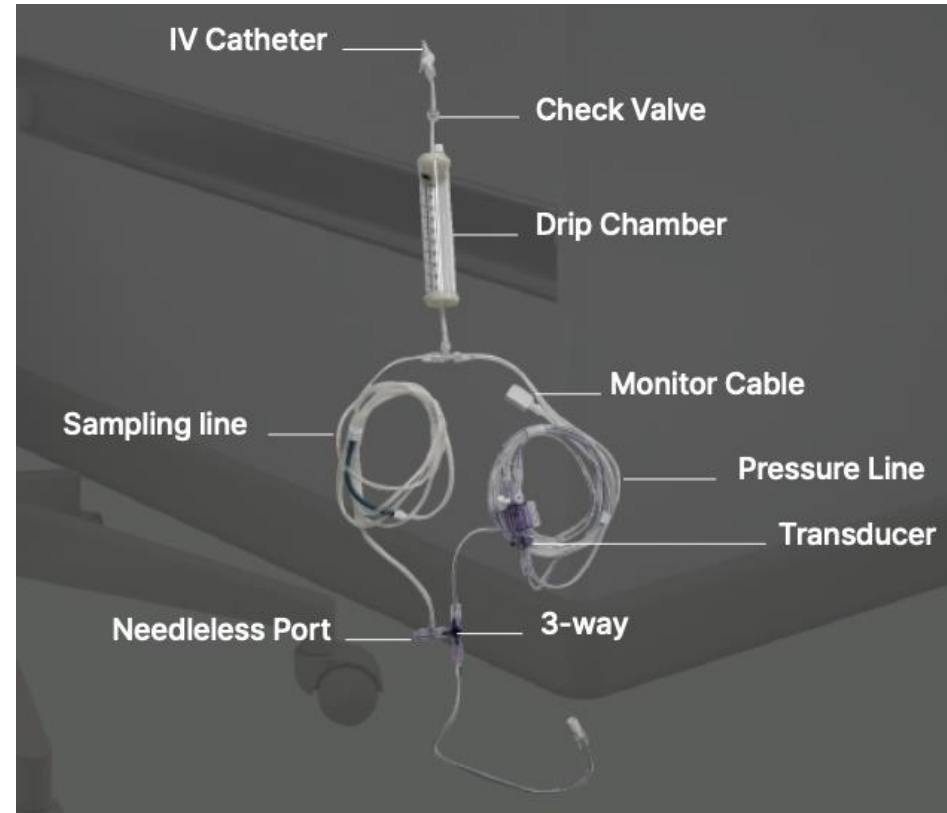# Invention of "LABline®", an automated blood sampling system through arterial line without blood loss

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Division of Acute Care Surgery, department of Surgery, Korea University Anam Hospital, Seoul, Korea

KU MEDICINE

What is "LABline®"?

LABLine®

Automated blood sampling system from A-line from Mune corp, Seoul, Korea

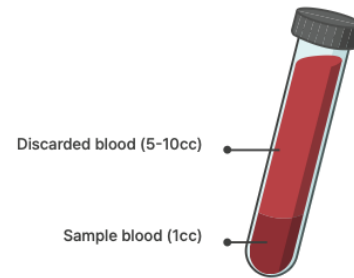# Why we invented new blood sampling device?

Background: The Clinical Problem

Discarded blood (5-10cc)

Sampling blood

"About 17% of blood loss in ICUs is due to diagnostic testing"

Discarded blood (5-10cc)

Sample blood (1cc)

ICU Arterial Line and Iatrogenic Blood Loss

Maximum Daily Discarded Blood Volume	About 240ml
Hb Level reduction rate	11.11%
Anemia Incidence after 7 days of ICU hospitalization.	97%

Arterial lines are widely used for frequent blood sampling in ICU patients.

However, initial volumes (clearing volume) are often discarded to avoid sample dilution, leading to significant iatrogenic blood loss.

This practice contributes to hospital−acquired anemia, especially in critically ill patients requiring frequent testing, contributing to the need for transfusions.
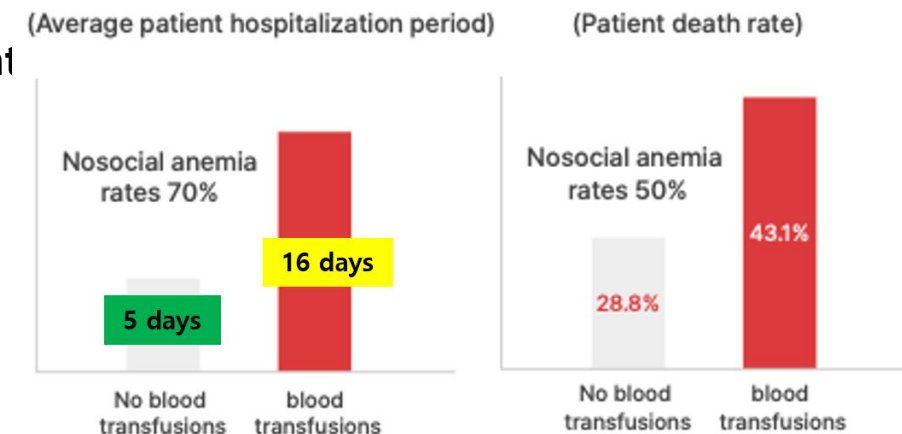
- 97% of patients experience hospital−acquired anemia by day 7 of hospitalization.
- Each arterial line sampling typically discards 4−10ml of blood.
- Cumulative blood loss can significantly impact hemoglobin and hematocrit levels.
- Increased blood transfusion requirements lead to associated complications and costs.

Background

The CRIT Study:

Anemia and blood transfusion in the critically ill--current clinical practice in the United States

- Study Overview
  - ✓ Design - Prospective, multicenter, observational cohort study
  - ✓ Setting - 284 ICUs across the United States
  - ✓ Population - 4,892 critically ill patients
  - ✓ Objective: **To evaluate the prevalence and impact of anemia and blood transfusion practices in ICU patients**
- Key Findings
  - ✓ Admission hemoglobin (Hb) - Mean 11.0 ± 2.4 g/dL
  - ✓ During ICU stay - **Hb levels progressively decreased in most patient**
  - ✓ Transfusion frequency - **44% of all patients received at least one**
  RBC transfusion.
- Clinical Outcomes
  Patients who received more RBC transfusions had
  1) Longer ICU stays and overall hospital stays
  2) Higher mortality

(Average patient hospitalization period)

Nosocial anemia rates 70%

16 days

5 days

No blood transfusions | blood transfusions

(Patient death rate)

Nosocial anemia rates 50%

43.1%

28.8%

No blood transfusions | blood transfusions
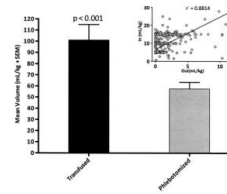
Background

Iatrogenic Anemia

When arterial blood is collected,
first blood is discarded
to eliminate diluted samples, resulting in patients developing iatrogenic anemia

4~10ml Discarded/Collection
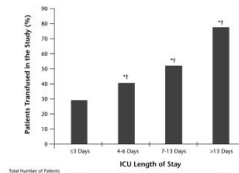**1~24** Collections/Day

~50ml Blood Loss/Day
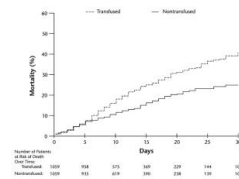
97% of patients develop anemia after **7 days**

Negative Effects Of Blood Transfusion

Correlation between blood removed for lab testing and transfusion (r²=0.8814)

Average patient transfusion rate according to length of stay

Blood transfusion and mortality comparison

Declining Blood Supply

The Red Cross reported that
the number of people donating blood
has dropped by 40% over the last two decades

U.S. Donor Blood Supply Running Low

Share of U.S. independent distribution infrastructure reporting the following levels of donor blood supply*

West Midwest South East

Supply for 0-1 days — 25%
Supply for 1-2 days — 47%
Supply for 3+ days — 2%
Data not available — 26%
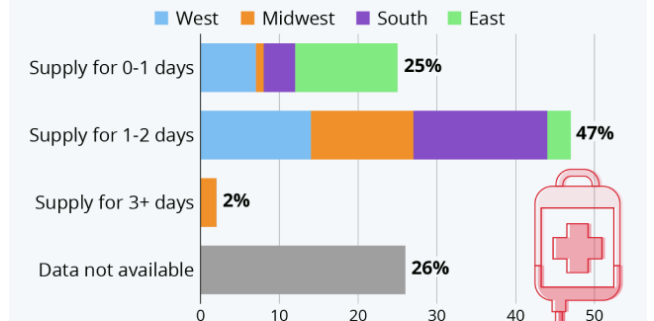
* as of Jan 10, 2022. Independent distribution accounts for 60 percent of U.S. donor blood supply
Source: America's Blood Centers

Background

- **Anemia is common among critically ill patients** and often **worsens** during ICU stay.

- Higher transfusion intensity was independently linked with poorer clinical outcomes.

- **It is important to prevent iatrogenic anemia**.

- **I want to sample without discarding the initial blood from A-line!**

Limitation of Existing Approaches: Need for Innovation

DIFFERENTIATION

Competitor solutions are inconvenient
and **have repeated FDA recalls**

**ICU Medical,
Safeset**

**Edwards Lifesciences,
VAMP**

**Merit Medical,
Safedraw**

Issues 01

Blood is trapped in reservoir structure with large surface area, causing clots

Issues 02

Induces damping of measurement of arterial pressure

Issues 03

Complicated usability causes errors in attachment, detachment, and operation of components

Solution 01

**Eliminate separate reservoir structure and employ peristaltic pump
for constant blood circulation**

Solution 02

Minimize components between the transducer and catheter in ABset

Solution 03

Automate the process, reducing user error, detachable components, and blood leakage

Initially, development began under the product name "HAMEL".

HAMEL: Hematic Auto-Management and Extraction for Arterial Line

Arterial Line

Hemodialysis machine peristaltic pump

LABline   IV hag
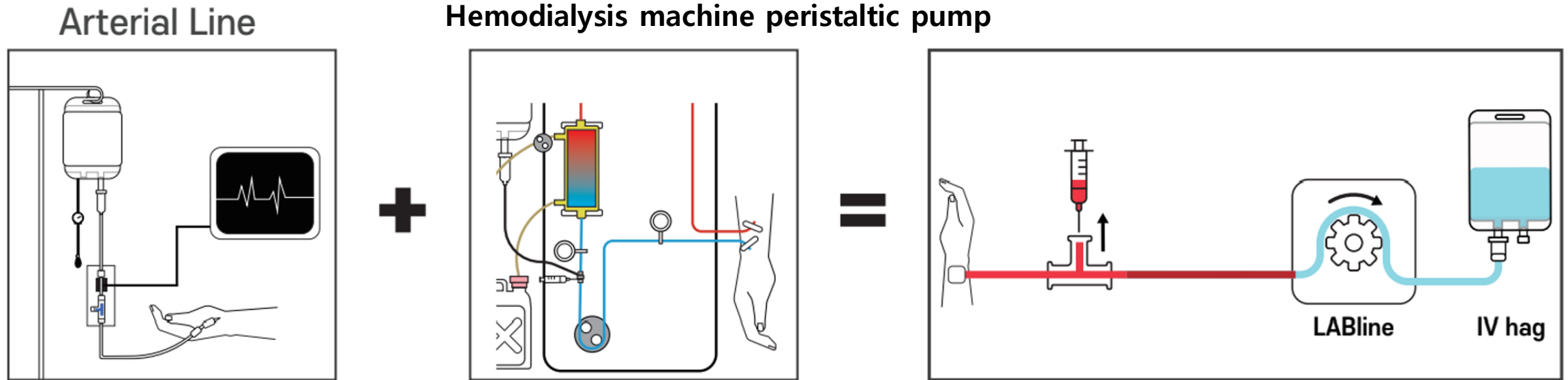
HAMEL is designed to preserve blood during arterial line sampling
by recirculating and clearing the dead space, eliminating unnecessary blood loss.

scientific reports

Check for updates

OPEN

Hematic auto-management and extraction for arterial line (HAMEL), a blood-preserving arterial line system: an animal study

Hanyoung Lee & Jae-myeong Lee

Invasive arterial line insertion is a common procedure in the intensive care unit ICU; however, it can cause unnecessary blood loss while procuring blood for laboratory tests. To reduce blood loss resulting from flushing out the arterial line dead space, we developed a new blood-preserving arterial line system: Hematic Auto-Management & Extraction for arterial Line (HAMEL, MUNE Corp.). Five male three-way crossbred pigs were used to evaluate the necessary amount of blood to be withdrawn before sampling to produce accurate results. We then tested whether the traditional sampling method and the HAMEL system showed non-inferior results for blood tests. Blood gas (CG4 + cartridge) and chemistry (CHEM8 + cartridge) analyses were used for comparison. The total unnecessary blood loss in the traditional sampling group was 5 mL/sample. For HAMEL, withdrawing 3 mL of blood before sampling yielded hematocrit and hemoglobin results within 90% confidence interval of traditional sampling group. Most intra-class correlation coefficients between the traditional sampling and HAMEL system groups were > 0.90. When compared to the traditional sampling method, withdrawal of 3 mL with HAMEL was sufficient before blood sampling. Utilization of the HAMEL system was not inferior to the traditional hand-sampling method. In addition, no unnecessary blood loss occurred in the HAMEL system.

Validation of Effectiveness with non-clinical studies

- Compare the blood test results of the control group (existing blood sampling method) and the experimental group LABline blood collection) by connecting the arterial lines to both femoral arteries, and analyze the equivalence of the results of each ABGA (arterial blood gas analysis) and electrolyte test results.

- The results of the blood tests are equivalent as a result of comparative analysis of intraclass correlation coefficient (ICC), proving the effectiveness of blood collection through LABline while simultaneously minimizing blood loss.

HAMEL Performance Validation
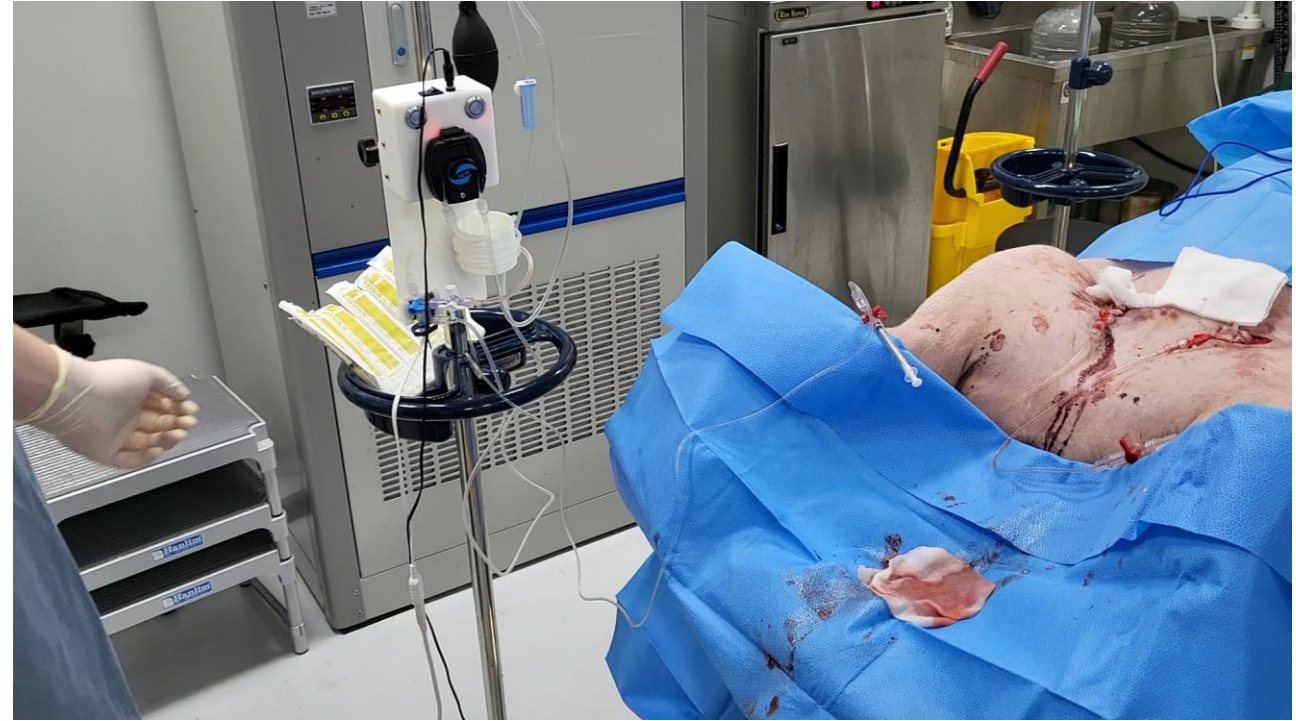
How HAMEL Works

SOLUTION

HAMEL PUMP

ABset (Single-Use)

Proven Technical Feasibility
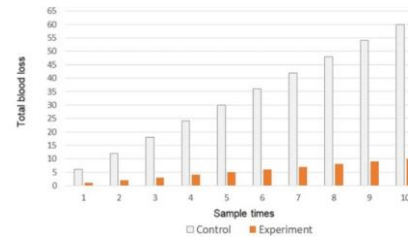
Total of 10 large animal experiments conducted from 2022 to 2023
Blood Test results of control group and LABline group are consistent (intraclass correlation coefficient analysis), proving consistent test results without blood loss
Research results listed in Scientific Reports
    (Sci Rep. 2023; 13:6845)

OPERATES IN

3 SIMPLE STEPS

1. REGURGITATE
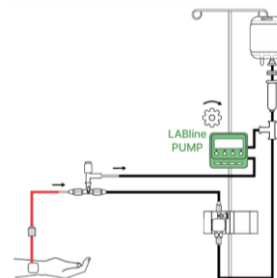
2. SAMPLE
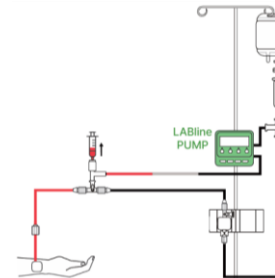
3. RETURN and FLUSH
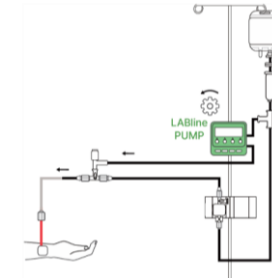
Prevents the occurrence of blood clots through **antithrombotic** mechanism of **periodic oscillation**

Figure 1. Comparison of HAMEL mechanism to traditional blood sampling method. HAMEL is automated for clearing out and flushing in of normal saline-mixed blood. Since entire process is performed inside closed system of fluid line, there is no unnecessary blood loss.

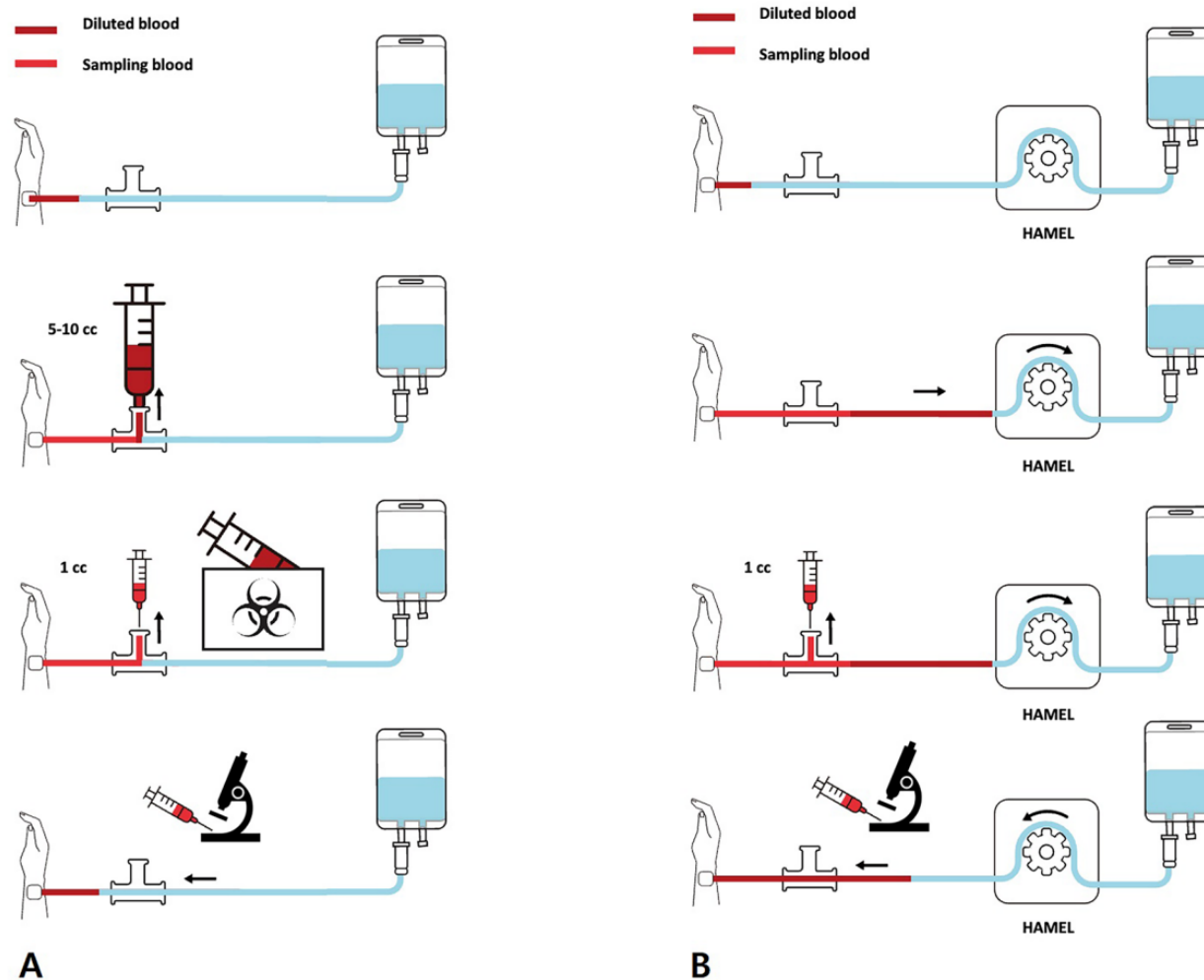|	ICC (2,1)	95% CI	p-value
pH	0.990	0.982–0.994	<0.001
pCO_2	0.984	0.971–0.991	<0.001
pO_2	0.987	0.977–0.992	<0.001
Base excess	0.890	0.806–0.938	<0.001
Bicarbonate	0.928	0.874–0.959	<0.001
Total CO_2	0.912	0.846–0.950	<0.001
Lactate	0.998	0.995–0.999	<0.001
Sodium	0.913	0.846–0.950	<0.001
Potassium	0.986	0.975–0.992	<0.001
Chloride	0.648	0.380–0.800	<0.001
Ionized calcium	0.988	0.979–0.993	<0.001
Glucose	0.993	0.988–0.996	<0.001
BUN	0.997	0.994–0.998	<0.001
Creatinine	0.988	0.978–0.994	<0.001
Hematocrit	0.965	0.939–0.980	<0.001
Hemoglobin	0.955	0.922–0.975	<0.001
Anion gap	0.719	0.506–0.840	<0.001

Table 1. Intraclass correlation coefficient (ICC) results comparing the control and experimental groups. Most results show ICC values higher than 0.9 with statistically significant p-values. The ICC model was a two-way random effect and single-measure model with absolute agreement. *ICC* intra-class correlation coefficient, *pCO_2* partial pressure of carbon dioxide, *pO_2* partial pressure of oxygen, *CI* confidence interval, *BUN* blood urea nitrogen.
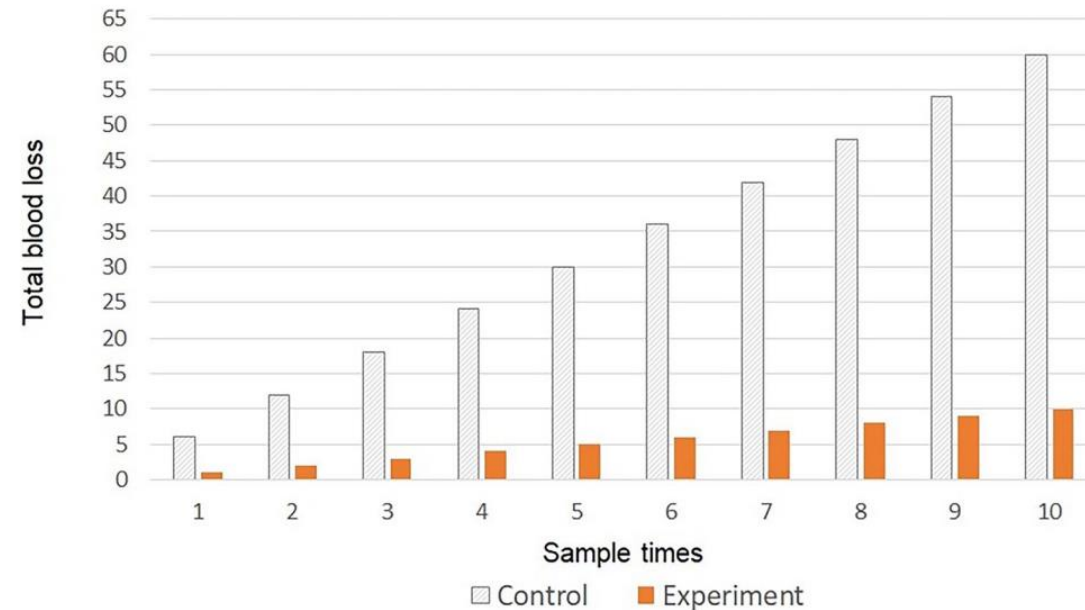
Figure 4. Difference in blood loss between the control and experimental groups. In the control group, 5 mL of dead space volume and 1 mL of sample volume were removed. In the experimental group, only 1 mL of sample volume was retrieved from the participant. (n = 50 for each group).

HAMEL Performance Results: Key Findings

Traditional Sampling:

Unnecessary blood loss: 5 mL per sample

Cumulative daily loss: 25-50 mL (5-10 tests)

Contributes to iatrogenic anemia

HAMEL/LABline System:

Unnecessary blood loss: 0 mL per sample

Only required sample volume drawn

Preserves patient blood volume

Validation Results:

Statistical analysis showed equivalent accuracy between traditional sampling and HAMEL system:

Most intra-class correlation coefficients (ICC) > 0.90 (excellent agreement)
Blood gas parameters (pH, pO_2, pCO_2): ICC = 0.92-0.98
Electrolytes (Na^+, K^+, Ca^{2+}): ICC = 0.90-0.97
Hemoglobin/Hematocrit: ICC = 0.94-0.95

Conclusion: The HAMEL/LABline system eliminates unnecessary blood loss while maintaining equivalent accuracy for all clinically relevant blood test parameters.

Post-Covid PBM Medical Technology Government Grant
(Korean health industry development institute)

보건의료기술 연구개발사업 협약서

중앙행정기관명	보건복지부		전문기관명	한국보건산업진흥원
사업명	포스트코로나시대 적정수혈을 위한 의료기술개발			
연구개발과제명	적정수혈을 위한 동맥관(arterial line) 혈액 보존채혈 자동화 시스템의 개발 및 임상적 유의성 근거확보 연구			
공고번호	보건복지부공고 제2022-317호		연구개발과제번호	HI22C129700
주관연구개발기관명	주식회사 뮨		연구책임자	오광빈
공동연구개발기관명	고려대학교 산학협력단		책임자	이재명

연구개발기간	전체		2022.07.01 - 2025.12.31 (42개월)
	단계	1	2022.07.01 - 2023.12.31 (18개월)
		2	2024.01.01 - 2025.12.31 (24개월)

연구개발비 (단위: 천원)	정부지원 연구개발비	기관부담 연구개발비		그 외 기관 등의 지원금				합계			연구개발비 외 지원금
				지방자치단체		기타()					
	현금	현금	현물	현금	현물	현금	현물	현금	현물	합계	
합계	700,000	46,666	70,000	0	0	0	0	746,666	70,000	816,666	0
1년차(22.07~22.12)	100,000	8,000	12,000	0	0	0	0	108,000	12,000	120,000	0
2년차(23.01~23.12)	200,000	17,333	26,000	0	0	0	0	217,333	26,000	243,333	0
1년차(24.01~24.12)	200,000	8,000	12,000	0	0	0	0	208,000	12,000	220,000	0
2년차(25.01~25.12)	200,000	13,333	20,000	0	0	0	0	213,333	20,000	233,333	0

Name change from "HAMEL" to "LABline"

The innovative blood-preserving arterial line system has been commercialized with a new product name:

HAMEL ➡ LABLine

The name LABLine better reflects its clinical focus on automated laboratory blood collection while preserving patient blood during arterial line sampling.

Emphasizes the connection to laboratory diagnostics

Aligns with commercial branding strategy

LabLine

LABLine: New Product Name

LABLine: Product Details and Specifications

Product name	LABline Pump
Dimensions	10.0 x12.5 x 9.0 (cm)
Weight	676g
Flow rate	1.1ml/s, 0.3ml/s(±5%)
Alarm	Obstruction, air, door, power
Manufacture	MUNE Corp.

Product name	LABline AB set
Dimensions	Refer to diagram
Measurement range	–50 ~ + 300 mmHg (±3%)
Humidity	10 ~ 90% RH
Operational Temperature	–20 ~ + 60 °C
Pressure range	–500 ~ +5000mmHg
Period of Protectin	3 year
Manufacturer	MUNE Corp.

LABLine: Product Details and Specifications

LABLine Pump

Blood sampling, transfusion & diagnostic device

Classification number: A66000

Approval number: No. 25-377

Automated blood preservation system

LABLine ABset

Intra-arterial pressure monitor kit

Classification number: A23020.01

Regulatory approval in process

Key Product Features:

Blood conservation system that eliminates wastage during arterial line sampling

Automated blood sampling process with closed-loop design

Compatible with standard hospital A-line setups and protocols

LABLine Advantages (1): Clinical Benefits

LABLine significantly improves patient outcomes by preserving blood volume that would otherwise be discarded during arterial line sampling procedures.

- Minimizes iatrogenic blood loss by eliminating the need to discard clearing volume

- Maintains patient hemoglobin and hematocrit levels, especially critical in ICU settings

- Reduces transfusion needs and associated complications (infection risk, immune response)

- Supports blood conservation strategies, particularly beneficial for patients requiring frequent testing

LABLine Advantages (2): User & Workflow Benefits

LABLine streamlines arterial sampling workflows and significantly improves user experience:

One-touch operation simplifies blood sampling procedure

Reduces manual handling and exposure risk with closed system

Minimizes user variability in sampling technique

Enables automated sampling process from clearing to flushing

Reduces sampling time and improves workflow efficiency

LABLine Advantages (3): Economic & Operational Impact

LABLine provides significant economic benefits while improving clinical outcomes, creating value for both patients and healthcare institutions.
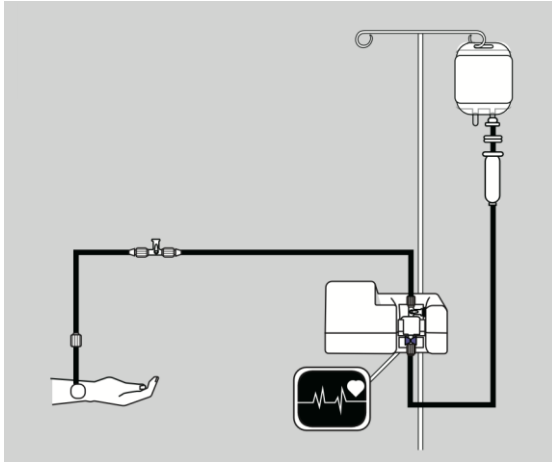
No additional consumable costs compared to standard arterial line setups

Not subject to extra reimbursement fees - classified as a medical device package

Wide adoption potential across multiple departments: ICU, Anesthesiology, Emergency Room, and Surgical units

Reduces transfusion-related costs by minimizing iatrogenic anemia

Current LABLine Operating Protocol

Simplified Structure to accommodate User Experience

Step-by-Step Operating Protocol

Automate Dead Space Clearing

System withdraws 3mL to clear dead space without blood waste

➡

Collect Accurate Sample

Draw 1mL blood sample for laboratory testing

➡

Maintain Closed System

System returns cleared blood and flushes line with normal saline
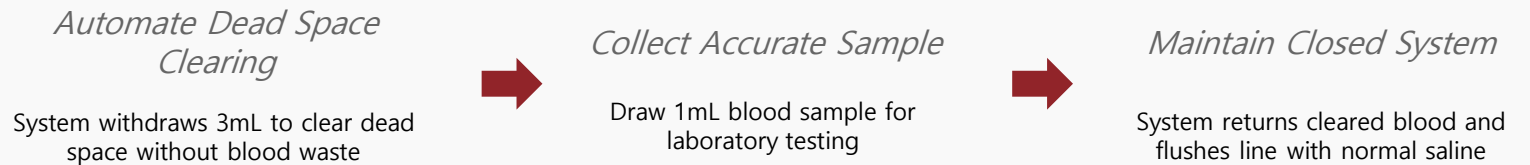
Key Benefit: Zero blood loss with automated protocol - preserves patient hemoglobin levels

LABLine simplifies the blood sampling procedure with a closed automated system that eliminates iatrogenic blood loss while maintaining sample accuracy.

Research Achievements & Roadmap

April, 2023	November 13-16, 2023	October, 2024	December 2024	September 17-20, 2025
1st Animal Study Publication	**MEDICA Exhibition**	**2nd Animal Study**	**Regulatory Approval**	**SABM, Annual Meeting**
Performance Validation Animal Studies	Presentation at international medical trade fair in Düsseldorf, Germany	Safety Validation Animal Studies Publication pending (peer review)	Completion of regulatory approval process	Infographics 3rd Place Award (2024, 2025)

Research Achievements

Scientific Publication: Research results published in Scientific Reports (2023)

Animal Study Success: Validation of blood sampling accuracy and zero blood loss

Research Grant: Awarded medical technology development project for post-COVID optimal transfusion

Future Development Plans

Automated Sampling: Integration of automated blood sampling technology

Clinical Trials: Multi-center validation studies planned for 2024

Market Expansion: International marketing and distribution partnerships

Future Plans & Product Roadmap

2024 Q3-Q4
Current Version
Basic automated blood sampling with peristaltic pump system

2026 Q1
ABset Approval
Simplified structure model,
Bio Compatibility Testing

2026 Q1
Version 2.0
Automated valve system integration for improved workflow

2026 Q2-Q3
Version 3.0
Direct integration with testing devices and hospital LIS

2026 Q4+
Global Version
International certification and global market expansion

Technical Enhancements

Valve Automation: Integration of automated valve systems to eliminate manual manipulation

Testing Device Integration: Direct connectivity with point-of-care testing devices

Full Automation: Complete sampling process automation reducing human intervention

Market & Clinical Development

Clinical Trials: Multi-center validation studies in major teaching hospitals

Global Expansion: Entry into EU, US, and Asian markets with local partners

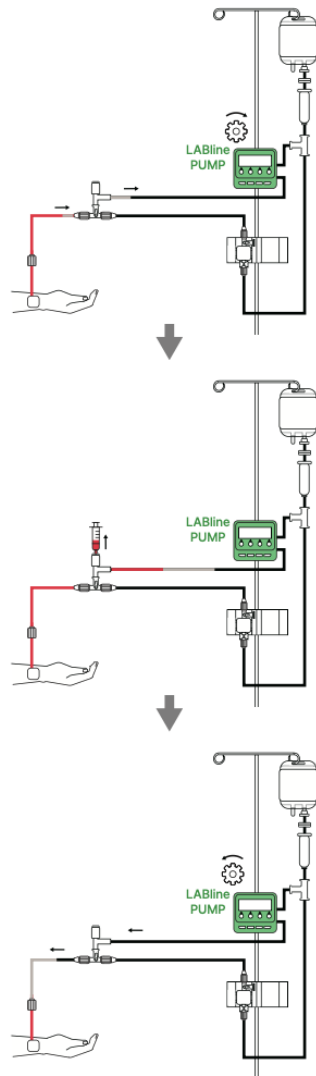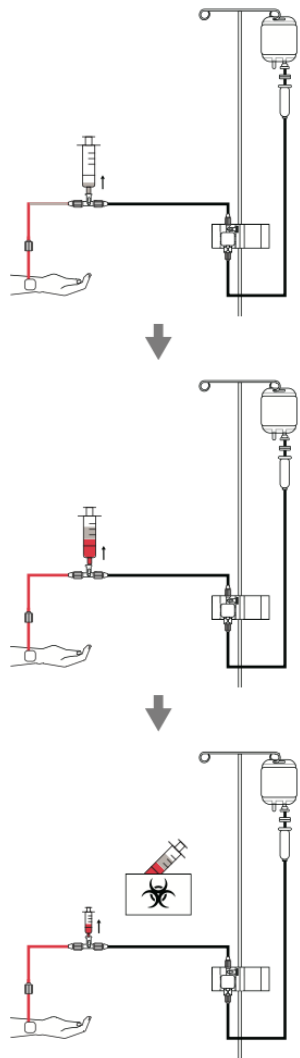Clinical Data Collection: Real-world evidence of blood conservation benefits

Next Steps

| Sampling Process Optimization | Hospital Information System Integration | Enhanced User Interface Development |

"LABline®" summary

HAMEL's automated blood sampling system features:

Peristaltic pump technology for precise fluid control

Automated regurgitation of dead space blood (clearing volume)

Blood sample collection - only the required volume is drawn

Automated re-infusion of clearing volume to patient

Key Innovation: Closed-loop system eliminates unnecessary blood loss while maintaining sample accuracy and integrity (ICC >0.90 in validation studies).

Thank you very much for your attention!

Reference

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