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ADVANCING MEDICAL DIAGNOSTICS: A PORTABLE ULTRASONIC-IMPEDANCE TOMOGRAPH FOR NON-INVASIVE LOWER URINARY TRACT MONITORING

ZAAWANSOWANA DIAGNOSTYKA MEDYCZNA: PRZENOŚNY TOMOGRAF ULTRADŹWIĘKOWY DO NIEINWAZYJNEGO MONITOROWANIA DOLNYCH DRÓG MOCZOWYCH

Abstract

Technological advancements in medical imaging techniques are opening new possibilities for diagnostics and monitoring health conditions. This study aimed to develop and evaluate a portable ultrasound-impedance tomograph designed for long-term monitoring of the lower urinary tract. This device combines ultrasound and impedance technologies, enhancing imaging accuracy and the non-invasiveness of procedures, which is particularly crucial for patients requiring regular examinations. The study used a prototype tomograph on patients with lower urinary tract disorders. To assess the device's effectiveness, images obtained from traditional diagnostic methods were compared with those generated by the new tomograph. This device utilizes advanced ultrasound beamforming technology and multiplexing of measurement channels, allowing for rapid and accurate diagnostics without requiring invasive sensor placement within the patient's body. The findings indicate that the newly developed tomography provides high-resolution and high-contrast images, facilitating better pathology identification than traditional methods. It was also demonstrated that the device effectively monitors changes over time, crucial for planning long-term treatment and monitoring patients. The development of this device opens new possibilities in diagnosing and monitoring medical conditions, enabling more precise and less burdensome diagnostic procedures. Its application could significantly improve the quality of life for patients and the efficacy of therapies in urology and other medical fields.

Streszczenie

Postęp technologiczny w medycznych technikach obrazowania otwiera nowe możliwości dla diagnostyki, a także monitorowania stanów zdrowotnych. Celem niniejszego badania było opracowanie i ocena przenośnego tomografu ultradźwiękowo-impedancyjnego, służącego do długoterminowego monitorowania dolnych dróg moczowych. Urządzenie to łączy technologie ultradźwiękową oraz impedancyjną, co pozwala na zwiększenie dokładności obrazowania oraz nieinwazyjność procedur, co jest szczególnie istotne w przypadku pacjentów wymagających regularnych badań. Badanie przeprowadzono poprzez zastosowanie prototypowego tomografu na grupie pacjentów z różnymi zaburzeniami dolnych dróg moczowych. Do oceny skuteczności urządzenia wykorzystano porównanie obrazów uzyskanych z tradycyjnych metod diagnostycznych z obrazami generowanymi przez nowy tomograf. Urządzenie to wykorzystuje zaawansowaną technologię formowania wiązki ultradźwiękowej oraz multipleksowanie kanałów pomiarowych, co pozwala na szybką oraz dokładną diagnostykę bez konieczności inwazyjnego umieszczania czujników w ciele pacjenta. Wyniki badań wskazują, że nowo opracowany tomograf zapewnia obrazy o wysokiej rozdzielczości i kontraście, umożliwiające lepszą identyfikację patologii w porównaniu do tradycyjnych metod. Wykazano również, że urządzenie jest skuteczne w monitorowaniu zmian w czasie, co jest kluczowe w planowaniu długoterminowego leczenia, a także monitorowania pacjentów. Opracowanie urządzenie otwiera nowe możliwości w diagnozowaniu oraz monitorowaniu stanów medycznych, umożliwiając wykonanie dokładniejszych i mniej obciążających procedur diagnostycznych. Jego zastosowanie może znacząco poprawić jakość życia pacjentów oraz efektywność terapii w urologii i innych dziedzinach medycyny.

Keywords: *ultrasound tomography, impedance tomography, beamforming, medical image reconstruction, signal processing, sensor integration*

Słowa kluczowe: *tomografia ultradźwiękowa, tomografia impedancyjna, formowanie wiązki, rekonstrukcja obrazu medycznego, przetwarzanie sygnałów, integracja czujników*

Introduction

Over the past few decades, medical imaging technologies have dramatically improved diagnosing and monitoring health conditions. While traditional methods such as magnetic resonance imaging (MRI) and computed tomography (CT) remain integral, emerging technologies like ultrasound and impedance imaging are gaining traction due to their non-invasive nature, cost-effectiveness, and safety. These technologies are up-and-coming for conditions affecting the lower urinary tract, which impact a significant portion of the population and considerably influence the quality of life.

Conventional diagnostic methods, often invasive and requiring contrast agents, pose risks and discomfort to patients. In contrast, ultrasound and impedance tomography provide a safer alternative, allowing for the detailed observation of physiological changes without direct physical intervention. Integrating these technologies in a portable ultrasonic impedance tomograph presents a novel solution that enhances diagnostic accuracy and minimizes patient discomfort. This innovative approach improves the frequency and precision of monitoring, which is crucial for managing chronic urinary tract conditions. By enabling continuous, non-invasive monitoring, the portable tomograph allows for real-time adjustments in treatment, potentially leading to better outcomes and an improved patient experience. Furthermore, the capability to conduct examinations at home reduces the need for frequent medical visits, paving the way for personalized medicine.

The ongoing research aims to provide not only technological insights but also empirical evidence of the clinical and economic benefits of this new device. The hypothesis is that combining ultrasound with impedance tomography in a single portable device will significantly enhance diagnostic precision for the lower urinary tract while reducing patient risk and discomfort associated with more invasive techniques. This technological synergy is expected to revolutionize the monitoring and treatment of urinary tract diseases, offering a more effective, patient-friendly approach to chronic condition management.

Research Methodology

The portable ultrasonic impedance tomograph is a sophisticated medical device designed for dual diagnosis of the urinary tract, integrating ultrasound (UST) and impedance (EIT) technologies. The device is composed of several PCB boards that are crucial for its operation: the mainboard, four ultrasound measurement cards (UST), one impedance measurement card (EIT), a WiFi communication module, a connectors module, and an LED board for operation status indication and battery pack. This configuration allows for a comprehensive approach to diagnosing lower urinary tract conditions.

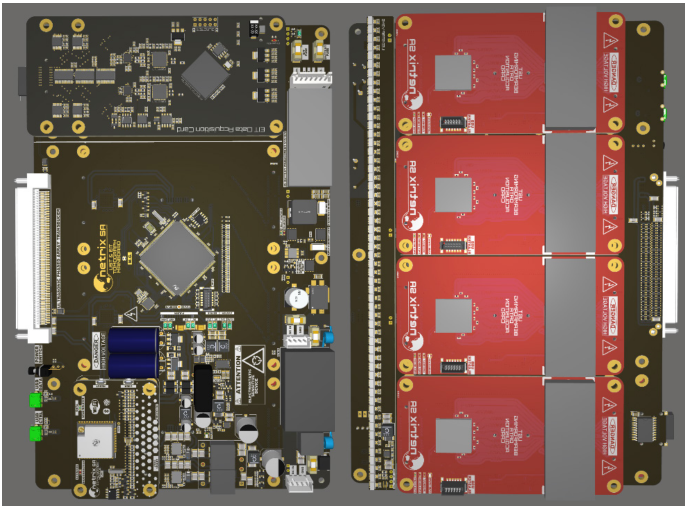
Figure 1. *3D model of UST & EIT tomograph construction*

Figure 2. *Visualization of a portable ultrasound-impedance tomograph with a sensor on the body*

The critical components of this device are designed to ensure reliability, accuracy, and safety in medical diagnostics. These include:

1. UST and EIT modules: These modules are equipped with FPGA (Field-Programmable Gate Array) chips that control the data acquisition control. The UST module uses an eight-channel MAX2082 chip that allows synchronization up to 1 ns for exposure control. The EIT module uses 16 textile electrodes for impedance testing using an LTC2203 ADC (25 MSPS) for data processing.

Figure 3. *Mainboard of a portable ultrasonic-impedance tomograph for bladder monitoring (left – top side, right – bottom side)*



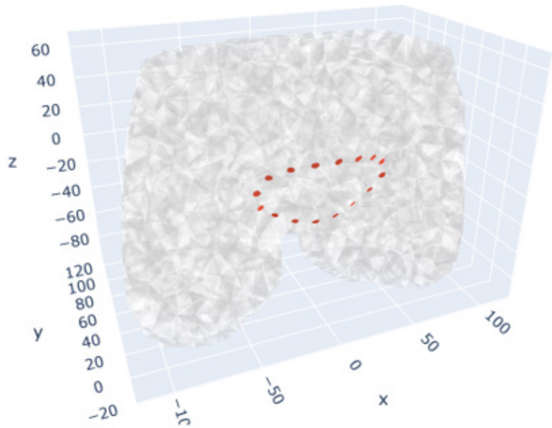
2. Software: provides access to manage scanning and processing parameters and provides functions such as amplitude adjustment and sampling rate. Processing algorithms used, such as Gauss-Newton damped filtering for EIT image reconstruction, a standard diagnostic function.
3. Power and Safety System: The device is powered by a pack of four 18650 batteries, managed by an advanced power controller with BMS (Battery Management System), surge protection, and primary power supply. Additional safety measures, such as material-resistant housing, protect the device from mechanical impacts and external events.

With these sophisticated elements, the portable ultrasonic-impedance tomograph is a highly efficient diagnostic tool, surpassing expectations in accuracy and safety within the medical diagnostic field.

Experimental Settings and Data Collection

The experimental project to validate the portable ultrasonic-impedance tomograph is meticulously planned to ensure thorough testing under controlled conditions. The device prototype integrates advanced modules such as UST (Ultrasound Tomography) and EIT (Electrical Impedance Tomography), which are crucial for precise and non-invasive diagnoses of the lower urinary tract (Kiczek, B. et al. 2022). The design incorporates FPGA-based control systems for precise data acquisition, which is essential for obtaining high-resolution images required in medical diagnostics. The experimental settings are carefully devised to simulate clinical conditions. The UST module, equipped with an eight-channel MAX2082 system, ensures signal precision at the nanosecond level, which is crucial for high-quality ultrasound images. Simultaneously, the EIT module utilizes 16 textile electrodes with an LTC2203 ADC system for accurate impedance measurement, enhancing diagnostic capabilities through detailed tissue characterization (Li R. et al. 2016). Data collection is automated through specially designed software, allowing adjustment of scanning parameters such as signal amplitude and frequency. In the design of the portable ultrasonic-impedance tomograph, a significant focus is placed on developing reconstruction methods to convert raw measurement data into detailed and interpretable diagnostic images (Hannan, S., et al. 2020). This process is vital for facilitating accurate and non-invasive diagnoses, particularly in the complex anatomical region of the lower urinary tract. The following explains the technological model and methodologies employed to achieve this (Bayford, R. 2006).

Figure 4. *Technology model*



The pelvic technological model consists of a finite element mesh for analyzing the pelvis's various structural, mechanical, and thermal properties. As part of the skeletal system, the pelvis presents a complex arrangement of tissues and bones that require precise imaging techniques to diagnose various conditions effectively (He, H., et al. 2021). Critical Elements of the Pelvic Mesh:

1. **Nodes:** These represent points in space where the mesh nodes are located, with each node assigned specific spatial coordinates (x, y, z).
2. **Elements:** These are the connections between nodes representing different structural areas of the pelvis. Depending on the numerical method used, these nodes can be triangular, quadrilateral, or other shapes.
3. **Material:** Each element is made from a specified material, and its mechanical properties (such as Young's modulus, Poisson ratios, etc.) are assigned based on the actual properties of the pelvic tissue.
4. **Boundary Conditions:** These define conditions at nodes or elements that reflect the actual boundary conditions of the pelvis, such as anchoring to the femur or spine.
5. **Numerical Algorithm:** The numerical method used to solve the mesh equations, such as the Finite Element Method (FEM) or another equally effective numerical method, is established.

After defining these elements, a numerical pelvis analysis can be conducted using Electrical Impedance Tomography (EIT). This imaging technique measures the electrical impedance of internal body tissue using electrodes placed on the surface. This software also handles complex data processing tasks, including signal filtering and image reconstruction using algorithms such as the Gauss-Newton damped method, ensuring effective integration of ultrasound and impedance data for a comprehensive diagnostic outcome (Wan, Y., et al. 2010. pp. S17–S29). Device validation encompasses various standard tests to assess the tomograph's functionality and accuracy:

1. **Resolution Test:** This test assesses the image resolution and clarity offered by the UST and EIT modules through scans of known phantoms mimicking human tissue.
2. **Reproducibility Test:** Conducts multiple runs of identical test conditions to guarantee measurement consistency and reliability.
3. **Safety and Compliance Test:** This test verifies compliance with relevant health and safety standards, focusing on electromagnetic compatibility and operational safety across different electrical loads.

To further solidify the tomograph's clinical applicability and ensure its robustness in real-world medical settings, additional evaluations have been integrated into the testing protocol:

1. **User Interface Testing:** This testing phase focuses on the user interface of both the hardware and software components. The aim is to ensure that medical personnel can operate the device with ease and minimal training, which is crucial for adopting new technologies in fast-paced clinical environments.
2. **Long-term Stability Tests:** These tests are designed to assess the durability and operational consistency of the tomograph over extended periods. This is critical, as medical devices must maintain high performance and accuracy over time despite regular use in varied clinical settings.

These enhancements to the testing protocol are designed to provide a comprehensive understanding of the tomograph's performance and reliability, ensuring that it meets the stringent requirements of medical diagnostics

(Zhao, Z., et al. 2021). By addressing these additional facets, the project not only reaffirms the device's functionality and safety but also enhances its readiness for deployment in clinical settings.

The image reconstruction process involves mapping the impedance distribution in the examined area based on current and voltage measurements at the electrodes (Baran, B., et al. 2023). Several reconstruction methods have been implemented, including Tikhonov, Gauss-Newton, Kotre, and Total Variation:

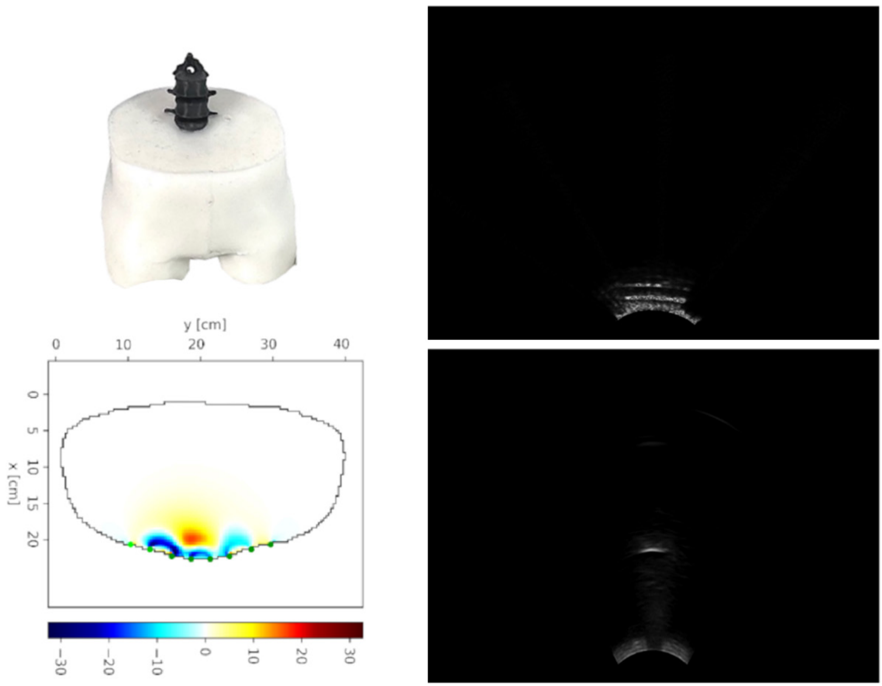
1. **Tikhonov Method:** this method is commonly used in inverse problems where numerical instability is an issue. It introduces regularization into the reconstruction equations by adding a penalty component related to the reconstruction parameter's L2 norm (Euclidean norm). This helps control numerical instability and improve image quality (Andreis, U., et al. 2008).
2. **The Gauss-Newton:** method is a popular iterative technique used in optimization problems. In the context of EIT, it minimizes the difference between actual and predicted impedance measurements by applying iterative corrections.
3. **Kotre Method:** This method is based on the concept of orthogonal trajectories. It transforms reconstruction equations so that each equation corresponds to one electrode, with measurements for different electrodes performed sequentially.
4. **Total Variation (TV):** this method is used to reconstruct images with minimal details (sparse images); TV in the context of EIT is used for regularization to minimize the total variation of the image, resulting in a smooth image while preserving edges and details.

These methods aim to solve the inverse problem in EIT, i.e., to reconstruct the impedance distribution of tissue based on surface measurements. Each method has advantages and limitations, and their selection depends on the specific problem, type of measurement data, and requirements for accuracy and numerical stability. The precision and reliability of Electrical Impedance Tomography (EIT) heavily depend on the accuracy of the underlying measurement processes. EIT systems meticulously measure electrical currents and voltages through various configurations of electrodes placed on the surface of the tissue under examination. The process involves cyclically injecting known currents through these electrodes and measuring the resulting voltages to explore the area of interest thoroughly. This comprehensive approach ensures the capture of a complete dataset reflecting accurate impedance variations throughout the tissue. The arrangement of electrodes is critical for achieving the desired resolution and depth in the impedance measurements. Electrodes are usually arranged strategically around the target area and selected based on the specific anatomical features and the clinical goals of the examination. This balance ensures optimal coverage and resolution while maintaining practical application. Following current injection and voltage measurement, the raw data undergo rigorous signal processing (Maciejewski, D., et al. 2021.). This step is crucial for filtering out noise, compensating for any mismatch in electrode impedance, and correcting any temporal signal drifts, all of which are vital for the quality of the resulting impedance maps. The refined measurement data are subsequently input into various reconstruction algorithms. The robustness of these measurements affects how effectively methods like Tikhonov regularization can stabilize solutions, or how accurately the Gauss-Newton method can reduce the discrepancies between actual and predicted impedance measurements (Zhao, Z., et al. 2020). A significant challenge in EIT measurements is addressing the complexity of body tissues exhibiting non-uniform and anisotropic electrical properties and managing the variability introduced by skin-electrode contact impedance. The accuracy of these measurements critically influences EIT's capability to produce reliable diagnostic images. High-quality measurements enable reconstruction algorithms to generate clear, detailed, and clinically valuable images. These are crucial for diagnosing diseases and monitoring real-time physiological functions such as cardiac activity and respiratory motions. Continual improvements in measurement techniques and enhancements in reconstruction algorithms are driving EIT towards broader applications in healthcare. Efforts are focused on enhancing image resolution and accuracy and simplifying operational processes to facilitate routine clinical use. Advances in measurement and reconstruction technologies are setting the stage for EIT's increased integration into medical diagnostics, therapeutic monitoring, and surgical guidance.

Reconstruction results

The portable ultrasonic-impedance tomograph has demonstrated substantial capabilities in producing high-resolution images that are pivotal for precise medical diagnostics. The comparative analysis with established imaging technologies, particularly the Philips Lumify system, highlights not only the competence of the new tomograph but also its superior adaptability and precision in clinical settings. It is using a medical phantom to simulate human tissue properties allowed for a controlled evaluation of the tomograph's imaging techniques (Wodack, K., et al. 2018).

Figure 5. *Reconstruction results*



Results displayed in Figure 3 offer a stark visualization of how different algorithms affect the clarity and utility of the images:

1. UST B-mode Algorithm: The images reconstructed using the B-mode algorithm displayed remarkable resolution, with a Peak signal-to-noise ratio (PSNR) of 29.45. This high PSNR indicates that the image noise is significantly lower than the signal, suggesting that the images are clear and precise, which is crucial for detecting subtle anatomical variations.
2. EIT Differential Reconstruction: The differential approach in EIT, capturing variations between filled and empty bladder states, utilized a Damped Gauss-Newton method with exceptionally low regularization (λ = 1e-9). This method highlighted minor impedance differences critical for applications like tumor detection or fluid dynamics within the body. The Structural Similarity Index (SSIM) for these images was recorded at 0.65, confirming good structural fidelity in the reconstructed images (Faragallah, O.S., et al. 2021)(Wang, Z., et al. 2004).

The tomograph's ability to integrate and juxtapose data from UST and EIT modalities in real-time offers a multidimensional view of the target anatomy, surpassing traditional systems offering singular perspective imaging. The synthesized view provided by our device aids clinicians in making more informed decisions with a higher degree of confidence (Baran, B., et al. 2023. 1553). While current results are promising, continuous advancements are essential for maintaining technological relevance and clinical efficacy:

1. **Algorithm Optimization:** Further refinement of the Damped Gauss-Newton method and exploration of adaptive regularization techniques could improve image quality. Implementing machine learning algorithms might offer predictive capabilities to adjust real-time parameters based on the tissue characteristics observed during initial scans.
2. **Higher Resolution and Faster Processing:** Enhancing the computational efficiency of the tomograph could allow for higher-resolution imaging without compromising the speed necessary for clinical settings. This could involve hardware upgrades, such as faster processors or more sensitive sensors, and software optimizations to streamline data processing.

3. **Extended Clinical Trials:** Broadening the scope of clinical trials to include a wider range of conditions and more diverse patient demographics will help us understand the tomograph's full potential. These trials should aim to quantify improvements in diagnostic accuracy and patient outcomes directly attributable to the enhanced imaging capabilities.

As medical imaging technology advances, the enhancements and breakthroughs in the portable ultrasonic-impedance tomograph are set to revolutionize diagnostic practices (Boone, K., et al. 1994. pp. A189–198). Adopting these advancements will not only improve patient care but also lead to pioneering developments in the realm of medical science.

Conclusions

The portable ultrasonic-impedance tomograph marks a significant breakthrough in medical diagnostics, particularly for monitoring lower urinary tract conditions. By integrating advanced ultrasound and impedance tomography technologies, this device provides higher resolution and contrast in imaging, outperforming traditional diagnostic methods. Its capability to deliver precise, real-time visualizations of complex anatomical regions enhances diagnostic accuracy and aids in effective long-term patient management.

Innovative features like the UST B-mode Algorithm and EIT Differential Reconstruction have proven effective in refining the clarity and detail of diagnostic images, further validating the tomograph's utility in clinical settings (Costa, E.L.V., et al. 2009. pp. 18–24). The incorporation of machine learning for adaptive algorithm optimization and the potential for hardware improvements suggest substantial future enhancements that will expedite processing and improve image quality.

Expanding clinical trials to include diverse conditions and patient demographics is essential to fully leverage the tomograph's capabilities and confirm its efficacy across various medical scenarios. The ongoing development of this technology aims to minimize invasive diagnostic procedures, thereby improving patient experiences and reducing hospital visit frequencies, which aligns with the goals of personalized medicine.

Ultimately, the portable ultrasonic-impedance tomograph is set to revolutionize diagnostic practices, offering a safer, more efficient, and patient-friendly alternative to conventional methods. As this technology advances, it promises to expand its applications beyond urology, potentially transforming diagnostic and therapeutic approaches in multiple medical fields.

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