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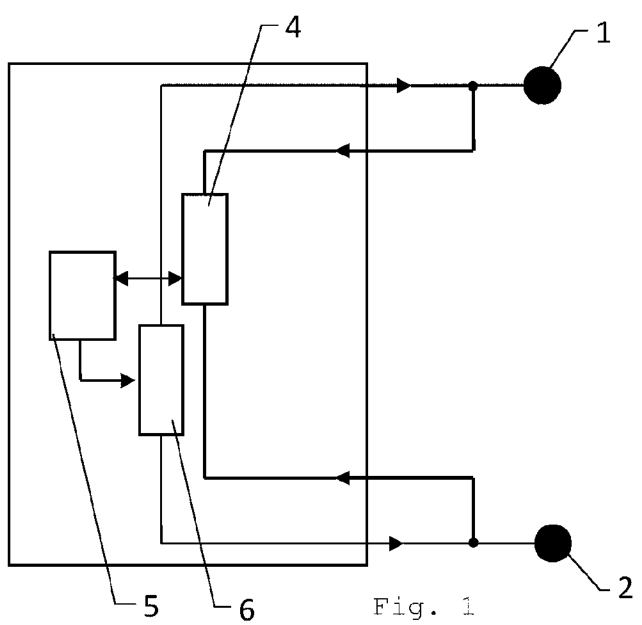

Fig. 1

(57) Abstract: A device for secondary caries detection characterized in that it contains a current generating block in its casing (6), advantageously equipped with the high linearity amplifiers, the current having the form of sinusoidally varying signal, advantageously with one frequency chosen from the range of frequencies from 200 Hz to 100 kHz and amplitude from 50 mV to 5 V; a block of preamplifiers (4), advantageously of high sensitivity and linearity with phase-sensitive detectors measuring components, advantageously with one frequency chosen from the range of frequencies from 200 Hz to 100 kHz as well as its multiples, advantageously integral in principle; microprocessor control unit (5), advantageously with a miniature keyboard and display unit, and at least one fixed electrode (2) placed on mucous membrane of the oral cavity and at least one moveable electrode to be mounted on a tooth (1).

WO 2012/144913 A1

2012246764 03 Aug 2016

A Device and Method for Detecting a Harmonic Response Characteristic of Secondary Dental Caries Diagnosis

The invention pertains to a device and method for detecting a harmonic response characteristic of secondary dental caries.

A method for studying biological cells with the aid of stimulating them with sinusoidal alternating current and studying the non-linear response of these cells has been described in the patent application WO 92/04630. The above-mentioned cells are located in the studied analytical environment, for example in the form of a suspension or biological tissue.

The described invention is used to study the properties of the solution or the biological tissue as a whole. In the case of *in vivo* studies, the existence of complex biological tissue systems which differ significantly as far as biophysical and biochemical parameters are concerned creates the main problem. In *in vivo* studies, the whole organs will be investigated in the majority of cases rather than tissues or groups of identical cells.

Thus, the described invention could not be used to diagnose secondary caries because a tooth is an organ composed of many tissues whose properties differ significantly, including hard tissues which have unique physical and chemical properties decidedly different from the properties of cell solutions or soft tissues which were supposed to be studied by the method described in the prior art invention.

When studying a tooth using a method quoted in prior art invention, it is impossible to mechanically separate one selected tissue without destruction.

A tooth is composed of mineral components, electrolytes and biological cells, also those located in soft tissues.

Thus, both the bio-impedance study method (including harmonic response study) of a human tooth *in vitro* or *in vivo* as a whole as well as the analysis of the results differ fundamentally from those of the isolated biological tissues.

Electrical properties (conductivity and dielectric permittivity) of a tooth or hard tissue in general are fundamentally different than the ones of soft tissue.

There are other sources of non-linearity in the tooth tissue than the ones described in the quoted patent.

At the moment secondary caries diagnosis is carried out using good eye and bitewing X-rays.

When using the above-mentioned method a tooth should be cleaned from the residue and dried. It also exposes the patient to potentially harmful ionizing radiation. The method is time-consuming and does not offer immediate diagnosis.

There are also modern optical methods, eg caries detection device Diagnodent which have a limited scope of detection. Amalgam fillings are not transparent and the performance of the device demonstrates low sensitivity and specificity.

The other method which has a wide application in the enamel quality diagnosis are bio-impedance measurements. They are popular in studying the root canal fillings, and lately have been used to study enamel quality among other things.

Bio-impedance measurements of enamel consist in the analysis of its ac impedance spectrum and allow to determine precisely the enamel dielectric and conductivity parameters which change significantly when the disease processes are present.

This method is especially accurate when the structure of a tooth is known. Moreover, the examination is non-invasive, it does not take much time and the cost of producing a measurement apparatus is relatively low. These advantages have already been used in the commercially available devices for bio-impedance enamel analysis (e.g., www.cariescan.com).

The above-mentioned method demonstrates very high sensitivity [correct identification of carious sites] in a physical rather than medical sense but very low resolution [correct identification of sound sites] which signifies that the response can be influenced by a number of biophysical factors and phenomena such as for example water presence, surface cleanliness including microbiological one. It cannot be used to study secondary caries.

Thus, there is still a need for a method and a device for secondary caries diagnosis which is quick, does not expose patients to ionizing radiation, has high resolution allowing to detect water environment presence such as bacterial microflora or changes in sound enamel caused by secondary caries development. This method should also consider specific electrical properties (conductivity and dielectric permittivity) of a tooth and its filling (the fact that amalgam is not transparent).

The first embodiment of the invention is a device for detecting a harmonic response characteristic of secondary caries. The device comprises a current generating block within a casing, the current generating block generating current having the form of a sinusoidally varying signal and having a chosen frequency from the range of frequencies from 200 Hz to 100 kHz and an amplitude from 50 mV to 5 V; a block of preamplifiers having phase-sensitive measuring components, configured to

2012246764 03 Aug 2016

measure the chosen frequency and integral multiples of the chosen frequency being generated by the current generating block, to provide a harmonic response spectrum; a microprocessor control unit connected to the current generating block and the block of preamplifiers; at least one fixed electrode suitable for being placed on a mucous membrane of an oral cavity connected to the current generating block and to the block of preamplifiers; and at least one moveable electrode configured to be mounted on a tooth and connected to the current measuring block and to the block of preamplifiers.

It is also advantageous that the device according to the invention, additionally contains an additional interface that can cooperate with the external device, advantageously with a computer or other peripheral device.

The second embodiment of the invention is a method for detection a harmonic response characteristic of secondary caries using at least one moveable electrode placed on a surface of an examined tooth and at least one fixed electrode secured on a mucous membrane of an oral cavity in the vicinity of the examined tooth. The method comprises:

a) supplying to the electrode an electrical stimulation signal having the form of a sinusoidally varying current and having a chosen frequency from the range of frequencies from 200 Hz to 100 kHz and an amplitude from 50 mV to 5 V;

b) measuring an amplitude and phase components of an electrical response at the electrodes, at the chosen frequency and integral multiples, of the chosen frequency being supplied to the electrodes to provide a harmonic response spectrum; and

c) analysis of the response spectrum to identify of features characteristic of secondary caries.

The method according to the invention is also advantageous because typically the characteristic features of the carious lesion spectrum are correlated with the presence of bacteria causing caries which leads to the conclusion that the lesions are present.

Embodiments of the present invention utilize all AC current flow associated nonlinear phenomena that are present in a human tooth, and correlate a harmonic response with the occurrence of secondary caries that consists in the change of enamel and/or dentine composition and structure as a result of carious processes. Unexpectedly, the present invention presents a solution to the above-mentioned problem.

Embodiments of the invention can be applied in dentistry.

The fact that dental caries have microbiological origin is used as the basis for detection and monitoring of secondary caries with the aid of bio-harmonic measurements according to the invention.

The impedance measurements that have been used so far were not selective enough in comparison with the bio-harmonic measurements according to the invention.

The response of the system obtained during the detection of caries using the bio-harmonic method contains also information concerning biological tissue structure and charge transfer or mass transport processes. All these phenomena together with microbiological processes are used to diagnose secondary caries with high sensitivity and specificity.

The examples of the invention realization are presented in figures: wherein fig. 1 illustrates the caries detection device, fig. 2 the caries detection device with interface 3 that cooperates with a peripheral device while fig. 3 and 4 demonstrate the examples of the results of the current flow

20122246764 03 Aug 2016

in a sound tooth (fig. 3) and in a tooth with secondary caries under an amalgam filling (fig. 4). Moreover, figures 3a and 4a illustrate the structure, figures 3b and 4b the directions of the current flow while figures 3c and 4c demonstrate the current density distribution. Fig. 5 illustrates schematically the setup used for *in vitro* measurements, fig. 6 shows the results obtained for a sound extracted tooth, fig. 7 shows the results obtained for a sound tooth with filling, and fig. 8 shows the results obtained for a tooth with filling and addition of bacteria, namely *Lactobacillus acidophilus*.

Example 1

A movable electrode was placed on the surface of a tooth with an amalgam filling and a fixed electrode was secured on the mucous membrane of the oral cavity in the vicinity of the examined tooth.

Then an electrical stimulation signal was applied in the form of sinusoidal waveform of a frequency of 100 kHz.

Then the measurement of amplitude and phase components of the system electrical response of a frequency of 100 kHz and its five integral multiples up to 1 MHz was made.

Next the analysis of response spectrum for identification of features characteristic of carious changes was made. The identical procedure was repeated for a sound tooth.

A simulation of alternating current flow through a sound tooth and a tooth with secondary caries under an amalgam filling in a linear response model was performed.

The simulation was performed using finite element method assuming alternating current flow (a frequency of 10kHz) on a two-dimensional half of the tooth in the gum with one electrode placed on the mucous membrane and the second one touching the occlusal surface of the tooth.

The existence of an amalgam filling and secondary carious lesion was simulated in a tooth.

The employed models and the results are presented in Figures 3 and 4. Figures 3a and 4a demonstrate the distribution of tissues representing different electrical properties on a tooth cross section. Different shades of color mark enamel, dentine and pulp. The electrode placed on the tooth was also marked.

The amalgam filling in the vicinity of secondary caries area is shown in Figure 4a. The simulated current direction flow is marked with fine lines in Figures 3b and 4b.

A map of current density calculated in the simulation is presented in Figures 3c and 4c. White areas mark the lowest current densities while the black ones the highest current densities.

It can be read from the simulation results that the highest current densities are observed in the pulp and in the dentine in the area between the point the electrode is placed and the point of the pulp located nearest to it.

The current density increases in the tooth with filling because of good electrical conductivity of amalgam and the decrease of the thickness of dentine layer that has worse electrical conductivity.

It causes still higher concentration of the lines representing current flow in the area where secondary caries may occur making the harmonic response characteristic of the carious tissue easier to measure.

Example 2

The device for secondary caries detection consists of a casing in which a current generating block 6 is located. It contains high linearity amplifiers. The generated current has the form of sinusoidally varying signal of a frequency of 100 kHz.

A fixed electrode 2 is connected to the measuring current generating block at one side and a movable electrode 1 the one placed on the tooth is connected at the other side.

A block of preamplifiers of high sensitivity and linearity a phase-sensitive detectors measuring components of a frequency of 100 kHz as well as its five multiples is connected to the above-mentioned electrode in parallel

A microprocessor control unit 5 with a miniature keyboard and display unit is connected to the preamplifier block 4 at one side and to the measuring current generating block 6 at the other side.

The measuring current generating block 6 produces measuring current that flows through the movable electrode placed on a tooth 1 and the fixed electrode 2.

Then the signal is read and amplified in the block of preamplifiers 4. The measuring current generating block 6 is controlled by the provided microprocessor steering unit 5 which is connected to the block of preamplifiers 4. The schematic diagram of the device is demonstrated in Figure 1.

Example 3

The device as described in the example 2 containing an interface 3 to be connected to the peripheral device connected with the microprocessor control unit 5. A computer has been connected to the interface. The schematic diagram of the device is demonstrated in Figure 2.

Example 4

in vitro results on extracted teeth

Measurements have been made on teeth extracted a few days earlier. The root of each tooth as well as the fixed electrode 2 were immersed in 0.9% aqueous solution of NaCl called saline solution. The tip of a standard dental explorer was used as the moveable electrode 1. Saline solution was also used to keep the teeth wet during measurements to simulate the conditions in the oral cavity. A sinusoidal signal of 1 kHz frequency and 2.5 V amplitude was applied to the electrodes 1 and 2 through 2 x 10 kΩ series resistors R and the response was analyzed in a digital harmonic analyzer 4, as depicted in fig. 5.

The measurements were conducted on sound teeth, in which a dentist made composite fillings, either clean or with addition of bacteria (namely *Lactobacillus acidophilus*). The screenshots in figures 6 to 8 represent the results obtained with the harmonic analyzer. The results are presented in frequency domain, i.e., the horizontal axis is a frequency axis with 1/32 kHz unit. The peaks at 32, 64, 96, etc. correspond to the excitation frequency 1 kHz and its harmonics, i.e., 2 kHz, 3 kHz, etc. The Y axis is the intensity of the tooth response at each frequency presented in logarithmic scale with respect to the excitation frequency response, i.e., the fundamental peak 1 kHz is always at 0 dB. The sensitivity threshold of the device used is about -100 dB for the second and third harmonic, and about -110 dB for higher harmonics; the peaks appearing below this level are artifacts.

Measurable harmonics were registered only when (living) bacteria were present (added) under the filling. In such cases, a non-linear bio-impedance spectrum of bacteria was obtained. Fig. 6 shows example results obtained for an extracted sound tooth (no filling and no bacteria added). Fig. 7 shows example results for a sound tooth with clean (no bacteria added) filling made by a dentist. Fig 8. shows example results obtained for a sound tooth where bacteria were added under the filling. These results were reproduced for different teeth.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

2012246764 03 Aug 2016

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A device for detecting a harmonic response characteristic of secondary caries comprising:

a current generating block within a casing, the current generating block generating current having the form of a sinusoidally varying signal and having a chosen frequency from the range of frequencies from 200 Hz to 100 kHz and an amplitude from 50 mV to 5 V;

a block of preamplifiers, having phase sensitive measuring components, configured to measure the chosen frequency and integral multiples of the chosen frequency being generated by the current generating block, to provide a harmonic response spectrum;

a microprocessor control unit connected to the current generating block and the block of preamplifiers;

at least one fixed electrode suitable for being placed on a mucous membrane of an oral cavity and connected to the current generating block and to the block of preamplifiers; and

at least one movable electrode configured to be mounted on a tooth and connected to the current measuring block and to the block of preamplifiers.

2. A device according to claim 1, further comprising an interface that can cooperate with an external device.

3. A device according to claim 1 or 2, wherein the current generating block comprises high linearity amplifiers.

4. A device according to any preceding claim, further comprising a miniature keyboard and display unit.

5. A method for detection of a harmonic response characteristic of secondary caries using at least one movable electrode placed on a surface of an examined tooth and at least one fixed electrode secured on a mucous membrane of an oral cavity in the vicinity of the examined tooth, comprising:

a) supplying to the electrodes an electrical stimulation signal having the form of a sinusoidally varying current and having a chosen frequency from the range of frequencies from 200 Hz to 100 kHz and an amplitude from 50 mV to 5 V;

b) measuring an amplitude and phase of an electrical response at the electrodes, at the chosen frequency and integral multiples of the chosen frequency being supplied to the electrodes to provide a harmonic response spectrum; and

c) analysis of the response spectrum to identify features characteristic of secondary caries.

6. A method according to claim 5, wherein the step of analysing comprises identifying features of the response spectrum that are correlated with the presence of bacteria which cause caries.

7. A method according to claim 4 or claim 5, wherein the movable electrode is placed on the surface of an amalgam filling.

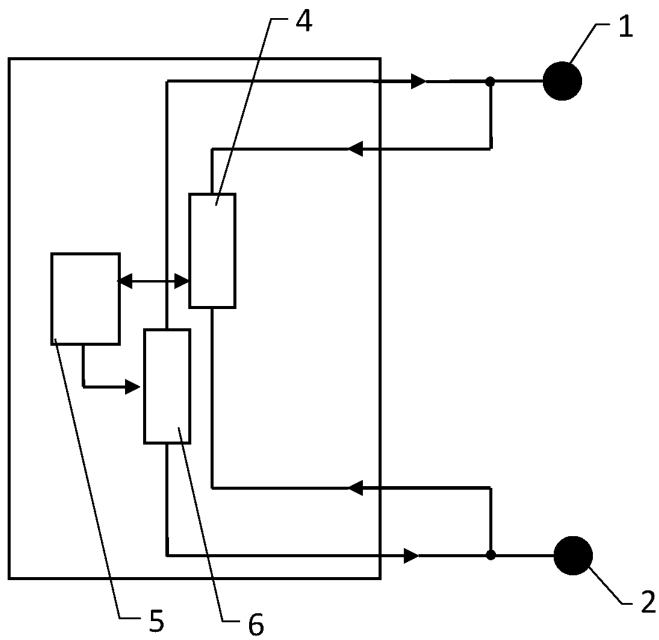

Fig. 1

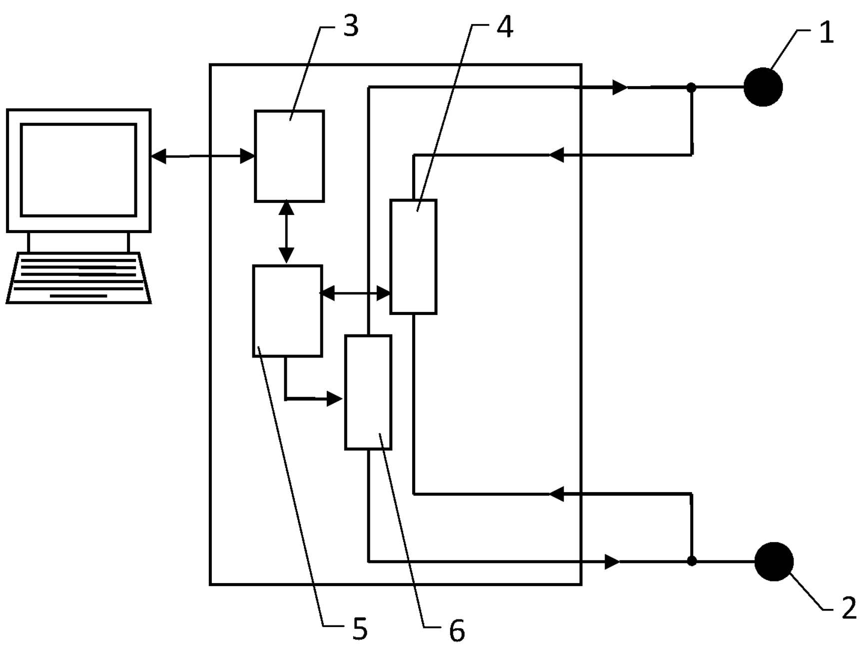

Fig. 2

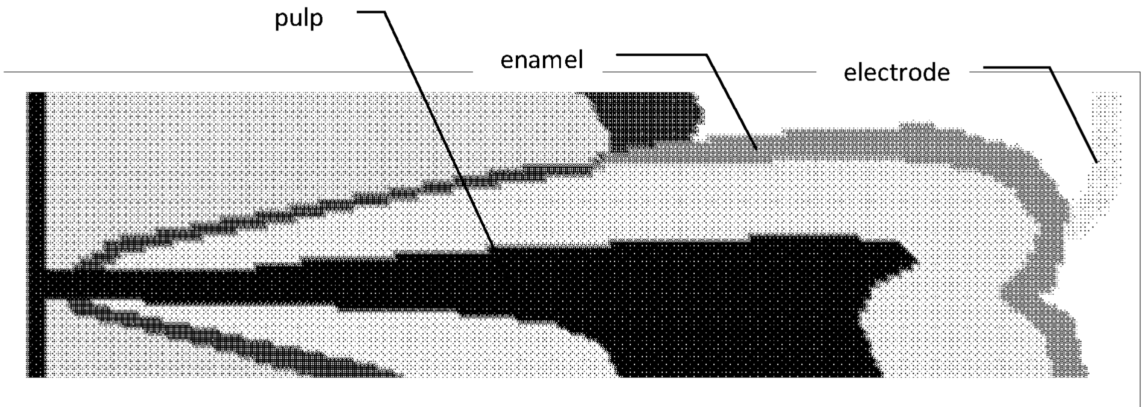

Fig.3a

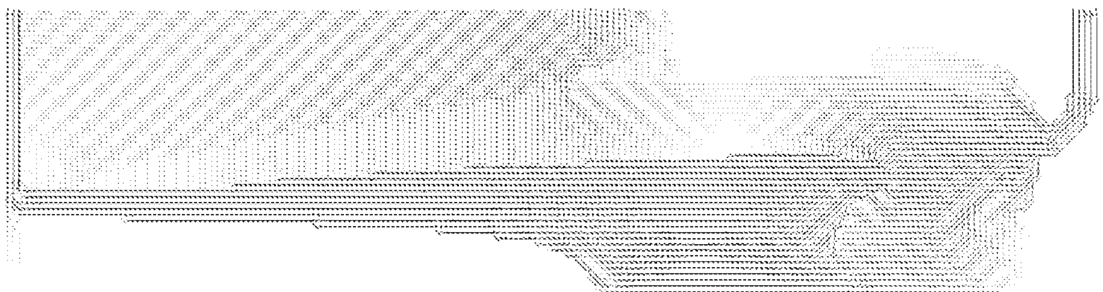

Fig.3b

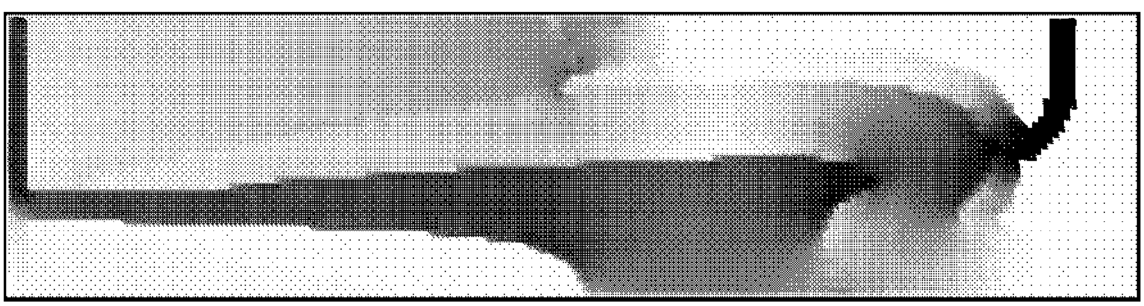

Fig. 3c

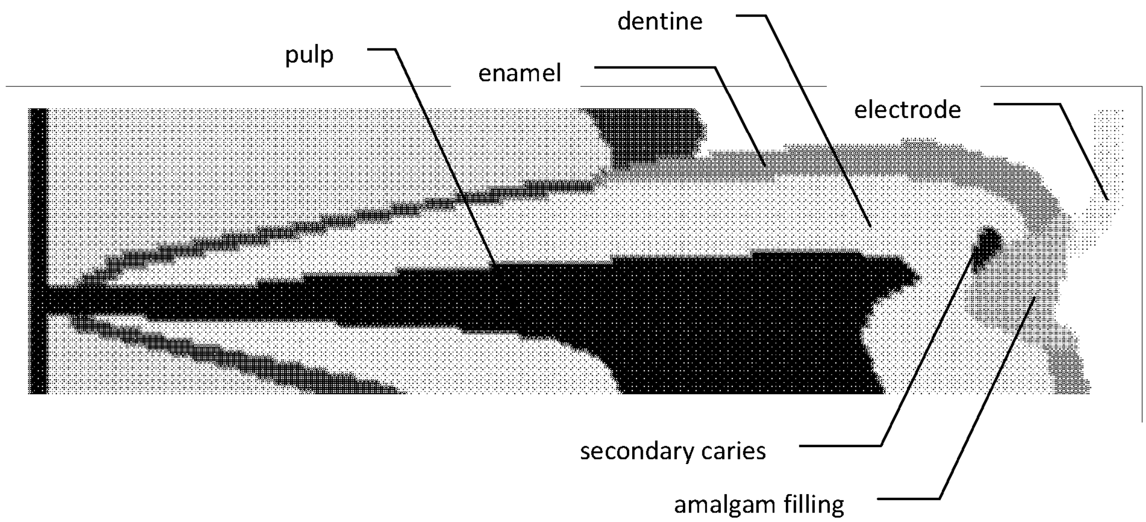

Fig. 4a

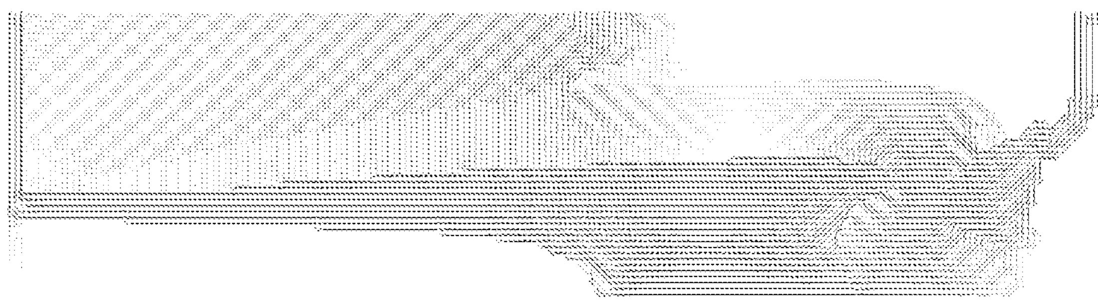

Fig. 4b

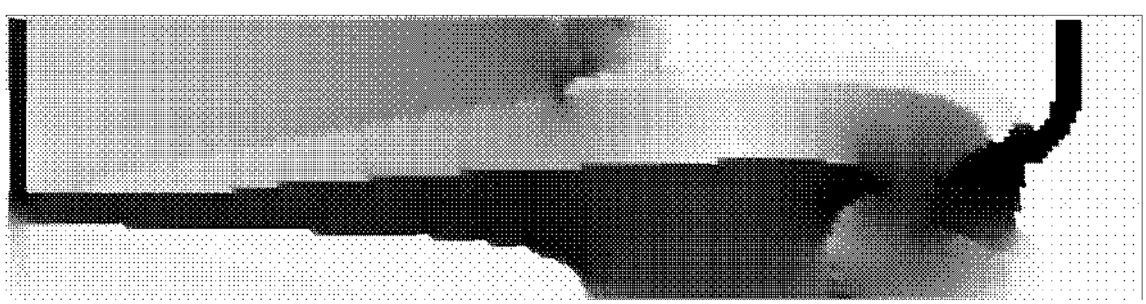

Fig. 4c

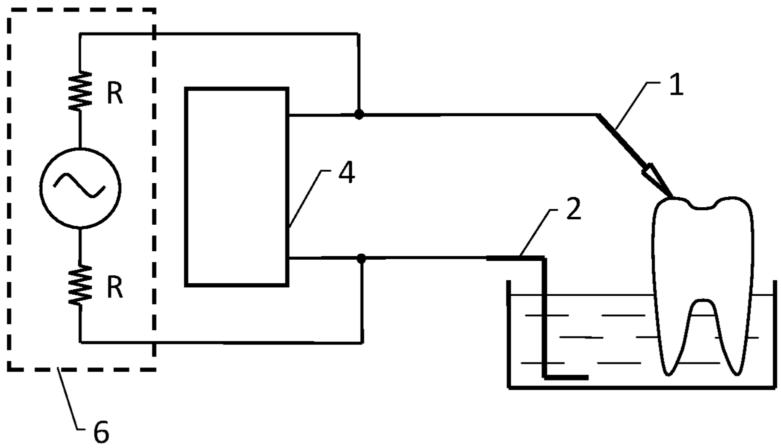
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Fig. 5

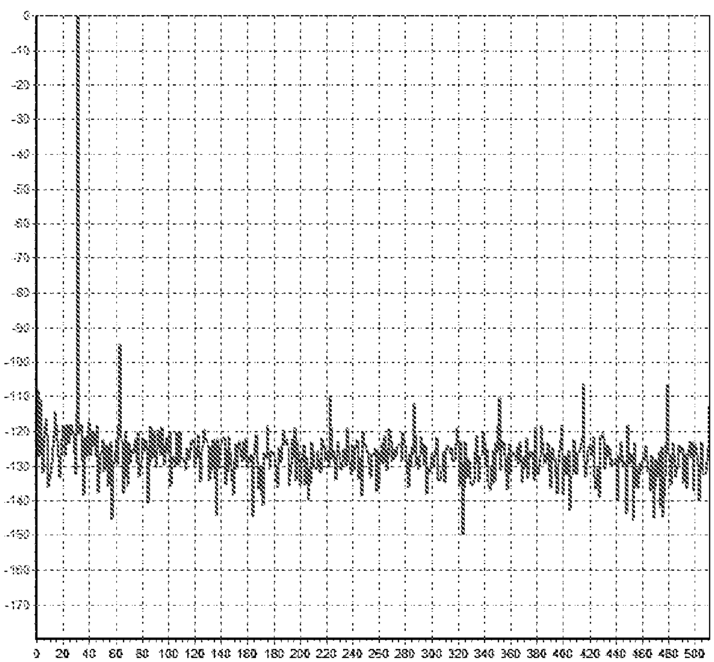
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Fig. 6

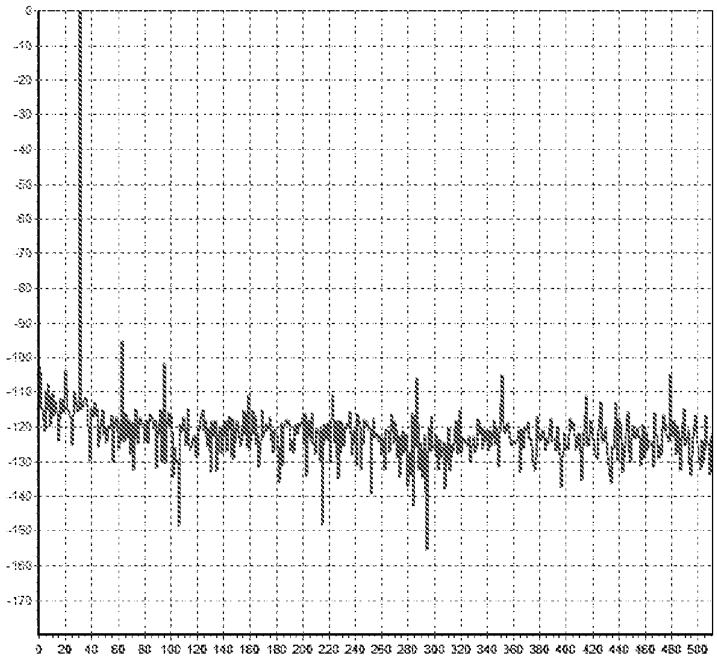
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Fig. 7

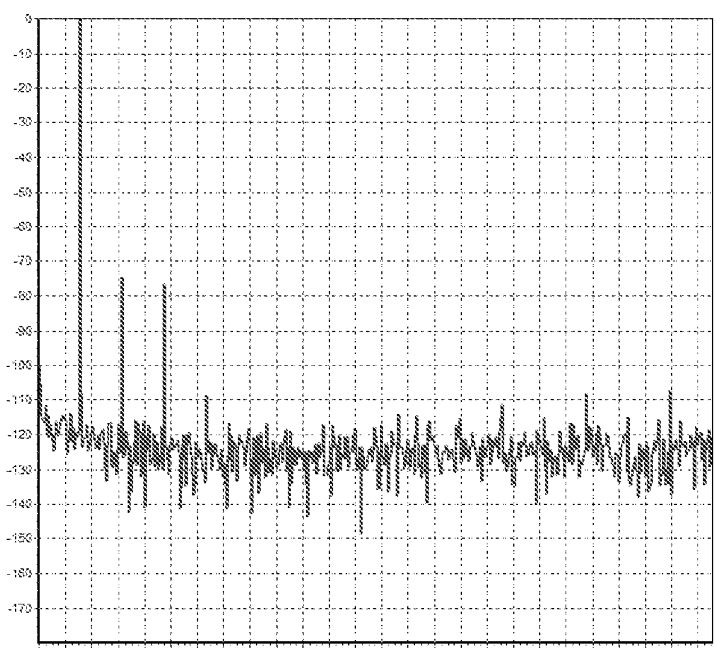
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Fig. 8