# **AIDA Frequently Asked Questions**

# Never have to fill out a label by hand again....

Special features of AIDA to support the unique environment of an ASC:

Many ASC's are stand alone entities that do not have a pharmacy. They do not have a special department to manage their drugs. So they don't have the resources to maintain a complicated drug formulary database in order for a computer labeling system to work.

AIDA utilizes the FDA NDC Directory. This is a publicly available database that is updated on a daily basis with every drug approved for use by the FDA in the United States. If the FDA has approved the drug, AIDA will recognize it and generate the proper colored label without any setup.

Out of the box, AIDA can recognize more than 100,000 drugs in use in the U.S. and generate a standards compliant label, that is easy to apply, and helps to eliminate medication mistakes.!

# **Expired Drugs**:

How do I know if a drug is expired?

Many drug vials and drug containers in the U.S. only have the month and year of expiry printed on the label. This can lead to confusion on what day the drug is expired. Don't worry, because AIDA knows. AIDA knows the day it expires too.

When AIDA scans a drug vial or container, it reads the expiration date and compares it to the system date. if the container is expired, the user is informed and AIDA will not put the label in the print queue. The system date is automatically kept updated if the AIDA unit is connected to Wi-Fi.

### Drug Recalls:

A drug recall is a voluntary action taken by a company to remove a defective drug product from the market. Drug recalls may be conducted on a company"s own initiative or by FDA request. FDA"s role in a recall is to oversee a company"s strategy, assess the adequacy of the recall and classify the recall.

https://www.fda.gov/drugs/drug-recalls/fdas-role-drug-recalls

The FDA maintains a publicly available database on all drug recalls in the U.S. ADIA utilizes this database to check that the drugs it scans have not been recalled. The Lot / Batch Number must be read from the drug vial in order to check for a recall.





The check is automatic, and AIDA will alert the user if it scans any drug that has been recalled. The FDA database sometimes takes several weeks to be updated after a company initiates a recall. So it may be possible that AIDA will not identify a drug has been recalled if the recall happened in the past two weeks. It all depends on how fast the drug company alerts its distributors and the FDA on the recall.

#### **Drug Extensions:**

The FDA maintains a list of drugs that can be used past their expiration dates. This list is periodically updated, and AIDA uses this list to check if a drug it scans has an extended expiration date. The Lot / Batch Number must be read from the drug vial in order to check for an extended expiration date.

https://www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages

If AIDA scans a drug with an extended expiration date, the user is informed of the new date, and this is recorded. AIDA also checks that the drug is not expired with the new expiration date.

FAQ continued on next page >>



## **AIDA Scanner:**

The AIDA system uses a patent pending camera system to read drug vials and containers. The system can recognize barcodes, and read the lot number and expiration date that is written on the drug vial.

During the development of AIDA, a barcode scanner was used to scan drugs. While this approach worked well to identify a drug vial or container, there were some downsides to this approach:

- When using a barcode scanner, the user had to aim the scanner at the barcode on the drug vial. Sometimes this would be unwieldy, and there wasn't a good place to put the barcode scanner when it was not being used.
- If the barcode scanner was in a fixed position, the user would present the drug vial to the scanner. There was a learning curve for the operator on where to place the drug vial, and how to orient the drug vial so that the barcode was visible to the barcode scanner. This took time, valuable time.
- · The barcode scanner sometimes would scan a drug multiple times. This would create multiple labels if the duplicate labels were allowed.
- Typically the barcode scanner provided audible feedback to the user that a scan was successful. However, this beep was annoying to many in the OR. In addition, many drug vials have multiple barcodes imprinted on the label. Sometimes the user would get a successful beep, but no label would be added to the queue, because they scanned the wrong barcode on the drug vial.
- And finally, the barcode scanner could not be used to read the lot number or expiration date on the vial, so this information could not be captured or verified.

So we went back to work to find a better way. The result was the AIDA scanner. The world's first barcode scanner replacement to quickly and accurately scan drug vials and other drug containers. The AIDA scanner also reads the lot number and expiration date on the drug vial. The AIDA scanner uses a high resolution camera and AI algorithms to detect areas of interest on the drug vial. This allows the scanner to detect and decode barcodes on drug containers very fast, typically less than half a second.

The AIDA scanner provides visual feedback to the user. You see what the AIDA scanner sees, which assists the operator to rotate the drug vial so that the lot number and expiration date can be read. Many times the lot number and expiration date are written on the opposite side of the drug vial from the barcode. The AIDA scanner recognizes when it is scanning a drug vial, and doesn't try to read another vial until it is removed from the scanner and a new vial is presented to the scanner.

The AIDA scanner is designed to assist the user in placement of a drug vial or box so that AIDA can quickly scan it. After using AIDA for less than one day, users report they can successfully scan their drug vials in less than 1 second.

Because the AIDA scanner captures the lot number and expiration date, additional safety checks can be made on the drugs that typically have to be done manually by the nurse or anesthesia provider. All these checks happen automatically and almost instantly.

- Check that the scanned drug is not expired.
- Check that the scanned drug is not recalled.
- Check if the scanned drug has an extended expiration date authorized by the FDA.

# How does AIDA ensure the expiration date and lot number are read accurately?

If you have ever tried to read the lot number and expiration date from a 1ml single use vial, you know how difficult it can be to accurately record the lot number and check the expiration date. The letter O and the number 0 look the same in a lot number. How can AIDA know the difference?

AIDA learns. AIDA learns the valid lot number and expiration date pairs associated with a specific drug every time AIDA scans a 2D barcode. AIDA can also learn a valid lot number and expiration pair through manual verification. AIDA can only successfully read a lot number and expiration date from a drug container if it has previously learned the lot and expiration date. Any lot number or expiration date that AIDA reads is compared to known lot number / expiration dates to ensure it is read accurately.

The FDA has mandated the use of 2D barcodes on drug containers in the smallest individual container that is for sale. So some drug vials have 2D barcode on them that contained the lot number and expiration date. When AIDA scans a 2D barcode, it remembers the lot number and expiration. If AIDA then scans a 1D barcode of the same drug, it can also now read the lot number and expiration date.

In order for AIDA to read lot numbers and expiration dates, the boxes the drugs come in should be scanned once. AIDA learns the lot number and expiration date, and then can recognize them, even without the 2D barcode in the future.

Everytime an AIDA unit scans a 2D barcode, this information is automatically shared with every other AIDA unit connected to the internet. Also, any time the AIDA app scans a 2D barcode, this information is shared with every AIDA unit.

When a user manually verifies a lot number / expiration date pair, this information is not shared with other AIDA units. (Too often people make mistakes when manually verifying lot numbers).

# Why does AIDA let users manually verify lot numbers and expiration dates for AIDA when creating labels?

When the AIDA scanner was being developed, we initially allowed the user to manually verify lot numbers and expiration dates that AIDA had not learned yet. However, there were some problems with this approach:

1) Users can not tell the difference between the letter O and the number 0. Sometimes they would verify lot numbers that were close, but not exact matches. So then AIDA would



- record the wrong lot number, which is a problem if you are trying to check if a drug has been recalled.
- 2) The operating theater is a fast paced environment. You don't have time in the middle of a procedure to verify the AIDA scanner has read a lot number and expiration date correctly. So sometimes the operator would just select the first option to verify, without actually checking it was correct.
- 3) If AIDA does not recognize a lot number or expiration date that it has read, it keeps trying up to 10 times to read it. This takes 2-3 seconds. This sometimes would create confusion and frustration for the operator.
- 4) Some drug manufacturers put dashes in their lot numbers. However, the lot number in the 2D barcode does not have dashes. While this isn't a problem for humans, computers like exact matches. This also caused problems with checking for drug recalls and drug extensions.

So the decision was made that AIDA would not allow manual verification of lot number and expiration dates while creating labels. It was too error prone, and AIDA was introduced to eliminate mistakes, not perpetuate them.

However, when we rolled this feature out, the users were adamant that there had to be a way to manually verify lot number and expiration dates. They did not like that they could not manually verify. So we added the feature back in, but these manually verified lot/expiration date pairs are not shared with other AIDA units – because they could be wrong. In addition, under the settings, you can review who manually verified a lot/expiration date pair, and delete manually trained lot/expiration date pairs if they are incorrect.



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#### Questions about how AIDA works:

# 1. How long does it take to setup AIDA once I receive it?

15 minutes. Here is the entire AIDA setup:

- 1. Take the AIDA unit out of the box and place it on the anesthesia cart.
- 2. Plug it in, and wait for the AIDA device to start up.
- 3. Select the Wi-Fi network and enter in the password.
- 4. Set the correct time zone.
- 5. Insert the ink cartridge and load the labels.

That's it! You are ready to create labels now for all the drugs you use in the ASC. AIDA already recognizes them and is ready to print some labels!

# 2. Why doesn't AIDA have usernames and passwords?

AIDA was designed to free up time for nurses and anesthesia providers so they can focus more on the patient, and less on administrative tasks.

AIDA does not have any patient information. It only knows the drugs you use, the lot numbers and expiration dates. The AIDA device is in the operating room, so there is already a level of security to get to the AIDA unit.

AIDA replaces the hand written labels used by anesthesia providers. You don't need to login to write on a label, so why do you have to login to print a label?

The user simply writes their initials on the screen. AIDA captures these initials and they are printed on the label that is generated. Signing in is as simple as writing your initials. Why complicate life with more passwords to remember, just so you can create a label?

# 3. Can I change the dosage on the label for a diluted drug?

Yes, simply push the label that is shown on the print queue. This brings up a window to change the dosage. AIDA remembers the last four dilution dosages you have used in the past. Simply choose one of them, or enter in a new one. No previous setup required.

# 4. Can I use AIDA without Wi-Fi?

Yes. AIDA will work fine even if not connected to Wi-Fi. However, there are a few things to know when operating without Wi-Fi.

- AIDA synchronizes its internal clock using NTP over Wi-Fi. It automatically recognizes Day light savings time, and keeps system time accurate to within 1 second. Over several months, the time could drift on the AIDA device if it is not connected to Wi-Fi. You can go into settings and manually set the time if this happens.
- 2. Every 30 days, AIDA automatically updates it internally stored NDC Directory. It uses this database to identify drugs. If you are not connected to Wi-Fi, the database will become out of date. It will probably take six or more months before you notice any issues with AIDA. You can turn on Wi-Fi and manually update the database in the settings. Then you can turn Wi-Fi off.
- 3. Every night, AIDA checks for new FDA recalls and FDA drug extensions. If you are not connected to Wi-Fi, the internal database for AIDA will become out of date. It will not recognize new drug recalls or drug expiration date extensions. Keep Wi-Fi on for 24 hours for this to update.
- 4. The openFDA Drug Database Screen will not function. Information on a specific drug is fetched over the internet at the time you scan the drug container.
- 5. AIDA Cloud services will not work.
  - # You will not be able to access a historical record of drugs used, including lot numbers.
  - # Automatic notification of new drug recalls of drugs you have used previously will not function.
  - # Sharing of lot number and expiration dates between AIDA units will not function.

#### 5. Who is Cornerstone Innovation?

Cornerstone Innovation is the company that designs, manufactures, sells and services AIDA. Cornerstone Innovation is headquartered in Santa Fe, New Mexico.

## 6. Can I connect AIDA to an iPhone hotspot?

Yes, but ensure the following:

- 1. Make sure the Maximize Compatibility is selected in the settings of your personal hotspot.
- 2. Your iPhones hotspot name might contain some special characters. These special characters in the name of your iPhone hotspot can cause connectivity



issues, and as a result, you will not be able to use your iPhone hotspot with AIDA. (Also can cause connectivity issues to Window computers)

So you will need to remove the special characters in the name of your hotspot. Here is what you can do:

- 1. On your iPhone, navigate to the settings app.
- 2. Fine and select the general option.
- 3. Find and select the about option and then click on the Name option.
- 4. Now enter a new name for your iPhone. Please don't use any special characters in the name of your hotspot. For example, use John iPhone instead of JOHN'S IPHONE.

When you have changed the name of your iphone hotspot, simply restart your iPhone and then turn on its hotspot.

