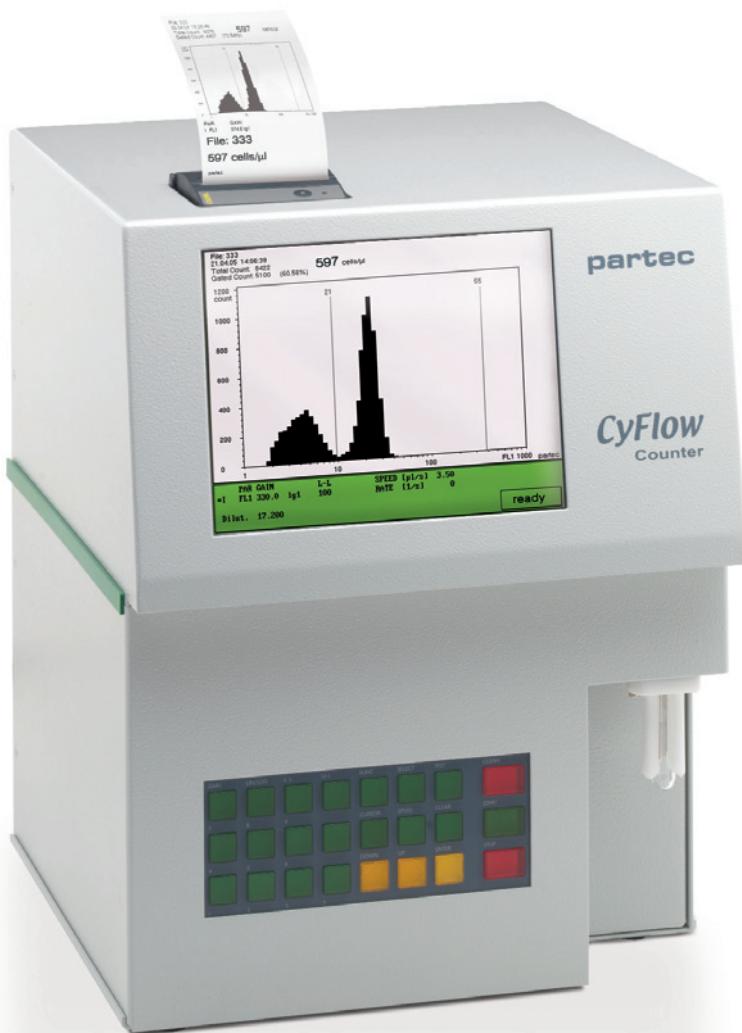




partec

CyFlow® Counter

Healthcare | Immunology



Portable FCM System for Routine HIV/AIDS Monitoring of Adult and Pediatric Patients

01 COMPANY

Flow Cytometry made in Germany



New sophisticated applications and increasing requirements for reliable results in research and clinical routine within the shortest possible time - The challenge for flow cytometry instrumentation, automation, and software.



partec

A well-established network of subsidiaries and distributors in more than 60 countries worldwide characterizes Partec's commitment to the increasing focus and need for global access to Flow Cytometry instrumentation and application support:

www.partec.com/partec/distributors.html



More than 35 Years of Experience and Professional Expertise

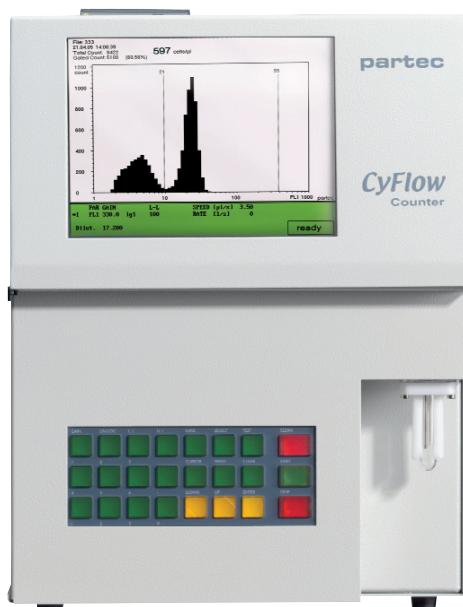
Partec – pioneer in Flow Cytometry since 1968 – responds to these requirements with the new generation of Windows™XP based CyFlow® and PAS™ FCM systems featuring innovative computer controlled flow systems, modular optical systems with advanced PMTs for all optical channels, most modern computer and digital electronic technologies including fast and precise 16 bit ADC converters and realtime data acquisition and display.

02 HIGHLIGHTS

CyFlow® Counter FCM System



- _ ultracompact and fully equipped mobile/portable instrument
- _ dimensions [cm]: L 30 x H 35 x D 38
- _ highest stability/robustness and highest precision
- _ single platform True Volumetric Absolute Counting (TVAC)
- _ high fluorescence sensitivity < 50 MESF (PE)
- _ power connection: regular 100/240 V AC or car battery and solar panels (12 V DC)
- _ set-up time: < 5 minutes
- _ volumetric absolute counting of CD4, CD45, CD8, CD3
- _ price per CD4 test: EUR 1.75
price per CD4% test: EUR 2.50
- _ capacity: up to 250 CD4 or CD4% tests per day
- _ price for CyFlow® Counter including 1000 CD4 tests: EUR 16,850



03 TECHNOLOGY

CyFlow® Counter FCM System



The ultracompact and portable CyFlow® Counter provides most accurate and uniquely affordable absolute cell counts for HIV/AIDS monitoring both, for adults and children.

| Compact and Affordable

The CyFlow® Counter is a fully equipped portable ultracompact desktop flow cytometer dedicated to routine CD4 counting (as well as CD8, CD3, CD45 counting). With its small size and its highest robustness the CyFlow® Counter is easy to place even in small hospitals and laboratories in remote and resource-poor areas such as on provincial and district levels. This enables decentralized use close to the patients. It is the perfect device in HIV monitoring to replace more expensive and highly service demanding large flow cytometers and CD4 counters. With the new alignFree™ technology, optical alignment and adjustment as known from the conventional systems are not required anymore, making the CyFlow® Counter the first and only real "plug&play" CD4 counter. A dramatical cut-down of the costs per CD4 count and the running costs are therefore achieved. Service and maintenance requirements are reduced to a neglectable minimum.

| alignFree™ Technology

The CyFlow® Counter benefits from the revolutionary alignFree™ technology. With this important innovation, difficult and time-consuming optical alignment and adjustment as are known

from the large conventional systems are unnecessary. Using the CyFlow® Counter, the lab can concentrate on the routine HIV monitoring without being urged to perform regular alignment and adjustment tasks. This significantly diminishes the dependency on techsupport, and general maintainance. Accordingly, the CyFlow® Counter is suitable even for the remotest locations.

The complete optical system of the CyFlow® Counter is designed as one solid metal block. Time consuming installation, optical checks, realignments of the laser and readjustments of the optical systems are not required any longer. In conjunction with the alignFree™ technology, the installation and set-up time of the CyFlow® Counter is reduced to a few minutes, only. In order to get the first CD4 cell count in the morning, it takes less than 15 minutes including the unique no lyse – no wash Partec CD4 easy count protocol.

| High Precision

The green solid state laser of the CyFlow® Counter shows a unique short and long term stability superior to water and air cooled gas lasers. Highest precision and most accurate T-cell enumeration are maintained by the extraordinary long lifetime of solid state lasers.

Selection of Fluorochromes for the CyFlow® Counter Light Source System

Type of laser

green solid state laser 532 nm

Fluorescence Channel

Fluorochromes

ORANGE
RED

PE
PE-Cy5

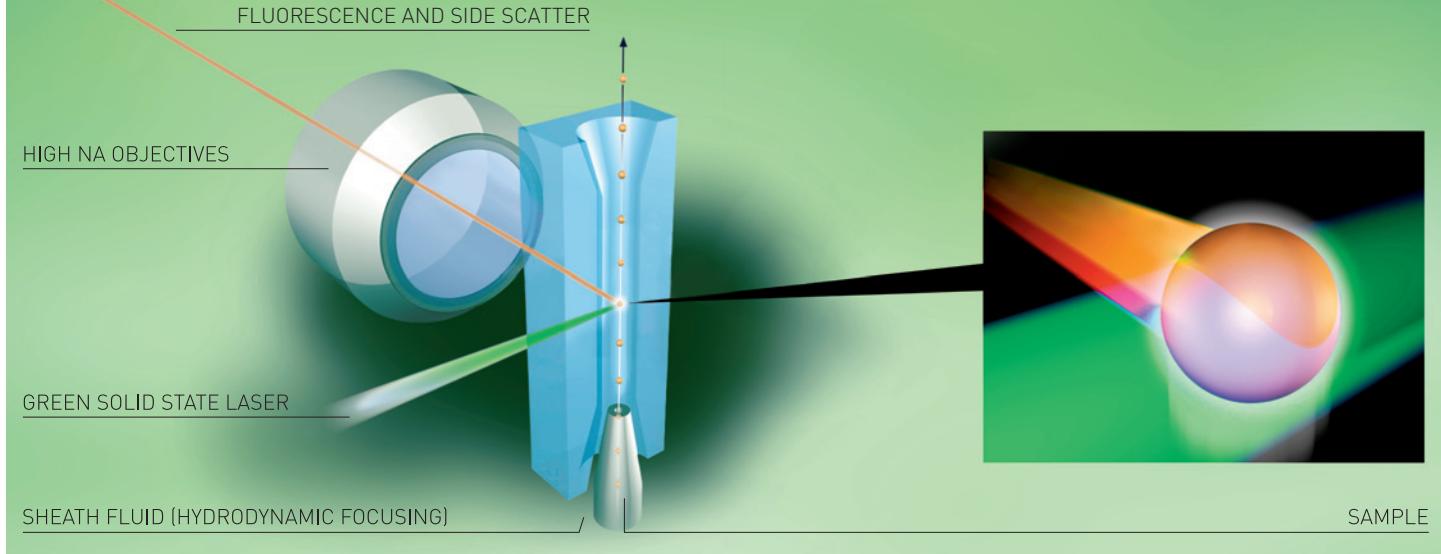
Alexa Fluor® 532
PE-Cy5.5

SYTO 80-83

PI

CY 3

7-AAD



The unique Partec flow cuvette is the heart of the CyFlow® Counter, ensuring that cells cross the excitation light with best possible precision.

The design of the flow cuvette incorporates more than 35 years of experience in handling fluids with sub-micrometer and nanoliter precision. Thanks to the optical and mechanical precision of the flow cuvette, superior results are guaranteed

for all parameters. The sample is transported with help of a computer controlled digital syringe pump, part of a virtually cross-contamination-free fluid system.

The True Volumetric Absolute Counting (TVAC) is a unique feature of all Partec Flow Cytometers, offering highest absolute counting precision and accuracy.

The CyFlow® Counter analyses concentrations of any particle or cell subpopulations of interest using True Volumetric Absolute Counting. This unique method is solely based on the fundamental definition of absolute counting respectively the particle concentration (c) which is equal to the counted number (N) of particles (e.g. cells) in a given volume (V), $c = N / V$. In the CyFlow® Counter, the volume is measured directly by mechanical means, rather than by calibration with expensive beads with a—sometimes doubtful—"given" nominal concentration. Thus, the precision of volume measurement is defined by a fixed mechanical design, eliminating any errors related to varying bead concentrations or bead aggregation. The CyFlow® Counter allows the analysis of a fixed volume as defined by the distance between two platinum electrodes reaching into the sample tube with a given diameter.

Alternatively, a well defined volume of free choice involving the digital sample speed control can be used. Benefits of True Volumetric Absolute Counting:

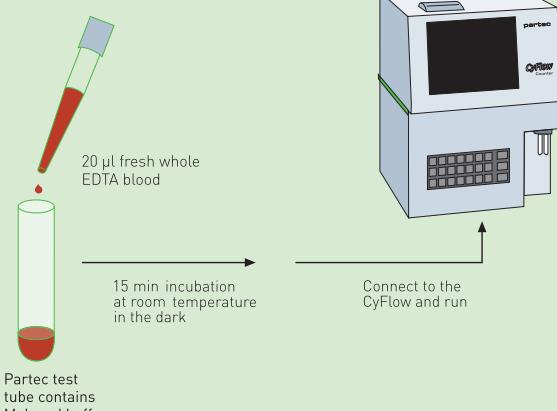
- **digital volumetric precision by mechanical design: $CV < 2\%$**
- **no errors related to calibration**
- **no additional time and preparation steps for reference beads or haematology reference count**
- **no expenses for calibration beads**
- **no separate haematology counter required**

04 ANALYZE

CyFlow® Counter FCM System



Get your accurate and precise counting results from the CyFlow® Counter for routine HIV/AIDS patient monitoring within shortest possible time.



CD4 Protocol

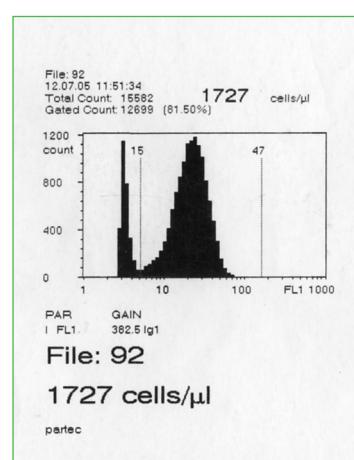
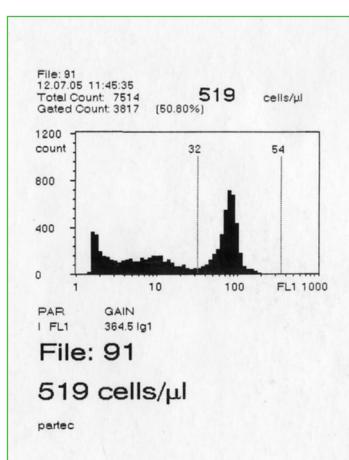
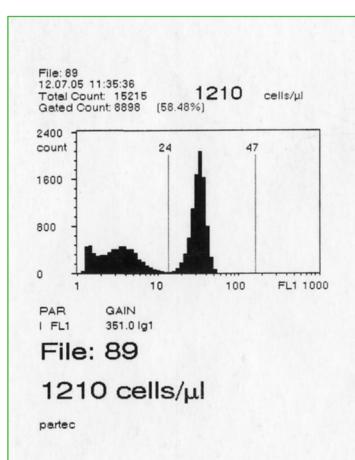
Analysis of absolute CD4+ T-Lymphocyte cell concentration from whole blood.

The CyFlow® Counter is designed to perform routine cell analysis, in particular true volumetric absolute counting of cells, to be used in routine HIV/AIDS follow-up diagnostic.

A breakthrough for the routine application in HIV/AIDS monitoring is reached by the development of an ultimately easy-to-perform 1-step blood preparation protocol. This protocol does not need any critical pipetting step. Therefore, the main source of error is eliminated.

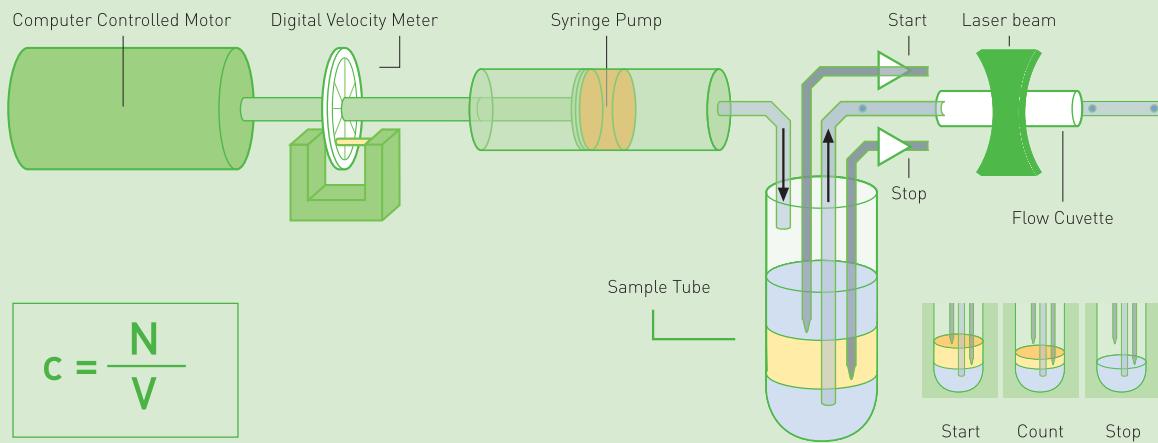
The results are directly displayed in terms of absolute cell number per microliter blood sample.

Automatic print-out of the cell counting results including cell distribution histograms as additional built-in quality control.



CD4, CD8, CD3 absolute cell counts from the same blood sample showing the excellent separation from the monocytes and accurate results:

- CD4: 1210 cells/µl**
- CD8: 519 cells/µl**
- CD3: 1727 cells/µl**



Principle of Partec True Volumetric Absolute Counting

The Partec CyFlow® Counter is your complete solution for routine immunophenotyping.

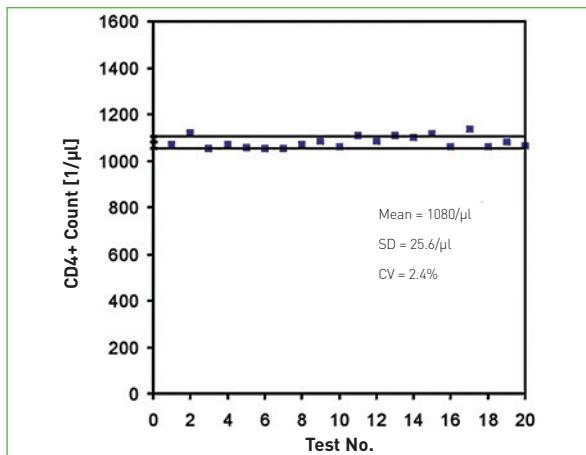
Computer system and software

Built-in PC-compatible computer and 10.4" Active Matrix TFT LCD Colour screen with 640x480 pixels. Real time data acquisition, analysis, and storage with 4096 channels. Histogram display with 512 channel resolution in real time. All data are automatically stored on built-in memory. Data can be transferred to other computers via Ethernet connection. The CA3 software provides instrument control, data acquisition, data analysis, and True Volumetric Absolute Counting. Concentration results are updated during acquisition (syringe counting method). Gates can be defined by cursors. Automatic peak analysis. Optionally available:

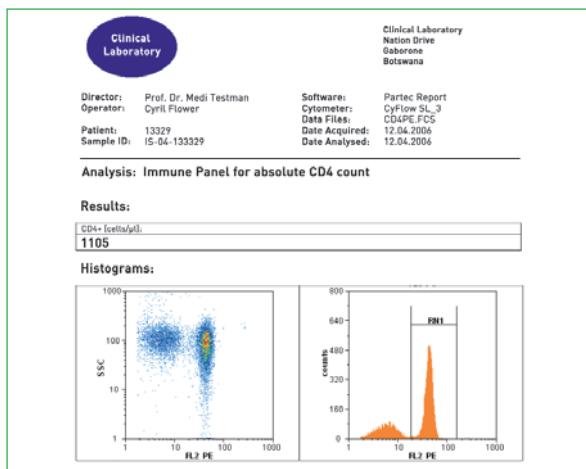
DPAC for Windows, the complete one parameter data evaluation software for numerical peak analysis and data transfer to other desktop publishing systems

FloMax® for Windows™ multiparameter analysis software for complete analysis of FCS data in one single Windows package

Partec Report software for automatic clinical report generation



Series of CD4+ absolute counting, showing the high reproducibility of the volumetric absolute counting technique.



Clinical report from CD4 analysis generated by Partec Report software: CD4+ T-cell population with prominent peak from bright fluorescence (right) are nicely separated from the weaker fluorescent CD4+ monocytes (lower peak left).

References:

- Cassens, U. et al.: A novel true volumetric method for the determination of residual leucocytes in blood components", Vox Sanguinis 2002; 82, 198-206
 Greve, B. et al.: A New No-Lyse, No Wash Flow-Cytometric Method for the Determination of CD4 T Cells in Blood Samples", Transfus Med Hemother 2003; 30:8-13
 Cassens, U. et al.: "Simplified True Volumetric Flow Cytometry Allows Worldwide Feasible and Accurate Determination of CD4 T-Lymphocytes in Patients with AIDS", Antiviral Therapy 2004; 9:395-405
 Imade, G.E. et al: "Comparison of a New, Affordable Flow Cytometric Method and the Manual Magnetic Bead Technique for CD4 T-Lymphocyte Counting in a Northern Nigerian Setting", Clinical and Diagnostic Laboratory Immunology, Jan. 2005, pp. 224-227
 Fryland, M. et al: The Partec CyFlow Counter® could provide an option for CD4+ T-cell monitoring in the context of scaling-up antiretroviral treatment at the district level in Malawi, Transactions of the Royal Society of Tropical Medicine and Hygiene (2006)

05_SPECIFICATIONS

CyFlow® Counter FCM System



www.cyclos-design.de

GENERAL

The CyFlow® Counter is a fully-equipped portable / desktop flow cytometer with laser excitation in green. It analyses up to three optical parameters (SSC and 2 fluorescences channels) plus time parameter. It performs both fluorescence analysis and true volumetric absolute cell counting without the need for reference beads.

ELECTRONICS

- _ parallel signal processing for each of the optical channels with selectable linear, 3- or 4-decade logarithmic scale
- _ pulse height, area and width analysis for doublet discrimination
- _ 16 bit analog-to-digital converters, trigger on any parameter or parameter combinations

LIGHT SOURCES

The CyFlow® Counter is equipped with a modern and powerful 532 nm green solid state laser light source.

POWER REQUIREMENTS

100/240 V AC, 60 VA, 50/60 Hz or 12 Volts DC/5A

OPTICS

Modular optical system with 1 to 3 optical parameters. Each parameter is equipped with a photomultiplier tube (PMT) and integrated electronic preamplifier.

DIMENSIONS & WEIGHT

30 x 35 x 38 cm + sheath fluid/waste rack = 14 kg

FLOW SYSTEM

Synthetic quartz flow cuvette (channel dimensions: 200 µm x 350 µm) for laminar sample flow. True Volumetric Absolute Counting based on precise counting and fluid volume measurement. Computer controlled precision syringe pump for contamination-free sample transport and volumetric absolute counting, pump speed continuously adjustable from 0-1200 µl/min, sheath fluid pressure continuously adjustable from 0-500 mbar. Fluid level indicators for full waste and low sheath fluid.

ORDER NUMBER

CyFlow® Counter CY-S-3021

Reagents

Partec CD4 easy count kit (100 tests) 05-8401

Partec CD4% easy count kit (100 tests) 05-8415

for CyFlow® Counter

Partec CD8 easy count kit (100 tests) 05-8801

Partec CD3 easy count kit (100 tests) 05-8301



For in vitro
diagnostic use.

partec

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