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A Device for Transcutaneous Stimulation of the Diaphragm

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Results obtained during the development of an original device for noninvasive transcutaneous stimulation of the diaphragm using electromagnetic radiation in the terahertz frequency range are presented. The block diagram and design of a terahertz emitter and a controlled current source for its power supply are presented, along with specialized software for selecting and setting the amplitude and time parameters of the stimulating signal.

Introduction

Currently, due to the COVID-19 pandemic, the number of patients with acute or chronic respiratory failure who are receiving medical care through mechanical ventilation of the lungs (MVL) has increased dramatically throughout the world. One of the most severe complications of mechanical ventilation and tracheal intubation is infection of the patient's respiratory tract with the development of bacterial and/or fungal ventilator-associated pneumonia (VAP). The hemodynamic effects of mechanical ventilation can be avoided by transcutaneous stimulation of the phrenic nerve, which innervates the diaphragm muscle, the main inspiratory muscle, which under physiological conditions provides up to 70% of the vital capacity of the lungs and up to 90% of the respiratory volume [1–3]. In this situation, mass transfer of gas will take place as a result of contraction of the diaphragm in response to its electrical stimulation, i.e., without forming positive pressure within the chest [4–6]. In turn, the absence of the need for tracheal intubation largely eliminates the risk of infection and reduces the incidence of VAP [7].

Transcutaneous stimulation of the diaphragm (TSD) can be used in a wide range of patients without surgical intervention, both in the hospital and in the clinic, as well as at home [8–13]. The potential circle of those in need of therapy is wide: a report from the N. I. Pirogov Russian National Research Medical University indicated that the number of patients with respiratory failure who need oxygen therapy or long-term home ventilation is about 8–10 per 10,000 of the population. Some 3–5% of patients suffer severe exacerbations with respiratory failure, which, if left untreated, can be fatal. It is also of note that electrical stimulation of the diaphragm can be used successfully along with other methods of treating patients with bronchial asthma [14]. The American Lung Association notes that one in 11 children and one in 12 adults have asthma.

Devices for radiofrequency electrical stimulation of the diaphragm are currently available on the medical equipment market: the electrical stimulators NeuRx DPS and TransAeris System from Synapse Biomedical Inc (USA). However, the clinical use of these devices is associated with invasiveness on implantation of the special electrodes (via bilateral thoracotomy), which can lead to infections, damage to the phrenic nerve during surgery, pneumothorax, upper airway obstruction, and paradoxical movement of the ribs, as well as discomfort experienced by patients on contraction of the closely spaced muscles of the abdominal wall, an inverse dependence of the effect of electrical stimulation on the thickness of the subcutaneous fat layer, and the frequently occurring pain of the procedure itself [1, 4]. In general, the cost of the technology and the requirement for prompt intervention do not allow these devices to provide wide coverage of the population.

As an alternative, a device for noninvasive TSD with terahertz radiation, is proposed to influence the phrenic nerve, which is responsible for contraction of the diaphragm is proposed. The main advantages of this stimulation method, in addition to its noninvasiveness, are ease of implementation in the treatment of chronic diseases of the respiratory system and the absence of serious contraindications and severe complications.

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The aim of the present work was to describe the principles of operation and design of an original device for noninvasive percutaneous stimulation of the diaphragm using electromagnetic radiation in the terahertz frequency range.

Description of Device

The device developed here for TSD includes a terahertz emitter based on a silicon semiconductor structure, a controlled current source to power the emitter, and a personal computer with specific software for selecting and setting the amplitude and time parameters of the stimulating signal (Fig. 1).

The main type of stimulating signal is a sequence of bursts of square-wave pulses with high-frequency filling of each pulse. In the general case, the shape of the stimulating signal is shown in Fig. 2.

The number of pulse series in a sequence, the time interval (frequency of their repetition), the number of pulses in a series, and the duration, repetition frequency, and amplitude of each pulse in a series can vary within specified limits. The device can also operate in continuous mode, without modulation of the emitter supply current.

1. *Terahertz emitter*

A terahertz emitter (TE) is a controlled oscillator operating in the far infrared wavelength range, from 1 to 700 μm, with THz and GHz modulation over the entire range of the radiation spectrum.

The solid-state emitter is manufactured by producing quantum-sized *p–n* junctions on the surface of monocrystalline silicon with a depth of 20 to 30 nm, containing cascades of ultra-narrow silicon quantum wells 2 nm wide, limited by delta barriers consisting of boron dipole centers with a negative energy correlation forming a structure with dimensions of 0.2 × 4.7 mm (Fig. 3) [15].

Fig. 1. CHSD device. The emitter bracket is optional.

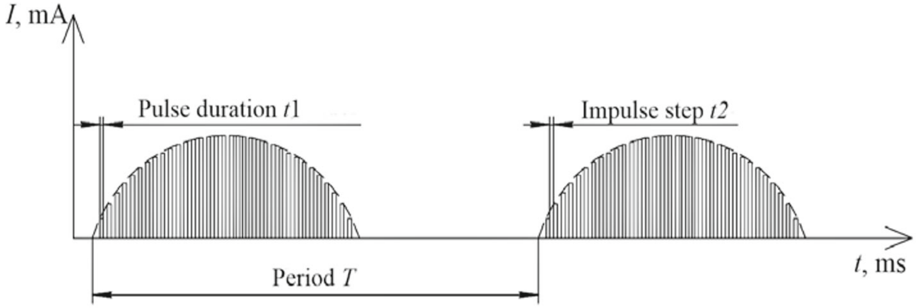


Fig. 2. Stimulating signal shape.

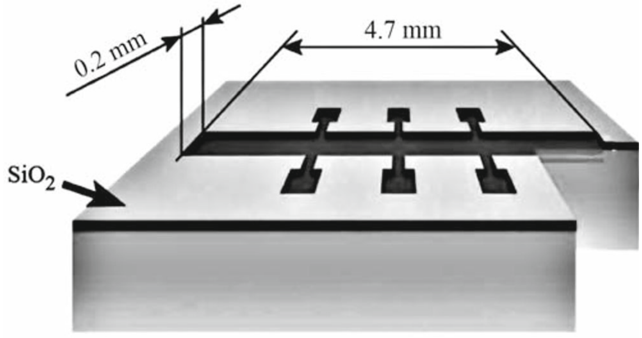


Fig. 3. Structure of TGI.

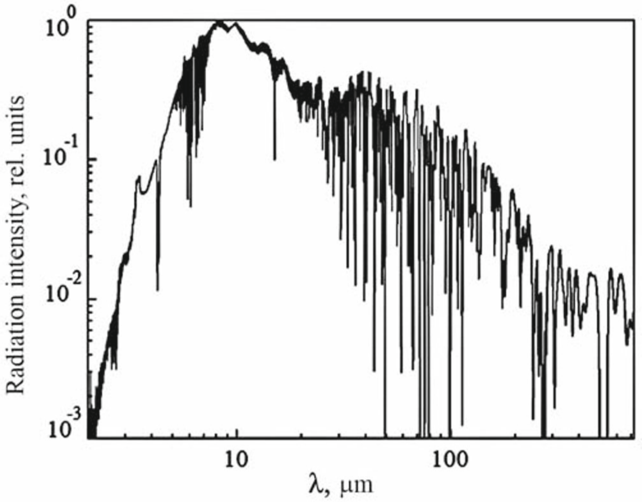


Fig. 4. Emission spectrum of silicon nanostructure. The total radiation power over the entire range when passing a direct current of 100 mA is 82.8 mW. The spectrum is modulated with a set of frequencies of 9, 20, and 90 GHz and 1 and 2.8 THz.

THz radiation occurs as a longitudinal current flows through the structure. The characteristics of this radiation are shown in Fig. 4 and were obtained using a Fourier-IR spectrometer.

2. *Controlled current source*

Figure 5 shows a structural diagram of a controlled current source (CCS).

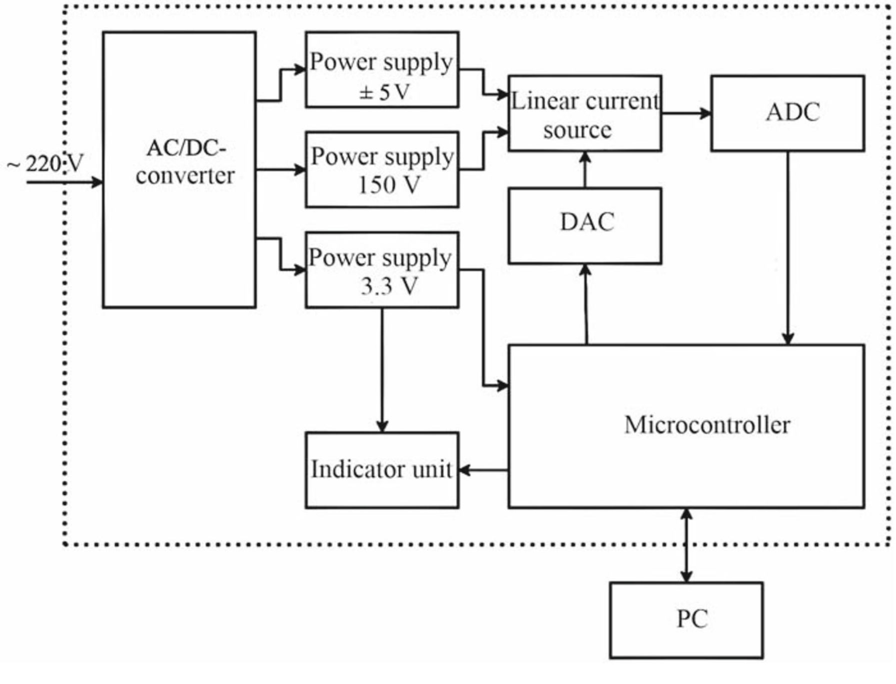
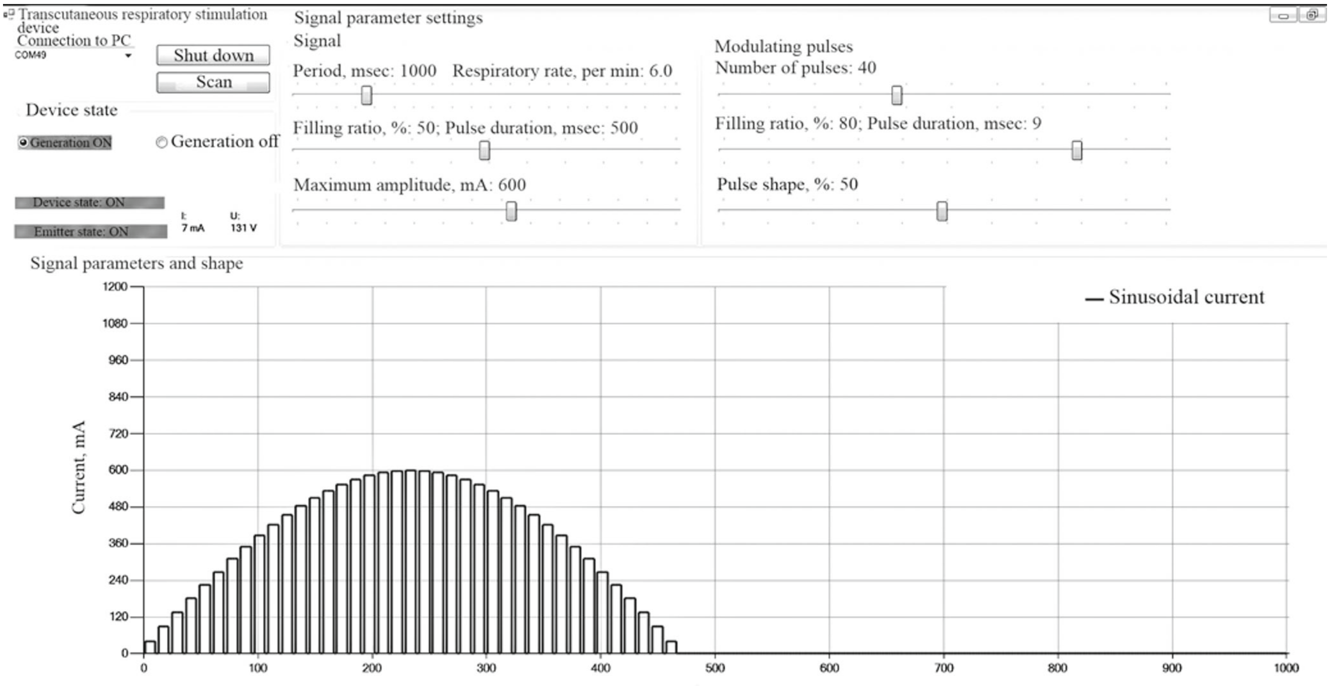


Fig. 5. Structural diagram of the CCS (see text for explanation).

The CCS includes a pulsed AC/DC voltage converter, a 150-V power supply, a microcontroller with a digital-to-analog converter (DAC), a linear current source, and a display unit consisting of three LEDs. A microcontroller is also used to organize communication with a personal computer (PC) via the USB interface using a proprietary protocol.

The pulse train set by the PC is generated by the DAC of the microcontroller, and the signals are then scaled to the required current values using the linear current


Transcutaneous respiratory stimulation device

Connection to PC
COM49

Device state
● Generation ON ○ Generation off

Device state: ON
Emitter state: ON
I: 7 mA
U: 131 V

Signal parameter settings

Signal
Period, msec: 1000 Respiratory rate, per min: 6.0
Filling ratio, %: 50; Pulse duration, msec: 500
Maximum amplitude, mA: 600

Modulating pulses
Number of pulses: 40
Filling ratio, %: 80; Pulse duration, msec: 9
Pulse shape, %: 50

Signal parameters and shape

Fig. 6. Specialized software interface.

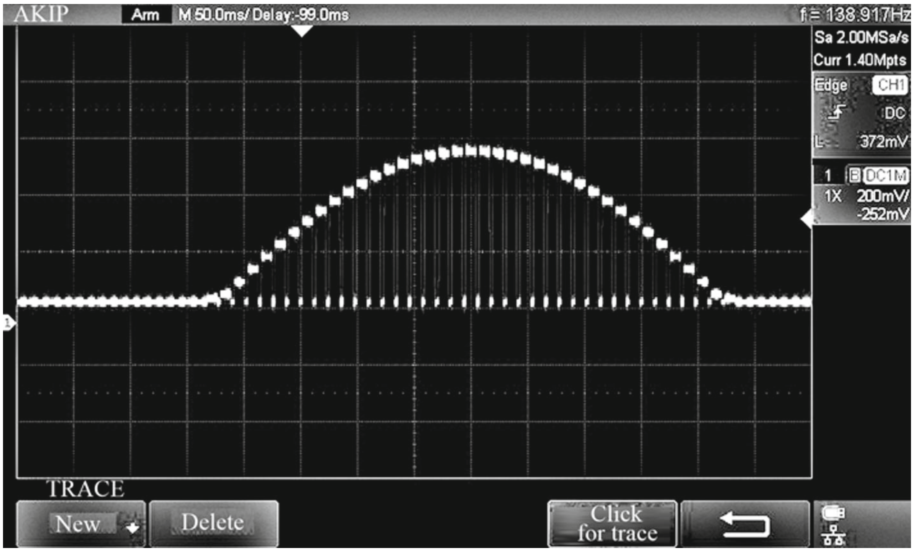


Fig. 7. Oscillogram of TE current pulse sequence.

source circuit. The voltage levels at the collector and emitter of the output signal of the CCS are digitized using the microcontroller analog-to-digital converters (ADC) and are processed by software to identify the open circuit condition of the power supply of the terahertz emitter.

The CCS electrical circuit is mounted on a double-sided circuit board and installed inside a small rectangular case made of ABS plastic using fused deposition modeling (FDM) printing.

Rapid indications of the functional state of the device are obtained from the three LEDs installed on the top cover of the CCS housing: green, blue, and red. The green LED indicates that the CCS is connected to the power supply and personal computer; the blue LED indicates that a sequence of current pulses is being generated; the red LED indicates that the emitter is connected to the CCS.

The CCS is powered by the single-phase AC network at 220 V and 50 Hz. The maximum power consumption is no greater than 22 W.

3. *Specialized software (SW)*

The operation of the CCS, including control of its functional state and visualization of the stimulating signal shape, is carried out using a computer with specialized software. The working window of the program is shown in Fig. 6.

The software is designed to set all the amplitude and time parameters of the sequence of pulse trains, to switch generation mode on and off, and to give indications of TE power supply circuit failure, ongoing load current and voltage, and the set and ongoing TE operation times.

The oscillogram (Fig. 7) shows one of the options for CCS settings. Load (TE) current pulse amplitude in each series of pulses rises and falls following the sine law over the range 0–100 mA. Series repetition rate is 1 Hz, the duration of a single pulse in a series is 9 ms, and the pulse repetition frequency within a series is 139 Hz.

Conclusions

These studies created a device suitable for noninvasive percutaneous stimulation of the phrenic nerve for therapeutic procedures in the treatment of a number of diseases.

The device provides ample opportunities for selecting the stimulating signal parameters, allowing it to be used with success in the TSD method using terahertz radiation developed in collaboration with researchers at the V. A. Almazov National Medical Research Center, Russian Federation Ministry of Health.

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