



IntelliFill® i.v.  
Using Weight Verification, Density  
and Specific Gravity to Ensure  
Syringe Filling Accuracy

## INTRODUCTION

The IntelliFill i.v. uses weight verification to ensure that its syringes are filled accurately. The system's software calculates the theoretical weight of a syringe using the solution density (weight/unit volume) to compute the *fluid weight* of the dose, and the *dry syringe weight* to determine the contribution of the syringe, label and cap to the theoretical syringe weight.

$$\text{SyringeWeight}_{\text{Dry}} + (\text{Density} \times \text{Total Fluid Volume})$$

The *total fluid volume* of the syringe is the sum of the *dose volume* (the volume intended to be delivered to the patient) and any *overflow* intentionally placed into the syringe. For this purpose, the overflow is considered to be homogenous with the delivered dose.

In the case where the system performs in-syringe dilution, the fluid weight portion is computed as the sum of the drug fluid weight and the diluent fluid weight.

$$\text{SyringeWeight}_{\text{Dry}} + (\text{Density}_{\text{Drug}} \times \text{Volume}_{\text{Drug}}) + (\text{Density}_{\text{Diluent}} \times \text{Volume}_{\text{Diluent}})$$

Specific gravity is a density adjusted for standard temperature and pressure, often reported to three or more places behind the decimal point. In pharmacy compounding devices, specific gravity has become synonymous with density, although strictly speaking the terms have different meanings. Pharmacists, therefore, often use the term "specific gravity" to refer to a measurement that is actually merely a density.

The weight verification process on IntelliFill i.v. is subject to variance from several sources. As a result, the density used to verify weight is, at best, an approximation or average, based on the materials available at the time the density is determined. Given the level of precision required of the IntelliFill i.v., this approximation is sufficient to identify an under-filled or over-filled syringe, which is the purpose of the measurement.

## DEFINITIONS

**Density** – a measurement of a fluid's weight per unit volume, usually reported in g/mL

**Dose Volume** – the amount of fluid that must be administered to a patient to provide a requested dose of a specific drug

**Overflow** – an amount of drug fluid in addition to the dose volume that must be placed in a syringe

**Specific Gravity** – a density adjusted for temperature and pressure

**Total Syringe Weight** – the theoretical weight of a syringe filled with a specified volume of a specific drug fluid

## DETERMINING DRUG DENSITY

The following procedure describes a method for users to determine their own drug solution density:

- Draw 11 mL of air in a banded syringe and tare weigh the syringe on the IntelliFill i.v. scale.
- Use another banded syringe and a needle to measure 10 mL of the drug solution to be evaluated.
- Inject the 10 mL drug volume into the tared syringe on the IntelliFill i.v. scale through its nipple lumen.
- Note the resulting tare weight of the drug fluid.
- Divide that weight by 10.

## SOURCES OF ERROR

Both the determination of the theoretical syringe weight and the assessment of the actual fluid weight in a syringe are subject to the following variances beyond the control of the device:

- **Drug Preparation Variance** – drugs that require reconstitution have a variance in the amount of drug placed in the vial by as much as  $\pm 15\%$ . This can result in as much as 1% variance in the density of the drug fluid.
- **Reconstitution Variance** – IntelliFill i.v. has a known pump variance of  $\pm 5\%$  in the diluent volume placed in the vial. Depending on the reconstitution volume, this also can affect the actual specific gravity of the drug fluid.
- **Dry Weight of the Syringe** – IntelliFill i.v. syringes come on a band and cannot be tare weighed before filling. As a result, the device uses a statistical mean weight (determined over large syringe runs) for the weight of a capped and labeled, but unfilled, syringe that can vary by  $\pm 0.2$  g.
- **Fluid Delivery Variance** – the volume delivered by the device can vary by  $\pm 5\%$ .
- **Syringe Scale Accuracy** – the accuracy by which a syringe measures fluid is determined by ISO 7886-1, which states that volume accuracy for a 10 mL syringe pulled to over half its volume is  $\pm 4\%$ .
- **Balance Accuracy** – the Mettler-Toledo balance used for weighing both the test syringe and the actual syringe has an error of  $\pm 0.01$  g.

In summary, errors in the process described for determining a drug fluid density can arise from:

- variance in powder fill of a vial to be reconstituted
- variance in the reconstitution volume
- scale inaccuracies on the measurement syringe
- user technique in measuring out the 10 mL volume
- variance in the scale precision
- variance in user technique for measuring the 10 mL of fluid to be weighed

Variance in syringe weight is mitigated by tare weighing the syringe.

The calculation of a theoretical syringe weight using the density to compute the fluid weight and an average syringe dry weight to compute the final theoretical syringe weight has a  $\pm 0.2$  g variance for dry syringe weight, as well as a potential variance related to the amount of drug powder actually in the vial. An error in density needs to reach nearly 10% before it is no longer masked by other errors inherent in the system, such as syringe scale variance, balance variance and variance in the reconstitution process (reconstitution volume variance and/or drug powder variance).

Because of the permitted variance in the placement of the measurement scale on the syringe, it is possible that a syringe that has been filled accurately by weight may appear to be under- or over-filled. For this reason, Baxa permits the positive and negative variances to be set separately and generally adjusts IntelliFill i.v. so that it appears to be accurately filled against the syringe scale.

Because of these variances, the most reliable way to handle questionable syringes is to have them visually inspected to see if the fill appears accurate. For this purpose, IntelliFill i.v. is configurable with both accept/reject and quarantine weight limits, so the user can cull out suspect syringes and perform a visual accuracy verification.

## CONCLUSION

The combination of the estimation of density and the use of accept/reject and quarantine limits described above allows users to ensure the syringes produced by the IntelliFill i.v. meet acceptable standards for accuracy. Given the sources of error inherent in the use of density to compute a theoretical syringe weight, use of a more precise determination of a density (or specific gravity) value would not result in more reliable system performance.

*IntelliFill i.v. is manufactured for Baxa Corporation by FHT, Inc.*