A box 14 having a body 13 is used with a transparent flexible bag containing a liquid such as an IV bag. First and second faces 12 are positioned relative to each other. The faces each have therewithin an end or fiber optic port 11 of a respective light path. A light source is optically coupled with the light path of the first face and a spectrometer is optically coupled with the light path of the second face. The light paths are coaxial and are disposed so that the transparent flexible bag is positionable therebetween. The spectrometer is disposed to detect an anomaly in the liquid within the transparent flexible bag, and to annunciate the anomaly to a human user. The box defines a reproducible light path length through the liquid. A caliper 29 having a body 22 may be used in spectrometric analysis of a transparent tube containing a liquid such as a syringe or an IV line. The caliper has finger pads 27 which permit opening the spring-loaded caliper as needed. Rivets 25 provide a pivoting action relative to a pivot structure 21 which can also serve as a distance gauge. Compression spring 24 urges the caliper jaws together at lens locations 26. Lens locations 26 are optically coupled with internal fiber optic lines 28, and thence to external fiber optic connectors 23. A light source is optically coupled with one of the connectors 23 and a spectrometer is optically coupled with the other of the connectors 23.

4 Claims, 4 Drawing Sheets
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FIG. 3
SPECTROMETRIC ANALYSIS OF FLUIDS IN-SITU

CROSS-REFERENCE TO RELATED APPLICATIONS


BACKGROUND

Counterfeiting and errors threaten patient safety. There are 1.25 million adverse reactions and 7,000 patient deaths annually in the United States as a result of drug errors. Existing verification relies largely on tagging and checking drug packaging. Of course, in a hospital setting, packaging and product are often separate.

Formulated medications created in the pharmacy, including but not limited to intravenous medication delivered in IV bags, pose a special challenge. Once the medicine or bag is made up, how do you tell whether it contains the proper medication, at the right concentration, and that the drug is both current and genuine? Opening the drug to sample it risks contaminating it.

For operating rooms, the identity of leftover waste drug is of concern. A hospital employee may try to steal leftover drugs and sell them, and substitute a substance such as saline or dextrose in the original container.

Immune globulin is often counterfeit.

Chemotherapy is expensive, as are antibiotics. Mistakes are even more expensive: an average lawsuit may cost nearly half a million dollars.

Patients may receive the wrong drug or the wrong dose, or an infused drug may spill or not be delivered correctly because of a blockage.

There is thus a great need for approaches to verify products in a hospital or long-term care environment. Such approaches need to be reliable, simple to use, and accurate. None of the prior-art approaches known to the applicants is completely satisfactory.

SUMMARY OF THE INVENTION

The present invention describes a verification system that works in the hospital or long-term care environment. The current invention verifies the product itself, checking for the correct medication, dosage, quality and purity, including a check for whether the drug is counterfeit.

The current invention, in its preferred embodiment, uses near-infrared spectroscopy (NIR) to look into the bag, including through the plastic, and tell in an instant whether it is right. The NIR shines a light on the substrate and compares its optical components to a chemical library, a gold standard.

The present invention makes it possible to verify that the waste in a container is in fact the drug, not a substitute, without having to send it to a lab for analysis. The current invention includes hardware and software for a portable detection system that can tell in seconds whether the substance matches what it is expected to be. An advantage of the current invention in its portable embodiment is that it can be used by a nurse or technician on site, and does not need to be in a lab.

The present technique also checks for quality and purity, even allowing in-syringe verification.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described with respect to a drawing in several figures, of which:

FIG. 1 is a perspective view of a box according to the invention.
FIG. 2 is a top view of the box of FIG. 1.
FIG. 3 is a side view of the box of FIG. 1.
FIG. 4 shows a caliper according to the invention.
FIG. 5 shows a face view of a lens location.
FIG. 6 shows a cross-sectional view of the lens location of FIG. 5.
FIG. 7 shows a clip according to the invention.
FIG. 8 shows a detail of a position or angle sensor according to the invention.

Where possible, like elements have been depicted with like reference designations among the figures.

DETAILED DESCRIPTION

A system and process is described in which a spectroscopic or similar instrumented technique, such as NIR, Raman IR, UV-VIS, x-ray, etc., suitably supported with identification, quantitation, diagnostic or control software, is used in operations where a substance or substances are being transported from one location to another, to identify the transported material, the rate at which the transfer is taking place, the amount of transfer accomplished during any given time interval, the recognition in some form of the transfer of a predetermined amount or amounts, the recognition in some form of a significant defined deviation from the expected integrated rate or rates of delivery, and similar such functions or operations as may be needed to more fully identify, quant-
The system may be employed in a hospital, long term care facility, or other health care environment to verify medication, checking for errors in dosage, concentration, medication, purity, and/or quality. It may be applied to formulated or compounded drugs. It may be applied to intravenous medication. It may be applied to medication in syringes. It may be applied to operating room waste or leftover medication.

Steps may include identification and/or confirmation of various infusate species, measurement of their concentrations and rates of flow, detection of leakages or blockages or changes in flow, and which may be coupled with a method for finding veins, where spectroscopic techniques, which can be of several kinds, including but not limited to ultraviolet, visible, near infrared, infrared, far infrared, Raman and other electromagnetic spectrum wavelengths in absorbance or reflectance mode, and can use double-beam methodologies, provide signals which can be processed to provide a variety of data outputs, including but not limited to instantaneous and integrated graphical displays, digital records of various kinds, visual and audible signals, etc.

A gold standard may be created, followed by checking other preparations against that gold standard.

One sequence of steps can be to test all the medications in a group and to identify outliers as potentially problematic.

It is also possible to use one or more optical fibers within the shaft of a needle used for infusion purposes, so that monitoring of one or more species occurs as the infusate leaves the tip of the needle inserted into a subject’s vein or body. It is possible to monitor the changing signal intensity in a spectroscopic measurement to detect the changing proximity of hemoglobin in blood as a means of locating a vein or artery to be used for a particular purpose, including but not limited to infusion.

It is also possible to employ wireless signal transmission from one or more measurement units to a central console where continual signal sampling and processing will generate a variety of desired outputs.

Particular detailed embodiments of the invention will now be described.

A box 14 (FIGS. 1, 2, 3) having a body 13 is used with a transparent flexible bag containing a liquid such as an IV bag omitted for clarity in FIG. 1. First and second faces 12 are positioned relative to each other. The faces each have there-in an end or fiber optic port 11 of a respective light path. A light source (omitted for clarity in FIG. 1) is optically coupled with the light path of the first face and a spectrometer (omitted for clarity in FIG. 1) is optically coupled with the light path of the second face. Typically the light paths are coaxial and are disposed so that the transparent flexible bag is positionable therebetween. Typically the spectrometer is disposed to detect an anomaly in the liquid within the transparent flexible bag, and to announce the anomaly to a human user. Typically the box defines a reproducible light path length through the liquid.

The box 14 may have a removable front face to allow for easier insertion and removal of the bag, as compared with stuffing the bag in from the top.

A caliper 29 (FIG. 4) having a body 22 may be used in spectrometric analysis of a transparent tube containing a liquid such as a syringe or an IV line. The caliper has finger pads 27 which permit opening the spring-loaded caliper as needed.
Rivets 25 provide a pivoting action relative to a pivot structure 21 which can also serve as a distance gauge. Compression spring 24 urges the caliper jaws together at lens locations 26. Lens locations 26 are optically coupled with internal fiber optic lines 28, and thence to external fiber optic connectors 23. A light source is optically coupled with one of the connectors 23 and a spectrometer 43 is optically coupled with the other of the connectors 23.

FIG. 5 is a face-on view of the lens location 26 disposed within body 22. FIG. 6 is a cross-sectional view of the lens location 26 disposed within body 22, showing the internal fiber optic line 28. As may be seen the surface at 26 which engages the syringe or IV line has some concavity and thus can capture the syringe or IV line and keep it in place.

The distance gauge 21 comprises a sensor sensing the relative positions of the first and second jaws, and the sensor communicates to the spectrometer information indicative of a diameter of the transparent tube. The spectrometric analysis is carried out making use of the information indicative of the diameter of the transparent tube.

Another embodiment is shown in FIGS. 7 and 8 with clip 33. Jaws 36 are V-shaped and are dimensioned so as to provide reproducible positioning relative to cylinders or transparent tubes of some range of diameters. Light paths 37, 38 are positioned so that each light path impinges upon the transparent tube normal thereto, and so that the light paths are diametrically opposed across the transparent tube. Spring 34 urges the jaws 26 together relative to a hinge or pivot 35. Handles 31, 32 may be squeezed by a human operator to open the jaws 36. A sensor 39 is shown in more detail in FIG. 8. A movable piece 40 (attached to one of the jaws 26) moves relative to LED-phototransistor sensors 41, 42, offering perhaps three different discrete sensed signals depending on whether the jaws 36 are separated by a first distance, a second distance, or a third distance. In this way, if the cylinders are of any of three different standardized diameters, they may be disambiguated.

It will be appreciated that it is not crucial to use the particular sensing mechanism portrayed here.

The methods to be carried out may include the following.

The clip is clipped onto a transparent intravenous drip line with the transparent intravenous drip line sealed within the groove of the first jaw and the groove of the second jaw. A liquid is passed through the transparent intravenous drip line and into a vein of a human being. After the clipping, light is passed through the light path of the groove of the first jaw, and through the transparent intravenous drip line and through the liquid, and through the light path of the groove of the second jaw, and to a spectrometer. A spectrometric analysis is carried out upon the light passing to the spectrometer. Later the clip is removed from the transparent intravenous drip line.

Alternatively the clip may be clipped onto a transparent syringe containing a liquid.

An IV bag may be placed into the box 14 and in contact with the opposed first and second faces 12. Light is passed through the light path of the first face, and through the transparent flexible bag and through the liquid, and through the light path of the second face, and to a spectrometer. A spectrometric analysis is carried out upon the light passing to the spectrometer. Later the the bag may be removed from the box. Still later the bag may be put to use in an intravenous drip, and some of the liquid may be passed into a vein of a human patient.

Those skilled in the art will have no difficulty devising myriad obvious improvements and variants without deviating in any way from the invention, all of which are intended to be encompassed within the claims which follow.

The invention claimed is:

1. A method for use with a transparent intravenous drip line, and for use with a clip having opposed first and second jaws urged toward each other, each jaw having a respective groove, the grooves opposing each other, each groove having therewithin an end of a respective light path, the method comprising the steps of:

- clipping the clip onto the transparent intravenous drip line with the transparent intravenous drip line sealed within the groove of the first jaw and the groove of the second jaw;
- wherein the transparent intravenous drip line is cylindrical in cross section and the light paths are disposed relative to the grooves so that each light path impinges upon the drip line normal thereto, and so that the light paths are diametrically opposed across the transparent intravenous drip line;
- passing a liquid through the transparent intravenous drip line and into a vein of a human being;

- after the clipping, passing light through the light path of the groove of the first jaw, and through the transparent intravenous drip line and through the liquid, and through the light path of the groove of the second jaw, and to a spectrometer, and carrying out a spectrometric analysis upon the light passing to the spectrometer;

- wherein the clip further comprises a sensor sensing the relative positions of the first and second jaws, wherein the sensor communicates to the spectrometer information indicative of a diameter of the transparent intravenous drip line, and wherein the spectrometric analysis is carried out making use of the information indicative of the diameter of the transparent intravenous drip line; and
- removing the clip from the transparent intravenous drip line.

2. A method for use with a transparent syringe containing a liquid, and for use with a clip having opposed first and second jaws urged toward each other, each jaw having a respective groove, the grooves opposing each other, each groove having therewithin an end of a respective light path, the method comprising the steps of:

- clipping the clip onto the transparent syringe with the transparent syringe sealed within the groove of the first jaw and the groove of the second jaw;

- after the clipping, passing light through the light path of the groove of the first jaw, and through the transparent syringe and through the liquid, and through the light path of the groove of the second jaw, and to a spectrometer, and carrying out a spectrometric analysis upon the light passing to the spectrometer;

- wherein the transparent syringe is cylindrical in cross section and the light paths are disposed relative to the grooves so that each light path impinges upon the syringe normal thereto, and so that the light paths are diametrically opposed across the transparent syringe; and

- removing the clip from the transparent syringe.

3. Apparatus for use in spectrometric analysis of a transparent tube containing a liquid, the apparatus comprising:

- a clip having opposed first and second jaws urged toward each other, each jaw having a respective groove,
grooves opposing each other, each groove having there-
within an end of a respective light path;
a light source optically coupled with the light path of the
groove of the first jaw;
wherein the clip further comprises a sensor sensing the
relative positions of the first and second jaws, wherein
the sensor communicates to the spectrometer informa-
tion indicative of a diameter of the transparent tube, and
wherein the spectrometric analysis is carried out making
use of the information indicative of the diameter of the
transparent tube; and
a spectrometer optically coupled with the light path of
second jaw.

4. Apparatus for use in spectrometric analysis of a trans-
parent tube containing a liquid, the apparatus comprising:

a clip having opposed first and second jaws urged toward
each other, each jaw having a respective groove, the
grooves opposing each other, each groove having there-
within an end of a respective light path;
wherein the clip further comprises a sensor sensing the
relative positions of the first and second jaws, wherein
the sensor communicates external to the clip informa-
tion indicative of a diameter of the transparent tube;
a connection point for a light source, the connection point
optically coupled with the light path of the groove of the
first jaw;
a connection point for a spectrometer, the connection point
optically coupled with the light path of second jaw.

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