



Biopharmaceutical Development Program

Standard Operating Procedure

Title: Measurement of Internal and External Dimensions Using the Mitutoyo Calipers

SOP Number: 22710

Revision Number: 03

Supersedes: Revision 02

Effective Date: JAN 4 2011

Originator/Date:

Approval/Date:

Approval/Date:

Table of Contents

- 1.0 Purpose
- 2.0 Scope
- 3.0 Authority and Responsibility
- 4.0 Setup
- 5.0 Measurement
- 6.0 Preventative Maintenance
- 7.0 References and Related Documents
- 8.0 Attachments

1.0 Purpose

This SOP describes how to measure internal and external dimensions using the Mitutoyo Calipers.

2.0 Scope

This instrument is portable and can be used by Process Analytics personnel to perform dimensional testing on vials and closure components.

3.0 Authority and Responsibility

- 3.1 The Director, Process Analytics has the authority to define this procedure.
- 3.2 Process Analytics is responsible for training laboratory personnel and documenting this training to Biopharmaceutical Quality Assurance (BQA).

- 3.3 Process Analytics personnel are responsible for the performance of the procedure.
- 3.4 Process Analytics is responsible for reviewing the data and documentation of the results of this procedure.
- 3.5 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this procedure.

4.0 Setup

- 4.1 Attach the power cable to the Digimatic Mini-processor and the data cable between the calipers and the input connector of the processor (see Attachment I for a diagram).
- 4.2 Turn both the calipers and the processor on. The calipers can read in either inches or millimeters. The in/mm button on the front of the calipers will toggle between the two systems.
- 4.3 Press CL on the processor to clear any data that was in the memory from the last measurements.
- 4.4 Zero the calipers.
 - 4.4.1 Put calipers in the zero position (push the roller as far left as possible) and press the ZERO button.
 - 4.4.2 To zero the low pressure calipers, place the adjustable roller so that the mark is in between the hatch marks and press the ZERO button.
- 4.5 To set the high and low limits (obtained from the specification form), press the TOL. LIMIT key on the processor.
 - 4.5.1 Set the calipers to the high limit measurement and press DATA.
 - 4.5.2 Next, set the calipers to the lower limit measurement and press DATA.
 - 4.5.3 Press TOL. LIMIT again and the processor will print out the high and low limits and the tolerance. The mini-processor will remember the limits as long as the power is on.

5.0 Measurement

- 5.1 When measuring an object, apply pressure to the roller in the positive direction. When measuring the outside diameter of an object, apply pressure to the roller in the negative direction.
- 5.2 When a stable reading is received, press the DATA button on the processor or on the data cable, after each sample measurement.
- 5.3 When finished collecting all of the measurements desired, press the STAT key to print out the statistics of that group of measurements.
- 5.4 Press the FEED key twice and tear the paper off the printer.

- 5.5 The printout contains the number of samples taken, maximum value, minimum value, range, mean, standard deviation, number that are out of range, percentage that are out of range, process capacity index, and a histogram.
- 5.6 In the space provided, enter name of operator and date/time that the operation was performed. On the line under Part Number, enter the name of the material being measured and the BDP lot number (i.e., 10 mL vials, [REDACTED]). Attach the printout to the Raw Material Test Request (Form 22002-01).
- 5.7 When a sample is mismeasured, i.e., the DATA button was pushed before the caliper was set, cross out the result, initial and date, and immediately re-measure the sample.
- 5.8 If the mismeasured result is below specification cross out the MIN result in the statistics section and review the data for the true MIN value. Circle the new value for MIN on the statistics printout. If the mismeasured result is above specification cross out the MAX result in the statistics section and review the data for the true MAX value. Circle the new value for MAX on the statistics printout.

Note: If 200 components were to be measured and there were 3 mismeasurements, the samples taken in the statistics section will be 203.

6.0 Preventative Maintenance

- 6.1 If the calipers will not turn on, replace the battery by removing the battery panel on the front of the calipers and replace with a SR44 battery.

7.0 References and Related Documents

- 7.1 Digimatic Caliper Manual.
- 7.2 Digimatic Mini-Processor Manual.

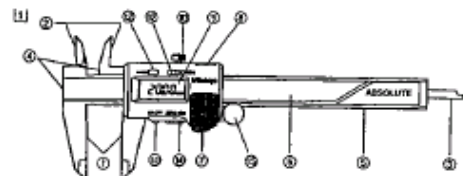
8.0 Attachments

- 8.1 **Attachment 1** Digimatic Caliper/ "DIGIMATIC"
- 8.2 **Attachment 2** User's Manual - Pages 15-18

Attachment 1 Digimatic Caliper/"DIGIMATIC"

GB D F J I E

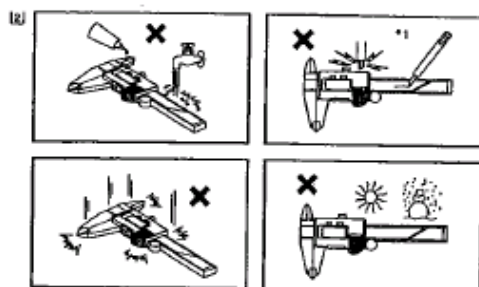
Digimatic Caliper/"DIGIMATIC" Meß



1 Name and Function of Each Part

- ① Outside measuring faces
- ② Depth measuring blade
- ③ Beam
- ④ Inside measuring faces
- ⑤ Step measuring faces
- ⑥ Main scale
- ⑦ Battery compartment lid
- ⑧ Display (LCD)
- ⑨ Output connector
- ⑩ Slider clamp screw
- ⑪ Power ON/OFF switch
- ⑫ Inch/mm conversion switch (only for inch/mm model)
- ⑬ ORIGIN switch (for setting absolute origin)
- ⑭ ZERO/ABS switch (switches between comparison and absolute measurements. Refer to Sec. 4.)
- ⑮ Thumb roller (depending on the model)

GB



2 Precautions on Use

Before using the Digimatic Caliper for the first time, wipe off the rust preventive oil from the caliper using a soft cloth soaked with cleaning oil.
*1: Do not apply any voltage to the caliper by such as an electric marker pen. Neither scratch the scale surface.

3 Battery Installation and Origin (zero point) Setting

- The Caliper does not come with the battery already installed. Install the supplied battery referring to the diagram. Upon installing the battery the display may indicate a meaningless value appended with or without E indication. It does not imply a malfunction.
- Always use the SR44 button-type silver oxide cell.
- Make sure the battery is installed with its positive side facing up.
- Never forget this origin (zero point) setting when the battery is replaced. Close the jaws, and hold down the ORIGIN switch for more than a second. This will bring up "0.00" in the LCD and this means completion of origin setting. Thus the caliper retains the origin for the entire battery life.

4 Comparison Measurement (INC) and Absolute Measurement (ABS)

- Perform the comparison measurement (INC model) as follows.
 - Bring the slider into a position on which the zero point is to be placed, then press and release (in a second or less) the ZERO/ABS switch. This zerosets the display and an "INC" indication appears in the LCD. Now it is ready to measure dimensions referring to this zero point.
- Perform the absolute measurement (ABS model) as follows.
 - Just after the power on the caliper is in the ABS mode and displays a dimension from the origin.
 - If "INC" is not displayed in the LCD, you can continue the absolute measurement.
 - If "INC" is displayed in the upper left of the LCD, hold down the ZERO/ABS switch for more than two seconds. This makes the "INC" indication disappear to be ready for a measurement referring to the absolute origin.

5 Error Symptoms and Remedies

- ErrC or display flicker: Occurs when the scale surface is stained. Clean the scale surface and coat a thin film of low-viscosity oil to keep out moisture.
- "E" in the least significant digit: This occurs when the slider is moved too quick, but it does not affect the measurement. However, if it stays on even when the slider is kept still, it means that the scale surface is stained. If this is the case, take remedies as for ErrC.
- "B" indication: Battery voltage is low. Replace the battery as soon as possible (Refer to Sec. 3).

6 Optional Accessories

- Connecting cable (with DATA switch: No.959149 (1m), No.959150 (2m))
- Data Hold Unit (No.959143): This is used to hold the display value.

7 Specifications

Resolution: 0.01mm or .0005"/0.01mm
Instrumental error: $\pm 0.02\text{mm}$ or $\pm .001"/\pm 0.02\text{mm}$
Repeatability: 0.01mm or .0005"/0.01mm
Maximum response speed: Not particularly provided
(No counting error due to scale speed)
Power supply: SR44 (silver oxide cell), 1 pc.
Battery life: 3.5 years under normal use
Operation temperature: 0°C to 40°C
Storage temperature: -10°C to 60°C

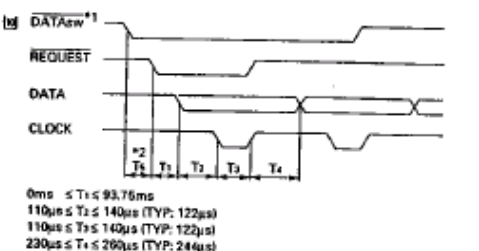
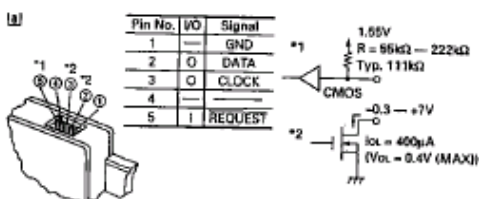
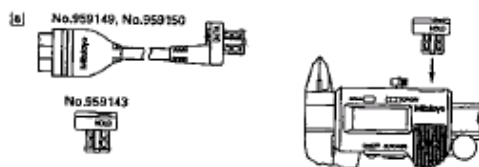
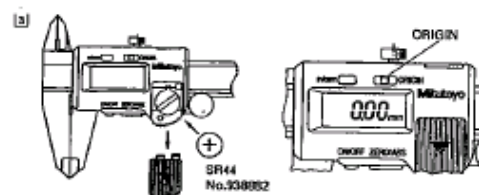
8 Connector Pin Assignment

9 Data Output Format



10 Timing Chart

- *1: DATAsw is LOW while the DATA switch is held down.
- *2: Time interval T_s between the falling of DATAsw to LOW and the input of REQUEST depends on the performance of the data processor to be connected.



Mitutoyo

Attachment 2 User's Manual – Pages 15-18

3. OPERATION

3.1 Key Functions

Key	Function		
	Mode 1, 2	Mode 3	
		Measurement mode	Calculation mode
CL (CLEAR key)	<ul style="list-style-type: none"> • Clears all the data. (Settings remain unchanged.) • Always press this key before setting the tolerance limits. 	<ul style="list-style-type: none"> • Re-input the data starting from No. 1 of the sub-group. 	<ul style="list-style-type: none"> • Clears all the data. (Settings remain unchanged.)
CE (CANCEL key)	<ul style="list-style-type: none"> • Cancels the previously entered measured data. 	<ul style="list-style-type: none"> • Cancels the previously entered measured data. 	<ul style="list-style-type: none"> • Cancels the measured data of the sub-group.
TOL.LIMIT (LIMIT key)	<ul style="list-style-type: none"> • Press this key when you enter into or exit from the setting operation of upper and lower limits. 	<ul style="list-style-type: none"> • Stops the measuring operation of the current sub-group and enters the calculation mode. 	<ul style="list-style-type: none"> • Enters the measurement for the next sub-group.
STAT (STAT key)	<ul style="list-style-type: none"> • Performs statistical analysis with all the data obtained, prints out the calculation results, and generates a histogram. 	<ul style="list-style-type: none"> • Calculates and prints out the X-bar and R values, then completes the measurement mode and enters the calculation mode.* 	<ul style="list-style-type: none"> • For the sub-groups whose data input has been completed, calculation of control limits is carried out and the results are printed.
FEED (FEED key)	<ul style="list-style-type: none"> • While you hold down this key, the recording paper is fed continuously. 		
DATA (DATA key)	<ul style="list-style-type: none"> • Logs data from the measuring unit. 		
PRINTER ON/OFF (PRINTER ON/OFF key)	<ul style="list-style-type: none"> • Turns the printer operation ON/OFF. If you press this key while printing, the printing operation will stop at the beginning of the next line. (This applies to data printing only.) 		

*: The number of measurements used for the sub-group 1 until the [STAT] key is pressed is determined as the sample size.
The [STAT] key operation for sub-group 2 and sub-groups following will be valid only after the specified sample size of data is entered.

Attachment 2 (Continued)

User's Manual – Pages 15-18

3.2 Mode Selection

The operation mode can be selected with the DIP switches located at the side of the main unit.

— : either ON or OFF will do

SW setting	4	3	2	1	0
Mode	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mode 1	—	—	OFF	OFF	—
Mode 2	—	—	OFF	ON	—
Mode 3	—	—	ON	—	—

3.3 Functions Available In Each Mode

Mode 1	Mode 2	Mode 3
<ul style="list-style-type: none"> • Purpose <p>To record measured data, perform statistical calculation, and generate a histogram.</p>	<ul style="list-style-type: none"> • Purpose <p>To generate a D-chart to graphically represent the displacement of measured data from the center. In addition, it is possible to record measured data, perform statistical calculations, and generate a histogram.</p>	<ul style="list-style-type: none"> • Purpose <p>By entering the data only, it is possible to calculate the X-bar, R value, and the control limit values to be used for generating an X-bar R chart.</p>
<p>a) Setting the limits</p> <p>Step 1: Press the [TOL.LIMIT] key of this unit when you wish to record GO/±NG judgment results or to generate a histogram. If you do not, proceed to the measuring operation.</p> <p>Step 2: Display one of the upper and lower tolerance limits on the measuring unit's display, then press the [DATA] key of this unit.</p> <p>Step 3: Display the other tolerance limit on the same display and press the [DATA] key again.</p> <p>Step 4: When the settings are completed, press the [TOL.LIMIT] key.</p>		<p>a) Measuring a sub-group</p> <p>Press the [TOL.LIMIT] key when entering the measurement mode.</p> <p>The maximum number of sub-groups is 9999.</p> <p>The sample size for a sub-group can be set from 2 to 10.</p>

Attachment 2 (Continued)
User's Manual – Pages 15-18

Mode 1	Mode 2	Mode 3
b) Measurement Logging and recording of the measured data starts in any of the following cases: the [DATA] key of this unit is pressed, timer signals are input, this unit receives data request commands via the RS-232C interface, or the foot switch or the data output switch of the measuring unit is pressed. At the same time, a GO/ \pm NG judgment is carried out and the results will be displayed and output as follows. ▲ ... Exceeding the upper limit ▼ ... Exceeding the lower limit	b) Measurement Logging and recording of the measured data and D-chart starts in any of the following cases: the [DATA] key of this unit is pressed, timer signals are input, this unit receives a data request command via the RS-232C interface, or the foot switch or the data output switch of the measuring unit is pressed. At the same time, a GO/ \pm NG judgment is carried out and the results will be displayed and output as follows. ► ... Exceeding the upper limit ◀ ... Exceeding the lower limit	b) Measurement Logging and recording of the measured data starts in any of the following cases: the [DATA] key of this unit is pressed, timer signals are input, this unit receives a data request command via the RS-232C interface, or the foot switch or the data output switch of the measuring unit is pressed. c) Statistical calculation Step 1: Pressing the [STAT] key in the measurement mode will start printing the X-bar and R calculation results for the specified sub-group. Step 2: Pressing this key in the calculation mode will start calculating the control limits and print out the results.
Note) Even if you switch over between Mode 1 and Mode 2 during the measuring operation, the previously obtained data and limit values are not erased.		
c) Statistical calculation Pressing the [STAT] key will start the statistical calculation for the measured data obtained to that point, and record the calculation results or generate a histogram.		

Attachment 2 (Continued) User's Manual – Pages 15-18

3.4 Timer-controlled Automatic Data Input

This function is used for automatically logging data from the measuring unit at regular intervals. Press the [FEED] key while you hold down the [PRINTER ON/OFF] key in order to enter the interval setting mode. The length of the interval can be determined by pressing any of the keys (see the table below for the correspondence between times and keys) to be pressed subsequently.

To exit this setting mode, hold down the [PRINTER ON/OFF] key and press the [CL] key.

Note 3.1

1. Even while logging data with the automatic data input function, the [CL], [CE], and [STAT] keys remain valid.
2. When exiting from the automatic data input function, the data remaining in the buffer will be printed.
3. In order to change the automatic data input interval, exit the automatic data input function, then set a new interval after pressing the [CL] key.

The relationship between the keys and the intervals is as follows.

Key	Interval
STAT*	0.3 sec
TOL.LIMIT*	1 sec
CE	5 sec
CL	30 sec
DATA	1 min
FEED	30 min
PRINTER ON/OFF	60 min

*: When the interval is set to either 0.3 sec or 1 sec, only the statistical calculation results can be printed. Measured data will not be printed out.

Example) Logging data at 0.3 sec intervals

Key operation	Printer operation
Step 1: Press the [FEED] key while holding down the [PRINTER ON/OFF] key.	* INTERVAL TIME *
Step 2: Press the [STAT] key.	0.3 SEC
	* PRINTER OFF *

Note) When 1000 measurements have been entered, statistical calculation will automatically start.