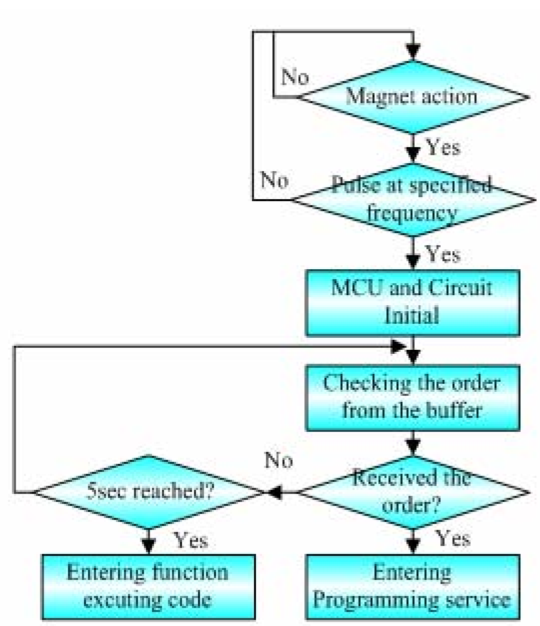

FIGURE IV
THE UPGRADE STARTING PROCESS

The MCU and the periphery circuit will be initialized after the device enters reset mode. And then MCU keeps reading the serial communication port's buffer to check whether there is the order to start the programming service code. If it receives the signal in 5 seconds, the MCU will enter the upgrade mode and start the service code to upgrade. The MCU erases the specified segments in the Flash, receives the data frames by order and stores them in RAM memory, then write to the Flash if the checksums are right.

III. Evaluation

The function and the feasibility of the method for upgrading the software of implantable medical devices were tested as follows when completed in designing and programming. The experiment used the upgrade file (ASCII text file), which was built with IAR EW430, sized 12KB, analysed and sent by the Pocket PC to reprogram the stimulator 10 times. The upgrades all completed successfully in 5 minutes. The result indicates that the method is feasible and can keep a high successful rate at the effective distance.

As a matter of fact, there are some factors affecting the communicating capability, such as the file size, the protocol, the file analysis arithmetic. The small file will reduce the time obviously, and the protocol should balance the efficiency and reliability. Increasing the amount of data in each frame will enhance the efficiency but the more data in one frame, the less reliable it would be. And the file analysis arithmetic also affects the efficiency, but the infection could be ignored as the Pocket PC processes much faster than the communication. Comparing with several experiments, the write frame containing 6 bytes code data works well. And optimizing the protocol and analysis arithmetic will be continued henceforth.

IV. Conclusion

A software upgrade method for implantable medical devices is described in this paper, which offers several novel and original features. Besides implementing the upgrade function, it aims at keeping high reliability and simplifying the system. As a result, there aren't adding any new elements to the original system, otherwise, specified impulse conditions and baud rate are designed to insure the safety. And it is different from the method embedded systems commonly adopting to upgrade the software, which acquire and check the upgrade data actively by the modem, Internet or some portable storage devices. It cuts out the MCU's code as simple as possible, realizes the IAP function through the Pocket PC and each frame will be checked. The upgrade uses file backup mode, even if the upgrade is unsuccessful, the implants can return original status. All of these enhance the system reliability effectively.

Reference

[1] FDA Updates Consumers on Guidant Corporation's Implantable Defibrillators. July 1, 2005 (http://www.fda.gov/bbs/topics/NEWS/2005/NEW01198.html)

[2] L.Xue, H.W.Hao, L.M.Li, B.Z.Ma. A new method of radio frequency links by coplanar coils for implantable medical devices. Proceedings of the 2005 IEEE Engineering in Medicine and Biology 27th Annual Conference, Shanghai, China, September 1-4, 2005

[3] Texas Instrument. Features of the MSP430 Bootstrap Loader. Application Report SLAA089C-February 2006