

Technical Note

For Pharmaceutical

January 2019



High Precision Mass Inspection with Accuracy of ± 0.5 mg* Achieved

Anritsu's capsule checkweighers have achieved the industry's highest weighing precision* of ± 0.5 mg. Here, we will describe the background as to why there is a demand for high precision mass inspections and also provide an explanation of the newly developed balance used in our capsule checkweigher.

* The highest weighing precision of ± 0.5 mg is based on our survey results.



Background showing the need for high precision mass inspections

• Appearance of next generation capsules

The most widely used general purpose capsules are currently "animal-derived capsules" that use gelatin as their raw material. However, for health and religious reasons, "plant-derived capsules" have come into use.

Animal-derived capsules

Gelatin (cattle, pigs, fish, etc.)

The manufacturing process has been established, enabling mass control within ± 4 mg

General purpose capsules

Ingredients

Quality

Characteristics

Plant-derived capsules

HPMC, pullulan (pulp, starch, etc.)

There are issues with the quality and variations in mass

Addresses BSE, health and religious issues

There are likely to be **variations in the mass** of plant-derived capsules during production; therefore, highly precise mass control is required.

• Increase in highly active pharmaceutical preparations (such as anticancer drugs and immunosuppressants)

The number of highly active pharmaceutical preparations is increasing. Even a slight variance in the fill content can change their efficacy, and variability in the mass of the capsules themselves cannot be ignored.

Example: Even for the same 10 mg capsule:



Because variability in the pre-filled (prelock) capsules results in **variability in the elution time and amount of active ingredient**, in addition to mass control of filled capsules, the mass of capsules prior to filling needs to be strictly controlled for highly active pharmaceutical preparations.

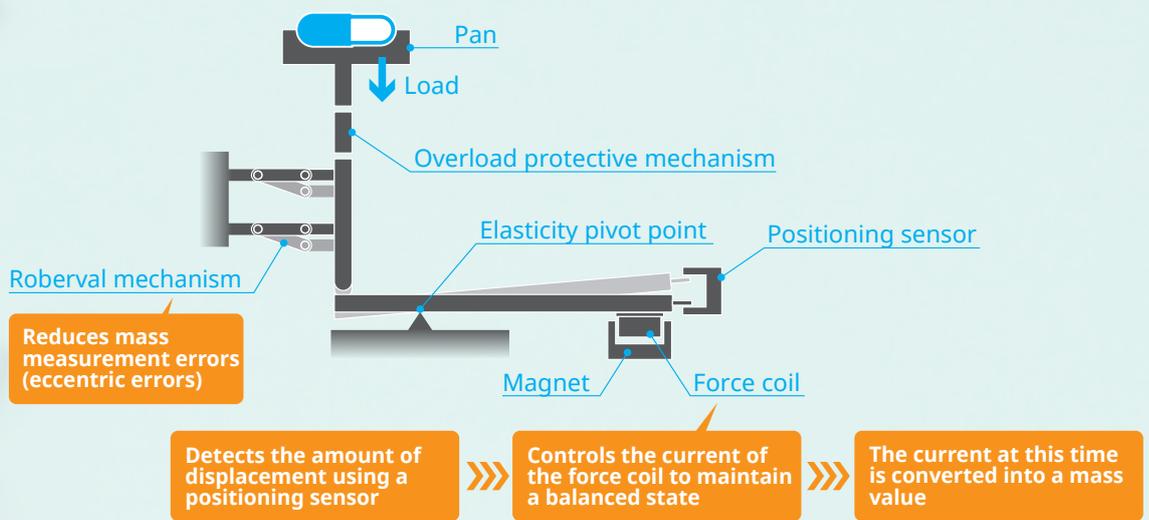
Anritsu's balance has achieved the industry's highest weighing precision

• From the differential transformer method to the force balance method

Our proprietary balance that employs the differential transformer method was used in conventional devices utilizing silicone oil as a damper and the displacement in the structural body using a spring is converted into an electric signal by the differential transformer to obtain the mass. Although it was highly precise (± 2 mg) in 1997, due to degradation of oil and distortion of the balance (the mechanism) from prolonged use, regular maintenance was required.

• Principle of the force balance method that enabled high precision of ± 0.5 mg to be achieved

In the force balance method, the load is balanced with a mechanical balance mechanism using a positioning sensor and an electromagnetic force. The mass is obtained from the size of the force coil current required for balancing. This enabled high precision of ± 0.5 mg to be achieved, and because the mechanism does not require oil or use of a spring, this means negligible deterioration of mechanical parts, and no need for maintenance.

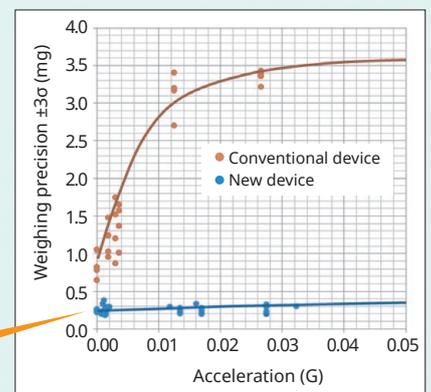


	Differential transformer	Force balance
Precision	± 2 mg	± 0.5 mg
Maintenance	Requires regular maintenance due to degradation of oil, etc.	Little deterioration of mechanical parts, no need for regular maintenance

• Resistant to extraneous vibration, provides consistent high precision

This method is more responsive than the differential transformer method, enabling highly precise mass measurements. Additionally, with a mechanism that makes fine adjustments to the balance state under a no-load condition, the impact of extraneous vibration was able to be reduced successfully.

This graph shows consistent precision even when the level of extraneous vibration (acceleration) is increased.



• Summary

Industry's highest weighing precision of ± 0.5 mg enhances both the production and mass check of pharmaceutical products. Please use this device to develop and manufacture state-of-the art pharmaceutical products.

Anritsu products information: <https://www.anritsu.com/infivis/>

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