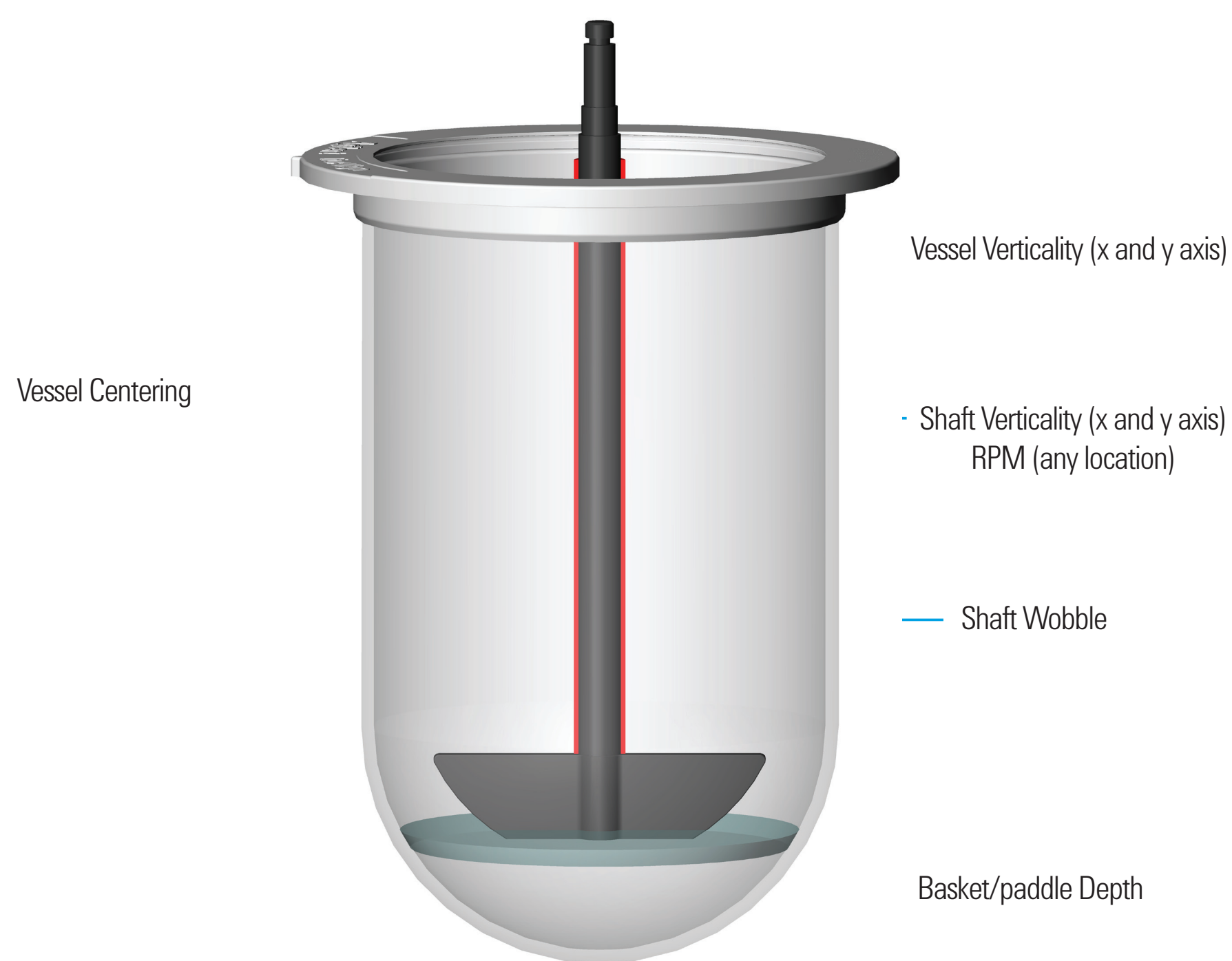


Vessel Measurement

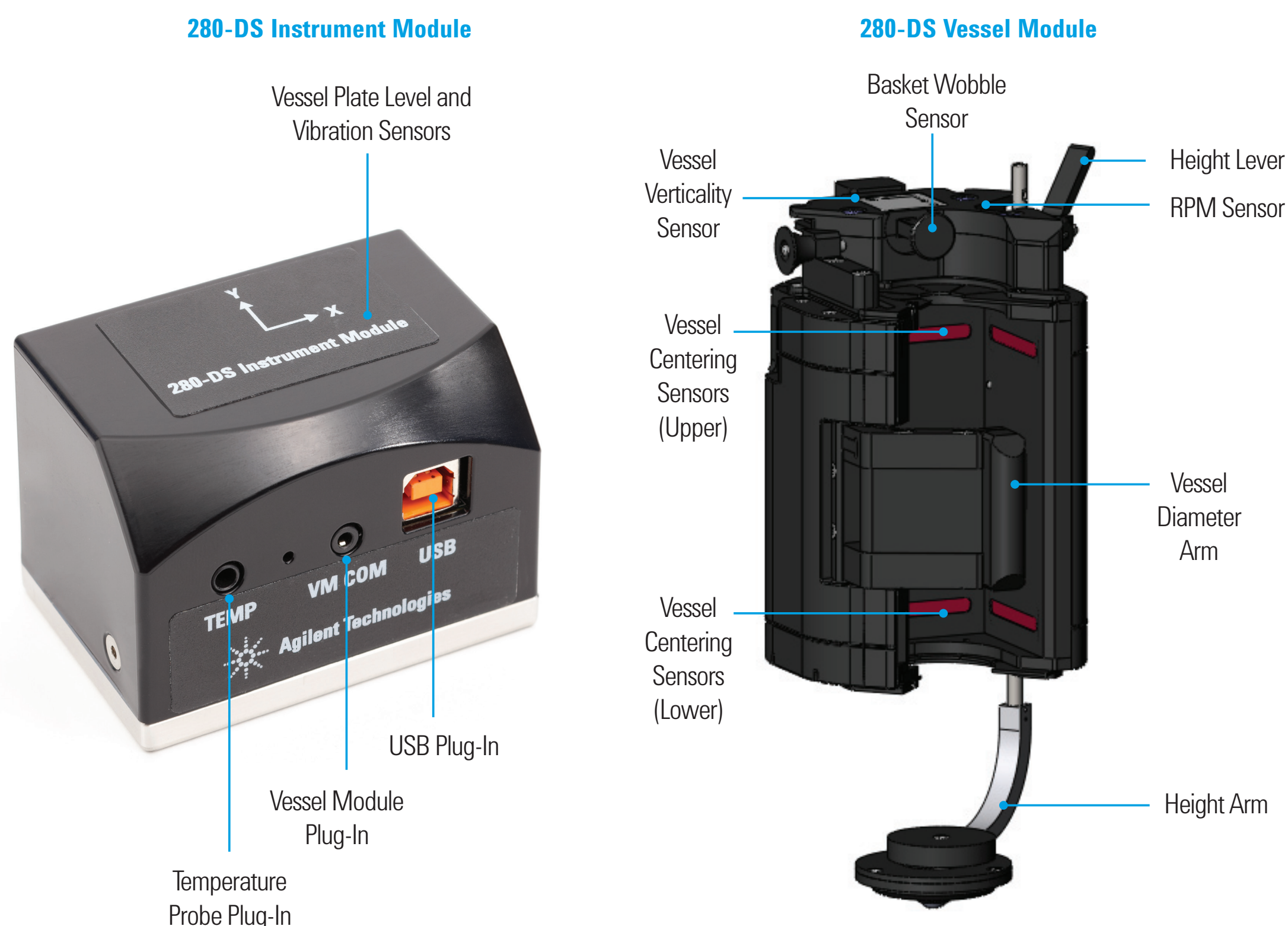


Basket Wobble and Vessel Plate Level Not Shown

Dissolution Mechanical Qualification Specifications and Tolerances

Parameter	ICH Harmonized (USP, JP, EP)	FDA DPA-LOP.002	ASTM E2503-07	USP Toolkit Ver 2.0
Basket and paddle depth	25 ± 2 mm	25 ± 2 mm	25 ± 2 mm (or <8%)	23-27 mm
Rotational speed	± 4% of specified rate	± 2 rpm of target	± 2 rpm or within 2% of target (larger)	± 1 rpm of target
Shaft wobble	No significant wobble	≤ 1.0 mm total runout	≤ 1.0 mm total runout	≤ 1.0 mm total wobble
Shaft verticality	Not measured	≤ 0.5° from vertical	Within bubble	Not measured
Basket wobble	± 1 mm	≤ 1.0 mm total runout	≤ 1.0 mm total runout	≤ 1.0 mm total wobble
Vessel/ shaft centering	NMT 2 mm from center axis	≤ 1.0 mm from center line	≤ 1.0 mm from center line	NMT 2.0 mm difference (4-90° positions)
Vessel verticality	Not measured	≤ 1.0° from vertical (2 - 90° positions)	≤ 1.0° from vertical (2 - 90° positions)	NMT 0.5° from vertical
Vessel plate level	Not measured	Not measured	Not measured	NMT 0.5° from horizontal
Performance Verification	USP Prednisone Tablets RS	Not measured	Not measured	USP Prednisone Tablets RS

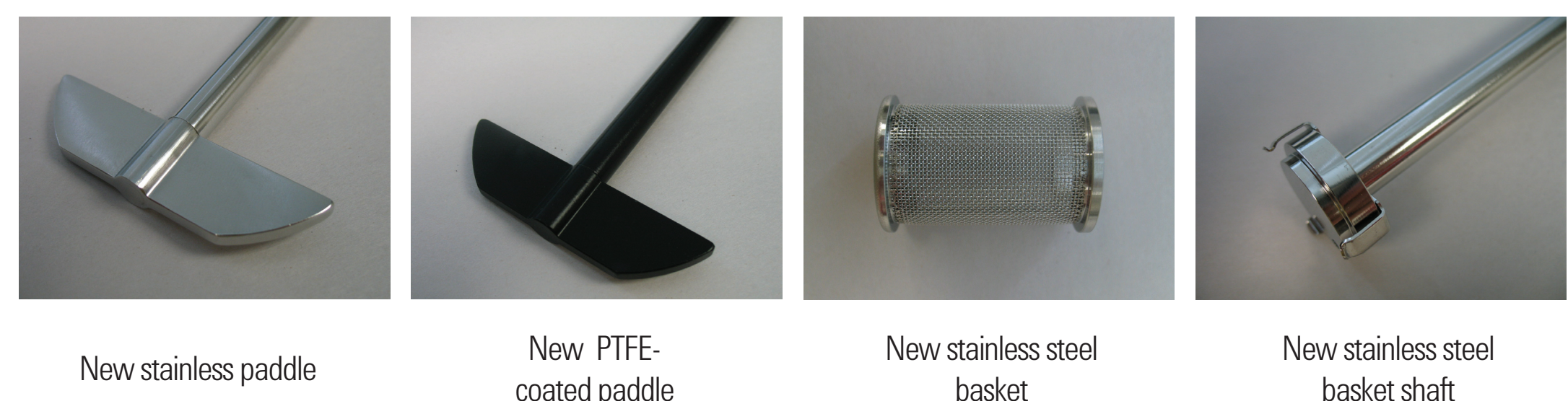
Measurement Capabilities



Accessory Inspection

Accessories can change in form with use. Thus, a critical element of MQ is inspecting the integrity of the dissolution instrument and its accessories prior to starting a test.

Acceptable Accessory Photos



Unacceptable Accessory Photos



Pre-run Checklist

- Vessel examination/orientation
- Paddle examination
- Basket/basket shaft examination
- Measurement of initial vessel temperatures
- Evaluation of vibration
- Ensure water bath is clean

Preventive Maintenance Recommendation

Preventative Maintenance should be performed every 6 months. The appropriate internal components should be lubricated, belts checked for wear, and all electrical connections inspected.

Dissolution Hotline

Questions? Contact us for complete method development, regulatory guidance and instrument-related support at dissolution.hotline@agilent.com

Contact Us

For more information on Agilent Dissolution Systems products and comprehensive service and support options, visit www.agilent.com/lifesciences/dissolution