CytoVision®

The platform for every cytogenetics lab

Living up to Life

Leica
MICROSYSTEMS

The Platform for every Cytogenetics and FISH Lab

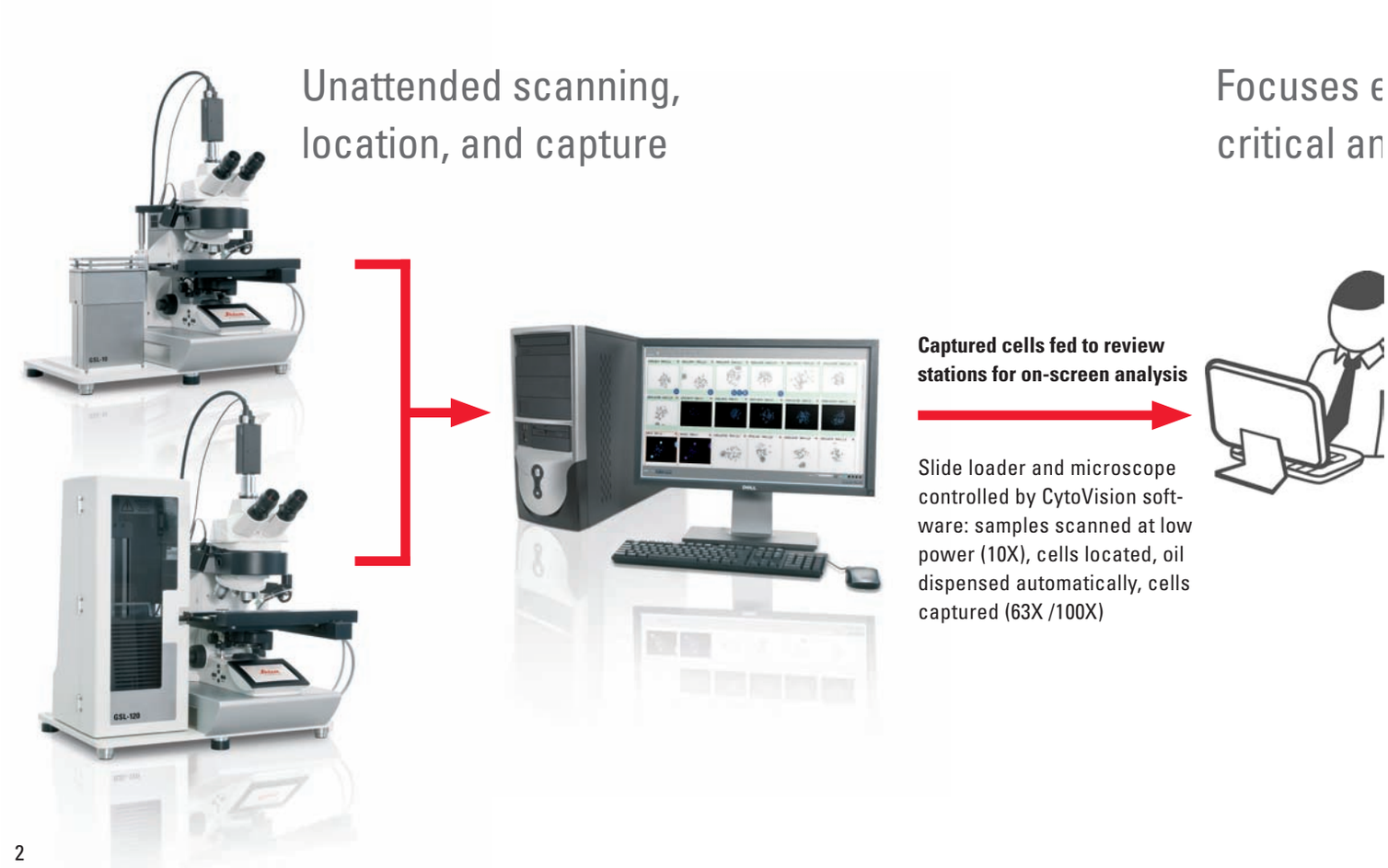
CytoVision is the one image analysis and case management system that provides cytogenetic laboratories with an integrated, scalable platform for brightfield and fluorescent samples. Only Leica Microsystems combines the expertise in image analysis, robotics, and microscopy needed to deliver and support a truly integrated cytogenetics platform.

A proven, future-proof platform

Used in over 2000 laboratories worldwide, the CytoVision platform provides the convenience and comfort of on-screen analysis together with flexibility in software and hardware configurations. CytoVision supports all laboratories from the simplest, single application workstation to fully networked, automated, multi-application, nationwide programs. CytoVision is highly cited in the literature across a breadth of applications from routine clinical diagnostics to contemporary stem cell and oncology research.

Reduce reporting times; improve consistency, free skilled staff to spend their time producing quality analysis and reports

Many facilities face growing demands to increase productivity efficiency, reduce backlogs, and improve reporting times. From our new high sensitivity cameras for manual capture to unattended scanning and capture using the unique combination of CytoVision software and GSL slide loaders, CytoVision enables every laboratory to improve efficiency.



Future-proof your laboratory with a choice of application modules and automation within CytoVision

A broad range of application modules ensures full flexibility to meet changing laboratory requirements. CytoVision is ready to grow with your lab, analysis modules can easily be added to new or existing systems to adapt to your evolving needs. The CytoVision platform enables expansion from a single capture station to fully automated scanning and capture stations with review stations supported by client / server networks and LIMS connections. CytoVision offers secure remote access servers and software to allow cases to be analyzed, reported and reviewed from anywhere in the world.

- Karyotyping
- FISH
- Tissue FISH
- Karyotype CGH
- M-FISH
- Flexible Karyotyping (for non-human)

Scanning platforms also feature:

- Metaphase scanning and capture
- Automated/manual Spot counting for cellular Fish

s experts on
analysis steps

Select and analyze cells at desktop review stations

Operator actions recorded for every case

Reduces reporting
and turnaround times

Operator results archived and reports generated

"Spending ages scanning slides is a thing of the past!"

Technologist at Cytogenetics Laboratory,
Yorkhill Hospital, Glasgow, UK

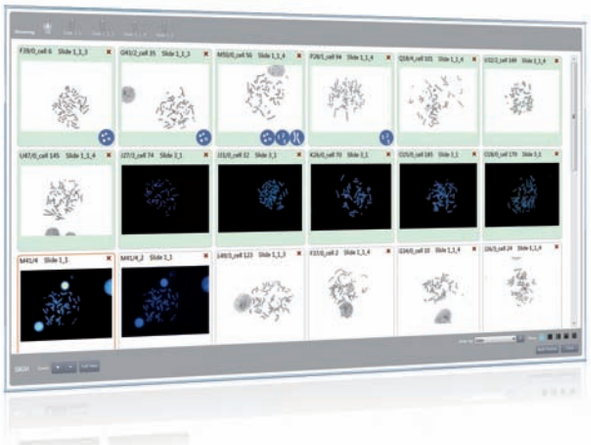
"With a work force reduction of 480 hours, the turnaround times were reduced by 0.3 days without compromising abnormality rate."

Christine M. Higgins,,
MMI Human Genetics Lab,
Omaha, NE, USA

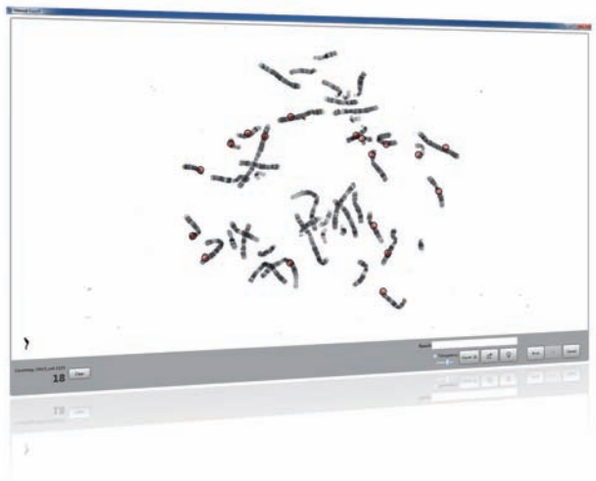
Brightfield Analysis On-Screer

CytoVision analysis modules support a variety of applications including metaphase finding and
In the example shown here, a simple interface leads the analyst through each stage of karyoty

Select the best captured cells from the Organize screen
Every cell is shown in a gallery.



Count and karyotype on the Analyze screen
Analysis of cells automatically tracked. Digital record of count and results kept for security. Progress tracked during analysis as each class is marked off.



en and in Comfort

and karyotyping for human and non-human cell lines.
yotyping and analysis.

Ensure quality control using the Clear Cells screen – easily check classes

Each class is marked with clearly visible homologues. Use karyotypes to clear classes and scroll through remaining cells to check any unclear classes. A record of karyotypes or metaphases is kept for each cell to ensure sufficient homologues are checked.

Review case summary on the Report screen

Digital records contain cell coordinates, images, and results. Images and reports can be annotated and printed or exported to a LIMS.

"I much prefer analyzing chromosomes on my large screen… easier on the eyes, more comfortable on the body and, more importantly, I am happier analyzing chromosomes when they are paired up side by side than at opposite ends of a metaphase."

Technologist at Cytogenetics Laboratory,
Yorkhill Hospital, Glasgow

On-Screen Analysis brings FIS

Fluorescence analysis modules in CytoVision support a variety of applications including FISH
Automated slide loaders enable unattended scanning, location, and capture of fluorescence ir
review stations for on-screen analysis. Simple interface screens guide the operator through th

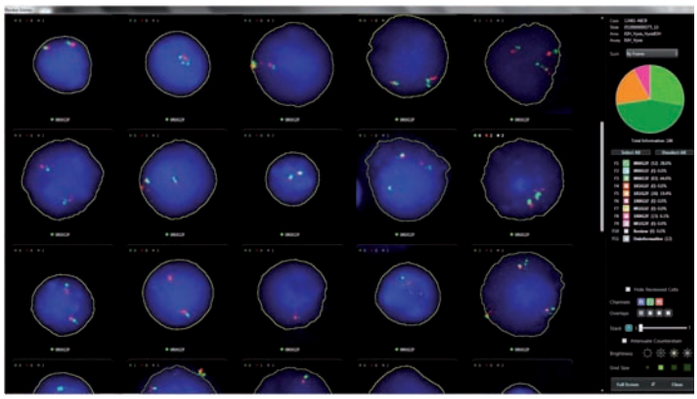
"I really enjoy the ability to analyse my FISH in the daylight. Being able to analyze the very same cells with a colleague has massive advantages."

Lisa Russell PhD
Leukaemia Research Cytogenetics Group
Northern Institute for Cancer Research
Newcastle University, UK

"Training new staff on interphase FISH scoring is made so much easier when you are able to show examples of nuclei and their signal patterns on a screen rather than trying to locate the same cell down the microscope."

Lisa Russell PhD
Leukaemia Research Cytogenetics Group
Northern Institute for Cancer Research
Newcastle University, UK

High throughput FISH capture
Low power scanning (10X) locates interphase cells. Frames are then captured at high power with DAPI masking of probe signals to eliminate extraneous fluorescence outside of cells. Proprietary Adaptive Image Processing algorithms are then used to classify cells based on user defined morphology. Cells that meet the classification are captured and displayed as frames ready for manual or automatic scoring.



Capture high quality images
Dynamic Z-stack multi-plane imaging captures images of counter stains and probes through each cell. Virtual microscopy enables dynamic focusing, up and down through the image.

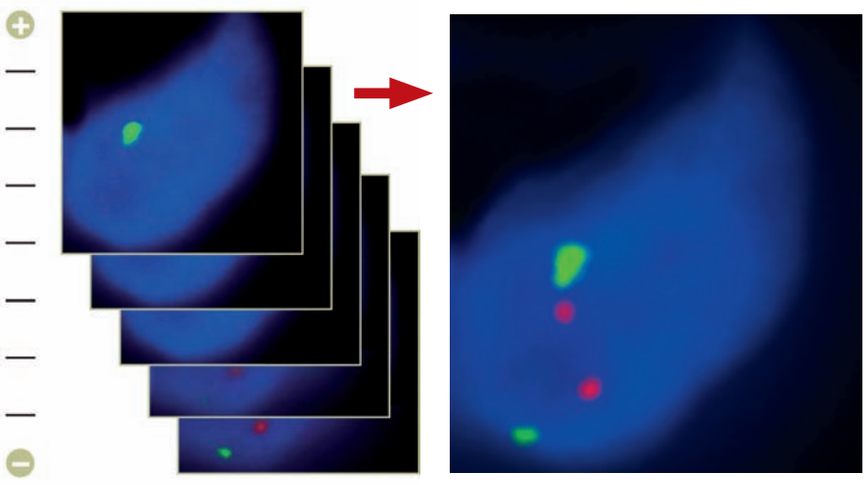


Image stack

Composite image

[SH out of the Dark Room

FISH, spot counting/interphase FISH, CGH, tissue FISH, and M-FISH
ce images, minimizing fading problems, and sending images to
gh the analysis workflow, as illustrated by this cellular FISH example.

Choose scoring process

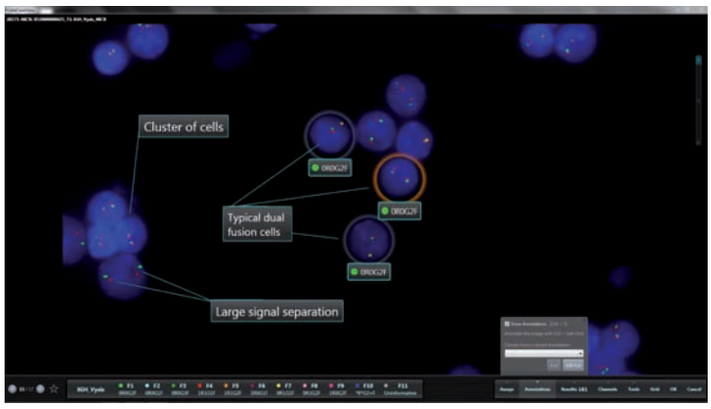
Automatic:

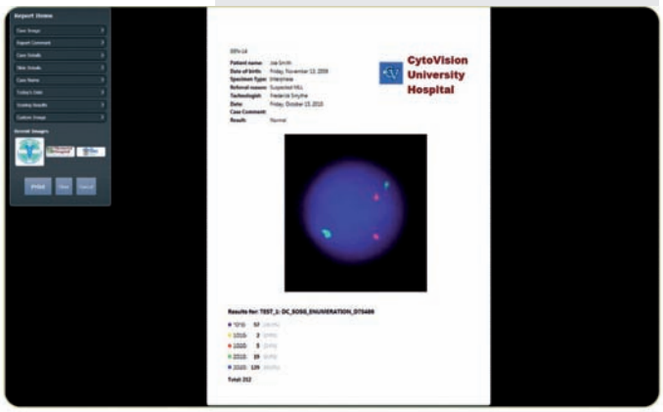
CytoVision 7.2 introduces new levels of automated FISH scoring for break-apart, enumeration, and fusion assays Display scored cells in a grid for easy viewing and sorting of cells assigned to each class. Interactive pie charts and keyboard controls allow rapid review of automated scoring and statistical assessment.

Manual:

Create assay, name classes and assign to function keys.
Class totals are updated as cells are scored.

Produce customizable reports for export





Include scores, patient data and images

Automation to meet your needs

CytoVision support a range of capture functions for the microscopes detailed below

CytoVision Capture Station Microscope Control

● Controlled by CytoVision ❍ Manual Control

	DM6000B	DM5500B	DM5000B	DM4000B	DM2500
Z-stacking	●	●	❍	❍	❍
Objective turret	●	❍	❍	❍	❍
Fliter Cube Turret	●	●	●	●	❍
Display	Leica SmartTouch	Leica SmartTouch	Leica SmartTouch	Info Only	None
Max number of filters	8	8	5	5	5

Improvements in Productivity
Extracts of Reports from arou

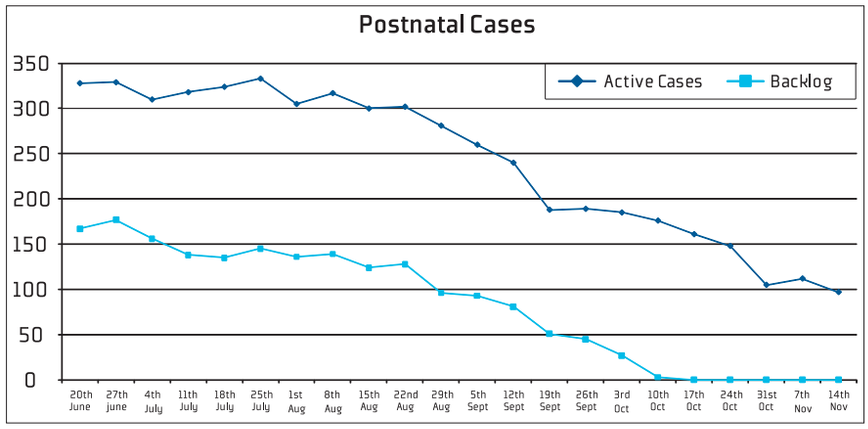
Benefits:

- Increase in quality of urgent and routine samples
- Decrease in reporting times
- Increase in % of cases reported within guideline times
- Increase in success rate, decrease in poor quality rate data

Data courtesy of L. Monkman, J. Colgan, L. Crawford, M. Campbell, G. Lowther
Cytogenetics Laboratory, Duncan Guthrie Institute of Medical Genetics, Yorkhill Hospital, Glasgow

The **West of Scotland Regional Cytogenetics Service,** U.K. provides a region-wide service for analysis of around 2800 post-natal blood samples per year. Each slide is scanned for up to a maximum of 300 metaphases, and the 50 best cells are captured for analysis.

Reduced backlog of cases



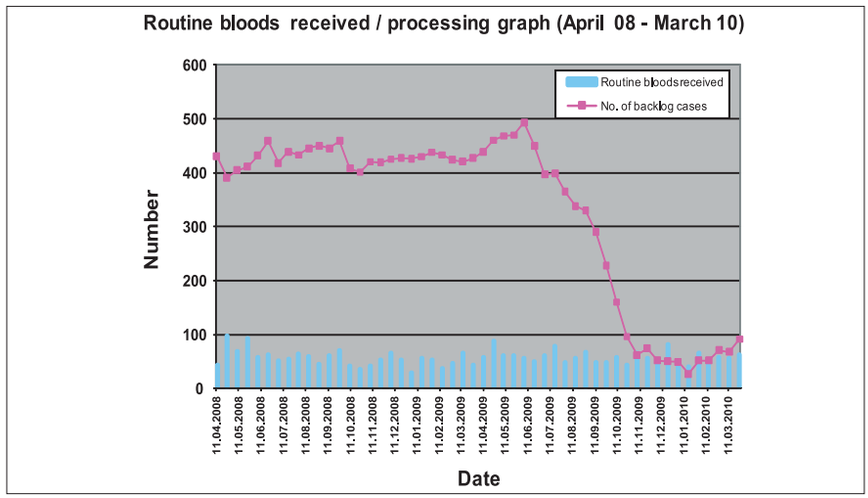
Within 30 days:

- CytoVision and GSL-120 integrated into in-house LIMS
- Classifiers designed for specific cultures
- Staff fully trained within 4 months:
- Fully automated workflow from scan to report for blood and pre-natal samples
- Backlog reduced from 500 to 70 cases
- Reporting times dropped from 116 days to 28 days
- Decrease in inscription errors
- Improved staff morale

Data courtesy of Victoria J. Anthony-Dubernet, Clinical Cytogeneticist, South West Thames Regional Genetics Service,
St. Georges Hospital, London

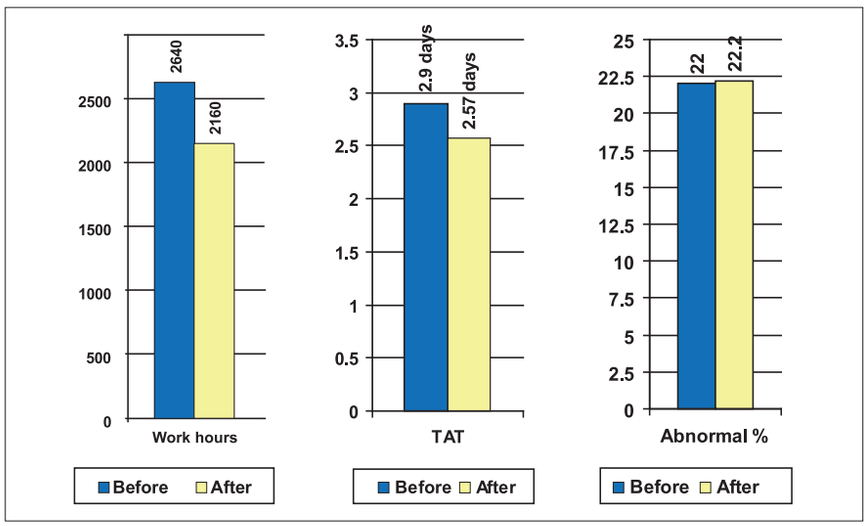
The **South West Thames Regional Genetics Service,** part of the St. George's Healthcare NHS Trust in the UK, had a routine blood sample backlog for nearly 4 years, due to staff shortages.

Backlog cleared 8 months ahead of schedule



y and Efficiency –
und the World

The **University of Nebraska Medical Center in Omaha**, Nebraska compared work hours, TAT, and abnormality rates between 60 day periods before and after implementation of a GSL-120 slide loader for unattended scanning, location, and capture.



Sonora Quest Laboratories in Tempe, Arizona evaluated efficiency gains by collecting time requirements for scanning, capture and karyotyping of 220 neoplastic cases and comparing with time required to run 152 cases using CytoVision and GSL-120.

Process before GSL-120	
Scan and analyze 20 cells: 126 min.	**151.9 min. per case (n=152)**
Capture min. 5 pictures: 12.8 min.	
Karyotype full case (~2-5 karyotypes per case): 13.1 min.	
Process after GSL-120 implementation	
Scan, analyze 20 cells capture and cut:	**120.8 min. per case (n=220)**

Benefits:

- Work hours cut by 480 hours
- Turnaround time (TAT) reduced by 0.3 days
- Abnormality rate maintained

Results

- Reduced time for case completion by 31.06 mins (20.45%)
- Decreased failure rate to 1.5%
- Removed human inattention from equation
- Located metaphases on slides (that previously) a technologist may have assumed to be empty

A Solution for every Cytogeneti

"We are delighted with the installation of and support provided for our CytoVision GSL 120 network. Within 4 weeks of training, our Bloods reporting time was halved, which resulted in a tangible improvement in staff morale"

Tony Herbert, PhD, Dip. R.C.Path
Assistant Director
Wessex Regional Genetics Laboratory, UK

Configurations to match applications, throughput, and networking requirements
Building from CytoVision software for review, workstation solutions can be configured to match the applications, throughput, imaging, and automation requirements of any cytogenetics lab.

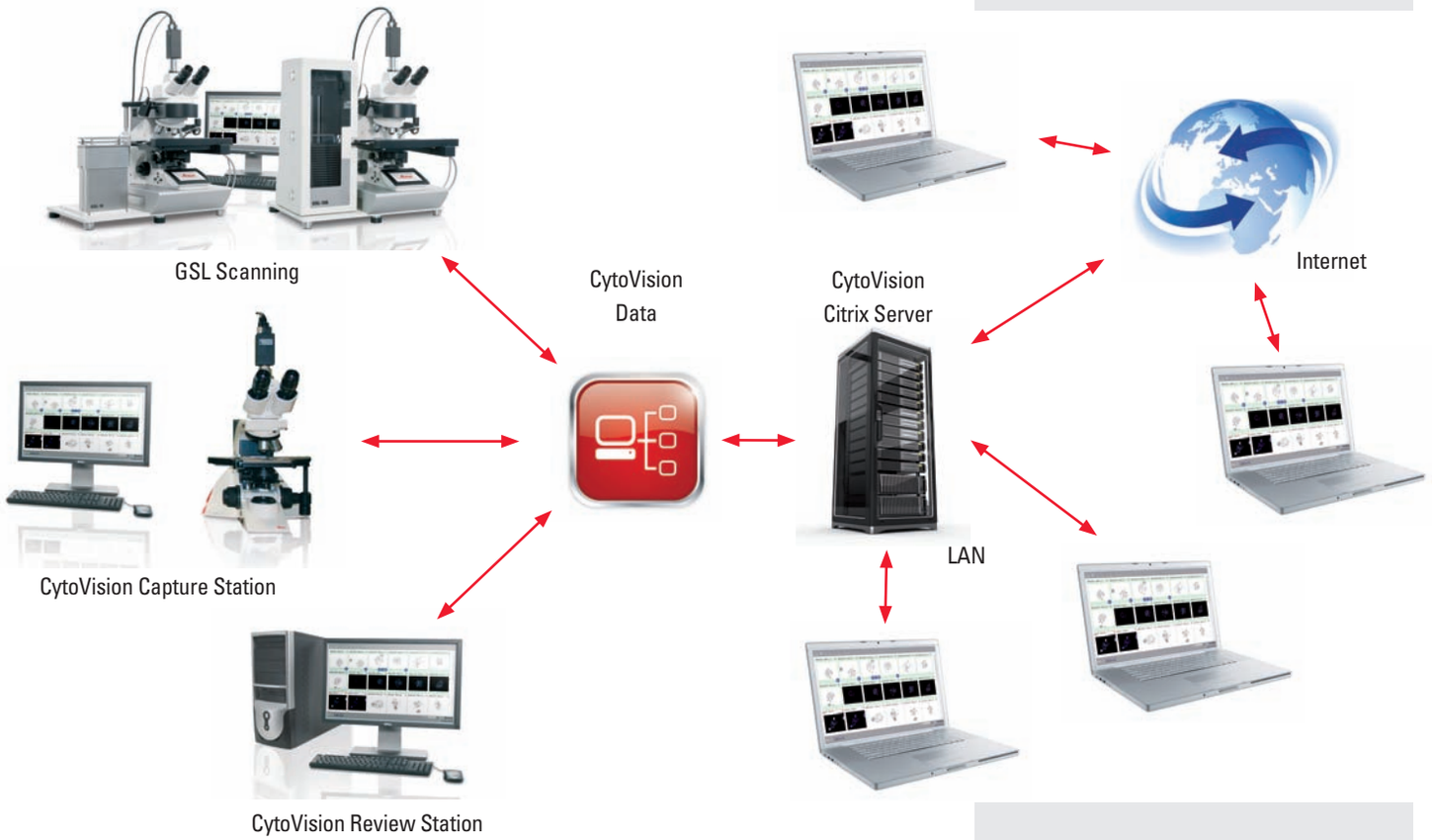
Ready to meet increasing caseloads and facilitate workload balancing
The CytoVision platform enables expansion from a single review station to fully automated scanning and capture stations with review stations supported by server networks and LIMS connections.

Remote access solution for analysis and review
CytoVison offers the option of remote access for brightfield and fluorescence analysis cases using a pre-configured and validated Citrix server. Access to CytoVision is also an ideal solution for Director review and labs that need to collaborate across geographical remote sites. The user experience is nearly identical to that of a local CytoVision workstation user*. Remote clients require no software installation** or local licence management, only a compatible web browser, internet or LAN connection. The CytoVision Citrix server has been shown to support up to 60 concurrent users for brightfield analysis and up to 30 concurrent users for fluorescence analysis.

* Display Latency is constrained by network speed
** Citrix Online plug-in for browser required, available as a free download.

	One step slide loading, scanning and capture	Scanning and capture with manual oiling
Software	CytoVision 7.2 using Windows 7 or Windows XP operating systems	CytoVision 7.2 using Windows 7 or Windows XP operating systems
Microscope	Leica DM6000 B	Leica DM6000 B
Digital Cameras	1600 x 1200 pixels	1600 x 1200 pixels
Slide loader or motorized stage	GSL-120 (up to 120 slides per run) or GSL-10 (10 slides per run)	8-bay motorized stage
Bar code reader and oiler	integrated	n.a.
Application options	Karyotyping FISH Spot counting and Tissue FISH	Karyotyping FISH Spot counting and Tissue FISH
Monitor	24'' LCD	24'' LCD
System architecture (1 to 9 stations)	Internal data server SQL CaseBase Data archive options up to 2TB RAID5	Internal domain server SQL CaseBase Data archive options up to 2TB RAID5
System architecture (10 or more stations)	External domain server SQL CaseBase Data archive: Up to 10Tb RAID5 array	External data server SQL CaseBase Data archive: Up to 10Tb RAID5 array
UPS	Standard	Standard

tics Lab



Standard capture station with on-screen analysis	Review station for on-screen analysis	Software license for review station
CytoVision 7.2 using Windows 7 or Windows XP operating systems	CytoVision 7.2 using Windows 7 or Windows XP operating systems	CytoVision 7.2 using Windows 7 or Windows XP operating systems
Leica DM6000 B, Leica DM5500 B, Leica DM5000 B, Leica DM4000 B, Leica DM2500	n.a.	n.a.
1300 x 1024 pixels	n.a.	n.a.
n.a.	n.a.	n.a.
n.a.	n.a.	n.a.
Karyotyping, FISH, MFISH, Tissue FISH Metaphase CGH, Flexible Karyotyping	Karyotyping, FISH, MFISH, Tissue FISH Metaphase CGH, Flexible Karyotyping	Karyotyping, FISH, MFISH, Tissue FISH Metaphase CGH, Flexible Karyotyping
24'' LCD	24'' LCD	n.a.
Internal domain server SQL CaseBase Data archive options up to 0.5TB RAID1	n.a.	n.a.
External data server SQL CaseBase Data archive: Up to 10Tb RAID5 array Standard	n.a. n.a.	n.a. n.a.

INTENDED USE – CYTOVISION® VERSION 7.2

The CytoVision® Image Analysis and Capture System is a rapid metaphase finder, image acquisition and computer aided chromosome analysis system which assists the operator in viewing the chromosome display and looking for cellular anomalies. CytoVision® enables a qualified Cytogeneticist to rapidly and accurately analyze the chromosome banding pattern.

All diagnostic decisions are made by the qualified clinician.
CytoVision® systems also provide open flexible tools for image capture and object enumeration. Customers are responsible for the validation of any tests based on these tools.

Regions where CytoVision® is available for clinical/diagnostic use

	Karyotyping	CEP XY	CGH	RX FISH	M FISH
USA	Approved	Approved	Research only	Research only	Research only
EU	Approved	Research only	Research only	Research only	Research only
Australia	Approved	Research only	Research only	Research only	Research only
Canada	Approved	Research only	Research only	Research only	Research only
India	Approved	Research only	Research only	Research only	Research only
Japan	Approved	Research only	Research only	Research only	Research only
Jordan	Approved	Research only	Research only	Research only	Research only
Malaysia	Approved	Research only	Research only	Research only	Research only
Mexico	Approved	Research only	Research only	Research only	Research only
Republic of South Africa (RSA)	Approved	Research only	Research only	Research only	Research only
Russia	Approved	Research only	Research only	Research only	Research only
South Korea	Approved	Research only	Research only	Research only	Research only
Thailand	Approved	Research only	Research only	Research only	Research only
Turkey	Approved	Research only	Research only	Research only	Research only

United States of America
In the US, CytoVision® is approved for *In-Vitro* Diagnostic Use for CEP XY and Karyotyping.

CytoVision® CEPXY_ENG is an accessory to the CEP® X Spectrum Orange™/ CEP® Y Spectrum GreenTM DNA Probe kit (Abbott Laboratories. Abbott Park, Illinois, U.S.A) and is limited to the analysis of CEP XY probes via high magnification capture and analysis of interphase nuclei. CEP XY is indicated for use to assess the effectiveness of bone marrow transplantation in opposite-sex transplants.

Rx Only

Rest Of World
CytoVision® Karyotyping is approved for *In-Vitro* Diagnostic Use in the following regions

Europe, Australia, Canada, India, Japan, Jordan, Malaysia, Mexico, Republic of South Africa, Russia, South Korea, Thailand and Turkey
All diagnostic decisions are made by the qualified clinician.
 CytoVision® systems are also capable of performing Comparative Genomic Hybridization (CGH), RxFISH Color Chromosome and M-FISH Color Chromosome Image Acquisition and Analysis. These are Research Applications* and are not further identified for In-Vitro Diagnostic Use. The flexible karyotyper is for Research use only. Not for Use in Diagnostic Procedures.

www.leica-microsystems.com

Note* : A Research Application is an application which is not intended for *in vitro* diagnostic or clinical use, but is intended solely for use in the research setting, for example university or pharmaceutical development. These applications are described as Research Applications or Research Use Only.

The statement by Ernst Leitz in 1907, "With the User, For the User," describes the fruitful collaboration with end users and driving force of innovation at Leica Microsystems. We have developed five brand values to live up to this tradition: Pioneering, High-end Quality, Team Spirit, Dedication to Science, and Continuous Improvement. For us, living up to these values means:
Living up to Life.

Leica Microsystems operates globally in four divisions, where we rank with the market leaders.

LIFE SCIENCE DIVISION

The Leica Microsystems Life Science Division supports the imaging needs of the scientific community with advanced innovation and technical expertise for the visualization, measurement, and analysis of microstructures. Our strong focus on understanding scientific applications puts Leica Microsystems' customers at the leading edge of science.

Leica Microsystems – an international company with a strong network of worldwide customer services:

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Belgium	Groot Bijgaarden	Tel. +32 2 790 98 50	Fax +32 2 790 98 68
Denmark	Ballerup	Tel. +45 4454 0101	Fax +45 4454 0111
France	Nanterre Cedex	Tel. +33 811 000 664	Fax +33 1 56 05 23 23
Germany	Wetzlar	Tel. +49 64 41 29 40 00	Fax +49 64 41 29 41 55
Italy	Milan	Tel. +39 02 574 861	Fax +39 02 574 03392
Japan	Tokyo	Tel. +81 3 5421 2800	Fax +81 3 5421 2896
Korea	Seoul	Tel. +82 2 514 65 43	Fax +82 2 514 65 48
Netherlands	Rijswijk	Tel. +31 70 4132 100	Fax +31 70 4132 109
People's Rep. of China			
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	Shanghai	Tel. +86 21 6387 6606	Fax +86 21 6387 6698
Portugal	Lisbon	Tel. +351 21 388 9112	Fax +351 21 385 4668
Singapore		Tel. +65 6779 7823	Fax +65 6773 0628
Spain	Barcelona	Tel. +34 93 494 95 30	Fax +34 93 494 95 32
Sweden	Kista	Tel. +46 8 625 45 45	Fax +46 8 625 45 10
Switzerland	Heerbrugg	Tel. +41 71 726 34 34	Fax +41 71 726 34 44
United Kingdom			
	Milton Keynes	Tel. +44 800 298 2344	Fax +44 1908 246312
USA and Canada	Buffalo Grove/Illinois	Tel. +1 847 405 0123, Tel. +1 800 248 0123,	Fax +1 847/405-0164

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