

WIRELESS CHARGED LOWER ESOPHAGEAL SPHINCTER STIMULATOR

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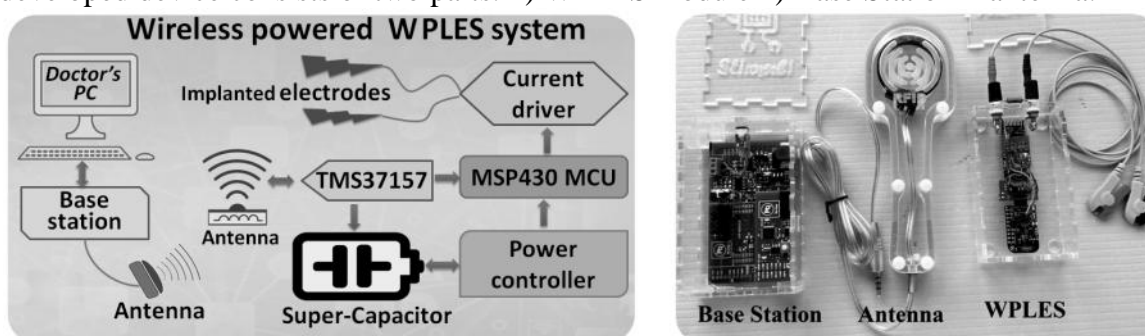
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Introduction. Clinical studies [1, 2] have demonstrated that electrical stimulation of the lower esophageal sphincter (LES) can significantly improve the quality of life of patients with gastroesophageal reflux disease (GERD) and low tone of the LES. Commercially available implantable stimulators like EndoStim® or Enterra®, Medtronic have sizes about 50 x 60 x 10 mm, are powered by non-rechargeable batteries and their implantation requires surgery under general anesthesia. Battery life is usually ≤ 5 years.

As part of the recent study [3] was developed a prototype of programmable LES electrostimulator, powered by a wireless charged supercapacitor (WPLES). Modern electric parts allows to develop device sized about 9 x 9 x 20 mm, with possibility to carry out the implantation via endoscope with minimal post-operative complications.

The developed device consists of two parts: 1) WPLES module 2) Base Station + antenna:



The WPLES consists of an antenna, an RFID transceiver (TI's TMS37157), a power & charge controller, a microcontroller (MSP430FR series) and a current driver for electrical impulses to electrodes. A 15.0 Farad Supercapacitor is used as an energy storage, with lifetime up to 20 years. The base station is used both for charging and adjustment of stimulation parameters from PC. Wireless charging is done via industry standard RFID signal, with frequency 134,2 kHz.

Electrical parameters of the WPLES

<i>Output voltage</i>	<i>Output current</i>	<i>Impedance</i>	<i>Pulse width</i>	<i>Pulse rate</i>
0,5 ... 5V	0,5-10 mA	100-500Ω	0,05 - 2000 ms	0,1 PPM - 100 PPS

With basic stimulation setting (3,0 mA, pulse width 0,2 ms, 20 PPS) stored energy is sufficient for ~ 120 cycles of 15 min stimulation. Supercapacitor's charge is enough for 30 days of triple daily application, while charging is taking about 30 min. At current stage the WPLES working distance from base station's antenna is up to 3 cm. Planned objectives for next stage of the project are:

- To reduce size of the WPLES prototype to 9 x 9 x 20 mm;
- To modify base station's antenna to get a 10-15 cm working distance;
- To perform *in vitro* tests using sample of tissues of a pig;
- To upgrade data wireless connection from RFIF to Bluetooth + develop an Android application.

[1] Rodríguez L., Rodriguez P., Gómez B., Ayala J.C., Oxenberg D., Perez-Castilla A., Netto M.G., Soffer E. Two-year results of intermittent electrical stimulation of the lower esophageal sphincter treatment of gastroesophageal reflux disease. *Surgery*, **2015**, 157(3): p.556-567.

[2] Banerjee R, Pratap N, Kalpala R, Reddy DN. Effect of electrical stimulation of the lower esophageal sphincter using endoscopically implanted temporary stimulation leads in patients with reflux disease. *Surgical Endoscopy*, **2014**, 28: p.1003-1009.

[3] Ungureanu S.N, Lepadatu K.I., Sipitco N.I., Vidiborschii V.L., Gladun N.V., Balica I.M. Influence of electrical stimulation on the function of lower esophageal sphincter in patients with gastroesophageal reflux disease. *Experimental and Clinical Gastroenterology*, **2016**, 128(4), p.51-55.