PixCell MEDICAL

℞ only

# HemoScreen

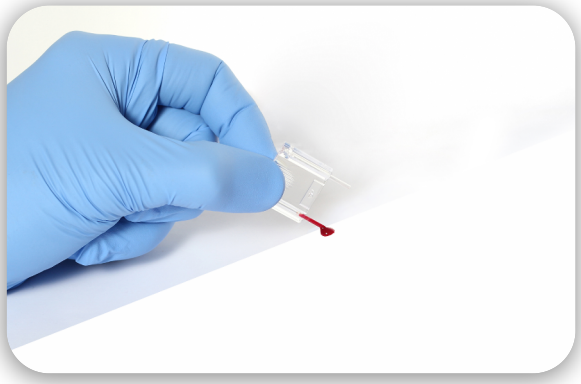
## True Point of Care Hematology


PixCell Medical Ltd. | 6 Hayezira St., POB113, Yokneam Illit, Israel | Office: +972-4-959-3516 | Mail: info@pixcell-medical.com

# Simplifying real-time blood testing for everyone, everywhere.

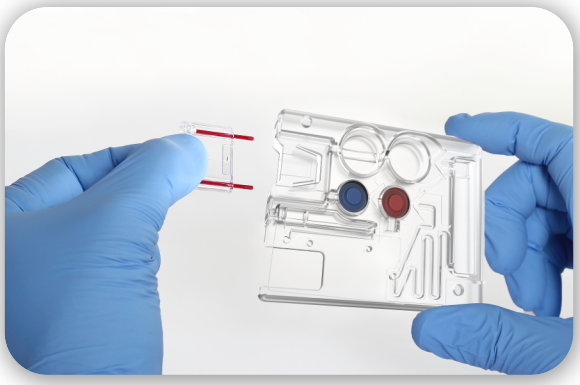
## Simple

The HemoScreen™ analyzer makes blood testing exceptionally simple, using a disposable cartridge that includes all necessary reagents and requires no maintenance or calibration.



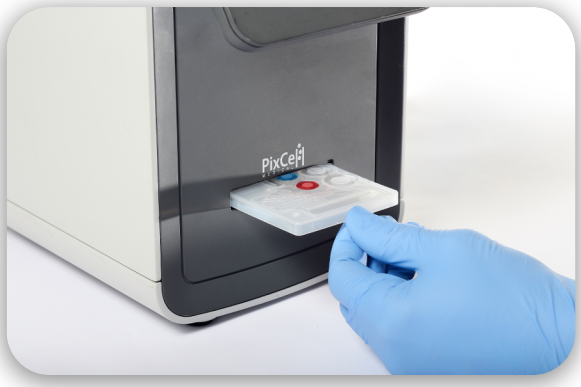
1

### Draw blood sample



2

### Insert sample into Cartridge




3

### Insert Cartridge into Analyzer

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# Rapid

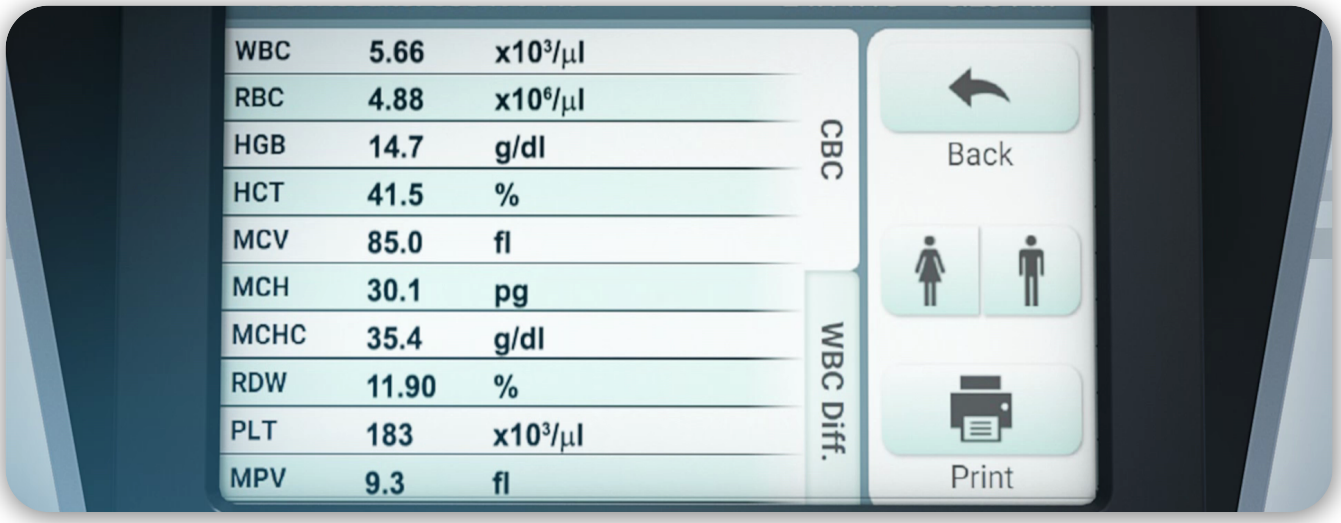
HemoScreen™ shortens turnaround time significantly by providing CBC results within 5 minutes, in the doctors office, ER, ICU, or expert clinics - no need for centralized labs. Physicians can diagnose, monitor, and make substantiated treatment decisions for patients during a single office visit.

**5 minutes** from test to result

# Accurate

HemoScreen™ measures 20 standard CBC parameters, including 5-part leukocyte differential, with the accuracy and precision of the most advanced central lab analyzers.
It's performance has been validated in multiple scientific peer-reviewed studies*, and the analyzer is **FDA**-cleared and **CE**-marked for both venous and capillary blood samples.
HemoScreen™ also offers a comprehensive flagging panel for the presence of WBC, RBC, and PLT distributional and morphological abnormalities.

* see www.pixcell-medical.com/evidence




# Robust

HemoScreen™ has been specifically designed to withstand the demanding point-of-care environment and maintain performance no matter the operator's experience level.
Manufactured according to the highest quality standards, HemoScreen™ uses the most durable components.
No maintenance and minimum downtime is guaranteed due to the analyzer's liquid-free design, as liquid reagents and blood samples reside in the cartridge throughout the process and do not come into contact with the analyzer.

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# Physical Specifications

**Analyzer dimensions & weight**

| Height | Width | Depth | Weight |
|---|---|---|---|
| 30 cm | 17.5 cm | 26 cm | 5.5 kg |
| 11.8 in | 6.9 in | 10.2 in | 12.1 lb |

**Throughput:** ~10 samples/hour

**Operating temperature & humidity:**
+17°c (+63°f) to +27°c (+81°f) - relative humidity of 10%-90% maximum, without condensation

**Specimen volume:**
CBC mode: 20µl | Diff mode: 20µl

**Power requirements:**
Power supply: 100–240VAC, 2-4A, 50/60Hz
Power consumption: Approx. 60W

# Software Specifications

**Data Processing**

- LCD display and touch panel
- Operating System: Windows 10
- Connection: Ethernet, USB
- Connectivity to LIS: HL7 & POCTIA
- Optional: bar code reader, printer

**Quality Control**

- PIX002 PIX-CBC 3-levels liquid control (R&D Systems, MN, USA, a Bio-Techne company)
- Target values download (USB, 2D bar code reader)

# Parameters & Performance Data

**20 parameters:**

| | | |
|---|---|---|
| WBC | RBC | PLT |
| NEU# & NEU% | HGB | MPV |
| LYM# & LYM% | HCT | |
| MON# & MON% | MCV | |
| EOS# & EOS% | MCH | |
| BAS# & BAS% | MCHC | |
| | RDW-CV | |

Including flagging of immature granulocytes (IG), nucleated RBC, blasts, and Atypical Lymphocytes.

**Linearity:**

| Parameters | Units | Linearity Limits |
|---|---|---|
| WBC | $10^3/\mu L$ | 0.5-80 |
| RBC | $10^6/\mu L$ | 1.0-8.8 |
| HGB | g/dL | 3.0-25.0 |
| HCT | % | 9.0-78.0 |
| PLT | $10^3/\mu L$ | 20-800 |

**Precision (repeatability):**

| Parameters | Units | CV (%) |
|---|---|---|
| WBC | $10^3/\mu L$ | ≤5.0 |
| RBC | $10^6/\mu L$ | ≤2.2 |
| HGB | g/dL | ≤2.2 |
| HCT | % | ≤2.3 |
| PLT | $10^3/\mu L$ | ≤3.5 |

# Measurement Principles

HemoScreen™ uses a patented technique called viscoelastic focusing, which causes the cells to perfectly align into a single plane. High resolution microscopic images are taken of the flowing cells. Each image is then analyzed using machine vision and AI algorithms, and the various cell types are differentiated and counted. WBCs are stained prior to analysis to enable differentiation between their subtypes and abnormal cells. HGB is calculated based on the optical density measured on individual intact cells.
The HemoScreen analyzer is factory calibrated. No further calibration is required.

# Standards

- IVDD 98/79/EC
- EN ISO 13485
- IEC 61010
- IEC 61010-2-101:2019
- EN 60601

# Approvals

- CE (IVDD Directive 98/79/EC Annex III)
- FDA Clearance Number: K180020
- ETL Mark (US & Canada): Listing Number 5012972
- TGA Approval (Australia)
- AMAR Certificate (Israel)

CE ⚠
See instructions for use

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EL-00012 Rev.02 HemoScreen Brochure

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