

CarbGeM Inc.

CarbGeM = Combating Antibiotic-Resistant Bacteria
by next Generation of Medical Device

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Business Enhancement leveraging DX/AI

Creating New Value Through Image Recognition AI and Generative AI

Image Recognition AI



- Acquisition of Visual Characteristics
 - Object Detection
 - Early Detection
 - Classification

X

Generative AI



- Text, Image, Video, Audio Generation
 - Support for Routine Tasks
 - Advanced Personalized Marketing
 - Support for Specialized Operations

Advantage to strengthen your business

Our strength

Creating New Value Through "Bio" x "Digital (DX/AI)"

Knowledge in the Life Science Domain

- Bio Research Hub (Kobe Biomedical Innovation Cluster)
- Information Hub in US Boston
- In-house capability of medical and pharmaceutical, and Academic Experts

Commitment to Social Implementation

- Projection for social implementation
- Image Sharing Platform (CarbConnect)
- Know-how in QMS etc.
- Operation Process Improvement

Trends in Biotechnology

- Catching and delivering the latest trends
- Owned Media (CarbGeM+)
- Strong network of Academia and Medical KOLs

Experienced Team

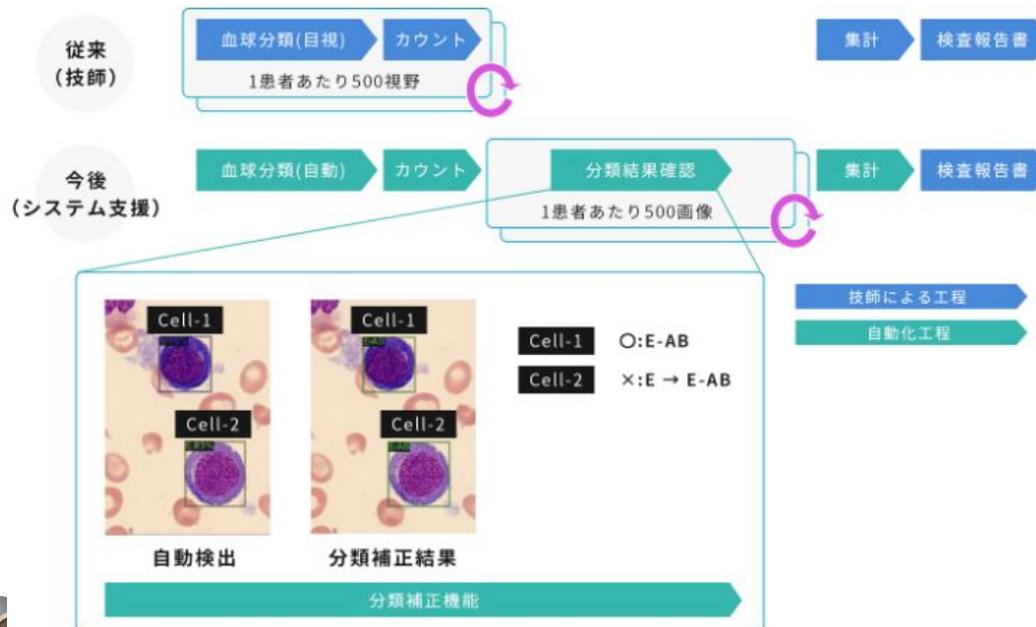
- Extensive experience in
- Business planning and development
- AI program medical device development and market entry
- DX/AI Projects across various industries

Life Science DX/AI Solution Case Study

AI-Powered Classification for Peripheral Blood Cells in Bone Marrow Smears

■ Project: AI-Powered Classification for Peripheral Blood Cells in Bone Marrow Smears

- **Objective:** Support for the classification of peripheral blood cells for MDS (Myelodysplastic Syndrome) diagnosis
- **Value:** Standardisation of diagnostic accuracy and efficient operations
- **Implementation:**
 - AI analyses microscopic images of smears and automatically detect and classify blood cells.
 - Streamlining operations with automated aggregation of classification results.



Standardisation of diagnostic accuracy Efficient operations

Standardizing diagnostic procedures that are challenging to pass on
High-throughput cell classification leveraging AI

Life Science DX/AI Solution Case Study

Image AI-Powered Bacteria Estimation in Infectious Diseases

■ Project: Image AI-Powered morphology/species estimation of causative bacteria in Infectious Diseases

- **Objective:** Early estimation of causative bacteria, leading to the appropriate empiric antimicrobial treatment
- **Value:** Estimation accuracy equivalent to specialists in infectious disease
- **Implementation:**
 - Learning dataset of the pairs of Gram-stained images and identified bacteria species
 - With an automated gram stainer, Gram stain quality is highly homogeneous.
 - Standardizing image quality using lens and smartphone attachment and smartphone app

Standardizing specimen preparation

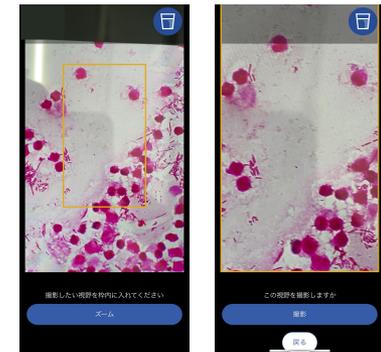


Remove difference between technicians
Minimizing variation due to methods/reagents

Standardizing image acquisition



Homogeneous capture condition (Hard)
- integration of lens and a smartphone case (left)
Uniform image capture magnification (soft)
- consistent image quality and magnification with the app



Life Science DX/AI Solution Case Study

Real-time Detection of Transmitted Light Intensity change Using Image recognition AI

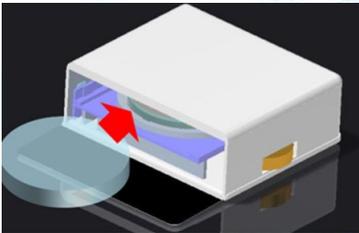
■ Project: Real-time detection of transmitted light intensity change using image recognition AI

- **Objective:** Early diagnosis of infectious diseases (early detection of minute change)
- **Value:** Rapid diagnosis and treatment in clinical settings and improved workflow efficiency.
- **Implementation:**
 - **Combination of thin-film transistor (TFT) light sensor developed by Japan Display Inc. and CarbGeM's image recognition AI.**
 - **Automated measurement of bacterial growth based on transmitted light intensity on a culture medium.**

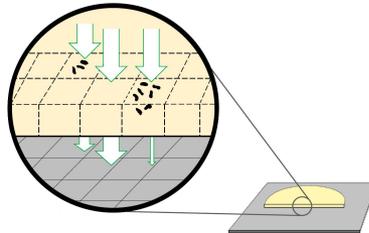
※Press release: 2024/11/22

[Collaborative development of "SOLTIMO-M" with Japan Display Inc. \(TSE: 6740\) \(Japanese only\)](#)

Standardization of image acquisition

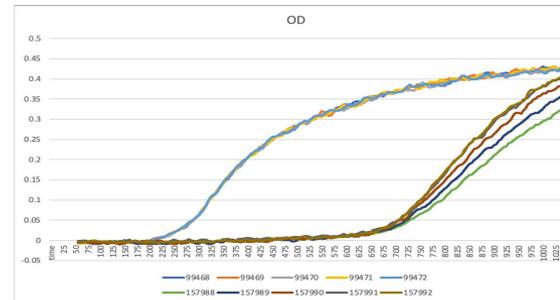


Specialized measurement device



Measurement of transmitted light intensity by TFT light sensor

Early detection by AI



Creating new value by integrating the device and image recognition AI realizing the detection of minor change

Life Science DX/AI Solutions

Know-how Cultivated in Medical Device Development for clinical testings

What is Life Science DX/AI Solutions

Provide **DX/AI solutions** including **image recognition AI** to resolves challenges in the healthcare and life science.

Leveraging the know-how and expertise obtained in product development of medical devices utilizing DX/AI in the clinical testing fields.

Our services are tailored for:



Company

Pharma. CRO, Medical Device
Food Industry



Enterprise

Opportunity of Busines
in life science industry

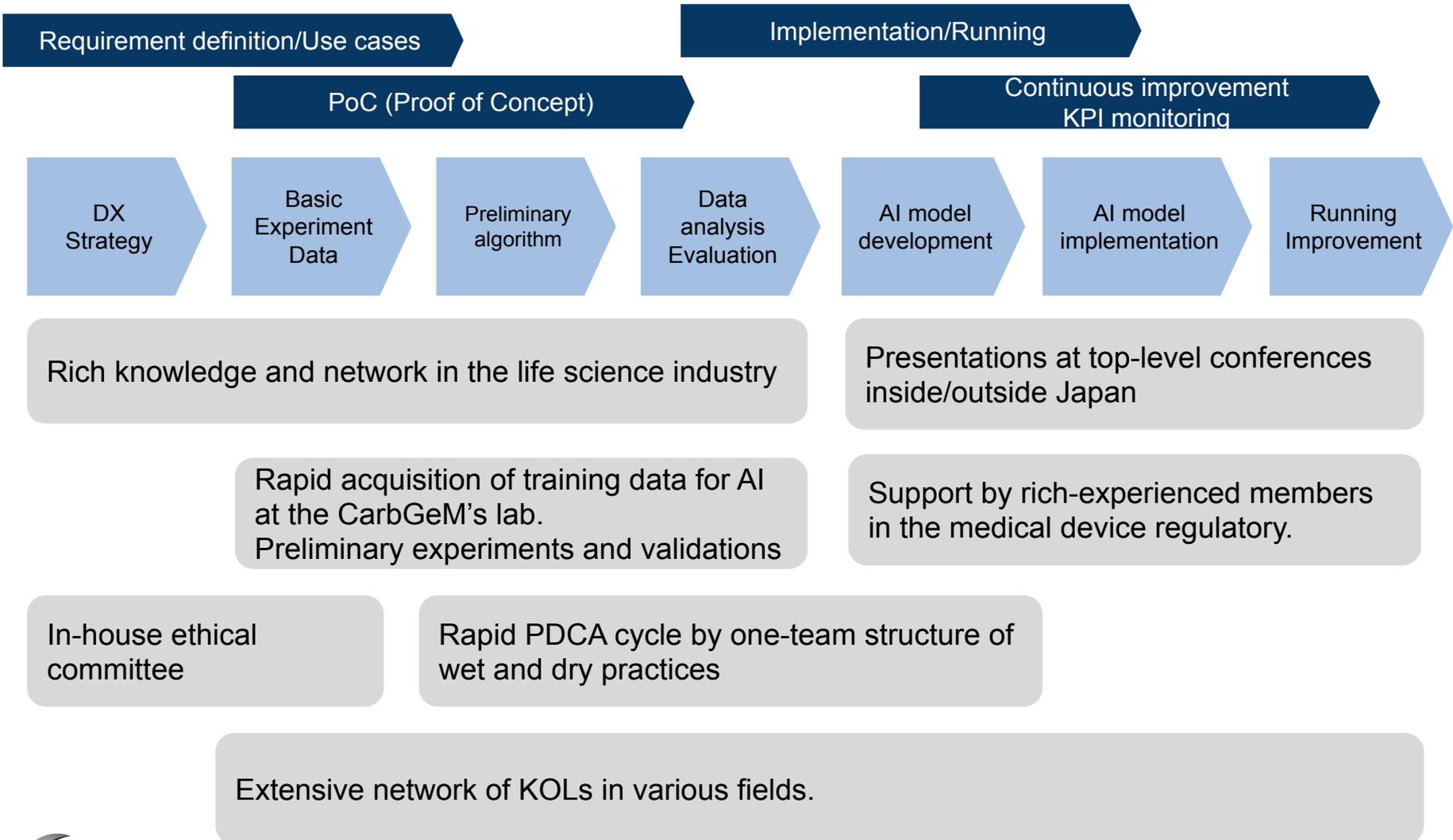


R&D

Academia, Startup
Medical facility

One-Stop DX/AI Solutions

Inclusive support from requirements definition, UI/UX design, PoC, DX/AI development, implementation



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Company Overview

Focus on AI-backed diagnostic technology for AMR and infectious diseases

- **CarbGeM Inc.** (URL <https://carbgem.com/>)
- **CEO: Masakazu Nakajima** **Foundation:** March, 2021
- **Location:** TOKYO (Headquarter), KOBE (Bio lab.), BOSTON (Innovation lab. (Prep))
- **Vision:** To protect humanity from the threat of infectious diseases and realise a safe and secure global society.
- **Scope of Business:**
 - Development and provision of life science AI solutions.
 - Development and provision of life science products.
 - R&D and sales of AI/Bioinformatics in a field of infectious disease and microbiology
- Medical device manufacturing and distribution license

Collaborators*

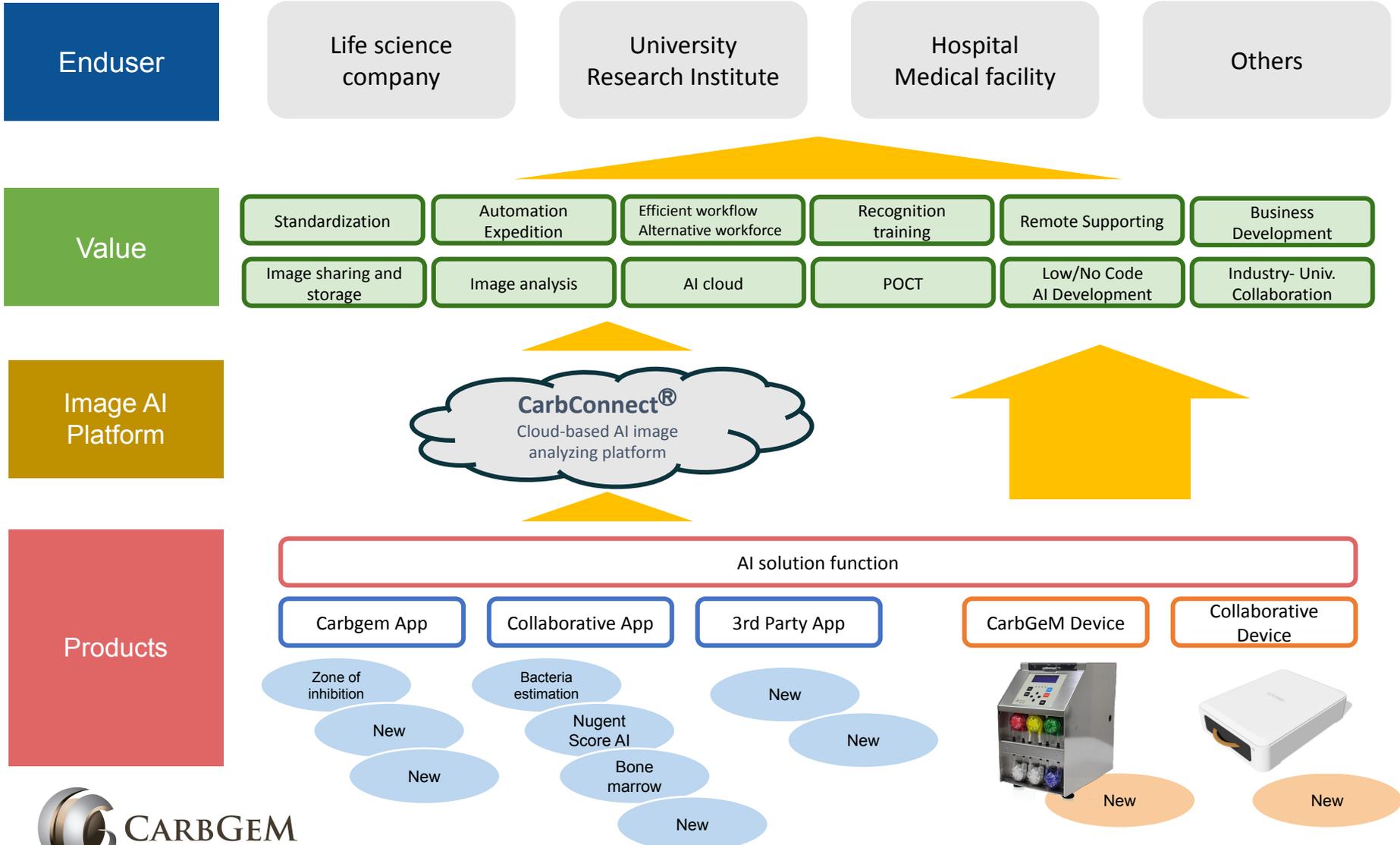


Grants and Subsidiary



Comprehensive Solutions

Solving Challenges in the Life Science Industry with focus on Image-Based Solutions



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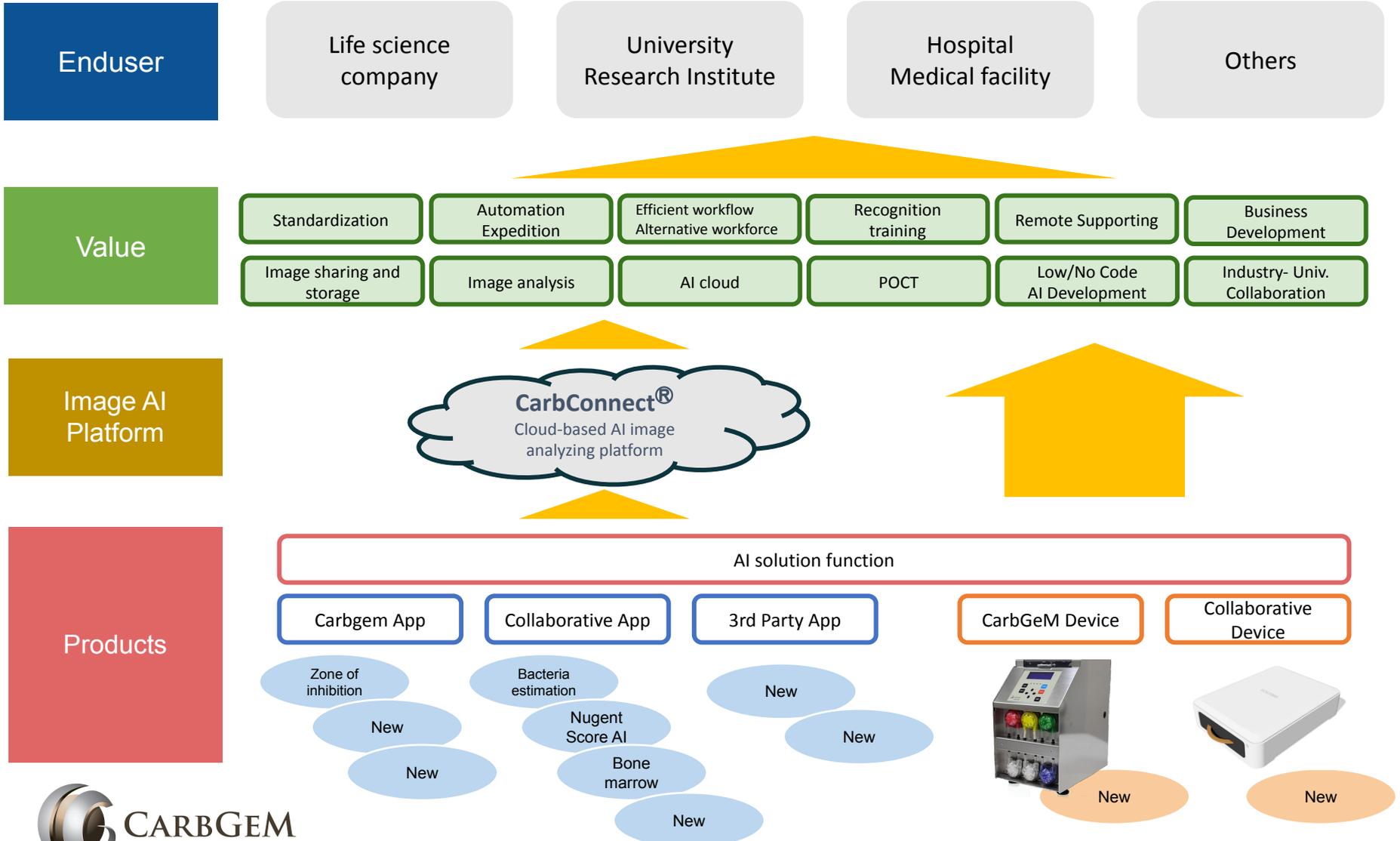
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Life Science Products

Comprehensive Solutions

Solving Challenges in the Life Science Industry with focus on Image-Based Solutions



Product Introduction

Clinical testing and research in Microbiology

- Standardization
- Automation Expedition
- POCT
- Image Analysis

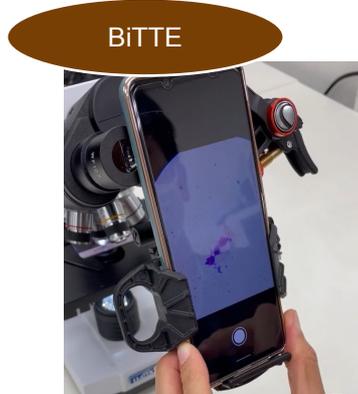


Prevent interruption of a series of processes and realises optimal testing/diagnosis rapidly.



Portable Gram Stainer

Automation of laborious staining procedure
High quality specimen preparation in five minutes



AI bacteria estimation antibiotic selection App

Support for microscopy of Gram stained specimen and appropriate use of antibiotics in resource-limited settings

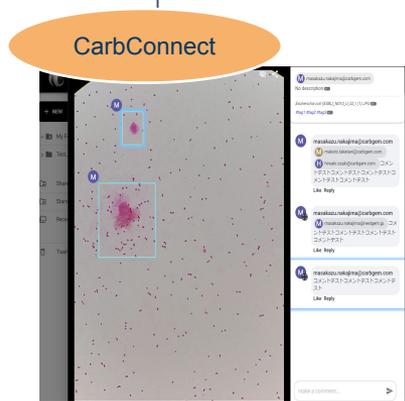
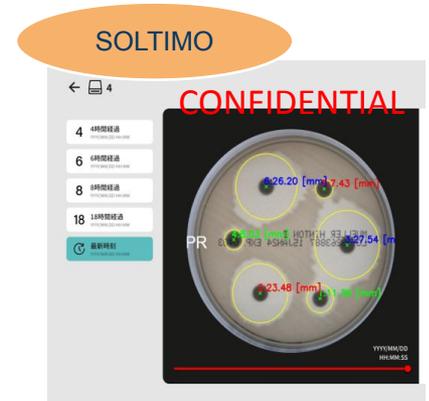


Image analysis and sharing platform

Sharing testing and research images. Supporting analysis and diagnosis by advice and comments by specialists



Rapid detection of bacteria culture

Continuous and automated measurement of zone of inhibition. Rapid and standardized antimicrobial susceptibility test



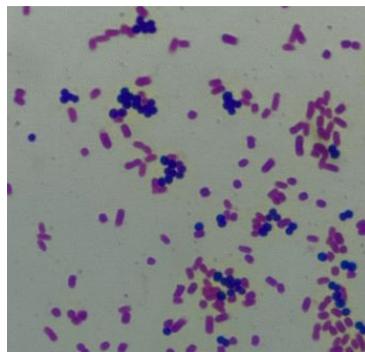
PoCGS[®] : Overview

Portable Gram Stainer

PoCGS[®]: Potable Gram Stainer



Gram stain image



Value

- Standardisation of staining quality.
- Automation and labour saving for staining
- High-quality specimen in about 5 minutes.
- Compact size: can be installed in locations without drainage facilities.

Summary

- Class I Medical Device (JP, 2024)
- Patent application
- Size : W204 × H350 × D280 (mm)
- Weight 8.7kg
- Power Supply AC100V (50-60Hz)
- Processing Capacity: One
- Reagents: Six reagents (including water)
- Drying and automated cleansing
- Standard and customized staining program

PoCGS[®] : Performance

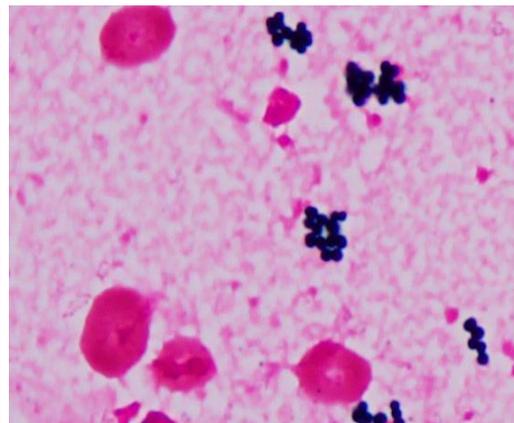
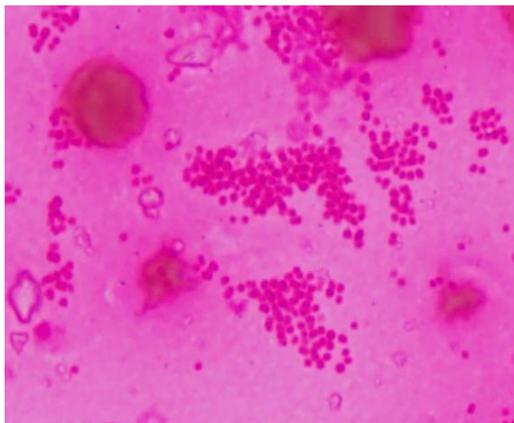
Equivalent to experienced clinical technicians (efficient and standardized)

Neisseria flavescens
(Blood culture)

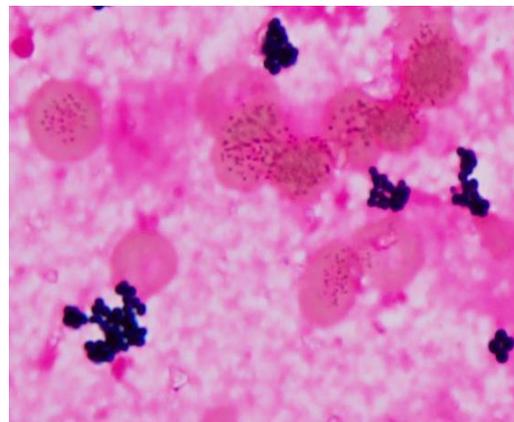
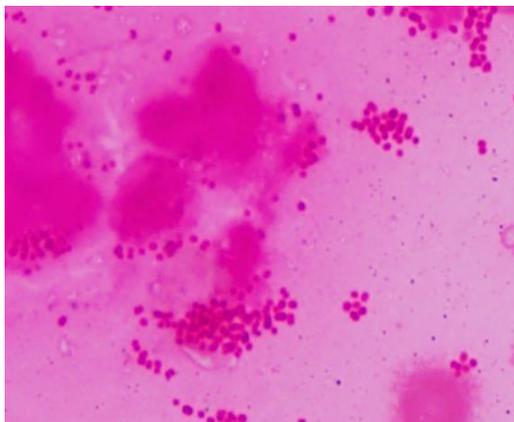
Staphylococcus aureus
(Blood culture)

Clostridium perfringens
Escherichia coli
(Blood culture)

Expert



PoCGS



BiTTE[®]: Overview

Smartphone App of AI bacteria estimation and antibiotic selection support

BiTTE[®]: Bacterial infection teller and treatment estimator

Value / Feature

- Supporting tool of Gram stain and empiric antimicrobial selection for medical facility/staff
- Clinicians and technicians without speciality
 - In an emergency department
 - Facility without a microbiologist

Overview

- Image recognition AI estimates bacteria morphology and species
- Propose effective antibiotics based on antibiogram (antimicrobial susceptibility data)
- Non-inferiority to specialists in infectious disease on seven classifications with accuracy of 95%. (Gram positive rods/cocci, Gram negative rods, multiple bacteria, No bacteria, others)
- 15 categories for species as reference
- Show spectrum score, AWaRe classification
- Urine: Class II program medical device
- Blood culture: RUO



※Images are under development, which can be altered.

Approval as program medical device (SaMD) 2024/12/16

カーブジェン、プログラム医療機器(SaMD) 承認取得「細菌感染症菌種推定支援AIソフトウェアBiTTE®-Urine」

[プレスリリース](#) 2024/12/16

国立国際医療研究センター・国際感染症センター、 神戸大学都市安全研究センター・医学部附属病院との共同研究

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本製品は、AI画像解析技術を活用し、尿のグラム染色画像から菌種推定を支援するソフトウェアであり、地域のアンチバイオグラムとの連携も可能です。

本製品は国立国際医療研究センター・国際感染症センター（NCGM）の山元佳 医師ならびに神戸大学都市安全研究センター・医学部附属病院検査部の大路剛准教授らとの共同研究において開発および実証実験を行ってまいりました。

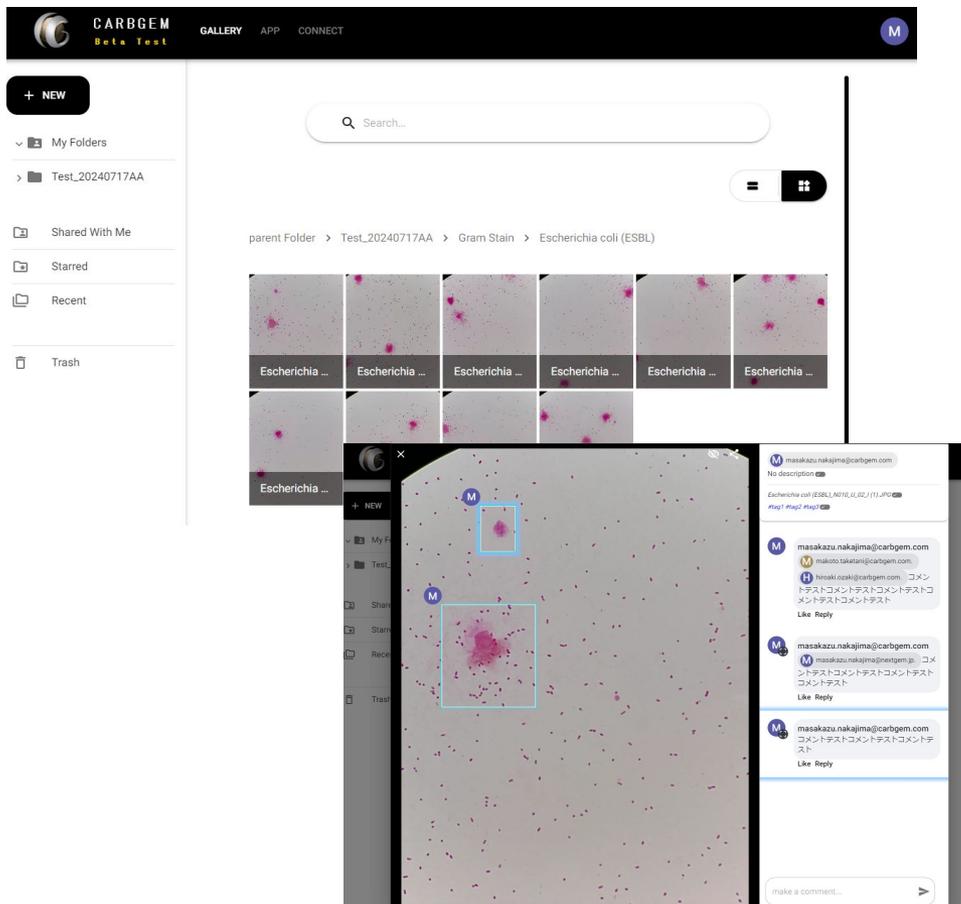
*本製品の開発にあたっては、一部、国立研究開発法人日本医療研究開発機構（AMED）の「医工連携イノベーション推進事業（課題名：薬剤耐性の抑制に資する菌種推定と抗菌薬適正使用支援システムの開発）」及び「医療機器開発推進研究事業（課題名：画像認識AIによる細菌感染症の菌種分類精度向上と抗菌薬適正使用に関する臨床研究）」の支援をうけております。



CarbConnect: Overview

AI/ML image analysis and sharing platform focusing on testings/research

CarbConnect (CBC): Image Data Sharing Platform



Value / Feature

- AI/ML image analysis and sharing platform focusing on testings/research
- Real-time data sharing and access
- One-stop collaboration with applications
- Projected low-code AI model construction

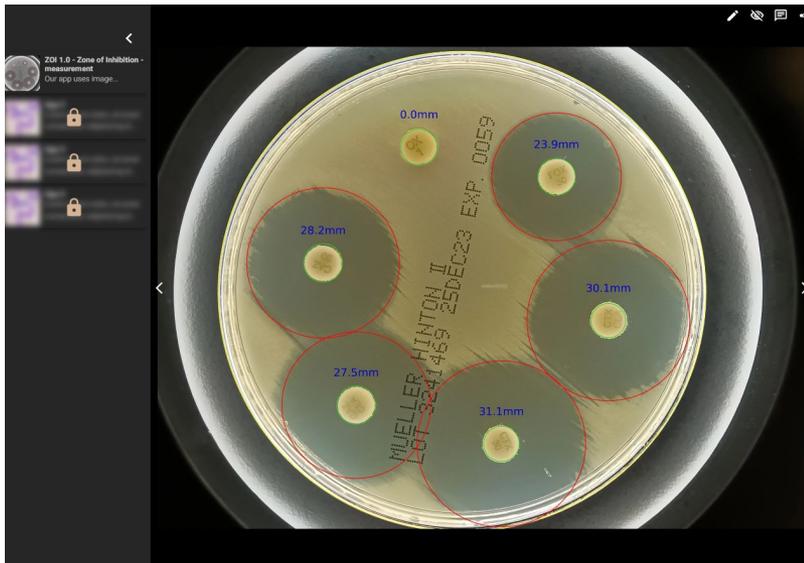
Summary

- Core function supports medical professionals and researcher with medical/biological images
- **Image storage and sharing:** images can be uploaded and shared across the globe
- **Communication:** remote communication via messages on an image or its specific regions
- **App Collaboration:** Image analysis app (carbGeM, 3rd Party apps)

AI image analysis application: Overview

ZOI (Zone of Inhibition Measurement)

- Automated inhibition zone measurement
- Automates previously manually-measured inhibition zone measurement
- Allows for manual adjustment.
- Carbconnect enables image storage, information sharing, and communication.



BiTTE lite

- BiTTE-iE Entry model (limited function).
- Image recognition AI provides bacterial morphology classification.
- Allows for manual adjustment.
- Carbconnect enables image storage, information sharing, and communication.



⌘Images are under development, which can be altered.

AI Image Analysis Application: Overview

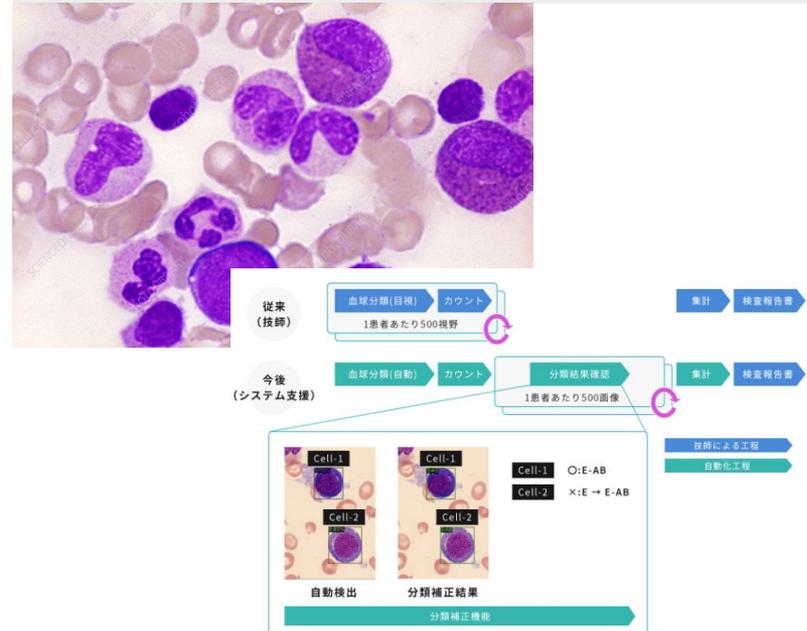
Nugent Score AI

- AI supports Nugent Score classification (four categories).
- Allows for manual adjustment (entering bacteria species etc).
- Carbconnect enables image storage, information sharing, and communication.



Blood cell classification App

- Support classification previously manually carried out.
- Allows for manual adjustment.
- Carbconnect enables image storage, information sharing, and communication.



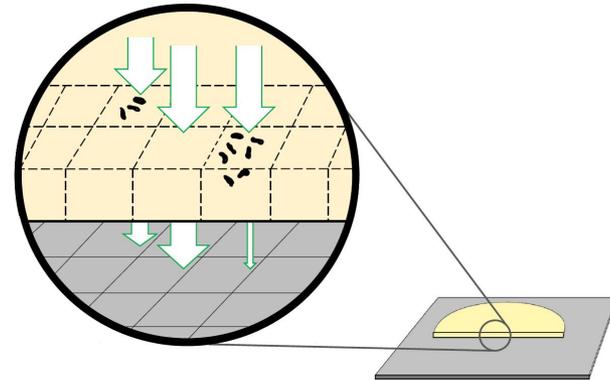
※Images are under development, which can be altered.

SOLTIMO-M: Overview

Rapid and automated bacteria growth detection on a culture media



Size (W:12, D:20, H:6 cm)



Principle: A sensor measures transmitted light intensity



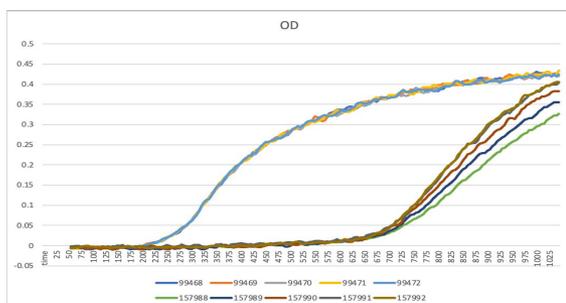
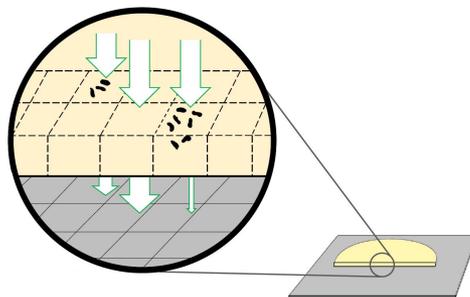
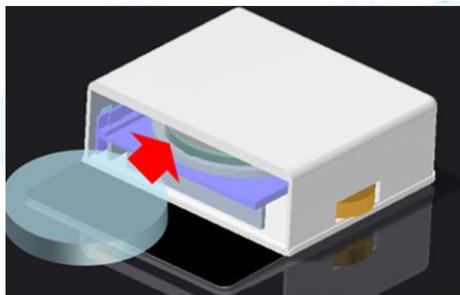
Devices can be piled up in an incubator.

- Install a device in an incubator, set the culture plate coated with microorganisms inside, and measure growth using a connected PC.
- The sensor measures transmitted light intensity every 5 minutes, and bacterial growth is detected.
- Multiple device can be installed in an incubator.
- Intended Use
 - **Rapid detection of bacteria growth:**
 - Rapid screening of antimicrobial resistance
 - **Automated antibiotic susceptibility analysis**
 - Continuous measurement is also available

BGM: Overview

Accelerating microbiological research using culture media (Under Dev.)

Bacterial Growth Monitor (BGM)



Value / Feature

- Realize first-ever optical density measurement for liquid culture media (Patent applied)
- Growth monitoring on solid culture media
- Detects growth/colony earlier than visual observation or camera-based methods

Summary

- Install a new algorithm in SOLTIMO hardware.
- Enables research on inner colonies and persisters, which were previously difficult to observe.
- Accelerates the development of new antimicrobial agents such as bacteriophages and microcins.
- Promotes joint research with companies doing R&D on microorganisms.

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