



The **System Access Manager™** is an account management module which strengthens your case for compliance by managing and maintaining user access to Perceptive Instruments software products such as the **Ames Study Manager** or **Comet Assay IV**. The **System Access Manager** will be of particular benefit to clients who are required to comply with GLP, GMP and the FDA 21 CFR Part 11 Final rule on Electronic Records and Electronic signatures.

- ❏ **Manages unique electronic signatures**
in line with the principles set down by the FDA and OECD
- ❏ **Secure user management module**
is entirely transparent and invisible to end users
- ❏ **Full and detailed audit trails**
record all login attempts and changes to user accounts
- ❏ **Highly configurable user account rules**
including minimum lengths for electronic signature components; account validity and program access permissions
- ❏ **Enforce regular password changes**
and set rules on password reuse
- ❏ **Login timeouts and lockouts**
to prevent unauthorised access
- ❏ **Comprehensively tested and validated**
in accordance with our Quality Management System which is approved to ISO 9001:2008 incorporating ISO 9003

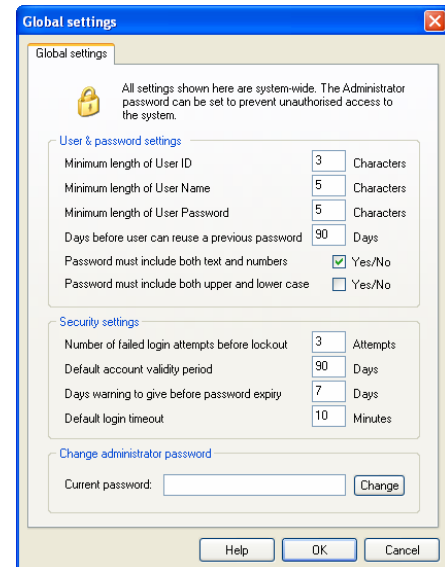
System Access Manager

Manage users in a compliant environment *with the System Access Manager*

Individual users are assigned unique user IDs and access rights to each product. The program manages user access via a wide range of password rules including expiry, length, use of characters and numbers and more.

User Administrators can add new end users to the database and assign them with a unique User ID, a User name and duration of password validity as well as defining a specific access level and time-out to each product.

A randomly generated password is communicated to the individual who then changes the random password into their own case sensitive text using an Update password utility. This ensures that the password is known only to the end-user concerned and, in conjunction with their User ID, constitutes the unique electronic signature.



Comprehensive audit trails *record all login events and user profile changes*

The **System Access Manager** provides comprehensive security and full audit trails which record all login attempts and changes to a user's account validity or access permissions. The audit trails can be filtered on any field, such as User ID, event description or date. Audit trails can then be exported to Excel for printing or review.

Every login event or alteration to an account is recorded in the audit trail along with the name of the current logged on Windows user account, so it is possible to record which users have logged in, when they logged in and what actions they have taken. The main program where user accounts are managed is itself protected by a password, ensuring only authorised personnel can gain access to it.

The **System Access Manager** is built around a secure Oracle database, providing complete security of user and audit data.

If you are interested in finding out more about the reporting and auditing features of the **System Access Manager**, and how you can benefit from the enhanced level of security the program provides, please contact us or visit our website at the address below.

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