

User Guide

Validation Tool Kit

74108004-B



Hanson

Quality • Technology • Science

Sales & Support

Congratulations on the purchase of your Validation Tool Kit. Please feel free to contact us at any time if you have questions or technical issues requiring our assistance.



NOTICES

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SR8-Plus, Classic 6, and Elite 8 are trademarks of Hanson Research Corp.



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Introduction

The Hanson Validation Tool Kit includes all of the tools to measure the following:

Vessel Plate Level—*Bubble Level*

Vessel Centering—*Sweep Gauge*

Paddle, Basket & Basket Shaft Wobble—*Wobble Gauge*

Paddle & Basket Height from Bottom of Vessel—*Digital Height Gauge*

The components of the kit are identified in *Figure 1—Validation Tool Kit Components*.

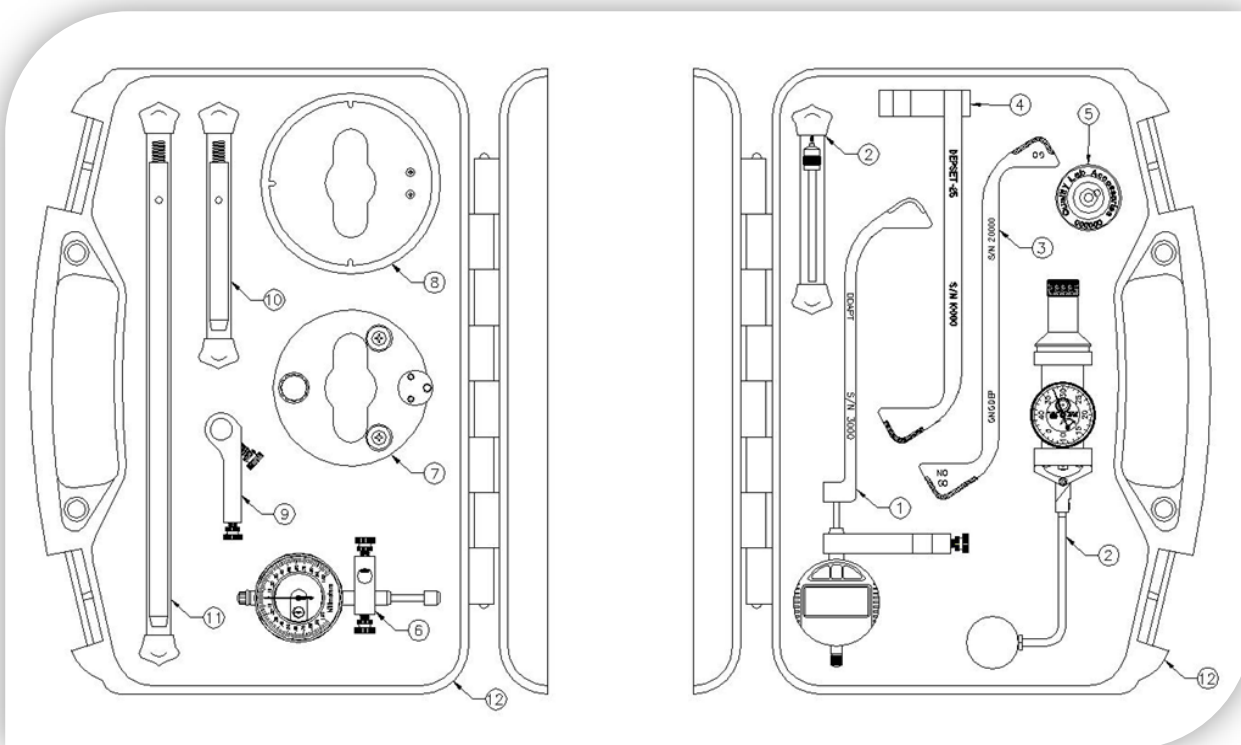


Figure 1—Validation Tool Kit Components

- | | | |
|-------------------------|--------------------------------|----------------------|
| 1. Digital Height Gauge | 5. Bubble Level | 9. Indicator Bracket |
| 2. Sweep Gauge | 6. Wobble Gauge | 10. Wobble Shaft |
| 3. Height Check Tool | 7. Wobble Bracket (non-Vision) | 11. Sweep Shaft |
| 4. Height Set Tool | 8. Wobble Bracket (Vision) | 12. Case (Qty=2) |

Vessel Plate Level

For leveling a dissolution tester, Hanson recommends using the **Bubble Level** (No. 1 in *Figure 1—Validation Tool Kit Components*).

1. Place the Bubble Level on the vessel plate near the front-center.
2. Adjust the height of the 4 feet (Classic 6 & non-Vision) or 5 feet (Elite 8) until it is level. Feet are adjusted and secured by lock nuts using a 13-mm wrench.

The dissolution tester is considered adequately leveled when the center of the bubble does not exceed the outer ring on the Bubble Level which is equal to 1.0° of inclination.

NOTE: The **Digital Level** may be used to obtain a specific degree of inclination the Bubble Level cannot provide. For more information, please refer to the *Digital Level Kit User Guide*.

Measurements Using Dial Indicators

Total Indicator Reading (TIR) is the difference between the 2 extreme indicator readings.

Needle displacement clockwise from zero is considered positive, and displacement counterclockwise is considered negative. Two examples for determining TIR follow:

Example 1: The needle starts at 0.20 mm and moves to 0.75 mm

$$0.75 \text{ mm} - 0.20 \text{ mm} = 0.55 \text{ mm TIR}$$

Example 2: The needle starts at 0.55 mm and moves across zero to -0.20 mm

$$0.55 \text{ mm} + 0.20 \text{ mm} = 0.75 \text{ mm TIR}$$

Vessel Centering

1. Assemble the **Sweep Gauge** according to *Figure 2—Sweep Gauge Assembly*.
2. Install the Sweep Gauge on the spindle of your choice.
3. Align the Sweep Gauge so that the edge of the ball is touching the vessel at approximately 1 cm below the top rim.
4. Tighten the clamp on the top of the spindle shaft.

NOTE: *The drive heads of the Elite 8 & non-Vision testers may be adjusted to aid in aligning the gauge within the vessel.*



Figure 2—Sweep Gauge Assembly
(No. 2 in Figure 1—Validation Tool Kit Components)

5. Set the motor speed to 25 RPM.
6. Observe the gauge for 1 full revolution while keeping the gauge handle from rotating.
7. Record the TIR. A passing value will not exceed a total of 4.00 mm TIR for USP qualifications, or 2.00 mm TIR for ASTM qualifications.

a. The gauge is read as follows:

10 = 1.0 mm

20 = 2.0 mm

30 = 3.0 mm

40 = 4.0 mm

NOTE: *The dial indicator may be rotated to aid in measurement.*

8. Stop the motor.

The sweep measurement must be repeated at the 500-mL mark within the vessel.

1. Position the Sweep Gauge so the edge of the ball is touching the vessel at approximately the 500-mL mark.

NOTE: To avoid an error in the reading, ensure the gauge handle does not come in contact with the vessel rim.

2. Set the motor speed to 25 RPM.
3. Observe the gauge for 1 full revolution.
4. Record the TIR. A passing value will not exceed a total of 4.00 mm TIR for USP qualifications, or 2.00 mm TIR for ASTM qualifications.

Paddle, Basket & Basket Shaft Wobble

Wobble Gauge Assembly

1. Screw the **Wobble Shaft** (No. 10 in *Figure 1—Validation Tool Kit Components*) into **Wobble Bracket** (No. 8 [Vision] or No. 7 [non-Vision] in *Figure 1*).
2. Insert the Wobble Bracket onto the vessel plate (Vision) or into the vessel (non-Vision).
3. Place the **Wobble Gauge** (No. 6 in *Figure 1*) onto the Wobble Shaft. Use screws to hold in place and adjust the gauge to touch the shaft.



Figure 3—Wobble Gauge Assembly
(shown on Elite 8)

Wobble Measurement

1. Adjust the height of the gauge on the Wobble Shaft until the gauge reading is approximately 2 cm above the apparatus. Check spindle shaft 2 cm above end of the shaft. Check basket at lower rim.

NOTE: *This height setting may also be accomplished by raising or lowering the drive head of the Elite 8 or raising or lowering the spindle shaft of the Classic 6.*

2. Set speed to 25 RPM.
3. Record TIR. All shafts and apparatuses should have less than 1.0 mm TIR.
4. Replace any shafts or apparatuses that do not meet the passing value of less than 1.00 mm TIR.

NOTE: *For the Classic 6, remove the waterbath before wobble measurement. Place the Wobble Gauge on the bench and hold in place to take wobble readings (see Figure 4—Classic 6 Wobble Measurement). It is recommended that 3 consecutive identical readings are observed before recording the value.*



Figure 4—Classic 6 Wobble Measurement

Paddle & Basket Height

Specific Measurements Using the Digital Height Gauge

1. For Vision testers, use the longer of the two arms provided in the Validation Tool Kit. For non-Vision testers, exchange the arm of the **Digital Height Gauge** (No. 1 in *Figure 1—Validation Tool Kit Components*) with the shorter arm supplied with the Validation Tool Kit (not pictured). The arms are attached to the indicator point using a hex head bolt sunken inside the arm.
2. Install the apparatus in the vessel position to be measured.
3. Raise the spindle shaft (Classic 6) or drive head (Elite 8 or non-Vision) to allow room to install the Height Gauge on the shaft.
4. Center the knob of the Height Gauge under the apparatus. With the spindle shaft or drive head suspended over the vessel, there should be approximately 1 cm between the knob and bottom of the apparatus.
5. Gently lower the spindle shaft or drive head into the test position. The bottom tip of the knob should be touching the bottom of the vessel.
6. Zero the gauge.
7. Place a finger underneath the indicator point as shown in *Figure 5—Indicator Point Position* and gently lift the arm until it contacts the bottom of the apparatus.



Figure 5—Indicator Point Position

8. Measure height. The final value for the height is obtained by adding the knob height (located on the Validation Tool Kit certificate) with the amount of travel. For example:

The certificate states that the height of the knob on the Height Gauge is 22.7 mm.

The travel on the gauge was 3.5 mm.

The total height is $22.7 \text{ mm} + 3.5 \text{ mm} = 26.2 \text{ mm}$.

9. Record the height. A passing value is $25 \text{ mm} \pm 2 \text{ mm}$ for USP specifications, or 8% of the desired height for ASTM specifications.

10. If the height fails to meet the specification, adjust the height of the apparatus (see *“Adjusting Height Using the Height Set Tool”*).

Non-Specific Measurements Using the Height Check Tool

For quick, non-specific measurements, a “GO/NO GO” **Height Check Tool** (No. 3 in *Figure 1—Validation Tool Kit Components*) is included with the Validation Tool Kit.

To determine if a basket or paddle is at the proper height, the smaller knob labeled “GO” must fit under the apparatus in the drive position, and the larger knob labeled “NO GO” must not. If the “GO” knob does *not* fit beneath the apparatus, or the “NO GO” knob *does*, the height needs to be adjusted (see *“Adjusting Height Using the Height Set Tool”*).

Adjusting Height Using the Height Set Tool

To adjust the height of the apparatus, use the **Height Set Tool** (No. 4 in *Figure 1—Validation Tool Kit Components*).

1. Raise the spindle shaft slightly so that the bottom of the apparatus is > 25 mm from the bottom of the vessel.

NOTE: For Vision testers, use a hex key to loosen the spindle shaft clamp and move the shaft. For non-Vision testers, follow the height set procedure in the operation manual for that model.

2. Place the Height Set Tool against the shaft so it fits into the notch on the upper part of the tool and the knob is directly below the apparatus.
3. Gently lower the Height Set Tool and shaft into the vessel so that the tool rests on the bottom of the vessel and the apparatus is above the tool.
4. Lower the apparatus until it touches the top of the Height Set Tool knob.
5. Tighten the spindle shaft clamp (Vision testers) or lock shaft in place (non-Vision).
6. Remove the Height Set Tool.
7. Check adjusted height using the Height Check Tool.

Troubleshooting

If your dissolution tester exceeds specified limits, here are a few recommendations:

- Spindle shaft height can be adjusted if necessary. See the user guide or operation manual for your dissolution tester for instructions.
- Hanson recommends replacing a paddle, basket, or basket shaft that fails to meet wobble specifications.
- Hanson dissolution testers are precision-aligned at the factory. Realignment should only be attempted by factory-trained and authorized personnel.

Contact Hanson for service and technical support.

Calibration

The Validation Tool Kit is supplied in 2 protective cases designed to maintain the accuracy of its precision components (see *Figure 1—Validation Tool Kit Components*). After each use, these components should be immediately returned to the case for storage.

Once a year, the complete Validation Tool Kit should be returned to Hanson for recalibration and certification. Please see the calibration tag on the outside of the protective case for the last calibration date and next required calibration date. These dates are also listed on the certificate supplied with your Validation Tool Kit.

Please contact Hanson to arrange returning your Validation Tool Kit for recalibration.