

Technical Note – TN100

Managing Users and Groups in Viota® Software

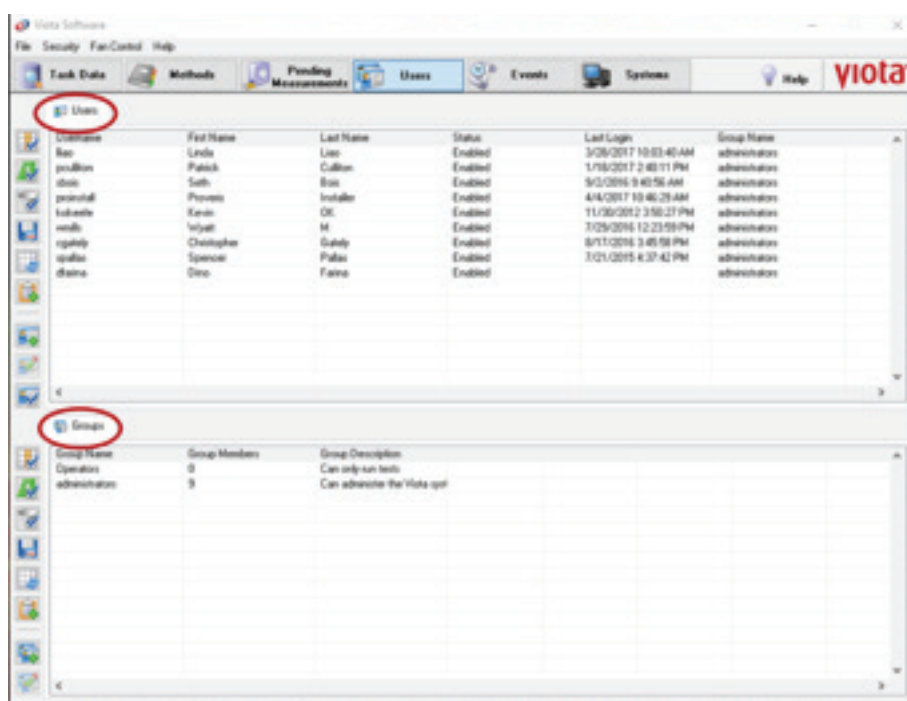


Viota® software is the platform for all Proveris instrumentation and utilizes a centralized database. It is fully compliant with 21 CFR Part 11. Each user has their own unique username and password to log in and operate the Viota® software which limits system access to authorized individuals. Electronic signatures are required whenever an electronic record is going to be generated, in order to meet the requirements for validation, audit trails, record retention, and record copying in the FDA guidance.

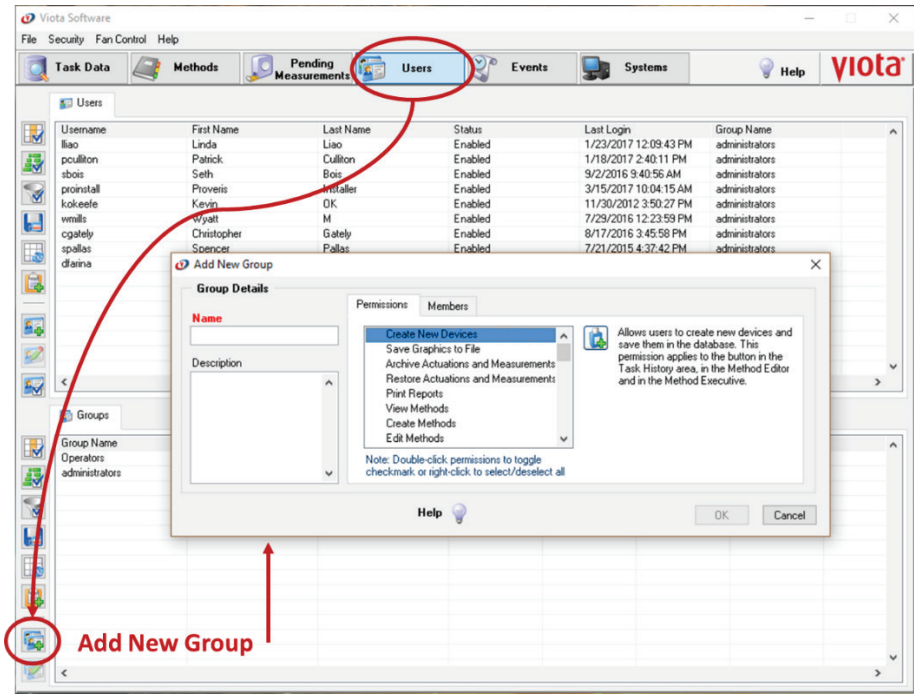
The Viota® software Users page includes two tables: Users and Groups. The Users table lists all active users who can access the software. The Groups table lists all of the groups defined in the software. All users must belong to a group. The group, in turn, defines the permissions that group members have in Viota® software.

Different Groups are created to accommodate the different levels of Users that will use Viota® software. For example:

- A "Technician" Group could permit member Users to view and run methods along with printing results.
- A "Lab Manager" Group could permit member Users to create new methods, edit existing methods and perform system verifications and calibrations.
- An "Administrator" Group could permit member Users to perform all operational tasks and administer all Users.

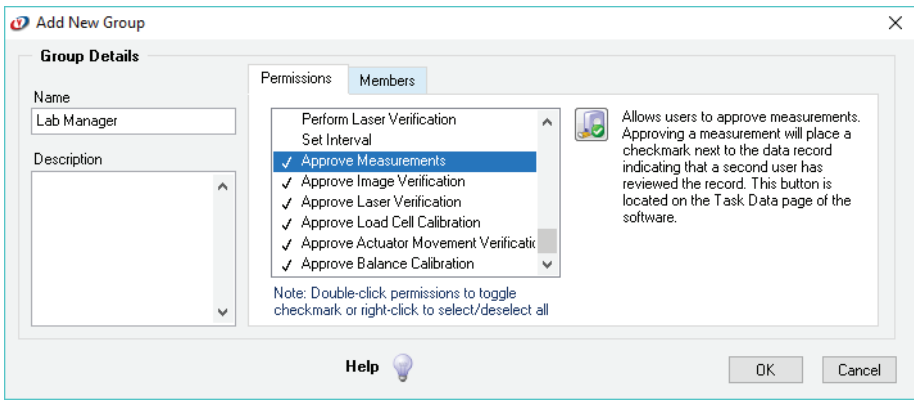


In Viota® software, a user administrator can build groups with different permissions as needed and assign users to different groups. Under the Users page, an administrator can choose **Add New Group** button to add a new group.

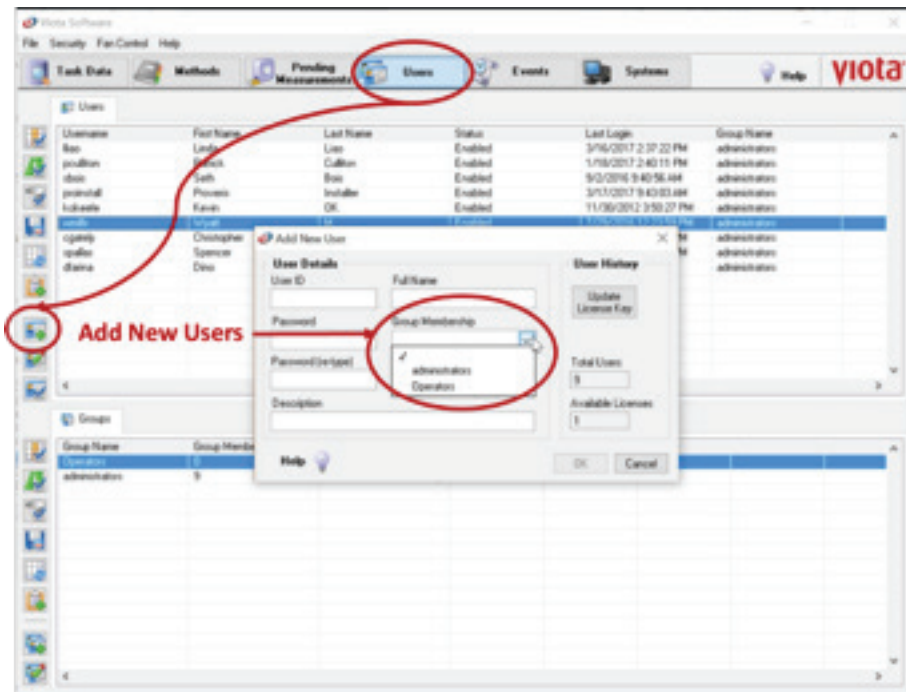


An administrator can then define the group name, add a group description, and choose the group's permissions. There are 38 different permissions in Viota® software. By selecting a permission, a brief description will show up on the right part of the "Add New Group" window. Table 1 lists the 38 permission types and their descriptions.

An administrator can select or deselect permissions by double clicking on the permission. A checkmark will show in front of the permissions selected for this group.

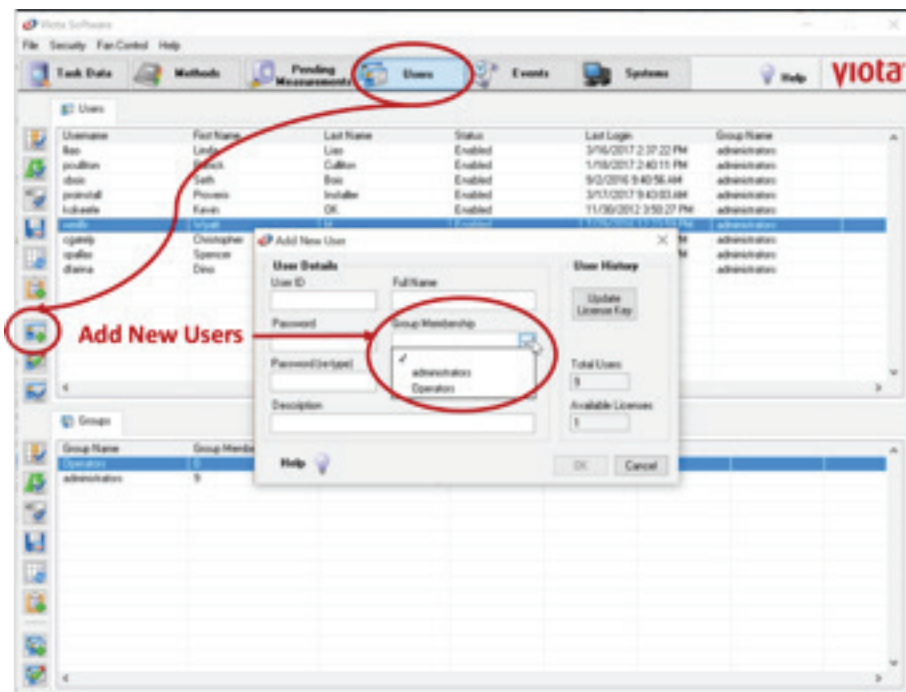


An administrator can then add new users by clicking the **Add New Users** button, set an initial password, and assign them to a group. The created user will be prompted to create their own unique password upon their first login.



Add New Users

Some users may also edit group permissions and/or user details by selecting the **Edit Group** button and **Edit User Details** button depending on their group's permissions.



Edit Group



Edit User Details

Table 1: Viota® Software group permissions and descriptions

PERMISSION TYPE	PERMISSION DESCRIPTION
Create New Devices	Allows users to create new devices and save them in the database. This permission applies to the button in the Task History area, in the Method Editor and in the Method Executive.
Save Graphics to File	Allows users to save graphical information to a file. Graphical information includes actuator position and force data and spray pattern and plume geometry images and video. The graphical data can be saved in a variety of file formats. This button can be found when viewing graphical data for various task types in the Task Data page.
Archive Actuators and Measurements	Allows users to perform archiving a selected set of actuation and their corresponding measurements will be achieved to a file specified by the user. The archiving feature is available from the Task History tab on the Task Data page of the software.
Restore Actuators and Measurements	Allows a user to restore information from a previously created archive file. The archiving and restore features are available from the Task History tab on the Task Data page of the software.
Print Reports	Allows the user to print measurement reports. This button is available from the Actuators, Spray Pattern, and Plume Geometry tabs if available) within the Task Data page.
View Methods	Allows access to the Methods page of the software. The Methods page button will be disabled for users that do not have this permission.
Create Methods	Allows users to create new methods. This button is located on the Methods page of the software.
Edit Methods	Allows users to revise existing methods. This button appears on the Methods page of the software.
Run Methods	Allows users to Run existing methods. Note that running a method may be further restricted by the method status and “Run Unapproved Methods” permission. This button appears on the Methods page of the software.
Run Unapproved Methods	Allows users to Run methods that have a status set to Unapproved. Unapproved methods can not be run without this permission. This permission applies when attempting to run a method by pressing the Run Method button on the Methods page of the software.
Update Method Status	Allows users to alter the status of a method. Enables retiring and approving a method for instance. This button is found on the methods page of the software.
View Measurements	Allows access to the Pending Measurements page of the software. The Pending Measurements page button will be disabled for users that do not have this permissions.
Run Pending Measurements	Allows users to move deferred measurements to the active measurement list. This button is found in the Deferred tab on the Pending Measurements page of the software.
Re-Measure	Allows users to re-measure a previous measurement. When multiple measurements are performed on a single actuation, they can be distinguished by measurement date. This button is available while viewing measurement graphical information on the Task Data page.
View Users and Groups	Allows access to the Users page of the software. The Users page button will be disabled for users this permission.
Create Users	Allows users to create new users. This button is available on the Users page of the software.

PERMISSION TYPE	PERMISSION DESCRIPTION
Edit Users	Allows users to edit the properties of existing users. This button is available on the Users page of the software.
Create Groups	Allows users to create new user groups. This button is available on the Users page of the software.
Edit Groups	Allows users to edit the properties of existing groups. This button is on the Users page of the software.
Alter Account Properties	Allows users to change the global account properties that apply to all users. Account properties include parameters such as minimum passport length and idle time until lockout. This button is located on the Users page of the software.
View Audit Events	Allows access to the Events page of the software. The Events page button will be disabled for users that do not have this permission.
Acknowledge Audit Events	Allows users to acknowledge events. Acknowledging events will place a checkmark next to the event indicating that a user has been informed of the event. Events can then be filtered to show only events that have not yet been acknowledged. This button is located on the Events page of the software.
Add Audit Events	Allows users to add custom events. This feature may be useful for documenting changes to the system that are not automatically logged. This button is located on the Events page of the software.
View Systems	Allows access to the System Systems page of software. The Systems page button will be disabled for users that do not have this permission.
Edit Systems	Allows users to edit system information such as part numbers and serial numbers of components if they are changed. This button is available within the System Info tab on the Systems page of the software.
Manage Data Capacity License	Allows access to the shot license manager where users can monitor and update the number of shots that have been licensed on the system. This button appears in the System Info tab on the Systems page of the software.
Perform System Verification	Allows users to perform System Verification for Spray Pattern and Plume Geometry measurement systems. This permission applies to Run Circle Test, Run Ellipse and Run Triangle Test buttons located in the Verification tabs on the Systems page of the software.
Perform Loadcell Calibration	Allows users to run loadcell calibrations on the system. This button is located in the Load Cell Calibrations tab on the Systems page of the software.
Perform Position Verification	Allows users to run actuator movement verifications on the system. This button is located in the Actuator Movement Verifications tab on the Systems page of the software.
Perform Balance Calibration	Allows users to perform balance calibrations on systems that include a balance. If applicable, this button is located in the Balance Calibrations tab on the Systems page of the software.
Perform Laser Verification	Allows users to perform laser verifications on SprayVIEW systems that use a laser to perform measurements. If applicable, this button is located in the Laser Verifications tab on the Systems page of the software.
Set Interval	Allows user to adjust the time interval between calibrations and verifications. The time interval for each calibration and verification can be set independently. This button is found in the calibration and verification tabs on the Systems page of the software.
Approve Measurements	Allows users to approve measurements. Approving a measurement will place a checkmark next to the data record indicating that a second user has reviewed the record. This button is located on the Task Data page of the software.

PERMISSION TYPE	PERMISSION DESCRIPTION
Approve Image Verification	Allows users to approve image verifications. Approving a verification will place a checkmark next to the data record indicating that a second user has reviewed the record. This button is located on the Systems page of the software.
Approve Laser Verification	Allows users to approve laser verification. Approving a verification will place a checkmark next to the data record indicating that a second user has reviewed the record. This button is located on the Systems page of the software.
Approve Load Cell Calibration	Allows users to approve load cell calibrations. Approving a calibration will place a checkmark next to the data record indicating that a second user has reviewed the record. This button is located on the Systems page of the software.
Approve Actuator Movement Verification	Allows users to approve actuator movement verifications. Approving a verification will place a checkmark next to the data record indicating that a second user has reviewed the record. This button is located on the Systems page of the software.
Approve Balance Calibration	Allows users to approve balance calibrations. Approving a calibration will place a checkmark next to the data record indicating that a second user has reviewed the record. This button is located on the Systems page of the software.



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