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DEVELOPMENT OF FUNCTIONAL PROTOTYPE OF ELECTRICAL LOWER ESOPHAGEAL SPHINCTOR STIMULATOR

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Abstract. Scientific and technical innovations done since 1960s resulted in successful development and implementation in medical practice active implantable devices. Most of them are using traditional chemical batteries with limited longevity. Further research progress and development of semiconductors and passive elements base are allowing now to develop fully battery-free implants that could do same tasks, but with much lower sizes, less complication and more ease of use. In this article will be shared results of own development of an wireless-powered, remote controlled, fully implantable electrostimulator of lower esophageal sphincter (WIPLES) aimed to treat gastroesophageal reflux disease, that is very common in current days.

Keywords: *battery-free, electrostimulator, implantable, reflux disease, wireless-powered.*

Rezumat. Inovațiile științifice și tehnice realizate începând cu anii 1960 au condus la dezvoltarea și implementarea reușită în practica medicală a dispozitivelor implantabile active. Majoritatea acestora utilizează baterii chimice tradiționale cu o durată de viață limitată. Progresul ulterior al cercetărilor și dezvoltarea bazată pe semiconductori și elemente pasive permit acum dezvoltarea implanturilor complet fără baterii, care pot îndeplini aceleași sarcini, dar cu dimensiuni mult mai mici, mai puține complicații și mai ușurință în utilizare. În acest articol vor fi împărtășite rezultatele propriei dezvoltări a unui electrostimulator complet implantabil, alimentat fără fir și controlat la distanță al sfincterului esofagian inferior (WIPLES), destinat tratării bolii de reflux gastroesofagian, care este foarte răspândită în zilele noastre.

Cuvinte cheie: *alimentare fără fir, boală de reflux, electrostimulator, fără baterie, implantabil.*

1. Introduction

Implantable electrostimulators were initially introduced within medical practice in the early 1960s, marking the debut of the portable pacemaker, later renowned for its high reliability and enduring nature 1. Since then, these devices have seen a consistent surge in their application for both therapy and the diagnosis of various diseases. The most common stimulator depending on end application are cardiac pacemakers 1, deep brain stimulators (DBS) 2, sacral nerve Stimulators (SNS) 2, vagus nerve stimulators (VNS) **Error! Reference source not found.**, cochlear implants 5, gastric neurostimulator 7, lower esophageal sphincter (LES) stimulator **Error! Reference source not found.** and other types.

An inherent limitation of these active implants is their usage duration, primarily dictated by the capacity of the internal battery, typically lasting up to 6-8 years [9-10].

Simultaneously, advancements in wireless communications have coincided with the evolution of wireless power transfer technologies, offering prospects to elevate electronic device development to unprecedented heights. For example, recent studies showed basis for energy transfer of implanted stimulators even in several centimeters of tissue [11,12]. Transitioning from relying on non-rechargeable portable battery sources to harnessing energy from electric and/or magnetic fields or even mechanical body movements [13] holds the promise of substantially reducing device sizes while enhancing their quality, safety, and user-friendliness. Implantable stimulators represent a diverse range of devices used in various medical applications, offering therapeutic benefits by delivering controlled electrical impulses to specific areas of the body.

This study focuses on development of implantable LES stimulator for possible application in gastroesophageal reflux disease (GERD) treatments. According to the latest literature review, the prevalence of GERD is 18.1−27.8% in North America, 8.8−25.9% in Europe, 2.5−7.8% in East Asia, 8.7−33.1 % in the Middle East, 11.6% in Australia and 23.0% [14].

Recent studies showed high efficacy and safety of electrical LES stimulation, where the specially designed traditional battery-powered stimulators are used. Taking in account confirmed advantages of batter-free implants, having experience in developing of wireless implants, we hereby present result of developing process for lightweight, miniaturized, wireless-powered, and battery-free device that can be entirely implanted [15-17]. These advancements offer capabilities that meet or surpass those of connected and battery-operated options, overcoming their inherent constraints.

2. Materials and methods

As a result of previous research, literature review and scientific exploration, the key components of a fully functional prototype of the lower esophageal sphincter electrical stimulator have been identified as below:

1) central microcontroller;
2) wireless power receiver;
3) wireless communication module according to Bluetooth 4.0 BLE standards;
4) nanoAmper power controller with timer for energy saving;
5) low voltage step-up DC-DC converter from 0.7V to 3.3V;
6) digital thermometer module;
7) super-capacitor for energy storage;
8) hybrid constant current (CC) pulse module.

The general block diagram of developed device is presented on Figure 1.

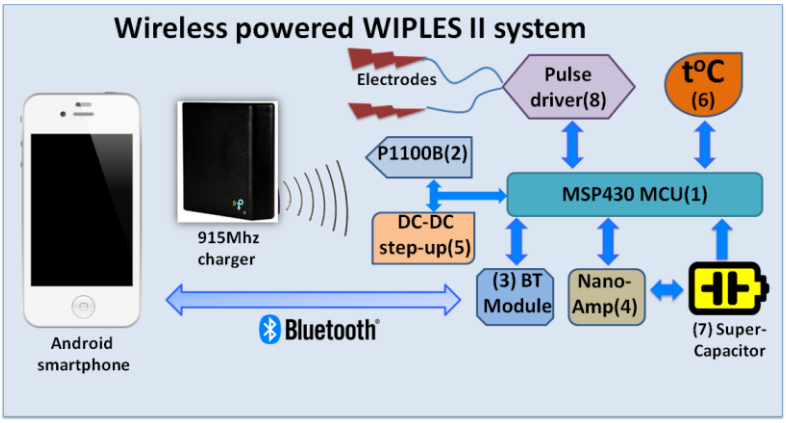


Figure 1. Functional block diagram of the prototype.

Below will be providing short description of each module included.

1) Central microprocessor is based on platform MSP430 from Texas Instruments™ (TI) MSP430 MCUs with non-volatile FRAM (ferroelectric random access memory) have 16-bit processing core, specially designed for ultra-low-power system management designs.

The unique features are the lowest standby power (up to 350 nA), 100 μA/MHz active power, and the ability to save and immediately restore system state after power failure. MSP FRAM MCUs are very reliable, having write endurance up to 10^{15} cycles, as well as 10-year data retention time, advanced code &data protection with integrated security features.

2) Wireless charging module is based on RF charging by cm waves, specially designed to work with 915 Mhz transceiver with power output 1W or 3W, with automatic disable function if is closer than 23cm to live organisms, to ensure necessary protection according to existing standards ERC 70-03 [18]. Technical parameters of the wireless module are listed in Table 1:

Table 1

Technical specification of a wireless power receiver module

Operating frequency	868...950 MHz
Output voltage	2.0...5.5 V
Output current	up to 50 mA
Input power	-12...10 dBm
Antenna type	50 Ohm
Type of energy store	super capacitor
Dimensions	15.9×10.9×2.3 mm

3) Wireless module used is type Bluetooth BLE 4.0 with GATT profile, which allows simple remote connection using any Serial port application. Module is based on low energy System-on-Chip from Dialog Semiconductor, model DA1458x, with chip dimensions of only 2.5×2.5×0.5 mm. Taking into account the high complexity of manufacturing a high-frequency wireless module of the Bluetooth standard, a ready-made module of the HJ-580B type based on the DA14580 chipset. This fully compliant with the Bluetooth BLE standard, the module has a standby consumption of only 2 μA, start time only 10ms and a maximum peak current of 500 μA.

4) NanoAmper power controller has a unique feature of radical reducing of system power consumption in idle state. Having inside nano-timer series TPL5xxx from TI with a watchdog feature, working in pair with load switch, this controller schematics is designed for battery-powered and battery-free applications. Usually these applications require use of a microcontroller, with keeping it in a low power mode to maximize current savings, waking up only during certain time intervals to collect data or doing service required.

Consuming only 35 nA in idle state, this type of controller offers power savings of almost two orders of magnitude, enabling the use of significantly power, especially in current application.

5) Low power DC-DC converter based on TPSxx platform from TI is designed to convert power energy, received by wireless charging module to standard system power of 3.3V. The distinctive feature is module starting only from 0.7V, providing necessary power even in worst conditions.

6) Digital thermometer series TMPxx from TI with ultra-low power consumption is used to provide precise temperature measurements of installed implantable prototype. It also is serving the function of remote monitoring of system state.

7) Super-capacitor was used to provide storage of necessary energy, received from wireless power receiving schematics. Taking in account, that super capacitors could be charged up to 100'000 times, the possible working period for implantable device could reach 20 years and even more, this is already more depends on biocompatibility properties of encapsulation cover.

8) Hybrid constant current (CC) pulse module is invention of author, having unique features of combining ultra-low supply current consumption with ease of digital current setting. This type of schematics ensures delivering same level of stimulation energy independent of stimulation electrode's impedance change during patient movements, contact aging or biological encapsulation [16].

Printed circuit board (PCB) design and prototype assembly

Complete design of the electrical circuit and printed circuit board was carried out in the Autodesk Eagle PCB and electronic schematics development environment.

The appearance of the PCB sized only 14×10 mm is shown on Figure 2.

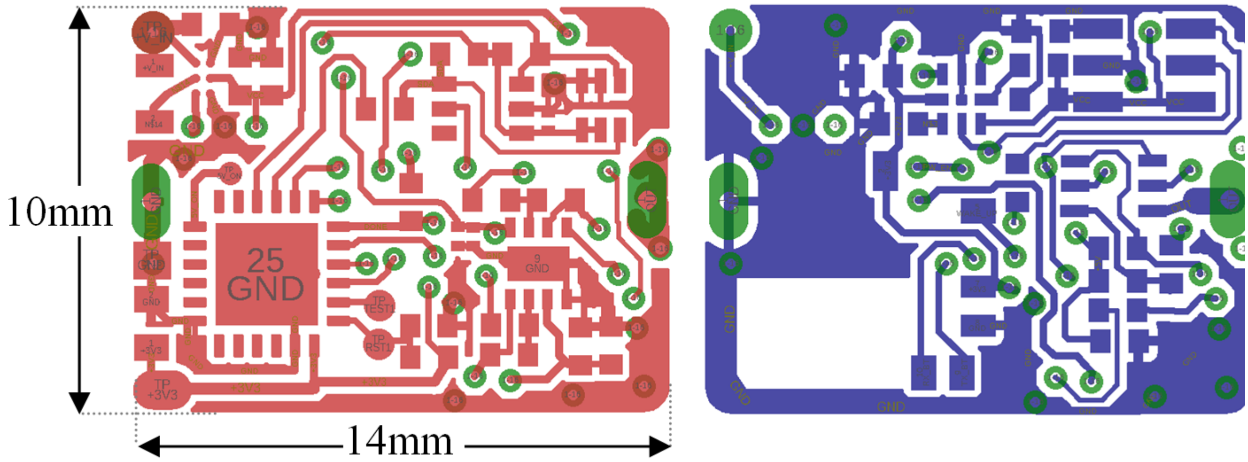


Figure 2. Developed PCB of the main board of prototype, top &bottom layers, scale 40:1.

Upon completion of the development of electrical circuits, a package of electronic drawings in Gerber format was prepared for the manufacture of printed circuit boards at a specialized factory with specification according to Table 2:

Table 2

Technical specification of developed PCB

Material	FR-4 TG130
Number of layers	2
PCB thickness	0.6 mm
Mask color	Green
Surface treatment	HASL (hot air solder leveling)
Minimum mask jumper	0.1 mm
Copper thickness	35 microns (300 g/m^2)
Minimum diameter of the via hole	0.2/0.25 mm
Minimum track width	0.12 mm

At the same time, the minimum size of discrete elements was only 0.60×0.30×0.23 mm (type SMD 0201). The minimum pin pitch of the microcircuits was only 0.3 mm.

The assembly of printed circuit boards was carried out using SMT technology with a laser stencil for applying solder paste.

Solder paste reflow was carried out in a controlled temperature environment using a digital programmable soldering oven type INFRARED IC HEATER T-962 with built-in industry standard temperature profiles for various soldering modes.

The appearance of the entire process is presented in Figure 3.

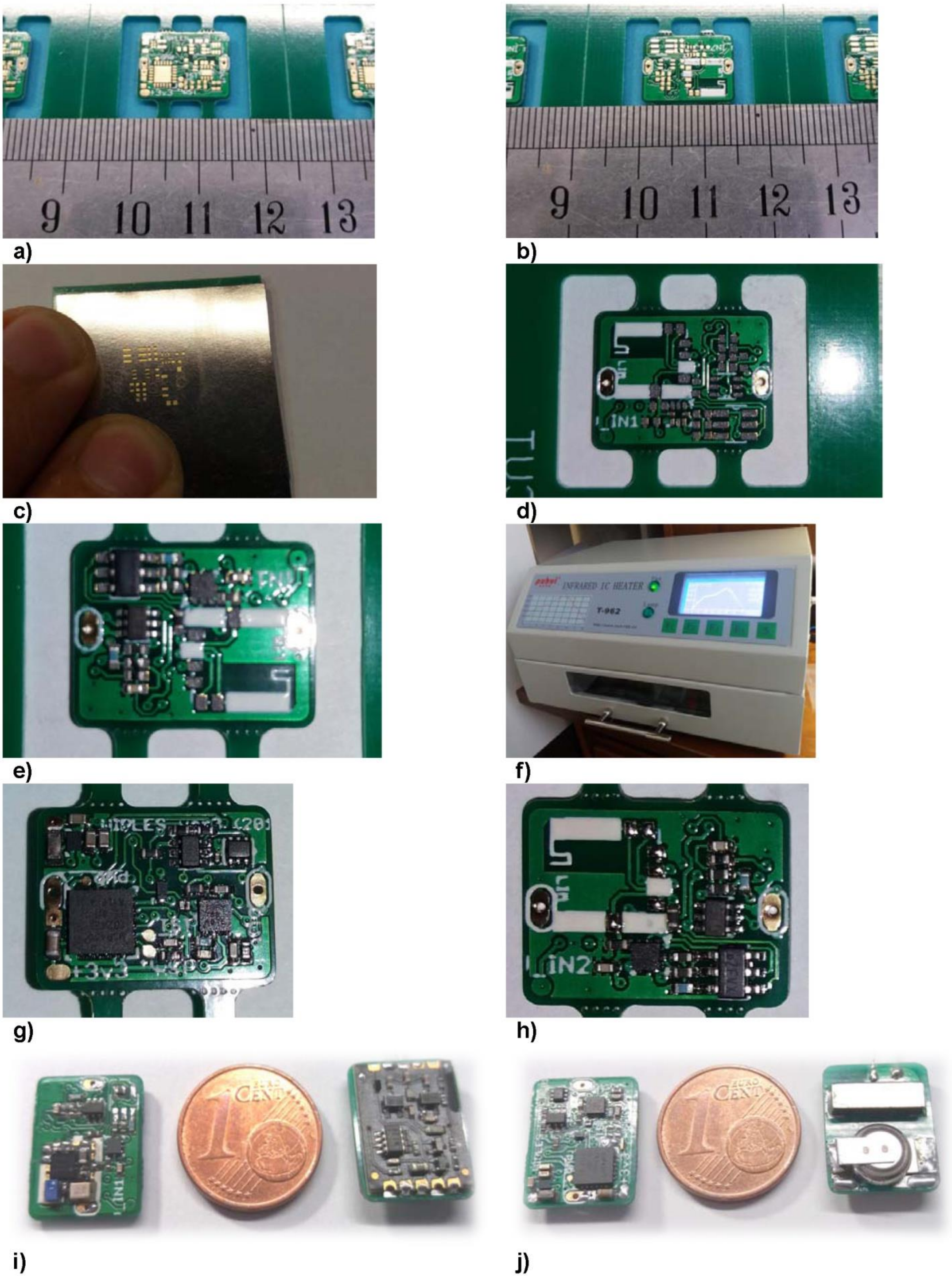


Figure 3. Step-by-step assembly of a printed circuit board: a) ready main PCB, top view; b) ready main PCB, bottom view; c) solder stencil matching; d) applied SMT solder paste; e) electronic components placed; f) SMT oven type IC HEATER T-962; g) soldered main PCB, top view; h) soldered main PCB, bottom view; i) assembled prototype (3 boards), top view; j) assembled prototype (3 boards), bottom view.

3. Results

After assembly and soldering of all PCB boards, further assembly of prototype was done. Final device is consisting of 3 boards:

- main PCB with MCU, power controller, 2.4 GHz Bluetooth BLE 4.0 module and constant current (CC) pulse driver [16];
- wireless charging module, working at 915 MHz [18];
- RF board with 915Mhz antenna and supercapacitor.

All 3 boards were linked together, as well was connected pair of stitch electrodes type Flexon™ (Covidien®, USA) and additional ¼ wave RF antennas.

After electric assembly, whole module was covered with two layer of biocompatible silicon compound, providing the necessary isolation from biological tissues and ensuring radio transparent transmitting and reception of RF signal [19, 20], see Figure 4.

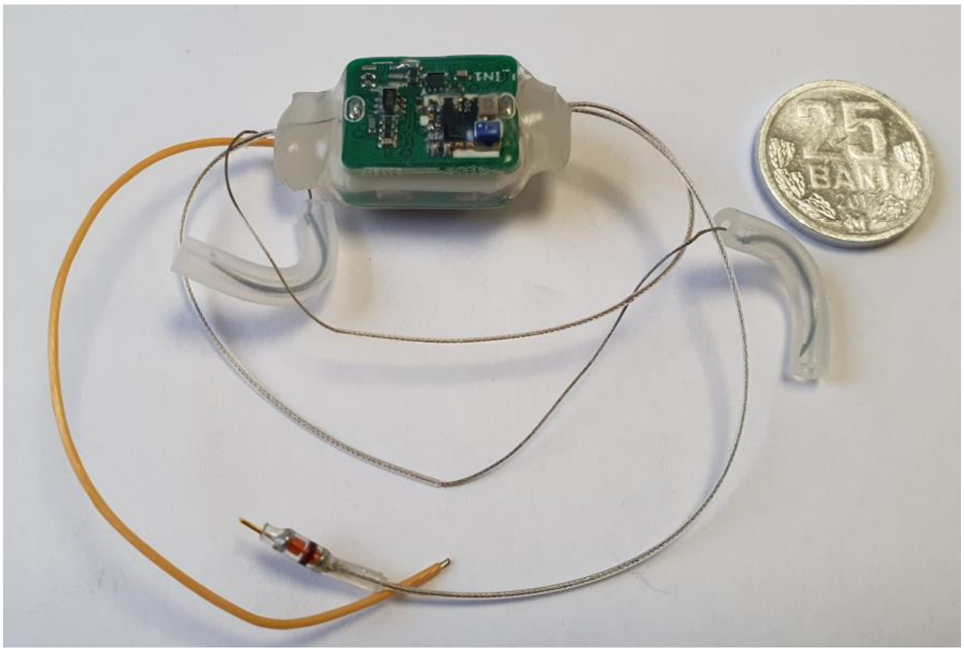


Figure 4. Assembled prototype.

Ready device is sized 25×12×8 mm only, including lateral isolation electrodes glands, made from silicone.

Several tests were carried out to evaluate the effectiveness of the device:

- measurement of the level of supplied current;
- measuring the range of stable communication;
- start-up test at different levels of accumulated charge.

The tests performed demonstrated stable energy transfer over a distance of up to 3 meters, while the relative spatial location of the transmitter and receiver of the device had virtually no effect on the received current, which ranged from 1 mA (at a distance of ~3 m) to 30 mA at (at distance of ~0.3 m).

At the same time, the quiescent current of the entire device was assessed, as well as the maximum operating time on a single charge. The measurement data demonstrated that the quiescent current varied with a frequency of several seconds, ranging from less than 1 μA to 48 μA, depending on the operating mode of the Bluetooth module and the sleep mode settings of the microcontroller.

According to processed tests, on a single charge the device remained functional for up to 12-15 hours, when using a supercapacitor with a capacity of 0.1 F.

Unique feature of developed device is using own elaborated constant current driver with ultra-low idle power consumption 16. Designed schematic is an invention of the author and will apply for a patent registration in Moldova.

During the performed tests, the CC module demonstrated the complete compliance of the real output characteristics to the calculated ones, namely:

- output current - within 0.1 - 10 mA, with a step of 0.078 mA;
- processed pulse width is within 100us – 500 ms;
- loading impedance range - from 10 to 1000 Ohms.

For further testing, the prototype was programmed for several operating modes, that could be selected after pairing of prototype with Android based smartphone with installed a simple BLE Serial port software, see Table 3.

Table 3

Prototype working modes

HEX command	ASCII symbol	Proposed action
0×31	1	Stimulation mode 1 (pulse 220 µs, frequency 20 Hz, 10s)
0×32	2	Stimulation mode 2 (pulse 100 µs, frequency 10 Hz, 10s)
0×32	3	Stimulation mode 3 (pulse 300 µs, frequency 40 Hz, 10s)
0×32	4	Stimulation mode 4 (pulse 220 µs, frequency 20 Hz, 60s)
0×32	5	Stimulation mode 5 (pulse 375 ms, 6 pulses/min, 60s)
0×6C	l	Set the stimulation current to 2 mA
0×6D	m	Set the stimulation current to 4 mA
0×68	h	Set the stimulation current to 6 mA
0×74	t	Measure ambient temperature
0×3F	?	Provide device version

Note: HEX means command in hexadecimal format, ASCII symbol - according to Windows-1252-character set.

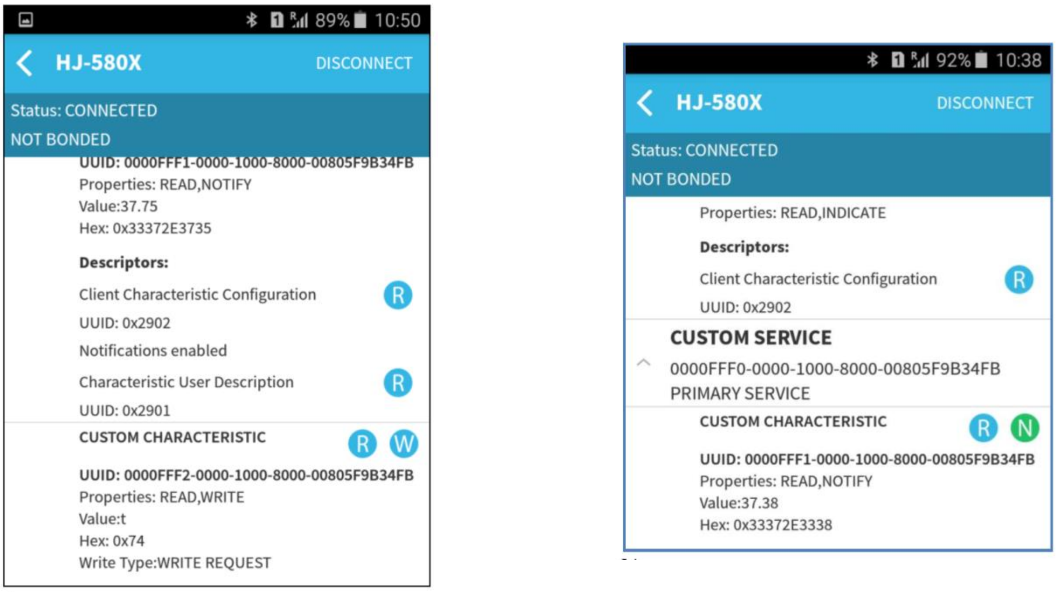
There are 5 different pulse stimulation modes and 3 output current levels. Additionally – device temperature measurement mode and displaying device version (WIPLES3_Vidiborschii).

Operating modes are set remotely using a mobile application “BLE Scanner v3.12” from BluePixel Technologies LLC, India.

This application is working with Bluetooth 4.0 enabled devices and uses next configuration:

- Application level - for a mobile application on an Android smartphone;
- Host level (Bluetooth module in prototype, type HJ-580X), using GATT profile;
- Communication with controller is done the HCI interface (UART format).

The following screenshots demonstrate various software operations on a smartphone, see Figures 5 and 6.

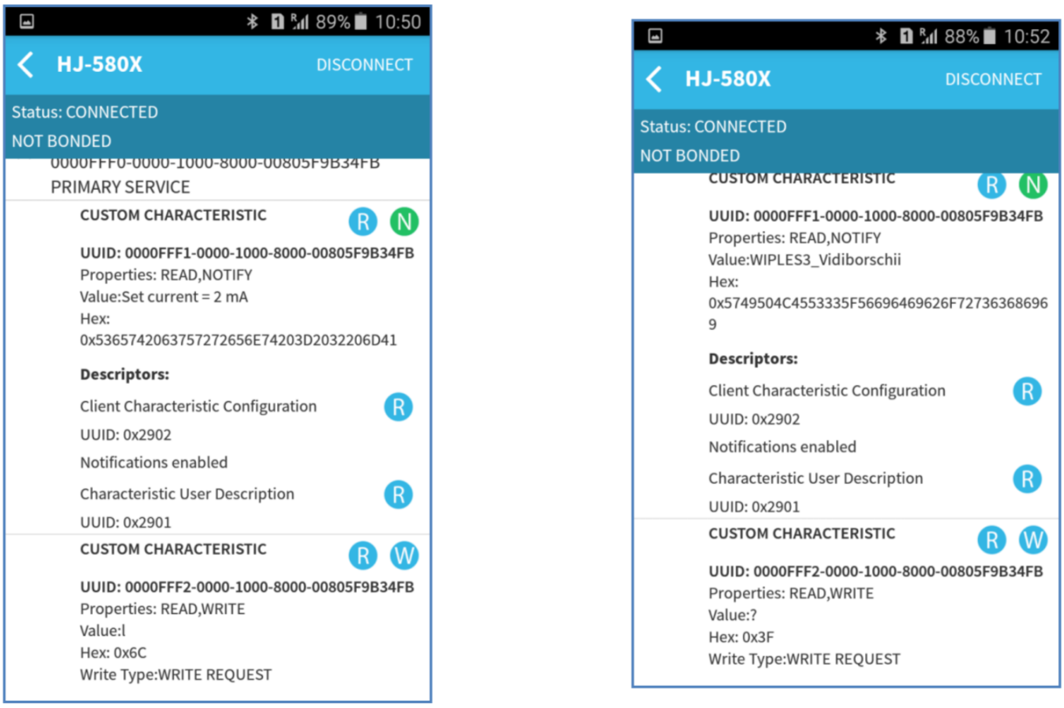


Status: CONNECTED
NOT BONDED
UUID: 0000FFF1-0000-1000-8000-00805F9B34FB
Properties: READ,NOTIFY
Value:37.75
Hex: 0x33372E3735
Descriptors:
Client Characteristic Configuration
UUID: 0x2902
Notifications enabled
Characteristic User Description
UUID: 0x2901
CUSTOM CHARACTERISTIC
UUID: 0000FFF2-0000-1000-8000-00805F9B34FB
Properties: READ,WRITE
Value:t
Hex: 0x74
Write Type:WRITE REQUEST

Status: CONNECTED
NOT BONDED
Properties: READ,INDICATE
Descriptors:
Client Characteristic Configuration
UUID: 0x2902
CUSTOM SERVICE
0000FFF0-0000-1000-8000-00805F9B34FB
PRIMARY SERVICE
CUSTOM CHARACTERISTIC
UUID: 0000FFF1-0000-1000-8000-00805F9B34FB
Properties: READ,NOTIFY
Value:37.38
Hex: 0x33372E3338

a) b)

Figure 5. Screenshots of working remote control software: a) sending command “t” (0x74) – measure temperature; b) response to temperature measurement command.



Status: CONNECTED
NOT BONDED
0000FFF0-0000-1000-8000-00805F9B34FB
PRIMARY SERVICE
CUSTOM CHARACTERISTIC
UUID: 0000FFF1-0000-1000-8000-00805F9B34FB
Properties: READ,NOTIFY
Value:Set current = 2 mA
Hex:
0x5365742063757272656E74203D2032206D41
Descriptors:
Client Characteristic Configuration
UUID: 0x2902
Notifications enabled
Characteristic User Description
UUID: 0x2901
CUSTOM CHARACTERISTIC
UUID: 0000FFF2-0000-1000-8000-00805F9B34FB
Properties: READ,WRITE
Value:l
Hex: 0x6C
Write Type:WRITE REQUEST

Status: CONNECTED
NOT BONDED
CUSTOM CHARACTERISTIC
UUID: 0000FFF1-0000-1000-8000-00805F9B34FB
Properties: READ,NOTIFY
Value:WIPLES3_Vidiborschii
Hex:
0x5749504C4553335F56696469626F727363686969
Descriptors:
Client Characteristic Configuration
UUID: 0x2902
Notifications enabled
Characteristic User Description
UUID: 0x2901
CUSTOM CHARACTERISTIC
UUID: 0000FFF2-0000-1000-8000-00805F9B34FB
Properties: READ,WRITE
Value:?
Hex: 0x3F
Write Type:WRITE REQUEST

a) b)

Figure 6. Screenshots of working remote control software: a) sending command 0×6C -> stimulation current 2 mA; b) received reply to “get version” command “?” (0×3F).

4. Discussion

The article discusses different application area of implantable stimulators. The development of an implantable electrical stimulator for the lower esophageal sphincter (LES) showcases significant technological advancements.

The transition from traditional battery-powered devices to a wireless, battery-free prototype presents a leap in implantable medical devices' design and functionality. The prototype successfully demonstrated stable energy transfer over distance, maintaining effective communication up to 3 meters.

The device's ability to deliver a range of current levels and pulse widths as per design specifications underscores its functionality.

Evaluation of the prototype's power consumption revealed encouraging results. With a supercapacitor of 0.1F, the device remained functional for 12-15 hours on a single charge. The utilization of an ultra-low idle power consumption constant current driver is a noteworthy feature that contributes to its energy efficiency.

The implementation of multiple stimulation modes and selectable output current levels, controlled remotely via a smartphone application, adds versatility to the device. This user-controlled customization enhances its adaptability for varying medical requirements.

The focus on developing an LES stimulator for gastroesophageal reflux disease (GERD) treatment aligns with the prevalence of this condition worldwide. The success of this prototype opens doors for potential clinical applications in addressing GERD and related esophageal disorders.

While the prototype demonstrated promising functionality, further rigorous testing and validation, especially in biological environments, will be crucial to ensure its safety and long-term feasibility for implantation within the human body.

5. Conclusions

Achievements and Innovation: The development of a functional prototype of an implantable LES stimulator represents a significant milestone in medical device innovation. The transition from traditional battery-operated devices to a wireless, battery-free implant demonstrates pioneering advancements in implantable medical technology.

Clinical Implications: The successful development of this prototype holds promising implications for the field of gastroenterology, particularly in addressing GERD. The device's customizable stimulation modes and energy-efficient design pave the way for potential therapeutic interventions for esophageal disorders.

Future Prospects: As this prototype undergoes further refinement and validation, its potential for clinical translation and broader applications in other medical domains becomes evident. Future research may focus on refining its design, enhancing its safety profile, and exploring its efficacy in diverse applications. After successful completions of additional safety tests, the research will move to the testing stage on laboratory animals.

Patent and Regulatory Considerations: The innovation of an ultra-low idle power consumption constant current driver within the prototype is a novel contribution eligible for patent registration, potentially fostering intellectual property development in medical technology. Ensuring compliance with regulatory standards will be imperative for its future deployment.

Closing Note: The successful development of this implantable LES stimulator prototype, with its wireless and battery-free design, marks a significant step toward enhancing the efficacy and usability of medical implants. Its potential impact on patient care underscores the importance of continued research and development in this area.

Conflicts of Interest: The author declares no conflict of interest.

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