



## Application Note

### Enhancing Process Flexibility With Automated Filling

#### Challenges in Aseptic Filling

Accurate and efficient filling of biopharmaceuticals in single-use bags, bottles, or vials is crucial. Even the smallest deviations in the filling volume can have a huge impact on the production process, or finally on the patient's therapy.

For example, if a liquid needs to be frozen for transport, overfilling or an inconsistent volume of single-use bags seriously increases the risk of bag leakage and product loss. In most cases, it is absolutely important that a patient receives exactly the same volume of the medication per injection.

Operational errors in aliquotation processes often occur due to manual intervention or limitations. The major challenges in aseptic filling are:

- Accuracy
- Consistency
- Flexibility
- Scalability

By implementing automated filling solutions with leading flow measurement technology, product and material loss, human errors, as well as the risk of contamination can be significantly reduced, while process flexibility can be substantially increased.

#### Solution Provider: Single Use Support

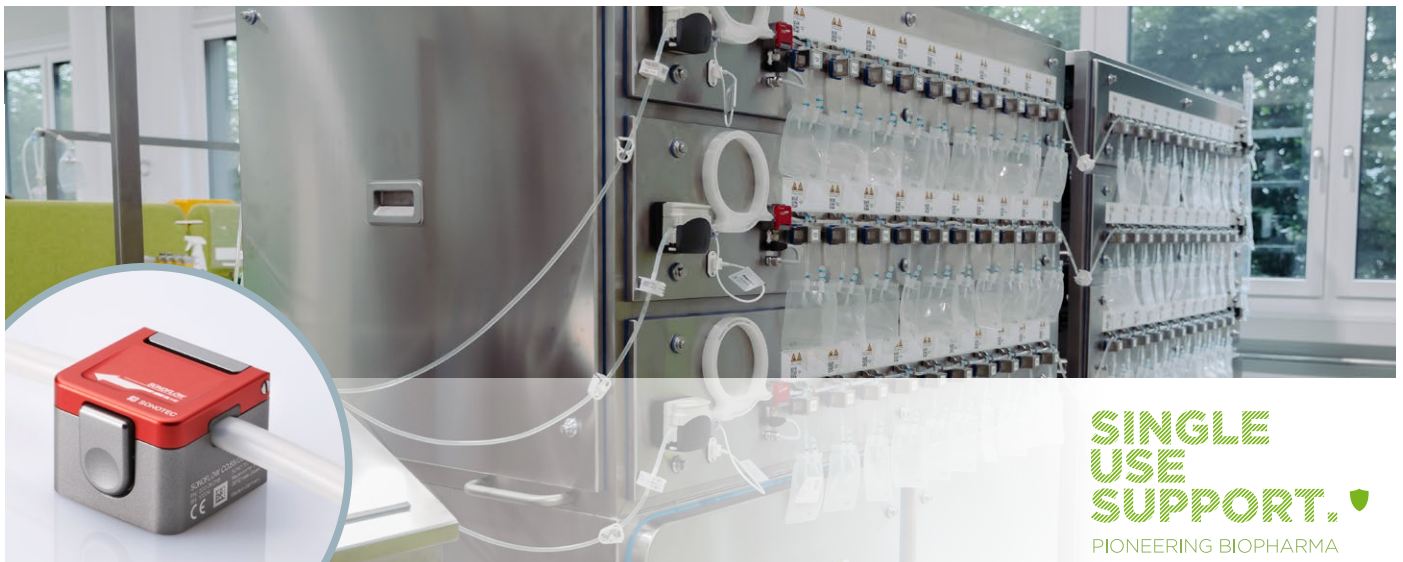
Innovative automated fluid management solutions provided by the company Single Use Support set a new standard in biopharmaceutical manufacturing.

The company offers specific expertise and fast solutions in processes regarding cell and gene therapies (CGT) but also commercial bulk drug substance handling and vaccine manufacturing transfers, and drug productions. With its expertise and advanced bioprocessing solutions, Single Use Support has become the market leader in the accurate filling of very small volumes in single-use bags.

*“The improved level of filling accuracy when aliquoting small volumes of biopharmaceuticals is a significant advancement in fluid management.”*

**Brian Moloney**

*Director New Products & Innovation  
Single Use Support GmbH*



**SINGLE  
USE  
SUPPORT.**   
PIONEERING BIOPHARMA

SONOFLOW CO.55 V3.0 flow meters installed in the RoSS.FILL CGT system,  
Sources: SONOTEC, Single Use Support

## Highest Accuracy for Better Operator's Control

With its fill & filtration platform RoSS.FILL, Single Use Support offers unlimited scalability for aseptic filling from laboratory to commercial production. The modular platform is designed for filling multiple smaller and larger volumes between 1mL and 1000L into single-use bags or bioprocessing containers.

For low volume dispensing at a commercial scale, accuracy and repeatability are essential. To achieve a filling accuracy range of even less than  $\pm 1$  mL with the RoSS.FILL platform, Single Use Support decided to implement SONOTEC's **SONOFLOW CO.55 V3.0** ultrasonic flow meters. The sensors are easily clamped on the tubing and measure without any contact and therefore without any risk of contamination or leakage.

Designed with a special focus on low flow applications, **SONOFLOW CO.55 V3.0** clamp-on flow meters combine excellent measurement accuracy over a wide flow range and highest clamp-to-clamp repeatability. Hence, the non-contact sensor is perfectly suited for single-use environments with regular tubing replacements.

With the smallest footprint in the market, the compact and reliable flow meter with built-in electronics has been easily integrated into the RoSS.FILL platform. All non-gravimetric small volume filling lines are equipped with an ultrasonic **SONOFLOW CO.55 V3.0** sensor to precisely measure and subsequently control the dispensed fluid. Thus, Single Use Support guarantees exact filling in bags from laboratory to commercial production.

## Unlimited Scalability and Flexibility

In biopharmaceutical manufacturing, it is crucial to maintain accuracy while also acknowledging the

### Key Findings

- Filling accuracy up to  $\pm 1$  mL with small volumes
- Scalability and flexibility of processes with modular filling system
- Enhanced process safety and efficiency with flow meters and bubble detectors
- Increased production speed



[RoSS.FILL CGT](#), Source: Single Use Support

importance of flexibility. If bag sizes or batch volumes vary due to scale-up or scale-down requirements, the filling system must do so accordingly. The modular RoSS.FILL platform can be adapted to the customer's needs: increase or lower the batch volume or bag size per rack. The highly accurate **SONOFLOW CO.55 V3.0** flow sensor ensures the configured filling volume in the single-use bags or bioprocessing containers.

## Advanced Process Safety With Bubble Detection

To ensure stable and safe filling processes, proactive and well-considered fluid management is necessary. With the integrated bubble detectors of the **SONOCHECK ABD06** series, Single Use Support guarantees airless filling of biopharmaceuticals in single-use bags or containers. The non-contact clamp-on **SONOCHECK ABD06** sensor detects air bubbles via ultrasound in the tubing.

Hence, RoSS.FILL users benefit from advanced process safety, flexibility, and scalability with accurate and airless volume dosing.

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