

How long has the ValiMed Technology been in use?

The first ValiMed System user, Dallas Children's Hospital, went live in October 2004.

What technology does the ValiMed System use?

The ValiMed System uses *UV fluorescence* to validate medications.

Do all medications fluoresce when exposed to UV light?

No. For new medications that are not in the ValiMed Library, drug samples need to be sent to the ValiMed laboratory to determine if they fluoresce. Our experience indicates that most medications do fluoresce. This lab testing determines the appropriate conditions under which to create an authentic signature.

How long has UV fluorescence been used?

More than 30 years.

How is the ValiMed Technology used in the pharmacy?

The validation is used as part of the QC process on drug preparations. The testing is always destructive, and no part of the ValiMed System comes in direct contact with the dose to be administered. The ValiMed Testing is one part of a comprehensive quality control process in the healthcare facility, and as such it should complement other methods of verification. ValiMed is also used to validate narcotic returns to reduce drug diversion.

How can the ValiMed Technology be used in homecare?

Validating batches and individual doses for med error prevention.

What does the ValiMed Technology validate?

The testing confirms a known drug sample and its concentration. The validation is a pass/fail process to confirm compounding accuracy.

What are the key applications for the ValiMed System?

The ValiMed System provides medication safety for:

- *End product testing* of high-impact medications (chemotherapy, insulin, antibiotics) and batch preparations
- *Validation of narcotic returns*
- *Detection of counterfeit drugs*

For example, the University of Michigan uses the ValiMed System to validate batches and individual doses before they are dispensed to patients. Dallas Children's uses the ValiMed System in their OR Satellite pharmacy to validate narcotic returns.

How long does it take the ValiMed to verify a medication?

Thirty to 60 seconds, depending on the medication.

What is that sound that the ValiMed makes when it's running?

The sound is the flash lamp shining UV light on the sample.

Why does the verification time differ by medication?

The strength of the fluorescent signal determines the required test time (drugs with weaker signals require a longer test time, stronger signal requires a shorter test time).

Can the device validate a drug directly in its container?

No, the ValiMed System requires that a sample of the test drug be removed from its container and placed in a disposable cuvette for validation. The test is destructive.

How much solution is required for a test?

The ValiMed Cuvettes require a 0.25 mL sample to perform the validation.

How big is the ValiMed System?

The unit is 21 inches wide by 9 inches high and 10 inches deep. The device is deployed with a keyboard and mouse but these are not required for day-to-day operation.

Do I need to operate the system in a hood?

No. The drug sample will not be used for patient delivery so it does not need to remain sterile.

Does the device store test results?

Yes, a record is stored for each test that is performed. This data can be retrieved through different forms of reporting.

What is the ValiMed System signature 'library?'

This is the list of drug 'signatures' that have been created for users. As of March 2006, there are 90 signatures on file.

What is a signature?

A signature is the comparative file that the ValiMed System uses to validate the medication sample. The signature represents a specific medication, concentration and diluent combination. For example, Vancomycin 10 mg/mL in D5W and 10 mg/mL in normal saline would be two separate signatures. Vancomycin 5 mg/mL D5W and Vancomycin 10 mg D5W would be two signatures.

How is a new signature created?

A facility sends its medication samples to the ValiMed Lab. The lab team tests the sample with different UV light wavelengths to determine its unique signature.

How long does it take to create a new signature?

About a week. Customers are asked to provide the drug sample necessary for creation of the signature.

Do you have a signature for TPN's?

No. Because the ValiMed Systems fluoresces the entire compounded sample, there are too many variables with an unlimited number of drug type, strength and diluent combinations to create TPN signatures.

How many signatures can be on the device?

There is no limit to the number of signatures that can be loaded. Currently, users have an average of 20 signatures loaded. University of Michigan is using 32 signatures and estimates they could use up to 70. Some users have found that work flow is optimized by dedicating individual ValiMed Units to specific functions (i.e., narcotic validation or high-impact drug testing) rather than loading all necessary signatures onto a single device.

How many signatures are in the contract?

The standard contract includes up to 30 signatures. Users may purchase additional signatures from Baxa if the need arises after implementation.

Can you have more than one ingredient in a signature?

Yes, as long as the ingredients have consistent doses. In the lab we have validated up to four medications in a sample.

Can the ValiMed System recognize electrolytes (potassium chloride, sodium chloride, potassium acetate, potassium phosphate)?

Elements do not fluoresce well in the ultraviolet range. We are working on a solution to validate potassium.

What medications cannot be validated?

The ValiMed System does not currently validate TPN's; very dilute Sufentanil, Remifentanyl and Alfentanyl; Fentanyl less than 50 mcg/mL; potassium and phenylephrine. Additional work also needs to be done to validate some chemotherapy drugs. We are working on technology that will allow us to expand the medications that can be validated by the system.

Can ValiMed validate suspensions and oral liquids?

In the Tucson lab, the ValiMed System has been able to validate both suspensions and oral liquids. As with any new drug, testing is necessary to confirm it can validate the medication.

Is there a list of medications that is currently in review?

The lab is continually reviewing medications and creating new signatures. The list of medications is determined by customers and qualified prospects.

What are the accuracy tolerances associated with each medication formulation?

We are currently working on a study to determine the specific variations for each tested medication.

How long is the implementation?

We are currently averaging 90 days from contract signing to go-live for determining signatures and any necessary validation.

What is comprised in the installation?

Our implementation specialist works with your facility team to review the work flow and medications to be verified. Medications samples are sent to the ValiMed Lab for creation of any new signatures. The requested signatures are then loaded onto the system and we set up the installation date and expectations.

How is system support handled?

Technical Support is available by phone during normal business hours. The ValiMed Units have limited warranty coverage for the duration of the lease period.

Are there competitive products to ValiMed?

Not directly. Hospitals have the option of sending samples to a testing lab (for example HPLC testing averages \$300 per test and three weeks for a response) or using a refractometer for validation.

What is a refractometer?

Refractometers measure how much a specific substance bends light. Refractometers identify a sample's refractive index; they do not identify the substance itself. Therefore, it is limited by the fact that multiple substances may have the same refractive index (for example, fentanyl and sterile water).

How does the ValiMed System compare to a refractometer?

ValiMed uses a different technology (UV fluorescence) to confirm both a specific medication and its concentration, therefore providing a qualitative validation versus a referential identification.

Does ValiMed facilitate compliance to USP<797> Testing?

Yes, for accuracy testing and no, for sterility testing.

Can the ValiMed test for sterility?

No.

Will the ValiMed Technology hold up in court?

The ValiMed Technology has not been challenged in court. The ValiMed System should be used as a screening tool. When a sample comes back 'Not Validated,' it should be sent to a lab for third-party validation if it will be necessary to have legal backup.

Can an employee legally be fired if a narcotic return is not validated?

ValiMed is used as a screening tool or to gather statistics. If a problem is suspected and validated, more documentation should be gathered to support the findings.

Can I use the ValiMed System for testing the stability of drugs according to USP standards?

No, not at this time.

Who are current users of the ValiMed System?

Dallas Children's; UC-Davis Medical Center (Sacramento, CA); University of Utah; University of Michigan; Loyola University Medical Center (Chicago); Maricopa Medical Center (Phoenix, AZ), University of Maryland; Mount Carmel Health System (Columbus, OH); All Children's Hospital (St. Petersburg, FL) and Henry Ford Hospital (Detroit, MI).