COMPUTATIONAL PROBLEMS OF ELECTRICAL ENGINEERING

Vol. 13, No. 2, 2023

AN IMPROVED METHOD AND MEANS WITH THE FUNCTION OF AUTOMATIC ADJUSTMENT OF ELECTRICAL SIGNAL PARAMETERS FOR DETECTION OF THE RECURRENT LARYNGEAL NERVE

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https://doi.org/10.23939/jcpee2023.02.

Abstract: The article presents the results of the development of software and hardware for identifying the recurrent laryngeal nerve (RLN). In the course of research, it was found that the effectiveness of detecting as result of stimulation of the RLN with a pulsed electric current depends on its frequency. On this basis, it is proposed to use software tools for automatically adjusting electrical signal parameters in order to stimulate the tissues of a surgical wound as efficiently as possible. In thyroid surgery, these tools are used to minimize the risk of damage to the RLN. An improved method for stimulating surgical wound tissue is presented. The main algorithms of the tools and the architecture of the software part are presented. The proposed device was tested on the basis of a medical centre in Ukraine.

Keywords: software and hardware; electrical signal; neck surgery, recurrent laryngeal nerve, electrical stimulation, intraoperative monitoring

1. Introduction

Thyroid gland diseases quite often require surgical interference. This type of interference can result in the damage of the recurrent laryngeal nerve (RLN). The damage of the RLN can be the cause of a decrease in the control of vocal changes or a complete loss of the patient's voice [1]. Therefore, the process of surgical removal of all or part of one's thyroid gland requires constant monitoring of the functioning the RLN [2]. Modern means of detection and monitoring of the RLN provide: nerve monitoring based on observation on a video monitoring device of the passage of electrical signals monitored using electrodes installed in the larynx to determine the electrical activity of the muscles [3]; visual observation of the surgeon using a surgical microscope or endoscope to visualize the larynx and laryngeal muscles [4]; stimulation of the RLN with electric current to detect its functionality [3]; the use of ultrasound to visualize the RLN and its structures [5]; clinical monitoring of symptoms or voice changes during surgery [6].

Among these methods, the most widespread are intraoperative monitoring and the use of stimulation of the nerve and tissues of the surgical wound with electric current, mainly in pulse form.[7]. At the same time, intraoperative monitoring does not fully protect against RLN damage, as it only checks the functionality of the nerve [2]. In order to reduce the risk of damage to the RLN, electrical stimulation of the surgical wound tissue is used to identify and locate the RLN. The next stage after electrical stimulation is recording the stimulation result. This can be done visually with the help of an electromyograph, which in real-time registers the electrical activity of the laryngeal muscles during nerve stimulation using special devices placed in the area of the vocal cords [2,8]. The authors of works [9-13] propose a device for recording the result of stimulation of the RLN and tissues of a surgical wound using a sound sensor (microphone) installed in the endotracheal tube [9-13]. In practice, this method of registration has proven to be quite effective to use [12]. At the same time, the problem remains in establishing the parameters of the stimulation signal depending on the electrophysiological properties of the tissues of the surgical wound of a particular patient, which turn out to be different. At this, in [9-15] it is proposed to use a mathematical model in the form of an algebraic equation [9,10] or a difference equation [11-14], which describes the distribution of characteristics of the acoustic signal received, for example its amplitude, depending on the point of irritation in the surgical wound. The adjustment of such a difference equation for a specific patient was carried out with the help of a short series of irritations of the tissues of the surgical wound [14]. However, this method turned out to be quite difficult to set up.

The authors of works [15-18] suggest that the effectiveness of the response to irritation of surgical wound tissues depends on the frequency and form of the electric current. These parameters may have different effectiveness depending on the patient. Therefore, the purpose of this work is to study these aspects and, based on them, to develop a method for automatical adjusting the electrical signal parameters in order to stimulate the tissues of the surgical wound in the most effective way.

2. Formulation of the problem

Let us consider the existing method and means for the detection of RLN during thyroid surgery, which are given in work [12]. Figure 1 shows a functional diagram of the device.

The breathing tube (1) with the sound sensor (3) is installed in such a way that the sensor is located above the vocal cords (4). The active electrode (5) is connected to the electric current generator (9). This generator is controlled by a single-board computer (8). With the help of the active electrode (5), the tissues of the surgical wound (6) are stimulated with electric current in the form of rectangular pulses. As a result, the vocal cords (4) are stretched due to the contraction of the muscles that control them. The air flow passes through the patient's larynx and is modulated by the vibration of the vocal cords. The resulting sound is recorded by the sound sensor (3) and transmitted to the single-board computer (8) for processing through the sound adapter. The results of stimulation and signal processing are displayed using the imaging unit (12) and are accompanied by audio information for the surgeon about the type of tissue (13).

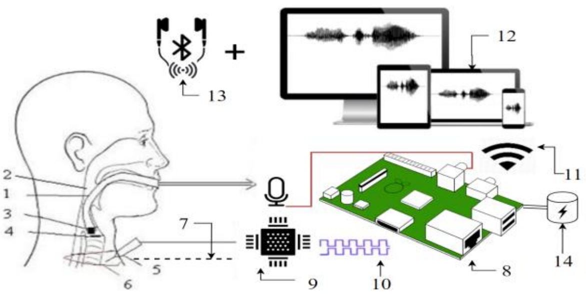


Fig. 1. Functional diagram of the process of intraoperative neuromonitoring of laryngeal nerves during thyroid surgery [12] : 1) breathing tube; 2) larynx; 3) sound sensor; 4) vocal cords; 5) active electrode; 6) surgical wound; 7) passive electrode; 8) Raspberry Pi single-board computer; 9) electric current generator; 10) rectangular pulses generated by Raspberry Pi.; 11) communication channel between devices (Wifi); 12) surgeon's visual information unit (tablet, phone, laptop); 13) surgeon's audio information unit (Bluetooth or radio headphones); 14) power supply unit.

It should be noted that the method of recording the result of RLN stimulation with an electric current requires the selection of irritation frequency to ensure the most intense sound reproduction of this result.

As it can be seen from Fig.1, the functional diagram of the device does not allow the frequency of stimulation pulses of the tissues of the surgical wound to be adjusted. Therefore, the purpose of these studies is to improve the efficiency of the method and device described above by introducing a system for automatically adjusting the frequency of electrical pulses to most effectively stimulate the tissues of the surgical wound.

3. Justification of method improvement

Based on the well-known electrophysiological properties of surgical wound tissue in general, and the RLN in particular, the key aspects of the choice of frequency and its effect on the RLN can be formulated. They are as follows: muscle perception (low frequencies, usually less than 5 Hz, may be more suitable for perception of muscle reactions); noise filtering (excessively high pulse frequency can cause signal interference); maximum stimulation effectiveness, associated with the reactive properties of the stimulation medium; perception of a nervous response.

As a rule, the frequency of electric impulses used to stimulate the laryngeal nerve during thyroid surgery may vary depending on the specific clinical case. However, in general, frequency values for electrical stimulation can range from a few to several tens of hertz. During the research process, it was proposed to test the hypothesis discussed above and, on this basis, develop a method of automatic adjustment of the frequency of electric impulses for the most effective stimulation of the RLN.

Clinical tests of the device for detecting the RLN which has been developed based on the functional diagram shown in Fig. 1, made it possible to receive a series of sound signals during the operation on the thyroid gland, some of which are shown in Fig. 2.

As we can see from Fig. 2, the nature of the sound signal changes depending on the frequency of the following pulses of the electrical signal, which are used to stimulate the RLN. At low pulse frequencies (Fig. 2. c), it is possible to recognize individual fragments of the sound signal. We can also see that its amplitude changes.

In Fig. 3 fragments of the spectra of the received signals are given.

As it is known from previous studies [12,15], the amplitude of the main spectral component depends on the point of irritation on the surgical wound. In this case, the amplitude of the selected main spectral component is inversely proportional to the distance from the stimulation point to the RLN. If the stimulation point belongs to the RLN, the amplitude of the main spectral component increases significantly. However, such patterns are inherent only in cases when the pulse tracking frequency is correctly selected in the process of stimulating the tissues of a surgical wound with pulsed current. Therefore, Fig. 3. fully confirms the assumption made.

Thus, at low frequencies of pulsed current (up to 5 Hz), the result of the RLN stimulation in the form of the amplitude of the main spectral component of the received sound signal is insignificant. A similar situation occurs when the frequency of following pulses of an electrical signal is too high (more than 20 Hz). The most effective is the pulsed current stimulation of the RLN with a frequency of about 10 Hz.

In Fig. 4. The diagram shows the dependence of the maximum amplitude of the main spectral component of the sound signal – the response to stimulation of the RLN with a pulsed current of different frequencies. As we can see from this diagram, it was the pulsed current with a frequency of 10 Hz that proved to be the most effective for stimulating the RLN in our case. It is worth noting that in Fig. 3 and Fig. 4, the normalized value of the amplitude of the main spectral component of the sound signal is given along the ordinate axis.

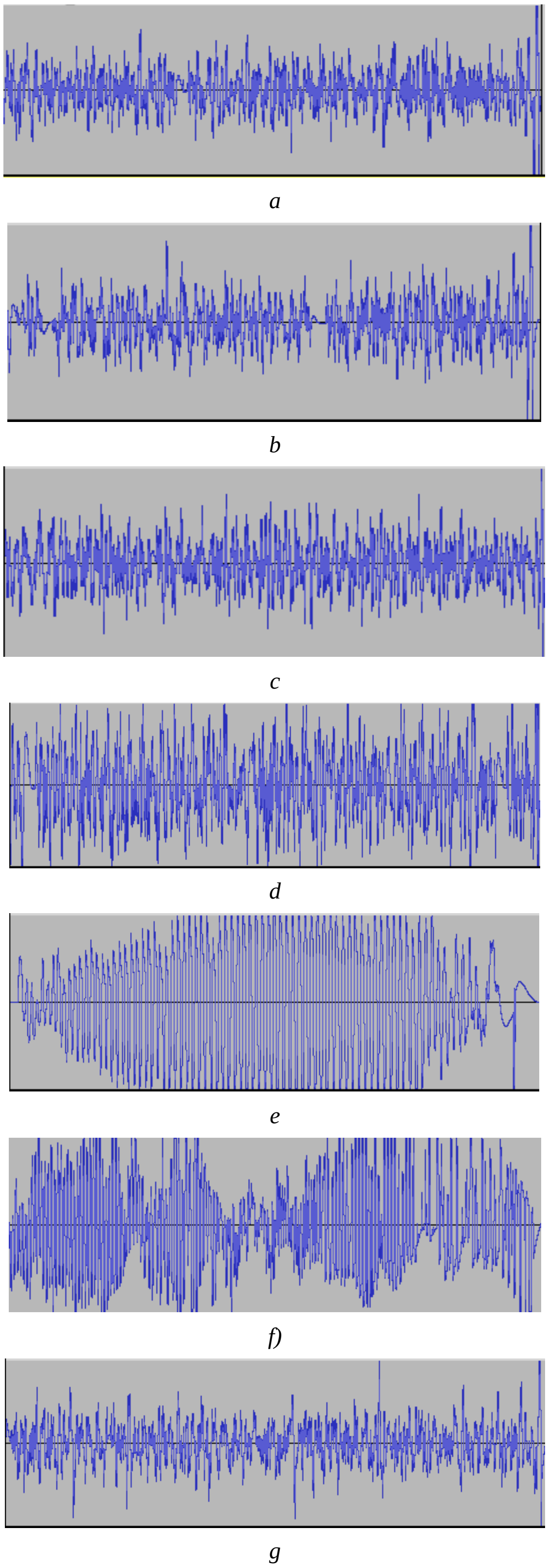


Fig. 2. A series of sound signals, as a reaction to the stimulation of the RLN by electric pulses of different frequencies: a) – without stimulation (audio signal of the patient's breathing); c) pulse frequency 1 Hz; c) pulse frequency 2 Hz: d) pulse frequency 5 Hz; e) pulse frequency 10 Hz f) pulse frequency 20 Hz g) pulse frequency 50 Hz.

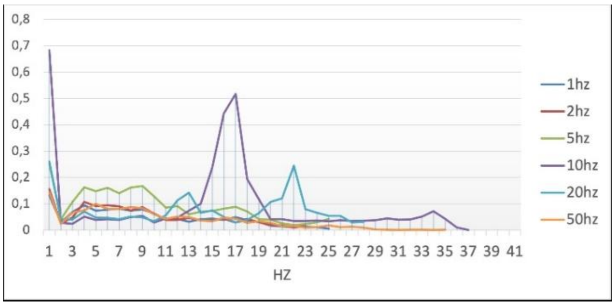


Fig. 3. Fragments of the spectra of sound signals depending on the frequency of the impulse current of stimulation.

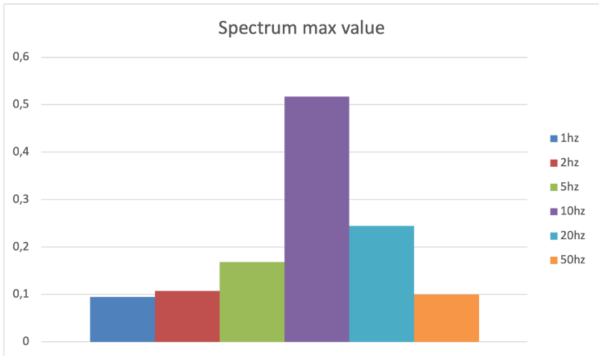


Fig. 4 The maximum amplitude of the main spectral component of the sound signal, depending on the frequency of the pulsed current of the stimulation of the ENT.

The conducted research provides an opportunity to improve the known method and the appropriate means of detection of RLN in the process of thyroid surgery.

4. An improved method with Adaptive adjustments of the pulsed current frequency

The proposed method, unlike the existing one, contains six steps, including setting the frequency of the pulsed current of the RLN stimulation.

Step 1. Stimulation of the surgical wound tissues with a pulsed electrical signal of a fixed frequency.

In our case, unlike the existing method [9-13], we stimulate the tissues of the surgical wound with a pulsed electric current with a frequency of 5 to 20 Hz. At the same time, we fix the current strength in the range from 0.5 mA to 2 mA.

Step 2. Receiving an information signal (as a result of stimulation of tissues of the surgical wound)

Using a microphone installed in the endotracheal tube, we obtaine a change in the sound signal during the patient's inhalation or exhalation phase due to vibration of the patient's vocal cords, modulated by a pulsed current due to stimulation of the surgical wound tissues. The resulting audio signal is sent to the audio adapter, where it is digitized and fed to the Raspberry Pi 4 single-board computer for processing.

All software is implemented on the basis of a single-board computer Raspberry Pi 4. It controls all other devices, including a generator of rectangular pulses, as well as processing of the received sound signal and visualization of the results of processing and classification of the surgical wound tissue at the point of stimulation.

Step 3. Information signal segmentation software.

The current step is necessary to isolate the response of the patient's vocal cords to tissue stimulation using sound signals received during inhalation or exhalation.

Fig. 5 shows the information signal and clearly demonstrates the principle of segmentation. As we can see from Fig. 5, there are two types of segments. Segments of the first type are the result of spread of the influence of each impulse along the RLN on the muscles that stretch the vocal cords. In Fig. 2 there are four such segments. Segments of the second type – reflect the intervals between stimulation signals and represent the sounds that the patient makes during one inhalation or exhalation. Other intervals are the intervals between the segments of the patient's breath. These intervals are not informative for the tissue classification method and are called noise. Thus, it is necessary to select segments of type 1, as shown in Fig. 5, during the segmentation process.

It should also be noted that unlike the existing technique [9-13], in our case there will be several such segments on one inhalation or exhalation, depending on the frequency of stimulation. This is due to the fact that the existing method of stimulating tissues of a surgical wound uses a frequency from 50 Hz to 1 kHz. Therefore, the muscles that tighten the vocal cords do not have time to relax in order to respond to the next impulse of irritation.

The main approach of automatic segmentation is based on the principle of threshold selection of an informative segment.

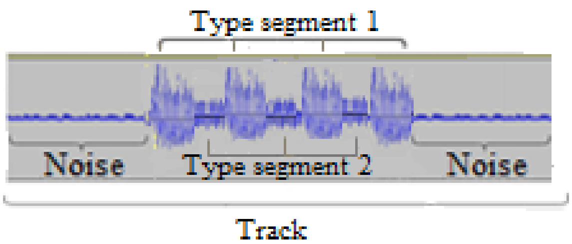


Fig. 5 Illustration of the information signal segmentation.

Representing the audio signal in digital form simplifies segmentation and allows software processing using Raspberry Pi 4. For this, a threshold method was used to determine the beginning and end of a fragment. Typically, regardless of the point of tissue stimulation, the amplitude of the information signal during stimulation is significantly higher than without stimulation (see Fig. 2). Determining an "informative" fragment is a simple task that involves the use of a threshold method. However, to avoid considering noise from the audio signal, it is proposed to use a window of n counts to calculate the average energy and compare it with the threshold.

Thus, to segment the information signal we will use the following algorithm:

To determine the types of segments 1 and 2 (see Fig. 2), it is proposed to estimate the average energy value E from n counts according to the formula:

$$E = ({}_{i=1}^{n} u_i^2)/n$$

where is the i-th sample of the information signal; n is the number of samples in the window, which is selected from the interval n =[3;10].u_i

Determination of the initial count of the fragment:

$$E \geq E_{tr} \text{then} u_{start} = u_n$$

Determination of the last count of the fragment:

$$E \leq E_{tr} \text{then} u_{stop} = u_n$$

Thus, the resulting segment consists of a set of readings:

$$U = u_i \in u_{start}; u_{stop}$$

In this case, the problem is to determine the threshold value of the reference energy. As noted earlier, the amplitude of the information signal is significantly higher during stimulation compared to the amplitude of this signal without stimulation. Thus, formula (1) can be used to obtain a threshold value for the signal without stimulation during inhalation or exhalation of the patient.E_{tr}

```
class FragmentSpectrum(BoxLayout):
def strem_amplitude_to_spectrum_Y(self, y):
y_L = y[::2]
y_R = y[1::2]
Y_L = np.fft.fft(y_L, nFFT)
Y_R = np.fft.fft(y_R, nFFT)
# Sewing FFT of two channels together, DC part uses right channel's
return abs(np.hstack((Y_L[int(-nFFT / 2):-1], Y_R[:int(nFFT / 2)]))) /
self.MAX_y
def display_fragment(self, Y):
max = np.max(Y)
self.fragment_line.set_ydata(Y)
self.fragment_line_X.set_ydata(np.full(nFFT – 1, max))

self.fragment_line_X_annotaion.set_text(round(max, 2))
self.fragment_line_X_annotaion.set_position((0, max))
self.fragment_line_X_annotaion.xy = (0, max)
```

Fig. 6. Code fragment for the main spectral component acquisition module.

Step 4. Isolation of the main spectral component.

As already mentioned above, the amplitude of the main spectral component depends on the point of irritation on the surgical wound. In this case, the amplitude of the selected main spectral component is inversely proportional to the distance from the stimulation point to the RLN.

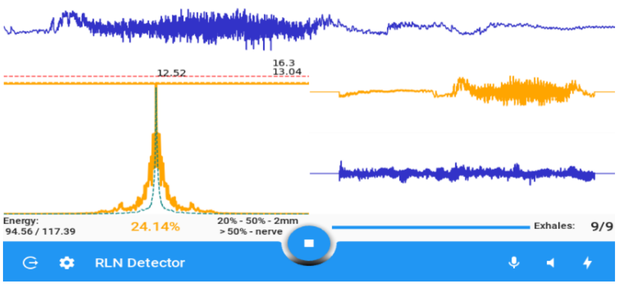
Therefore, it is proposed to use the amplitude of the main (with the maximum amplitude) spectral component of the signal segment for tissue classification at the point of stimulation. To do this, first, for the selected fragment of the information signal, it is necessary to obtain its frequency spectrum using the fast Fourier transformation [15]. In the software implementation, we use the FragmentSpectrum module, developed using the Python library and installed on Raspberry Pi 4. The FragmentSpectrum module also implements the visualization of a fragment of an information signal, which is processed using an FFT. Fig. 6 shows a code fragment of this module.

The classification results are visualized, and an audible signal alerts the surgeon on the placement of the stimulation point on the RLN. Figure 7 shows fragments of the stimulation results visualization interface. The visualization results are shown in Fig. 7 – a) illustrate the lack of stimulation of the tissues of the surgical wound or stimulation at a significant distance from the RLN during the patient's breathing. Figure 7 b) shows RLN stimulation.

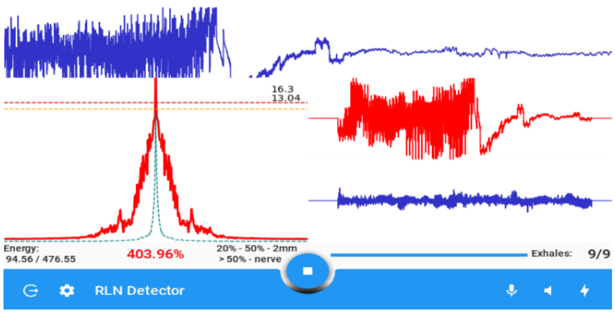
Step 5. Classification of tissues and visualization of the result.

As already mentioned, the main drawback of the existing method is the lack of a procedure for automatically adjusting the parameters of the electrical signal to stimulate the tissues of the surgical wound in the most effective way.

Therefore, an additional step is added in the proposed method to ensure this automatic adjustment. It should be noted that this step is used only at the beginning of the monitoring procedure.



a



b

Fig. 7. Fragments of the interface for visualization of the results of tissue stimulation: a) the result of stimulation of tissues around the RLN; b) stimulation of the RLN.

Step 6. Setting the parameters of the electrical signal to stimulate the tissues of the surgical wound.

As mentioned above, in the course of the previously conducted clinical tests of the device, it was possible to establish the range of the most effective frequencies of following electrical pulses of the excitation current of the RLN in the range from 5 Hz to 20 Hz. This range is determined by the limits of the possible response of muscle tissues to electrical impulses. To adjust this parameter of the stimulation signal to the optimal values, we set a program cycle between the stimulation frequency and the evaluation of the result in the form of the calculated amplitude of the main spectral component at three points of the surgical wound: around the RLN – at a distance of 2-3 mm; at a distance of more than 1 cm from the RLN. The algorithm for each point is as follows.

Step 6.1. Setting the pulsed current frequency value to 2 Hz. Go to step 1

Step 6.2. Implementation of steps 1-5.

In this case, the result is the amplitude of the main spectral component. Let us denote it $A_b\ f$, where f – the frequency of the impulse current of stimulation.

Step 6.3. Audit:

If$A_b\ f\ > A$*then* $A:=\ ;A_b\ f\ f_{opt} \coloneqq f$

If$f < 20$ *then f:=f+1 and proceeding to step 1,*

else save and stop step 6.f_{opt}

It is worth noting that the meaning of the symbol: = in step 6.3. means to assign, and the expression "*save* f_{opt} *and stop step 6* means that this step is no longer used in the process of calculation and monitoring of the RLN, and "f_{opt}- the frequency of stimulation remains unchanged.

5. Results and discussion

Based on the results of preliminary research and design, software was developed for the operation of the identification system for the localization of the RLN during surgery on the thyroid gland. The main functions of the developed software:

• Desktop application;

• Control of the pulse current forming process;

• Implementation of the module for receiving information from the sound sensor placed in the endotracheal tube;

• Automatic adjustment of electric signal parameters for stimulation of surgical wound tissues in the most effective way;

• Information signal visualization;

• Visualization of a fragment of an information signal;

• Calculation and visualization of the spectrum of a fragment of an information signal;

• Classification of tissue types;

• Displaying a visual representation and playback of a sound message to indicate the type of fragment in the information signal;

• Output of the information signal to a sound device (both external – headphones and internal – speakers);

• Recording of an information signal on an information medium (file system)

The software is designed to be installed on a Raspberry Pi 4. It uses a Python-based code development platform optimized for mathematical calculations. The Raspberry OS is optimized for software in this language.

The main libraries used in software development:

Kivy –is an open source software library for rapid development of applications equipped with novel user interfaces such as multi-touch applications [19].

Numpy –is a library that provides a multidimensional array object, various derived objects (such as masked arrays and matrices), and a set of routines for fast array operations, including mathematical, logical, shape manipulation, sorting, selection, input/output., discrete Fourier transforms, basic linear algebra, basic statistical operations, random modelling [20].

Matplotlib –is a comprehensive library for creating static, animated and interactive visualizations [21]. This tool allows users to create graphs of various types and levels of complexity.

Pyaudio – provides Python bindings for PortAudio v19, a cross-platform audio I/O library. With PyAudio, you can easily use Python to play and record audio on a variety of platforms such as GNU/Linux, Microsoft Windows, and Apple macOS [22].

The architecture of the software is shown in Fig. 8.

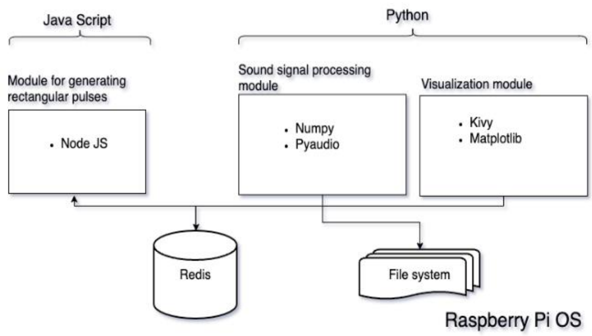


Fig.8 Software architecture.

The hardware module for generating rectangular pulses uses a subroutine written in Node JS. A separate process runs this subroutine and communicates with the main application via the Redis database. The program's main process is responsible for monitoring changes in Redis and restarting the pulse generator subprocess whenever there are changes.

The study of the developed system was tested in the "VITASANA" medical centre in Ternopil during a surgical intervention on the thyroid gland.

6. Conclusions

The method and means for detecting the RLN in the process of operations to remove fragments or the entire thyroid gland are considered. The functioning of the means of detection of the RLN consists in irritating the tissues of the surgical wound with a pulsed current and evaluating the reaction to the irritation with the help of a sound sensor installed in the endotracheal tube. With the use of these tools, in the course of clinical trials, it was established that the effectiveness of detection of the RLN depends on the parameters of the electric current that stimulates the tissues of the surgical wound, namely on the frequency of the pulsed current. The established properties served as the basis for the development of an improved method for identifying the location of the RLN. In contrast to the existing method and means of its implementation, the proposed method and means provide automatic adjustment of the parameters of electrical signals for effective stimulation of the tissues of the surgical wound. After the research, the software architecture of the device was developed to perform the following functions: control of the pulse current generation process; receiving information from the sound sensor placed in the endotracheal tube; automatic setting of electrical signal parameters for stimulation of surgical wound tissues in the most effective way; visualization of the form of the information signal; classification of tissue types; message about the type of stimulated tissue; recording of an information signal on a storage medium.

Validation of hardware and software for automatic adjustment of electrical signal parameters to identify the RLN during operations on the thyroid gland was carried out in the medical centre "VITASANA" in Ternopil.

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УДОСКОНАЛЕНИЙ МЕТОД ТА ЗАСОБИ З ФУНКЦІЄЮ АВТОМАТИЧНОГО НАЛАШТУВАННЯ ПАРАМЕТРІВ ЕЛЕКТРИЧНОГО СИГНАЛУ ДЛЯ ВИЯВЛЕННЯ ЗВОРОТНОГО ГОРТАННОГО НЕРВА

Андрій Дивак, Володимир Тимець

У статті представлено результати розробки програмно-апаратних засобів для ідентифікації зворотного гортанного нерва (ЗГН). В процесі досліджень встановлено, що ефективність виявлення результату стимуляції ЗГН імпульсним електричним струмом залежить від його частоти. На цій основі запропоновано програмні засоби для автоматичного регулювання параметрів електричного сигналу, щоб максимально ефективно стимулювати тканини операційної рани. При хірургічних операціях на щитовидній залозі ці інструменти використовують для мінімізації ризику пошкодження ЗГН. Представлено вдосконалений спосіб стимуляції тканин операційної рани. Наведено основні алгоритми інструментальних засобів та архітектуру програмної частини. Проведена апробація запропонованого пристрою на базі медичного центру в Україні.

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