Infusion pump testing to IEC 60601-2-24

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Executive Summary

Infusion pumps provide measured dosing of many drug therapies for patients, including life-saving or life-sustaining medications. These devices are used for critical care, emergency care, and long- and short-term disease maintenance.

IEC 60601-2-24:2012 testing

IEC 60601-2-24:2012 is the internationally recognized particular standard that provides essential performance and basic safety requirements for infusion pumps. The test equipment needed to conduct the IEC 60601-2-24:2012 tests is very costly and specialized, requiring specific setup to reduce vibration and other environmental conditions that interfere with test results. Manufacturers use these test reports as part of their applications for regulatory approvals around the world.

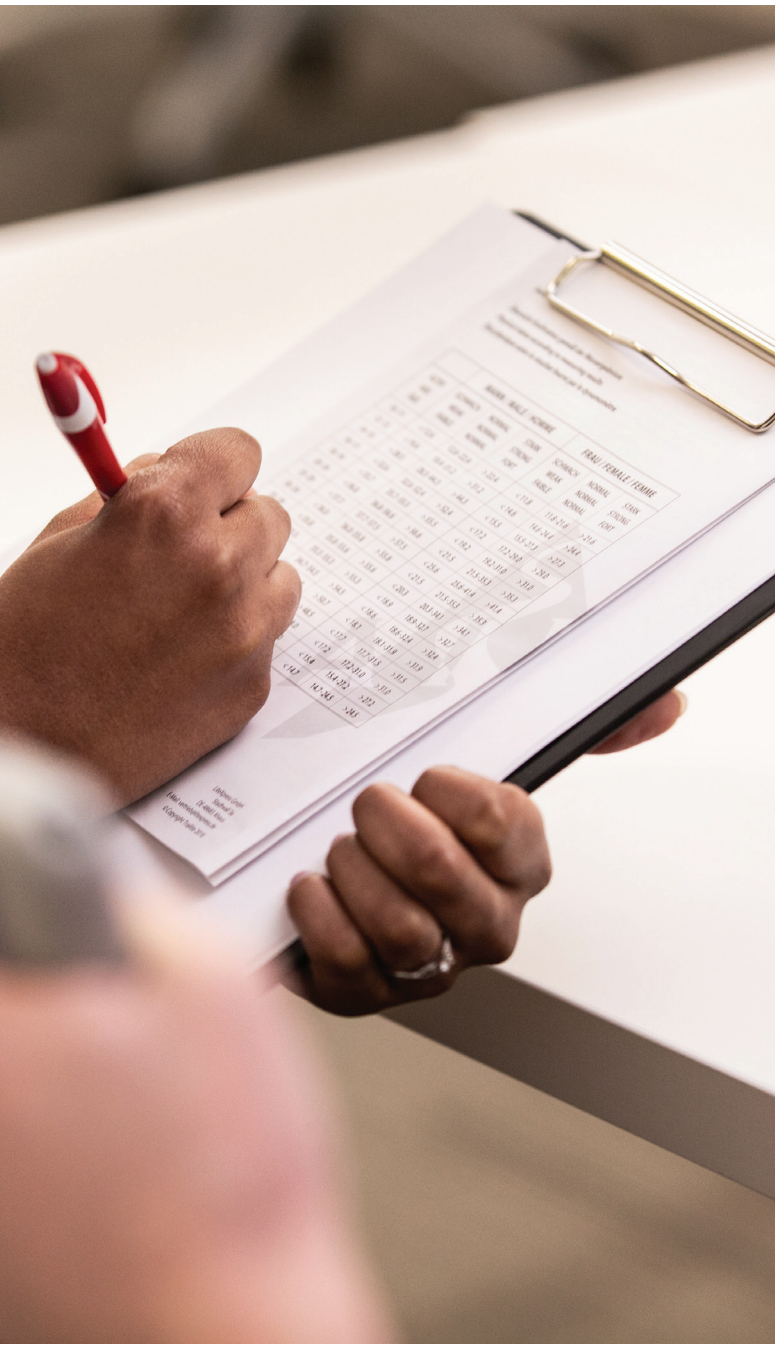
To test for device accuracy it is important to know common procedures, considerations and mistakes that can impact testing outcomes. A diverse and complete array of accuracy test setups is necessary to provide sufficient results for a defined accuracy.

Administration set/syringe selection

The number of representative samples and tests are based on several factors related to administration sets and/or syringes frequently encountered in a clinical or home health care setting. These factors include items such as, but not limited to:

- Tubing material
- Filters
- Drip chambers
- Syringe plunger materials
- Size of syringe

Pump/equipment parameters such as minimum rate values, stroke and volume output, in addition to how the pump/equipment administers liquid to the patient, also affect set/syringe selection. When items such as clamps, extra IV tubing, or additional IV fixtures are introduced, percentage and volume errors can increase significantly. Tight regulation of variables and minimal setup allows for accurate and stable reporting. But these factors should be considered for accuracy claims in the instructions for use.



Critical consumables

The fluids used in testing the accuracy should be considered during each test. If the infusion pump is for generic use (no specified liquid), the IEC 60601-2-24 standard requires use of a test solution of ISO 3696:1987 Class III water. However, some applications include very specific liquids that, not which may have different viscosity or other characteristics that are significant to the test or environmental conditions in which the test is being run.

The specific characteristics of the liquids should be considered and test solutions to simulate these characteristics should be used in place of the ISO 3696:1987 Class III water during accuracy testing to perform representative testing. Some example characteristics for the liquid include, but not limited to, the following:

- Density
- Conductivity
- Oxygen content (mg/l), maximum
- pH
- Viscosity change with temperature
- Freezing point of the liquid (note that IEC 60601-1-11 requires lower environmental ambient conditions)

Additional ingredients (oils for evaporation rate reduction) used as part of the test setup should also be taken into account and controlled as critical consumables to allow repeatability in testing.

Test setup

The diagram below represents the general testing setup in IEC 60601-2-24.

The general standard application shown in the diagram is the level placement of an 18 gauge needle. The size of needle or delivery system in the test setup should be carefully considered with clinical end application in mind, as some infusion pumps are intended for specific delivery application, and accuracy could be based on the back pressure of this delivery system/needle. To ensure repeatability, the rationale used to deviate from the 18 gauge needle should be noted in the test report. In the diagram below, the needle is positioned so that it is under the water (and under any oil, if used) so as not to affect accuracy of the measurement.

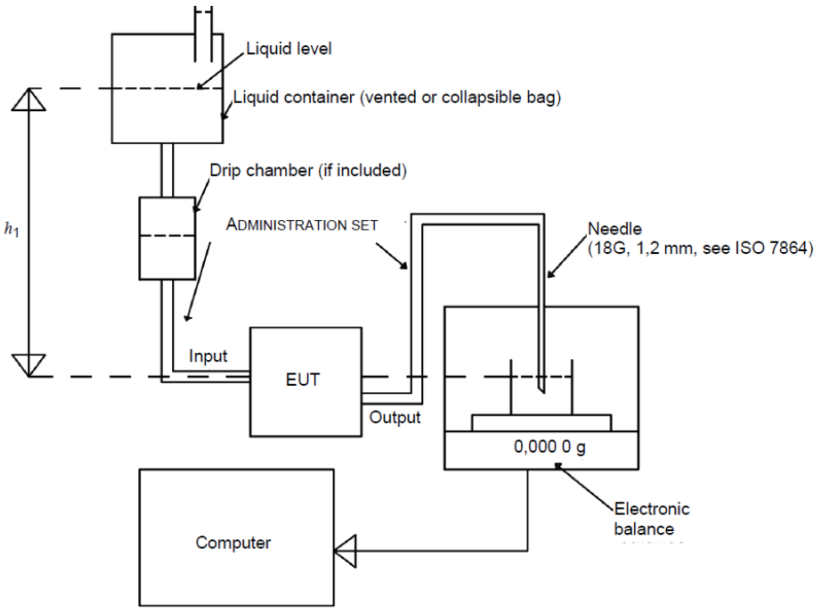


Figure 01: Test apparatus for volumetric infusion pumps and volumetric infusion controllers

The tubing is properly primed and checked for kinks, which is important to prevent reduced flow rate. Additionally inspection should verify that any mechanism intended to stop the flow in the administration set tubing is open.

Tubing and connections should be checked for air bubbles, and any air in the line should be reduced as much as possible. An identical setup to the collection vessel used (oil and test solution) should be placed on a separate scale to calculate evaporation rate. The evaporation rate should be calculated and then factored into the result calculations for a more accurate delivery rate and trumpet curves.

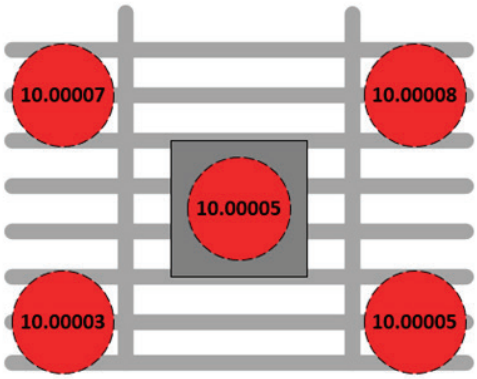
Scale setup

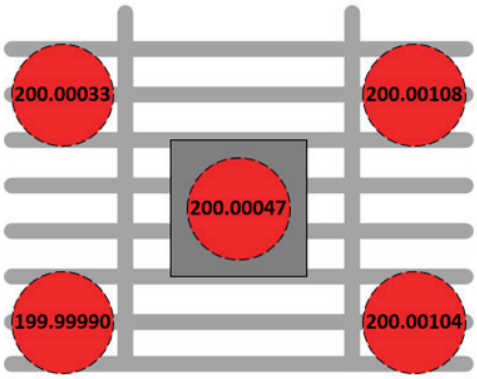
The placement of the collection vessel on the scale can significantly affect measurements as shown in the figure below. For the most accurate results, the vessel should be placed on a balanced scale as close to the center of the weighing surface as possible. As indicated in Mettler Toledo's documentation:

"With an analytical balance, a corner load deviation of typically 0.1 ... 0.2 mg may be expected, at half capacity and with the load placed entirely at the edge of the pan." (Weighing uncertainty, a white paper by Mettler Toledo)

In addition to placement of the collection vessel, the scale needs to be as flat as possible since an inclination of the scale can significantly affect measurements. If not perfectly perpendicular, then the balance does not measure the total weight force, but measures the normal force exerted on the weighing platform.

Normal force = Gravity * Cosine of the angle of the mass on the scale





Air in line

Air in the test setup is one of the most common reasons for inconclusive accuracy tests. It is recommended to very carefully check for air bubbles, and even microbubbles, in the tubing and other connections of the setup. Microbubbles can build over time and once large enough they can become trapped in connection points in the test setup or be injected into the collection vessel. The air bubble is different in density, and therefore will affect the delivery rate calculation. Additionally, the air bubble tends to float to the surface during the test. The good news is that often this situation can be easily discovered in the test data.

Tubing and connections should be checked for air bubbles, but it should also be noted that during the initial setup, time should be allowed to let the container/oil settle.
A deliberate effort should be made to remove air bubbles from the test setup as these are another factor that can affect the accuracy measurements during testing.

Sample interval/test time and scale selection

Sample rate, volume of reservoir, and administration set interval are used to calculate the duration of the test itself. The sample rate could be the shot cycle, which is the period from the start of one injection to the start of the next injection (Type 2), or 15 minutes (Type 1), or based on the drip rate. The correct determination of sample rate is imperative for test validity and to minimize retesting, because the rate is used directly in the calculation of the flow rate.

Scale selection/resolution depends on many factors, and some the major limiting factors in scale selection include the following:

- Total mass
- Flow rate
- Density of fluid
- Administration set interval or size of source container
- Size and mass of collecting vessel
- Accuracy required
- Draft shields provided

The scale should be selected so that it can hold the complete mass during the test. This can be calculated by using the flow rate of the pump and the size of the container or administration set interval, which are then used to calculate the total volume for the duration of the test. Then the mass of the collection vessel is added. This will give the total test weight which should not exceed the measurement capability of the scale. Additionally, as part of the scale selection, the uncertainty of measurement should be calculated to determine if sufficient accuracy is provided.

A scale should be used that is calibrated by a calibration provider accredited to ISO 17025, with the range of measurements in their scope of accreditation. As part of the calibration, the scale needs to be calibrated for the range of measurements used during the intended testing.
A helpful note when calibrating scales is that the scale should be properly acclimated to the environment being used and before testing or calibration of the scale is started. Consider that some scales have recommended warmup times before accurate measurements can be made.

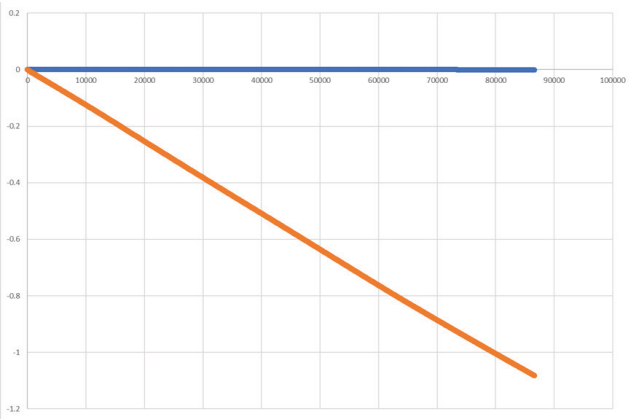
Environmental influences and other variables

Environmental conditions, as outlined below, can affect testing and should be considered. This is especially important when testing for IEC 60601-1-11 or IEC 60601-1-12 in which the testing needs to be performed over a range of conditions (temperature, humidity and barometric).

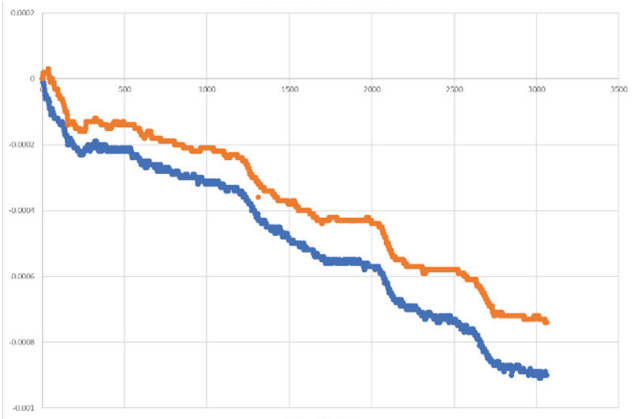
Temperature - The white paper, Weighing uncertainty, by Mettler Toledo serves as a baseline for this subject. One strong point made in this paper is device acclimation related to environmental factors. The accuracy values can vary greatly when temperature environments change, and it must be considered during testing. Temperature can affect the following contributors: weight (fluid density), viscous friction (flow), force (buoyance), motion and syringe and tubing rigidity. These examples can all be affected by even a few tenths of a degree temperature change and affect many aspects of the test setup.

Humidity/oil/size of collecting vessel - Humidity can affect weight by condensation or evaporation in the collection vessel. If humidity is high, it will reduce the evaporation rate but it may lead to condensation which could drop onto the weighing surface or collection vessel. Having a low humidity will increase the evaporation rate that must be accounted for in the accuracy calculation. The evaporation rate can be reduced by adding a layer of oil. By taring the scale to zero before the test, the oil will have a negligible effect on measurement. The thickness of the oil will have some effects on the evaporation rate as shown below.

Evaporation rate of oil versus no oil



Evaporation rate of water through oil



Additionally, to reduce the surface area that allows evaporation to occur through the oil, the smallest possible vessel should be used. You can see from the graphs below that the larger the surface area, the more evaporation occurred, even with the same thickness of oil layer on top of the water.

Light source — Light sources can add heat to the test setup, heat up administration set/syringes/IV tubing and can alter densities of the liquid being used for the test. Any of these factors could affect the accuracy testing or the performance of the pump under test.

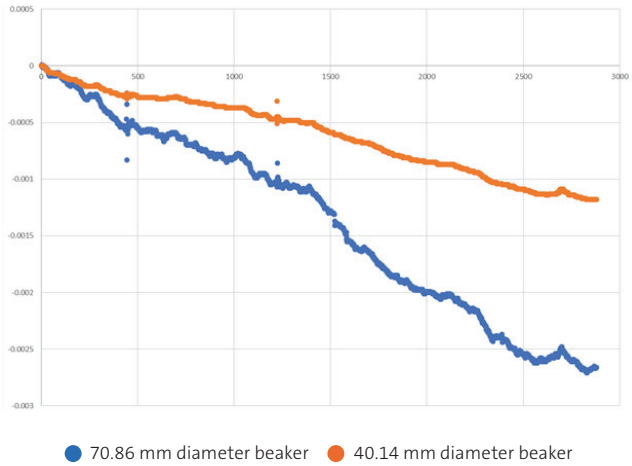
Atmospheric pressure/buoyance — Changes in pressure from weather or large changes in atmospheric pressure can affect readings and decrease overall accuracy. The larger the flow rate for the infusion pumps, the less the pressure affects the test. The smaller the flow rate is for the infusion pump, the more the atmospheric pressure will affect accuracy. It is suggested to tare the scale before each test and record pressure changes that can then be accounted for as part of the measurement. If pressure change cannot accurately be measured, it is suggested to find a way to eliminate or minimize pressure changes from the test setup (such as testing inside a controlled pressure chamber).

Air drafts — Air drafts can affect pressure/buoyance of containers, can change evaporation rates, and may not allow for a scale to stabilize for a proper measurement. Draft shields are recommended to reduce this. Additionally, position the scale away from vents used for air circulation, heating, or cooling of the room. Vent shields to deflect the airflow away from the scale is another option in addition to the draft shields.

Vibration/bumps — Vibrations caused by peripheral equipment, table shifts, or intermittent occurrences can destabilize the test and cause inaccurate readings and flow-rate fluctuations. This can affect trumpet curve results, testing times, and calculations. To reduce the effects of vibration during the test, anti-vibration slabs and table should be used as part of the test setup. Caution should be taken when going near the test setup during testing as well.

Electro-magnetic interference — If the scales are placed near equipment or sources that can create high magnetic fields, such as transformers or electrical boxes, instability or "noise" can be introduced into the scale readings and decrease accuracy of the test.

Evaporation rate with collection vessel size



"Pressure changes in the environment of the balance leads to pressure differences between outside and inside of the balance. Since the feed-through channel of the weighing platform cannot be hermetically sealed by a membrane - suffice it to mention the barometric distortion, as well as the guiding forces introduced by such a membrane - the balance's exterior and interior remain connected to each other. These pressure differences generate compensation currents, which will exert flow forces onto the weighing pan or the weighing cell, disturbing the weighing value. As every weighing object takes up a certain volume, it is a subject to a buoyancy force which is opposed to the weight force and diminishes the latter."
(Weighing uncertainty, a white paper by Mettler Toledo)

Summary + Conclusion

Through controlled environments and knowledge of the most common sources of error, proper test methods and repeatability of tests can be established. It is important to implement UL services and procedures to provide greater test accuracy. Consumables, test setup, time intervals, scale selection, and external factors all have a significant impact on testing outcomes for infusion pumps and their components. Measurement accuracy is crucial to the success of each device and, ultimately, patient safety and well-being.

For more information on infusion pump testing methods and medical device testing, email medical.inquiry@UL.com or visit UL.com/healthcare.