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Testing the Performance of Infusion Devices

White Paper

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Infusion devices (pumps and controllers) are one of the highest numbers of medical devices in hospitals and clinics worldwide. They are used to control the delivery of a wide range of medications, nutrition and blood products. In anesthesia, the infusion device controls the delivery of narcotics, short-acting barbiturates and paralytics whose properties and actions on the physiology include analgesia, amnesia, paralysis and sedation. In the ICU they are used for sedation and paralysis as well as infusing medications that help speed the healing of disease and chronic conditions.

Infusion devices have been the target of many clinical outcome investigations with human error, mechanical and electronic failure being the leading causes for failure. In fact, the FDA reported 56,000 adverse events, over 500 deaths and 87 recalls related to infusion devices recorded between 2005 and 2009 in the United States alone. Incorrect readings from a poorly-performing infusion pump can put patients at great health risk, including death. It is therefore very important to test the performance of infusion devices to ensure they are performing in accordance with manufacturers' specifications and clinicians' expectations.

The mechanical performance of infusion pumps hasn't changed much in recent years, but their safety features have. Pumps are now equipped with sophisticated software and are being integrated into information networks and other clinical systems. It is important to understand the variety of mechanisms used in infusion pumps to control the flow rate and volume delivered by these important medical devices. The most widely used mechanisms are roller (Fig. 1), linear peristaltics (Fig. 2) and syringe (Fig. 3). Each has different points of probable failure. The function of each has its own impact on the fluid flowing through the infusion tubing which, in turn, affects the measurement being made to assess performance to the manufacturer's specification.

Infusion pumps require preventive maintenance at least once a year. Hospitals generally test infusion pumps at incoming inspection, scheduled PM and post repair; OEMs test infusion pumps for quality control. Preventive maintenance practices include verifying the pump is administering flow, volume and boluses accurately and occluding appropriately. These pumps are either tested based on protocols suggested by manufacturers or medical facilities, or according to the IEC 60601-2-24 standard.

Roller

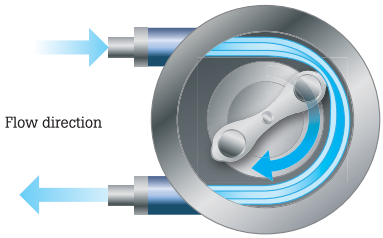

Figure 1

Fingers (Linear peristaltics)

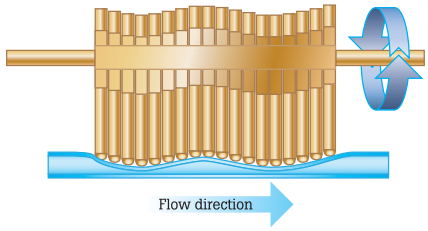

Figure 2

Syringe pump (driven by threaded row mechanism)

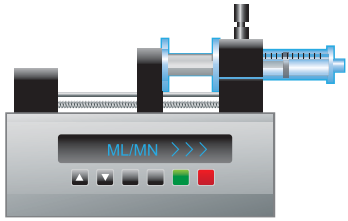

Figure 3

The IEC standard calls for volumetric infusion pump and volumetric infusion controller flow rates to be assessed over a 120 minute test period using an intermediate flow rate of 25 ml/min. The infusion is to be delivered into a beaker and scale testing system.

Sources of error in the testing system suggested by the IEC standard include:

- Failure to zero the scale/balance with an empty, dry beaker.
- Miscalculation of the volume by weight (which is why the standard suggests an electronic scale/balance whose output is fed into a computer running the appropriate calculation to obtain the volume by weight).
- Loss of volume by evaporation (due to the length of the testing period). It should be noted there is evidence in peer review articles that evaporation is negligible under normal ambient conditions.

There are, however, other test systems besides the beaker and scale that will produce the same accurate results. For example, one can use a graduated burette and stopwatch, or an infusion device analyzer (one that incorporates and automates both the graduated burette and the stopwatch functionality).

As the name implies, a graduated cylinder or burette is a cylindrical glass (or plastic) tube sealed at one end with a calibrated scale etched or marked on the outside wall. Graduated cylinders come in a range of sizes (volume capacities), and much like a measuring cup, volume is measured by adding liquid to the cylinder and comparing the liquid level to the graduated scale. The measured volume corresponds to the volume of liquid contained in the cylinder.

Test apparatus for volumetric infusion pumps

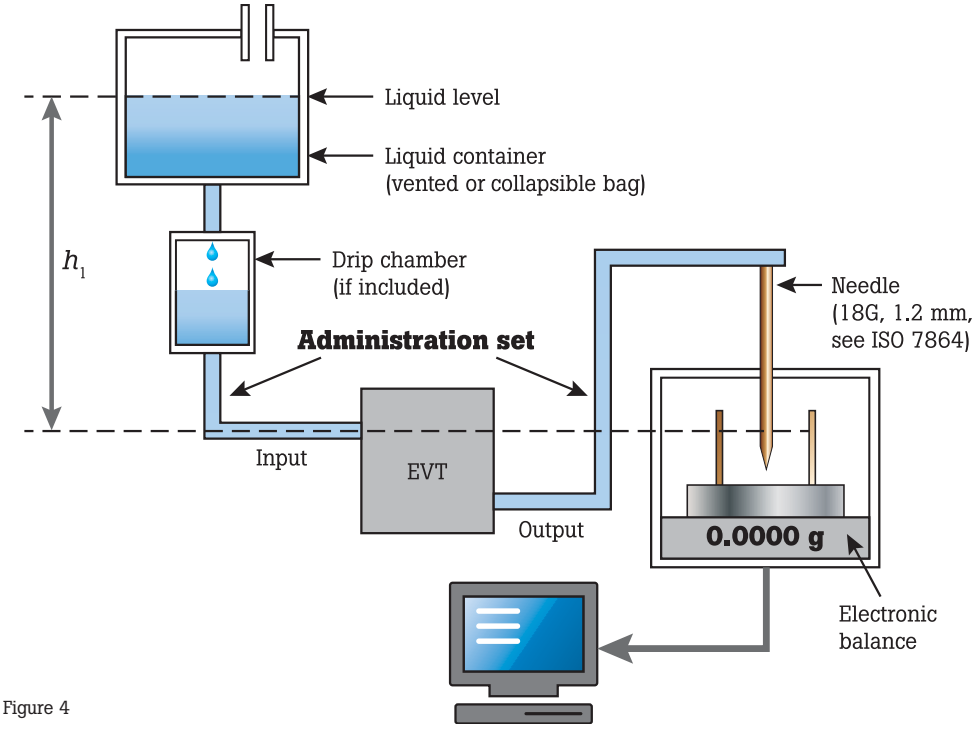

Figure 4

It is very important to ensure that one is looking directly level with the meniscus of the liquid in the burette to determine the volume at the etched scale marking (Fig. 5).

It is also critical that the stopwatch be started at the exact time the infusion pump begins its delivery of liquid.

Improper viewing of the meniscus or the need to interpolate between graduation markings, combined with any mismatch in timing between the infusion device and the stopwatch will result in errors in measurement.

The IDA-5 Infusion Device Analyzer from Fluke Biomedical simplifies the process stated above by integrating the burette "graduating" it with IR sensors to measure the level of liquid infused, and uses electronic stopwatch function technology, among many other features and functions in its design. It is based on sophisticated measurement technology trusted by biomedical professionals around the world for over 20 years. The IDA-5 is a full-featured device that measures instantaneous flow, average flow, occlusion pressure and dual flow based on IEC60601-2-24

Measurements are continuously updated and stored so that graphs can be produced and displayed live to enhance the assessment of the performance of the infusion device under test.

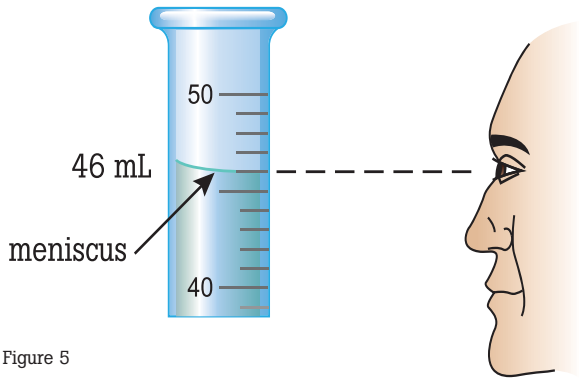

Figure 5

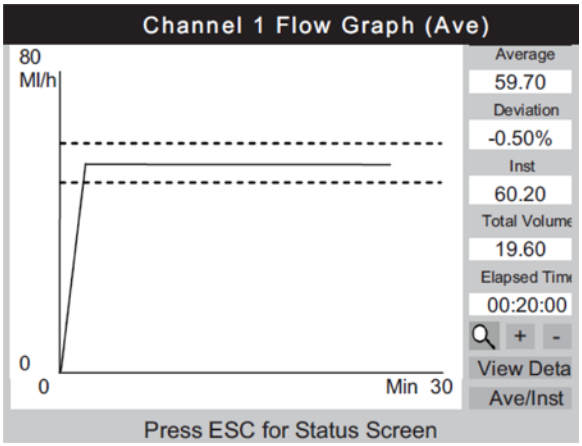

Figure 6

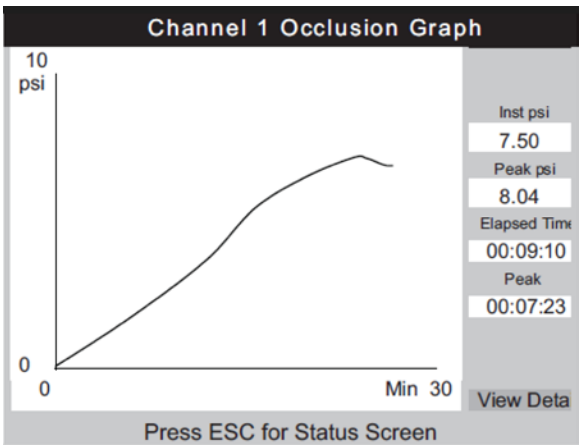

Figure 7

The built-in measurement technology in the IDA-5 eliminates the need for constant supervision and attention required with manual methods of infusion pump performance verification. Once the pump is connected to the IDA-5 and flow begins, the user can walk away. The test can be set to stop based on volume collected or elapsed time. Once the test is complete, an audible indicator will alert the user. At this point another test can be executed or the electronic data and graphs (as illustrated by Fig. 6 and Fig. 7) stored in the instrument can be downloaded.

If users want to program multiple tests in succession with minimal user intervention, the IDA-5 features built-in automation. This allows creating custom test sequences combining various tests. This is particularly useful when testing different models or brands of infusion pumps, a test template for each type can be created and stored on the IDA-5 for quick and standardized infusion pump analysis ensuring the pump is tested the same way each time. With its built-in memory, the IDA-5 records test results internally or exports to a computer. This is a significant advantage of using an infusion pump analyzer—the electronic data documentation reduces human error related to data capture and saves time related to archiving.

No matter which testing method you decide to use, please note that infusion device measurement accuracy is also affected by the compliance of the infusion device and delivery tubes. This is because there is a momentary blockage of flow when the measurement transducer is emptied. The back-pressure created by these events could cause some of the flow to be diverted into the compliance of the infusion device. For most infusion devices, the effect is trivial (less than 0.5 %), but with very soft connecting tubing and large air pockets in the device or tubing it could be significant. The tubing between the infusion device and the IDA-5 (or other testing system) should therefore be fairly rigid and all air should be removed before starting each flow test. At high flow rates it may be desirable to increase the compliance of the inlet tubing (longer or softer tube) if the back pressure interferes with the occlusion sensing alarms in the infusion device.

By making sure you understand the testing system and the medical device being tested, and by managing sources of error properly, any of the systems described in this article should deliver appropriately accurate and repeatable test results to show that the infusion device under test is safe and effective for clinical use. There are, however, definite advantages to using an infusion device analyzer due to benefits associated beyond the measurement itself. Using an electronic analyzer ensures your tests are performed and documented accurately. Both are critical to patient safety. With manual methods you risk making an error. You can never be sure how accurate your testing is. With an electronic analyzer, you are testing the same way consistently. Additionally an electronic analyzer allows you to mitigate risk by reducing the human error associated with testing, documenting and archiving your data in a standard electronic form for easy retrieval when needed.

References

1. Anesthesia and Analgesia, The Delivery Rate Accuracy of Portable Infusion Pumps Used for Continuous Regional Analgesia, November 2002; < http://www.anesthesia-analgesia.org/content/95/5/1331.full> (June 2010)
2. New York Times, F.D.A. Steps up Oversight of Infusion Pumps, April 2010; <http://www.nytimes.com/2010/04/24/business/24pump.html> (June 2010)
3. ECRI, General-Purpose Infusion Pumps, October 2007; < https://www.ecri.org/Documents/Infusion_Pumps_Evaluation.pdf> (June 2010)
4. U.S. Food and Drug Administration, Guidance for Industry and FDA Staff – Total Product Life Cycle: Infusion Pump – Premarket Notification [510(k)] Submissions, April 2010; <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm206153.htm> (June 2010)
5. Wikipedia, Volumetric Flow Rate, December 2007; <http://en.wikipedia.org/wiki/Volumetric_flow_rate>; (June 2010)
6. Eastern Illinois University, Liquid Volume Measuring Devices: The Graduated Cylinder and Burette; <http://www.eiu.edu/~eiuchem/GenChem/EquipmentGuide/volumetric.pdf> (June 2010)
7. Teacher Vision, Measuring: Liquid Volume, 2000; <http://www.teachervision.fen.com/tv/printables/botr/botr_155_28-28.pdf> (June 2010)
8. Fluke Biomedical, IDA-5 Operators Manual

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