

Healthcare and Pharmaceutical Label Printing

Tools for 21 CFR Part 11 Compliance

This applies to versions 7.x or greater of LABEL MATRIX PowerPro



LABEL MATRIX® PowerPro label design software provides features to aid in the FDA's 21 CFR 11 compliance process. These software features can be configured to meet your internal requirements, as well as those of the FDA, to set up a compliant solution.

LABEL MATRIX Features:

Secure Access for Label Design

Global Security

You can set up secured access to label design functions by establishing a list of users, each with their own user name and password. Secured access means that each time LABEL MATRIX is started, the user is prompted to enter a user name and password. Once the user has opened the program, the level of functionality (design, print, database functions, etc.) available depends on the access rights that were granted when the user was added.

Label Security

You can set up password protection on a label design file, requiring the user to enter the correct password in order to modify the label. If security is enabled, a user is required to enter the password upon opening the label. If the user enters an incorrect password, the user is not allowed to modify the label in any way. In addition, you can require users to enter a password in order to print the secure label. Note: A password is also required in order to insert a password protected label design file into another label design.

Manage Variable Data

Pick List

The Pick List data source allows you to specify a list of valid choices, so that at print time you can enter a value by selecting it from a list. You can limit user input to only items in the pick list to ensure valid entries, or allow other entries besides those on the list.

Values from Previous Print Jobs

The Keep Changes drop-down list allows you to specify if your Keyboard Input or Counter value will be saved. If set to No, users must enter/select the variable data before each print job.

Double Entry Verification

When entering Keyboard Input data at print time, the user is prompted to enter the data and then prompted again to enter the data a second time, to verify that the data was entered correctly.

Variable Data Filter

Users are forced to enter variable data that match the specified filter set. You can choose from one of the standard filters (numeric, alphanumeric, etc.) or set up your own custom filter set.

Audit Trail Options

Write Data to a File

The "Write Data" tool allows you to write both the image data and/or the variable information from databases, counters or keyboard input to a comma-delimited text file. This ability to export the label's data is useful for facilitating print job reruns or activity audits.

LABEL MATRIX Configuration Steps for 21 CFR Part 11 Compliance

Follow these three simple steps to configure LABEL MATRIX PowerPro to meet your compliance requirements:

Step I – Set up secured access for label design

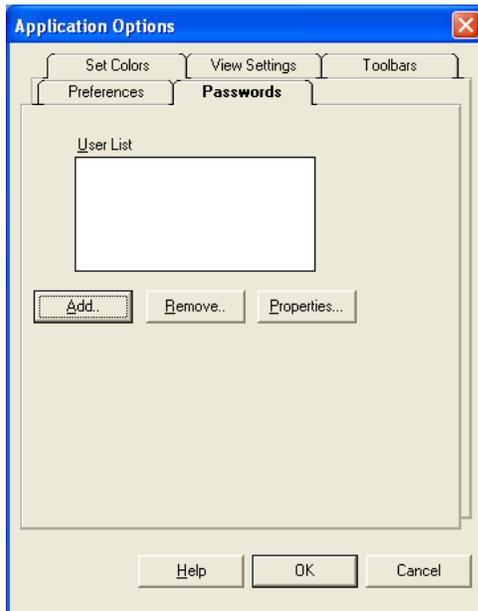
Step II – Manage variable data

Step III – Write data to a file

Step I – Set up secured access for label design

Global Security

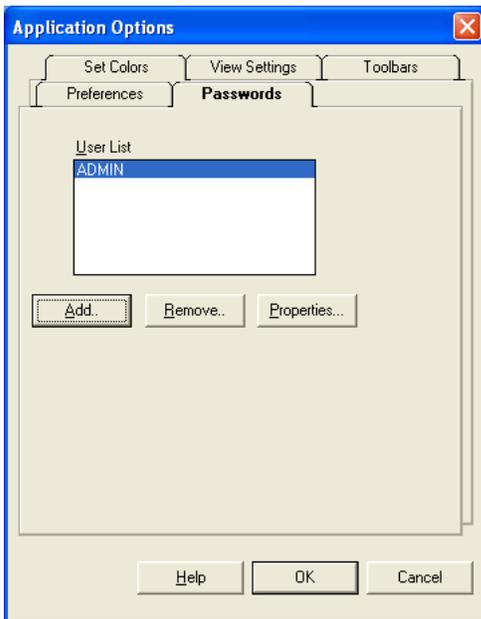
1. Choose **Setup** from the **Tools** menu.
2. Click the **Passwords** tab.



3. Click **Add** to set up the first user account. The first user to set up a password is automatically granted administration privileges, meaning that this person is the only user allowed to add and modify user accounts.



4. Enter a User Name and Password for the first user (the administrator) and click **OK**.
5. Click **Add** again to add another user.



6. Enter a User Name and Password, and click the appropriate Access check boxes to set up access privileges for this user.

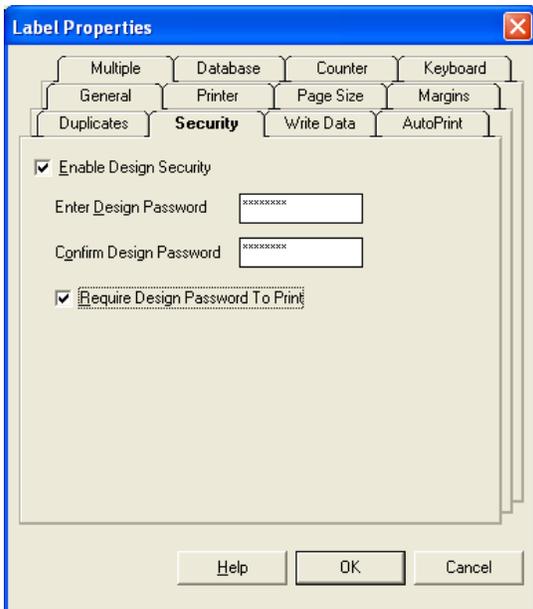


7. Continue to add as many users as necessary.

Label Specific Security

Clear variable values after each print job

1. Choose **Label Properties** from the **File** menu.
2. Click the **Security** tab.

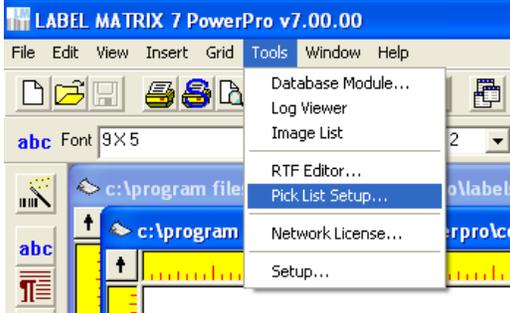


3. Click the **Enable Design Security** check box.
4. Enter and confirm a password to set up security on the active label design file.
5. If you want to require users to enter the password in order to print this label, click the **Require Design Password To Print** check box.

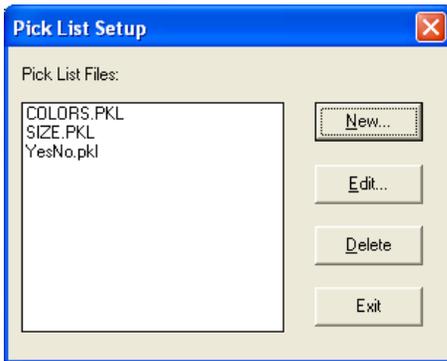
Step II – Manage Variable Data

Configure and Enable Pick Lists

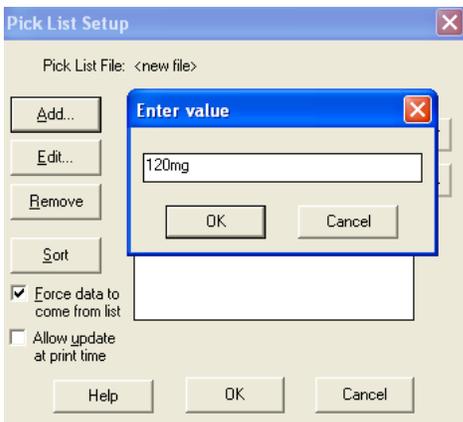
1. Open the Pick List setup dialog by Selecting Tools>Pick list setup from the File Menu.



2. The Pick List Setup dialog will open. Click New to create a new Pick List.



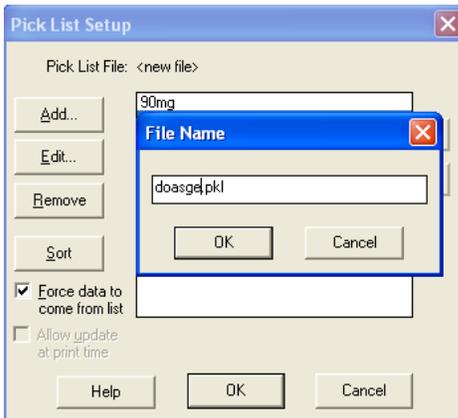
3. The Pick List configuration dialog opens. Click Add to enter values to the Pick List.



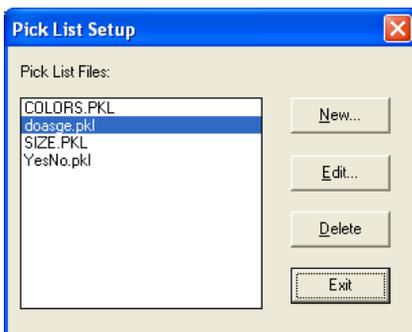
4. Be sure to enable the checkbox labeled 'Force data to come from list'.



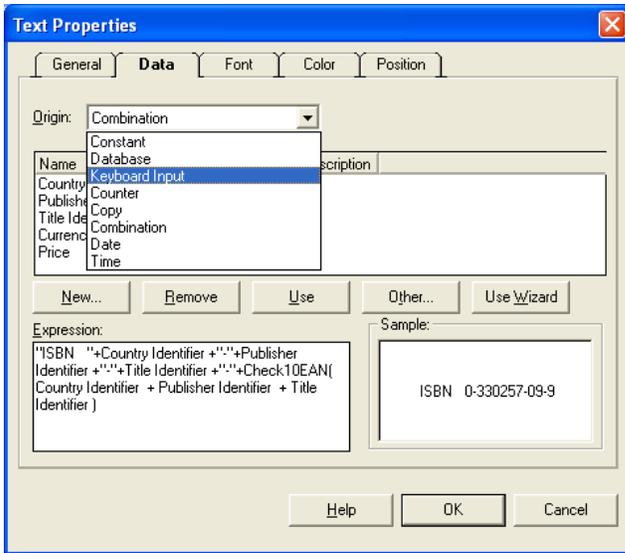
5. Click OK and enter a file name for the new pick list.



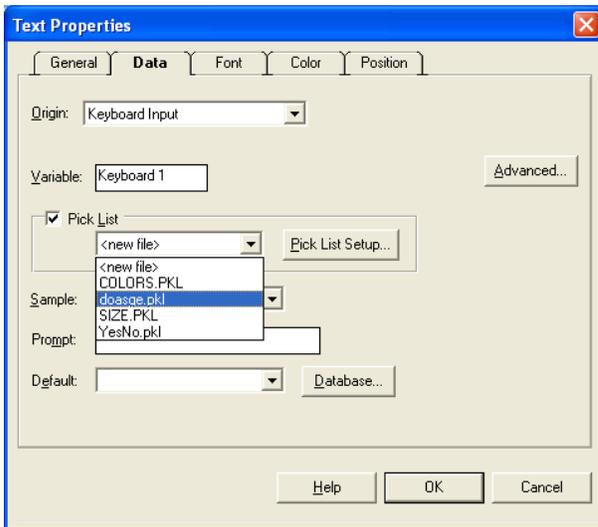
6. Click Exit to close Pick List Setup.



7. Create a text field on your label, or double-click an existing text field to open the text properties. On the Data tab, select Keyboard Input as the Origin.



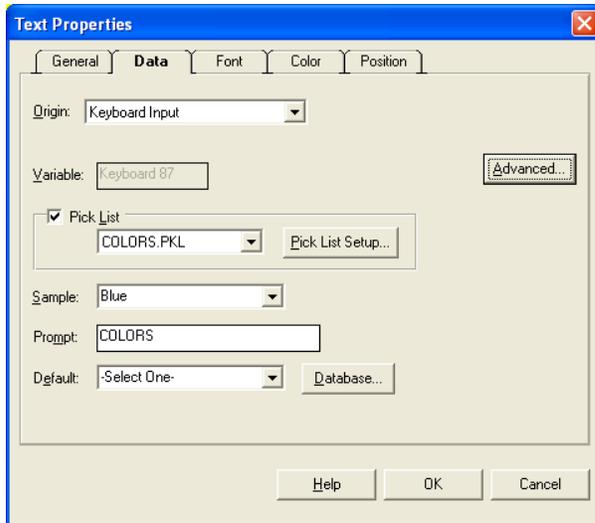
8. Enable the Pick List checkbox and select the desired pick list from the combo box.



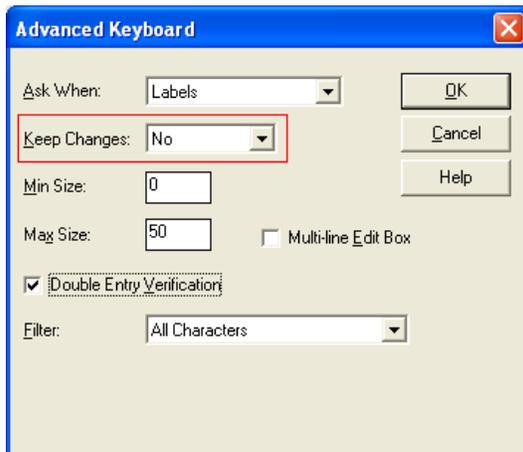
9. Once you have finished configuring your Pick List field, click OK to exit.

Values from Previous Print Jobs

1. Create a Counter or Keyboard Input field.
2. On the **Data** tab, click the **Advanced** button to access the advanced properties.



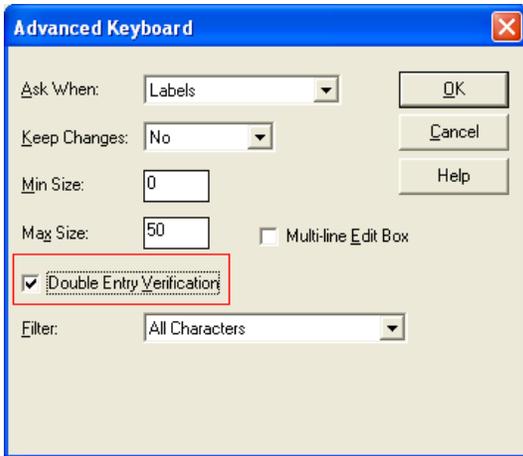
3. Set the **Keep Changes** option to **No**.



This will ensure that users must enter/select the variable data before each print job (the value entered for the last print job will NOT be saved).

Double Entry Verification

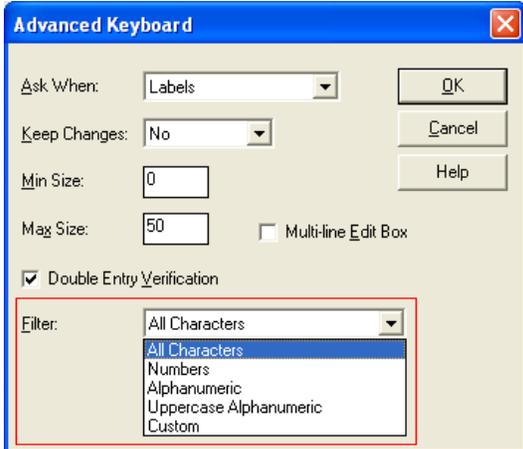
1. Create a Keyboard Input field.
2. On the **Data** tab, click the **Advanced** button to access the advanced properties.
3. Click the **Double Entry Verification** check box.



With this option enabled, at print time the user is prompted to enter the data and then prompted again to enter the data a second time to verify that the data was entered correctly. If both values do not match the user will not be allowed to proceed with the print job.

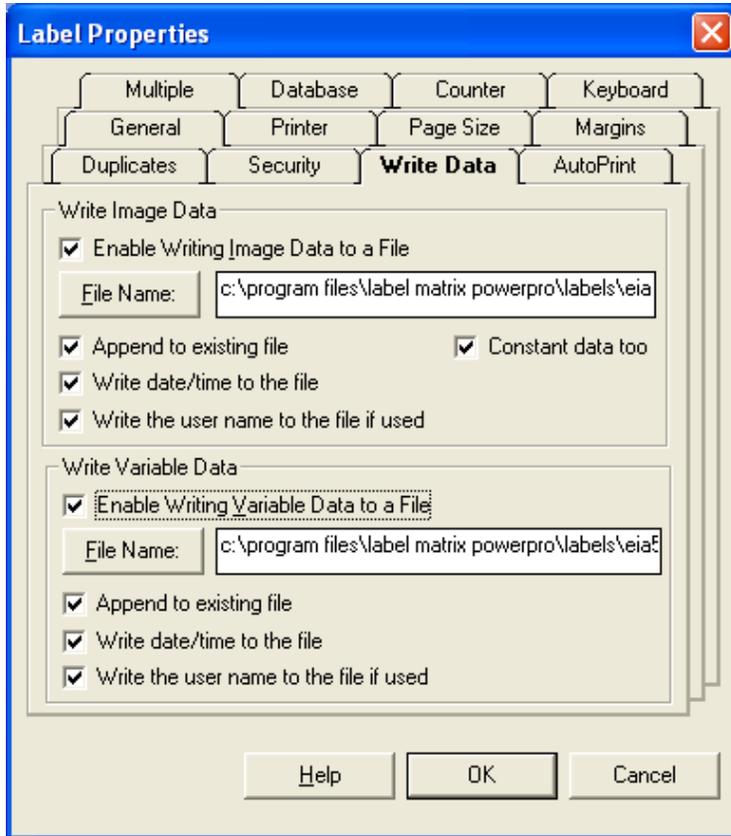
Variable Data Filter

1. Create a Keyboard Input field.
2. On the **Data** tab, click the **Advanced** button to access the advanced properties.
3. Click the **Filter** drop-down list and select the appropriate filter set. The filter set specifies the type of data that must be entered for this Keyboard Input prompt at print time. For example, you could set up this keyboard prompt to accept only numeric data.



Step III – Write data to a file

1. Choose **Label Properties** from the **File** menu.
2. Click the **Write Data** tab.



3. Click the appropriate check boxes on this tab to write image data (data as it appears on the label) and/or variable data to a comma-delimited text file (.TXT extension). This allows you to keep a record of all label information that is printed.

Summary

TEKLYNX software assists companies and its investigators in complying with 21 CFR Part 11. Using proper design techniques and tools can make compliance easier. This document is intended to make it easier for you to comply with any future FDA regulations on discovery using LABEL MATRIX.