Container Labeling System™

Manufactured for Codonics, Inc. by BIQ Consultores de Engenharia e Gestão Industrial, Lda.

User's Manual

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Regulatory & Agency:

- **IT class equipment meeting EN55022(B), EN61000-3-2, EN61000-3-0, EN55024 and EN 60950 standards**
- **CLS is intended for use in medication production and inventory management control environments.**
- **CLS is not intended for use in patient care areas and is not a medical device**
- **Components safety marked by original manufacturer (CE, CCC, etc.)**

USER'S MANUAL
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1. PURPOSE AND SCOPE

Refer to this User's Manual for procedures on how to perform the Container Labeling System's user operations, including:

- Setting up the hardware and software
- Overview of terms and system configuration
- Entering configuration information
- Entering master data
- Printing labels
- Exporting data
- Maintaining the system
- Monitoring events and log files

2. MANUFACTURER INFORMATION

The following image is the Help | About screen that displays the manufacturer information of BIQ Consulting Inc. for Codonics as the Container Labeling System (CLS).

3. PRODUCT INFORMATION

For technical assistance with the Container Labeling System, call Codonics Technical Support at the following number:

Phone: **+1.440.243.1198**
Toll Free: **800.444.1198 (USA only)**

Codonics Customer Service is available weekdays from 8:30 AM to 5:30 PM EST (U.S. holidays excluded). Technical Support is also available online via email and the Codonics web site:

Email: **support@codonics.com**
Web Site: **www.codonics.com**

General product information can also be requested by sending email to:

Email: **info@codonics.com**

Please include your postal mailing address and telephone number in the email message. Basic product information is returned via email. Complete product literature is sent by postal mail.

4. INDICATIONS FOR USE

The Codonics Container Labeling System (CLS) integrates software and hardware to provide site management over the labeling of medication vials for identification purposes under pharmacy control. CLS is a pharmacy level system/tool that aids in the "production/inventory/site identification" of parental vial medications. Site specified UDI are in addition to manufacturer vial labeling and do not obscure original vial labeling in any way. CLS labels added to vials assist in site tracking, inventory management, and identification of medications purchased and approved for distribution within the institution. CLS barcodes are configured to meet industry symbology standards for easy integration with devices that read machine readable codes. The product is not a medical device and the PC (computer), barcode scanner and printer components are marked by the original manufacturer for their intended use, installation environments and WEEE disposal instructions. CLS is not to be placed in a patient care area.

5. CONTAINER LABELING SYSTEM COMPONENTS

The Codonics Container Labeling System (CLS) is comprised of software, hardware and label media.

The software includes the following features, which are detailed throughout this manual.

- Integration with desktop printer
- Integration with barcode scanner.
- Container ID code formatting
- User group roles
- Manufacturer configuration
- Drug configuration
- Manufacturer drugs configuration
- Route configuration

- Concentration configuration
- User configuration
- Printer configuration
- Verification workflow
- Workflow approval
- Lot and expiration date tracking
- Container code verification
- Manufacturer code verification
- Label printing
- Export of CLS data in CSV format

The hardware provided with your system includes the following items:

- An easy-to-use Zebra® desktop direct thermal printer
- An easy-to-use Motorola® barcode scanner

The label media (see NOTE below) provided with your system includes three unique label designs for use in pharmacy, which are detailed throughout this manual.

- Flag labels intended to be wrapped around the neck of drug containers.
- Round labels intended to be applied to the bottom of drug containers.
- Rectangular labels intended to be applied to the side of drug containers.

NOTE: Use only Codonics labels to ensure proper operation of the device and proper labeling of drug containers. Using unapproved labels could lead to unacceptable results, including poor print quality and poor label adhesion to the drug containers. Please contact Codonics Customer Support to order label media for your CLS system.

NOTE: Storage of Codonics labels is recommended to be in a dark place at a relative humidity between 45 percent and 65 percent and a temperature below 77°F (25ºC) will assure satisfactory performance.

6. SETTING UP YOUR SYSTEM

It is recommended that the Container Labeling System be set up in the following order:

1.) Install the printer according to the Zebra installation guide and Zebra disc included.
   a. Unpack.
   b. Install the power supply.
   c. Install connectivity (USB or Ethernet)
   d. Run the Zebra set up software – ZebraSetupUtilities & ZebraDesigner
   e. Install label media.
2.) Install your scanner according to Motorola quick start guide.
   a. Unpack.
   b. Install connectivity

3.) Configure your scanner for use with the Container Labeling System software. Please refer to the Codonics supplied Release Notes document – part number 901-448-001 – with your scanner named "Container Labeling System Barcode Scanner Configuration" to program your scanner.
4.) Install the Container Labeling System software per the instructions provided in this manual.
5.) Configure your printer in the Container Labeling System software per the instructions provided in this manual.
6.) Perform a printer calibration in Container Labeling System software per the instructions provided in this manual.

7. GLOSSARY OF TERMS

User Groups
There are four user group types (administrator, manager, technician, operator). Each user account created is granted permissions in the system by being assigned to one of the four group types.

	System Configuration	Barcode Search	Manual Search	Workflow Approval	Print Container Labels
Administrator	✓	✓	✓	✓	✓
Manager		✓	✓	✓	✓
Technician		✓	✓		✓
Operator		✓			✓

Workflow Approval
An administrative or managerial workflow process of the CLS allows for the quality assurance review of confirming a technician's or operator's label selection prior to the labels being printed.

This optionally enabled verification as assigned at the Drug record will require authorized Workflow Approval users to review the containers to be labeled and the label intended to be printed. Authorized users with Workflow Approval will enter their user name and password to approve the label printing or cancel the pending system request if a selection error occurred by the technician or operator.

Verification Workflow
An administrative workflow process of the CLS which allows for quality assurance review for confirming the configuration of specific container codes to manufacturer codes.

This optionally enabled verification will provide a CLS to have a "double-check" confirmation process prior to releasing each specific association of a container code to a manufacturer code into an "in use (production)" state.

Manufacturers
The name of the companies or laboratories that will be managed in the CLS as providers of drugs used in the hospital's pharmacy.

Drugs
Drugs that will be tracked in the CLS. Associated data includes a container code, drug name, Tallman spelling, concentration value, concentration units and route.

Manufacturer Drugs
A CLS association of a specific drug as supplied by a specific manufacturer.

Manufacturer IDs
The value assigned to a manufacturer as defined by your hospital.

Manufacturer Codes (Barcodes)
The barcode value printed on a manufacturer's box of drug containers.

Container Code
The ID value entered or system assigned to uniquely identify a drug type by container.

Concentrations
The values and units that are defined to a container's drug.

Routes
The intended delivery method type of the container's drug to a patient.

Labels
Labels are printed labels by the CLS printer for application to drug containers. Labels are available in three die-cut shapes:

Flag (Neck) – intended to be wrapped around and adhered to the neck of a container.

Rectangular (Seam) – intended to be applied and adhered to the side of a container.

Round (Bottom) – intended to be applied and adhered to the bottom of a container.

Events
Details of actions and activities as performed in the CLS for an administrator to review.

8. OVERVIEW OF CONTAINER ID FORMATTING FOR DRUG CONTAINERS

The Container ID Formatting configuration should be carefully considered prior to the start of the utilization of the Container Labeling System. Evaluation of the identification numbering system for the drugs in your pharmacy is critical to ensure that each drug's container can be uniquely labeled. Considerations include identification methodology that are already in use in your hospital, national standards in place by your country's government or emerging national standards that are being implemented for use within your country, or with drugs imported from neighboring and/or partner countries.

If your hospital and/or country does not have any existing standards for an identification numbering system, a schema of parameters can be defined for use in the Container Labeling System to assign unique identifiers for each drug. The defined schema can then be used via the Container Code Auto-Assign functionality when each drug is entered into your CLS.

The Container ID (CID) parameters will be required to be set for the format of choice for your Container Labeling System upon system start up.

Application Identifier – this is site configurable, with a default value of "COD". This value is a prefix intended to help uniquely identify the drug containers used by your hospital, i.e. your hospital network. This value can be configured from 0-4 characters with alpha-numeric values (A-Z, a-z and 0-9). Optionally, if no value is configured, there will be no Application Identifier included in the barcode for the CID.

It is highly recommended to utilize a value for the Application Identifier as this will allow a distinguishing value to be used in your printed barcode labels which can mitigate the possibility of conflicting with any existing or emerging standard. An example with the default configuration of the Application Identifier value of "COD" and the Variable Identifier (described below) of 13 digits would create a barcode value of "COD0000000000123".

Fixed Identifier – this is site configurable, with no default value. This value is a secondary prefix intended to further help in uniquely identifying the drug containers used by your hospital network, i.e. a regionally based hospitals where you may want to distinguish drug containers in one region differently than those at another region. The value can be configured from 0-4 characters with numeric values only (0-9). If included in your configuration, this prefix value is included in the drug's overall CID barcode value. Optionally, if no value is configured, there will be no Fixed ID included in the barcode for the CID.

It is recommended to utilize a value for the Fixed Identifier as this will allow for further distinction of your barcode values for mitigation of conflicts with any existing or emerging standard. An example with the Application Identifier of "COD", a Fixed ID of "7777" and a Variable Identifier of 9 digits (described below) would create a barcode value of "COD7777000000123".

Variable Identifier – this is site configurable, with a default value of 13 digits. This value is required for uniquely identifying the drug containers used by your hospital. The value can be configured numerically from a minimum of a 6-digit length up to 15 digits in length. This value will be included in the barcode for the CID.

Please refer to the "Parameters of the System" section of this manual for the details on the configuration of the Container ID Formatting parameters for your Container Labeling System.

Please refer to the "Parameters of the System" section of this manual for the details on the configuration editing of the Container ID Formatting parameters for your Container Labeling System.

Please also see the WARNING section in Chapter 12 entitled "WARNING: Changing the Container ID Format and Database" to ensure that you fully understand and accept the implications for changing your Container ID parameters after your CLS has been configured and placed into use.

9. OVERVIEW OF DATABASE CREATION FOR MASTER CLS DATA

The database creation process for the Container Labeling System requires the entry of the following types of data based upon the drugs inventoried and utilized within your hospital's pharmacy:

Manufacturers
The name of the company or laboratory that manufactured the drugs inventoried and utilized in your hospital's pharmacy.

Drugs
The drugs inventoried and utilized in your hospital's pharmacy.

Manufacturer Drugs
An association that connects a specific manufacturer to a specific drug for utilization in your hospital's pharmacy.

It is recommended that the database entry process occur in the order of the terminology outlined above, which is Manufacturers followed by Drugs and completed with Manufacturer Drugs.

Database entry is only available to users that are granted with rights of the Administrative group. Please see the User Group permissions table.

Entering information into your CLS database for Manufacturers is the process for managing specific companies or laboratories that your hospital procures drugs from for your pharmacy. This can be accomplished by entering the data based upon lists of Manufacturers that you have available from your hospital's information system or inventory management systems as well as the physical boxes of drugs inventoried in your pharmacy. Please refer to the "How to Add Manufacturers" section of this manual for the details of the data entry process.

Entering information in your CLS database for Drugs is the process for managing specific drugs that your hospital procures for your pharmacy. This can be accomplished by entering the data based upon lists of Drugs that you have available for your hospital's information system or inventory management systems as well as the physical boxes of drugs inventoried in your pharmacy. Please refer to the "How to Add a Drug" section of this manual for the details of the data entry process.

Entering information in your CLS database for Manufacturer Drugs is the process for associating a specific Drug to a specific Manufacturer. Having the physical drug container boxes available on hand is required as you will scan the barcode provided by the drug's manufacturer or laboratory. The physical boxes that have an available barcode to scan may either be on an individual box of drug containers or on a larger carton containing multiple smaller boxes of drug containers. Please refer to the "How to Add a Manufacturer Drug" section of this manual for the details of the data entry process.

To accomplish the entry of data into your system, an administrative user will perform the following steps to create CLS master data for utilization. An example data entry use case for CLS master data would be entered in the following order:

1. Manufacturers
2. Drugs
3. Manufacturer Drugs

The entry of the data would be accomplished in the following manner with this example data of 3 manufacturers, 10 drugs and 10 manufacturer drugs associations:

As an administrator of the system, enter your 3 manufacturers into the CLS database.

Manufacturer 1
Manufacturer 2
Manufacturer 3

Now that you have your 3 manufacturers entered, you will then enter your 10 drugs into the CLS database.

Drug 1
Drug 2
Drug 3
Drug 4
Drug 5
Drug 6
Drug 7
Drug 8
Drug 9
Drug 10

At this point, your CLS database includes 3 manufacturers and 10 drugs. The last step in setting up your data is to associate specific manufacturers to specific drugs.

Manufacturer 1
- Drug 1
- Drug 5
- Drug 8

Manufacturer 2
- Drug 2
- Drug 3
- Drug 9
- Drug 10

Manufacturer 3
- Drug 4
- Drug 6
- Drug 7

Your CLS database now includes 3 manufacturers, 10 drugs and 10 manufacturer drugs for use in printing barcode labels for your drug containers.

10. HOW TO UPGRADE CLS

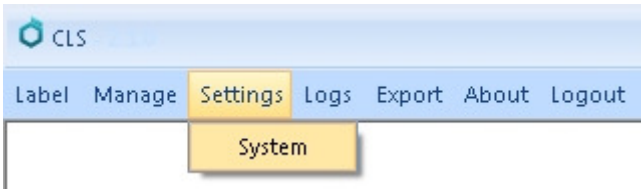
This option is used to upgrade the CLS software

Note: This option is only available before the application is upgraded and while there is no data in the new CLS database.

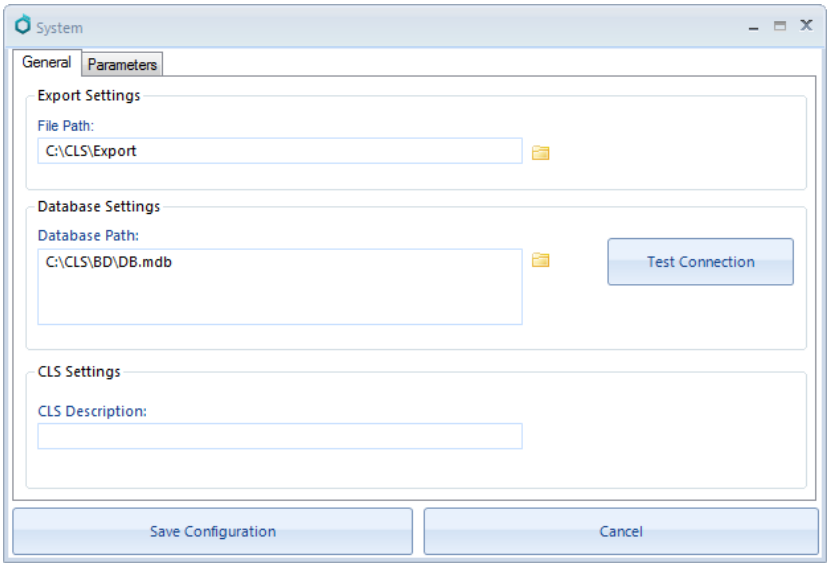
10.1 Backup the Database

Please backup your CLS database. This database backup file will be used during the upgrade process to import the existing data from your current CLS software version to the upgrade version.

To find your Database file, click *Settings* and then *System*. The *System* configuration window is displayed.



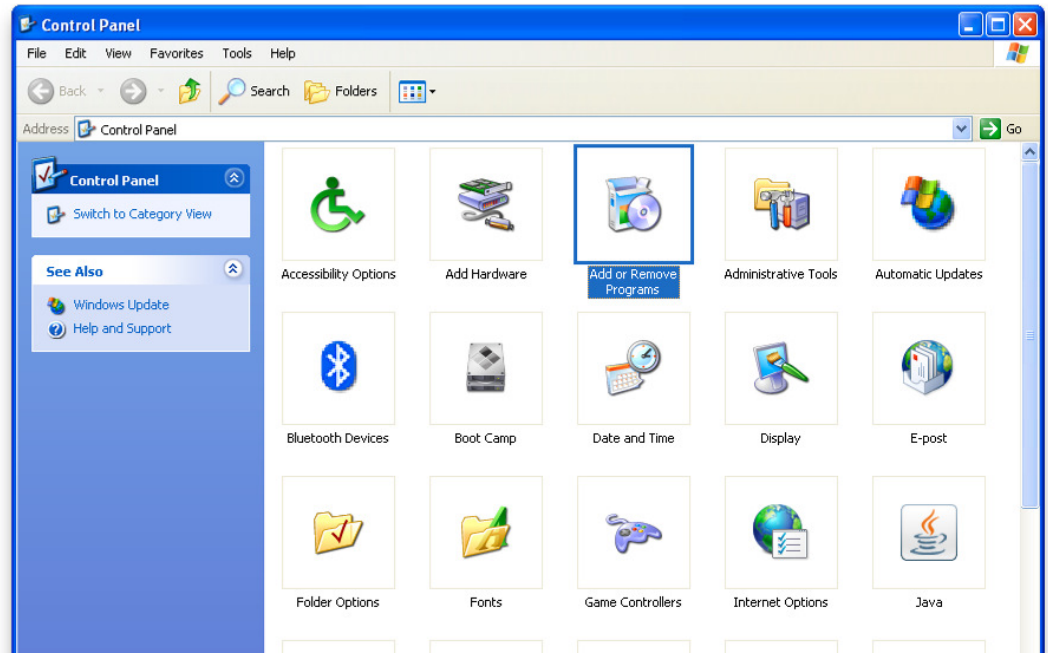
Under the *General* tab you can find the *Database Path* field which defines the path to the database that the CLS is using. The default path is C:\CLS\BD\DB.mdb. Backup your database file in a secure location – out of CLS application folder.



Check the root CLS folder defined in the *File Path* field. The default root folder for the application is C:\CLS.
You will need to remove the CLS folder later in this section of the manual.

10.2 Uninstall CLS

Go to Windows *Control Panel*. Run the *Add or Remove Programs* option.



The *Currently installed programs* list is displayed. Select the CLS application from the list and uninstall it.

10.3 Remove CLS folder

In Windows Explorer, remove the CLS root folder with all subfolders and files. The default root folder is C:\CLS.

10.4 Install new CLS version

For further information on how to install a new CLS version please see the *HOW TO INSTALL CLS* section of this manual.

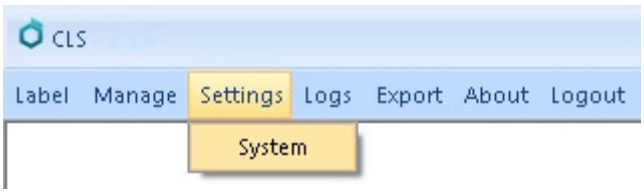
10.5 Update the license

When starting a new version of CLS for the first time, a new license will be required to activate the CLS.

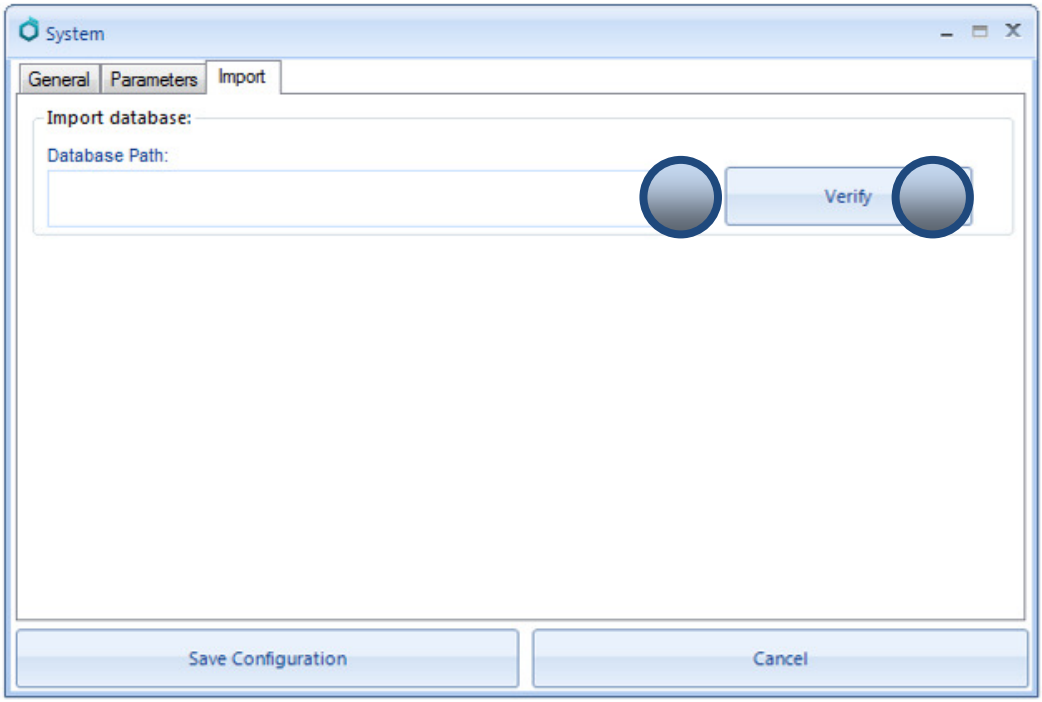
For further information on how to activate the product please see the *HOW TO RUN THE APPLICATION FOR THE FIRST TIME* section of this manual.

10.5 Import Database

When running the new version of CLS application for the first time after the license process, the *System* configuration window is displayed. Otherwise, click *Settings* and then *System*.



Click on the tab *Import.*



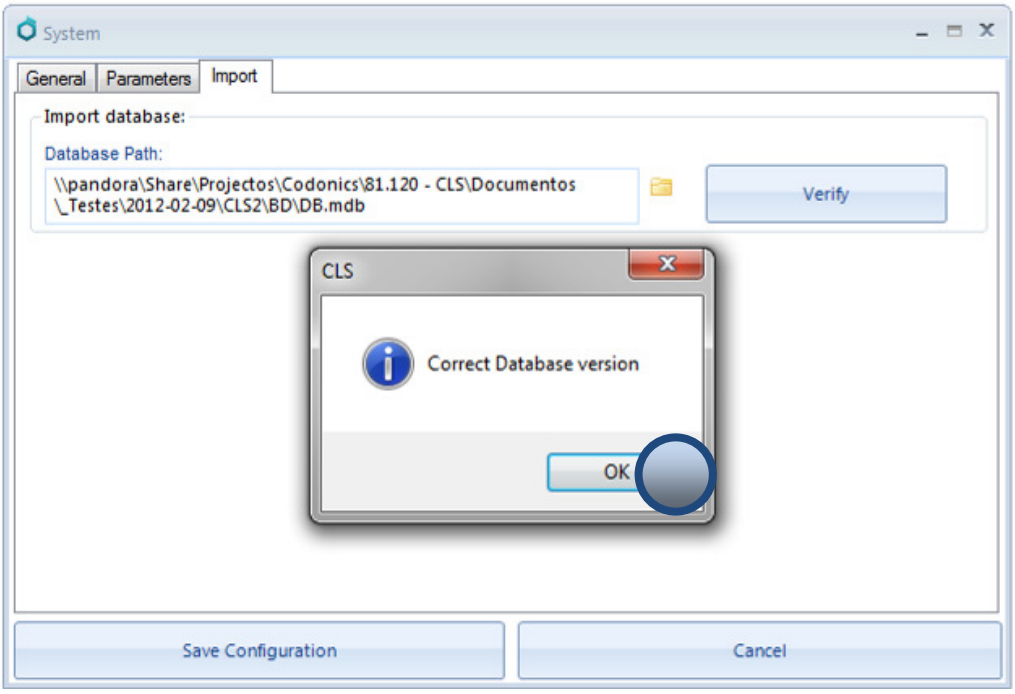
Click on the folder icon to select the database backup file. Select the backup file you created previously in this section.

Note: You need a valid backup file of the CLS database in order to proceed.

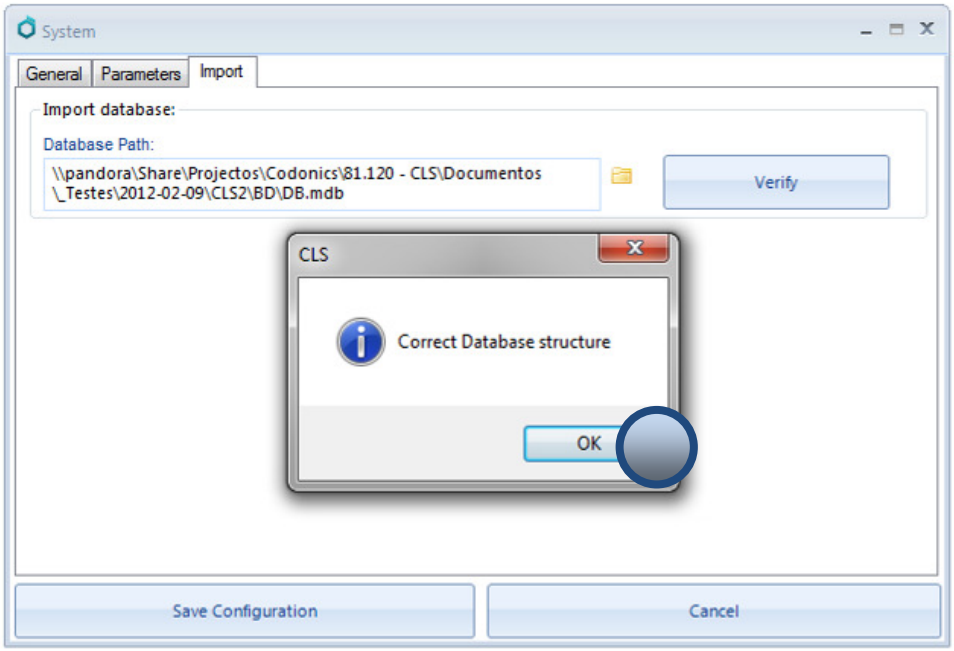
Press the *Verify* button to verify the selected file.

If the selected backup file is correct, a *Correct Database version* message is prompted.

Press the *OK* button after database version validation.

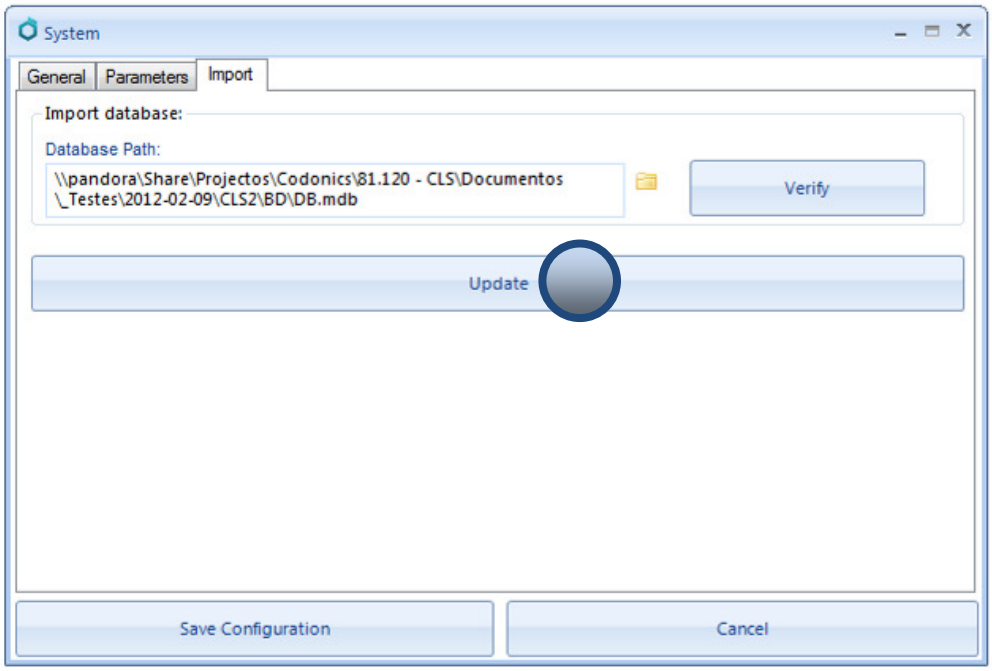


Press the *OK* button after database structure validation.

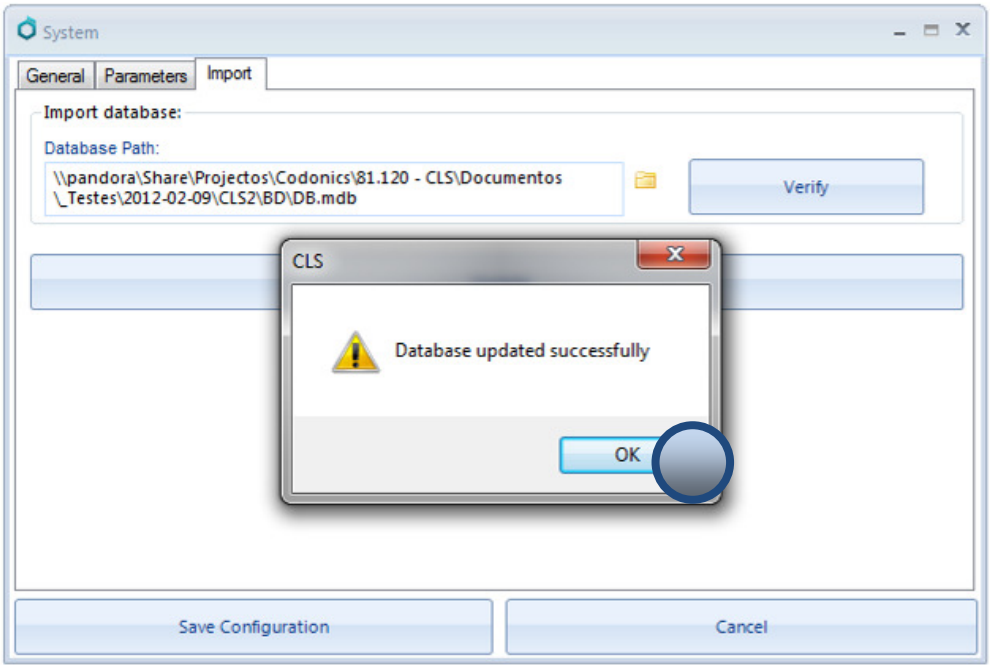


If validation process completes successfully, the *Update* button is available.

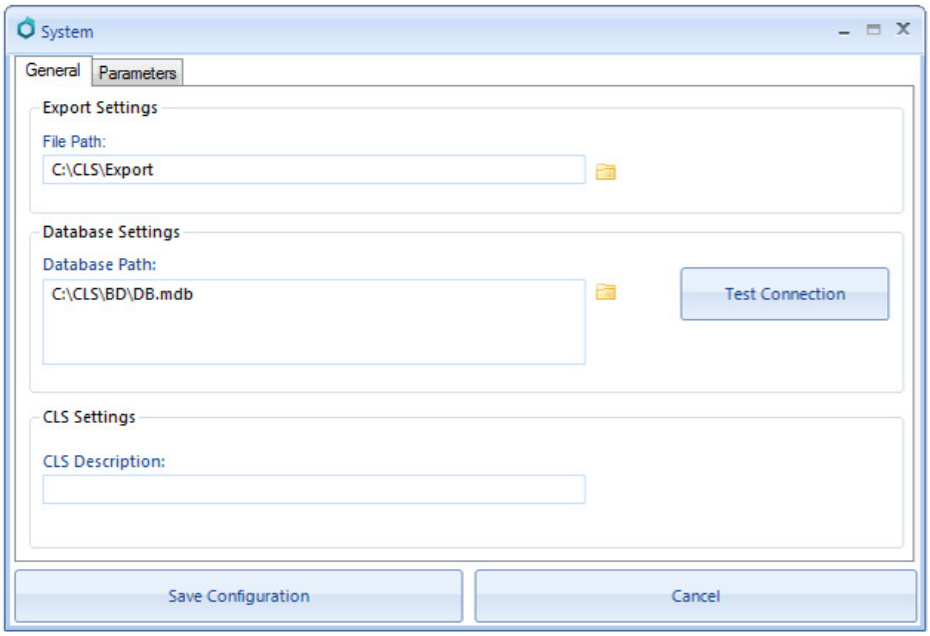
Press the *Update* button to update the application.



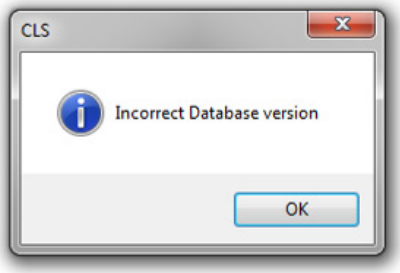
Press the *OK* button after update process is finished.



Press the *Save Configuration* button after update process is finished.



Note: If the wrong backup file is selected, "*Incorrect Database version*" message is prompted.



11. HOW TO INSTALL CLS

This chapter explains how to install the CLS on your computers.

The following minimum system standards are required for deployment on intended computers:

- Windows XP Professional SP3 or Windows 7 Professional SP1 (32-bit or 64-bit)
- .Net Framework 3.5
- 500MB available disk space
- 2GB RAM
- Intel Core 2 Processor or AMD Athlon64 X2

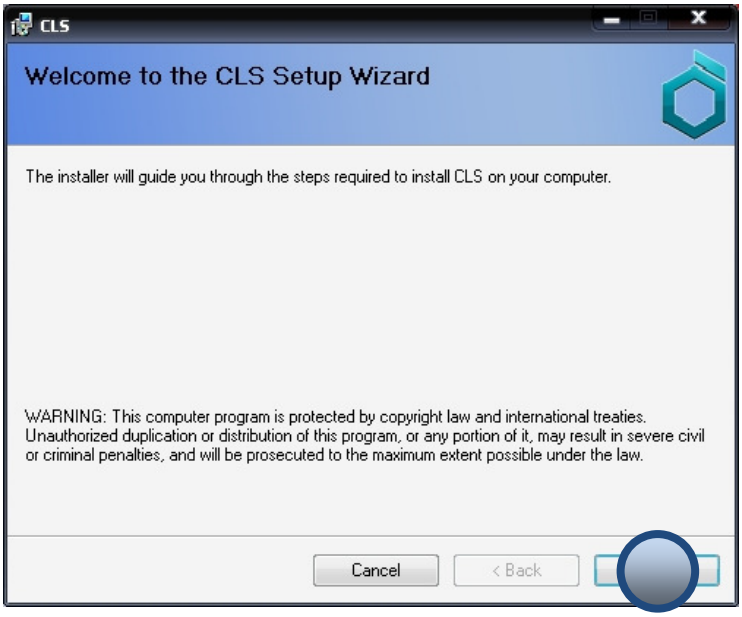
Installation

Copy the files from the CLS software installation set to your local operating system. Please note where you copy the files, as they will be required later in the configuration process.

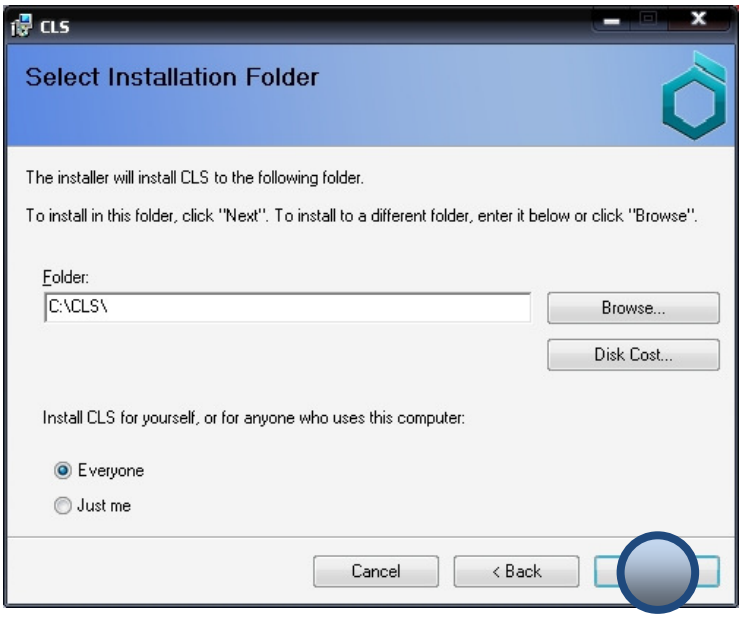
To install CLS, you need to double click on the setup.exe icon.

.

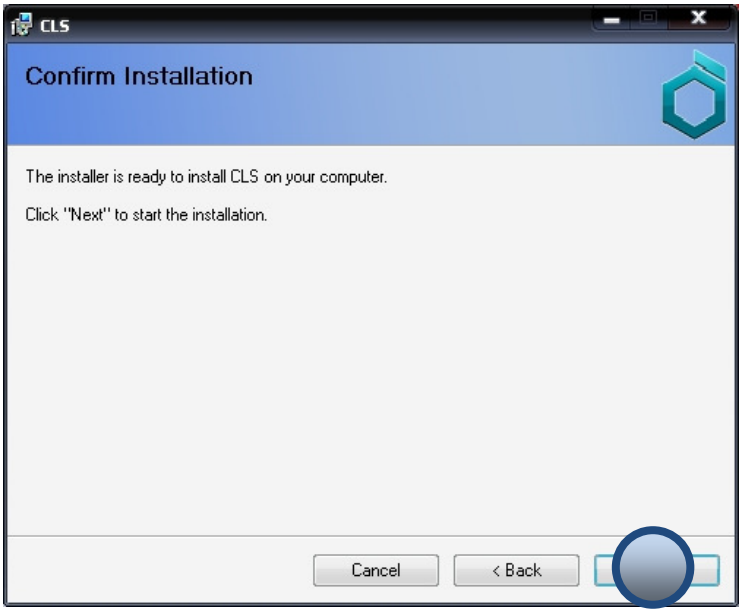
Welcome to the CLS Setup Wizard, click on the *Next* button.



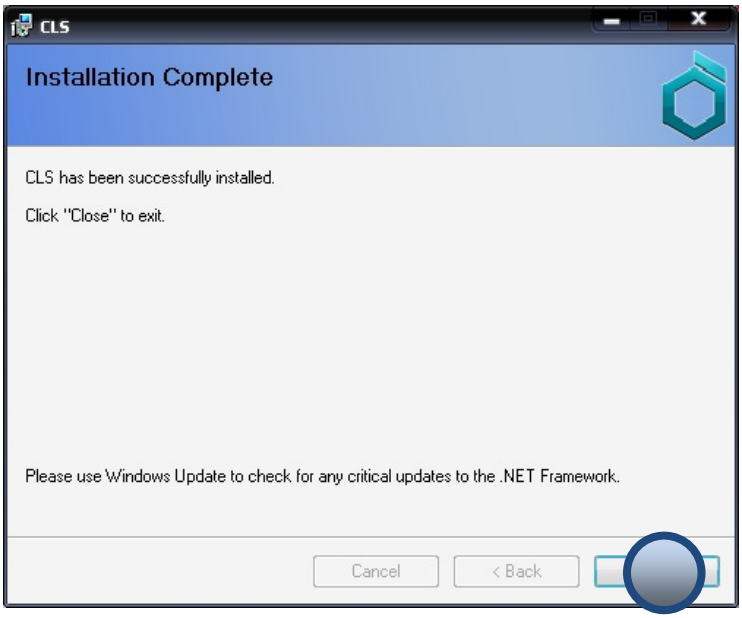
Choose the destination folder (the user should have writing permissions) and click *Next*.



On the next window, confirm the installation and click the *Next* button.



When the installation is complete, click on the *Close* button.



To access the application, the

icon will be available on your computer's desktop and on the Start menu.

12. HOW TO RUN THE APPLICATION FOR THE FIRST TIME

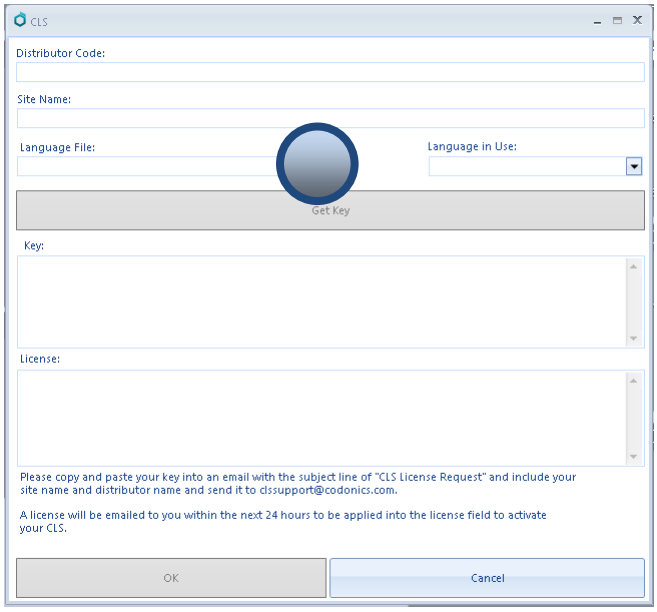
To run the application, double click on the icon on the desktop or select from the Start menu.

License

When starting the application for the first time, a license will be required to activate the CLS.

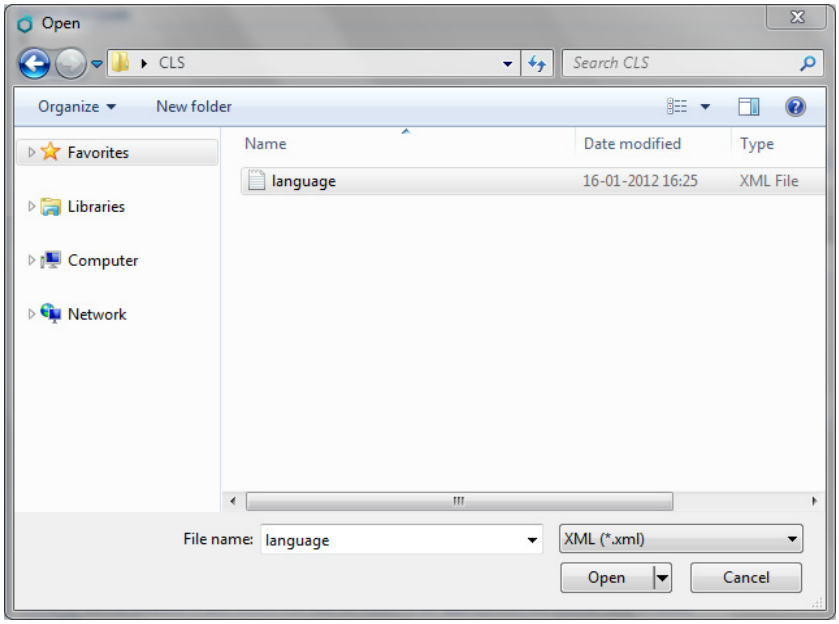
Note: the license that is provided to activate your CLS software is workstation-specific. Please ensure that the application is installed on the specific workstation or workstations that will utilize the Container Labeling System software. A license cannot be transferred to another workstation.

Enter the requested information in the fields displayed with the given information.



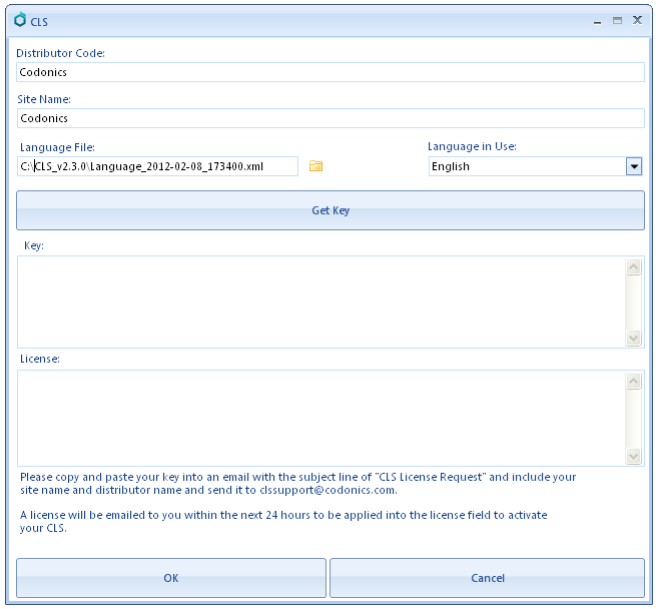
In the Language File option, find the *'Language.xml'* file. It will be located with the CLS setup.exe where you placed the files on your local operating system from the CLS software installation set at the start of your installation process.

Note: The *'Language.xml'* file is not located within the CLS directory created during the installation process.

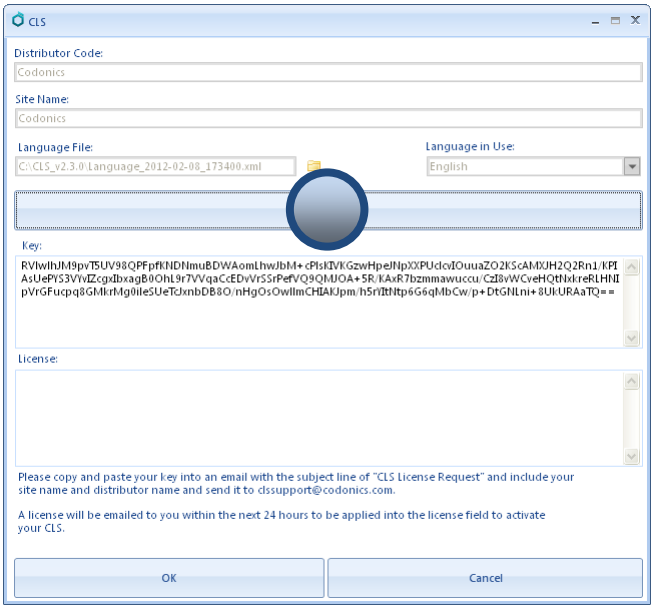


Upon selecting the *Language.xml* file, the default language in use will be English. You can select another supported language as provided in the drop-down list.

To generate a key for the application, click on *Get Key* button.

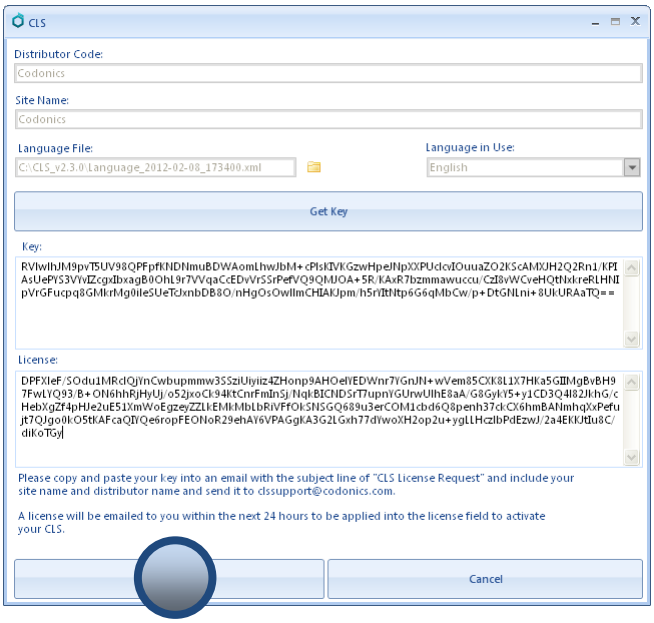


The application key will be generated and displayed in the *Key* field.



To request the *License* for activating your system, please copy the key and paste it into an email with the subject line '*CLS License Request*' and send it to clssupport@codonics.com. Please include your distributor name and site name in the email. A response will be sent within 24 hours.

When you receive the email with the License, copy and paste it into the *License* field.



To activate your CLS, click on the *OK* button.

If any of the fields were selected incorrectly upon generating your system's key, the license activation will notify you with an error message.

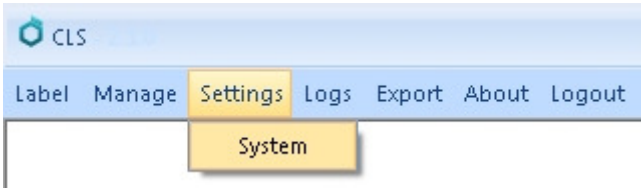
If all fields were entered correctly upon generating your system's key, the license activation will be accepted and a message will be displayed welcoming you to the CLS.

Now you will be prompted to configure the system settings, explained in *HOW TO CONFIGURE SYSTEM SETTINGS*.

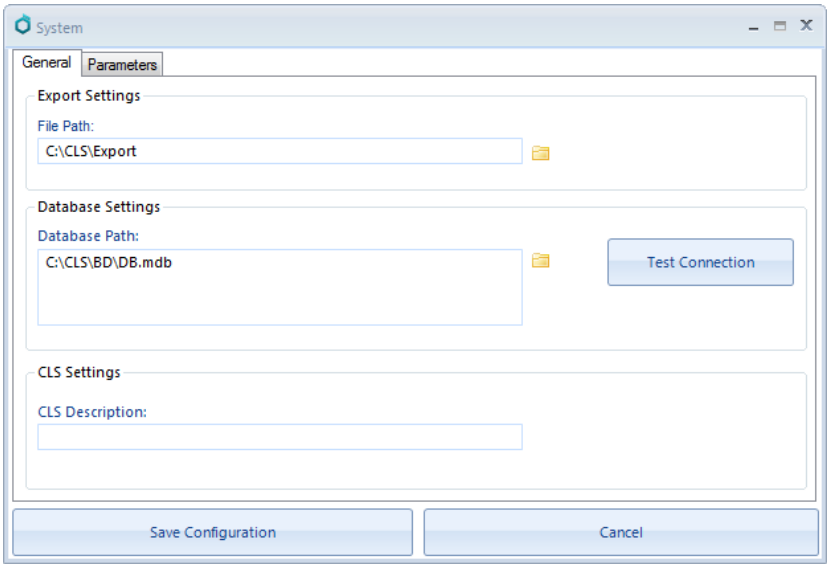
Upon completion of the system settings, the CLS is ready to be utilized.

13. HOW TO CONFIGURE SYSTEM SETTINGS

When running the CLS application for the first time after the license process, the *System* configuration window is displayed. Otherwise, click *Settings* and then *System*.



General Settings



File Path

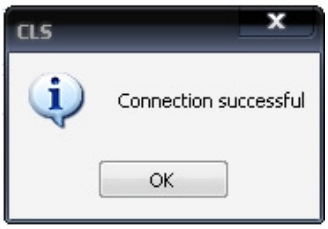
The *File Path* field defines the destination folder for exported CSV files. The default destination folder is C:\CLS\Export. If a different folder is desired, select the browse folder icon to choose a different folder, which will then be displayed in the *File Path* section.

Database Path

The *Database Path* field defines the path to the database that the CLS will use. The default path is C:\CLS\BD\DB.mdb. If a different path is desired, select the browse folder icon and select the path to where the DB.mdb file was placed, which will then be displayed in the *Database Path* section.

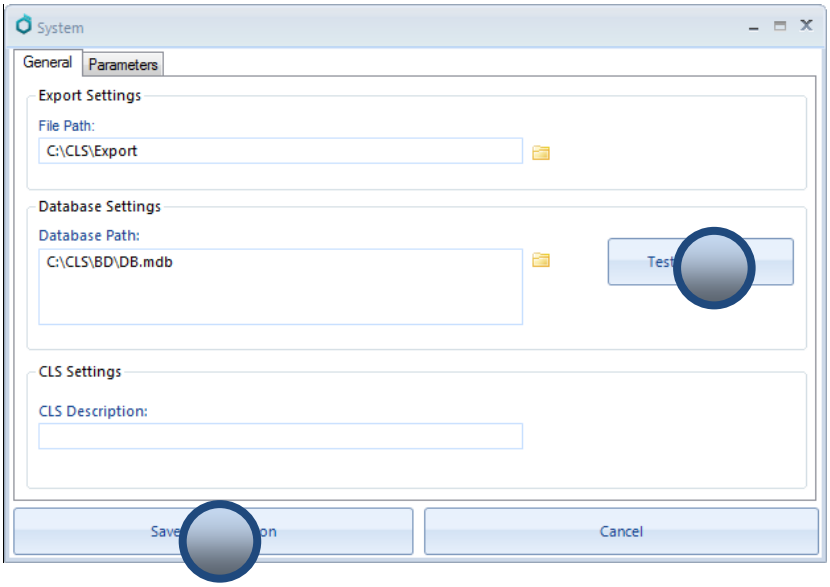
After defining the database path, test the database connection by pressing the *Test Connection* button to check its availability. If *Test Connection* fails, the CLS will give an error message.

If the connection to the database is successful, the CLS will give a success message.



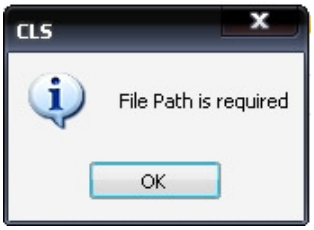
CLS Settings

CLS Description identifies the computer in use with the CLS system as more than one computer can be configured for use. This description will identify each computer being utilized by the CLS system.

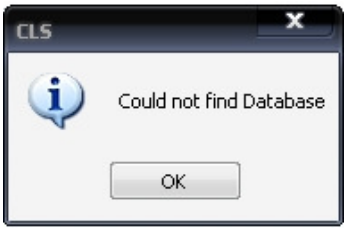


Note: All the fields are required, except the *CLS Description* field.

If you leave *File Path* field empty, the CLS will provide an error message.

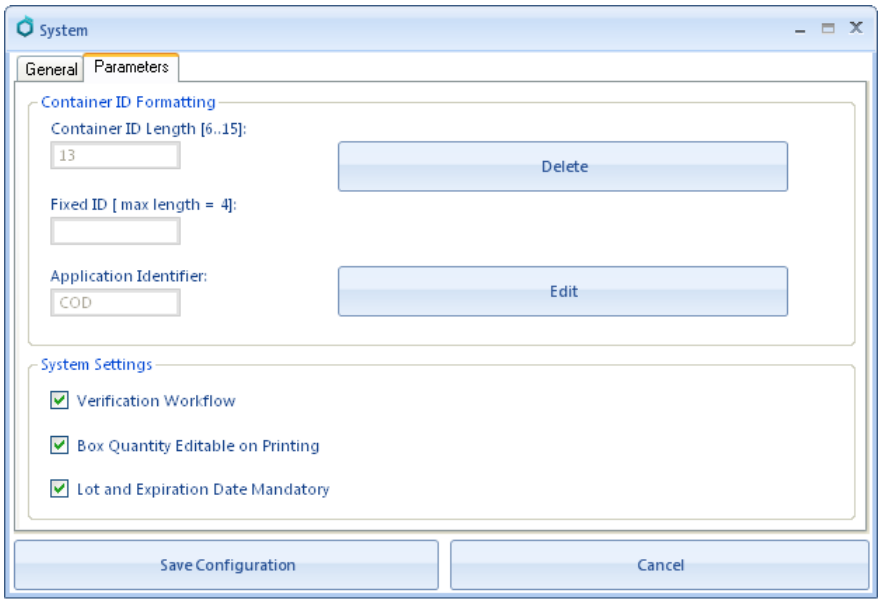


If CLS can't find a database on the given path , the application will provide an error message.



Parameters of the System

To change the application parameters click on the tab *Parameters*



Container ID Formatting

The Container ID Formatting for the Container Labeling System may be edited or deleted. Please ensure that you fully read and understand the information below prior to editing or deleting your container ID formatting.

WARNING: Changing the Container ID Format and Database

The CLS is designed to ensure that each new drug added to the system is associated with a unique Container ID. CLS will not allow duplicate Container IDs to exist in the database. This is an important feature for the safe operation of the CLS. Many devices and applications that use drugs labeled by the CLS rely on each drug having a unique Container ID.

Because having a unique Container ID associated with each drug is so important, this section of the User's Manual describes some HIGH RISK functions of CLS that can cause duplicate Container IDs to be assigned to drugs. The functions described in this section should only be used by experienced administrators who fully understand the operation of the CLS and the implications of changing the Container ID Format or deleting the database.

The CLS provides two special functions to Edit Container ID Format and Delete the Container ID database. These functions should only be used when no other options are available. Please study the information in the section carefully before using these functions.

Warning: Use of the functions described in this section can result in duplicate Container IDs.

WARNING: Overview of Editing the Container ID Format

The CLS can be set up to produce unique Container IDs that conform to a specific format. The Container ID Format includes an Application Identifier, a Fixed ID and a total Container ID Length. Once the Container ID Length is set, the CLS will not allow the length to be changed without deleting the entire Container ID database.

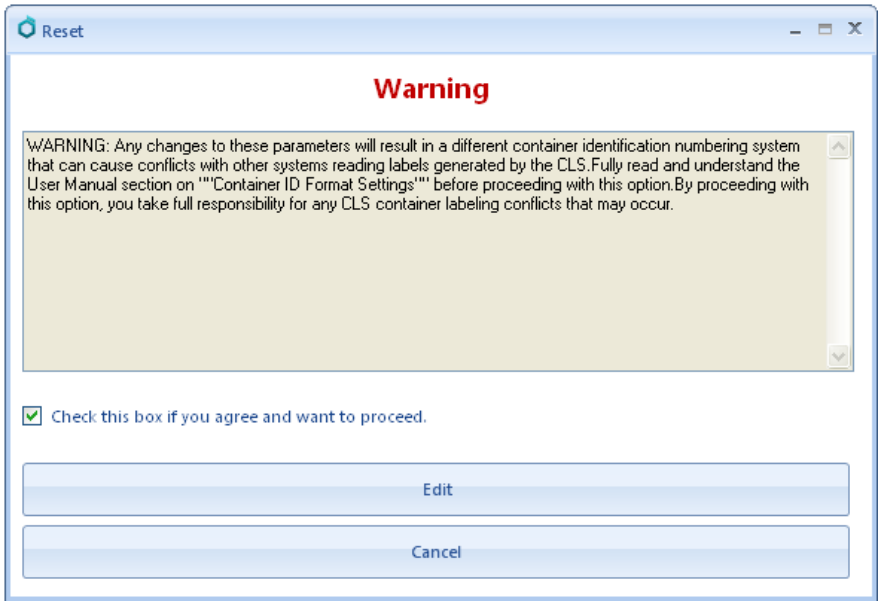
The Application Identifier and Fixed ID number can be changed, but should be done so using EXTREME CAUTION.

The Fixed ID is often used in Hospitals systems with multiple locations that are labeling drugs. Assigning a unique Fixed ID number to each location using the CLS allows Container IDs to be created that will not conflict with other sites. This can be useful if multiple locations are exchanging drugs that were labeled on different CLS systems. Changing the Fixed ID format at a location may cause a conflict with another location if the same Fixed ID is already in use.

EXAMPLE: If Location A is using Fixed ID 3333 and the current Container ID is 333300000001, and Location B is using Fixed ID 4444 and the current Container ID is 444400000001, then changing Location A from Fixed ID 3333 to 4444 will result in the same Container ID being issued by two different CLS systems. Different drugs labeled at each location will have the same Container ID.

It is HIGHLY RECOMMENDED that once the CLS is configured with a Container ID Format and drugs are being labeled by CLS, that Container ID Format not be changed.

The CLS will provide a warning and require confirmation when a user attempts to Edit the Container ID Format.



WARNING: Overview of Deleting the Container ID Database

The CLS stores all Container IDs in a database. Each time a new drug is added, a corresponding Container ID is created. CLS always verifies that each new Container ID is not a duplicate of another in the database. This guarantees that each new drug added to the CLS will have a unique Container ID assigned.

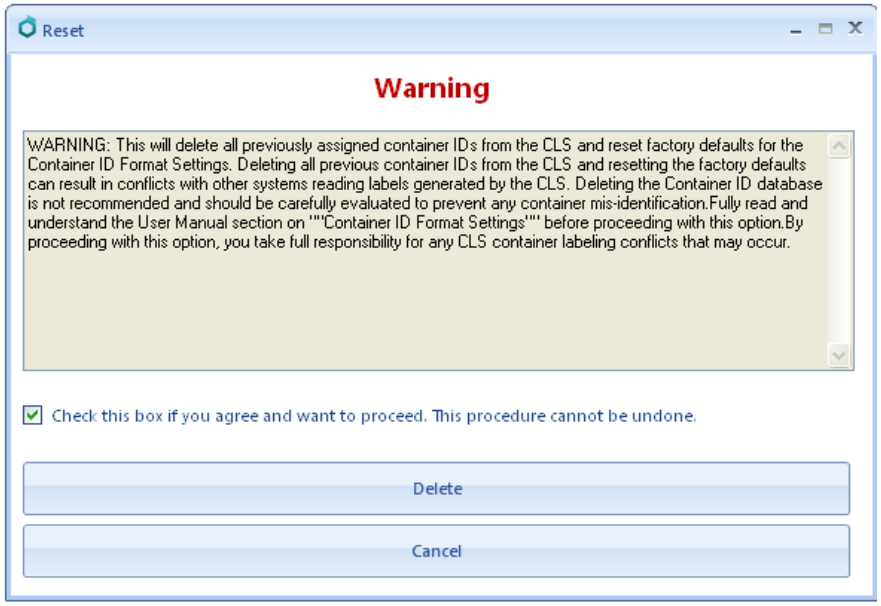
Deleting the Container ID database will erase all information about previous Container IDs from the system and prevent the CLS from verifying that new Container IDs are unique. When deleting the Container ID database, the CLS will continue to automatically generate new Container IDs using the last number that was created before the database was deleted.

Deleting the Container ID database on CLS can result in different drugs being labeled with the same Container ID. This applies mostly to Container IDs that manually entered into the CLS but can also apply to Container IDs that are generated automatically be the CLS.

EXAMPLE: If Container ID 0000000000123 was manually entered into CLS and originally assigned to the drug Propofol, deleting the CLS Container ID database will allow Container ID 0000000000123 to be manually re-entered and assigned to a different drug such as Penicillin . Scanning a Propofol drug vial with Container ID 0000000000123 would report Penicillin.

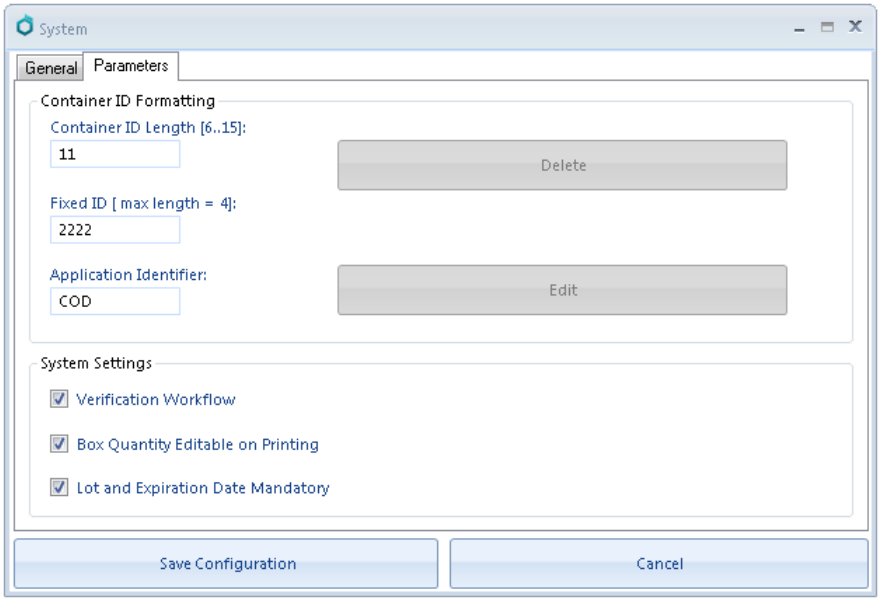
It is HIGHLY RECOMMENDED that once the CLS is configured with a Container ID Format and drugs are being labeled by CLS, that the CLS Container ID database not be deleted.

The CLS will provide a warning and require confirmation when a user attempts to Delete the Container ID database.



Container ID Formatting

The CLS is designed to ensure that each new drug added to the system is associated with a unique *Container ID*. The length of the *Container ID* can be set between 6 and 15 characters, sharing it with the *Fixed ID*. We can allocate up to 4 characters of the *Container ID length* to be a *Fixed ID*.



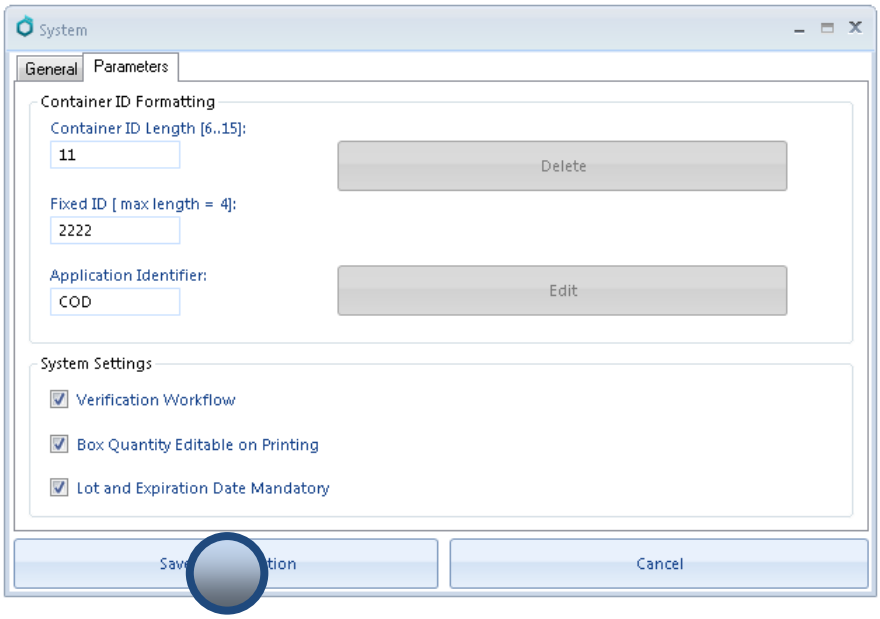
Keep in mind that the *Container ID Length* is shared with the *Fixed ID* and there's a minimum of 6 characters following the *Fixed ID*. For example, having the Container ID Length of 10 characters and the Fixed ID of 4 characters (i.e. 0001) leaves the minimum of 6 characters available as a Container ID.

System Settings

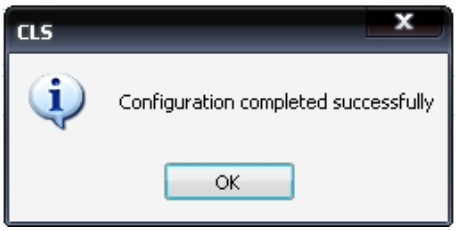
If the *Verification Workflow* field is checked then CLS will set *Manufacturer Code Status Pending* for new associations of Manufacturers to Container Codes. If not checked, then all associated Manufacturer Codes will be set to Approved/In Use.

If the *Box Quantity Editable on Printing* field is checked, the user can change the number of labels to print with each print job.

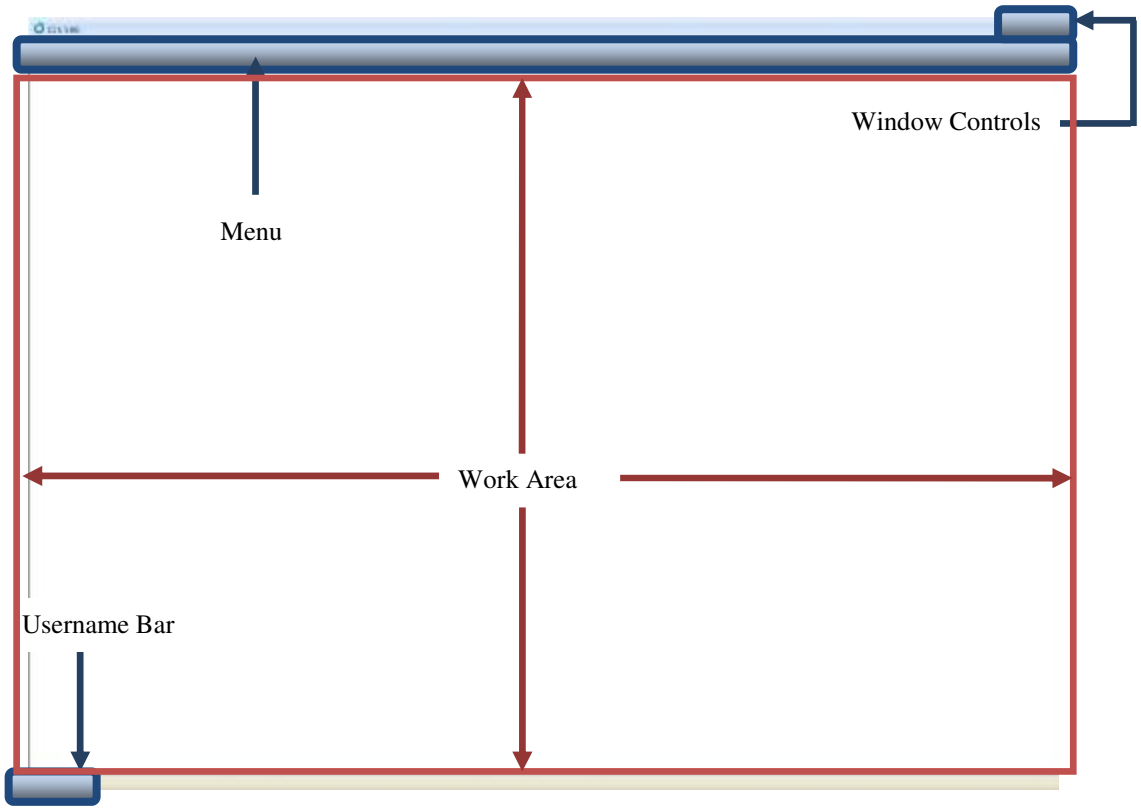
If the *Lot and Expiration Date Mandatory* field is checked, the user must specify the lot and expiration date prior to printing labels.



To save the changes made, press the *Save Configuration* button and the following dialog will be presented confirming your changes.



14. HOW THE CLS APPLICATION IS STRUCTURED

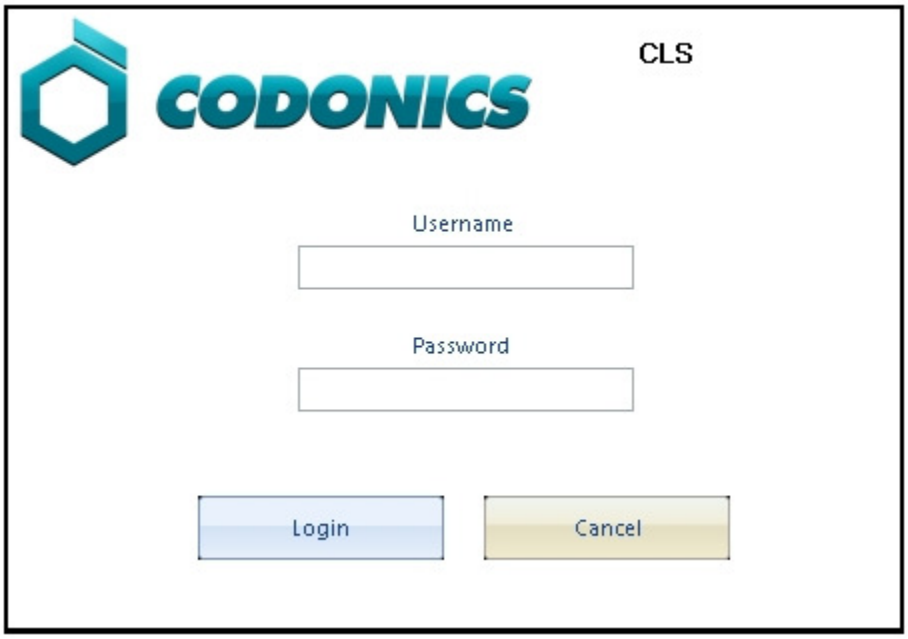


Menu – Access to different features of the application. The menu is different for each type of user.

Window Controls – Allow to minimize, maximize and close the CLS application.

Username Bar – Show the currently logged in user.

15. HOW TO USE THE APPLICATION FOR THE FIRST TIME



The first time you logon to CLS, the database is empty, therefore no users are available yet. To logon to the application for the first time, you need to use the default Codonics username and password as shown below:

Username: admin
Password: DDMM*

*Where DD represents the day and MM represents the month of date that you are accessing the application.

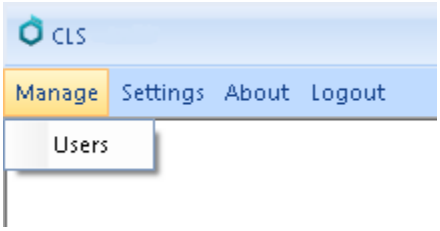
> Example: You are accessing the application on the September 26th, so the password will be 2609. This password is always 4 numeric characters long.

If you mistyped the username or password the following message will be displayed:

If the username and password are entered correctly, the application will be available.

Adding Users

In the main menu choose *Manage* then *Users.*



Enter the Name, Username, Password, Status and Group of the User and press the *Add User* button.

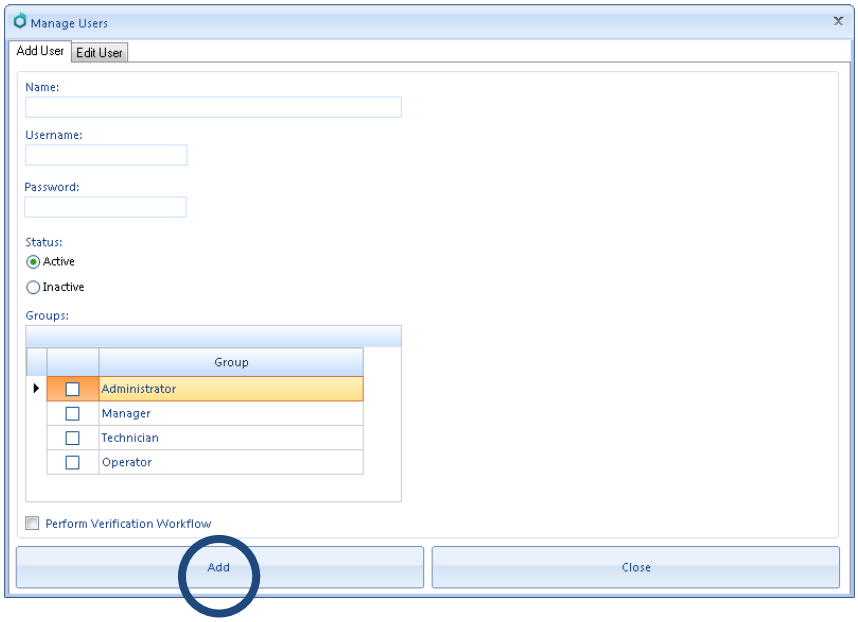
Note: See the "HOW TO ADD A NEW USER TO CLS" section for definition about application roles available for each CLS Group type.

If the *Perform Verification Workflow* field is checked then the user will have permission to Approve or Reject manufacturer's codes that were associated to container codes. In case of approval, it will be available in system to be used, if rejected, it won't be available for use to print labels.

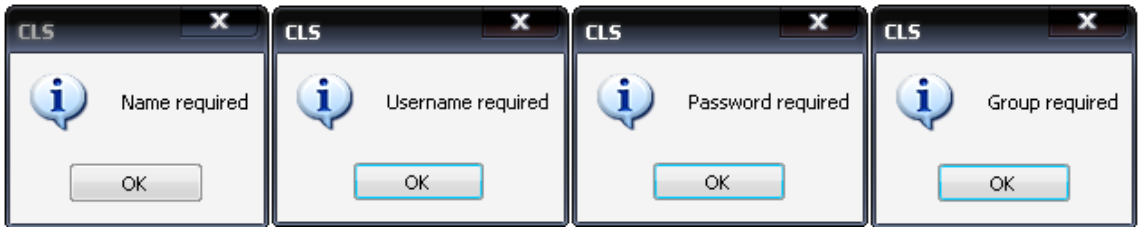
This procedure is later explained in the section named "HOW TO VERIFY A MANUFACTURER CODE".

All of these fields are required except the checkbox for *Perform Verification Workflow*, which is optional per user.

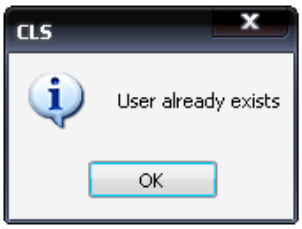
NOTE: No user will be able to log in until an Administrator User is enabled. The "Admin" Username is a reserved username that will no longer be available for log on (it is a one-time use only log on to initialize the system).



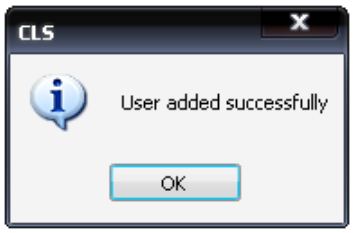
If any of the required fields are not configured, the corresponding messages will be displayed:



It is not possible to add users with the same username. The following message will appear if a username is duplicated:



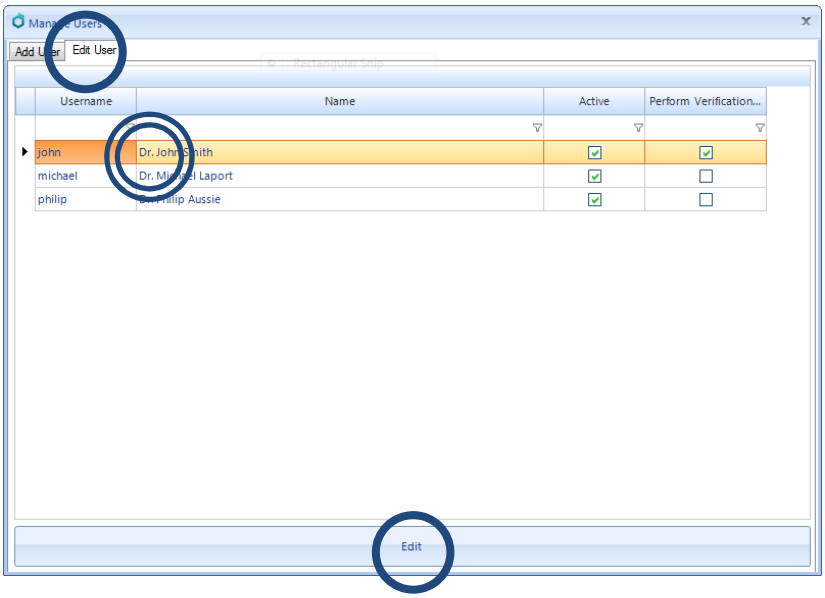
If no error(s) occurs, the user was entered successfully and the following message appears:



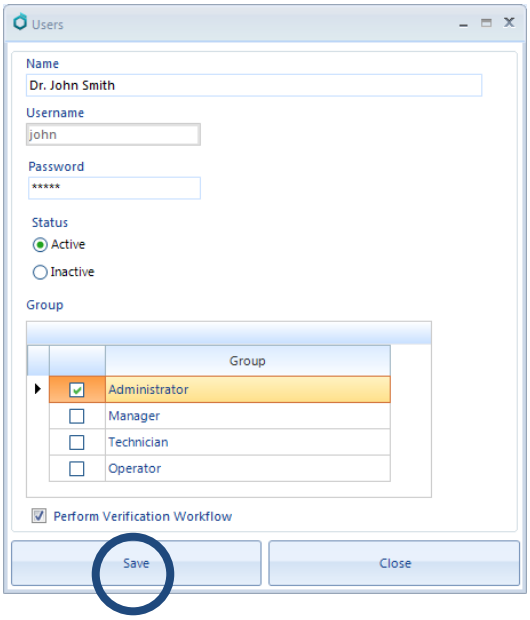
Note: After you add an Administrator user, the Codonics username and password is no longer available (it is a one-time use only log on). Please be sure to create at least one Administrative user account for ongoing maintenance and configuration of the CLS system.

Edit Users

The *Edit User* tab allows editing of the existing users in the database. To edit a user, double click on the desired user or select it and press the *Edit User* button.

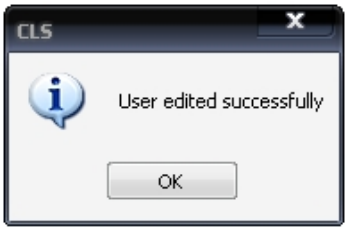


Edit the user data and press the *Save* button.



If any of the fields are not configured, the corresponding messages will appear:

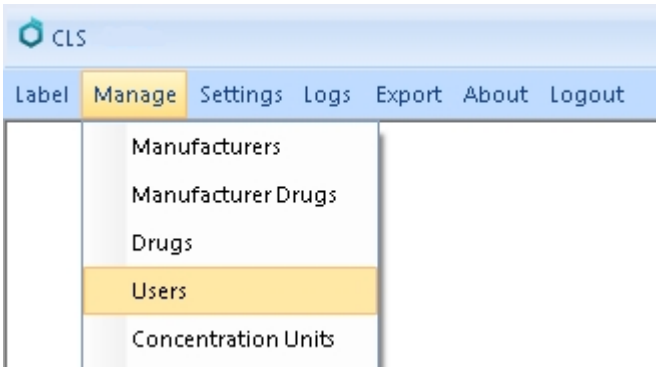
If no error occurs, the following message will appear:



Now you're ready to logout and start using CLS with the created users.

16. HOW TO ADD A NEW USER TO CLS

In the main menu choose *Manage* then *Users.*



Fill in the Name, Username, Password, Status and Group of the User and press the *Add User* button.

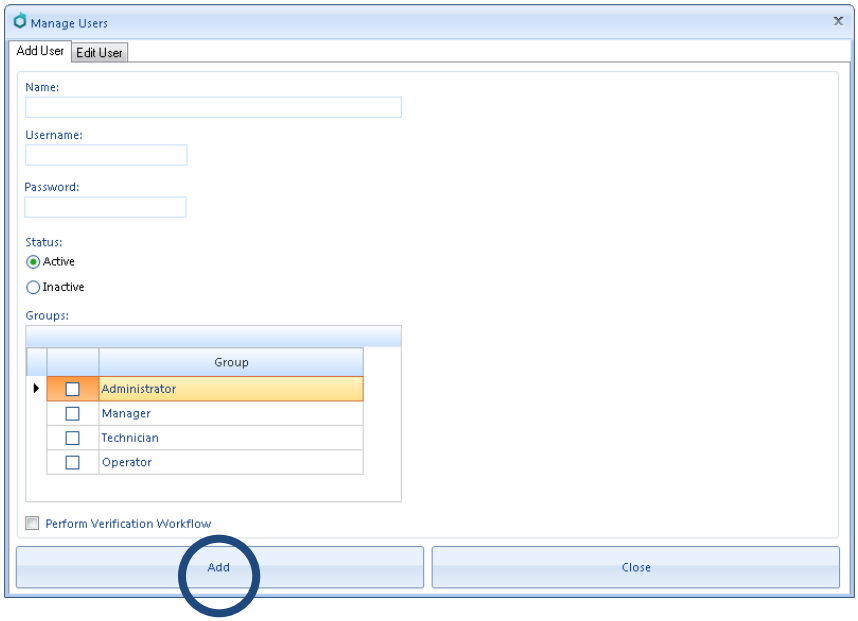
There are four user group types (administrator, manager, technician, operator). Each user account created is granted permissions in the system by being assigned to one of the four group types.

	System Configuration	Barcode Search	Manual Search	Workflow Approval	Print Container Labels
Administrator	✓	✓	✓	✓	✓
Manager		✓	✓	✓	✓
Technician		✓	✓		✓
Operator		✓			✓

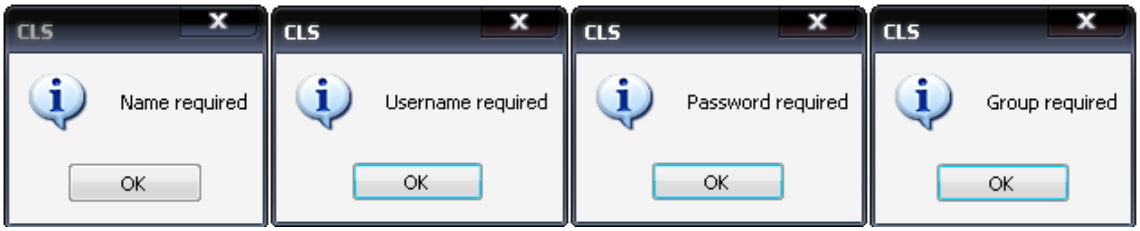
If the *Perform Verification Workflow* field is checked then the user will have permission to Approve or Reject manufacturer's codes that were associated to container codes.

All of these fields are required except *Perform Verification Workflow*.

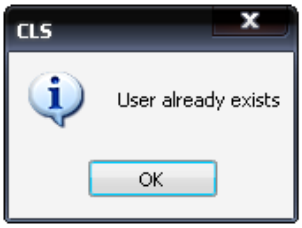
NOTE: No user will be able to log in until an Administrator User is enabled. The Admin Username is a reserved username that will no longer be available for log on.



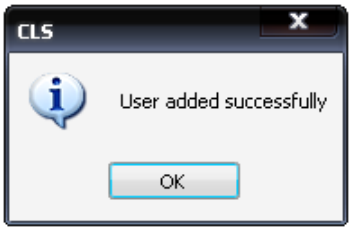
If any of the fields are not configured, the following messages will appear:



It is not possible to add users with the same username. If a username is duplicated, the following message will appear:

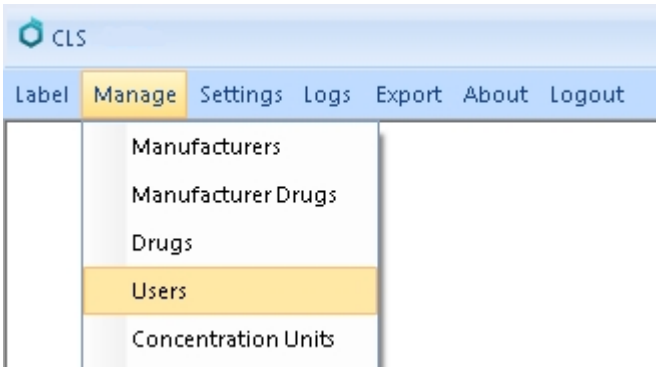


If no error occurs, the user was entered successfully and the following message appears:



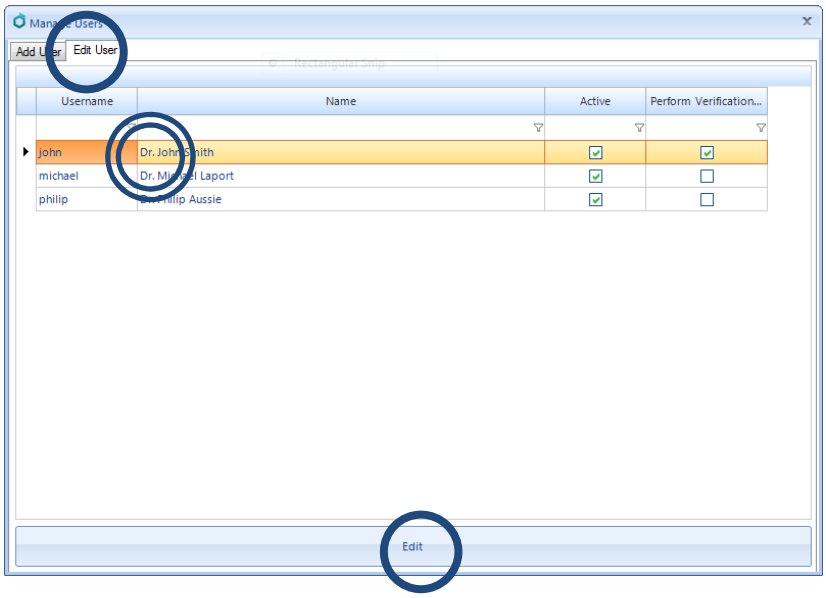
17. HOW TO EDIT USERS

In the main menu choose *Manage* then *Users.*

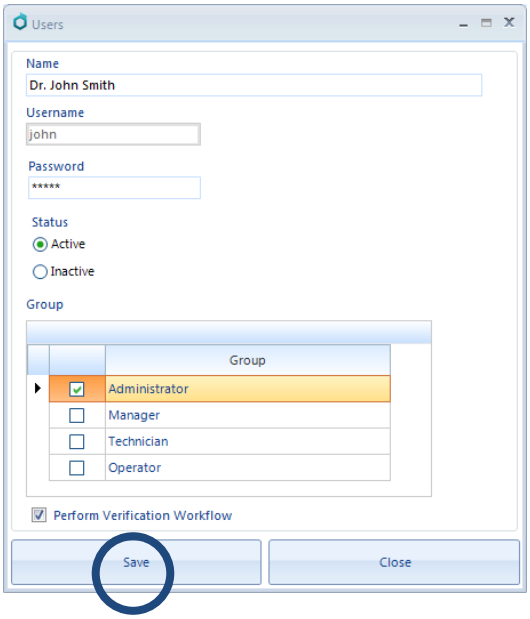


Click on the *Edit User* tab, double click on the desired user or select it and press the *Edit User* button.

Note: A user may be inactivated from the CLS, but not deleted. This allows the Events logs to maintain the history performed in the system by all users (active or inactive). Additionally, an inactivated user may also be reactivated as needed by the administrator.

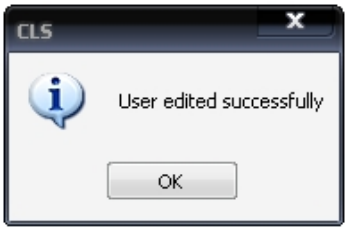


Edit the user data and press the *Save* button.



If any of the fields are not configured, the corresponding messages will appear:

If no error occurs, the following message will appear:

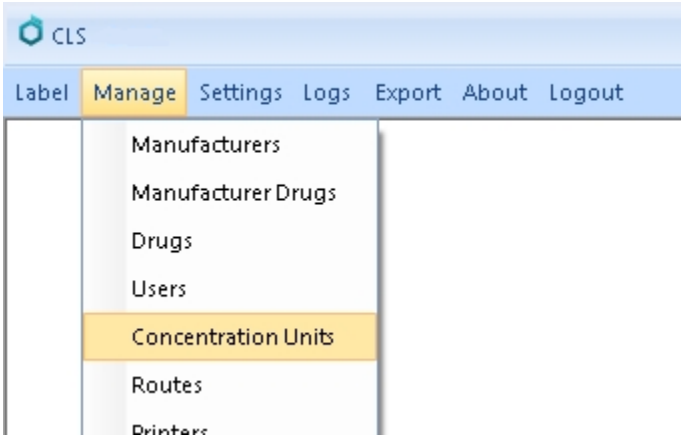


18. HOW TO ADD CONCENTRATION VALUES

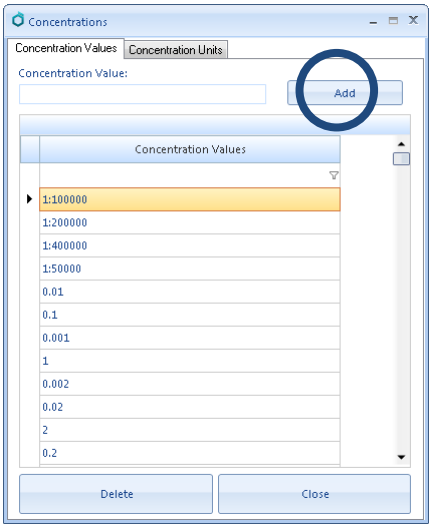
In the main menu choose *Manage,* then *Concentration Units*.

Note: The CLS is pre-populated with a default set of concentration values.

Note: The default values are separated with periods. Values can be modified as needed including using commas rather than periods.



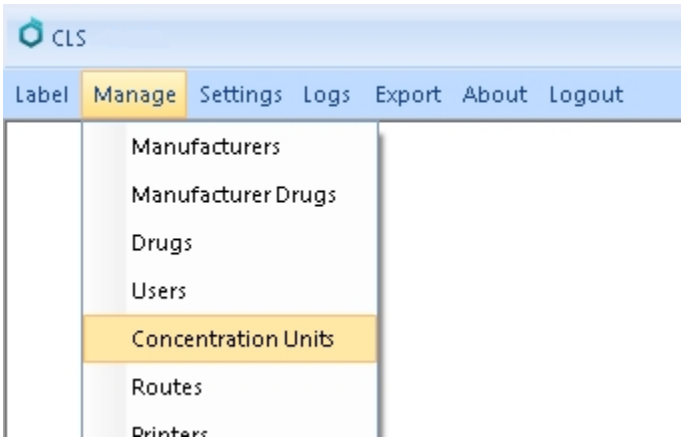
To add a new concentration value, fill in the *Concentration Value* field and press the *Add* button.



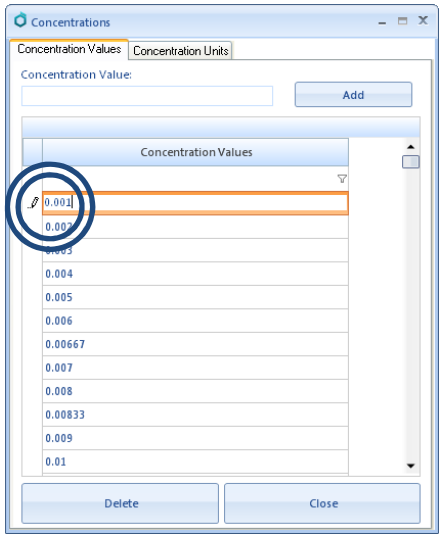
When you've finished adding values, press the *Close* button.

19. HOW TO EDIT CONCENTRATION VALUES

In the main menu choose *Manage,* then *Concentration Units*.



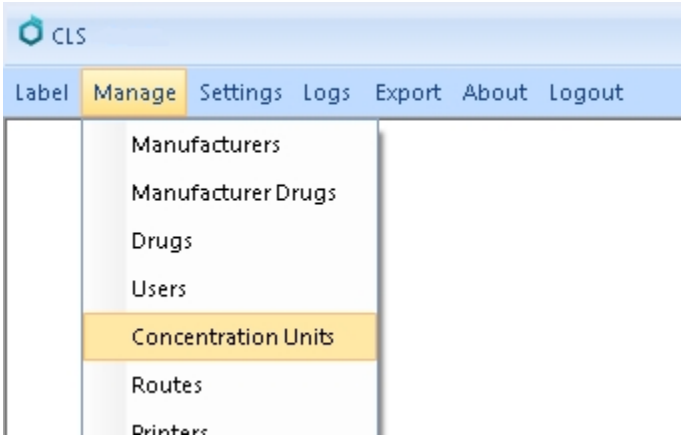
To edit an existing concentration value, double click the desired value and modify it as needed.



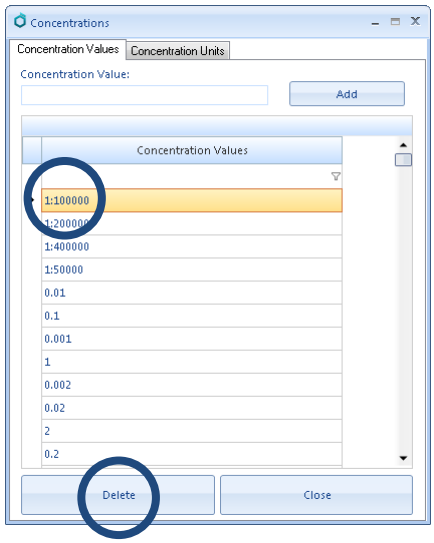
When you've finished editing values, press the *Close* button.

20. HOW TO DELETE CONCENTRATION VALUES

In the main menu choose *Manage,* then *Concentration Units*.



To delete a concentration value, click the desired value and press the *Delete* button.

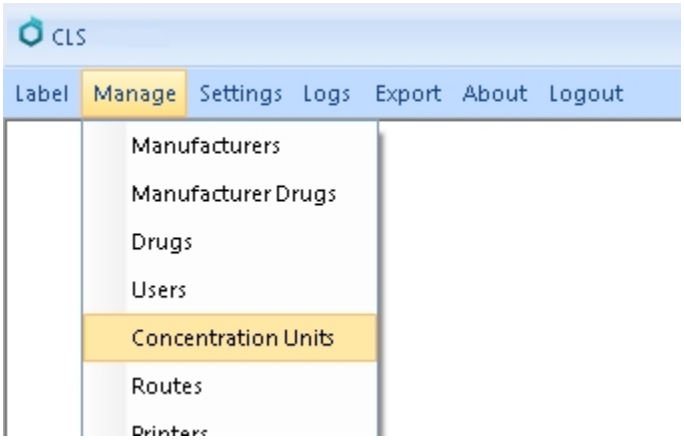


When you've finished deleting values, press the *Close* button.

21. HOW TO ADD CONCENTRATION UNITS

In the main menu choose *Manage,* then *Concentration Units*.

Note: The CLS is pre-populated with a default set of concentration units.

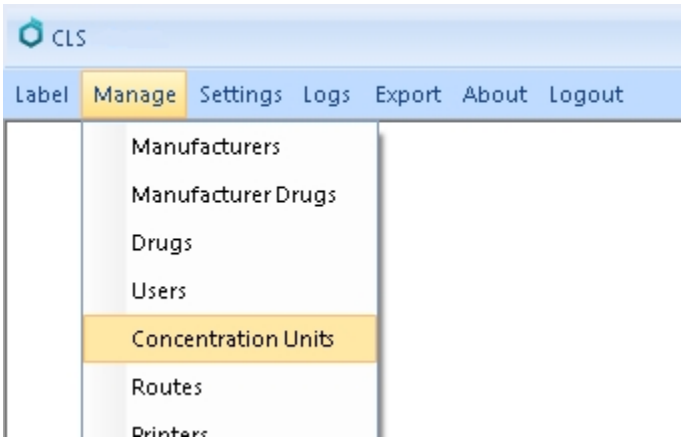


To add a new concentration unit, select the *Concentration Units* tab, fill in the *Concentration Unit* field and press the *Add* button.

When you've finished adding units, press the *Close* button.

22. HOW TO EDIT CONCENTRATION UNITS

In the main menu choose *Manage,* then *Concentration Units*.

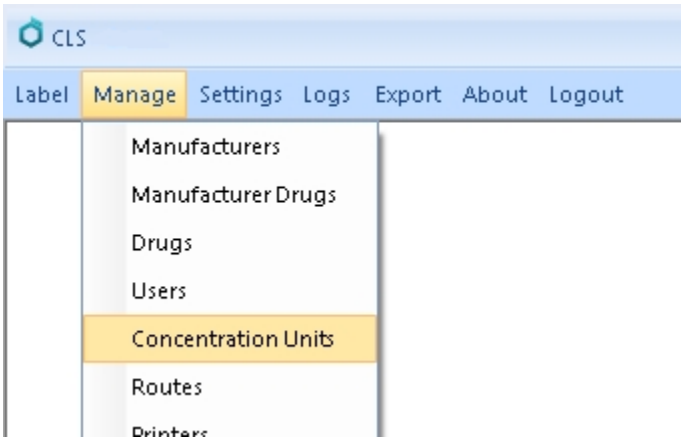


To edit an existing concentration unit, double click the desired unit and modify it as needed.

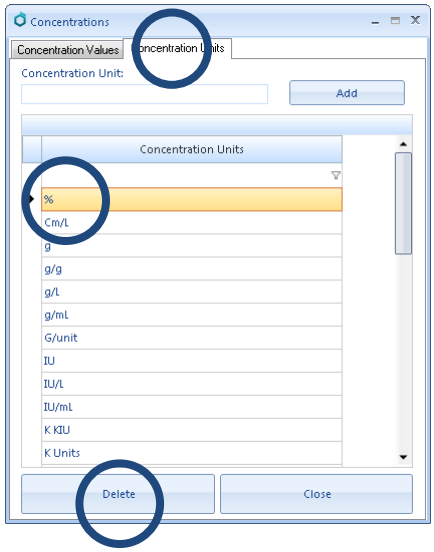
When you've finished editing units, press the *Close* button.

23. HOW TO DELETE CONCENTRATION UNITS

In the main menu choose *Manage,* then *Concentration Units*.



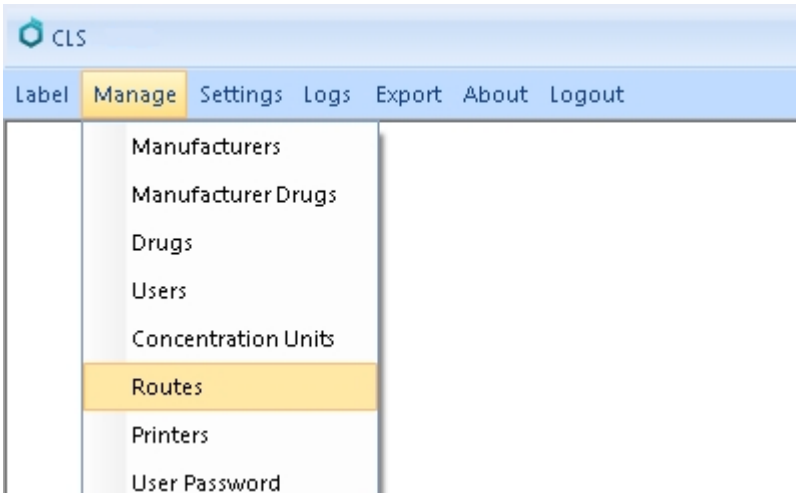
To delete a concentration unit, click the desired unit and press the *Delete* button.



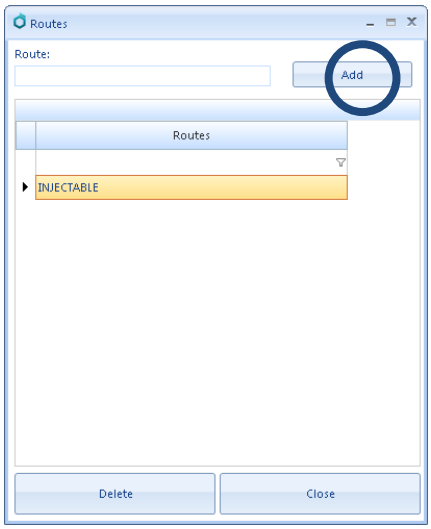
When you've finished deleting units, press the *Close* button.

24. HOW TO ADD ROUTES

In the main menu choose *Manage,* then *Routes*.



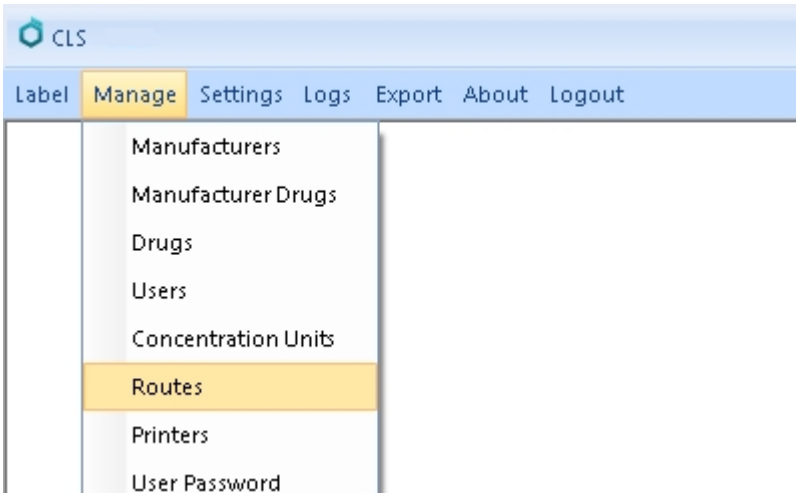
To add a new route, fill in the *Route* field and press the *Add* button.



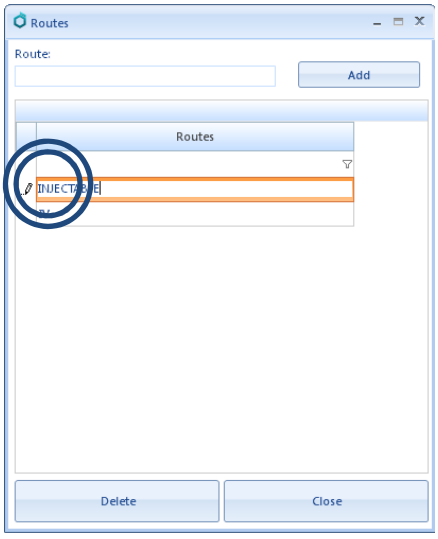
When you've finished adding *Routes*, press the *Close* button.

25. HOW TO EDIT ROUTES

In the main menu choose *Manage,* then *Routes*.



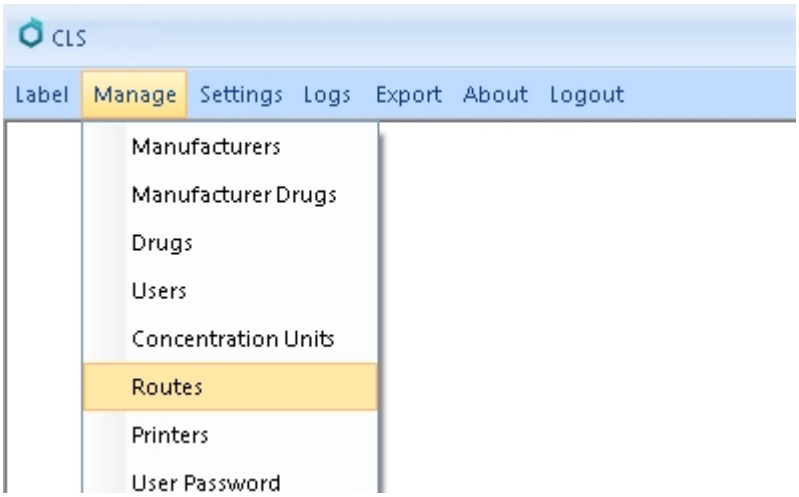
To edit an existing route, double click the desired route and modify it as needed.



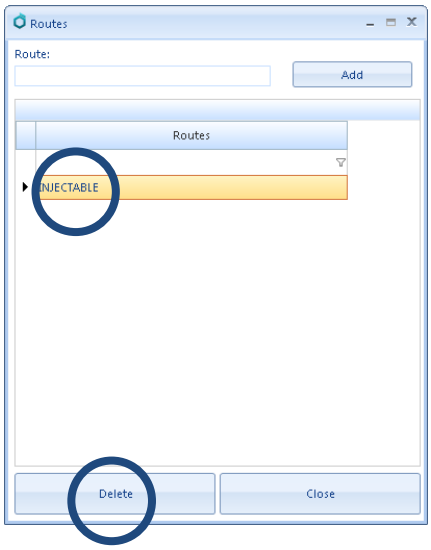
When you've finished editing, press the *Close* button.

26. HOW TO DELETE ROUTES

In the main menu choose *Manage,* then *Routes*.



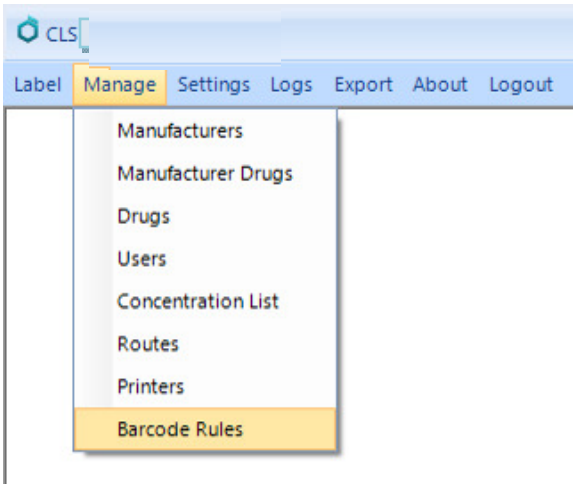
To delete, click the desired route and press the *Delete* button.



When you've finished deleting *Routes*, press the *Close* button.

27. HOW TO ADD BARCODE RULES

In the main menu choose *Manage,* then *Barcode Rules*.



The *Barcode Rules* option is used to define Barcode parsing for the barcodes scanned on manufacturer's drug boxes and CLS printed barcodes. In this configuration, the administrative user can define barcode parsing rules according to Barcode Symbology, Application Identifier and Barcode length.

Additionally, the configuration enables the ability to set up Lot and Expiration Date if those values are available on the barcodes provided by the manufacturers.

The administrative user can create multiple barcode rules.

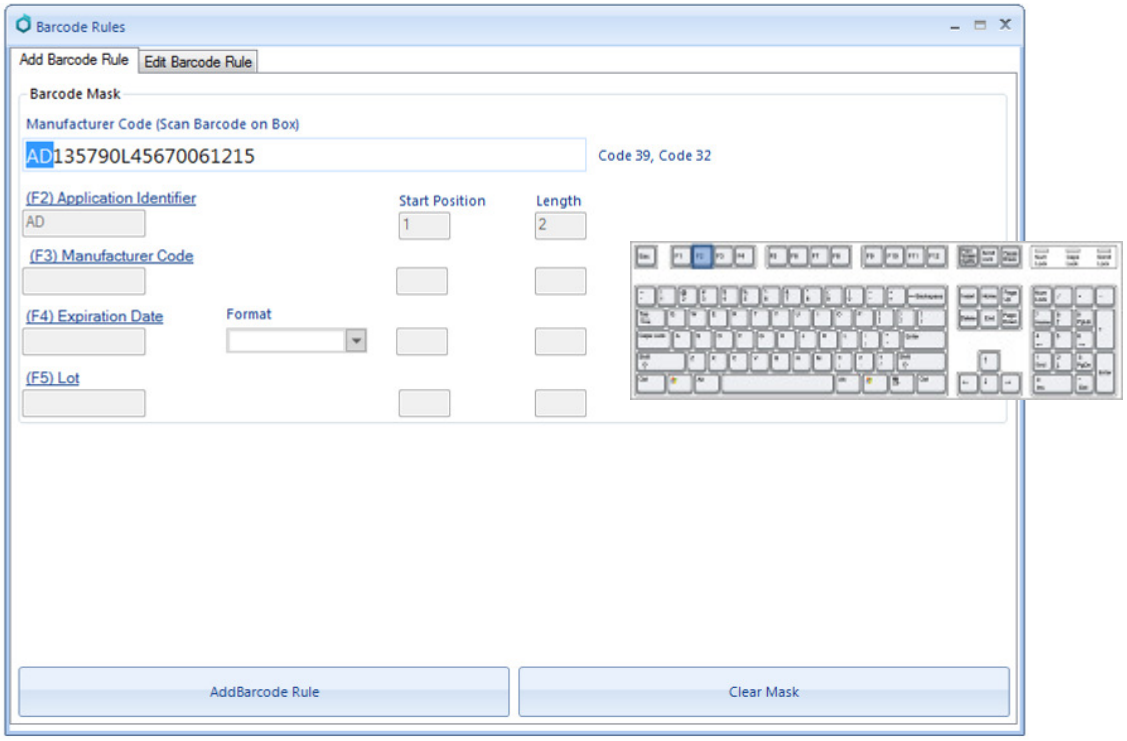
Note: Only the *Manufacturer Code* field is mandatory for a barcode parsing rule.

1 – In the *Manufacturer Code* scan a Manufacturer Barcode on a selected drug box.

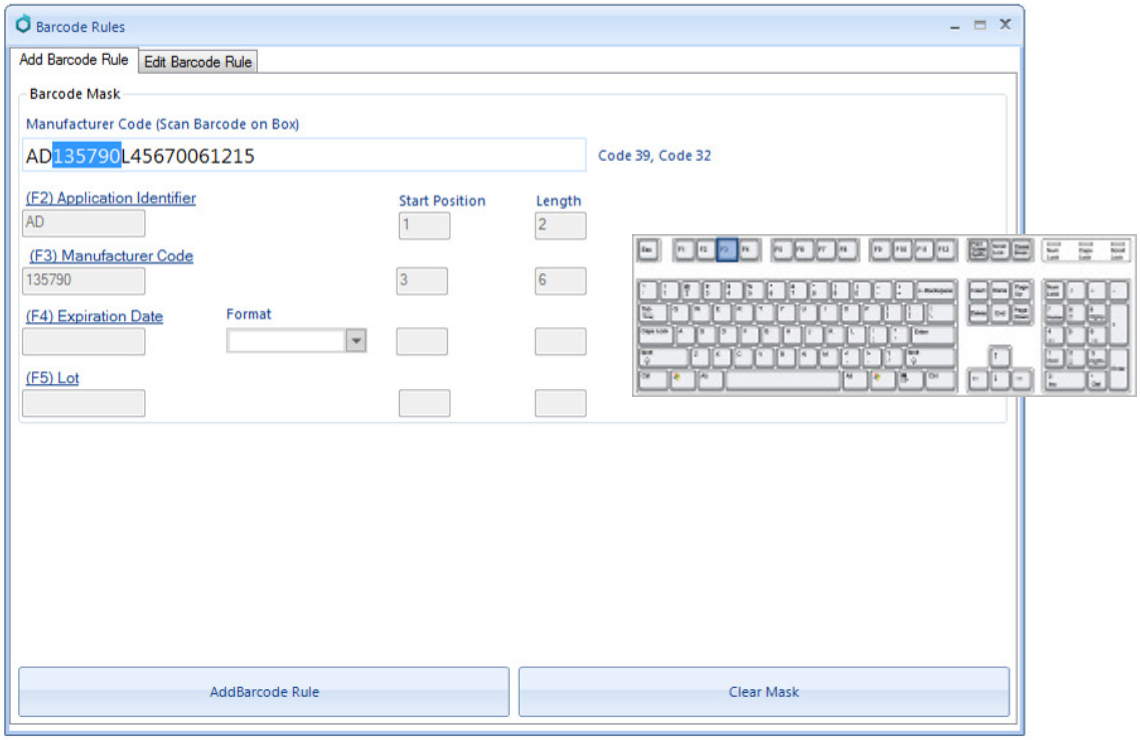
Note: your CLS hand scanner must be configured with the programmed barcode configuration provided in CLS Technical Briefs provided with your hand scanner. Please see the CLS software version 2.4.0 or higher Technical Brief for the DS9808 hand scanner or the CLS software version 2.4.0 or higher Technical Brief for the DS4208-HC hand scanner.

Note: the barcode symbology is automatically detected by the hand scanner and identified on the *Add Barcode Rules* screen as shown below. Additionally, the barcode symbology identifier is added as a prefix to the barcode value.

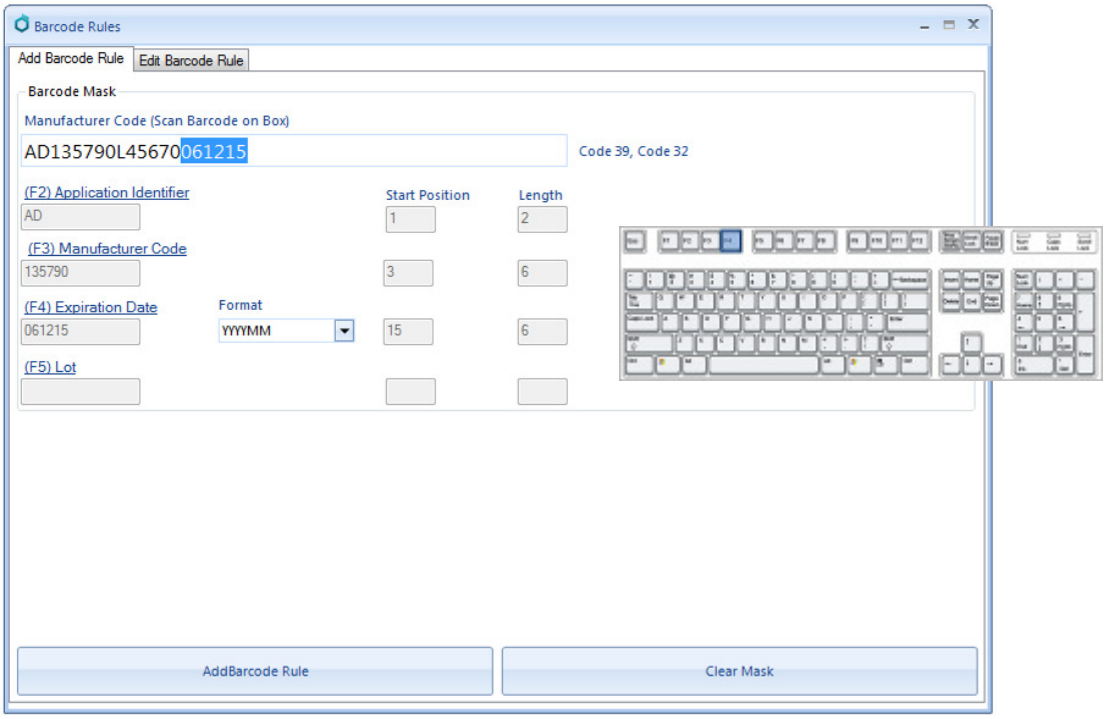
2- Using the mouse, highlight the characters that define the *Application Identifier* and press the F2 key on the keyboard.



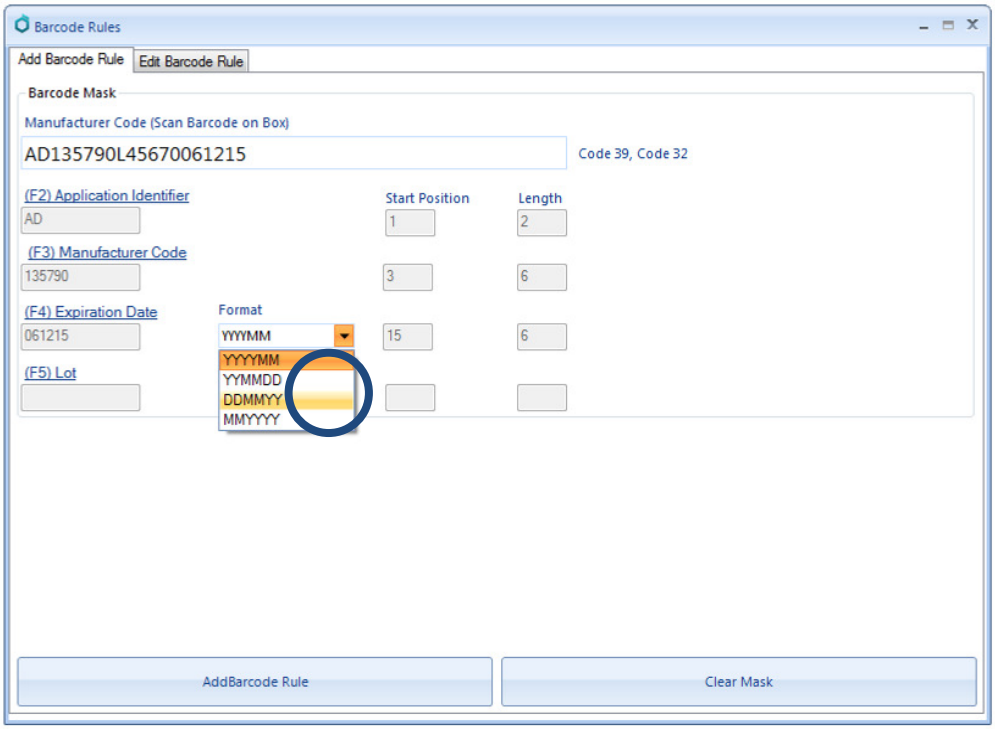
3 - With the mouse, highlight the characters that define the *Manufacturer Code* and press the F3 key on the keyboard.



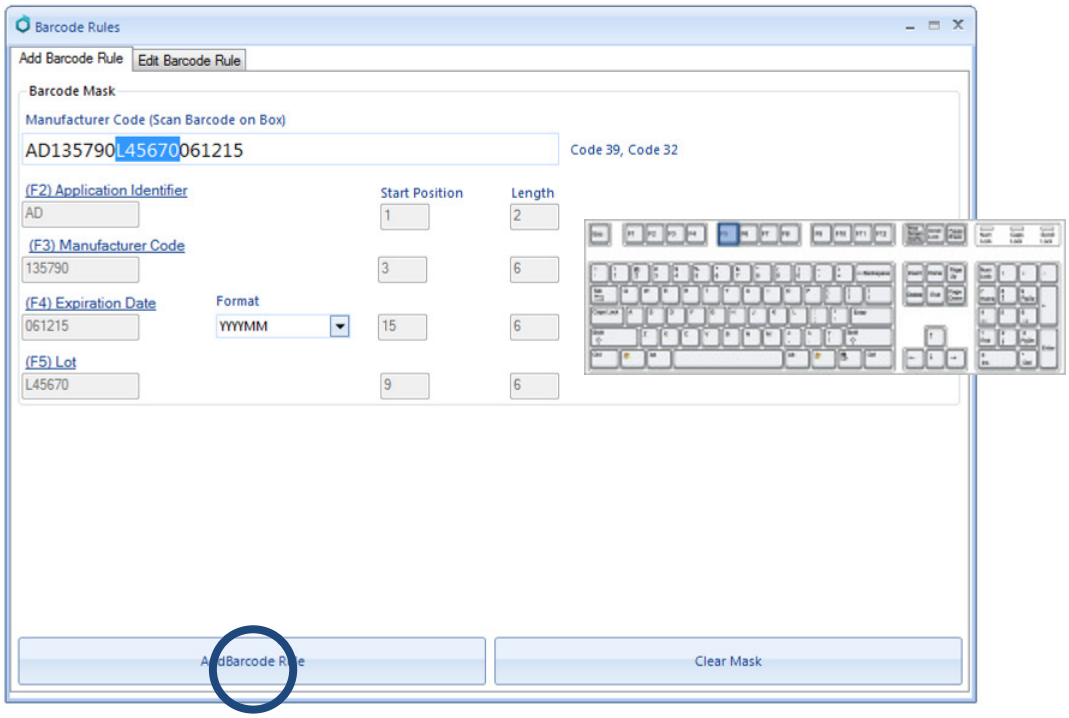
4 - With the mouse, highlight the characters that define the *Expiration Date* and press the F4 key on the keyboard.



5 – From the drop-down menu, select the proper format for the *Expiration Date*.



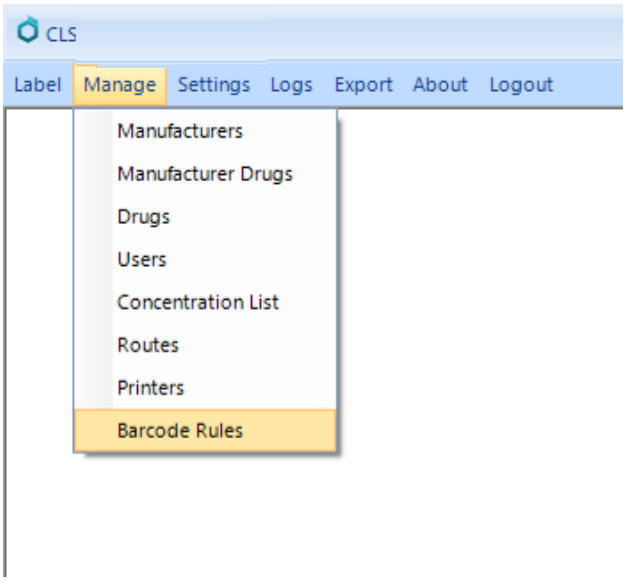
6 - With the mouse, highlight the characters that define the *Lot* and press the F5 key on the keyboard.



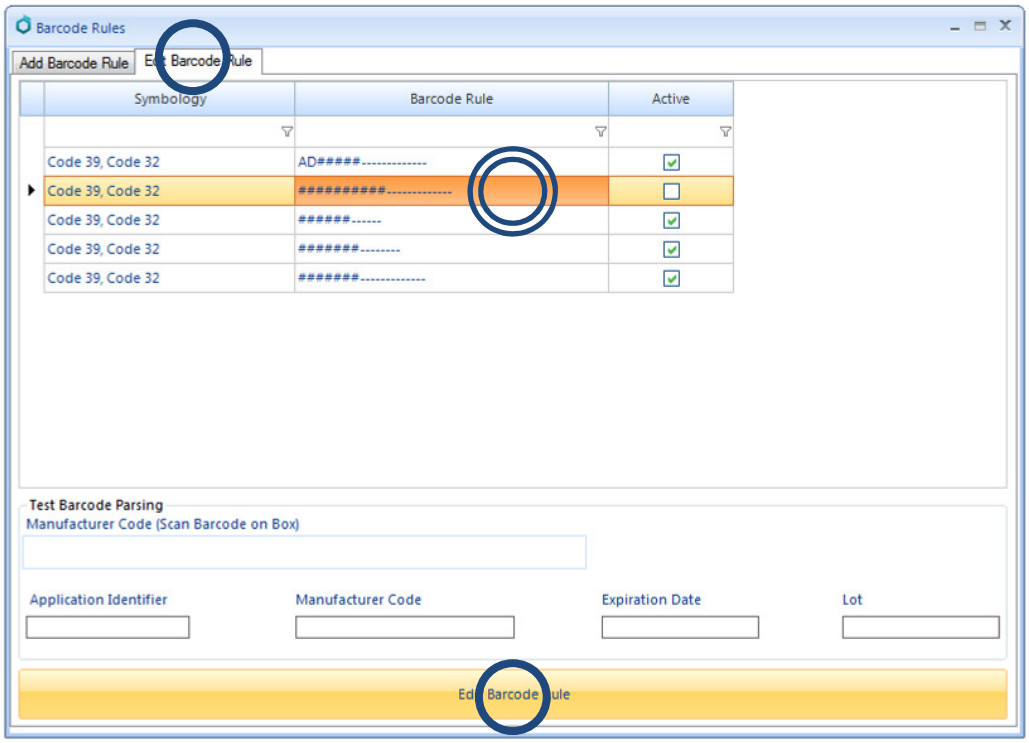
Press the Add Barcode Rule button to save the rule.

28. HOW TO EDIT BARCODE RULES

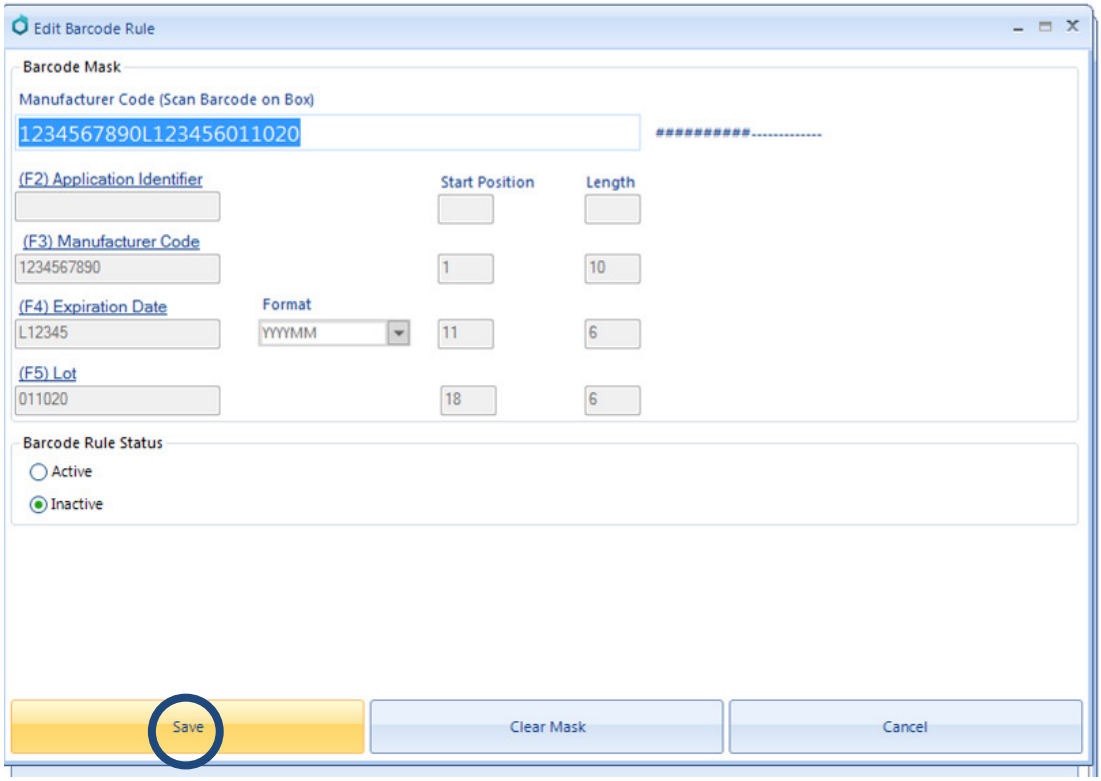
In the main menu choose *Manage,* then *Barcode Rules*.



To edit an existing rule, go to the *Edit Barcode Rule* tab and double click the desired rule or select the rule from the grid and press the *Edit Barcode Rule* button.



The *Edit Barcode Rule* window will be opened. Modify the rule as needed and apply the changes by pressing the *Save* button.

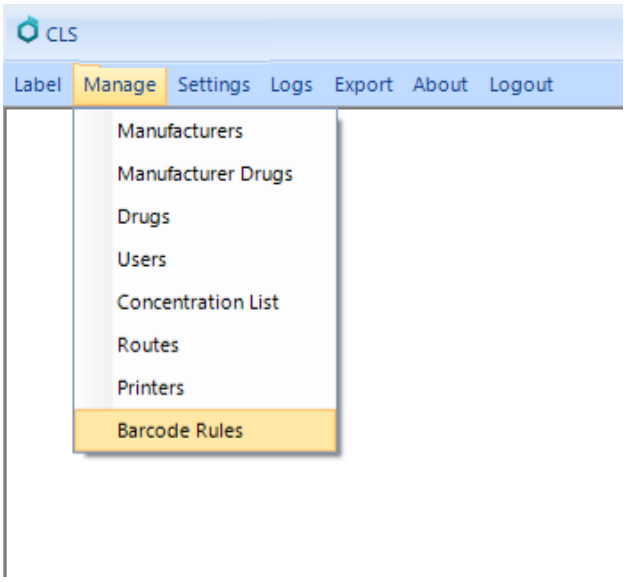


To clear the existing mask, press the *Clear Mask* button.

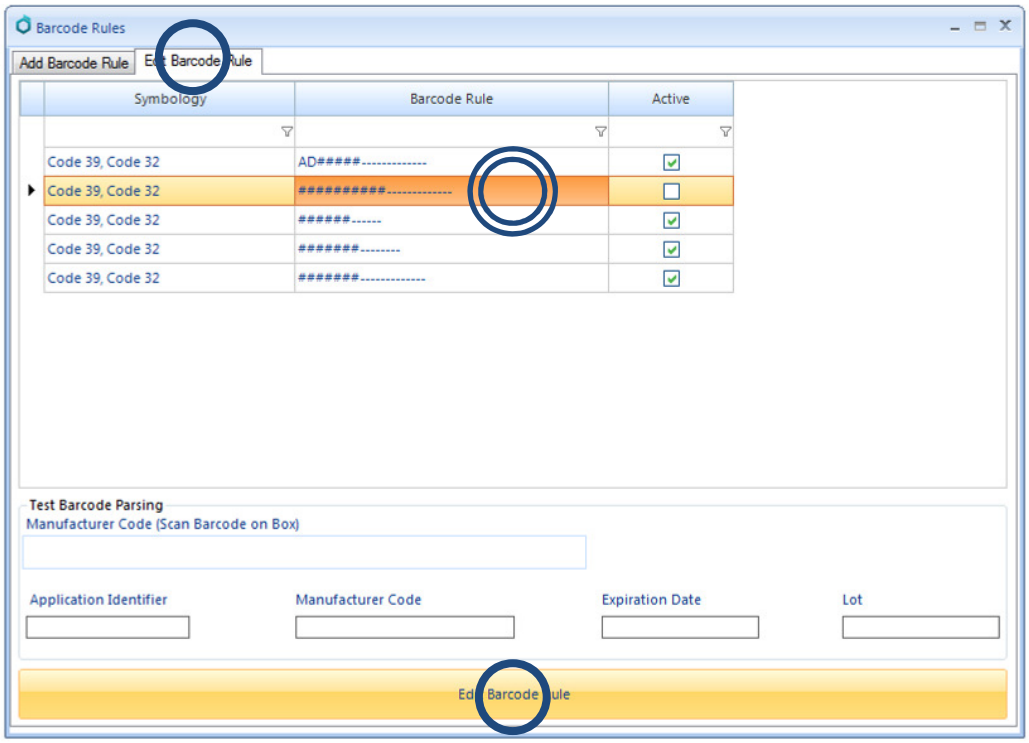
Note: For further information on how to edit the *Barcode Rule* please read the *HOW TO ADD RULES* section of the manual.

29. HOW TO INACTIVATE (OBSOLETE) BARCODE RULES

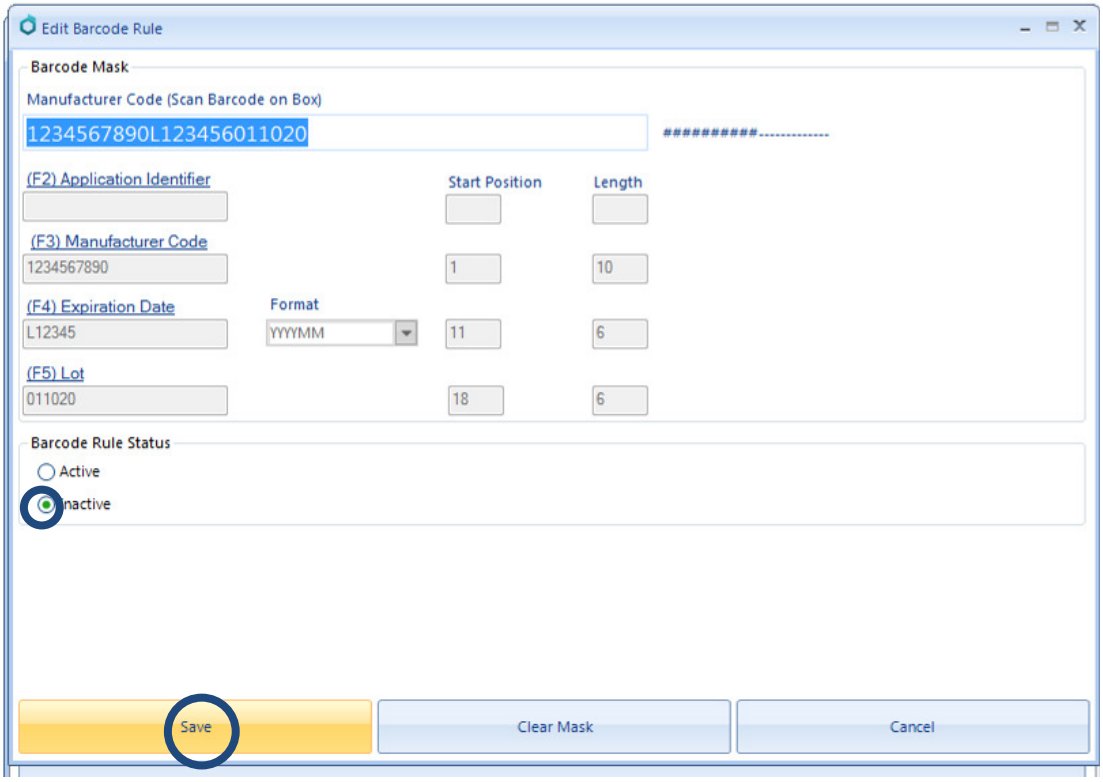
In the main menu choose *Manage,* then *Barcode Rules*.



To edit an existing rule, go to the *Edit Barcode Rule* tab and double click the desired rule or select the rule from the grid and press the *Edit Barcode Rule* button.

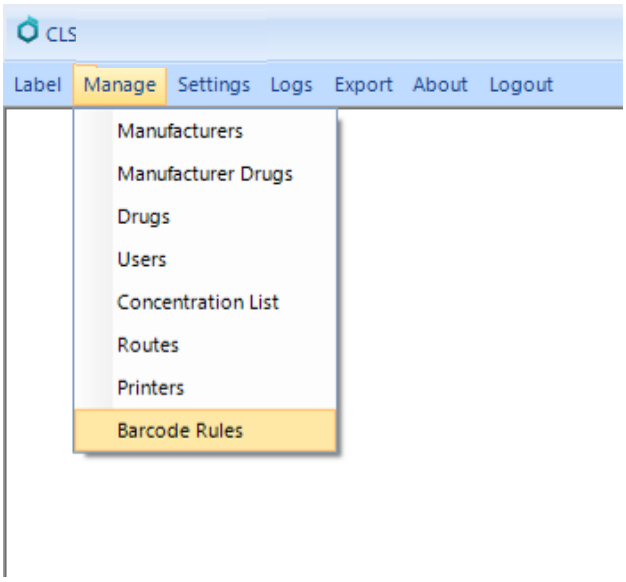


The *Edit Barcode Rule* window will be opened. Change the rule's state to *Inactive* and apply the changes by pressing the *Save* button.



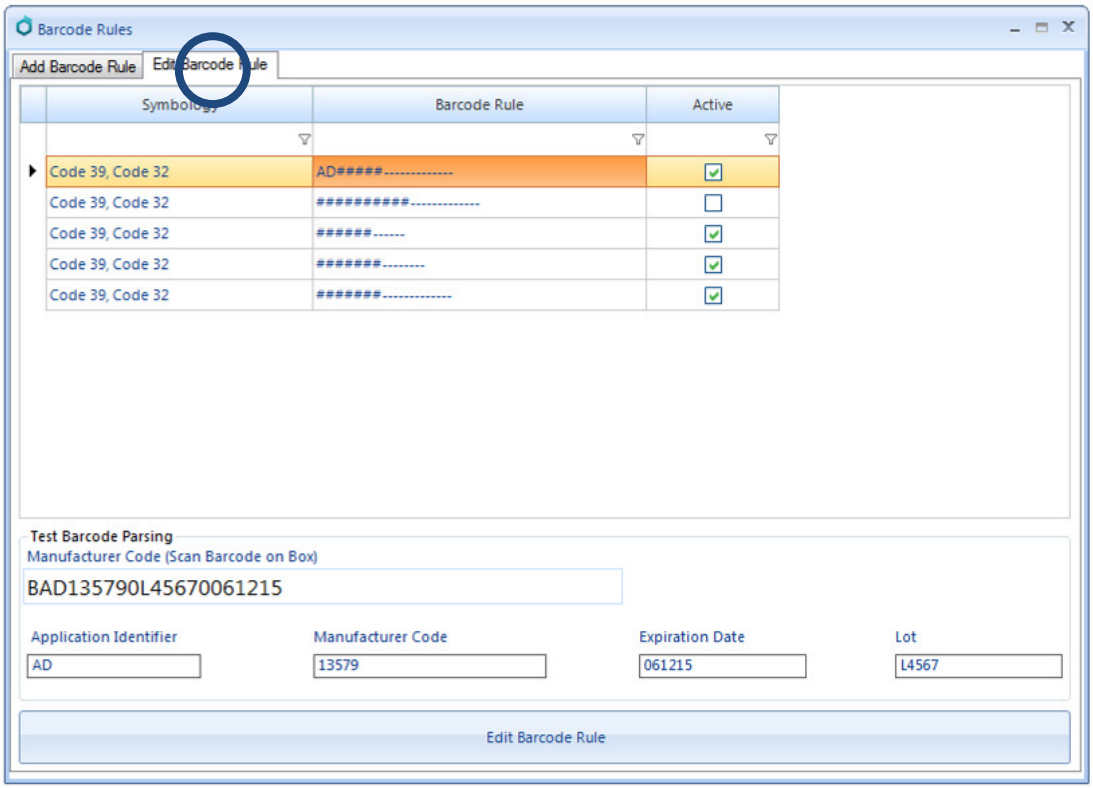
30. HOW TO TEST BARCODE PARSING

In the main menu choose *Manage,* then *Barcode Rules*.



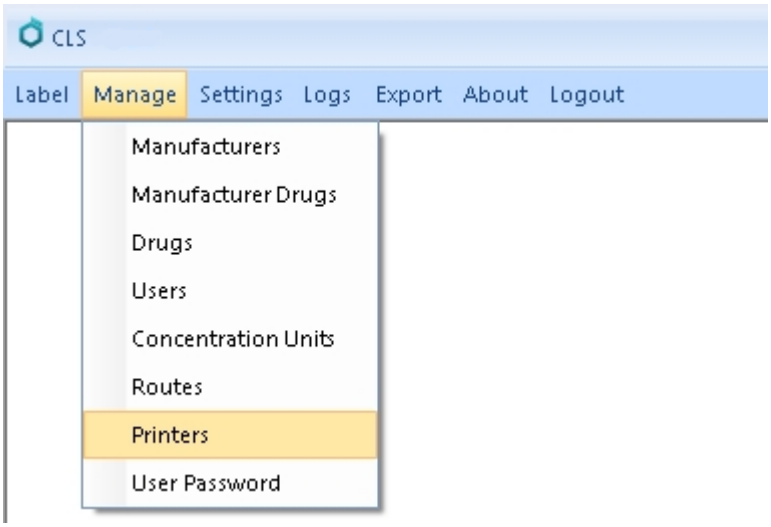
To test a barcode parsing rule, go to *Edit Barcode Rule* tab and scan a barcode in *Manufacturer Code* text box.

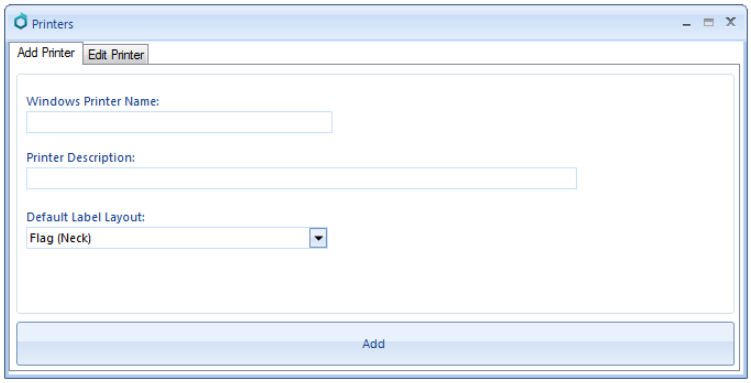
The barcode will be parsed and the respective text boxes will display the data per the configured barcode rule. The rule used for the parsing will be highlighted in the grid.



31. HOW TO ADD A PRINTER

In the main menu choose *Manage,* then *Printers*.





Windows Printer Name
Enter the same name of the printer configured in Microsoft Windows.

Printer Description
Enter a description clear enough to distinguish which printer and label is associated.

NOTE: You can add the multiple printers with different layouts. The printer description must be unique in the example as shown below:

Two physical printers & 3 virtual printers

- Windows Printer Names – Zebra1 and Zebra2
- CLS Printer Descriptions – Zebra1 Round, Zebra1 Rectangle and Zebra2 Flag
- Default Label Layouts – Round (Bottom), Rectangle (Seam) and Flag (Neck) respectively to CLS Printer Descriptions

Choosing the label layout

There are three kinds of label layouts available, enabling you to selectively choose the right one for each type of drug container. The human-readable portion of the label is for identification of the containers to be labeled and the die-cut is for the machine-readable barcode to be applied to the containers.

NOTE: Use only Codonics labels to ensure proper operation of the device and proper labeling of drug containers. Using unapproved labels could lead to unacceptable results, including poor print quality and poor label adhesion to the drug containers. Please contact Codonics Customer Support to order label media for your CLS system.

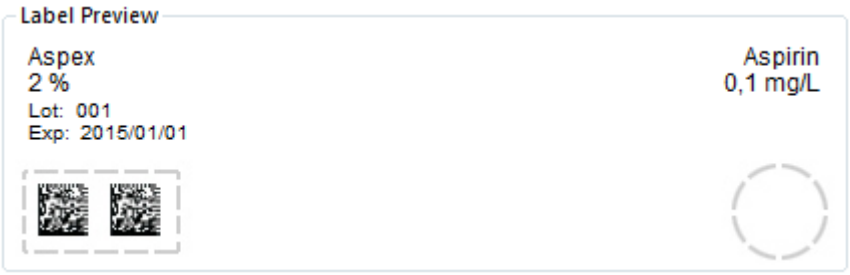
NOTE: Storage of Codonics labels is recommended to be in a dark place at a relative humidity between 45 percent and 65 percent and a temperature below 77°F (25ºC) will assure satisfactory performance.

Flag

Flag labels have this structure. These are best suited for container necks that are ½ inch in diameter or less.

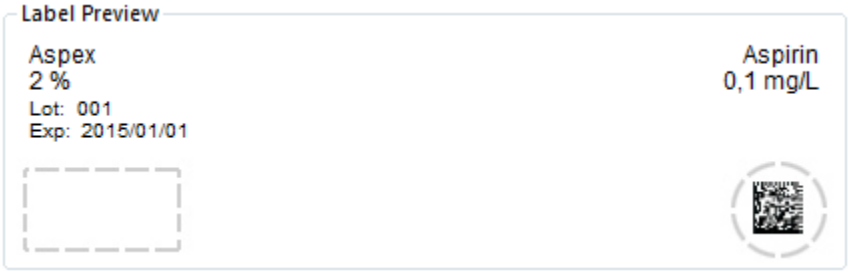
Rectangle

Rectangle labels have this structure.

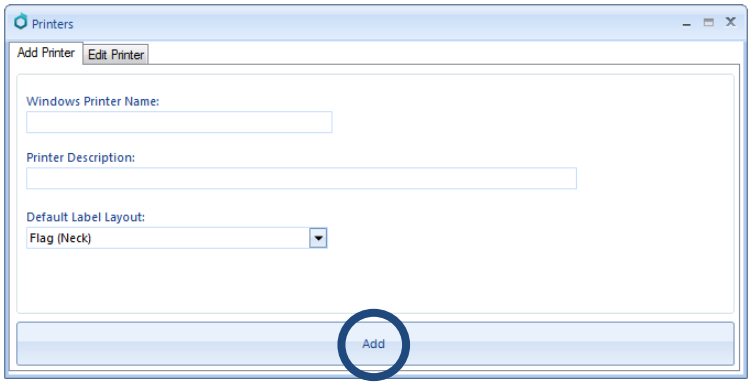


Round

Round labels have this structure.

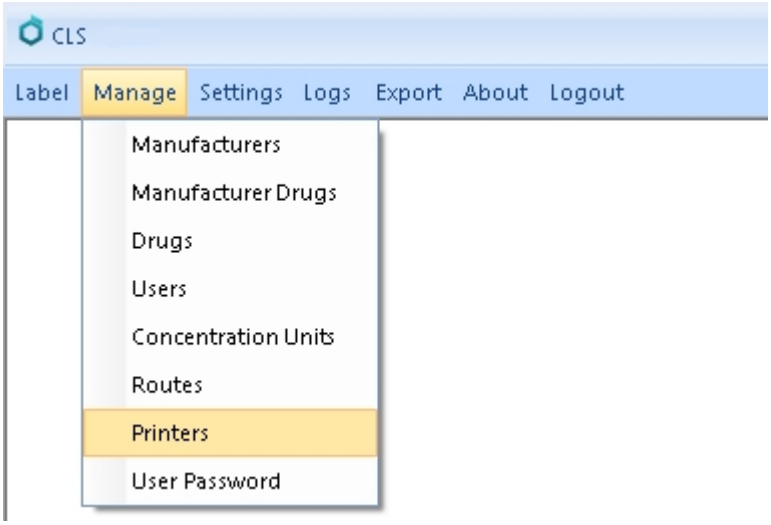


Fill in all the fields and press the *Add Printer* button.

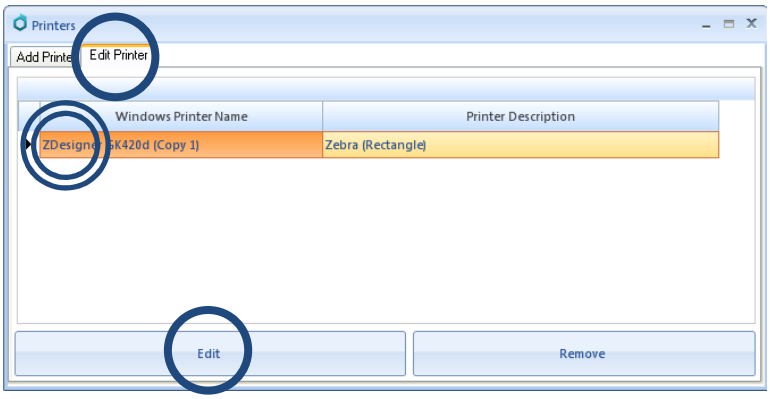


32. HOW TO EDIT A PRINTER

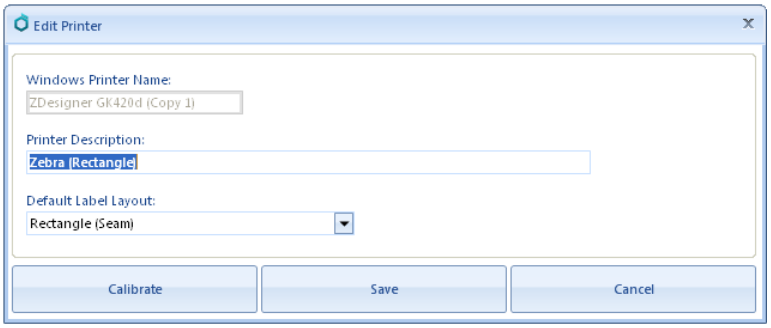
In the main menu choose *Manage,* then *Printers.*



Select the *Edit Printer* tab and double click on the desired printer in the list or select it and press the *Edit Printer* button.



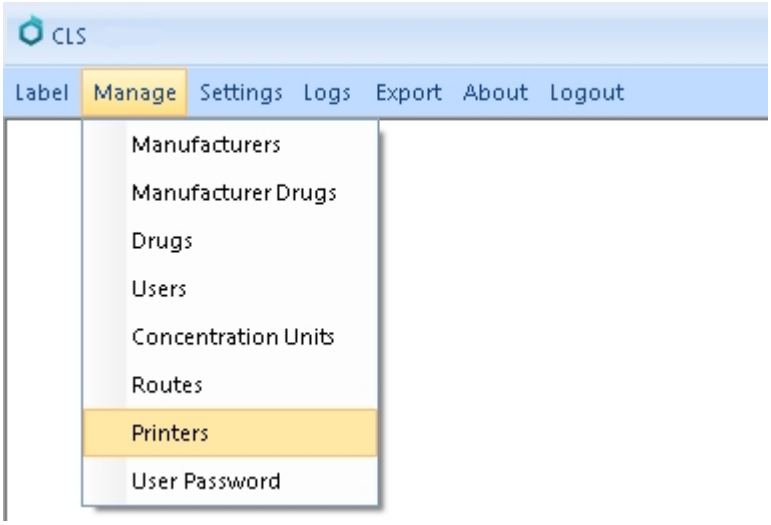
The Edit Printer window will be displayed to edit the selected printer.



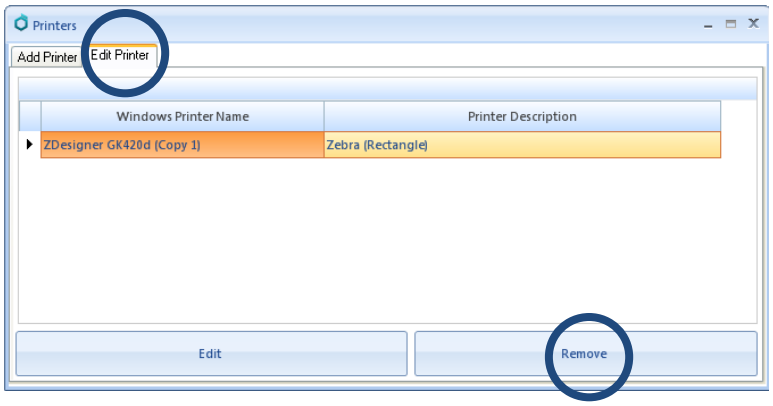
Make the necessary changes and click the *Save* button to save or the *Cancel* button to cancel the changes.

33. HOW TO DELETE A PRINTER

In the main menu choose *Manage,* then *Printers*.

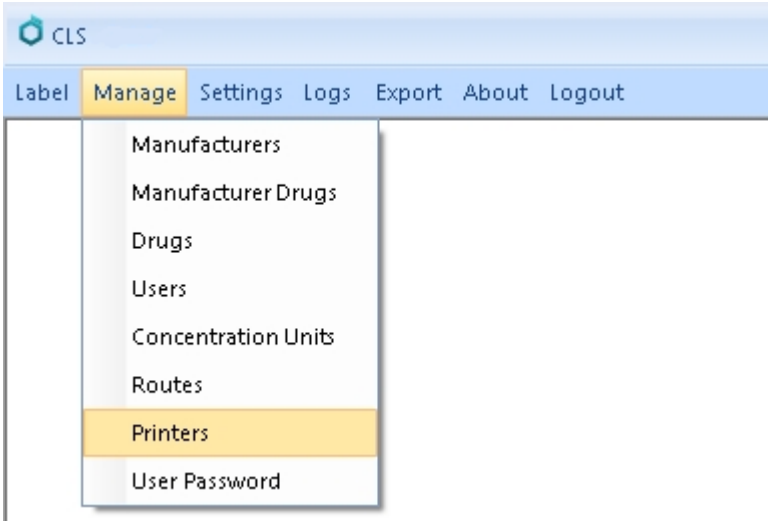


To remove an existing printer, select the printer you want to delete and press the *Remove Printer* button.

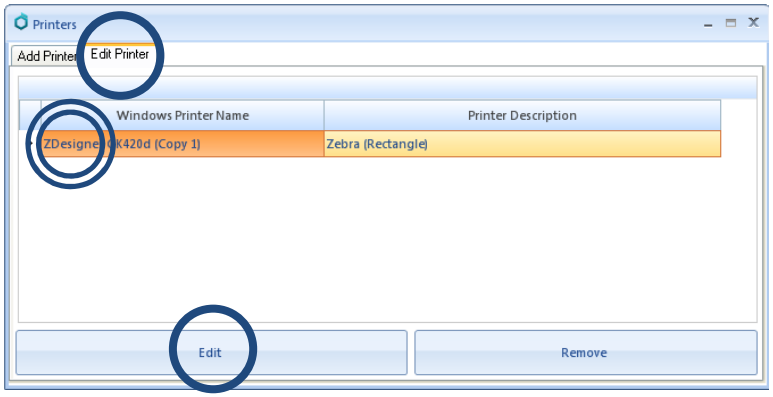


34. HOW TO CALIBRATE A PRINTER

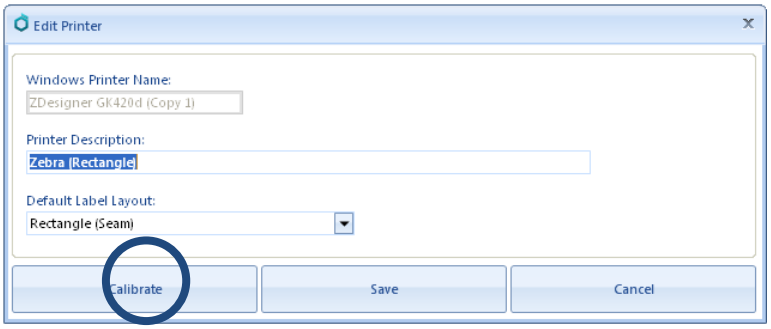
In the main menu choose *Manage,* then *Printers*.



Select the *Edit Printer* tab and double click the desired printer in the list or select it and press the *Edit Printer* button.



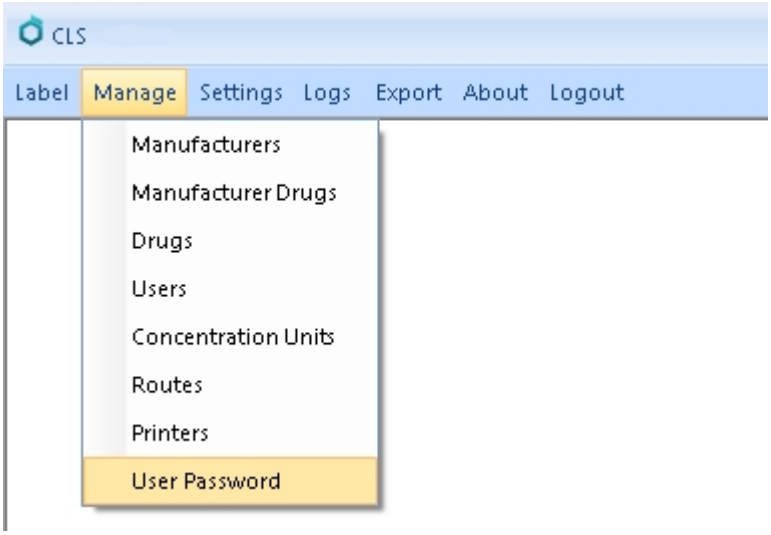
Press the *Calibrate* button, which will send a print calibration job to your configured printer.



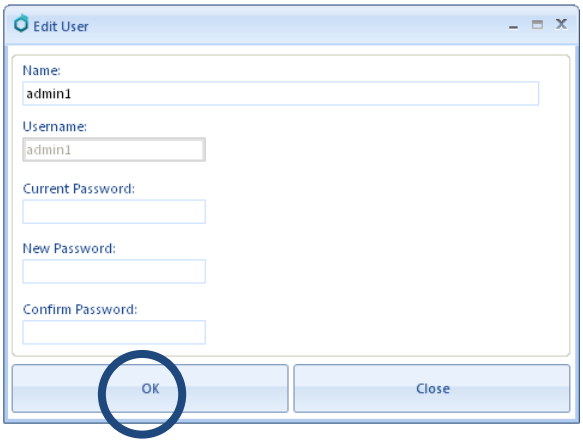
Close the window by either selecting the *Save* button or the *Cancel* button.

35. HOW TO EDIT YOUR USER ACCOUNT

In the main menu choose *Manage*, then *User Password*.



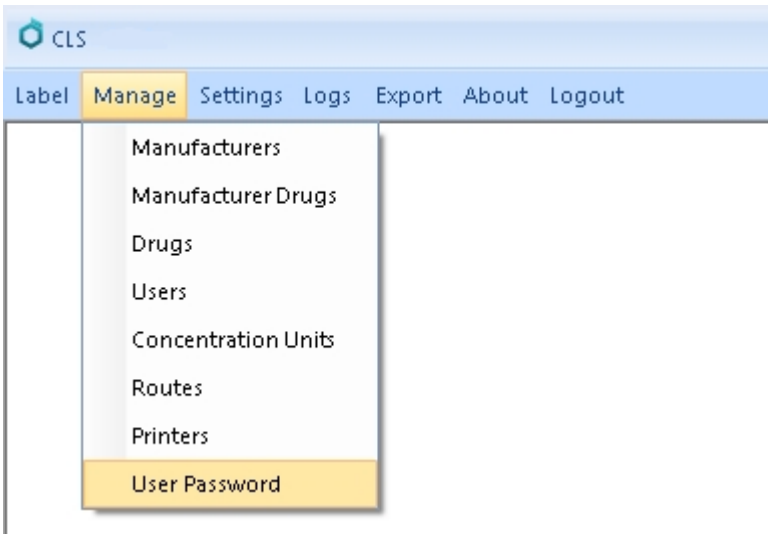
You are able to change the name of the user in the *Name* field.



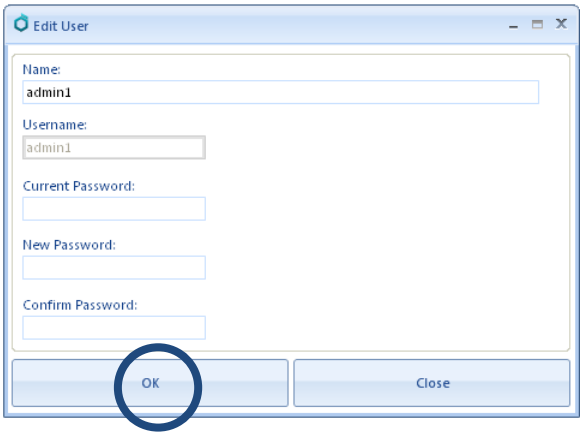
After the intended changes are made, press the *OK* button to save or press the *Close* button to cancel.

36. HOW TO CHANGE USER PASSWORD

In the main menu choose *Manage,* then *User Password*.



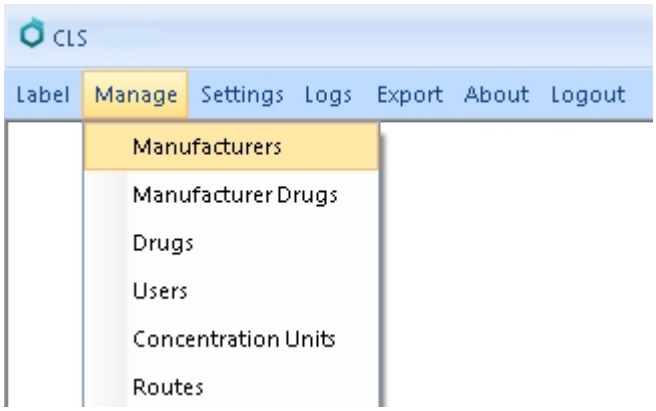
Enter your current password, then type your new password and confirm the new password in the respective fields. The changes only apply when the current password is correct, and the confirmation of the new password corresponds to the new password.



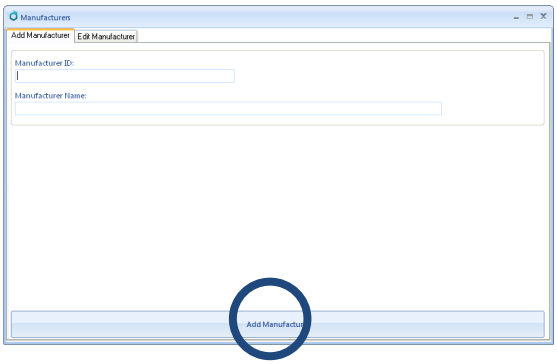
After the intended changes are made, press the *Ok* button to save or press the *Close* button to cancel.

37. HOW TO ADD MANUFACTURERS

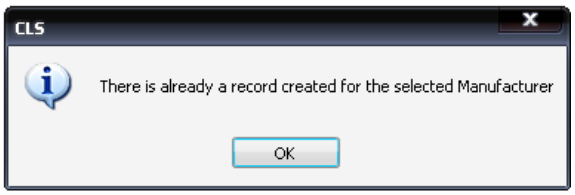
In the main menu choose *Manage,* then *Manufacturers*.



To add new manufacturers, enter the Manufacturer ID and Manufacturer Name and press the *Add Manufacturer* button.



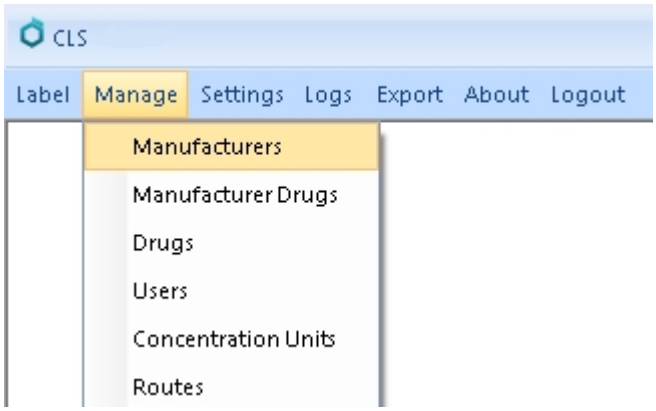
Manufacturer IDs must be unique or the CLS will prompt the user with the following message:



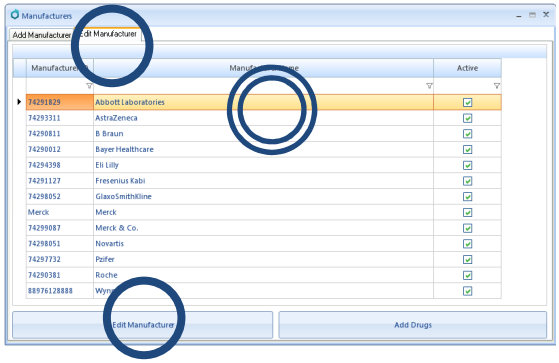
Note: Leading or trailing spaces in the *Manufacturer Name* will be truncated.

38. HOW TO EDIT MANUFACTURERS

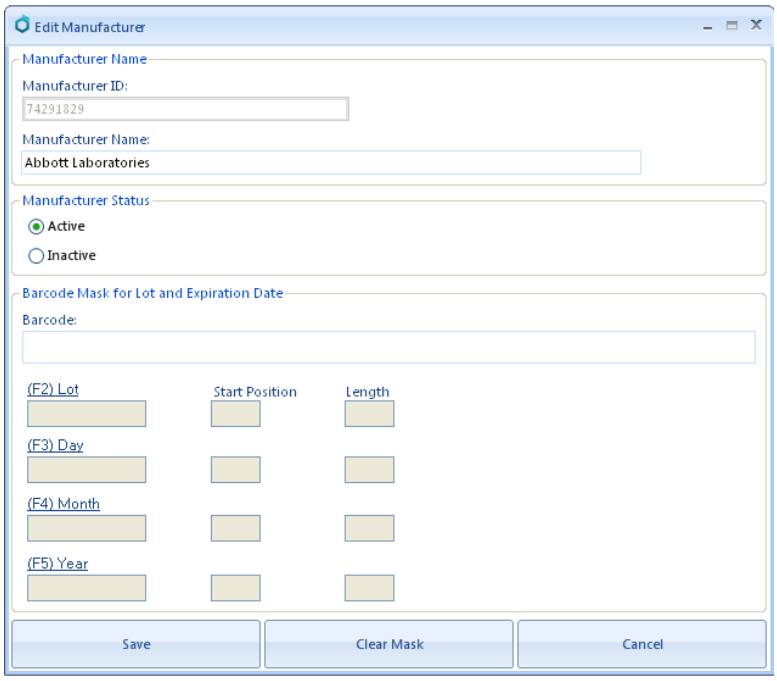
In the main menu choose *Manage,* then *Manufacturers*.



To edit a Manufacturer, select the manufacturer from the list and press the *Edit Manufacturer* button, or double click on the desired manufacturer.

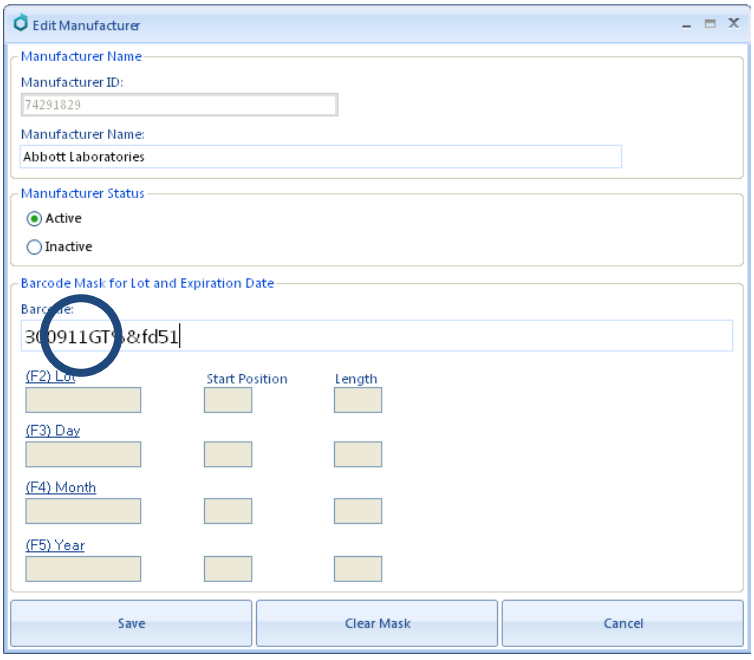


When editing a manufacturer a new window is displayed.

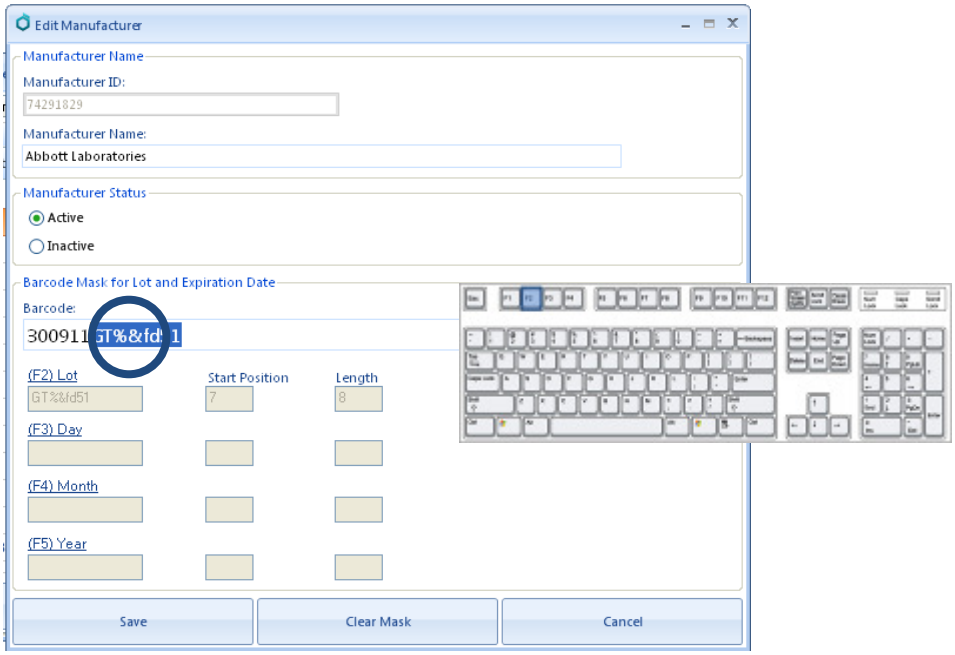


In this window you can change the Manufacturer Name, its Status and define a *Barcode Mask*. The *Barcode Mask* is optional, which is only utilized if the manufacturer includes lot and expiration date data in the box's barcode. The Barcode mask defines this manufacturer barcode structure, and is configured in the following manner:

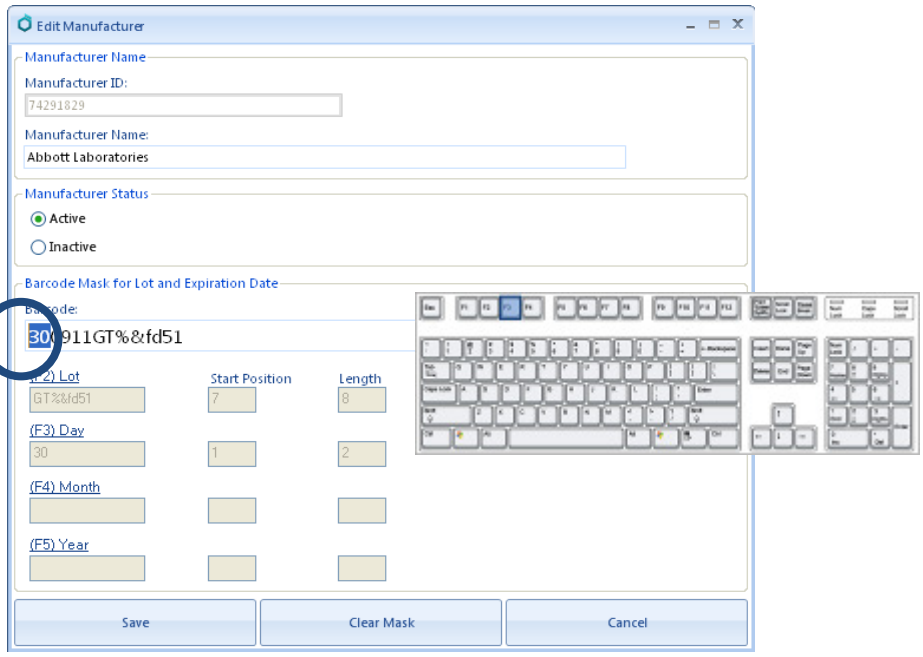
1 – In the Barcode field, scan a Manufacturer Barcode.



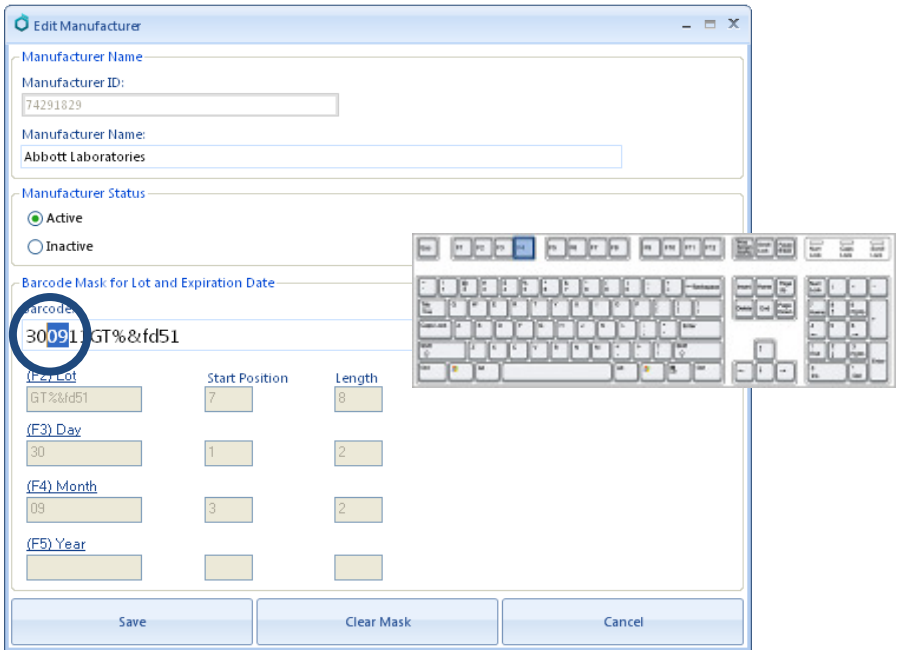
2- With the mouse, click and drag to select the characters that define the Lot and press the F2 key on the Keyboard.



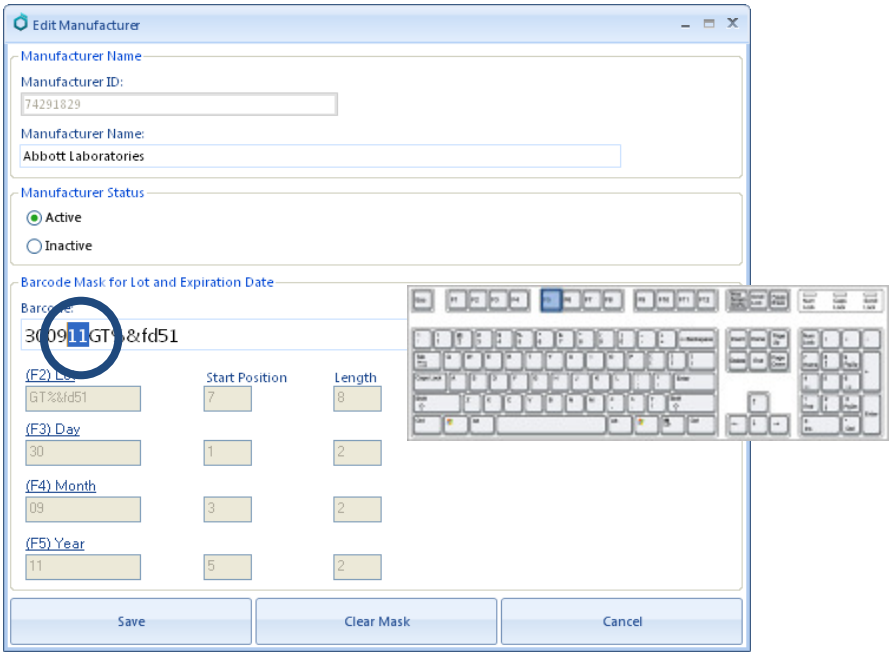
3- With the mouse, click and drag to select the characters that define the Day and press the F3 key on the keyboard.



4- With the mouse, click and drag to select the characters that define the Month and press the F4 key on the keyboard.



5- With the mouse, click and drag to select the characters that define the Year and press the F5 key on the keyboard.



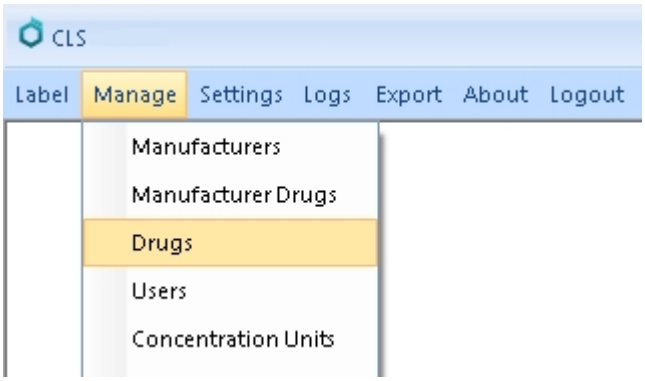
To save the changes, click the *Save* button, and you will return to the *Edit Manufacturer* window.

Note: The manufacturer barcode parsing does not interact in any way with the barcode parsing based on the *Barcode Parsing Rules*.

The *Manufacturer Barcode Mask* is optional and is only used when the manufacturer provides a specific structure to include lot and expiration date data in the box's barcode.

39. HOW TO ADD A NEW DRUG TO CLS

In the main menu choose *Manage,* then *Drugs*.



To add a new drug, fill in the Container Code or click on the *Auto Assign* button icon to give a system-generated unique ID based upon the *System* settings for *Container ID Formatting*. The *Auto Assign* gets the last Container Code, auto assigned or manual assigned, and increments by one.

Note: If you manually enter a Container Code with the maximum permitted number of digits based upon your system setting configuration (See "How to Configure System Settings), the *Auto Assign* will not have any additional numbers to automatically assign.

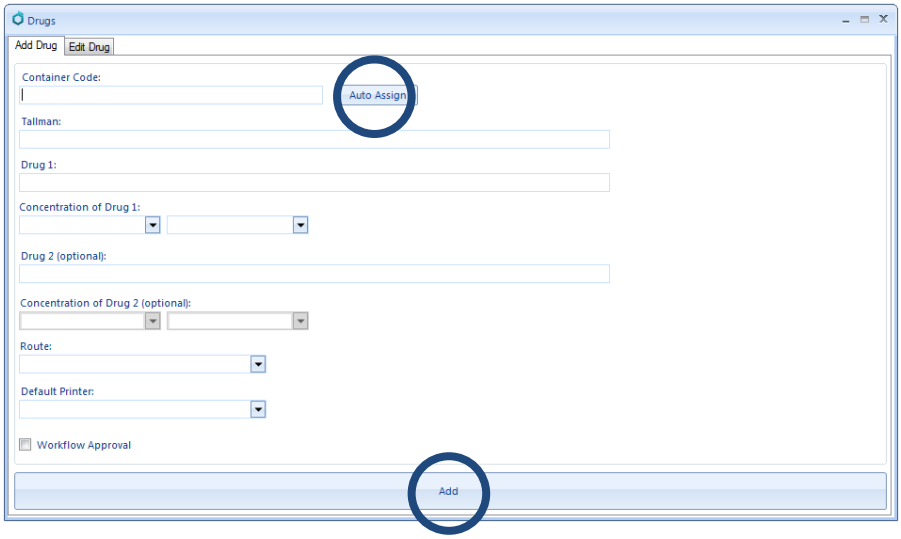
If desired, fill the *Tallman* field for the drug. Enter a description in the *Drug 1* field, select its *Concentration Value* and *Concentration Units*, *Route* and a *Default Printer*.

The Workflow Approval configuration requires administrative approval for each print job for the drug labels.

Only the *Container Code*, *Drug 1, Concentration Value,* and *Concentration Unit* fields are required.

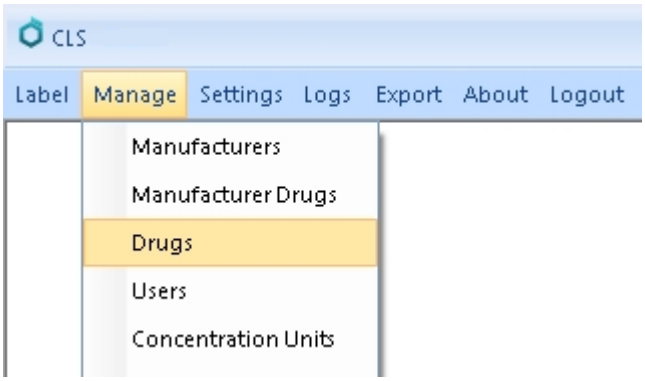
Note: *Drug 1* field has a maximum length of 30 characters when *Drug 2* field is empty. *Drug 1* field has a maximum length of 15 characters when *Drug 2* field is not empty.

To save, click the *Add* button.

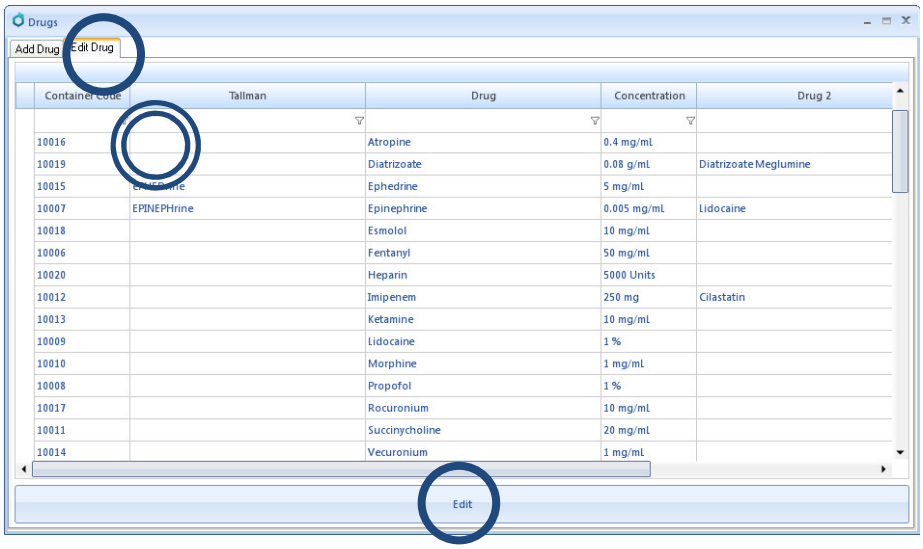


40. HOW TO EDIT A DRUG

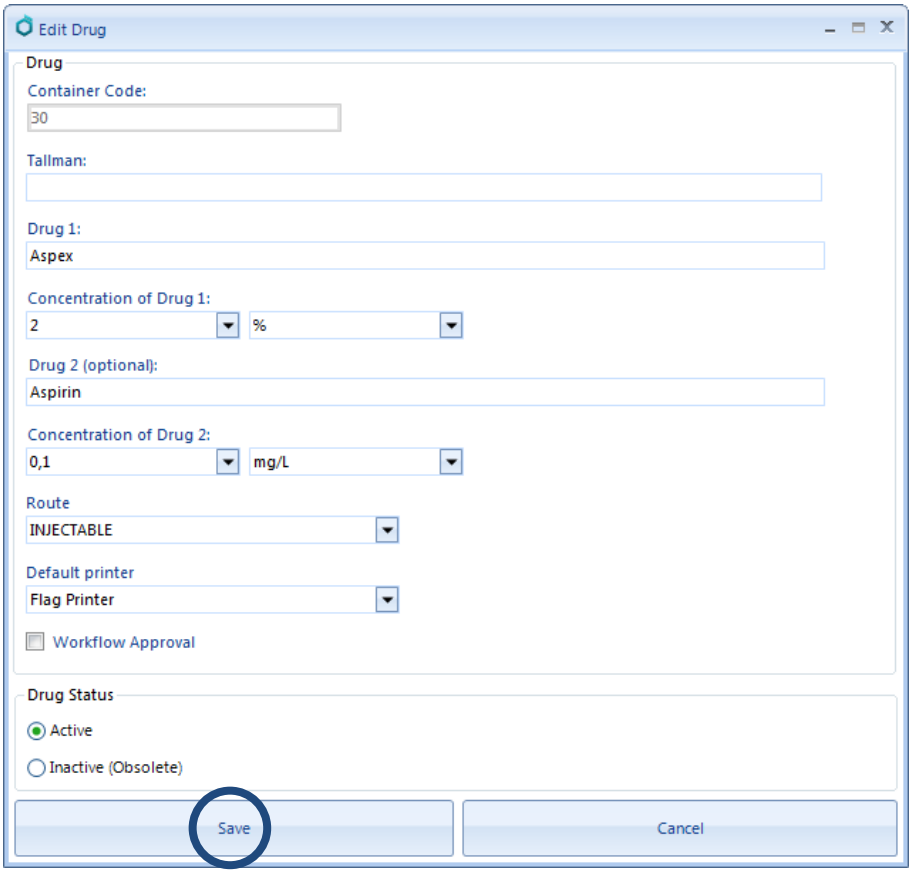
In the main menu choose *Manage,* then *Drugs*.



To edit a drug, first select the drug from the list and click the *Edit Drug* button, or double click on the desired drug.

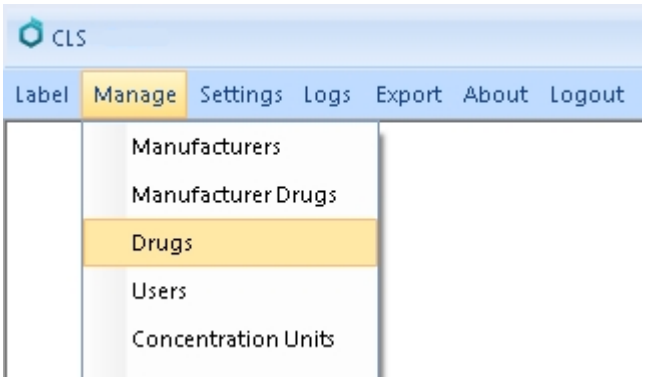


Make the necessary changes and press the *Save* button or the *Cancel* button to cancel.



41. HOW TO INACTIVATE (OBSOLETE) A DRUG

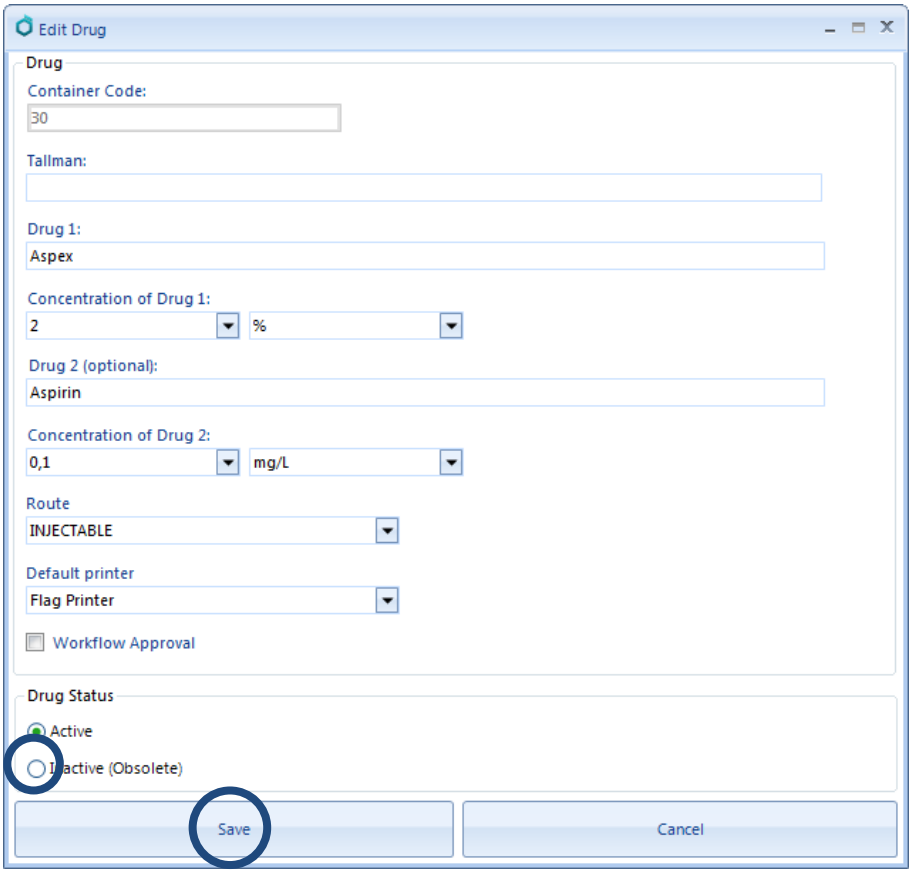
In the main menu choose *Manage,* then *Drugs*.



To inactivate a drug, select the drug from the list and click the *Edit Drug* button, or double click on the desired drug.

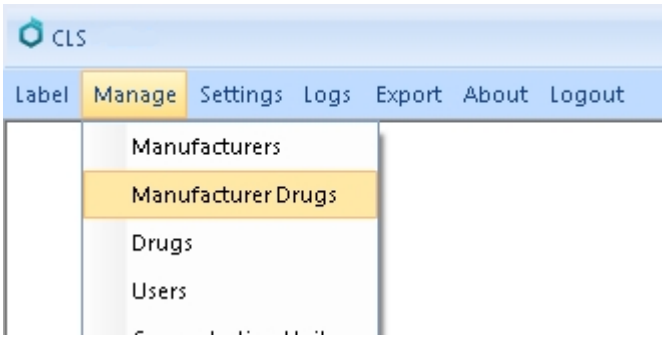
On *Drug Status,* change from *Active* to *Inactive (Obsolete)* and press the *Save* button or the *Cancel* button to cancel.

Note: Drugs marked as *Inactive (Obsolete)* are not available to be selected in the system for a new Manufacturer Drug record. Drugs that are marked as *Inactive (Obsolete),* remain unchanged as previously assigned to Manufacturer Drug records. If a drug needs to be inactivated for use, please delete the drug from the Manufacturer Drug records (please see the "HOW TO DELETE MANUFACTURER DRUG ASSOCIATION" section of this document).

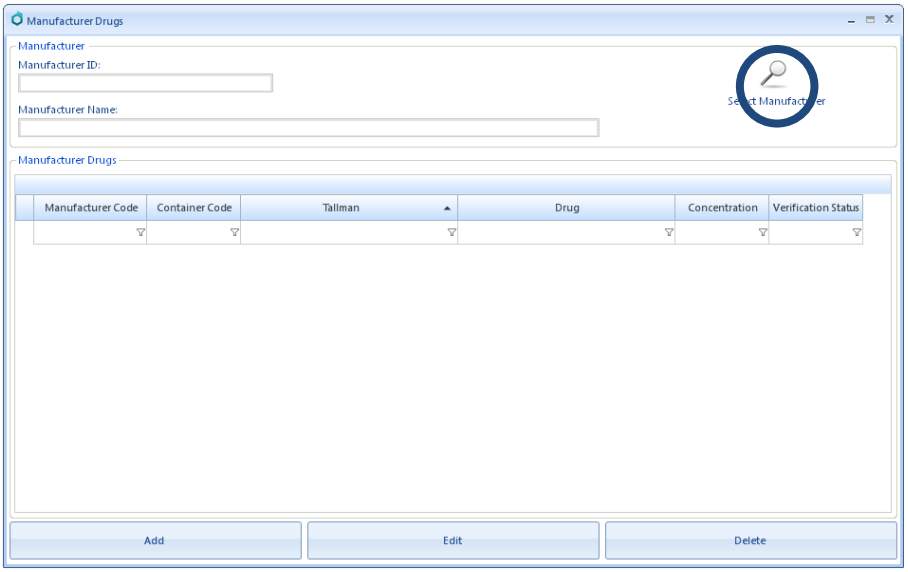


42. HOW TO ASSOCIATE DRUGS TO MANUFACTURERS

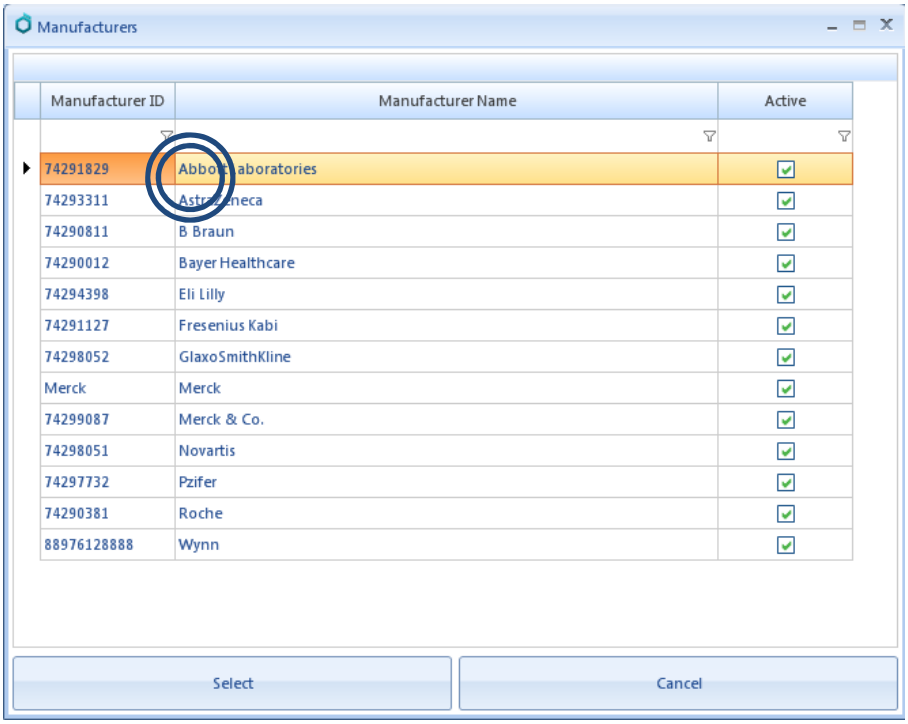
In the main menu choose *Manage,* then *Manufacturer Drugs*.



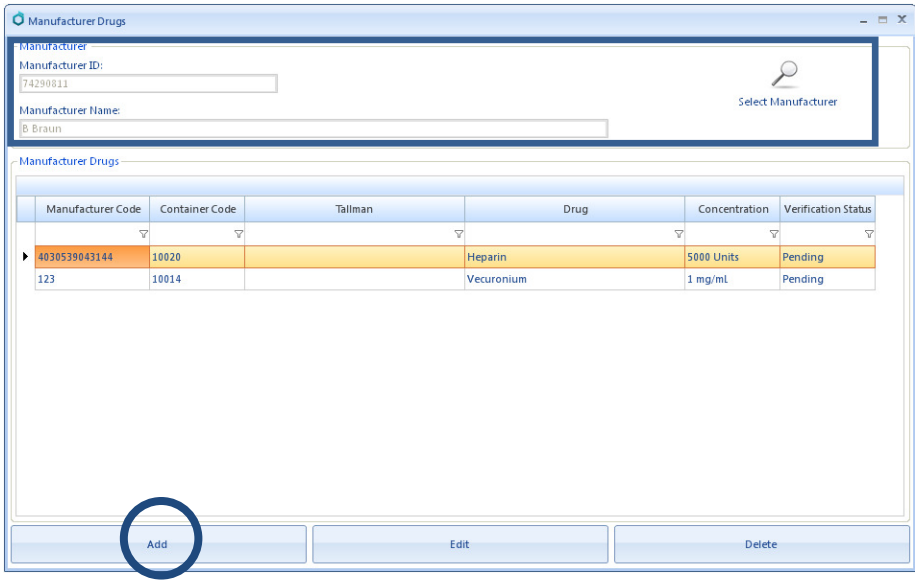
To associate a drug to a manufacturer, first select the desired manufacturer with the button.



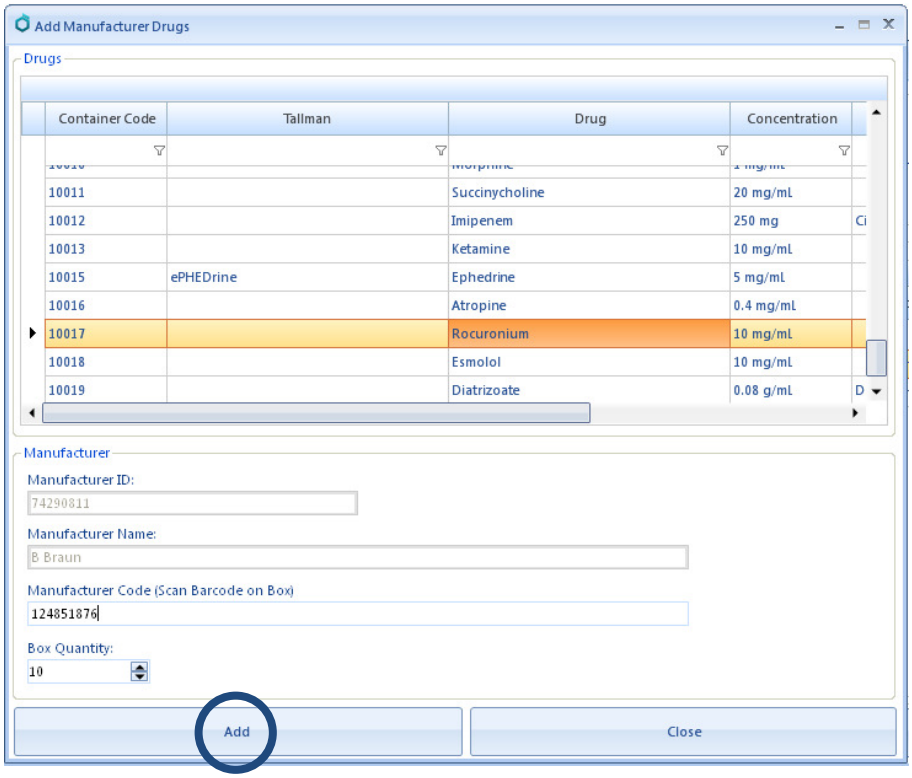
Double click on the desired manufacturer or select it and press the *Select* button.



Now click on the *Add* button to bring the *Add Manufacturer Drugs* window to select the drug to be associated to the select manufacturer.
Note: The drugs already associated to this manufacturer appear in the list below.



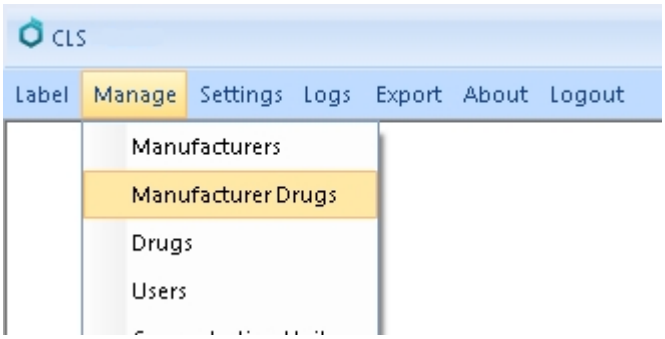
Choose the drug from the list and enter a Manufacturer Code by barcode scanning the manufacturer box's barcode. Enter the appropriate number of drug containers that are supplied in the manufacturer's box in the *Box Quantity* field.



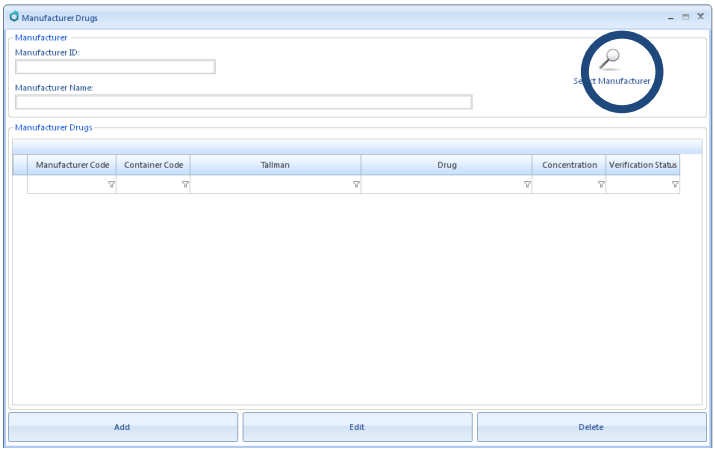
To save, click on the *Add* button.

43. HOW TO EDIT MANUFACTURER DRUGS ASSOCIATIONS

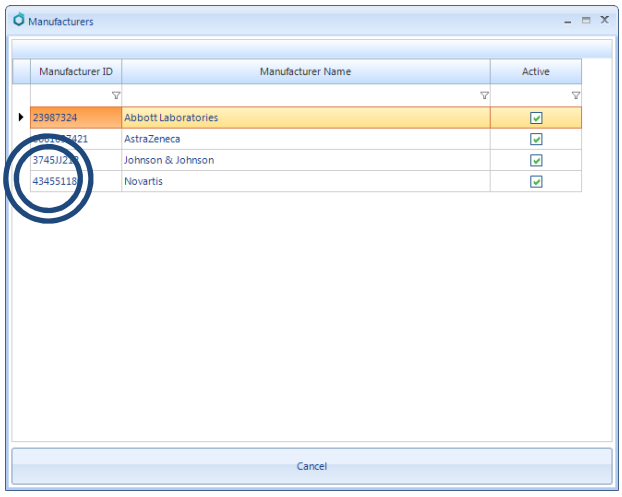
In the main menu choose *Manage,* then *Manufacturer Drugs*.



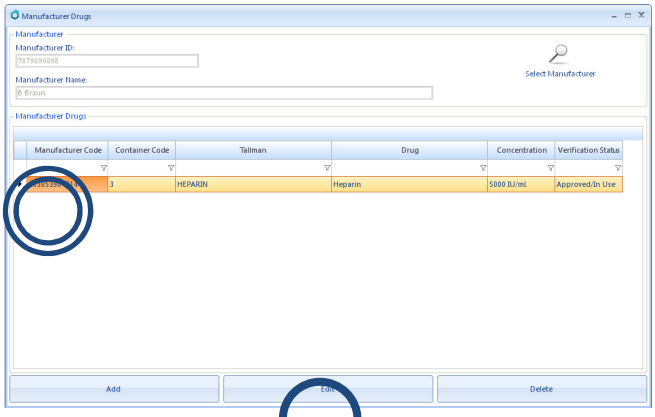
To edit associations of drugs to a manufacturer, first select the desired manufacturer with the *Select Manufacturer* button.



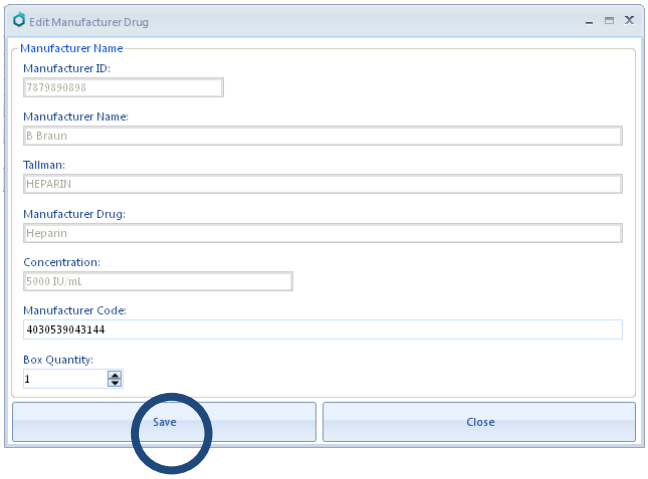
Double click the desired manufacturer.



Now, double click the desired drug or select it and press the *Edit* button.

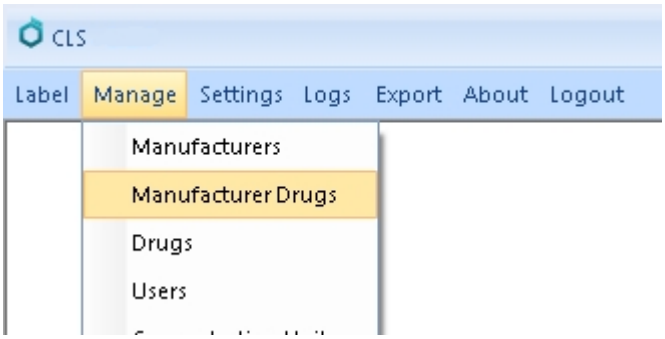


Make the necessary changes and press the *Save* button or the *Close* button to cancel.

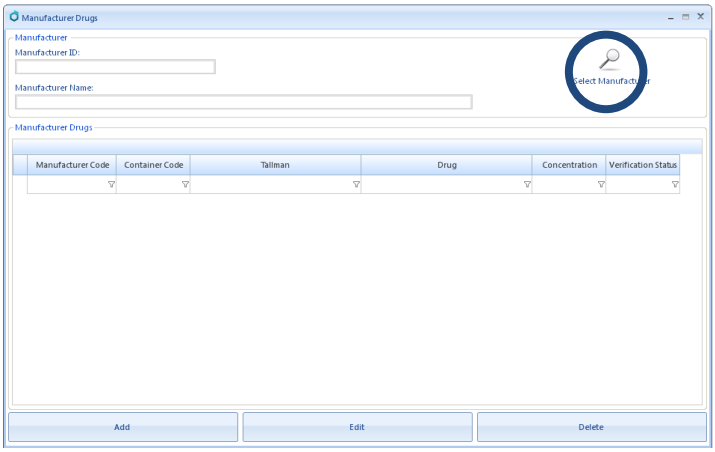


44. HOW TO DELETE MANUFACTURER DRUGS ASSOCIATIONS

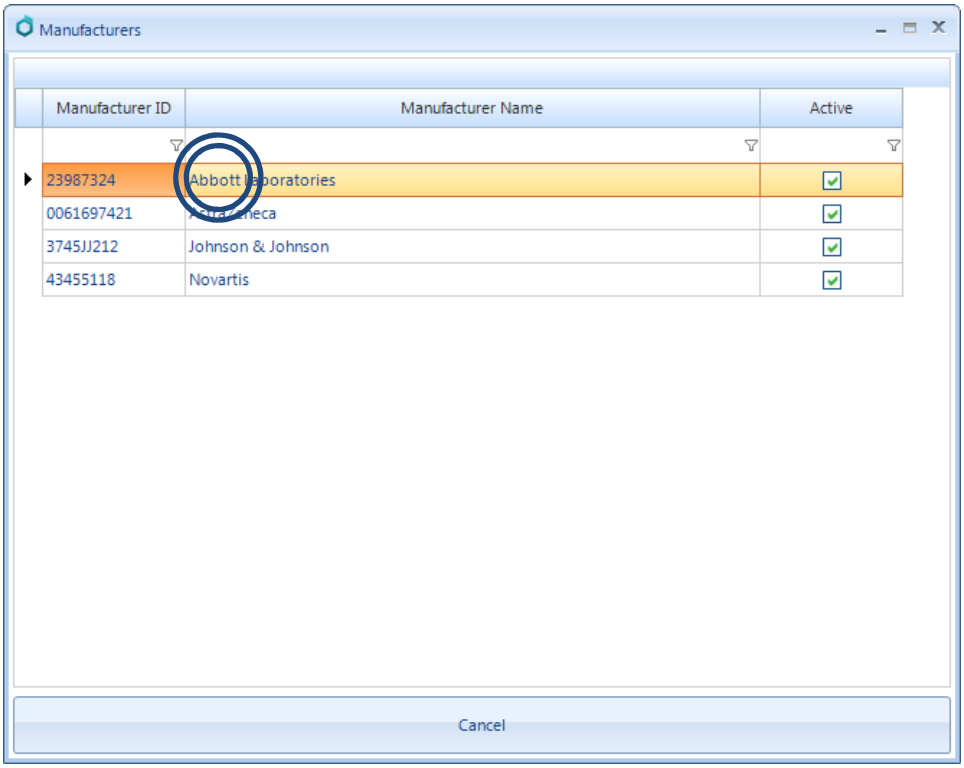
In the main menu choose *Manage,* then *Manufacturer Drugs*.



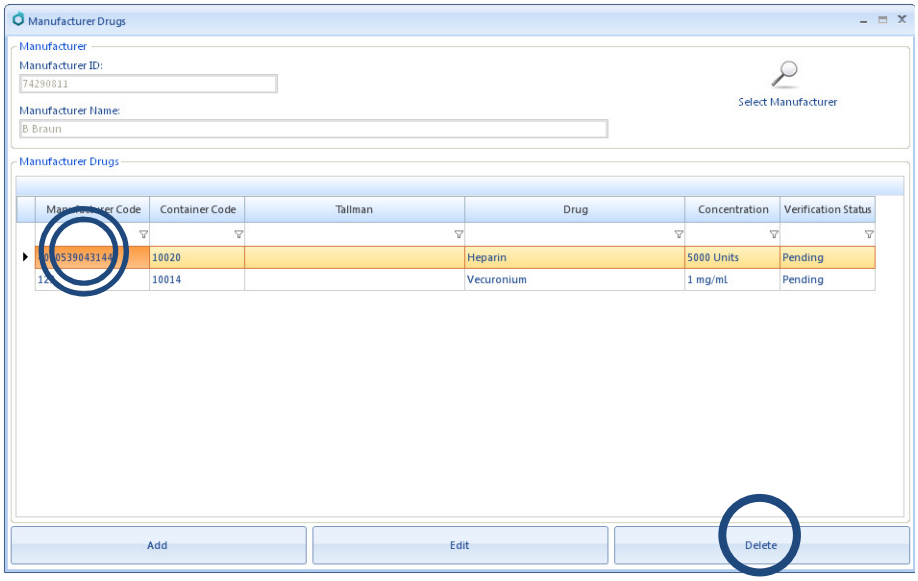
To delete associations of drugs associated to a manufacturer, first select the desired manufacturer with the *Select Manufacturer* button.



Double click the desired manufacturer.

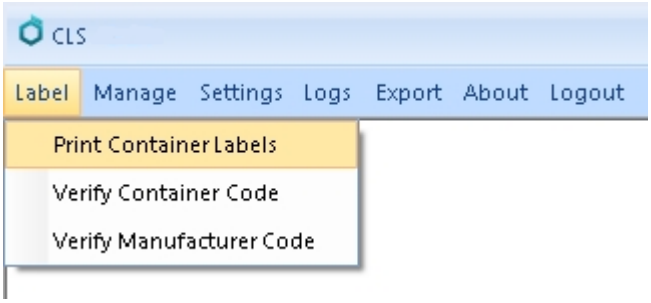


Now, select it and press the *Delete* button.



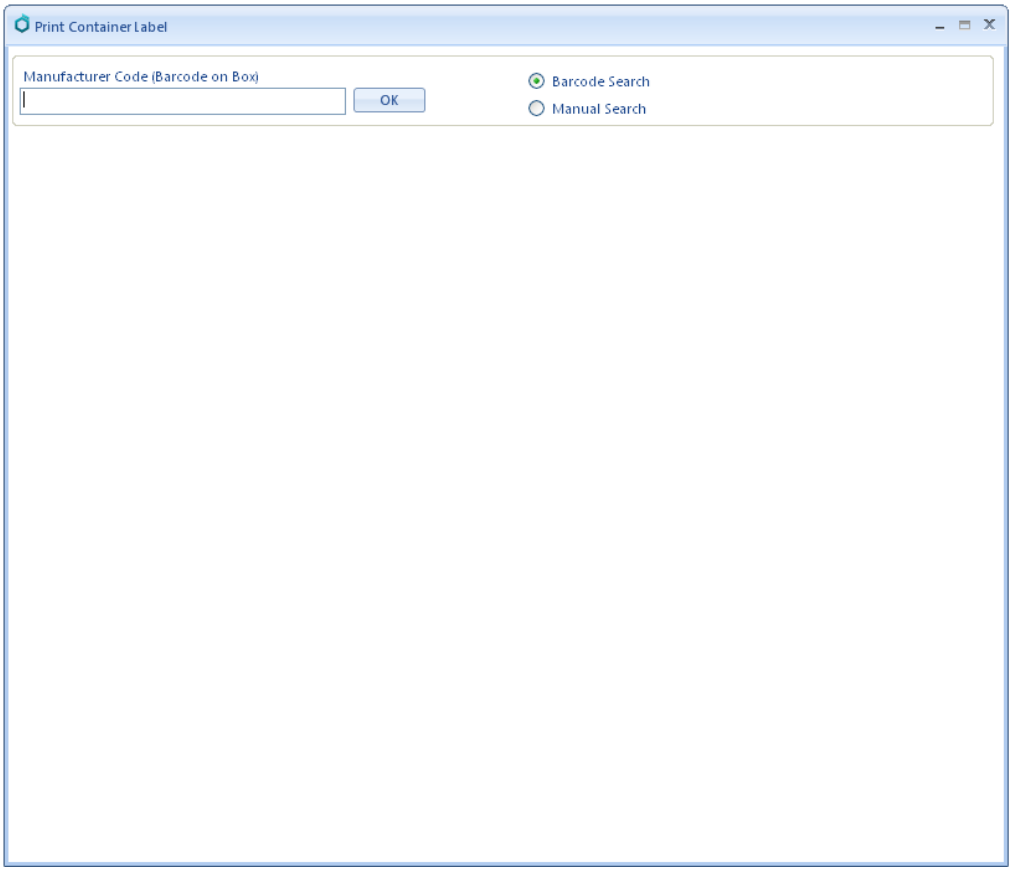
45. HOW TO PRINT A CONTAINER LABEL

In the main menu choose *Label,* then *Print Container Labels*.



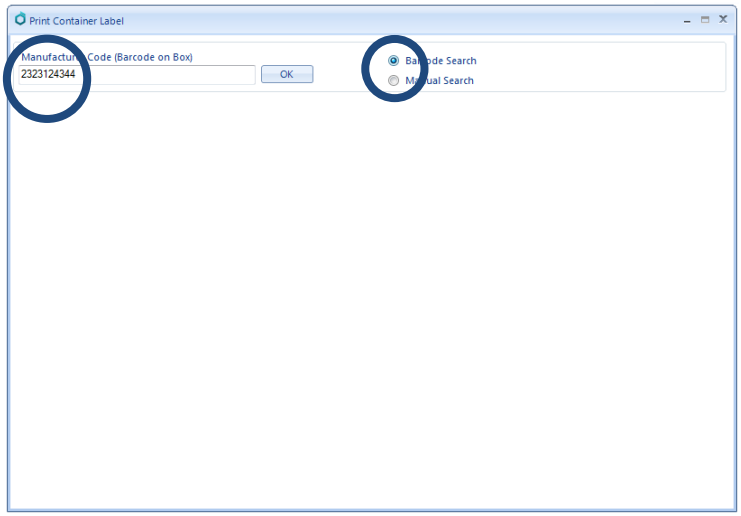
You can print labels by scanning the Manufacturer Barcode on the box or by a manual search of the drug description.

Note: Manual Searching is only available to users assigned to the Administrator, Manager or Technician groups. Operators are not able to perform a Manual Search.

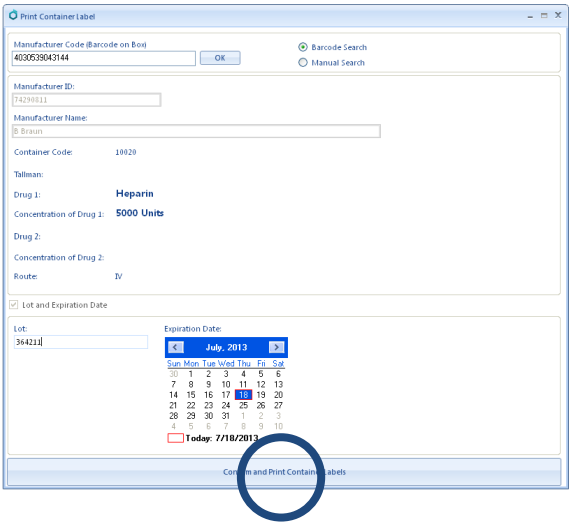


Using Manufacturer Barcodes

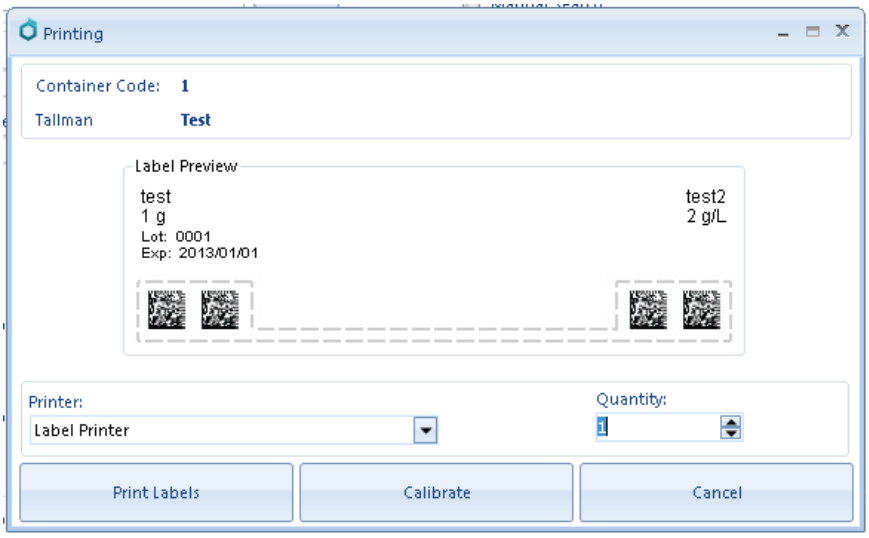
With the Barcode Search field selected, you can scan the barcode of the manufacturer box to fill the Scan Manufacturer Barcode on Box field to obtain information of the scanned drug.



Confirm the information displayed and press the *Confirm and Print Container Labels* button.



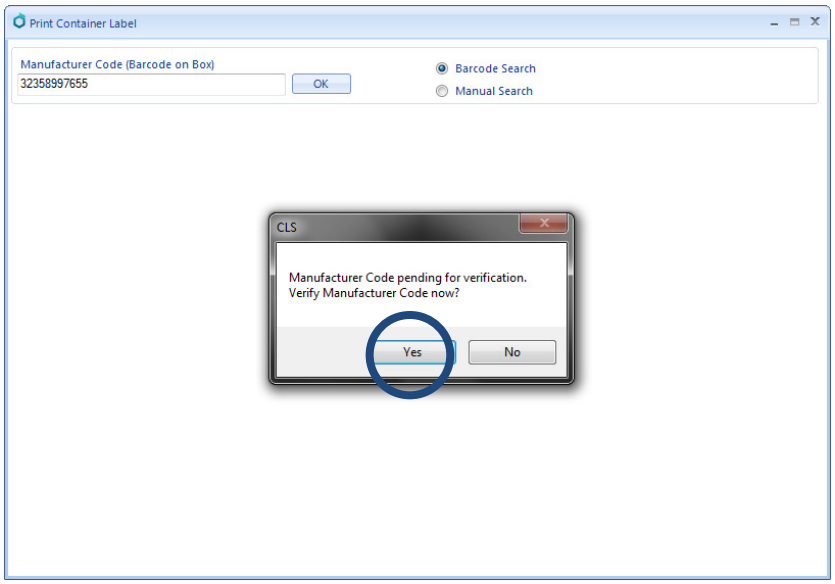
Finally, choose the printer and the quantity of labels that you want to print.



Note: Each print job submitted will include one blank label to be included at the end to allow for ease of separating the printed labels from the label stock. It is recommended that the printed labels be separated by using the perforation on the label media and leaving the blank label connected to the label stock.

Exceptions

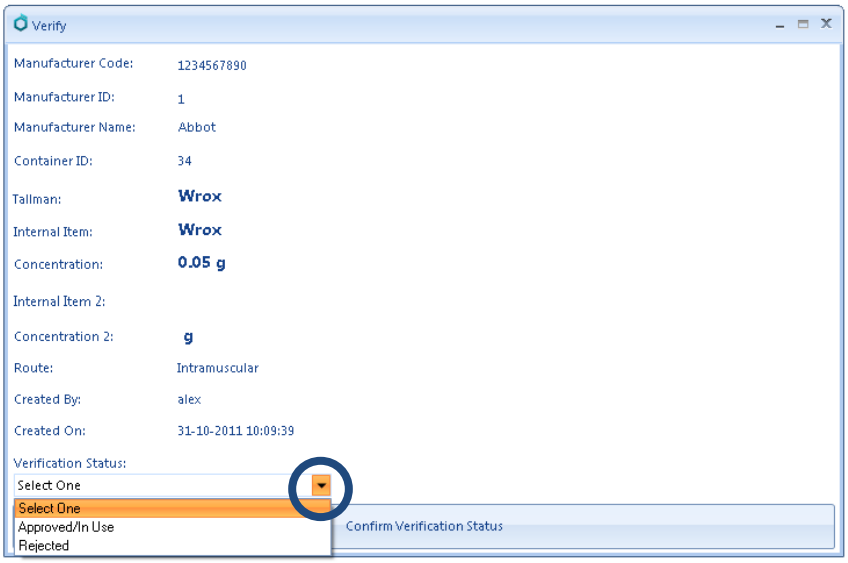
If the Manufacturer Code scanned is pending for verification a message box will be displayed indicating that it is not yet approved for use. If the user has user rights for *Perform Verification Workflow*, they will be able to choose to verify the Verify the Manufacturer Code.



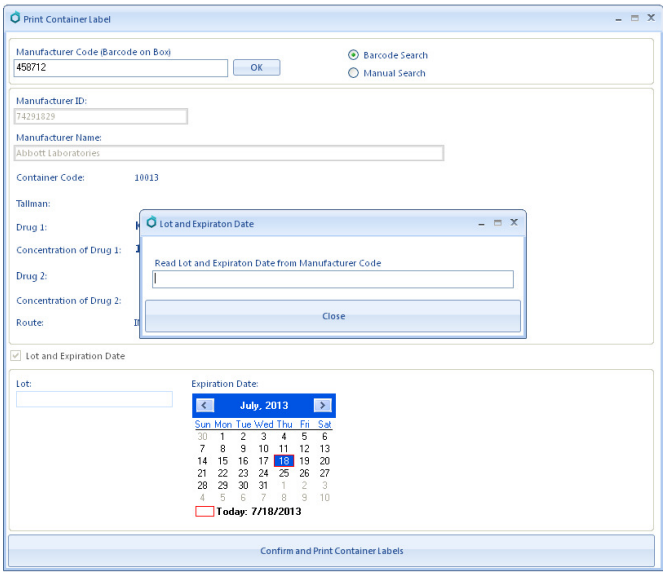
If the user decides to verify it, a new window will appear asking for a username and password with permissions to *Perform Verification Manufacturers Codes*.

If a valid username is entered with Perform Verification Workflow user rights, then it will be possible to Approve or Reject the introduced Manufacturer Code.

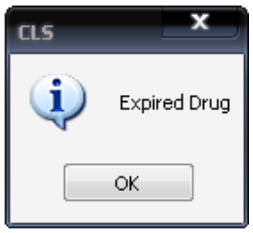
In the event the user chooses to reject the Manufacturer Code, it will not be available to print labels. If the user Approves the Manufacturer Code then the window will close and the process will continue.



If the manufacturer of this container has Lot and Expiration Date configured in a Barcode Mask, the barcode can be scanned in this screen to verify the information.



This will check the expiration date of the container. If the container date is expired, the following message will be displayed.



If the code for Lot and Expiration Date is correct, it will display the information for this container.

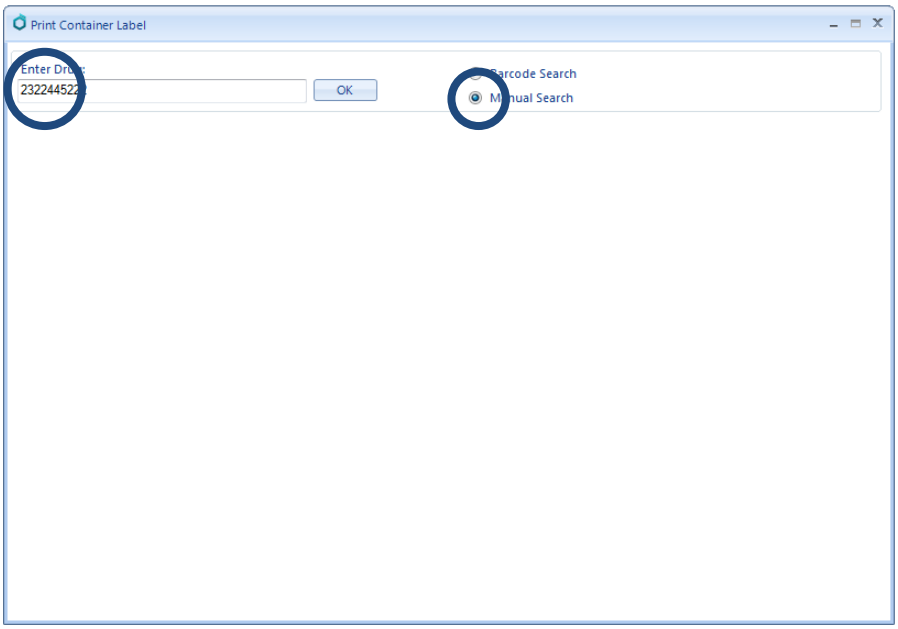
If this container has workflow approval configured a window for approval will appear, asking a user with permissions to enter their username and password to verify the labels to be printed for this container.

With the granted permission, the Print Preview window is displayed.

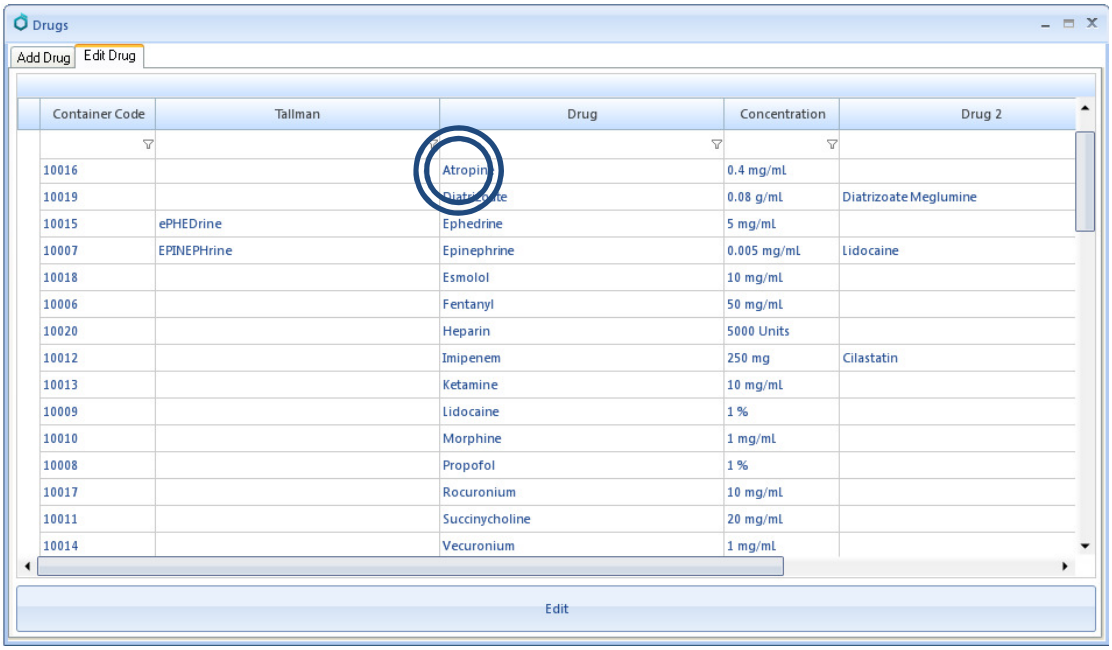
When there is no Manufacturer Barcode

With the Manual Search field selected, you can search by drug description.

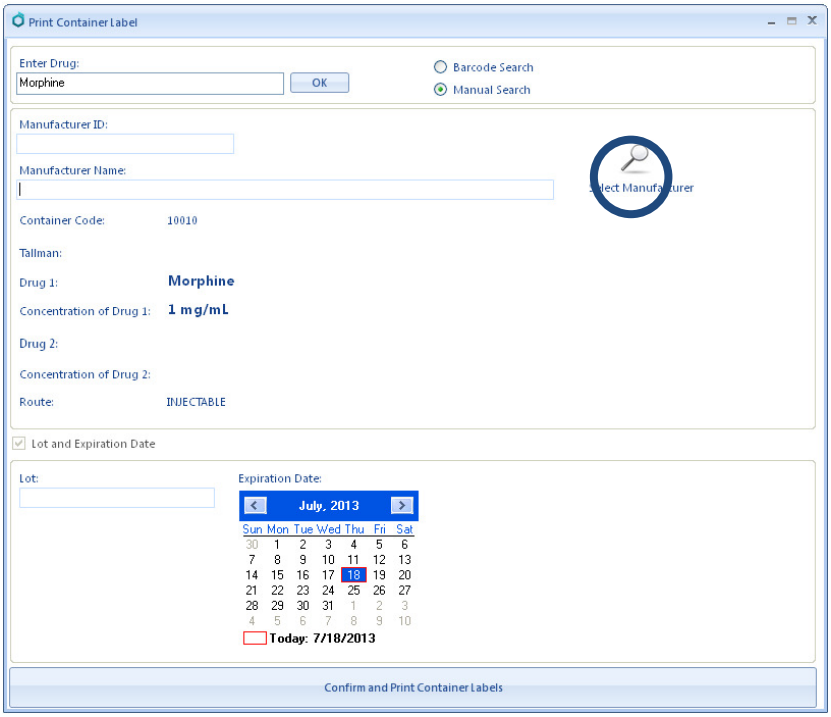
Note: Manual Searching is only available to users assigned to the Administrator, Manager or Technician groups. Operators are not able to perform Manual Searching.



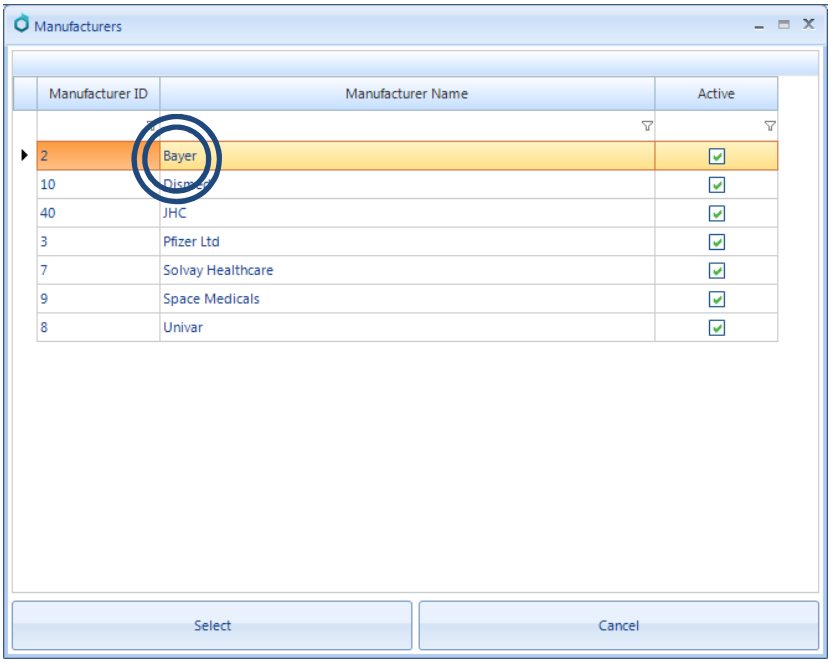
Enter part of or the full name of the drug, press the *OK* button and a list of drugs will be displayed in a new window.



Double click the desired drug to select it.

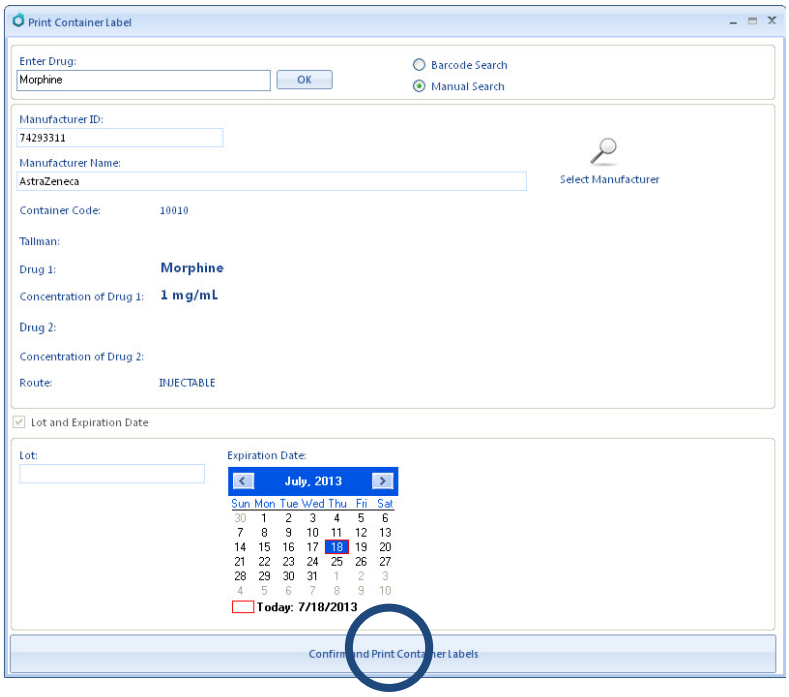


You can associate, at this point, the selected drug to a manufacturer, by clicking on the *Find Manufacturer* button where the list of manufacturers appears.

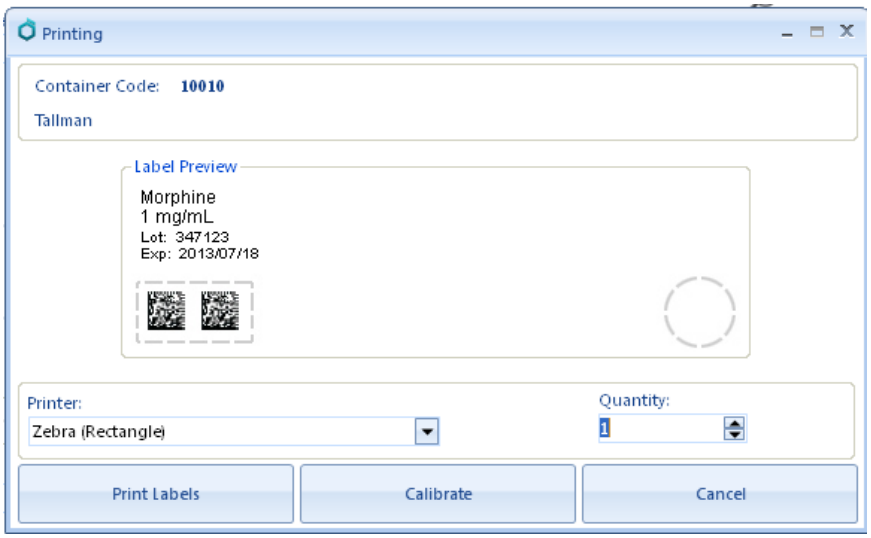


Select the desired manufacturer and press the Select button or double click it.

Confirm the information displayed and press the *Confirm and Print Container Labels* button.



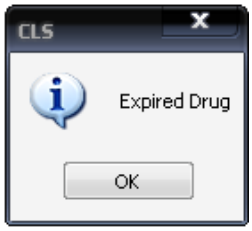
Finally, choose the printer and the quantity of labels that you want to print.



Note: Each print job submitted will include one blank label to be included at the end to allow for ease of separating the printed labels from the label stock. It is recommended that the printed labels be separated by using the perforation on the label media and leaving the blank label connected to the label stock.

Exceptions

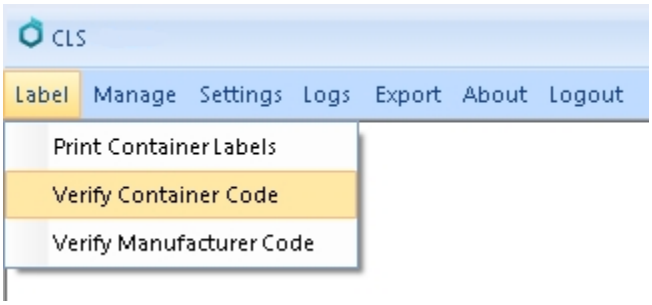
If the container date is expired the next message will show up.



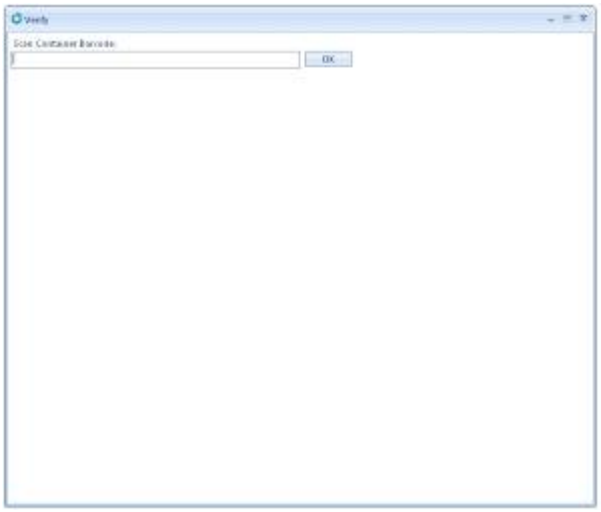
If this container has workflow approval configured a window for approval will appear, asking a user with permissions to enter their username and password to verify the labels to be printed for this container.

46. HOW TO VERIFY A CONTAINER CODE

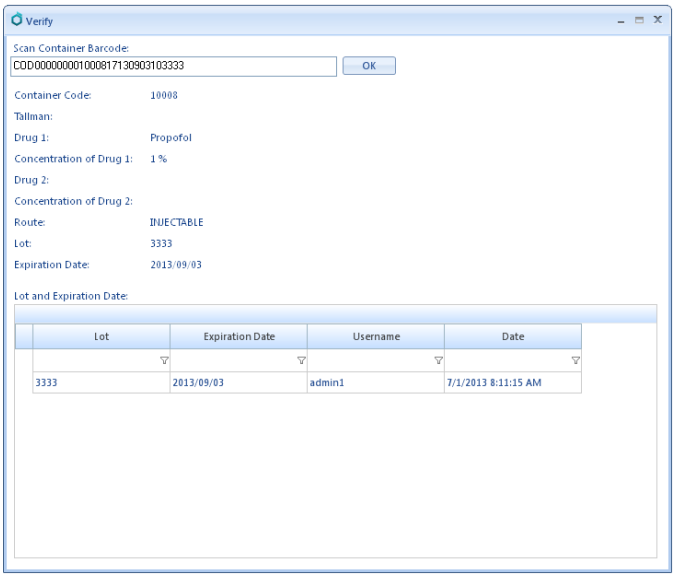
To check all information on a printed label, go to the main menu choose *Label* then *Verify Container Code*.



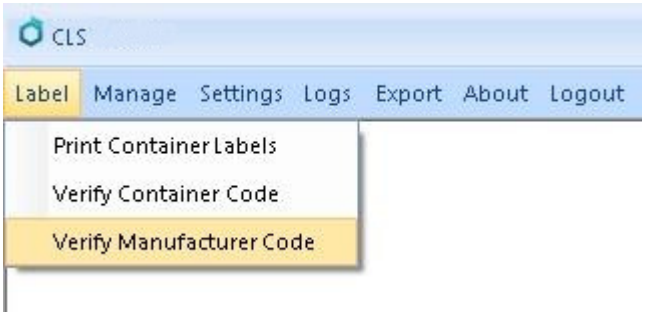
Using your barcode scanner, scan the barcode on the CLS printed label.



Check the data displayed on screen.



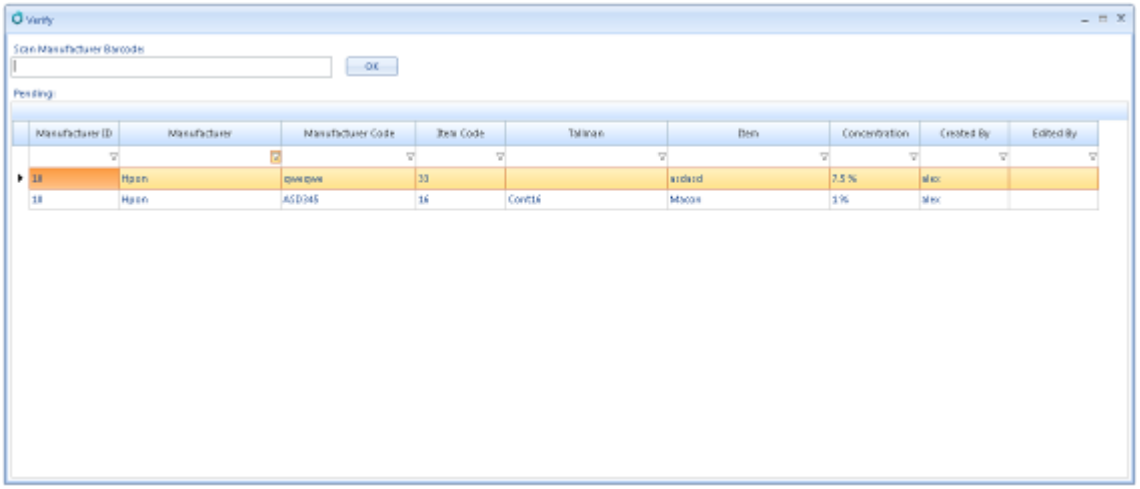
47. HOW TO VERIFY A MANUFACTURER CODE



If the Verification Workflow is selected in the System Settings, this option allows the user to scan a Manufacturer Code that is pending for Approval, and for user convenience there is a list of Manufacturer Codes that are pending Approval.

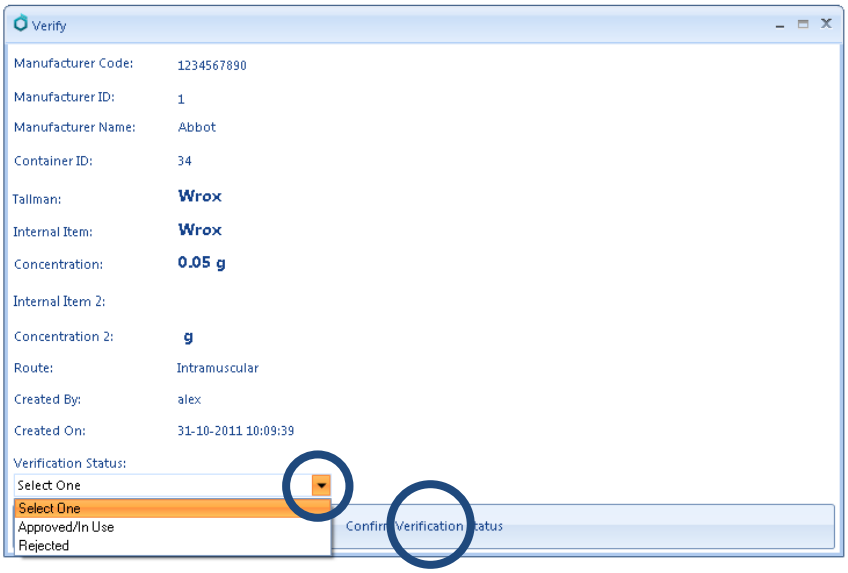
The list of Containers is for reference only as you are not able to manually select a container to verify. To start the verification process, please scan a manufacturer's barcode from one of the listed pending codes.

Note: You should have the manufacturer box and container available for review in order to properly verify the manufacturer code and container.

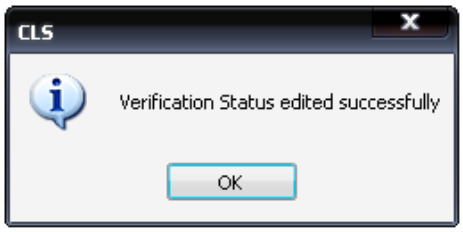


After scanning a Manufacturer Barcode, the following window appears and the user will have the option to Approve or Reject.

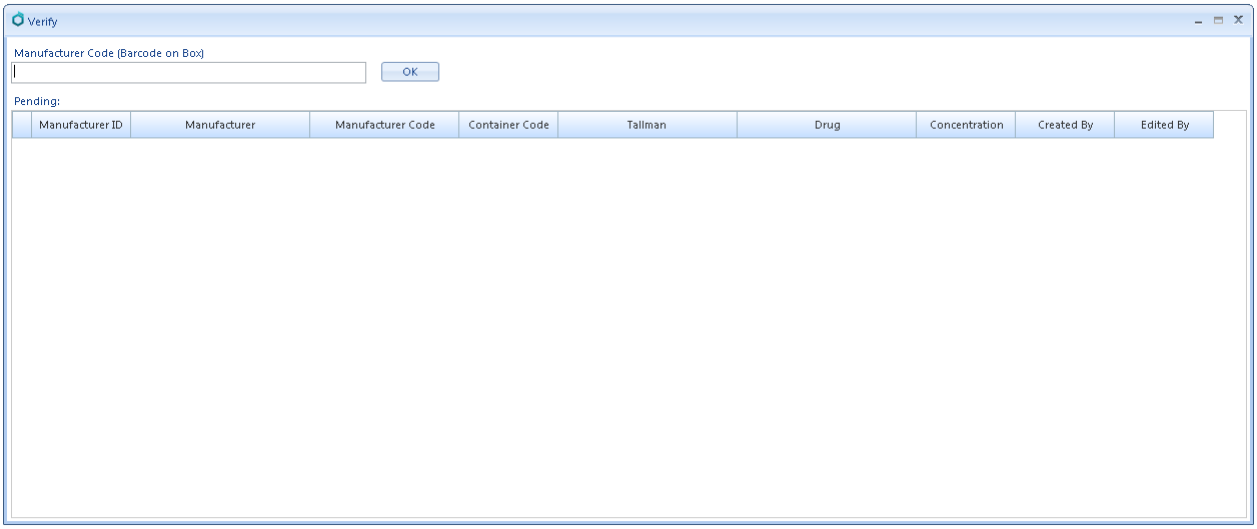
To confirm the option made, click on the button Confirm Verification Status.



CLS informs that the action was successful.



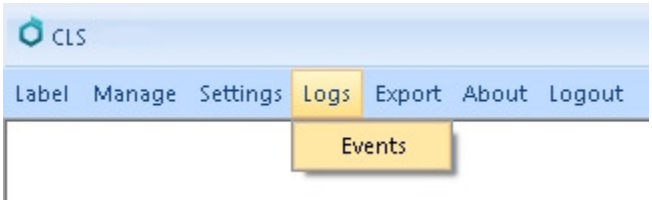
Approving or Rejecting the Manufacturer Code will update the pending list on the Verify Manufacturer Barcode Window.



If approved, you can now print the labels.

48. HOW TO ANALYZE THE LOGS

In the main menu choose *Logs,* then *Events*.



This allows you to view the events of adding manufacturers, printing labels, resetting the system parameters, adding and editing barcode rules and approving drugs performed by all users.

Add Barcode Rule
Presents a list of barcode rules that were added to CLS, followed by the responsible user, symbology, barcode rule and date/time of the procedure.

Add Manufacturers
Presents a list of manufacturers that were added to CLS, followed by the responsible user and date/time of the procedure.

Edit Barcode Rule
Presents a list of barcode rules that were edited, followed by the responsible user, symbology, barcode rule and date/time of the procedure.

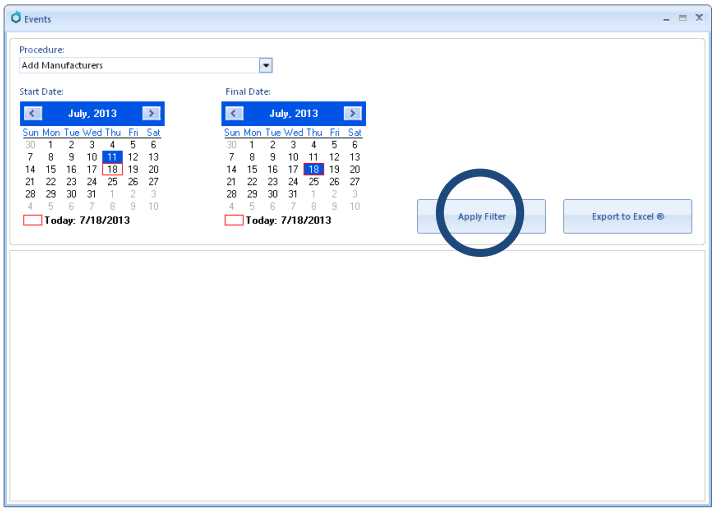
Print Labels
Presents a list of labels that were printed by CLS, containing all information about the label, the number of copies, the responsible user and date/time of the procedure.

Reset
Presents a list of the users and date/time that reset the system parameters.

Drugs
Presents a list of containers that were associated with a lot and validation for printing, followed by the responsible user and date/time of the procedure.

Verification
Presents a list of manufacturer codes that were Approved or Rejected, the manufacturer information, the responsible user and date/time of the procedure.

To see an Event, first select the Procedure, the date's interval and press the *Apply Filter* button.

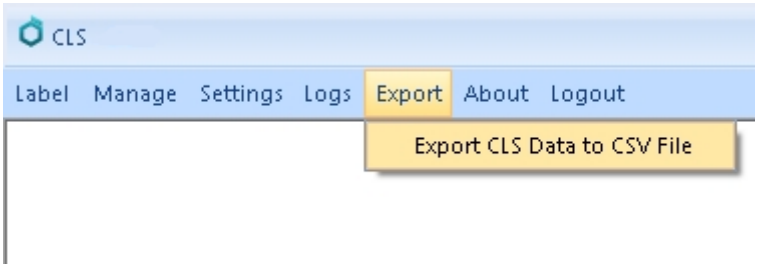


Pressing the *Export to Excel* button exports the list to an Excel file.

49. HOW TO EXPORT DATA TO A CSV FILE

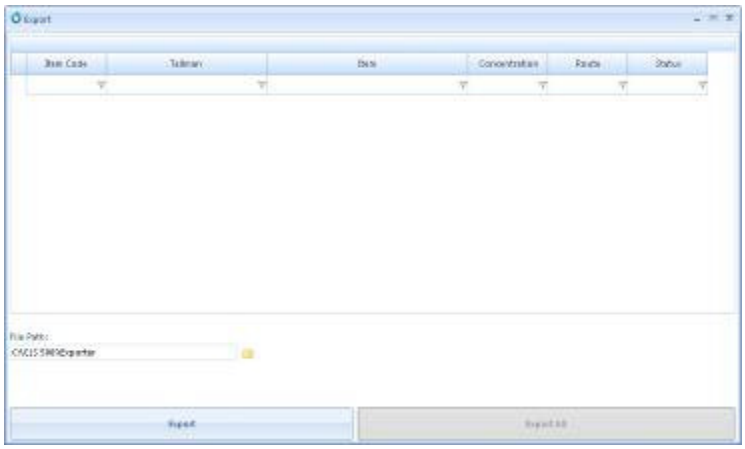
When a user logs out, if drugs were added or edited, CLS will export this data into a CSV file to the folder specified in *System Settings*.

If you want to export in a middle of a session, go to the main menu and choose *Export* then *Export CLS Data to CSV File*.



All added and edited drugs in this session will show in this window. To export this data, select the intended folder in *File Path* field (the *File Path* from *System Settings* will default) and press the *Export* button.

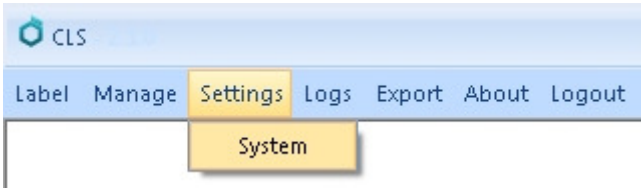
If all of the information in your CLS database is required to be exported, please contact Codonics Technical Support for use of the *Export All* button.



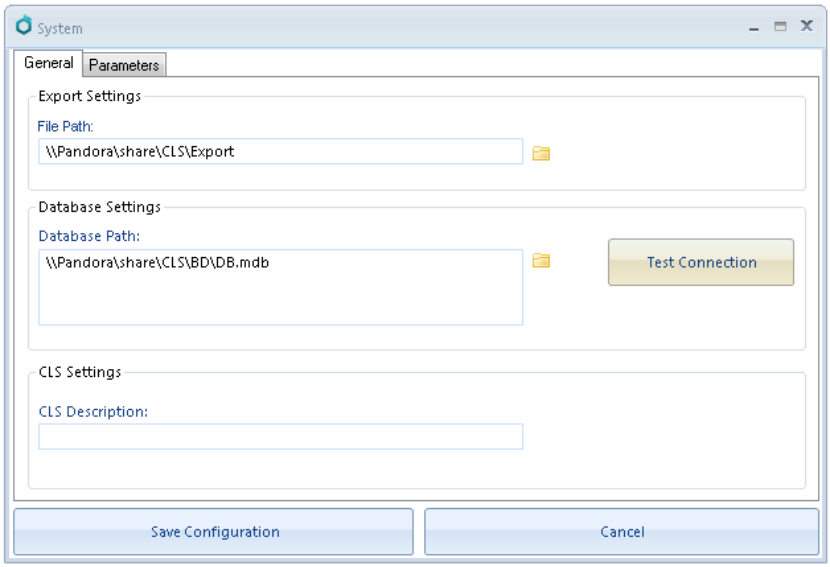
50. HOW TO USE CLS ON A NETWORK

In Windows Explorer, create in a shared folder on the network, a folder for the exports and a folder to accommodate the database. Copy the database you want to use to this folder.

In CLS, in the main menu choose *Settings,* then *System*.



Here you should change the *File Path* to the export folder you just created and the *Database Path* to the database you just copied.



Repeat the same process in all the CLS clients that are going to share this database.

51. HOW TO SECURE YOUR CLS

Backup

Your CLS data should be backed up as often as possible, ideally after every major session on your PC. Put your CLS folder (defined in the installation) in your backup list. In the event of a serious system crash, you can usually restore the operating system and programs that you use, but your CLS data may be irreplaceable.

There are dozens of programs available to help you to make backups. They vary in price but most have the same basic features - you create a list of the files and folders you want to back up and decide whether you want to save the registry entries. You can either backup your files and folders straight away or set the program to perform the backup automatically later. A basic but useable backup program comes with all Windows operating systems. You can find the Microsoft Backup Utility in the Start menu under Accessories > System Tools.

Never store your backups on your main hard drive. If you do and your hard drive crashes, your backup files will be lost along with everything else. Ideally, backups of your most important data should not be stored in the same room or even on the same site as the original.

Protect against Malware and Intruders

While there is no method that guarantees your computer will not be infected with malware, there are a number of steps that you can take to lessen the probability of this happening.

- Install antivirus and antispyware programs from a trusted source
- Update software regularly
- Use strong passwords and keep them secret
- Never turn off your firewall
- Use flash drives cautiously

To protect your computer, you can install and run an up-to-date antivirus product such as Microsoft Security Essentials, a free solution from Microsoft available for small businesses with up to 10 PCs. If your business has more than 10 PCs, you can protect them with Microsoft Forefront Endpoint Protection. This kind of software provides real-time protection from viruses, spyware, and potentially unwanted software.

It is best practice to run a scan with your antivirus/antispyware product on a regular basis.