

#### **Digital Healthcare**

# Disruptive Technology Innovation



A pioneer in Point-of Care Test for universal healthcare service

### **Our Disruptive Technology**

Small Machines has been developing advanced on-site in vitro diagnostic medical devices based on the convergence of NT, IT, and BT technologies. Bio-MEMS, the core of Small Machines technology, is completed by seamlessly integrating MEMS (Micro-electro Mechanical Systems) and biotechnology. Small Machines' LOBA stands for technology convergence for biomedical innovation.

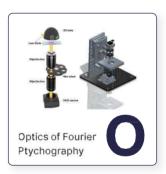
#### **LOBA**: Technology Convergence for Innovation

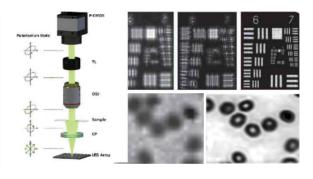




### Precision technology for semiconductor integration

Bio lab  $(70\text{m}^2) \rightarrow \text{LoC } (7\text{cm}^2)$ 1000 times better





### High-level digital optical technology

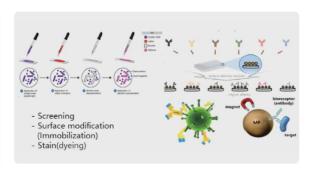
Analog optics (Resolution 95.7)

→ Digital FPM optics (Resolution 971.3)

10 times better

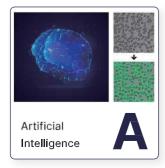
\* FPM: Fourier Ptychographic Microscopy

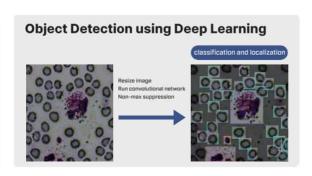




### Collaborative research on various bio-protocols

Complete Blood Count, Antigen-Antibody





### YOLO5 Artificial Intelligence Algorithm

For large area and high resolution images

### **Change Our Life in the Future**

Today, professional healthcare services are mostly concentrated in large hospitals with high cost, which makes equal access to medical services difficult. Biomedical innovation through the convergence of advanced technologies such as digital precision optical technology and artificial intelligence realizes the popularization of field-type diagnostic systems. This means that specialized diagnoses were only possible in large hospitals can be performed at nearby clinics or at your own home. With only a small amount of finger blood test without inconvenience, periodic health check is possible, allowing you to manage your own health data proactively and systematically. This will be a future game changer that can protect our health, which is exposed to aging and various intractable diseases. This is the future medical innovation that Small Machines' WHOPE project is trying to implement.

#### WHOPE Project for a better world

(Whole Blood Home Predictive Examination)

#### As Is: Not easy to access





To be: Open to anyone

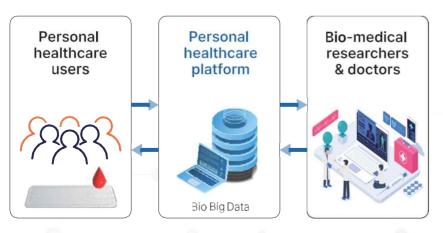


In large hospitals with high cost

Anytime, Anywhere, Myself

#### Why Invest in SMALL MACHINES

Small Machines will strive to create social value that promotes the health of all of us through the realization of medical welfare. At the same time, we will promote the establishment of a global platform service model for personal health care to increase the value of our investors.





### **CELLOP**<sup>TM</sup>

#### Automated Cell Morphology Analyzer

CELLOP is a computational microscopic image-based cell analyzer providing information about cell concentration, viability, aggregates, size distribution as well as functions of conventional cell counter.

CELLOP's optical system provides super resolution image with wide field of view(FoV), deep-depth of focus(DoF) and the A.I. engine recognizes the images highly reliable & repeatable.

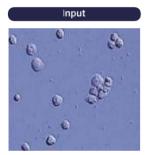
- · Auto Focusing & Intuitive User Interface
- · Simple Preparation Disposable Micro-Fluidic Cartridge
- · Accurate Cell Viabilities(%) & Size Distribution Histogram
- · DQ, IQ, OQ Validation (Certificate)



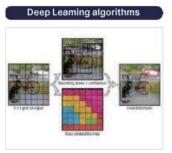
#### Technology

#### A.I. Recognition and Visualization

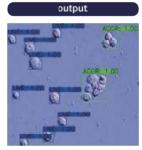
CELLOP's deep learning A.I. engine analyzes the acquired images by SR algorithm and provides visualized information such as cell concentration, viability, aggregates, size, distribution



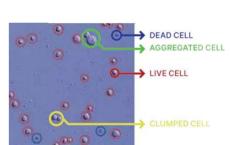
Image



- · SxS grid on input
- · Bounding Boxes + Confidence
- · Class probaility map



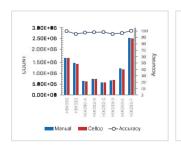
- · Bounding Box Data
- · Classification
- · Score



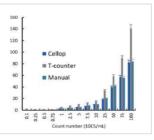
#### **Application**

CELLOP analyzes the image of large-area cells through the A.I. algorithm, separates dead and living blood cells, and measures, size, and density of each cell to monitor the quality of cell culture in cGMP.

#### Accuracy

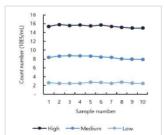


<Manual count vs. Cellop Count> Accuracy: ave. 97.93%



<Competitor Accuracy Comparison>

#### Repeatability



CV(%)	1.86	3.89	4.53
SD	28,694	32,667	11,712
MEAN	1,543,000	839,300	258,500
	n=10	n=10	n=10
	High	Medium	Low

High reproducibility (CV(%): less than 5% @Repeat by concentration)

#### Cell Culture Monitoring of Biopharmaceutical Production

- Stem Cell Therapy
- · Biosimilar Production

#### Cell & Micro-organism Research

- · Oncology (Cancer cell)
- Hematology
- · Bacteria & Micro-organism

### **DELISA**

#### Digital ELISA - Immunoassay Platform

DELISA is a highly sensitive multiple immunoassay platform based on microfluidic and magnetic bead control technology.

DELISA offers easy-to-use, benchtop platform for biomarker detection at the earliest stages of disease progression or biomedical research.

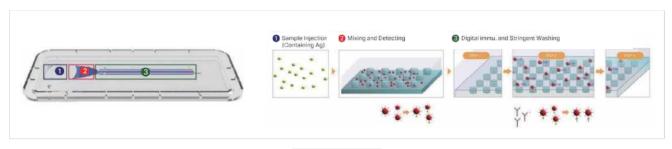
- · Fast procedures in 15 minutes
- · Simple Preparation Disposable Micro-Fluidic Cartridge
- · High Accuracy & Sensitivity Digitalized Detection
- Low LoD(Limit of Detection) & LoQ(Limit of Quantification)
- · No need fluorescent labeling

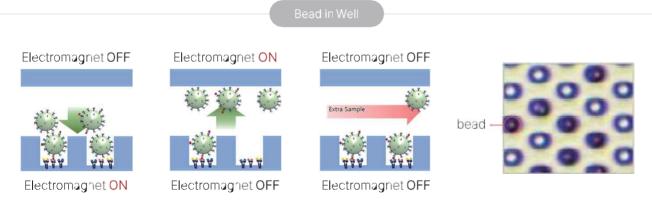


Technology

#### Digitalized Detection: Magnetic bead-target molecule Complex

To overcome the sensitivity limitations of existing diagnostic techniques, samples are digitalized through a discrete process, and the target molecules are quantified by counting the magnetic beads complexes through analysis of high-resolution images.





[ Principle and Method of DELISA ]

**Application** 

#### POC(Point-of-Care) Testing & Detection of Low Abundance Biomarker

- · Alzheimer(amyloid β, Tau)
- Acute myocardial infarction (Cardiac Troponin)
- · Vitamin D2/D3

Other Biomedical Researches

### WHOPE<sup>TM</sup>

#### CBC (Complete Blood Count) Analyzer

WHOPE is a computational microscopic image-based CBC analyzer for identification and count of blood cell such as red blood cell, white blood cell and platelet.

Minimal invasive blood collection (20mg)

- . Simple Preparation Disposable Micro-Fluidic Cartridge
- . Point of Care, Benchtop type for small sized medical site

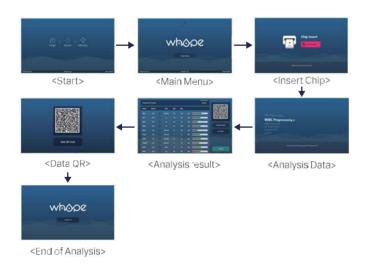


Technology

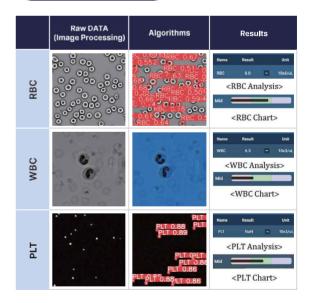
#### Morphology based A.I. analysis process

- 1. Capture image of blood cells injected into the cartridge (chip)
- 2. Analyze the morphology of the blood cells with the deep learning image library
- 3. Identify the blood cells type and count the blood cells
- 4. Realized morphological analysis of whole blood cells by acquiring high-resolution images of extracts arge-area based on computational optical system

#### **Work Flow**



#### A.I. Recognition



Application

#### Hematology

Completed Blood Count (CBC): 17 kinds RBC, HCT, MCV, RDW, WBC, 5-diff (Eosinophil(%), Neutrophil(%), Basophil(%), Lymphocyte(%), Monocyte(%)), PLT, PCT, MPV, PDW, HGB, MCH, MCHC

### Disposable Microfluidic Chip



CELLOP Chip (25×75×1.6 mm)



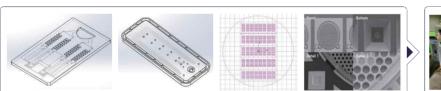
DELISA Chip (34×84×2.5 mm)



Lab-on-a Chip OEM/ODM Service (Customized)

In the field of microfluidic chips, we provide a variety of analysis and diagnostic chips through our internal capabilities from design to manufacturing

- . Micro-fine pattern design and mold technology using MEMS technology
- . Design technology for simultaneous macro-micro injection molding
- . Plastic surface treatment technology for receptor immobilization
- . Microfluidic system design & analysis (Lab-on-a Chip customization)



< Design + MEMS fabrication >





< Injection and assembly process >

#### **Awards**





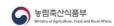


#### **Partners**

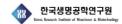








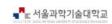












































A pioneer in Point-of Care Test for universal healthcare service

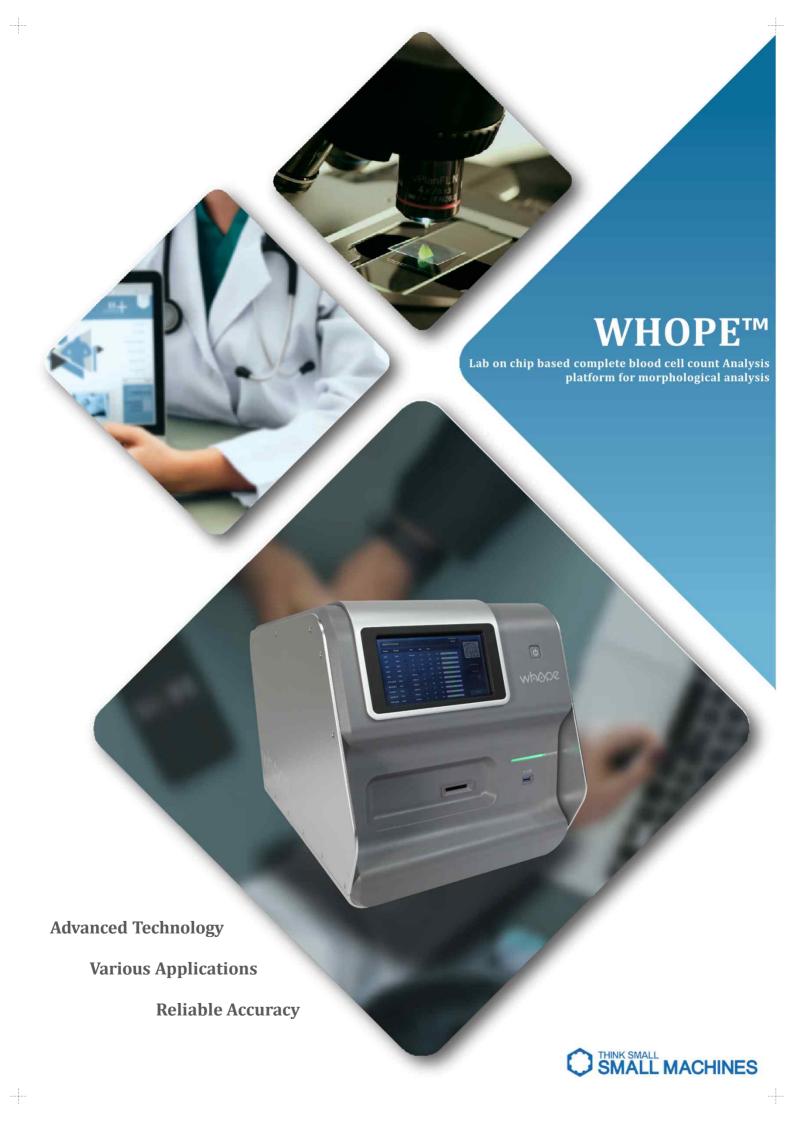
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## WHOPE™ - Lab on chip based complete blood cell count Analysis platform for morphological analysis

#### WHOPE<sup>TM</sup> is

• The WHOPE automatic blood cell analyzer is a device that measures the shape and blood count of various cells such as red blood cells, white blood cells, and platelets through image analysis of blood samples in cartridges (chips) using FPM-based precision optical technology developed by SMALLMACHINES.

#### **Features**

Fourier Ptychographic Microscopy

- Extracts large-area
- High-resolution images

Artificial Intelligence (AI) Recognition

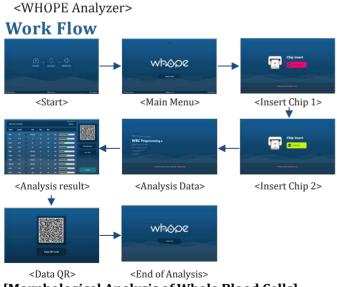
- High accuracy
- High repeatability

#### **Applications**

Completed Blood Count (CBC): 17 Kinds

- RBC, HCT, MCV, RDW, WBC, 5-diff[Eosinophil(%), Neutrophil(%), Basophil(%), Lymphocyte(%), Monocyte(%)], PLT, PCT, MPV, PDW, HGB, MCH, MCHC





#### [Morphological Analysis of Whole Blood Cells]

Analyzes the captured image of blood injected into the cartridge (chip) to find the shape of blood cells in the AI -trained image, and then measures the size and number of blood cells.

#### A.I. Recognition

	Raw DATA (Image Processing)	Algorithms	Results
RBC		RBC 0.63 RBC 0.50 0.68 RBC 0.50 0.50 0.68 RBC 0.50 0.50 0.68 RBC 0.50 0.50 0.66 RBC 0.78 0.78 0.66 0.66 RBC 0.6	Name Result Unit  RBC 8.0 - 10x6/uL <rbc analysis=""> Mid</rbc>
W B C		WBC	Name Result Unit WBC 6.3 - 10x3/uL <wbc analysis=""> Mid   <wbc chart=""></wbc></wbc>
PLT		PLT 0.88 PLT PLT 0.89 PLT PLT 0.89 PLT 0.86 PLT 0.86 PLT 0.86	Name Result Unit PLT NaN = 10x3/uL <plt analysis=""> Mid <plt chart=""></plt></plt>

#### **Accuracy & Repeatability**

	Category	Unit	Performance	Certification Standards
	Inspection items	Species	14	-
	Accuracy	%	95% ↑	CLSI H26-A2, EP09-A3
-	Image resolution	μm	0.76 ↓	1961 USAF Resolution Target
	Phase value height resolution	μm	0.1 ↓	Height resolution of phase value
	FoV	mm²	15 ↑	1961 USAF Resolution Target
-	Short term imprecision	CV%	5% ↓	CLSI H26-A2, EP09-A3
	Inaccuracy in inspection equipment	CV%	5% ↓	CLSI H26-A2, EP09-A3
	Lowest detection limit	CV%	1.645% ↑	CLSI H26-A2, EP09-A2
	Lowest limit of quantitation	CV%	15% ↓	CLSI H26-A2, EP09-A2



