MILLER MEDICAL

Full Blood Counts In Minutes

iMOST® Hematology Analyzer

The Power of the Lab, **without the Lab**

Arrange a Trial or Demonstration Today

FAST | ACCURATE | PORTABLE | RELIABLE
POWERED BY LITHIUM

CE Mark Approval

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> “For the first time we can run an CBC in clinic and act on it straight away — patients love it”
>
> GP PARTNER, PRIMARY CARE NETWORK

ACCURATE
Provides reliable test results even under imperfect conditions

FAST
Delivers results within minutes

EASY-TO-USE
Portable, intuitive, and seamlessly connected for smooth operation

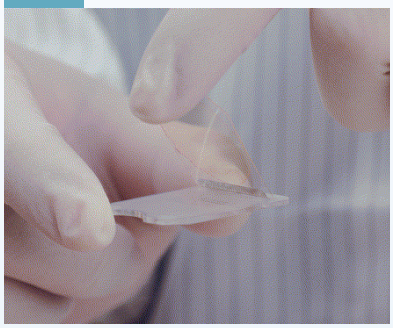
COST-EFFECTIVE
Simple and affordable devices and tests

RELIABLE
Features on-chip quality control and image records for consistent accuracy

PORTABLE
Lithium battery allows 30 tests on one charge

Easy to use

1



Open Q-Card and place it on the presser

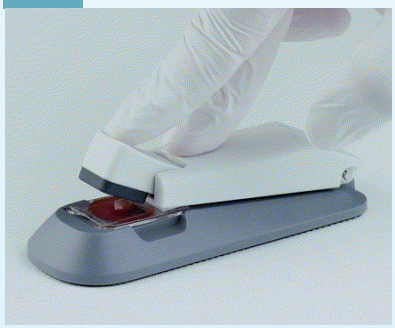
2

Apply 10µL capillary or venous blood

3

Drop blood onto the Q-Card

4



Close the Q-Card

5

Insert it into Analyzer

6

Delivers results in approx. 4 minutes

iMOST® U IS INTENDED FOR USE:

- COMMUNITY CLINICS
- HOSPITAL EMERGENCY DEPARTMENTS
- INPATIENT WARDS
- HEALTH & TESTING CENTERS

For the quantitative measurement of key CBC parameters in small-volume (10 microliters) venous and capillary blood samples. iMOST® U should be used only with the iMOST® U test cards (Q-Card). iMOST® U is suitable to be used for testing for adults and adolescents, and children. iMOST® U supports integration with electronic medical record systems.

Features

Built in battery for portability

Small 10mcl sample from the finger

Results in under 4 minutes

Complete blood count including RBC, WBC with 5 part differential

KEY CLINICAL BENEFITS

- **Full blood counts in minutes** for faster triage and treatment
- **Lab-quality accuracy** without waiting for central laboratory processing
- **Supports urgent decisions** in ED, ambulatory, GP community hubs, and wards
- **Improves patient flow** by reducing bottlenecks and retests
- **Ideal for fragile or limited samples** — works with ~10µL capillary or venous blood

SIMPLE, RELIABLE TESTING

- Minimal training required
- Disposable Q-Cards contain sealed reagents — no mixing, measuring, or manual prep
- Reduced risk of handling error from fully guided testing
- Automated analysis and interpretation via advanced imaging and AI
- Built-in quality controls to support repeatable, trusted results

SMART TECHNOLOGY IN A SMALL FOOTPRINT

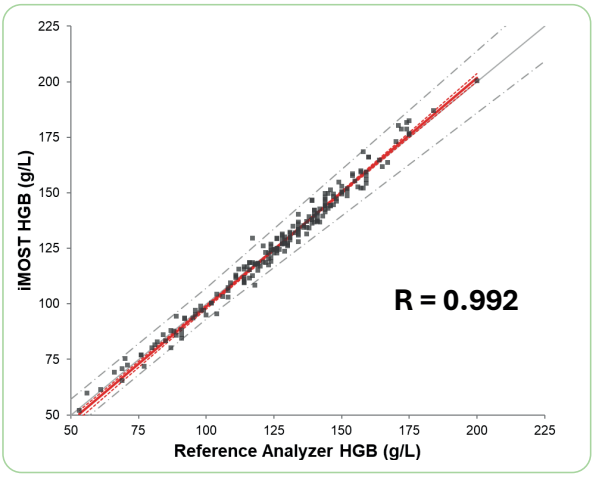
- Combines micro- and nanotechnology, biochemical processing, and computer vision
- Compact, lightweight design — easy to position where care happens
- No complex installation, specialist staff, or external reagents
- Can be deployed in settings with limited space or resources

TECHNICAL SPECIFICATIONS

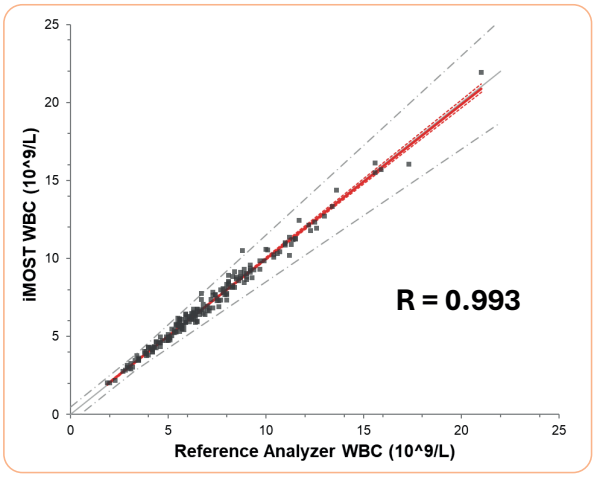
Current Parameters	19 (HGB, WBC, PLT, RBC, 5-DIFF, etc.)
Measuring Time	4 - 4.5 minutes
Data Analyze	Local on device
Sample	Capillary blood or K2EDTA venous blood
Sample Volume (on Q-Card)	10 µL
Dimensions	220 mm x 110 mm x 80 mm
Weight	997 g
Connection / HIS-LIS	Support connection to HIS/LIS via WIFI or 5G

Accuracy You Can Trust

Hemoglobin (g/L)



White Blood Cell (x 109 /L)



CURRENT TEST PARAMETERS

TEST PARAMETERS	iMOST®-U
Hemoglobin (HGB)	✓
White Blood Cell Count (WBC)	✓
Platelet Count (PLT)	✓
Red Blood Cell Count (RBC)	✓
Neutrophil Percentage (NEU%)	✓
Lymphocyte Percentage (LYM%)	✓
Monocyte Percentage (MON%)	✓
Eosinophil Percentage (EOS%)	✓
Basophil Percentage (BAS%)	✓
Neutrophil Count (NEU#)	✓
Lymphocyte Count (LYM#)	✓
Monocyte Count (MON#)	✓
Eosinophil Count (EOS#)	✓
Basophil Count (BAS#)	✓
Mean Corpuscular Volume (MCV)	✓
Hematocrit (HCT)	✓
Mean Corpuscular Hemoglobin Concentration(MCHC)	✓
Mean Corpuscular Hemoglobin (MCH)	✓
Red Blood Cell Distribution Width (RDW)	✓

CORRELATION COEFFICIENT (R)

MEASURED	VENUS	CAPILLARY	SELF TEST
HGB (g/L)	0.996	0.993	0.994
WBC (x10³ /µL)	0.997	0.997	0.998
NEU# (x10³ /µL))	0.996	0.997	0.998
LYM# (x10³ /µL)	0.981	0.979	0.977
MON# (x10³ /µL)	0.993	0.991	0.992
EOS# (x10³ /µL)	0.904	0.920	0.920
BAS# (x10³ /µL)	0.964	0.957	0.974

*Correlation coefficient (r) vs. Lab Gold-Standard Analyzer Reference

- iMOST® analyzer provides a reliable, clinically validated alternative to centralized CBC testing, enabling immediate and accurate diagnostic decisions
- One of the biggest hurdles in hematology is maintaining accuracy between venous draw and capillary prick. iMOST® eliminates this gap

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iMOST® FAQs

This FAQ is intended for general informational purposes. Regulatory status, permitted use, and commercial terms are subject to local laws, approvals, and distributor agreements

Regulatory & Market Access

1. **What regulatory approvals does iMOST® currently have?**

   The iMOST® platform (specifically iMOST®-L and iMOST®-U) carries CE-IVD / IVDR marking. It is registered or deployed across multiple regions, including the EU and parts of Asia. Manufacturing occurs in ISO 13485–certified facilities that have been audited by global IVD partners

2. **Is Point-of-Care Testing (POCT) included in its intended use?**

   Yes. Under current CE-mark approvals, POCT is explicitly included in the intended use. This supports deployment in decentralized and near-patient settings

3. **Does iMOST® support Patient Self-Testing (PST)?**

   iMOST® is currently obtaining PST-specific approvals in select regions. For CE-marked regions, the platform is currently positioned for POCT (professional use) rather than PST. However, preparation for future PST support is underway. Always refer to local labeling/ IFU for defined users and settings

4. **What is the FDA status of iMOST®?**

   The iMOST® platform is not yet cleared or waived by the FDA. U.S. FDA 510(k) and CLIA waiver submissions are currently in preparation

Product & Performance

5. **What are the primary differences between iMOST®-L and iMOST®-U?**

Feature	iMOST®-L	iMOST®-U
Parameters	12 parameters (including 5-part diff)	19 parameters (Full CBC + Indices)
Runtime	~3–3.5 minutes	~4–4.5 minutes
Sample Transfer	Direct finger-to-card transfer	Recommended K2EDTA tube collection

6. **How much blood is required?**

   Each test requires approximately 10 µL of blood applied to the Q-Card.

   For iMOST®-L, direct finger-to-card transfer is supported. If there will be a delay before testing, collecting the sample in an Essenlix-recommended K2EDTA tube is recommended to help maintain sample integrity.

   For iMOST®-U, it is recommended to collect capillary blood into an Essenlix-recommended K2EDTA tube (approx. 100 µL) prior to testing

7. **Does iMOST® support capillary blood testing?**

   Both capillary (fingerstick) and venous samples are supported per local labeling

8. **How accurate is the system?**

   iMOST® demonstrates lab-comparable agreement with high-end central lab analyzers, such as the Sysmex XN series. Clinical studies show strong correlation across CBC parameters, including HGB (r≈0.99) and WBC (r≈0.99)

Usability & Workflow

9. **How complex is the testing process?**

   The workflow is designed for maximum simplicity: One Q-Card, one press, one insertion. There is no need for complex sample preparation, dilutions, or multi-step mixing

10. **What training is required?**

    Training is minimal. Remote or online sessions lasting 30 to 60 minutes are typically sufficient for operators. Usability studies confirm that users with limited lab experience can operate the device effectively

Quality Control & Calibration

11. **What QC mechanisms are built into the platform?**

    iMOST® utilizes a multi-layered QC approach:

    - Automatic Checks: Electrical, optical, and system-level self-checks
    - Solid QC Card: A physical card for pass/fail verification
    - Liquid QC: Optional support for third-party liquid materials

12. **Is routine calibration necessary?**

    No. Devices are factory-calibrated, and no routine user calibration is required

13. **What happens if a Quality Control (QC) check fails?**

    The response protocol depends on the specific error type. While troubleshooting can often be conducted remotely, certain situations may necessitate a service or a formal device inspection

14. **Does Essenlix participate in external QC programs (e.g., CAP, Randox)?**

    Participation in external QC programs needs to be evaluated. Please note that traditional QC materials may not always be compatible with the system due to unique differences in measurement principles

Connectivity & IT

15. **Can iMOST® integrate with LIS/HIS systems?**

    Yes. iMOST® supports HL7 for direct LIS/HIS integration

16. **Is cloud connectivity required?**

    No. Cloud connectivity is optional. All analysis is performed locally on the device

Manufacturing & Logistics

17. **Where is iMOST® manufactured?**

    The iMOST® platform is manufactured in Shanghai, China, within ISO 13485–certified facilities. These sites have successfully undergone rigorous audits by global IVD partners

18. **What are the recommended storage conditions for Q-cards?**

    Q-Cards support room temperature storage (-5°C to 40°C, humidity < 90%)

19. **What is the shelf life of Q-cards?**

    Current validated shelf life is 12 months, with studies ongoing to extend this to 24 months

Service, Maintenance & Spare Parts

20. **When is the analyzer considered out of warranty?**

    The analyzer is deemed out of warranty under the following conditions:

    - Expiration: The standard warranty period has concluded
    - Usage Limits: The device has exceeded the specified warranty test-volume limit as defined in commercial terms
    - Misuse: Damage or malfunction occurs due to unauthorized modification, improper handling, misuse, or operation outside of specified environmental conditions

    After the warranty period ends, Essenlix provides paid technical support, including spare parts and repair or replacement options. Specific duration and coverage details are governed by your applicable commercial agreement and warranty policy

Future Roadmap

21. **Is iMOST® limited to CBC testing?**

    No. iMOST® is a multi-assay platform; CBC is the first available test

22. **What assays are planned for future expansion?**

    Subject to development progress, regulatory approvals, and market priorities, the following expansions are currently planned for the iMOST® platform:

    - Urine Analysis: Sediment cell analysis and ACR (Albumin-to-Creatinine Ratio)
    - Blood Analysis: CRP (via docking station), CD-4 test
    - Chemistry panels: kidney, liver, lipid),
    - Immunoassay and molecular tests

For more infomation scan the QR code

What makes the iMOST®-U different

The iMOST-U is fast, user-friendly, and cost-effective, while ensuring the accuracy and reliability of lab-quality test results. It is built to be fault-tolerant, delivering dependable outcomes even when samples, devices, or operating conditions are less than perfect.

Experience the IMOST Hematology Analyzer in your clinical setting

NANOTECHNOLOGY

ADVANCED IMAGING

NANO ENABLED-AI

NEW BIOCHEMICAL

GET IN TOUCH TO REQUEST A TRIAL OR A DEMONSTRATION.
LIMITED NUMBER OF TRIAL UNITS AVAILABLE.

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