



Aillis, Inc.



nodoca™



Wireless Connectivity Test Set MT8862A

Aillis, Inc., Challenging to Realize the Reliable "AI Medical Device" by Wireless Connectivity Collaborating with Anritsu to Evaluate the Telecommunications Performance of Devices in Usage Environment.

Aiming to use Wi-Fi®*1 to transfer pharyngeal (throat) imaging data to the cloud to facilitate quick and reliable performance evaluation for the first time in this usage environment.

Background and Challenges

Complete on-time evaluation of new medical device transmitting imaging data to AI by wireless communication technology.

Reasons for Selection

Leverage Anritsu's professional expertise in Wi-Fi evaluation, which is challenging for medical devices.

Results and Prospects for Introduction

Gain knowledge and know-how in Wi-Fi technology. Support further improvement and future development.



Hardware Engineer
Mr. Ken Takahashi



Software Engineer
Mr. Kosuke Oka



Name: Aillis, Inc.

Established: November 2017

Capital: JPY 100 million (at October 31, 2022)

Business Description: Solving social challenges, such as medical disparities in care by formalizing the skills of physicians through the development of medical devices assisting the diagnosis of infectious diseases using AI technology.

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Background and Challenges

Completing on-time evaluation of new medical device transmitting imaging data to AI by wireless communication technology.

Aillis, Inc. develops medical devices using artificial intelligence (AI). The company has developed nodoca™, a new medical device that assists medical diagnostics by capturing images of the throat (pharynx) for analysis using AI in conjunction with information from physician's interviews to detect characteristics of influenza virus infection.

More than 100 diseases can be diagnosed by visual examination of the throat, which is an important part of a physician's examination. To data, however, so far there has been no easy way to save and easily reference throat imaging data.

This is unfortunate because ad hoc observations of the throat cannot be used as reference data for the throat 'treasure house'. Storing clinical data – including images – about the throat will facilitate research on different diseases, and combination with AI learning will help the development of AI medical devices supporting the more accurate diagnosis.

As a key part of the nodoca™ development, Aillis engineers concluded that the captured image data should be transmitted by wireless

communication technologies to cloud storage. If Aillis can realize nodoca™ as a reliable and essential medical instrument for physicians to conduct visual inspections, the medical techniques in diagnoses can advance dramatically. "We wanted to improve the handling of the pharyngeal endoscope as well as the transmission of captured imaging data to the cloud immediately for further use by using wireless communication technology", recalls hardware engineer Mr. Ken Takahashi about the early development stage.

However, to transmit image data by wireless communication technology, Aillis needed to quickly determine whether the novel wireless communication function meets the required functions and performance while complying with electromagnetic compatibility (EMC) standards for medical equipment. To solve these issues, Aillis collaborated with Anritsu's Solution Service, providing evaluation, investigation, and technical support for telecommunications equipment and radio-wave environments.

Selected Solutions

Anritsu's Solution Service
using Wireless LAN tester
(Wireless Connectivity Test Set MT8862A)

Reason for Selection Leverage Anritsu's expertise in Wi-Fi evaluation, which is challenging for medical devices.

Aillis envisioned the integration of Wi-Fi (Wireless LAN) technology with nodoca™. The choice was based on the large data size of transmitted images and ease-of-use of the wireless technology. Wi-Fi allows for a simple configuration to transmit images directly to the cloud via a router.

However, simply using a commercial off-the-shelf Wi-Fi module when installing Wi-Fi into an electronic device does not instantly guarantee the expected functionality and performance, because the measures to comply with EMC standards sometimes result in poor Wi-Fi performance on the device. Aillis wanted to release nodoca™ as a tool that physicians could use safely by relieving that it works exactly as they expect, without relying on the guarantee of Wi-Fi performance by

module vendor. As a result, Aillis decided to rigorously assess Wi-Fi communications reliability before releasing nodoca™.

Trouble-free introduction of Wi-Fi technology into nodoca™ requires a thorough understanding of:

- Handling of radio signals and radio components
- Evaluating communications performance

Furthermore, from the long-term perspective, wireless test equipment will be required along with the training for engineer to acquire the knowledge and skill to use wireless technology. In addition, it was necessary to complete the timely evaluation of nodoca™ in parallel with speedy business development by catching up the technical advances in wireless technology.

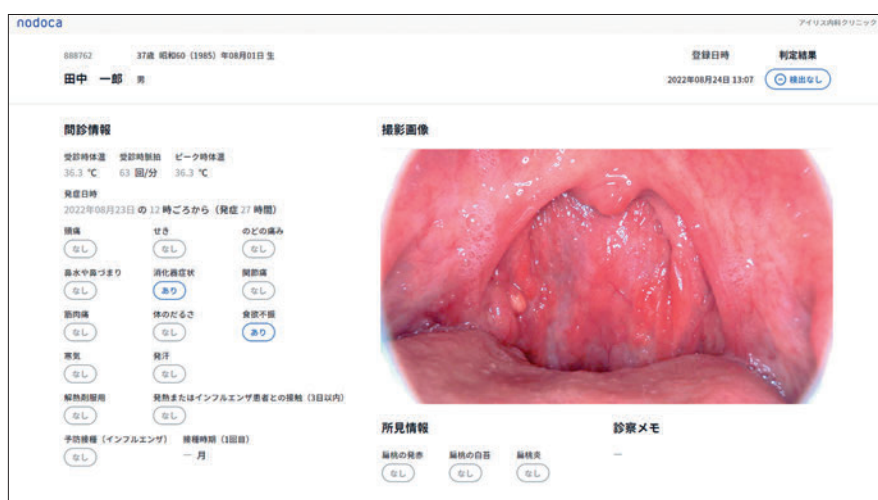
To achieve this initial goal in the limited time frame, Aillis sought a partner combining evaluation expertise with evaluation facilities and evaluation service plus advice on technical issues and problems.

Software engineer Mr. Kosuke Oka decided to partner with Anritsu for this work, explaining, "I often saw Anritsu articles in technical magazines on radio technology, which I was reading to deepen my knowledge of radio and high-frequency waveforms. When searching for materials on radio technology, I found that many textbook materials were available on Anritsu's website, giving me confidence that Anritsu could provide support based on its deep knowledge of radio technology. So, Anritsu became my first-choice candidate."

Anritsu's Solution Service offers a one-stop-shop support service including:

- Explaining general evaluation methods
- Proposing evaluation methods tailored to target and purpose
- Introducing and procuring necessary equipment
- Providing evaluation staff

Anritsu also proposed a more detailed evaluation and verification menu based on consultation with Aillis. However, based on past experience, evaluation may not proceed smoothly if all necessary evaluation and verification menus are formulated and implemented before the performance of the client's product is well understood. With this in mind, Anritsu proposed a menu of services that would allow evaluation to proceed in stages, for cost-effectiveness.



nodoca™ uploads captured images to the cloud, so physicians can check the information from medical interviews and AI image analysis on a web browser.

Results and Prospects for Introduction Gain knowledge and know-how in Wi-Fi technology. Support further improvement and future development.

"Aillis selected a Wi-Fi module (chip) for nodoca™ with the assured traceability required by medical devices and compatibility with the service API used to manage the data handled by AI", said software engineer Mr. Oka.

"By working with Anritsu on evaluation, we both numerically evaluated the WLAN performance using the MT8862A and analyzed the protocol using the Frame Capture function to visualize reception performance and check communication messages. This gave us a better understanding of configurations accommodating various use cases," said hardware engineer Mr. Takahashi.

To evaluate actual performance, Anritsu configured a full-scale Wi-Fi test environment in a radio anechoic chamber at their Atsugi laboratory. Alongside Aillis engineers, skilled Anritsu Solution Service staff ran various wireless communication tests, and a stable connection was obtained from

start to finish to produce evaluation results that satisfied Aillis.

Looking to the future, Mr. Oka said, "We would like to conduct a thorough preliminary evaluation

using evaluation boards and other equipment when selecting a commercial Wi-Fi module. We are going to ask Anritsu for support again next time."



Example of Wi-Fi evaluation using Anritsu's MT8862A (Not actual nodoca™ evaluation data)

nodoca™ received manufacturing and marketing approval by the government of Japan on April 26, 2022. This is the first case in Japan where a medical device with AI has been approved as a 'new medical device'*² (based on research by Aillis*³). Japan National Health Insurance coverage

for diagnosis of influenza virus infection using nodoca™ started on December 1, 2022.

Collecting and researching clinical data is essential to deepening the medical knowledge and advancing the medical technology. Full-scale rollout of nodoca™ will help collect high-quality

diagnostic data on throat infections in a massive and shareable format, bringing new insights to medical researchers and fostering effective medical technology. Anritsu's wireless test evaluation technologies support these meaningful challenges and efforts.



Wireless technology is essential in making this 'visual stethoscope' as useful as a physician's regular stethoscope.



Evaluating prototypes in preparation for nodoca™ release

*1: Wi-Fi® and the Wi-Fi logomark are registered trademarks of Wi-Fi Alliance®

*2: One classification for approving manufacturing and marketing of a medical device. Defined in 1.2 (2) of the Application for Manufacturing and Marketing Approval of Medical Devices (Notification No. 1120-5 of Pharmaceutical and Food Safety Bureau of Japan (Yakushoku) dated November 20, 2014).

*3: List of new medical devices from FY2021 to FY2011 published by Pharmaceuticals and Medical Devices Agency (PMDA) (<https://www.pmda.go.jp/review-services/drug-reviews/review-information/devices/0018.html>) and confirmed by Aillis as approved medical devices in 2022.

Anritsu Advancing beyond

Specifications are subject to change without notice.

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