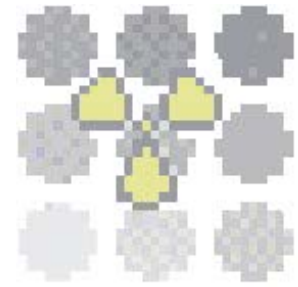
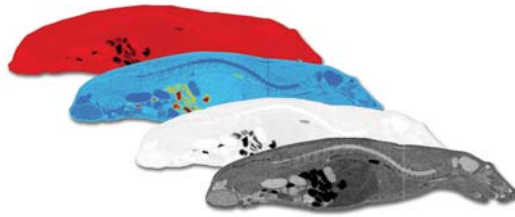




Seescan™ 2

Image Analysis Software for QWBA

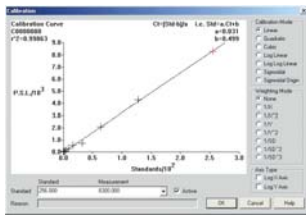


- Provides an intuitive, comprehensive and user friendly method for rapid image analysis
- Analyses image files from popular direct imaging systems including Molecular Dynamics, Fuji, BIOSPACE and Cyclone
- Software is application specific and easy to use
- Data can be reported as raw measured data, or calibrated data when using standards
- Provides a full range of tools for defining regions of interest within an image for measurement
- GLP compliant operating mode may be selected on a study to study basis
- In GLP mode all actions are automatically documented making GLP compliance easy and complete
- Software is password protected providing full user access control from the supervisory level
- All data including study protocol are time, date and user stamped, maintaining a full audit trail
- 32-bit application, which runs under Windows® 95/98/ME/NT4/2000/XP
- Supports direct data transfer of results to Microsoft® Excel and Microsoft® Word via Document Management System
- FDA 21 CFR Part 11 Compliant
- 'Digital' interface with Debra™ ADME LIMS

Setting up a study

To start a study, the user defines the protocol. This provides an experimental description, defines whether the study is to be GLP compliant and defines whether the data is to be calibrated. Before starting the measurements, the user can either complete the study protocol by entering the sections and tissues to be measured, or input this during the course of analysis.

Calibration



If the study images contain calibration standards, raw measurements can be converted into calibrated units. For each standard, the user measures and enters its nominal value. The calibration curve is calculated and displayed. Calibration algorithms include linear, quadratic, cubic, log/linear and sigmoidal. The best fit to the curve may be obtained using the different calibration algorithms. Suspect data points may be excluded from the curve but remain visible on the graph.

Image Display

A variety of image display functions are provided. These include normal, image inversion, contrast enhancing and pseudo-colouring. The software also allows four images to be montaged using the same pseudo-colour scale for comparison.

Taking Measurements

Measurements can be taken by framing the region of interest with a variety of drawing tools. These include circular, rectangular or user drawn frames of variable size. Selected areas can be defined using grey level thresholds. The image may also be zoomed and contrast enhanced to allow accurate analysis of small or poorly defined tissues.



Results

For each measurement, the region area, the raw/calibrated result and the measurement reliability (% error) are stored. Results can either be displayed individually or as a mean for the tissue being measured. Individual results can be cross-referenced with the region from which they were obtained, by simply clicking on the measurement - the image appears with the measured region highlighted. All data can be reviewed and transferred to other Microsoft® Office applications.

The software has been designed for use at two levels, supervisor and user, both password controlled. The supervisor has the ability to: access all studies, set up and delete users, and restrict access to studies and software. Only users defined in the protocol have access to the study. All data entered, including the protocol, is time, date, and user stamped. If any data is altered or excluded, the user is forced to enter a reason, which is stored with the data in the study audit trail. All data for each study is stored in an encoded study file.

Security

Seescan™ has a comprehensive and flexible security structure, which is used to control access to menu items and form-level functions. Given that Seescan™ is used in a regulatory environment, it is important that Seescan™ is able to guard against unauthorized access to data.

Debra™ ADME LIMS Link

Seescan™ is able to integrate with Debra™ enabling users to select the study and appropriate data direct from Debra™. Following analysis of the data the resulting information can then be seamlessly transferred back to the Debra™ study database ensuring data integrity and preventing errors.



Regulatory and FDA 21 CFR Part 11 Compliance

Seescan™ is designed to fully support GLP and associated regulatory requirements and specifications for both laboratory operations and laboratory software design. This includes functionality to meet with the FDA 21 CFR Part 11 ruling for electronic signatures and electronic records. The system allows for System Manager control of signature points on key events. Each area of the application that could require a signature is configurable. Administrators can disable the signatures, set a silent signature which doesn't require any action on the users part, set a single signature or 2 signatures (the second signature normally being approval of the first). Signed electronic records contain information associated with the signing that clearly indicates all of the following:

- The printed name of the signer
- The date and time when the signature was executed
- The meaning (such as review, approval, responsibility, or authorship) associated with the signature

Quality Assurance



Certificate No:1535/97



Certificate No:1535/97

Quality of service and product is of paramount importance to LabLogic and this is reflected in our systems. Our continued efforts in this area have resulted in ISO 9001 accreditation for:

Design, development and supply of laboratory information management systems, scientific applications software with ongoing maintenance support, including the supply of instrumentation systems for pharmaceutical, agrochemical and contract research organisations.

Client

Hardware

minimum 100Mhz Pentium
minimum SVGA 800x600, 16 colours
minimum 16Mb RAM (32Mb preferred)
mouse or other pointing device
printer (or access to a network printer)

Operating system

Microsoft® Windows 95
Microsoft® Windows NT4 Workstation
Microsoft® Windows 98
Microsoft® Windows Millennium
Microsoft® Windows 2000 Professional
Microsoft® Windows XP Professional

Oracle® software (optional)

SQL*Net 2.x and Required Support Files with Oracle® 7.3
SQL*Net 8.x and Required Support Files with Oracle® 8.x

Storage

~10Mb for a local client installation
~10Mb for a typical amount of data

Installation

It is possible to store the Seescan™ executable program and online help either locally or on a network fileserver. Issues to consider in order to make this decision include the fact that storing the executable on a central server will ease updating the software and also the client installation process. Conversely, storing the executable locally will reduce network traffic and improve the performance of the software by an amount.

Server (optional)

Hardware, operating system and Oracle® software

Due to the nature of Oracle® and the client/server architecture of Seescan™, the server platform is largely immaterial. However, Seescan™ supports only the following Oracle® server versions.

- Oracle® Server 7.3.4 or higher with SQL*Net 2.x
- Oracle® Server 8.x with SQL*Net 8.x

Typical Platforms

- 200MHz Pentium running NT4 and Oracle® 7.3
- 766MHz Pentium III running Windows 2000 and Oracle® 8.x
- Dual 500MHz Pentium III running NT4 and Oracle® 8.x

Storage

Initial recommended sizing of the database at install-time is 10Mb.



LabLogic Systems Limited . Paradigm House
3 Melbourne Avenue . Broomhill . Sheffield

England S10 2QJ . UK

t. +44 (0) 114 266 7267

f. +44 (0) 114 266 3944

w. www.lablogic.com

e. solutions@lablogic.com