Operating Instructions

Quality Lab Accessories LLC

Vessel Centering and Verticality Alignment Gage

For use with USP Apparatus #1 & #2

Part Number MANCNTGAG-MI Rev. A

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1. General Information

1.1 Introduction

Thank you for purchasing the QLA Vessel Centering and Verticality Alignment Gage. This gage is a unique measuring tool that provides an accurate reading of vessel centering anywhere within the dissolution vessel. With the purchase of the optional 80mm Standard, 80mm Spacer and Shaft Collar, the gage can also be used to determine vessel verticality as described in the new FDA specifications outlining the use of an Enhanced Mechanical Calibration procedure as an alternate approach to current Apparatus Suitability procedure for Dissolution Apparatus 1 and 2 as described in the USP General Chapter <711> Dissolution. The gage is maintenance free, easy to use and should be returned to QLA once a year for recalibration.

1.2 Product Specifications

Parameter	Specification
Model #	CNTGAG-MI
Range	0.0 -5.0 mm
Accuracy	+ / - .10mm

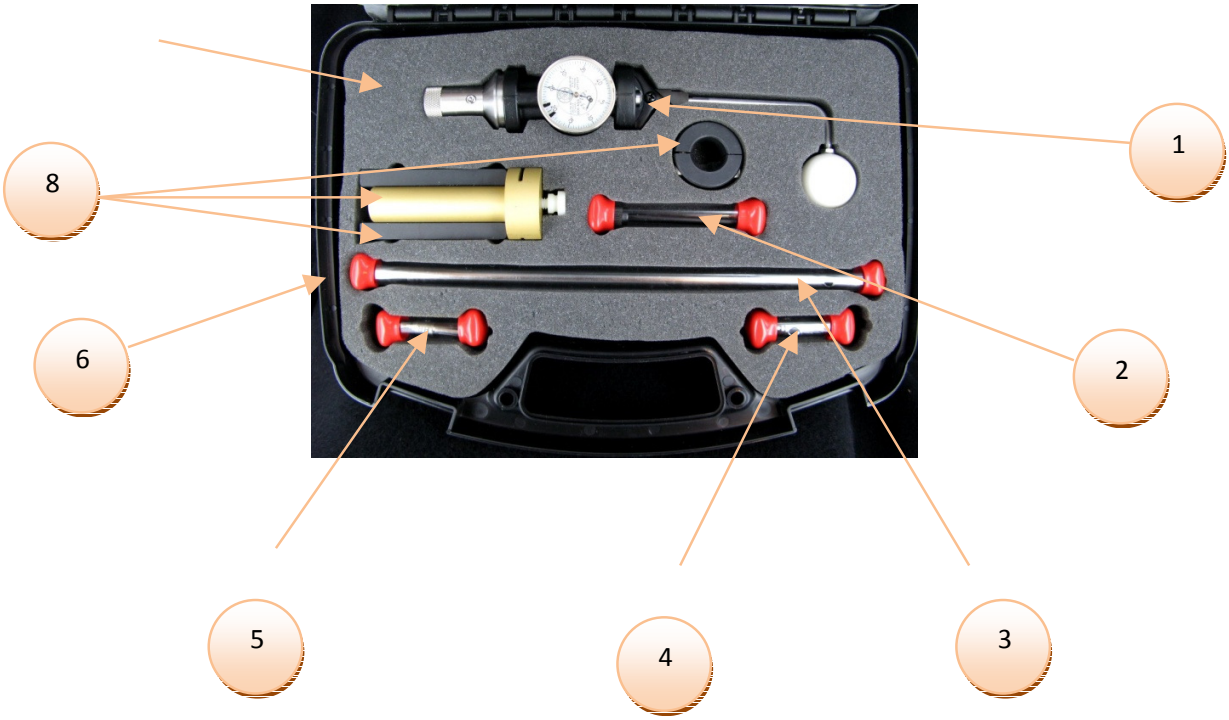
2. Unpacking

The gage is shipped in a foam padded storage case to minimize damage during transport. The case can also be used to return the gage to QLA for recalibration.

Unpack the gage carefully. After unpacking, check the gage for possible damage. Report any damage to the forwarding shipper immediately and inform QLA or your local representative.

3. Product Description

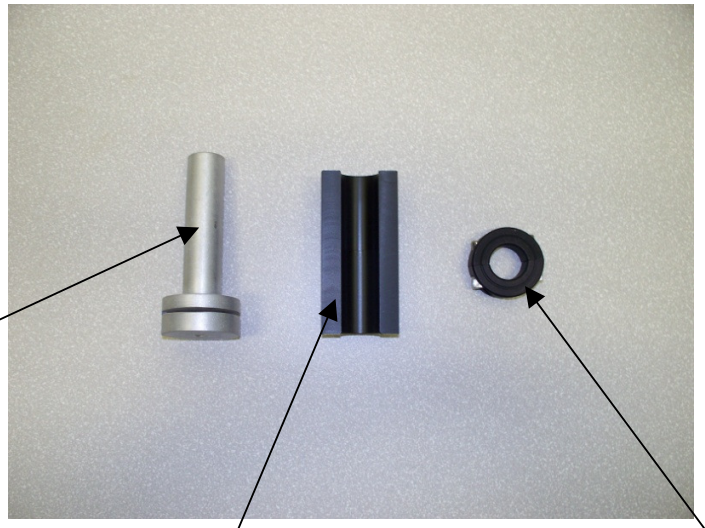
3.1 Diagram of Centering Gage



Item #	Description	Part Number
1	Centering / Verticality Gage	970-05-21
2	Anti-Rotation Handle	Included with Gage
3	Indicator Shaft	10001006
4	Spin Shaft Adapter for Hanson	ADPT-HR
5	Spin Shaft Adapter for VK	ADPT-VK
6	Storage Case	807-40
7	Foam Insert	950-05-32
8	Vessel Verticality Options	See Section 3.2

3.2 Diagram of Vessel Verticality Options

NOTE: The following items are not included with the CNTGAG-MI Gage as described in section 3.1 and must be purchased separately.



80mm Standard, for use with VanKel / Varian Testers. P/N STD-80

80mm Spacer, for use with Hanson and Distek Testers. P/N SPCR-80

Shaft Collar. P/N COLLAR-75

4. Installation

4.1 For Dissolution Testers with Solid Shafts

Raise the dissolution tester to its highest position. Remove any existing paddle or basket shafts and replace it with the Indicator Shaft with Gage as shown in figure #1.

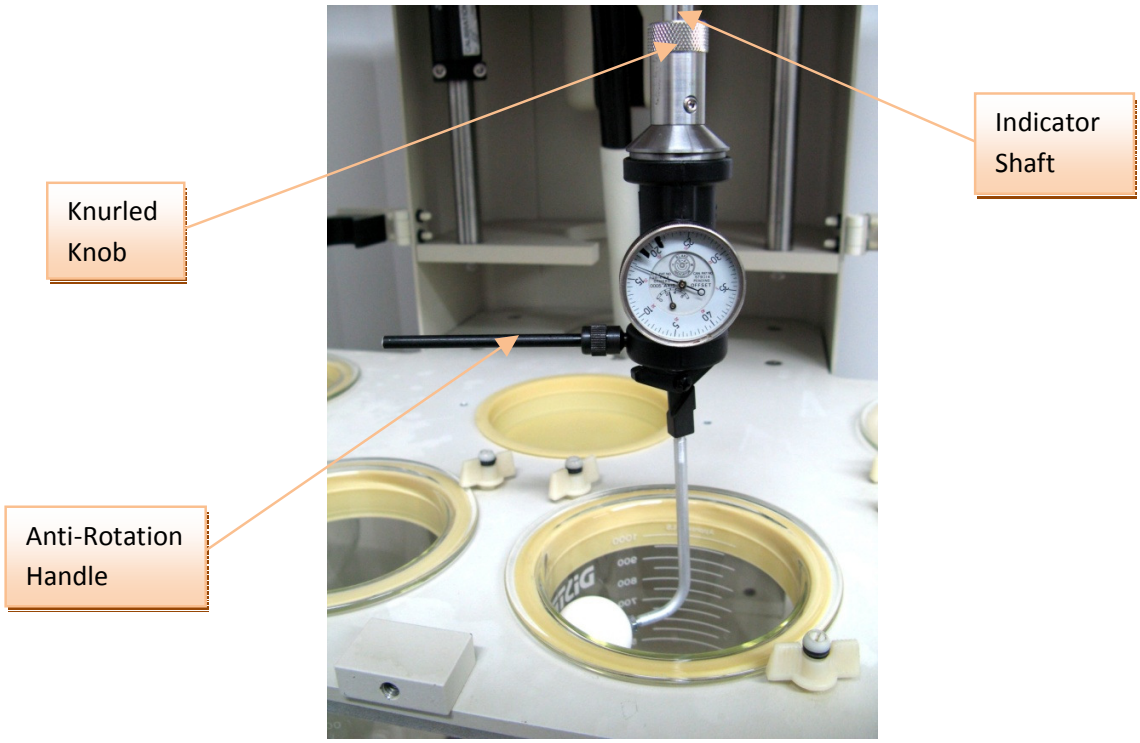


Figure #1

Insert the indicator shaft into the spindle such that the hole on the shaft protrudes about 1 inch below the spindle assembly.

Attach the top of the gage to the bottom of the indicator shaft by turning the knurled knob clockwise until snug. Use the anti-rotation handle to insert thru the indicator shaft. Hold the gage handle in place and then fully tighten the knurled knob. Raise the assembled gage into the spindle assembly and then fully tighten the Chuck Assembly. (Chuck assemblies are not used on Distek

Dissolution Testers. See section 4.2 for Bathless Testers with (2) Piece Spin-Off Shafts.)

4.2 For Dissolution Testers with (2) Piece, Spin-Off Shafts

Follow the instructions in section 4.1 with the following exceptions. Remove only the lower portion of the paddle or basket shaft assembly and replace it with one of the following Spin-Shaft adapters as shown in figure #2. (Distek Testers do not require the use of an adapter.)

Figure #2

5. Operation / Centering

5.1 Measuring Vessel Centering

Specification: Use a mechanical centering device that centers the inside of the vessel around the shaft or a surrogate shaft. The centering is measured at two positions inside the vessel in the cylindrical portion, one near the top but below the rim and one just above the spherical portion of the vessel. The shaft or surrogate shaft must be centered within 1.0mm from the center line.

STEP #1: While gently pressing back on the gage shaft to avoid hitting the vessel rim or centering ring as shown in figure #3. Lower the dissolution drive head so that the indicator ball is positioned about 2mm above the top of the vessels spherical radius as shown in Figure #4. (This approximates the normal paddle or basket position)

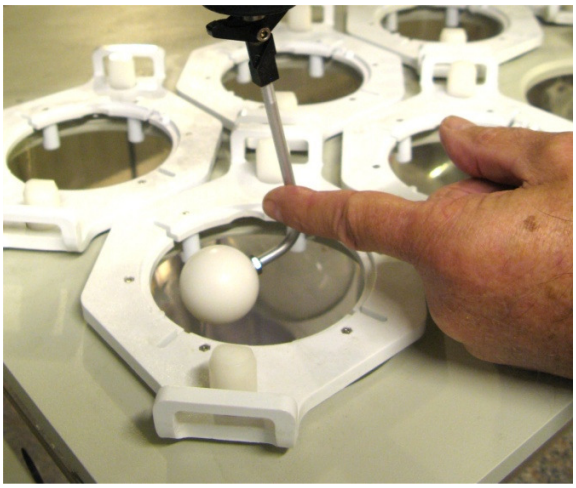


Figure #3

STEP #2: Set the dissolution tester speed to 25 RPMs and place one finger in front of the anti-rotation handle as shown in figure #4. (Some Distek 5100 series instruments may be equipped with a drive head position limit switch that prevents spindle rotation. These instruments require manual rotation.)

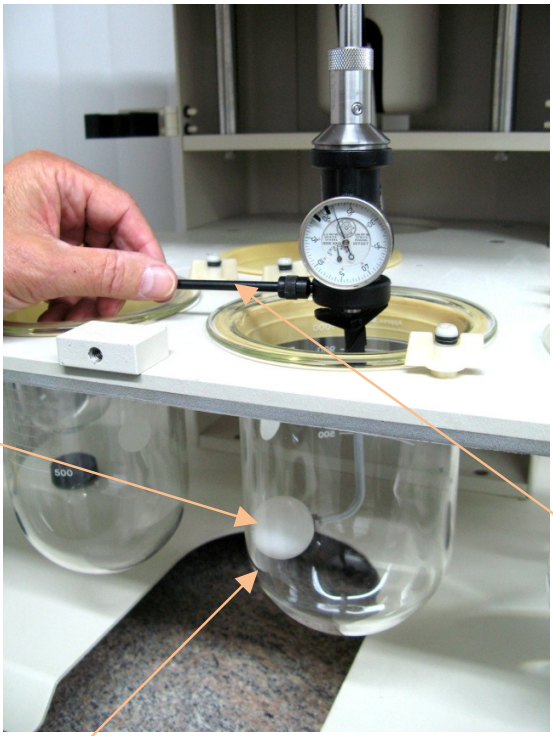


Figure #4

STEP #3: Start the spindle rotation and observe the dial indicator travel. Rotate the dial face so that the minimum counter clockwise pointer position coincides with 40 on the indicator.

STEP #4: As the shaft rotates, the pointer will move clockwise to a maximum value. This distance is the total indicated reading or T.I.R.. Each division on the dial indicator is equal to .05mm.

STEP #5: Stop the spindle rotation and raise the drive head so that the indicator ball is near the top of the vessel just below the rim and repeat steps #2 to #4.

STEP #6: Repeat this procedure for each shaft position.

5.2 Calculating Vessel Centering

The actual vessel centering or spindle to vessel misalignment is calculated by dividing the total indicated reading or T.I.R. by two.

Example: The dial indicator moved clockwise from 40 to 15. The total indicated reading is 1.5mm. Thus, 1.5mm divided by two equals .75mm. This vessel Passed.

Example: The dial indicator moved clockwise from 40 to 25. The total indicated reading is 2.5mm. Thus, 2.5mm divided by two equals 1.25mm. This vessel Failed

6. Operation / Vessel Verticality

6.1 Measuring Vessel Verticality

Measuring vessel verticality requires the purchase of the vessel verticality option as described in section 3.2.

Specification: The vessel verticality can be calculated using the centering measurements and the difference in height between the two measurements. The verticality should be determined at two positions 90 Degrees apart. The vessel must be < / = 1.0 Degree.

NOTE: The Anti-Rotation Handle may be removed to measure vessel verticality.

STEP #1: While gently pressing back on the gage shaft to avoid hitting the vessel rim or centering ring, lower the dissolution drive head so that the indicator ball is positioned about 2mm above the top of the vessels spherical radius. (This approximates the normal paddle or basket position) Install the Shaft Collar onto the left rear leg of the dissolution tester as shown in figures #5 and #6.

NOTE: For VanKel / Varian Dissolution Testers, the Shaft Collar is not required. Use the adjustable stop located on the left rear leg to adjust the position of the drive head. See Figure #8.

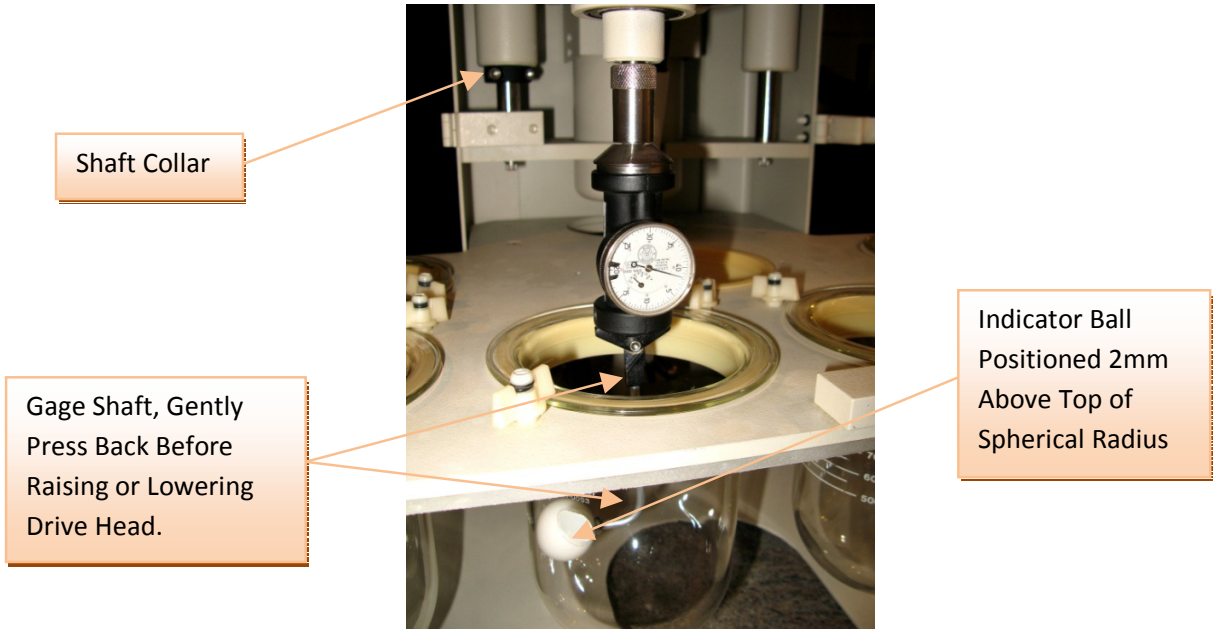


Figure #5

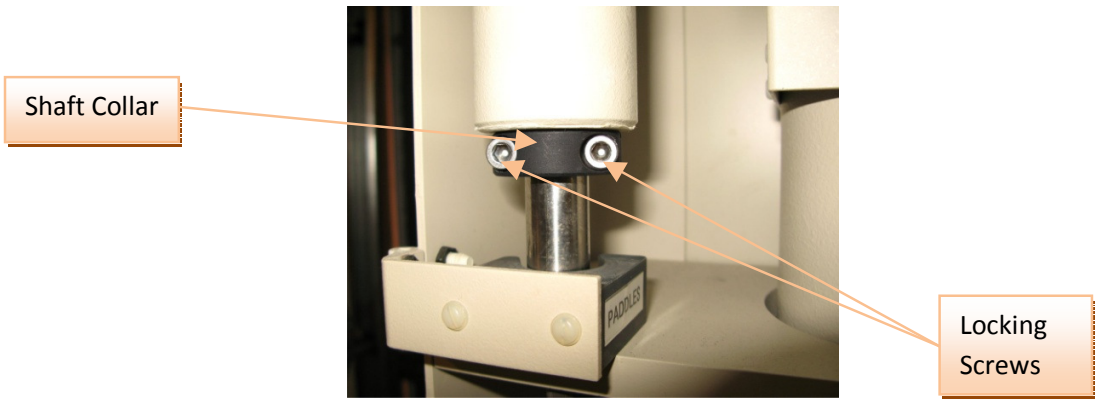


Figure #6

STEP #2: Rotate the dial face so that the pointer position coincides with 40 on the indicator.

STEP #3: While gently pressing back on the gage shaft, raise the dissolution drive head high enough to insert the appropriate 80mm Spacer or 80mm Standard as shown in figures #7 and #8.

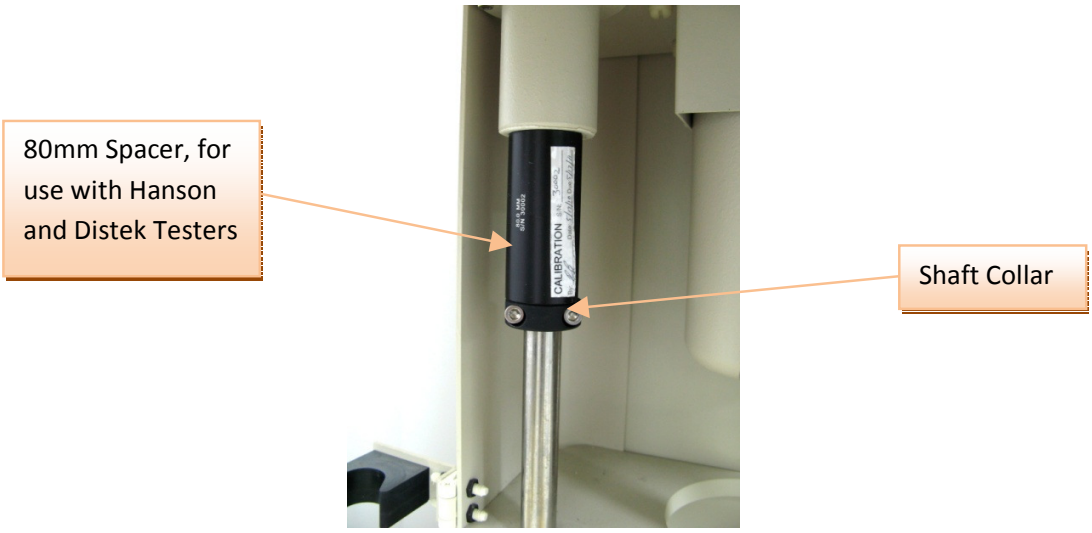


Figure #7

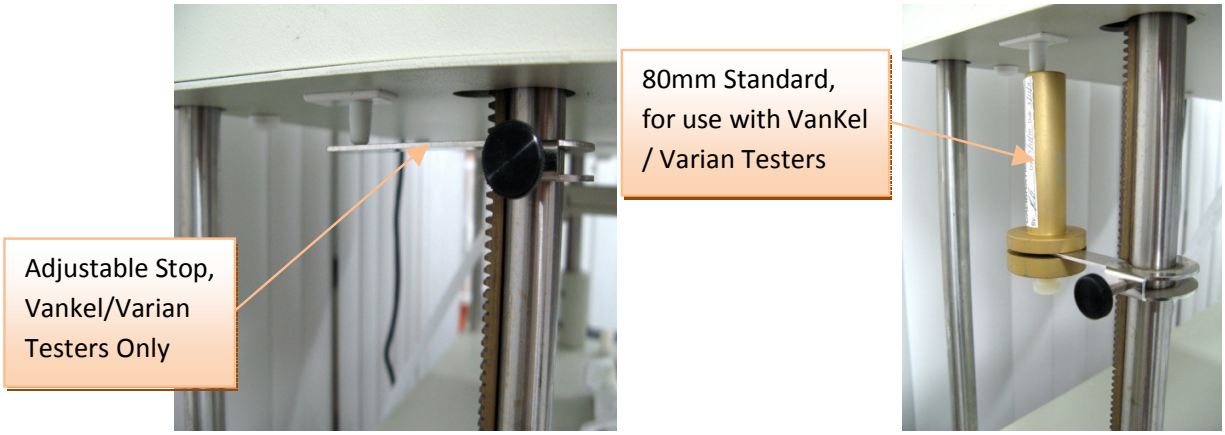


Figure #8

STEP #4: While gently pressing back on the gage shaft to avoid hitting the vessel rim or centering ring, lower the dissolution drive head until it touches the top of the standard or spacer, release the gage shaft and observe the reading on the gage. The difference between the reading at the bottom of the vessel and the top of the vessel is the displacement.

STEP #5: Rotate the gage 90 Degrees and then repeat steps #2 to #4.

STEP #6: Repeat steps #2 to #5 for each shaft location.

6.2 Calculating Vessel Verticality

A simple calculation has been performed to determine that the maximum allowable displacement over a distance of 80mm at a 1 Degree angle shall not exceed 1.36mm.

Example: The dial indicator moved clockwise from 40 to 5. The displacement or total indicated reading is .50mm. This vessel Passed.

Example: The dial indicator moved counter clockwise from 40 to 30. The displacement or total indicated reading is 1.00mm. This vessel Passed.

Example: The dial indicator moved counter clockwise from 40 to 5. The displacement or total indicated reading is 3.50mm. This vessel Failed.

7. Qualification and Validation

Prior to shipment, the gage is calibrated and includes a Certificate of Calibration. The gage should be returned to QLA for recalibration once a year.

8. Maintenance

The gage is maintenance free and does not require any daily service

9. Warranty

This gage is warranted to be free from defects in materials and workmanship under normal installation, use and service for a period of (1) year from the date of purchase as shown on the purchase order receipt. The obligation of QLA under this warranty shall be limited to repair or replacement (at our option) during the warranty period, provided the product is returned to QLA with transportation charges prepaid. This warranty shall be invalid if the product is damaged as a result of defacement, misuse, accident, destruction or alteration of the serial numbers, repair alteration or maintenance by any person or party other than our own service facility or authorized QLA service technician.