Tatiana Gladilina

ANALYSIS OF THE MAIN TECHNICAL REQUIREMENTS FOR THE TEST EQUIPMENT AND THEIR IMPACT ON THE PARAMETERS OF THE FINAL PRODUCT AND ITS VARIANTS

Technical requirements for the equipment and their impact on the quality of the final product

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The article presents the results of analyzing the technical requirements and calibration testing of equipment developed for a sensor capsule intended for the non-invasive measurement of acidity in liquid media using electromagnetic spectroscopy. Particular attention is given to evaluating the effects of sensor design, measurement range, operating temperature, sample composition, suspended particles, and chemical additives on measurement accuracy, sensitivity, and repeatability.

Based on comparative experimental studies, the authors identify a planar printed-circuit-board solenoid as the most effective sensor configuration, providing improved sensitivity while reducing capsule dimensions and increasing the available internal volume. The study demonstrates that the proposed measurement system maintains high accuracy and stability under a wide range of operating conditions and exhibits excellent repeatability during repeated measurements. The article also outlines recommendations for further optimization of the sensor capsule design and proposes additional validation under conditions that more closely simulate real biological environments.

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Contents

SIZE of the capsule, – sensor capsule dimensions

The technical specification defines the following required dimensions for the sensor capsule.

Diameter – 30 mm.

Length – 100 mm.

Following modeling and experimental testing, the test team concluded that, if necessary, the external dimensions of the capsule can be reduced to the following.

Diameter – up to 25 mm.

Length – up to 80 mm.

A key factor enabling this reduction is the use of a planar solenoid as the sensor, implemented as a flat coil on a single-layer printed circuit board.

The dimensions of this printed circuit board – 16 mm in diameter and 1.5 mm in thickness – make it possible to free up additional space and volume within the sensor capsule.

Measurement Ph range (3–10), – measurement of acidity over an extended pH range

The calibration test range was expanded, with calibration tests performed on samples having pH values from 2 to 10.

In principle, there are no limitations on the pH values that can be measured using the new technology.

The capability to measure pH values as low as 1 (hydrochloric acid used for sample preparation) and as high as 14 (various household alkaline solutions) was experimentally verified.

The specified measurement range is fully achievable.

Operational temperature range – 20 +45 degree

In accordance with the technical specification, the measurement procedure and accuracy were evaluated at sample temperatures of 10, 25, and 40 °C with a pH value of 6.

In addition, the parameters and pH values were measured for samples with pH levels of 3, 4, 5, 6, and 7 at temperatures of 23 and 39 °C.

The measurement results demonstrated that the prototype provides sufficient sensitivity across the entire tested temperature range for all sample pH values.

Measurement resolution (Ph) 0.01

During the configuration of the test equipment, software was used that allowed the signal frequency and amplitude to be adjusted with resolutions of up to 0.001 MHz and 1 mV, respectively.

As a result, the critical parameter of the measurement system is the amount of energy available for signal generation.

Battery modeling and evaluation of its operating characteristics will be carried out during the subsequent stages of the project. However, the feasibility of achieving the required high measurement accuracy has already been demonstrated.

Accuracy of Ph measurement –0.1

The required measurement accuracy was achieved during the calibration testing of the system.

Because the calibration procedure was based on differences in the acidity levels of liquid samples with highly accurate pH measurements, while simultaneously performing real-time reference

measurements of temperature and the presence of colorimetric content, the transition to glucose concentration measurements provided the same level of measurement accuracy.

Content (particles)

The influence of coarse whole-wheat flour in the sample at the concentrations specified in the technical specification – 100, 200, and 400 g/L – was evaluated.

(The penetration depth of the signal generated by the pulse generator into the liquid sample, when using a planar coil fabricated as a single-layer printed circuit board, is 1–1.5 mm.)

Because the flour settles to the bottom of the sample, its presence has virtually no effect on the measurement results.

Additional experiments were performed by adding orange pulp to gastric juice with a pH of 6 at a concentration of 10 g per 100 mL of gastric juice. In this case, the sample with a pH of 6 and the corresponding sample containing orange pulp produced virtually identical measurement results.

Feed content

As required by the technical specification, the influence of various substances added to the samples on the measurement results was evaluated. Because the samples were prepared using simulated gastric juice, hydrochloric acid, and tap water containing dissolved salts and hardness salts at a concentration of 400 mg/L, the effects of the additives were not uniform.

Additives at concentrations of 10 and 60 mg/L had no effect on the measurement results.

Additives at a concentration of 0.6 g/L also showed no significant effect on the measurement results.

Additives at a concentration of 1.2 g/L produced different results at different signal frequencies. However, at a measurement frequency of 25 MHz, the results were identical to those obtained for samples with a pH of 6 without additives.

Additives at a concentration of 6 g/L also produced different results at different signal frequencies. However, at a measurement frequency of 25 MHz, the results were identical to those obtained for samples with a pH of 6 without additives.

Simulation of Capsule Orientation, Including Contact Between the Sensor Surface and the Patient's Body

Influence of a 5 mm Thick Beef Plate Positioned 2 mm from the Planar Sensor Coil

The influence of a 5 mm thick beef plate positioned 2 mm from the planar sensor coil was evaluated.

(The penetration depth of the signal generated by the pulse generator into the liquid sample, when using a planar coil fabricated as a single-layer printed circuit board, is 1–1.5 mm.)

A beef plate positioned 2 mm from the face of the planar coil has no effect on the quality or accuracy of the measurements.

Influence of a Beef Plate in Direct Contact with the Planar Sensor Coil (The penetration depth of the signal generated by the pulse generator into the liquid sample, when using a planar coil fabricated as a single-layer printed circuit board, is 1–1.5 mm.)

To compensate for direct contact between the beef plate and the planar sensor coil, the planar sensor coil should be positioned at a depth of 1.5 mm within the sensor capsule.

Repeatability of the measurement results

Test Procedure:

More than one gallon of distilled water and one gallon of tap water were prepared.

The sample containers were hermetically sealed.

The test was conducted using the following signal parameters.

Frequency – 26.25 MHz. Amplitude – 9,850 mV for distilled water and 9,590 mV for tap water.

The same comparative test was performed five times at intervals of three days using the same water samples.

The measurement results obtained for samples with identical chemical compositions were completely identical.

Technical requirements analysis.

The following verification activities were performed during calibration:

- Analysis of compliance with, and feasibility of meeting, the project technical requirements.
- Evaluation of the instrument's operational lifetime.
- Verification of the instrument dimensions.
- Verification of the pH measurement range.
- Verification of the instrument operating and environmental temperature range.
- Evaluation of pH measurement accuracy.
- Verification of the measurement limits and resolution for determining the pH of gastric juice using the instrument.
- Evaluation of the influence of food particles or other substances present on the patient's skin at the measurement site on pH measurement results.

– Evaluation of the influence of the concentration of various components present within the measurement zone on pH measurement results.

All of the above parameters demonstrated that the equipment, materials, and instruments are fully prepared for testing in accordance with the first-stage test program.

Results of Equipment and Measurement System Preparation for Testing and the Impact of the Obtained Results on the Design Principles of the Autonomous Device (Sensor Capsule) and on the Evaluation of Measurement Results for Identifying pH or Other Target Parameters.

- Selection and experimental evaluation of structural materials.
- Selection and experimental evaluation of protective coatings.
- Selection and experimental evaluation of the sensor design, including a comparative analysis of alternative sensor configurations.
- Selection and experimental evaluation of the test setup.
- Preparation of liquid samples for testing.
- Procedure for measuring pH before and after testing.
- Influence of temperature on pH.
- Influence of time on pH stability.
- Influence of sample chemical composition on pH.
- Influence of organic materials or fruit juices in the sample on pH.
- Influence of coarse whole-wheat flour in the sample at the concentrations specified in the technical specification (100, 200, and 400 g/L).

(The penetration depth of the signal generated by the pulse generator into the liquid sample, when using a planar coil fabricated as a single-layer printed circuit board, is 1–1.5 mm.).

Considerations for Subsequent Calibration and Experimental Testing

The following potential evaluation should be considered during subsequent calibration and experimental testing.

Influence of a 5 mm Thick Beef Plate Positioned 2 mm from the Planar Sensor Coil.

(The penetration depth of the signal generated by the pulse generator into the liquid sample, when using a planar coil fabricated as a single-layer printed circuit board, is 1–1.5 mm.).

A 5 mm thick beef plate positioned 2 mm from the face of the planar sensor coil should not affect the quality or accuracy of the measurements. Influence of a Beef Plate in Direct Contact with the Planar Sensor Coil.

(The penetration depth of the signal generated by the pulse generator into the liquid sample, when using a planar coil fabricated as a single-layer printed circuit board, is 1–1.5 mm.)

To compensate for direct contact between the beef plate and the planar sensor coil, the planar sensor coil should be positioned at a depth of 1.5 mm within the sensor capsule.

Calibration of the Primary Test Equipment for Evaluating the Fundamental Feasibility of the Technology.

The Principal Objectives Achieved During the Proof-of-Concept Evaluation of the Technology:

- Determination of measurement differences and comparative evaluation for controlled liquid samples with the following characteristics.
- Distilled water samples with pH values ranging from 4 to 7, adjusted by the addition of hydrochloric acid.

- Tap water samples with pH values ranging from 4 to 7, adjusted by the addition of hydrochloric acid.
- Distilled water samples with pH values ranging from 2 to 7, adjusted by the addition of hydrochloric acid.
- Tap water samples with pH values ranging from 2 to 7, adjusted by the addition of hydrochloric acid.
- Distilled water samples with pH values ranging from 4 to 7, adjusted by the addition of hydrochloric acid and tested at 25 °C.
- Tap water samples with pH values ranging from 4 to 7, adjusted by the addition of hydrochloric acid and tested at 25 °C.
- Distilled water samples with pH values ranging from 4 to 7, adjusted by the addition of hydrochloric acid and tested at 39 °C.
- Tap water samples with pH values ranging from 4 to 7, adjusted by the addition of hydrochloric acid and tested at 39 °C.
- Hydrochloric acid–based samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water and tested at 25 °C.
- Synthetic gastric juice samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water and tested at 25 °C.
- Hydrochloric acid–based samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water and tested at 40 °C.
- Synthetic gastric juice samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water and tested at 40 °C.

- Hydrochloric acid–based samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water and tested at 25 °C.
- Synthetic gastric juice samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water and tested at 25 °C.
- Hydrochloric acid–based samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water and tested at 10 °C.
- Synthetic gastric juice samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water and tested at 10 °C.
- Hydrochloric acid–based samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water and fruit juice and tested at 25 °C.
- Synthetic gastric juice samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water and fruit juice and tested at 25 °C.
- Hydrochloric acid–based samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water and table salt and tested at 25 °C.
- Synthetic gastric juice samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water and table salt and tested at 25 °C.
- Hydrochloric acid–based samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water and baking soda and tested at 25 °C.
- Synthetic gastric juice samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water and baking soda and tested at 25 °C.

- Hydrochloric acid–based samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water, tested at 25 °C, and evaluated 1 hour after preparation.
- Synthetic gastric juice samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water, tested at 25 °C, and evaluated 1 hour after preparation.
- Hydrochloric acid–based samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water, tested at 25 °C, and evaluated 24 hours after preparation.
- Synthetic gastric juice samples with pH values ranging from 2 to 7, adjusted by the addition of distilled water, tested at 25 °C, and evaluated 24 hours after preparation.
- Synthetic gastric juice samples with a pH of 6 containing 10% fruit juice with pulp.
- Synthetic gastric juice samples with a pH of 6 containing 1% table salt.
- Synthetic gastric juice samples with a pH of 6 containing 2% table salt.
- Synthetic gastric juice samples with a pH of 6 containing 1% baking soda.
- Synthetic gastric juice samples with a pH of 6 containing 2% baking soda.

Design of the Container and Upper Flange for Mounting the pH Sensor Capsule Simulator

The liquid sample container is designed so that its upper flange fits the cylindrical body of the container without any gaps.

The pH sensor capsule simulator is also equipped with a support flange that mates with the upper flange of the container without any gaps.

As a result, the sample is completely isolated from the ambient air during measurements, preventing oxidative processes caused by direct exposure of the sample to atmospheric oxygen.

One group of samples consists of mixtures with pH values of 4, 5, 6, and 7. During testing, up to 1,000 combinations of the frequency and amplitude of the directed pulse generated by the pulse generator are evaluated.

A second group of samples consists of mixtures with pH values of 2, 3, 4, 5, 6, and 7. During testing, up to 1,000 combinations of the frequency and amplitude of the directed pulse generated by the pulse generator are evaluated.

Design of the Container and Upper Flange for Mounting the pH Sensor Capsule Simulator

The liquid sample container is designed so that its upper flange fits the cylindrical body of the container without any gaps.

The pH sensor capsule simulator is also equipped with a support flange that mates with the upper flange of the container without any gaps.

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One group of samples consists of mixtures with pH values of 4, 5, 6, and 7. During testing, up to 1,000 combinations of the frequency and amplitude of the directed pulse generated by the pulse generator are evaluated.

A second group of samples consists of mixtures with pH values of 2, 3, 4, 5, 6, and 7. During testing, up to 1,000 combinations of the frequency and amplitude of the directed pulse generated by the pulse generator are evaluated.

An additional chemical reagent used for sample preparation was high-purity hydrochloric acid certified by leading chemical laboratories in California.

A precision dropper was used to introduce hydrochloric acid into the sample volume.

After each addition, the resulting pH value was measured using a laboratory-grade instrument, followed by verification with a reference instrument. Before each use, the reference instrument was calibrated using pH 4 and pH 7 buffer solutions.

The primary component used for the preparation of test and measurement samples was simulated gastric juice without pepsins.

A precision dropper was used to introduce the simulated pepsin-free gastric juice into the sample volume.

After each addition, the resulting pH value was measured using a laboratory-grade instrument, followed by verification with a reference instrument. Before each use, the reference instrument was calibrated using pH 4 and pH 7 buffer solutions.

As the prototype measurement device (sensor capsule), a system incorporating a conventional solenoid coil was designed. The solenoid coil was wound on an inner sleeve through whose central axial channel all electrical leads were routed to the external instrumentation.

Several coil configurations with different wire diameters and different numbers of turns were evaluated experimentally.

Based on the overall test and measurement results, the most effective sensor design is a planar coil fabricated as either a single-layer or a multilayer printed circuit board.

For the tested configuration, the printed circuit board has the following dimensions.

Outside diameter – 16 mm. Thickness – 1.5 mm.

The PCB layout incorporates two spiral structures: a single-turn spiral and a concentric planar solenoid consisting of 29 turns.

Two mounting configurations for the PCB sensor were evaluated: installation inside the prototype capsule housing with an intermediate membrane, and installation inside a cylindrical housing without an intermediate membrane.

Testing demonstrated that the PCB installed in a cylindrical housing without an intermediate membrane provided the best measurement performance.

The test and measurement results further showed that the most sensitive and stable configuration is a planar solenoid mounted in a dedicated external recess on the capsule housing and protected by a chemically resistant coating.

Assuming the proposed capsule dimensions of 30 mm in diameter and 80 mm in length, this mounting approach preserves the entire internal cylindrical volume of the capsule housing-22 mm in diameter and 72 mm in length – for the installation of the remaining capsule components while maintaining the simplest possible geometric configuration.

This simplified capsule geometry also makes it possible to apply advanced protective coatings over the entire external surface of the capsule, including an artificial diamond film.

Preparation of Liquid Samples for Testing and Measurement

The following materials were used to prepare the liquid samples for testing and measurement.

Since all primary measurements are intended to be performed in gastric juice or its synthetic equivalents, simulated

gastric juice with an initial pH of 1.0–1.4 was used as the base material. Because both the technical specification and the biological characteristics of gastric juice indicate that the most significant pH variations occur within the range of pH 3–7, this material was used to prepare test samples using two different approaches.

The first approach used distilled water with a pH of 7 as the base liquid, with simulated gastric juice added to produce samples with pH values of 6, 5, 4, 3, and 2.

The second approach used simulated gastric juice as the base liquid, with distilled water added to increase the pH from 1.0–1.4 to 2, 3, 4, 5, 6, and 7.

The same methodology was used to prepare distilled water–based and tap water–based samples. The tap water had a conductivity of 240 μS/cm, and hydrochloric acid with a pH of 1 was added to the mixtures.

The first approach used distilled water with a pH of 7 as the base liquid, with hydrochloric acid added to obtain pH values of 6, 5, 4, 3, and 2.

The second approach used hydrochloric acid as the base liquid, with distilled water added to increase the pH from 1.0–1.4 to 2, 3, 4, 5, 6, and 7.

RESULTS of the Preparation of the Test Equipment and Monitoring Device, and the Influence of the Measurement and Test Results on the Design Principles of the Autonomous Device (Sensor Capsule) and on the Evaluation of the Obtained Measurement Data for Identifying Sample Parameters, Including the pH of Synthetic Gastric Juice.

Selection and experimental evaluation of structural materials.

Selection and experimental evaluation of protective coatings.

Selection and experimental evaluation of the sensor design, including the results of a comparative analysis of alternative sensor configurations.

Selection and experimental evaluation of the test setup.

Preparation of liquid samples for testing.

Procedure for measuring pH before and after testing.

Influence of temperature on pH.

Influence of time on pH stability.

Influence of sample chemical composition on pH.

Influence of organic materials or fruit juices present in the sample on pH.

All matters and objectives specified in the technical requirements and technical specification will be addressed in the subsequent sections of the final report.

Principle of measurement (electromagnetic coupling with object under test)

Schematic of RIST-sensor Figure 1. (depicted with solid line).

1 – source of an alternating electric field with frequency sweep (sweep generator)

2 – excitation coil

3 – sensing coil

4 – data acquisition system

Electromagnetic response of object under test (depicted with dash line).

5 – vertical displacement currents (dielectric polarization)

6 – vertical ionic currents and eddy currents

7 – linear conductance, displacement and ionic currents caused by difference in electrical potential spread along of the sensing coil.

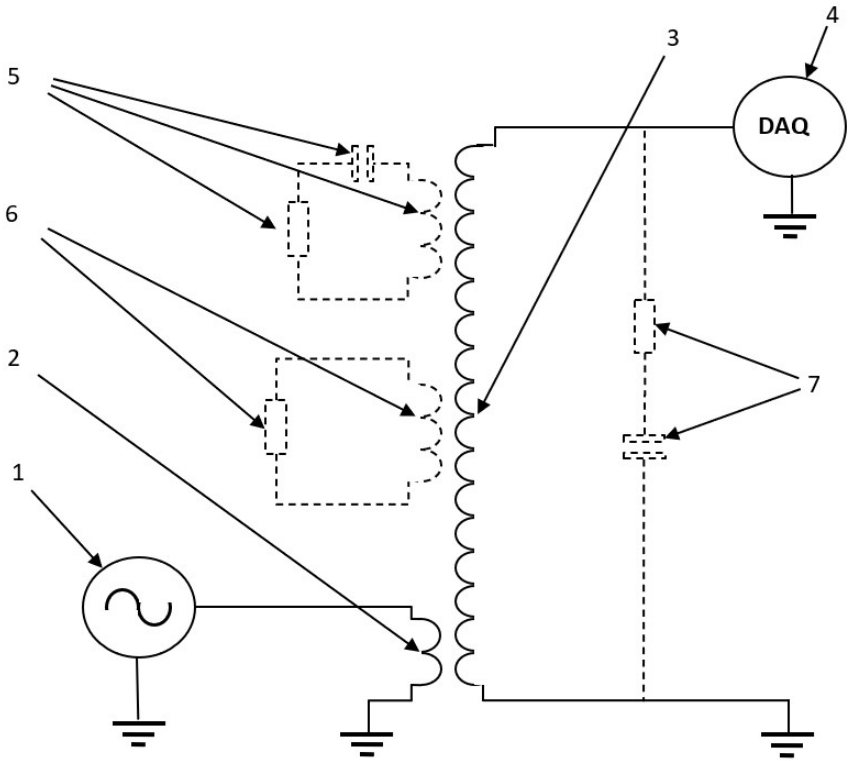

Figure 1. Equivalent circuitry of RIST-sensor illustrates an electromagnetic coupling with analyte

Schematic of RIST-sensor Figure 2. (depicted with solid line).

1 – source of an alternating electric field with frequency sweep (sweep generator)

2 – excitation coil

3 – sensing coil

4 – data acquisition system

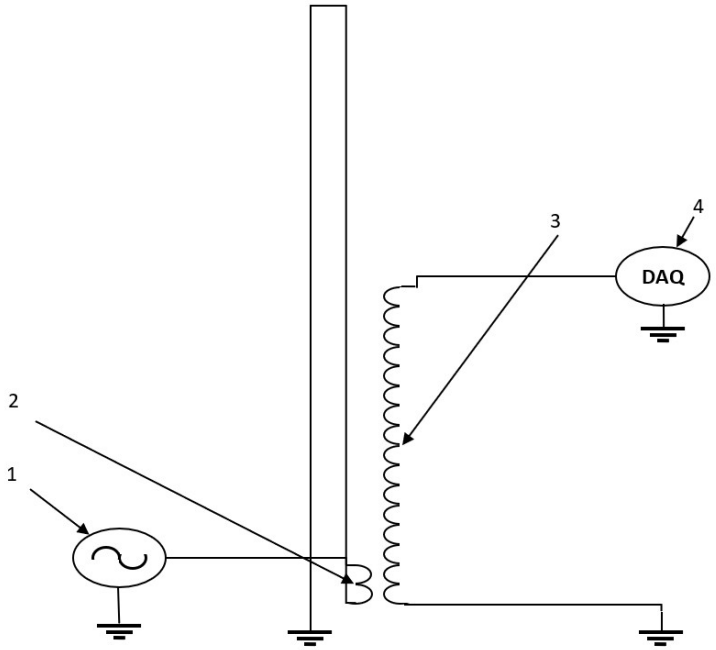

Figure 2.

Evaluation of the sensor response to changes in the temperature of the monitored liquid

Since the patient's body temperature is approximately 36.5 °C, it is important during calibration to determine how the electrical conductivity and resonant response of ordinary drinking water change at this temperature.

The experiments showed that when the temperature of drinking water increased from 24 to 39 °C, its electrical conductivity increased from 0.5 to 0.7 units.

Due to the increased number of active ions in the water, the measurement process became more precise and required less energy.

During the next stage of testing, all water samples with different pH values should be heated to 36.5 °C before measurements are performed.

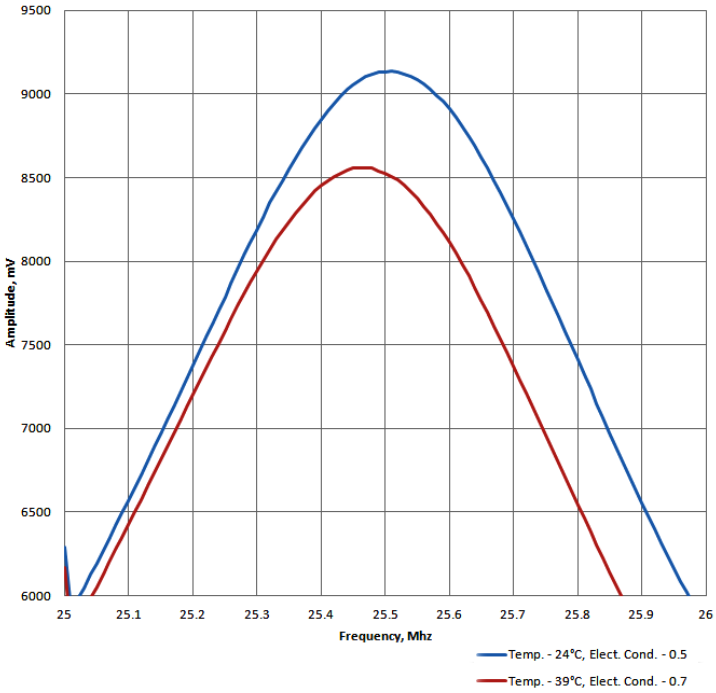

Figure 3. Tap water at different temperatures

Here's the translation in the same style:

The initial pH value should be verified and, if necessary, adjusted after the sample has been heated to 36.5 °C and immediately before the start of the test.

If the pH changes as a result of the temperature increase, the required amount of hydrochloric acid should be added to the sample using a precision dropper. The pH value should then be remeasured, followed by a verification measurement of the sample temperature before testing.

Evaluation of the Effect of Sensor Immersion Depth in the Monitored Liquid

Calibration measurements showed that the best measurement performance is achieved when the sensor cylinder is immersed in the test liquid to the maximum possible depth.

The preliminary results indicate that the wall thickness of the cylinder inserted into the sample container does not have a significant influence on the measurement results.

Evaluation of the Difference Between the Sensor Response in Distilled Water and Drinking Water

The figure shows the results obtained with the sensor fully immersed in the test liquid.

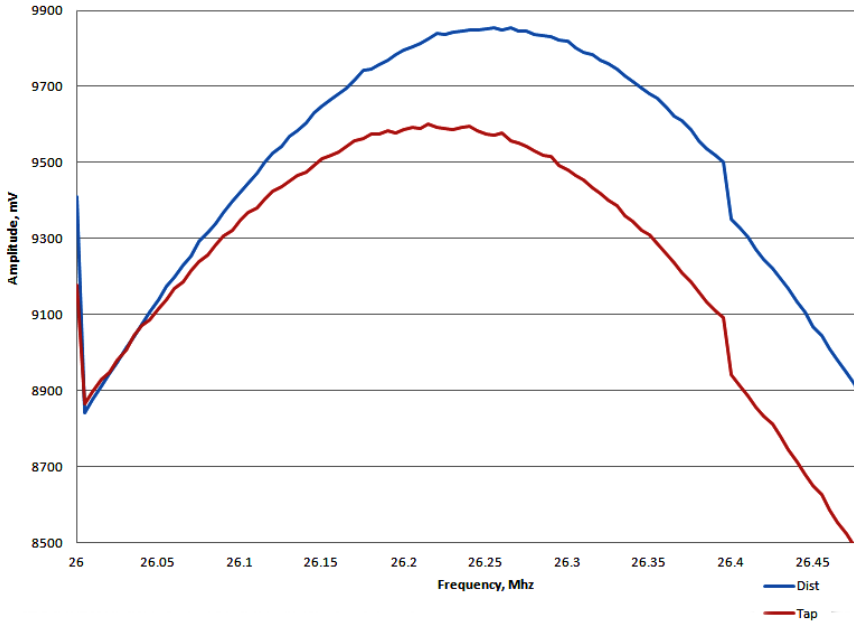

Figure 4. Amplitude-Frequency Response

As shown in the graph, there is a pronounced contrast of approximately 400 mV between the responses measured in distilled water and those measured in drinking water.

The next stage of testing will be performed using the same sensor configuration while varying the pH from neutral (pH 7) to moderately acidic (pH 4).

Evaluation of System Performance at a Low Operating Frequency

For the selected device dimensions and measurement parameters, experiments performed at a reduced operating frequency showed that, in media with a low concentration of active ions (distilled water and drinking water with low electrical conductivity), this frequency does not provide sufficient contrast between the measurement results.

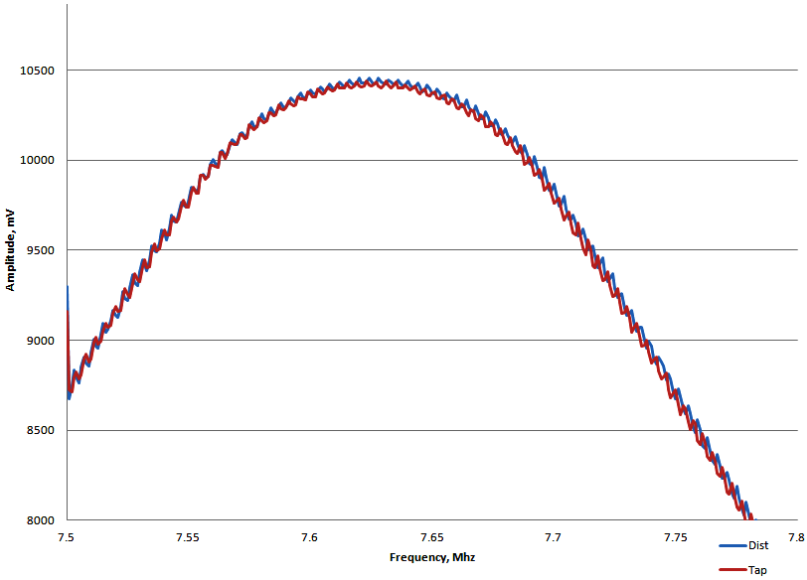

Figure 5. Amplitude-Frequency Response

A similar evaluation is planned using drinking water samples containing dissolved drops of concentrated hydrochloric acid, with pH values below 7.

Analysis of the Effect of Cable Length on System Sensitivity

Following the identification of this issue, a series of measurements and experiments was conducted. The results demonstrated a partial dependence of signal quality on the length of the cables (conductors) connecting the sensor solenoids to the signal analysis unit.

The same parameters will be evaluated using samples with higher electrical conductivity and correspondingly stronger sensor signals.

Procedure and Materials for Adjusting the pH of Liquid Samples

Based on the recommendations of a leading Silicon Valley laboratory, concentrated hydrochloric acid, shown in the following photographs, was selected for adjusting the pH of the test samples.

The pH of the samples will be adjusted by introducing hydrochloric acid into the liquid dropwise.

In addition, to simulate the presence of a defined concentration of nutrients in the samples during this stage of the calibration testing, drops of food-grade vinegar will also be added in parallel with the hydrochloric acid.

Comments on the Calibration Tests

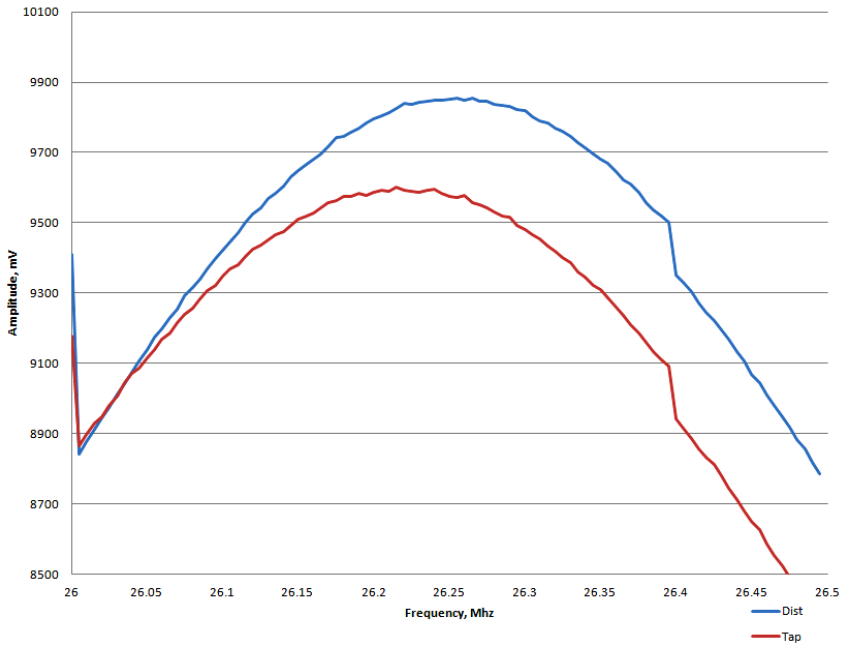

Diagram 1. Amplitude-Frequency Response

The diagram presents the measured frequency and amplitude responses for distilled water and tap water samples at room temperature, using identical and equivalent signal (pulse) parameters.

The objective of this experiment was to verify whether the instrument provides sufficient sensitivity to distinguish between distilled water and tap water.

The evaluation was performed using the test bench while varying the frequency and amplitude of the transmitted signal (pulse).

The results demonstrated the high sensitivity potential of the technology, as it was able to distinguish between the two

types of water despite the minimal difference in their physical characteristics.

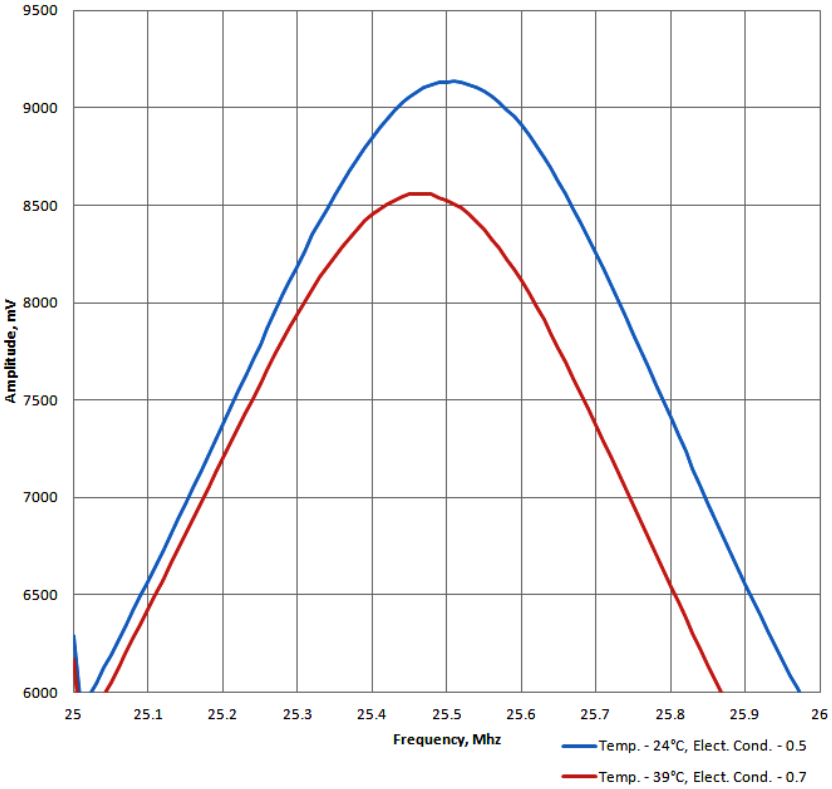

Diagram 2. Tap water at different temperatures

The diagram presents the measured frequency and amplitude responses for tap water samples at room temperature (24 °C) and at 39 °C, using identical and equivalent signal (pulse) parameters.

The objective of this experiment was to verify whether the instrument provides sufficient sensitivity to distinguish between tap water samples at two different temperatures, separated by a 15 °C difference.

The evaluation was performed using the test bench while varying the frequency and amplitude of the transmitted signal (pulse).

The results demonstrated the high sensitivity potential of the technology, as it was able to distinguish between the responses at the two temperatures despite the relatively small change in the properties of the water.

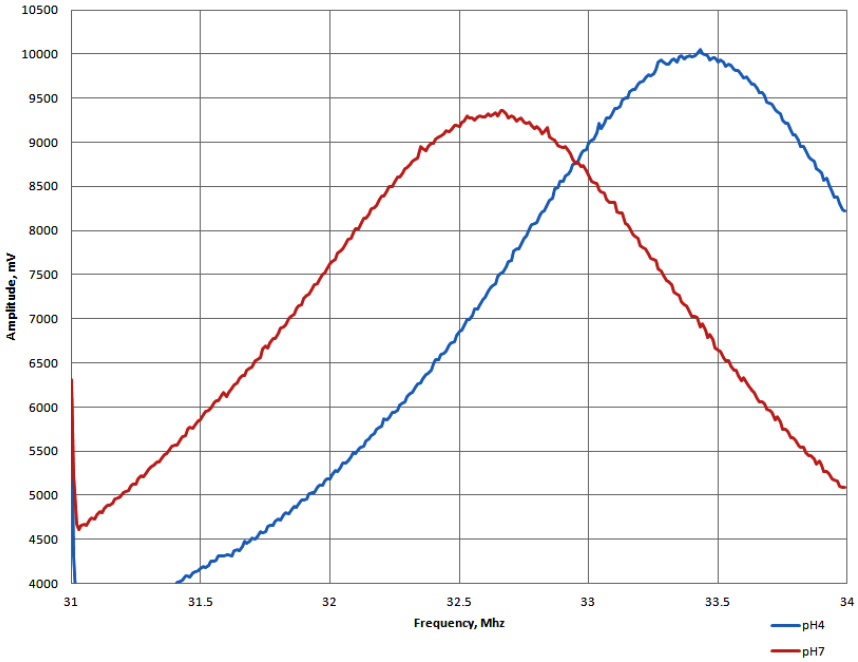

Diagram 3. Amplitude-Frequency Response

The diagram presents the measured frequency and amplitude responses for samples based on distilled water and tap water with pH values of 4 and 7, at room temperature, using identical and equivalent signal (pulse) parameters.

The objective of this experiment was to verify whether the instrument provides sufficient sensitivity to distinguish

between pH levels of 4 and 7 in samples based on distilled water and tap water, where the pH was adjusted by adding hydrochloric acid to the samples.

The evaluation was performed using the test bench while varying the frequency and amplitude of the transmitted signal (pulse).

The results demonstrated the high sensitivity potential of the technology, as it was able to distinguish between samples with pH values of 4 and 7 despite the minimal differences between distilled and tap water and the low salt concentration in the samples, conditions under which detecting differences in acidity is particularly challenging.

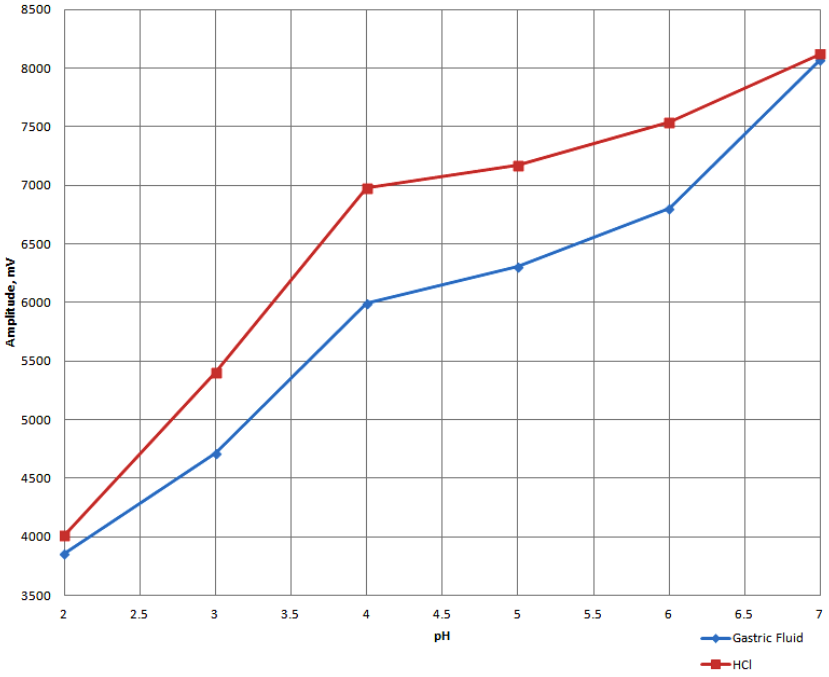

Diagram 4. Amplitude vs pH

The diagram presents the measured frequency and amplitude responses for samples based on simulated gastric juice and hydrochloric acid, with pH values of 2, 3, 4, 5, 6, and 7, at room temperature, using identical and equivalent signal (pulse) parameters.

The objective of this experiment was to verify whether the instrument provides sufficient sensitivity to distinguish between pH values of 2, 3, 4, 5, 6, and 7 in samples based on simulated gastric juice and hydrochloric acid, where the pH was adjusted by adding tap water to the samples.

The evaluation was performed using the test bench while varying the frequency and amplitude of the transmitted signal (pulse).

The results demonstrated the high sensitivity potential of the technology, as it was able to distinguish between samples with pH values of 2, 3, 4, 5, 6, and 7 despite the minimal differences between the two sample types. Detecting differences in acidity under these conditions is particularly challenging because of the relatively low salt concentration in the samples.

The diagram presents the measured frequency responses for samples based on simulated gastric juice and hydrochloric acid, with pH values of 2, 3, 4, 5, 6, and 7, at room temperature, using identical and equivalent signal (pulse) parameters. Measurements were performed at 1-hour intervals.

The objective of this experiment was to verify whether the instrument provides sufficient sensitivity to distinguish between pH values of 2, 3, 4, 5, 6, and 7 in samples based on simulated gastric juice and hydrochloric acid, where the pH was adjusted by adding tap water to the samples.

The evaluation was performed using the test bench while varying the frequency and amplitude of the transmitted signal (pulse).

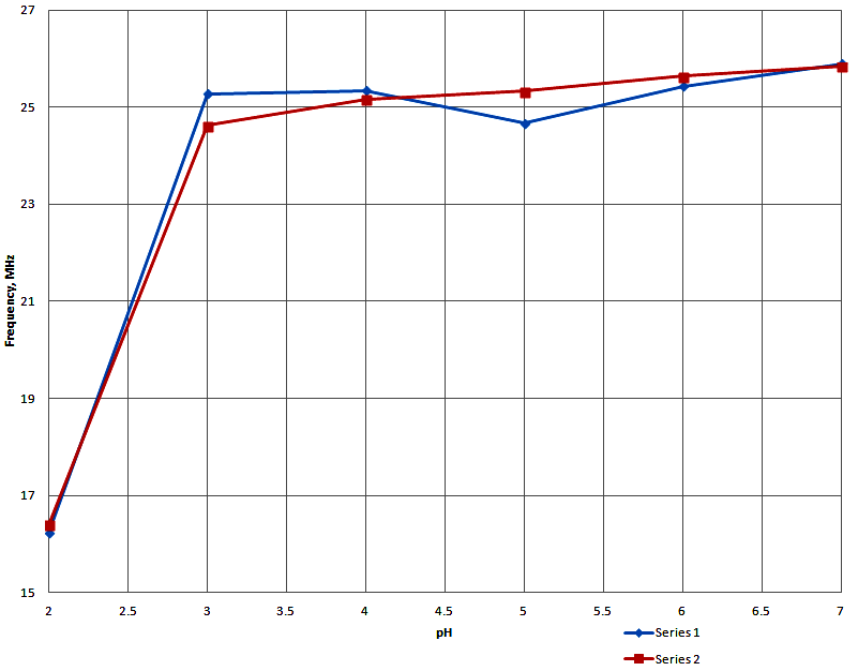

Diagram 5. Frequency vs pH

The results demonstrated the high sensitivity potential of the technology, as it was able to distinguish between samples with pH values of 2, 3, 4, 5, 6, and 7 despite the minimal differences between the two sample types. Detecting differences in acidity under these conditions is particularly challenging because of the relatively low salt concentration in the samples.

The diagram presents the measured frequency responses for samples based on simulated gastric juice and hydrochloric acid, with pH values of 2, 3, 4, 5, 6, and 7, at room temperature, using identical and equivalent signal (pulse) parameters.

The objective of this experiment was to verify whether the instrument provides sufficient sensitivity to distinguish between pH values of 2, 3, 4, 5, 6, and 7 in samples based on

simulated gastric juice and hydrochloric acid, where the pH was adjusted by adding tap water to the samples.

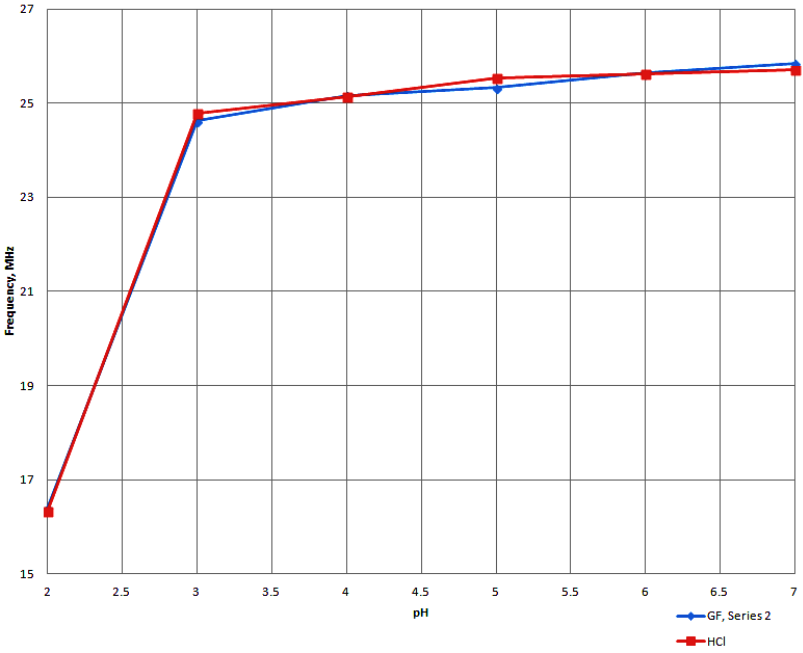

Diagram 6. Frequency vs pH

The evaluation was performed using the test bench while varying the frequency and amplitude of the transmitted signal (pulse).

The results demonstrated the high sensitivity potential of the technology, as it was able to distinguish between samples with pH values of 2, 3, 4, 5, 6, and 7 despite the minimal differences between the two sample types. Detecting differences in acidity under these conditions is particularly challenging because of the relatively low salt concentration in the samples.

The diagram 7 shows the results of frequency measurements for samples based on simulated gastric juice and hydrochloric

acid, with acidity levels of 2, 3, 4, 5, 6, and 7 units, at room temperature and with similar and equivalent signal (pulse) parameters.

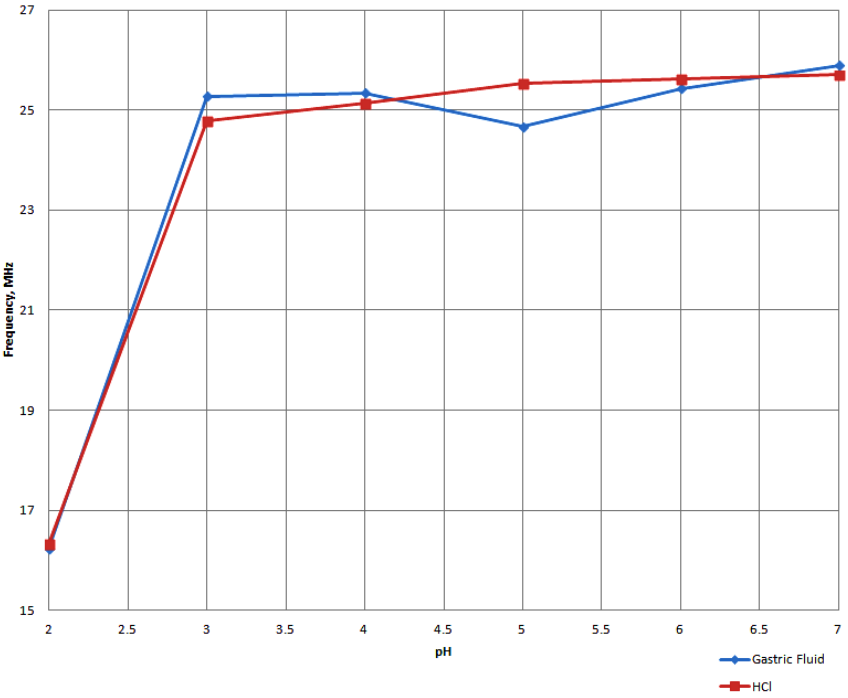

Diagram 7. Frequency vs pH

The purpose of this experiment is to verify that the sensitivity of the device is sufficient to distinguish between acid levels of 2, 3, 4, 5, 6, and 7 units in samples based on simulated gastric juice and hydrochloric acid, while adjusting the acid level by introducing tap water into the sample The test was carried out on a test bench when changing the frequency and amplitude of the directional signal (pulse). The test showed a high potential for the sensitivity of the technology, due to the fact that the difference in the characteristics of

the two types of samples is minimal, and the acid level of 2, 3, 4, 5, 6, and 7 units in combination with a low level of salt concentration in the samples is quite difficult to catch.

The diagram presents the measured amplitude responses for samples based on simulated gastric juice and hydrochloric acid, with pH values of 2, 3, 4, 5, 6, 7, and 8, at room temperature, using identical and equivalent signal (pulse) parameters.

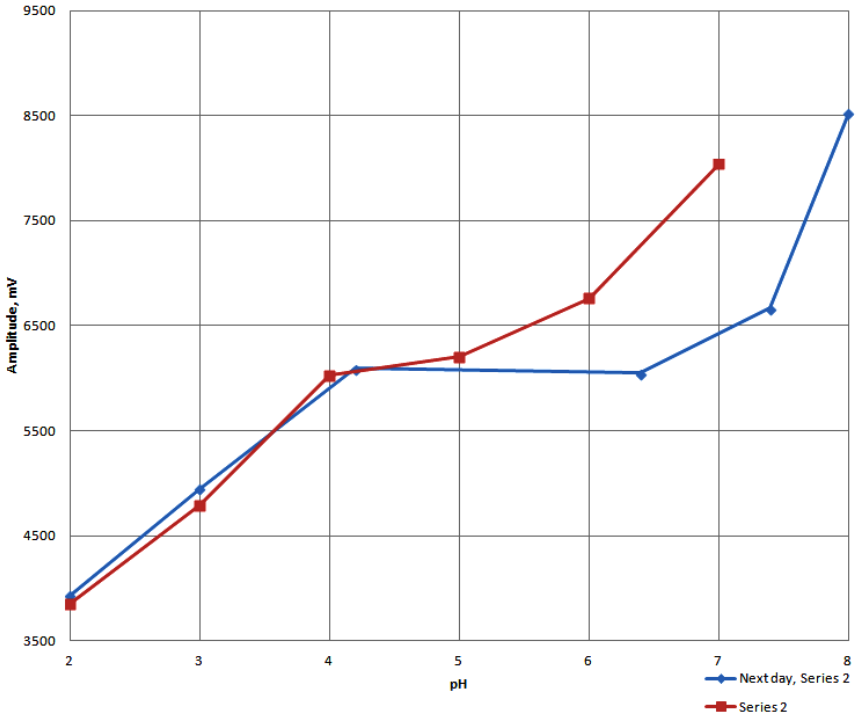

Diagram 8. Amplitude vs pH

The objective of this experiment was to verify whether the instrument provides sufficient sensitivity to distinguish between pH values of 2, 3, 4, 5, 6, 7, and 8 in samples based on simulated gastric juice and hydrochloric acid, where the pH

was adjusted by adding tap water to the samples. Measurements were performed at 24-hour intervals.

The evaluation was performed using the test bench while varying the frequency and amplitude of the transmitted signal (pulse).

The results demonstrated the high sensitivity potential of the technology, as it was able to distinguish between samples with pH values of 2, 3, 4, 5, 6, 7, and 8 despite the minimal differences between the two sample types. Detecting differences in acidity under these conditions is particularly challenging because of the relatively low salt concentration in the samples.

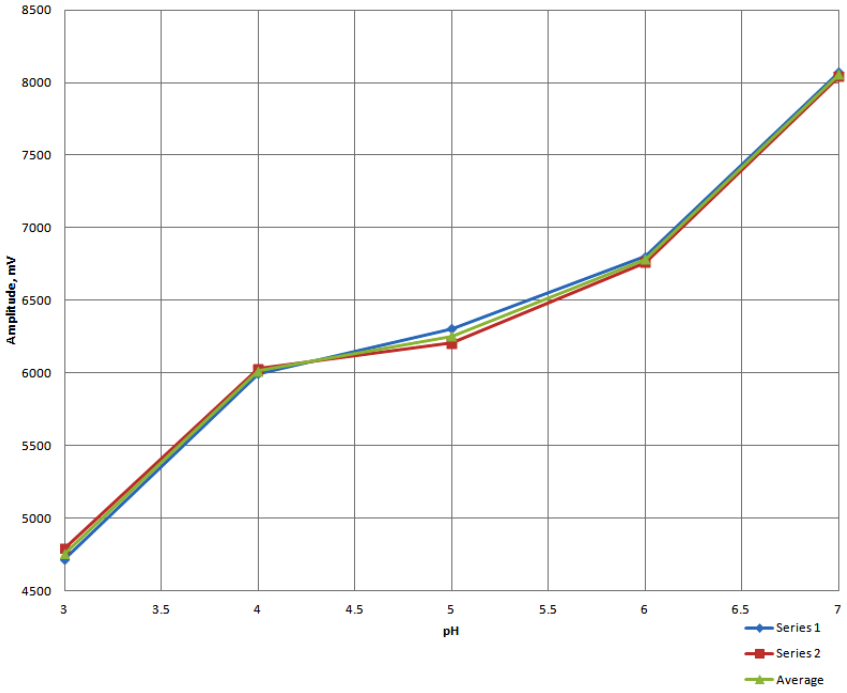

Diagram 9. Amplitude vs pH

Diagram 9 presents the measured amplitude responses for samples based on simulated gastric juice and hydrochloric acid, with pH values of 2, 3, 4, 5, 6, 7, and 8, at room temperature, using identical and equivalent signal (pulse) parameters.

The objective of this experiment was to verify whether the instrument provides sufficient sensitivity to distinguish between pH values of 2, 3, 4, 5, 6, 7, and 8 in samples based on simulated gastric juice and hydrochloric acid, where the pH was adjusted by adding tap water to the samples. Measurements were performed at 1-hour intervals, and the average amplitude value was determined.

The evaluation was performed using the test bench while varying the frequency and amplitude of the transmitted signal (pulse).

The results demonstrated the high sensitivity potential of the technology, as it was able to distinguish between samples with pH values of 2, 3, 4, 5, 6, 7, and 8 despite the minimal differences between the two sample types. Detecting differences in acidity under these conditions is particularly challenging because of the relatively low salt concentration in the samples.

Furthermore, the two measurement series performed at 1-hour intervals exhibited only minimal variation in both amplitude and frequency, demonstrating good repeatability of the measurement results.

Diagram 10 presents the measurement results for various samples with a pH value of 6 (corresponding to the technical specification and the table of 22 samples). The samples were prepared by mixing distilled water with simulated gastric juice and adding either 10% fruit juice, table salt at concentrations of 1 g/100 mL and 2 g/100 mL, or baking soda at concentrations of 1 g/100 mL and 2 g/100 mL.

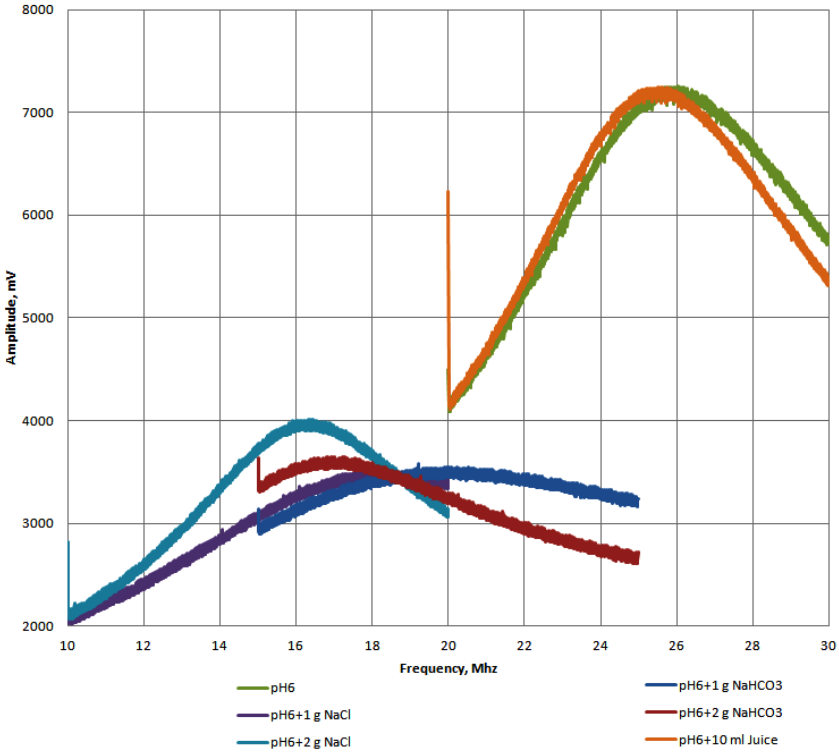

Diagram 10. Amplitude-Frequency Response

The addition of fruit juice produced virtually no change in the amplitude response at a frequency of 25.5 MHz compared with the reference sample having a pH value of 6.

Similarly, the addition of baking soda and table salt produced comparable measurement results at a frequency of 16 MHz, closely matching the response of the standard sample with a pH value of 6 measured under the same conditions.

Diagram 11 compares the measurement results obtained for a simulated gastric juice sample with a pH value of 6 and the same sample after the addition of 10% fruit juice with pulp (10 mL per 100 mL), using a signal frequency of 25.5 MHz.

As shown in the figure, the measurement results are virtually identical.

The addition of fruit juice with pulp at a frequency of 25.5 MHz produces virtually no change in the amplitude response compared with the reference sample of simulated gastric juice with a pH value of 6.

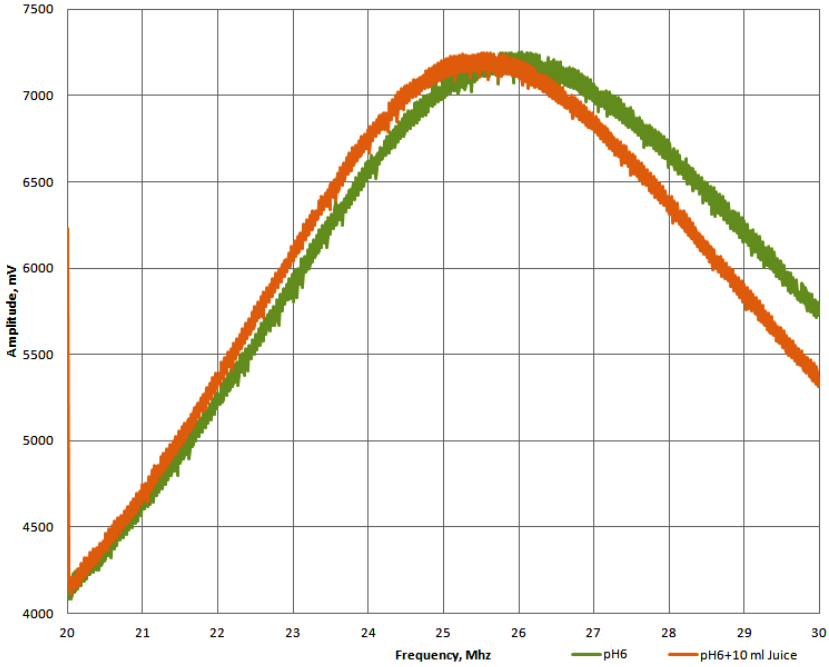

Diagram 11. Amplitude-Frequency Response

Diagram 12 presents the measured amplitude responses obtained during testing of simulated gastric juice samples with pH values of 1, 2, 3, 4, 5, 6, 7, and 8 at temperatures of 10 °C, 23 °C, and 40 °C (in accordance with the technical specification and the table of 22 test sample variants).

During the measurements, changes in the pH values of the samples at different temperatures were also monitored.

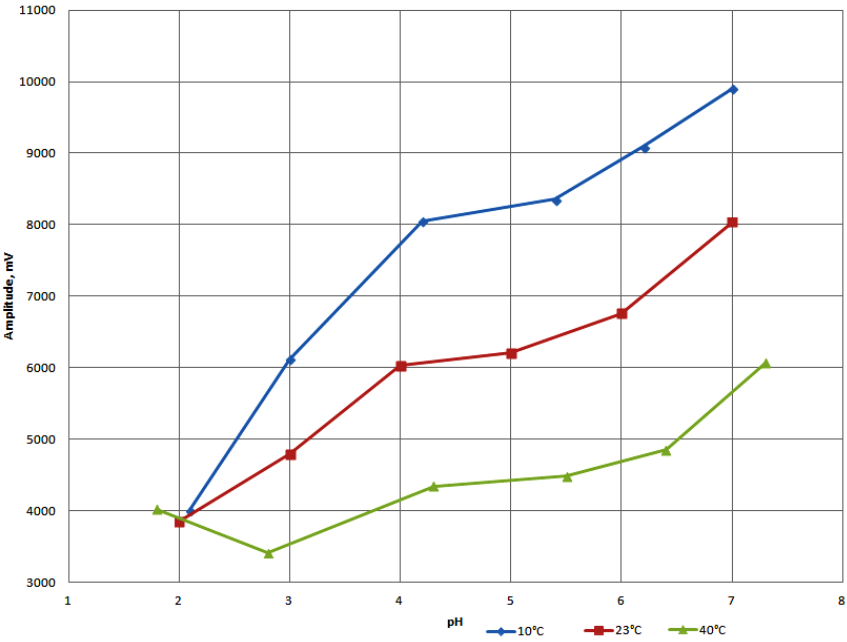

Diagram 12. Amplitude vs pH

At 23 °C, the measured pH values of the samples were 2, 3, 4, 5, 6, and 7.

At 10 °C, the corresponding pH values changed to 2.1, 4.2, 5.45, and 6.25.

At 40 °C, the corresponding pH values changed to 1.8, 2.8, 4.35, 5.5, 6.47, and 7.3.

The comparative measurement results demonstrate that it is possible to establish precise tolerance limits and reference amplitude values for measurements performed on samples over the temperature range from 10 °C to 40 °C.

Diagram 13 presents the measured frequency responses obtained during testing of simulated gastric juice samples with pH values of 1, 2, 3, 4, 5, 6, 7, and 8 at temperatures of 10 °C,

23 °C, and 40 °C (in accordance with the technical specification and the table of 22 test sample variants).

During the measurements, changes in the pH values of the samples at different temperatures were also monitored.

At 23 °C, the measured pH values of the samples were 2, 3, 4, 5, 6, and 7.

At 10 °C, the corresponding pH values changed to 2.1, 4.2, 5.45, and 6.25.

At 40 °C, the corresponding pH values changed to 1.8, 2.8, 4.35, 5.5, 6.47, and 7.3.

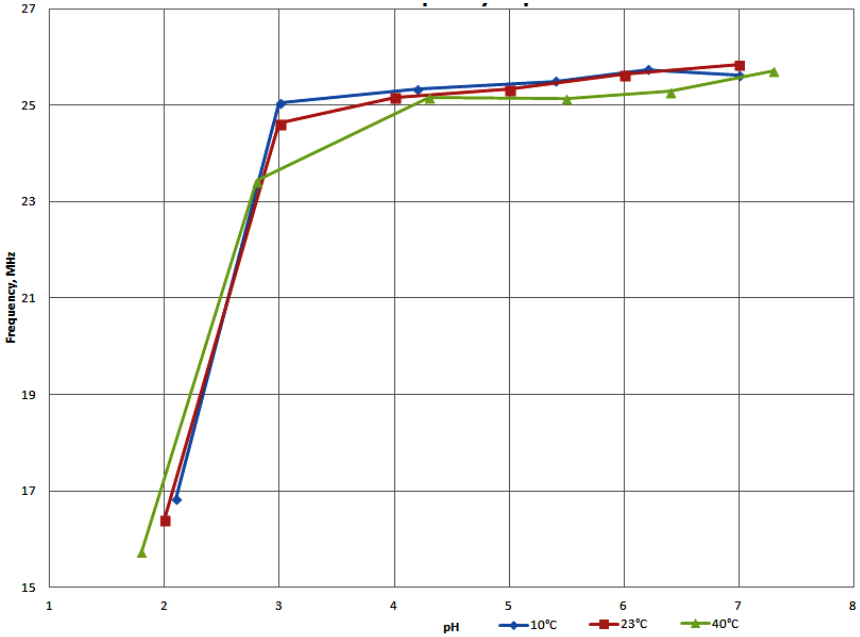

Diagram 13. Frequency vs pH

The comparative measurement results demonstrate that it is possible to establish precise tolerance limits and reference frequency values for measurements performed on samples over the temperature range from 10 °C to 40 °C.

The diagram presents the measured frequency and amplitude responses for samples based on simulated gastric juice and hydrochloric acid with pH values of 5 and 7, at room temperature, using identical and equivalent signal (pulse) parameters. Each sample was measured three times at 1-hour intervals.

The objective of this experiment was to verify whether the instrument provides sufficient sensitivity to distinguish between pH values of 5 and 7 in samples based on simulated gastric juice and hydrochloric acid, where the pH was adjusted by adding tap water to the samples. Three consecutive measurements were performed for each sample, with a 1-hour interval between corresponding measurements.

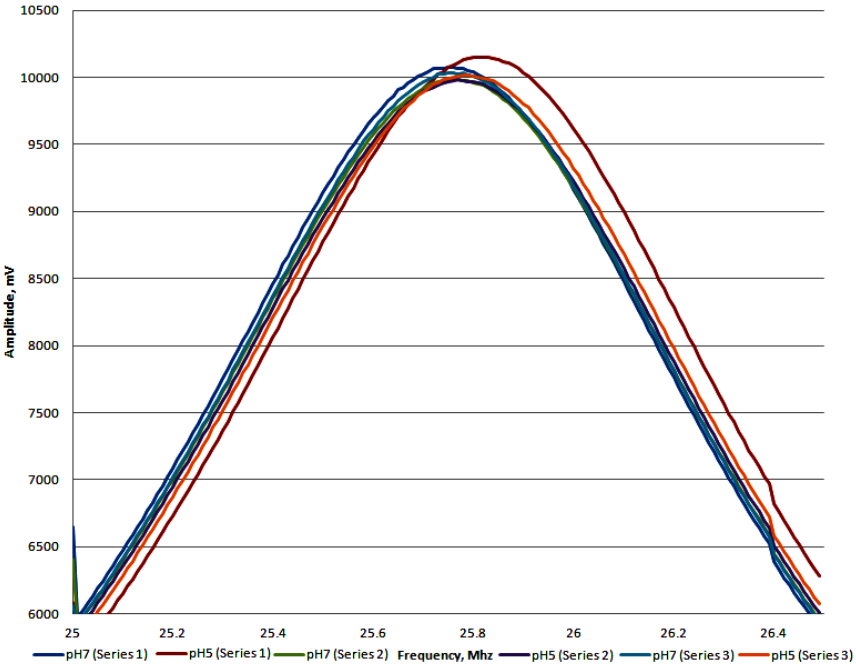

Diagram 14. Amplitude-Frequency Response

The evaluation was performed using the test bench while varying the frequency and amplitude of the transmitted signal (pulse).

The results demonstrated the high sensitivity potential of the technology, as it was able to distinguish between samples with pH values of 5 and 7 despite the minimal variation between repeated measurements taken at 1-hour intervals. Detecting differences in acidity under these conditions is particularly challenging because of the relatively low salt concentration in the samples.

Additional Comments on the Report

Question: Positive Factors and Results Obtained During the Two Calibration Test Cycles

– Both completed test phases demonstrated the high capability of the technology to measure amplitude and frequency parameters in liquid samples for identifying the actual pH level within the range from pH 3 to pH 7.

At an average signal frequency of 25.324 MHz, the differences between the amplitude readings were as follows:

pH 3 to pH 4:
6,050–4,750 = 1,300 mV
pH 4 to pH 5:
6,200–6,050 = 150 mV
pH 5 to pH 6:
6,730–6,200 = 530 mV
pH 6 to pH 7:
8,080–6,730 = 1,350 mV

Therefore, for a measurement accuracy of 0.1 pH units within the pH range from 3.0 to 3.9, the difference between the readings is 130 mV.

Therefore, for a measurement accuracy of 0.1 pH units within the pH range from 4.0 to 4.9, the difference between the readings is 15 mV.

Therefore, for a measurement accuracy of 0.1 pH units within the pH range from 5.0 to 5.9, the difference between the readings is 53 mV.

Therefore, for a measurement accuracy of 0.1 pH units within the pH range from 6.0 to 6.9, the difference between the readings is 135 mV.

Example: an amplitude value of 4,880 mV means that this value corresponds to 4,750 + 130 = pH 3.1 at a signal frequency of 25.324 MHz.

Since the system is capable of detecting an amplitude difference of 2 mV, the specified accuracy and sensitivity fully ensure the required level of performance.

- The system determines the amplitude value with equal accuracy for different compositions of the tested sample, for example, samples based on simulated gastric juice and samples based on hydrochloric acid.
- The system determines the amplitude value with equal accuracy at different temperatures of the tested sample. Tests were performed at 10 °C, 25 °C, and 40 °C.
- The system does not require a significant amount of energy for testing and measurements, with energy consumption remaining within 20 mW per test or measurement.
- The system can operate effectively with a planar sensor coil. Such a coil is a printed circuit board with a specified topology and a specified number of layers.
- Adjusting or changing the number of printed circuit board layers makes it possible to vary the signal penetration

depth into the monitored liquid. The minimum penetration depth is 1.5–2 mm with one active layer in the printed circuit board, while the maximum penetration depth is 50–60 mm with four active layers.

- The tests established that the printed circuit board can be used without a protective membrane, allowing the separating layer to be minimized. The thickness of the protective coating on the printed circuit board is approximately 50 μm. This makes it possible to eliminate measurement interference when the end of the capsule comes into contact with the patient's skin.
- The tests established that the printed circuit board can be used without a protective membrane, allowing the separating layer to be minimized. The thickness of the protective coating on the printed circuit board is 25–30 μm. This makes it possible to eliminate measurement interference when the end of the capsule comes into contact with solid particles on the surface of the patient's skin, for example, wheat flour (samples 18, 19, and 20 in the table of parameters for the 22 samples).
- The tests established that using a planar sensor coil in the future capsule will significantly increase the internal volume available for accommodating the capsule components.
- The tests established that the system can measure differences in the pH levels of samples based on both simulated gastric juice and hydrochloric acid with high accuracy one hour after the first measurement and 24 hours after the first measurement. This confirms and demonstrates the high sensitivity of the measurement method.

- The tests established that the optimal measurement signal frequency for gastric juice within the pH range from 3 to 7 is between 25 MHz and 25.5 MHz.
- The tests established that the specified overall dimensions of the capsule are optimal: a diameter of 30 mm and a length of 100 mm.
- The measurements established that comparative pH measurements in stable liquids, such as distilled water and tap water, demonstrated complete repeatability of the results obtained from the same samples at measurement intervals of 1 hour, 1 day, 1 week, 2 weeks, and 3 weeks.

Comments on the Report: PROPOSALS FOR PROJECT CONTINUATION

Following the successful completion of the measurement program, it is proposed that the project continue with two additional testing phases, each lasting 50 hours, to determine the repeatability of autonomous measurements of pH and blood glucose levels.

During the previous two 50-hour testing phases, the practical feasibility of measuring the characteristics of simulated gastric juice samples using electromagnetic spectroscopy and a signal-generation method based on a planar sensor coil was successfully demonstrated.

In preparation for the previous testing phases, an intermediate capsule design was developed and evaluated, incorporating a planar sensor coil mounted on the outer end face of the cylindrical capsule housing.

This design provided additional advantages for the measurement process, which warrant further investigation in several areas.

The following design parameters and measurement conditions were not evaluated during the first two testing phases:

- Simulated gastric juice does not contain pepsins; therefore, the influence of pepsins on the acidity of gastric juice has not been evaluated.
- Natural gastric juice contains bacteria that contribute to the digestive process and influence gastric acidity. The effect of these bacteria on the measurement results has not yet been evaluated. Likewise, various bacteria may be present on the patient's skin, requiring verification of their influence on measurement accuracy and sensitivity.
- During the preparation of test samples for the previous testing phases, the acidity of the simulated gastric juice was adjusted by mixing it with distilled or tap water. The chemical mixing process continued throughout the testing period, resulting in an increase or decrease of approximately 0.5 pH units one hour after the initial measurement.

Under these conditions, meaningful repeatability testing of the measurement system is practically impossible.

To evaluate the repeatability of the results obtained during the first two testing phases, the samples should be allowed to stabilize for a longer period after mixing, for example, 4–5 hours, in order to reduce the activity of the ongoing chemical reactions, followed by recalibration immediately before the measurements.

The first additional testing phase will include simulated gastric juice samples prepared by adding distilled water to produce pH values of 3, 4, 5, 6, and 7.

After completion of these measurements, an identical set of simulated gastric juice samples should be prepared using tap water instead of distilled water to produce pH values of 3, 4, 5, 6, and 7.

A total of ten samples will therefore be evaluated, with each sample measured five times at intervals of five hours.

The sample temperature shall be maintained between 36 °C and 39 °C.

The objective of this testing phase is to demonstrate measurement repeatability with minimal deviations.

The duration of this phase will be 50 hours.

The following testing phase will evaluate the same groups of samples after the addition of pepsins immediately before the measurements.

This phase will include simulated gastric juice samples (with subsequent replacement by physiological saline) prepared using distilled water to produce pH values of 3, 4, 5, 6, and 7.

Following completion of these measurements, an identical series of simulated gastric juice samples (with subsequent replacement by physiological saline) shall be prepared using tap water to produce pH values of 3, 4, 5, 6, and 7.

If the second additional 50-hour testing phase is approved, the composition of the pepsin preparation and the procedure for mixing it with the test samples will be agreed with a specialized laboratory in Santa Clara, California.

This testing phase shall also include evaluation of measurement repeatability.

The sample temperature shall be maintained between 36 °C and 39 °C.

References, Patent, and Licensing Information

1. Altshuller, G. S. *The Theory of Inventive Problem Solving (TRIZ): Theory and Methodology for the Development of Technical Systems.*
2. U.S. Patent No. 5,871,814. *Pneumatic Grip.* Issued February 16, 1999.
3. U.S. Patent No. 6,139,714. *Method and Apparatus for Adjusting the pH of a Liquid.* Issued October 31, 2000.
4. U.S. Patent No. 9,310,076. *Emulsion, Apparatus, System and Method for Dynamic Preparation.* Issued April 12, 2016.