



ELECTRONIC BALANCE

Installation Qualification

Installation Qualification Report

System Name AP 225 WD

System ID No. _____

Installation Site PT Meritama Tirmaku Mercusuar

The undersigned performer reports that the Installation Qualification Protocol has been successfully completed for the system stated above

• Performer



Signature

Print

P. DITEK JAYA
JAKARTA-INDONESIA

Ruth Mega

Date

18 / 07 / 2024

Title Service Engineer

Certificate No. 612112023
(Shimadzu-certified Performer only)

Company PT Ditek Jaya

The undersigned reviewer and manager report that the performer has completed the Installation Qualification Protocol successfully.

• Reviewer

Signature

Date

Print

/ /

Title

Company

• Manager

Signature

Date

Print

/ /

Title

Company

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1. Definitions

1-1 Documentation

1. The purpose of this document is to record the results of the Installation Qualification of the Shimadzu Electronic Balance.
This document checks the installation site/environment, confirms equipment specifications, checks documentation such as instruction manuals, and verifies the condition of the installed equipment.
2. The following are established as the responsible parties in the execution of inspections.
 - **Performer**
The Performer is the individual who actually performs the procedures stipulated in the Installation Qualification Protocol and the Operational Qualification Protocol.
The Performer shall either be an individual who, having been trained by the Quality Assurance Department of the Analytical & Measuring Instruments Division of Shimadzu Corporation, has been certified as an IQ/OQ inspector by the General Manager of the Quality Assurance Department, or an individual recognized by the Manager to be equipped with the ability to conduct this inspection.
 - **Reviewer**
The Reviewer is an individual designated by the Manager charged with responsibility for the system.
The Reviewer verifies the contents of the Installation Qualification Protocol and Operational Qualification Protocol documentation. In addition, the Reviewer shall attend the inspection procedures together with the Performer, and evaluate the procedures.
The Manager can serve concurrently as the Reviewer.
 - **Manager**
The Manager is the individual responsible for administering the electronic balance being inspected.
As well as verifying the contents of the Installation Qualification Protocol and Operational Qualification Protocol documentation, the Manager shall also grant final approval to the inspection procedures.
3. The **Performer** shall check each unit and execute inspections using the protocol described in Installation Qualification Protocol (Document No. _____). After checking all items, the Performer shall sign and date the cover sheet of this document and submit this document as a report.
(IQ must be performed by a trained and knowledgeable individual in accordance with 21 CFR Part 211 Section 211.25 (cGMP, USA promulgated 29 September 1978)).
4. The **Reviewer** shall first check the content of this entire document. After the performance of each inspection (Pre-Installation Qualification, Installation Qualification and Equipment Management), the Reviewer shall check their results. After checking all items, the Reviewer shall sign and date the cover sheet of this document as approval of the Installation Qualification.
5. The **Manager** shall first check the content of this entire document. After the performance of all installation qualification protocols, the Manager shall check their results. The Manager shall enter a unique document control number in the Document No. space at the top right of the cover sheet, and then sign and date the cover sheet of this document as final approval of the Installation Qualification.
6. This document is comprised of 1. Definitions, 2. Preliminary Checks, 3. Pre-Installation Qualification, 4. Installation Qualification, 5. Change List, and 6. Attached Documents. All of these sections must be included.
7. This document contains important information and any form of duplication, photography, or reproduction without the permission of the General Manager of the Quality Assurance Department, Analytical & Measuring Instruments Division, Shimadzu Corporation, is prohibited. However, the records of the inspections conducted using this document may be duplicated at the discretion of the Manager.

1-2 Scope

This IQ inspection shall apply to the equipment installed at the following site.

(Address): Ruko Brickhouse Jl. Raya Bogor Km.31 NO.52, Cisaruk

(Company): PT Messifarma Timaku Mercusuaru

(Department): RnD

(Installation Site): Laboratory

(System ID No.):

(Product Model Name) AP 225 WD

(Scope of Installation Qualification)

The Installation Qualification Protocol shall include the following.

• Pre-Installation Qualification

Confirmation of the specifications of the electronic balance.

Confirmation and maintenance of documents (instruction manuals, Qualification Protocol and certificates).

Confirmation of installation site and conditions.

Confirmation of the delivered equipment.

• Installation Qualification

Confirmation shall be executed by verifying that the electronic balance is connected correctly.

• Confirmation of Firmware

The scope of the Installation Qualification extends to the verification of firmware. Verify the actual version displayed when the power is turned on. Verifications with the power turned on shall be executed in accordance with the OQ (Operational Qualification) Protocol.

During installation, the firmware may be upgraded to versions regarded appropriate by Shimadzu Corporation. In this case, enter the new version in the version information entry column in "4. Installation Qualification", and clearly state a comment to this effect in the margin.

1-3 Entries and Revisions**1. Making entries**

Use a permanent ballpoint pen, or equivalent, when recording results.

Names should be clearly printed.

Confirm that all items, except "Remarks" columns, are completed, and that there are no omissions.

Draw a diagonal line (from bottom left to top right) across all blank columns. (When making no entries, it is not necessary to enter the "Change No. __", "Date" or "Signature", or to write down the reason for the change in the Change List of this document.)

Columns in which nothing has to be written in have been filled in with "N/A" in advance.

If choices are available within an item, place a checkmark in the box to select the appropriate decision.

2. Deletion and correction of mistakenly filled items

To correct mistaken entries such as inspection results, delete the entire entry by drawing a diagonal line through it and enter the correction in the margins. To correct numerical values or symbols (checkmarks), draw 2 horizontal lines across the mistake and re-write the entry. Moreover, write the date, the signature, and the reason for the change. (When deletion and correction of mistakenly filled items, it is not necessary to enter the "Change No. __", "Date" or "Signature", or to write down the reason for the change in the Change List.)

3. Changing or deleting steps, procedures or acceptance criteria

If there are parts of the steps or procedures which will not be applied, draw a diagonal line through the entire item and write "Change No. __" above the line and assign a number to it. Date and sign it. Enter the necessary information in the Change List.

When making a change, delete the existing description as explained above, enter the change point, and then write down the reason for the change in the Change List.

4. Revising entries

If the need to alter the contents of an entry arises, change the entry in accordance with "2. Deletion and correction of mistakenly filled items", and then write the reason for the change in the Change List.

When adding a new description, write it in the margins of the relevant page, and write "Change No. __" and date and sign the entry. Then, write down the reason for the change in the Change List.

5. Handling program

Any problems identified in Installation Qualification must be investigated and appropriate actions must be taken. All such actions must be documented and be approved by the Manager.

6. In the event of a fail

If problems occur during an inspection and the item fails the inspection, place a checkmark in the "Fail" box and describe the problem in the margins of the relevant page. Write "Change No. __" and date and sign the entry. Enter an outline of the problem in the Change List.

After the problem is solved, describe the solution and the result ("Pass") in the margins of the relevant page. Write "Change No. __" and date and sign the entry. Enter the outline of the solution in the Change List.

If necessary, pages can be added. To add a page, write the "Change No. __" on the page and date/sign it. Add an alphabetical letter (starting from A) to the page number (e.g., 5-A), and insert the added page after the relevant page. Add the page number of the added page to the Table of Contents and record it in the Change List.

7. Other

Every item entered into the Change List shall be approved by the Reviewer and Manager.

2. Preliminary Checks

2-1 Reviewer Confirmation

Before conducting this inspection, enter the name of the Reviewer designated by the Manager.

Reviewer

Name: _____

Title: _____ Date: ____/____/____

Use the spaces below if more than one Reviewer is to be set. If the spaces are not used, place a checkmark in the "Not Applicable" box.

Reviewer 2 (☐ Not Applicable)

Name: _____

Title: _____ Date: ____/____/____

2-2 Identification and Approval of Performer

Identify and approve the Performer. Choose the entry section according to the way in which the Performer is selected.

If revisions are to be made to the document by Performers other than the persons certified in the table below, make a note of the fact that the Performer has been changed (entry of the qualification certificate number included) in "5. Change List".

☒ If the Performer is a service technician authorized by Shimadzu Corporation, complete the following.

This is to certify that the below-signed person has received training in the Quality Assurance Department of the Analytical & Measuring Instruments Division of Shimadzu Corporation. The person has been certified by the General Manager of the Quality Assurance Department as a qualified IQ/OQ inspector, as proven by the certificate. The person performs the Installation Qualification Protocol as the Performer.

PerformerName: Ruth MegaDate: 18 / 07 / 2024Title: Service EngineerCompany name: PT Ditek JayaCertificate No.: 612112023Signature: Pong

Use the spaces below if more than one Performer is to be set. If the spaces are not used, place a checkmark in the "Not Applicable" box.

Performer 2 (☒ Not Applicable)

Name: _____

Date: / /

Title: _____

Company name: _____

Certificate No.: _____

Signature: _____

The above-signed persons are hereby recognized as certified IQ/OQ inspectors and approved to perform the Installation Qualification Protocol as the Performer.

Reviewer

Signature: _____

Date: / / **Manager**

Signature: _____

Date: / /

☐ If the Performer has been appointed by the Manager, complete the following.

Performer

Name: _____

Date: ____/____/____

Title: _____

Company name: _____

Signature: _____

The above-signed person is hereby recognized as a certified IQ/OQ inspector and approved to perform the Installation Qualification Protocol as the Performer.

Reviewer

Signature: _____

Date: ____/____/____

Manager

Signature: _____

Date: ____/____/____

3. Pre-Installation Qualification

3-1 Equipment List

Systems can be configured by combining options according to equipment model. Electronic balances and options are shown in the list below. In this list, place a checkmark in the "Applicable" box for the electronic balance and options that configure the system, and enter a model name and serial number (S/N) if available. For electronic balances and options that do not configure the system, place a checkmark in the "Not Applicable" box.

Applicable	Not Applicable		Model Name	Serial No. (S/N)
☒	☐	Electronic balance	AR 225 WD	D316310030
		Options		
☒	☐	Printer	Balance Printer EP-110	
☐	☐	Keyboard		N/A
☐	☐	Foot switch		N/A
☐	☐	Battery pack	N/A	N/A
☐	☐	Windbreak (option)		N/A
☐	☐	Comparator buzzer	N/A	N/A
☐	☐	Specific gravity measurement kit		N/A
☐	☐	Animal bucket set	N/A	N/A
☐	☐			
☐	☐			
☐	☐			

We hereby approve the system configuration specified above.

Performer (signature) *Rmgf*

Date: 18 / 09 / 2019

Reviewer (signature)

Date: / /

3-2 Instruction Manuals

Applicable	Not Applicable	Instruction Manual	P/N	Revision Code	Storage Site
☐	☐	Electronic balance			
☐	☐				
		Options			
☐	☐				
☐	☐				
☐	☐				
☐	☐				
☐	☐				

Performer (signature) *P. M. J.*

Date: 18 / 07 / 2019

Reviewer (signature)

Date: / /

3-3 Certificates

Shimadzu Corporation attaches Certificates of Compliance for each electronic balance inspected in accordance with the Installation Qualification Protocol.

Enter the model name, make sure that the "Certificate of Compliance" is attached, and place a checkmark in the relevant box.

Model Name	Certificate of Compliance
AR 225 WD	☒

Performer (signature) *Rina*

Date: 18 / 09 / 2024

Reviewer (signature)

Date: / /

3-4 Installation Environment

The environmental conditions specified below shall be satisfied for the equipment to operate normally.

3-4-1 Environment

Temperature	5 to 40 °C Small daily temperature fluctuations within the above range. An environment restricting temperature fluctuations to within 2 °C is required to meet the control standards for the repeatability test and linearity test.
Relative humidity	20 to 85% (no condensation)
Table	
• Space	Must be the dimensions described in the instruction manual or larger. Sufficient space for the computer, printer, and options if positioned on the table.
Other	Avoid direct exposure to air-blow from air-conditioners. Avoid exposure to direct sunlight. No vibrations. Clean location free of corrosive gases or dust. Away from equipment which generates strong magnetic fields.

3-4-2 Power Supply

Voltage	100 V – 240 V (-15% to +10%): Note, however, that power supply specifications must satisfy the listed requirements of the AC adapter in use.
Frequency	50/60 Hz: Note, however, that power supply specifications must satisfy the listed requirements of the AC adapter in use.

3-5 Equipment Information

Check the equipment information for each unit. The check items are as follows.

Product name:	Electronic Balance		
Manufacturer:	Shimadzu		
Model name			
Product number (P/N):	321-74501-12		
Serial number (S/N):	D316310030		
Dimensions (mm):	Approx.	(W) ×	(D) × (H)
Power supply:	AC 100 V – 240V		
Frequency:	50/60 Hz		

Performer (signature) *Peng*

Date: 18 / 07 / 2024

Reviewer (signature)

Date: / /

4. Installation Qualification

4-1 Electronic Balance

☒ Applicable ☐ Not Applicable

A. External Appearance and Functions

1. Level Gauge

- (Outline) Make sure that the level of the electronic balance can be adjusted.
- (Procedure) Turn the level adjuster so that the bubble on the level gauge is located in the circle.
- (Criteria) The size of the air bubble must be 90% or less of the circle.
The air bubble must be locatable in the center of the circle.

2. LCD Display

- (Outline) Make sure that the LCD display works correctly.
- (Procedure) After checking the instruction manual, install the LCD display, and turn the power on.
- (Criteria) No missing segments are allowed in the LCD display.
Mass must be displayed.

(Results)	<u>Item</u>	<u>Pass</u>	<u>Fail</u>
	Level gauge	☒	☐
	LCD display	☒	☐

B. Standard Accessories

Refer to the list in the instruction manual, and make sure that all standard accessories are present.

(Results)	<u>Item</u>	<u>Pass</u>	<u>Fail</u>
	Standard accessories	☒	☐

Performer (signature) *Randy*

Date: 10 / 07 / 2016

Reviewer (signature)

Date: / /

Installation Qualification

Installation Qualification

4-2 Printer Model name: EP-110

☒ Applicable ☐ Not Applicable

Connect the printer cable to the electronic balance, turn the power on, and make sure that printing is performed when the [PRINT] key is pressed.

(Results)	Item	Pass	Fail
	Printing	☒	☐

4-3 Keyboard Model name:

☐ Applicable ☒ Not Applicable

Connect the cable to the electronic balance, press each of the keys, and make sure that the respective function works.

(Results)	Item	Pass	Fail
	Key functions	☐	☐

4-4 Foot Switch Model name:

☐ Applicable ☒ Not Applicable

Connect the cable to the electronic balance, and make sure that the foot switch works when it is stepped on.

(Results)	Item	Pass	Fail
	Functions	☐	☐

4-5 Battery Pack (for 100 V)

☐ Applicable ☒ Not Applicable

Connect the DC jack from the battery pack to the electronic balance, and make sure that numerical values are displayed on the electronic balance's LCD display when the power is turned on.

(Results)	Item	Pass	Fail
	Numerical value display	☐	☐

Performer (signature) P. M. A.

Date: 18 / 07 / 2019

Reviewer (signature)

Date: / /

4-6 Windbreak (Option) Model name:
☐ Applicable ☒ Not Applicable

Make sure that windbreak (option) is installed on the electronic balance, and that the door opens and closes smoothly.

(Results)	Item	Pass	Fail
	Sliding of door	☐	☐

4-7 Comparator Buzzer

☐ Applicable ☒ Not Applicable

Connect the comparator buzzer to the electronic balance, set the upper and lower limit values, and make sure that the buzzer sounds when there is a load present between upper and lower limit values.

(Results)	Item	Pass	Fail
	Buzzer operation	☐	☐

4-8 Specific Gravity Measurement Kit

Model name:
☐ Applicable ☒ Not Applicable

Make sure that the specific gravity kit is installed on the electronic balance, and that the electronic balance's mass display is free of abnormalities.

(Results)	Item	Pass	Fail
	Display on electronic balance	☐	☐

4-9 Animal Bucket Set

☐ Applicable ☒ Not Applicable

Make sure that the animal bucket set is installed on the electronic balance, and that the electronic balance's mass display is free of abnormalities.

(Results)	Item	Pass	Fail
	Display on electronic balance	☐	☐

Performer (signature) RWA

Date: 18 / 07 / 2024

Reviewer (signature)

Date: / /

5. Change List

When changing or deleting the contents of this document, or adding new information to this document, record revision coed, change number, page number, reason, date, and name of the Performer in the Change List below, and obtain the approval of the Reviewer and the Manager.

Revision Code: Enter an alphabet character starting from A. Assign the same revision code to changes that are performed at the same timing.

Change No: Enter the change number assigned in sequence from 1 onwards in accordance with "1.3 Entries and Revisions". Even if the revision code is different, assign the next number for the change number without returning the change number to 1.

Page: Enter the page number in which the change, deletion or addition was made.

Reason: Enter the reason for the change, deletion or addition.

Date: Enter the date on which the change, deletion or addition was made.

Revision Code	Change No.	Page	Reason	Date	Performer	Reviewer	Manager

6. Attached Documents

Attached	Item	Description	Page
☒	3-3	Certificate of Compliance	

Performer (signature) *Rmff*

Date: 18 / 07 / 2029

Reviewer (signature)

Date: / /

Document No. _____

ELECTRONIC BALANCE

Operational Qualification

Operational Qualification Report

System Name AP 225 WD

System ID No. _____

Installation Site PT Merisfarma Tirmayu Mercusuar

The undersigned performer reports that the Operational Qualification Protocol has been successfully completed for the system stated above.

• Performer



Signature

PT DITEK JAYA
JAKARTA-INDONESIA

Date

18 / 07 / 2024

Title Service Engineer

Certificate No. 612112023
(Shimadzu-certified Performer only)

Company PT DITEK Jaya

The undersigned reviewer and manager report that the performer has completed the Operational Qualification Protocol successfully.

• Reviewer

Signature

Date

Print

Title

Company

• Manager

Signature

Date

Print

Title

Company

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1. Definitions

1-1 Documentation

1. The purpose of this document is to record the results of the Operational Qualification (OQ) implemented on the Shimadzu Electronic Balance. If the inspections pass the criteria and the results have been approved, it has been verified that the instruments operate properly in accordance with their intended purpose.
2. The following are established as the responsible parties in the execution of inspections.
 - **Performer**
The Performer is the individual who actually performs the procedures stipulated in the Installation Qualification Protocol and the Operational Qualification Protocol.
The Performer shall either be an individual who, having been trained by the Quality Assurance Department of the Analytical & Measuring Instruments Division of Shimadzu Corporation, has been certified as an IQ/OQ inspector by the General Manager of the Quality Assurance Department or an individual recognized by the Manager to be equipped with the ability to conduct this inspection.
 - **Reviewer**
The Reviewer is an individual designated by the Manager charged with responsibility for the system.
The Reviewer verifies the contents of the Installation Qualification Protocol and Operational Qualification Protocol documentation. In addition, the Reviewer shall attend the inspection procedures together with the Performer, and evaluate the procedures.
The Manager can serve concurrently as the Reviewer.
 - **Manager**
The Manager is the individual responsible for administering the electronic balance being inspected.
As well as verifying the contents of the Installation Qualification Protocol and Operational Qualification Protocol documentation, the Manager shall also grant final approval to the inspection procedures.
3. The **Performer** shall check each unit and execute inspections using the protocol described in the Operational Qualification Protocol (Document No. _____). After checking all items, the Performer shall sign and date the cover sheet of this document and submit this document as a report. (OQ must be performed by a trained and knowledgeable individual in accordance with 21 CFR Part 211 Section 211.25 (cGMP, USA promulgated 29 September 1978)).
4. The **Reviewer** shall first check the contents of this entire document. After each inspection is finished, the Reviewer shall check its result. After checking all inspection items, the Reviewer shall sign and date the cover sheet of this document as approval of the Operational Qualification.
5. The **Manager** shall first check the contents of this entire document. After all inspections in the Operational Qualification Protocol have been implemented, the Manager shall check their results. The Manager shall then enter a unique document control number in the Document No. space at the top right of the cover sheet, and then sign and date the cover sheet of this document as final approval of the Operational Qualification Protocol.
6. This document is comprised of 1. Definitions, 2. Preliminary Checks, 3. Operational Qualification Record, 4. Change List, and 5. Attached Documents. All of these sections must be included.
7. This document contains important information and any form of duplication, photography, or reproduction without the permission of the General Manager of the Quality Assurance Department, Analytical & Measuring Instruments Division, Shimadzu Corporation, is prohibited. However, the records of the inspections conducted using this document may be duplicated at the discretion of the Manager.

1-2 Scope

This OQ inspection shall apply to the equipment installed at the following site.

(Address): Ruko Brickhouse Jl. Raya Bogor km. 31 No. 52, Cibadak

(Company): PT Merifarma Tirmaku Mercusuar a

(Department): RND

(Installation Site): Laboratory

(System ID No.):

(Product Model Name): AP 25 W0

Performer (signature) 

Date: 10 / 07 / 2024

Reviewer (signature)

Date: / /

1-3 Entries and Revisions

1. Making entries

Use a permanent ballpoint pen, or equivalent, when recording results.

Names should be clearly printed.

Confirm that all items, except "Remarks" columns, are completed, and that there are no omissions. Draw a diagonal line (from bottom left to top right) across all blank columns. (When making no entries, it is not necessary to enter the "Change No. __", "Date" or "Signature", or to write down the reason for the change in the Change List of this document.)

Columns in which nothing has to be written in have been filled in with "N/A" in advance.

If choices are available within an item, place a checkmark in the box to select the appropriate decision.

2. Rounding of numeric values

If measurement results are obtained with a degree of precision that exceeds the range of the electronic balance display, results are rounded to figures whose degree of precision exceeds the range of the display by one digit. For example, when the electronic balance display is down to the 0.1's digit, the numerical value of the 0.001's digit in the result value is rounded to the nearest digit, i.e. 0.01's digit.

3. Deletion and correction of mistakenly filled items

To correct mistaken entries such as inspection results, delete the entire entry by drawing a diagonal line through it and enter the correction in the margins. To correct numerical values or symbols (checkmarks), draw 2 horizontal lines across the mistake and re-write the entry. Moreover, write the date, the signature, and the reason for the change. (When deletion and correction of mistakenly filled items, it is not necessary to enter the "Change No. __", "Date" or "Signature", or to write down the reason for the change in the Change List.)

4. Changing or deleting steps, procedures or acceptance criteria

If there are parts of the steps or procedures which will not be applied, draw a diagonal line through the entire item and write "Change No. __" above the line and assign a number to it. Date and sign it. Enter the necessary information in the Change List.

When making a change, delete the existing description as explained above, enter the change point, and then write down the reason for the change in the Change List.

5. Revising entries

If the need to alter the contents of an entry arises, change the entry in accordance with "3. Deletion and correction of mistakenly filled items", and then write the reason for the change in the Change List.

When adding a new description, write it in the margins of the relevant page, and write "Change No. __" and date and sign the entry. Then, write down the reason for the change in the Change List.

6. Handling problems

Any problems identified in the Operational Qualification must be investigated and appropriate actions must be taken. All such actions must be documented and be approved by the Manager.

7. In the event of a fail

If problems occur during an inspection and the item fails the inspection, place a checkmark in the "Fail" box and describe the problem in the margins of the relevant page. Write "Change No. __" and date and sign the entry. Enter an outline of the problem in the Change List.

After the problem is solved, describe the solution and the result ("Pass") in the margins of the relevant page. Write "Change No. __" and date and sign the entry. Enter the outline of the solution in the Change List.

If necessary, pages can be added. To add a page, write the "Change No. __" on the page and date/sign it. Add an alphabetical letter (starting from A) to the page number (e.g., 5-A), and insert the added page after the relevant page. Add the page number of the added page to the Table of Contents and record it in the Change List.

8. Attaching data

Attached data are added by assigning page numbers as "A, B, C..." for each inspection item. If, for example, there is a total of 3 sheets for attachment A, notate the pages as "16-A-1/3 – A-3/3", ensuring that no numbers are omitted. The Performer shall date and sign the attached data.

9. Other

Every item entered into the Change List shall be approved by the Reviewer and Manager.

2. Preliminary Checks

2-1 Confirmation of Reviewer

Before conducting this inspection, enter the name of the Reviewer designated by the Manager.

<u>Reviewer</u>	
Name: _____	
Title: _____	Date: ____ / ____ / ____
Use the spaces below if more than one Reviewer is to be set. If the spaces are not used, place a checkmark in the "Not Applicable" check.	
<u>Reviewer 2</u> (☐ Not Applicable)	
Name: _____	
Title: _____	Date: ____ / ____ / ____
<u>Reviewer 3</u> (☐ Not Applicable)	
Name: _____	
Title: _____	Date: ____ / ____ / ____

2-2 Identification and Approval of Performer

Identify and approve the Performer. Choose the entry section according to the way in which the Performer is selected.

☒ If the Performer is a service technician authorized by Shimadzu Corporation, complete the following.

This is to certify that the below-signed person has received training in the Quality Assurance Department of the Analytical & Measuring Instruments Division of Shimadzu Corporation. The person has been certified by the General Manager of the Quality Assurance Department as a qualified IQ/OQ inspector, as proven by the certificate. The person performs the Operational Qualification Protocol as the Performer.

PerformerName: Ruth MegaDate: 18 / 07 / 2024Title: Service EngineerCompany name: P1 Ditek JayaCertificate No.: 612112023Signature: Ruth Mega

Use the spaces below if more than one Performer is to be set. If the spaces are not used, place a checkmark in the "Not Applicable" box.

Performer 2 (☒ Not Applicable)

Name: _____

Date: _____ / _____ / _____

Title: _____

Company name: _____

Certificate No.: _____

Signature: _____

The above-signed persons are hereby recognized as certified IQ/OQ inspectors and approved to perform the Operational Qualification Protocol as the Performer.

Reviewer

Signature: _____

Date: _____ / _____ / _____

Manager

Signature: _____

Date: _____ / _____ / _____

Operational Qualification

Preliminary Checks

☐ If the Performer has been appointed by the Manager, complete the following.

<u>Performer</u>	
Name: _____	Date: ____/____/____
Title: _____	
Company name: _____	
Signature: _____	
The above-signed person is hereby recognized as a certified IQ/OQ inspector and approved to perform the Operational Qualification Protocol as the Performer.	
<u>Reviewer</u>	
Signature: _____	Date: ____/____/____
<u>Manager</u>	
Signature: _____	Date: ____/____/____

2-3 Planning Items to Be Evaluated in Operational Qualification

Before conducting this operational qualification procedure, determine the evaluation items, and have them approved by signing the signature column at the end of this section.

No signature or date entry is required for evaluation items with a checkmark in the "Not Applicable" box on the Implementation Record page.

2-3-1 Checking the Model

Enter the model name and serial number (S/N) of the electronic balance.

<Model>

Model Name	Serial Number (S/N)
AP-22	D316310030

We hereby approve the system configuration specified above.

Performer (signature)

Pang

Date: 18 / 07 / 2029

Reviewer (signature)

Date: / /

2-3-2 Planning Evaluation Items

Before conducting this operational qualification procedure, confirm the items to be evaluated. Place a checkmark in the "Applicable" box for items to be evaluated, and "Not Applicable" for items not to be evaluated. Enter a diagonal line in the entire Pass/Fail column (from bottom left to top right) for "Not Applicable" items.

No.	Item	Outline	Applicable	Not Applicable
3-1 Test 1	LCD display	Make sure that the indications on the LCD display are correct.	☒	☐
3-1 Test 2	Level gauge	Make sure that the level of the electronic balance can be adjusted.	☒	☐
3-1 Test 3	Level adjuster	Make sure that the level adjuster functions correctly.	☒	☐
3-1 Test 4	TARE function	Make sure that the TARE function works correctly.	☒	☐
3-1 Test 5	Clock	Make sure that the date and time are set correctly on models with a clock function.	☒	☐
3-1 Test 6-1	Automatic door	Opening and closing functions are performed correctly.	☒	☐
3-1 Test 6-2	Automatic door Position memory function	Make sure that the position memory function of automatic door works correctly.	☒	☐
3-1 Test 7	Touch-less sensor	The touch-less sensor responds correctly and performs the assigned function.	☒	☐
3-2	Performance	Follow the qualification procedures and criteria if specified by the Manager. If procedures and criteria are not specified, follow inspection protocol as laid down by the Quality Assurance Department, Analytical & Measuring Instruments Division, Shimadzu Corporation, or the Shimadzu authorized distributors, and check repeatability, eccentric error and linearity in the inspection protocols laid down by the Quality Assurance Department, Analytical & Measuring Instruments Division, Shimadzu Corporation, or the Shimadzu service representatives. (Protocol document No.:)	☒	☐

We hereby approve the system configuration specified above.

Performer (signature)

[Signature]

Date: 18 / 07 / 2029

Reviewer (signature)

Date: / /

2-4 Calibration Certification and Instruments Used

The instruments used in the inspections are listed below.

When instruments controlled by the Shimadzu authorized distributor are to be used, copies of the Certificate of Traceability or the Quality Assurance sheet will be submitted.

However, if the assured performance satisfies the required specifications, calibrated instruments controlled by the customer may be used in the inspections.

☒ When prepared by Shimadzu Corporation or the Shimadzu authorized distributor

Instruments for which the traceability certificate will be submitted

Certificates of traceability are attached to the following instruments controlled by the Shimadzu service company.

* Weights

Weights that are traceable to national standards are required.

☒ Weight(s)	Article No. <u>51405267 / 2190079</u>	Certificate No. <u>G2162 / ENBPAQ</u>
☐ Weight(s)	Article No. <u>N/A</u>	Certificate No. <u>N/A</u>
☐ Weight(s)	Article No. <u>N/A</u>	Certificate No. <u>N/A</u>

☐ When the customer uses their own calibrated controlled instruments

* Weights

Weights that are traceable to national standards are required.

☐ Weight(s)	Article No. _____	Certificate No. _____
☐ Weight(s)	Article No. <u>N/A</u>	Certificate No. <u>N/A</u>
☐ Weight(s)	Article No. _____	Certificate No. _____

The instruments, tools, and other items described in sections 2.4 are approved for use in the inspections.

Performer (signature) Rmg

Date: 18 / 07 / 2019

Reviewer (signature) _____

Date: _____ / _____ / _____

3. Operational Qualification Record

Place a checkmark in the "Applicable" box for items to be evaluated, and "Not Applicable" for items not to be evaluated. Enter a diagonal line in the entire Pass/Fail column (from bottom left to top right) for "Not Applicable" items.

Here, inspection results are recorded along the procedure of section 4 in Operational Qualification Protocol.

Model Name:	AP 22
Serial No. (S/N)	0 3 1 6 3 1 0 0 3 0
ROM Ver.	

3-1 External Appearance and Functions

Test 1 LCD display

☒ Applicable ☐ Not Applicable

Item	Criteria	Results	
		Pass	Fail
LCD display	All segments must light without any missing sections.	☒	☐

Test 2 Level gauge

☒ Applicable ☐ Not Applicable

Item	Criteria	Results	
		Pass	Fail
Level gauge	The size of the air bubble must be 90% or less of the circle.	☒	☐
	The air bubble must be locatable in the center of the circle.	☒	☐

Test 3 Level adjuster

☒ Applicable ☐ Not Applicable

Item	Criteria	Results	
		Pass	Fail
Level adjuster	The level adjuster must be free of any rattling or unevenness.	☒	☐

Performer (signature) <i>Rong</i>	Date: 18 / 07 / 2020
Reviewer (signature)	Date: / /

Operational Qualification

Operational Qualification Record

Test 4 TARE function

☒ Applicable ☐ Not Applicable

Item	Criteria	Results	
TARE function	The zero display must be indicated.	Pass	Fail
		☒	☐

Test 5 Clock

☒ Applicable ☐ Not Applicable

Item	Criteria	Results	
Clock	The date and time must be correctly set.	Pass	Fail
		☒	☐

Test 6-1 Automatic door

☒ Applicable ☐ Not Applicable

Item	Criteria	Results	
Automatic door	Opening and closing functions are performed correctly.	Pass	Fail
		☒	☐

Test 6-2 Automatic door Position memory function

☒ Applicable ☐ Not Applicable

Item	Criteria	Results	
Automatic door Position memory function	Position memory function works correctly.	Pass	Fail
		☒	☐

Test 7 Touch-less sensor

☒ Applicable ☐ Not Applicable

Item	Criteria	Results	
Touch-less sensor	The touch-less sensor responds to execute the assigned function correctly.	Pass	Fail
		☒	☐

Performer (signature)

[Signature]

Date: 18 / 07 / 2019

Reviewer (signature)

Date: / /

3-2 Performance

☒ Applicable ☐ Not Applicable

Enter each control standard and the observation points of linearity in the tables on this page from the applicable inspection protocol. In the case of dual-range models, the upper and lower tables are used for the large and small ranges, respectively. In the case of models other than dual-range models, use only the upper table, and draw a diagonal line in the lower table from bottom left to top right. After inspection, enter the inspection results in the tables.

In blank columns, draw a diagonal line from bottom left to top right.

Large Range (dual-range models)					Results	
Item	Criteria			Results	Pass	Fail
Repeatability	200	±0,0005	g or less	0,0002 g	☒	☐
Eccentric error	100	±0,0005	g or less	Max. 0,0002 g	☒	☐
Linearity	No.1 (smallest) observation point	0	g ± 0,0005	g or less	0,0000 g	☒
	No.2 observation point	5	g ± 0,0005	g or less	5,0001 g	
	No.3 observation point	10	g ± 0,0005	g or less	10,0001 g	
	No.4 observation point	50	g ± 0,0005	g or less	50,0000 g	
	No.5 observation point	100	g ± 0,0005	g or less	99,9999 g	
	No.6 observation point	200	g ± 0,0005	g or less	199,9997 g	

Small Range (dual-range models)					Results	
Item	Criteria			Results	Pass	Fail
Repeatability			g or less	g	☐	☐
Eccentric error		±	g or less	Max. g	☐	☐
Linearity	No.1 (smallest) observation point	g	± g or less	g	☐	☐
	No.2 observation point	g	± g or less	g		
	No.3 observation point	g	± g or less	g		
	No.4 observation point	g	± g or less	g		
	No.5 observation point	g	± g or less	g		
	No.6 observation point	g	± g or less	g		

Performer (signature) *Rmgf*

Date: 18 / 07 / 2024

Reviewer (signature)

Date: / /

3-3 Electronic Balance Inspection Record Data

Paste the inspection record data sheet for each item in the box below in case of using the printer for inspection,

Using Printers ☒ Applicable ☐ Not Applicable

Range (Large range for multiple range) ☐ Applicable ☐ Not Applicable	Range (Small range for multiple range) ☐ Applicable ☒ Not Applicable
Repeatability 10:54:07 2024/07/18 Repeatability 11:05:54 2024/07/18 200.0003 g 200.0002 g 200.0002 g 200.0002 g 200.0002 g 200.0002 g 200.0002 g <i>Rough</i> 10 Jul 2024	Repeatability ┌
Eccentric Error Eccentric Error 11:11:06 2024/07/18 100.00004g 100.00001g 100.00016g 100.00000g 100.00020g <i>Rough</i> 10 Jul 2024	Eccentric Error ┌
Linearity Linearity 11:14:47 2024/07/18 0.00000g 5.00005g 10.00006g 50.00004g 99.99985g 199.9997 g <i>Rough</i> 10 Jul 2024	Linearity ┌
Comment ☒ None	

4. Change List

When changing or deleting the contents of this document, or adding new information to this document, record revision coed, change number, page number, reason, date, and name of the Performer in the Change List below, and obtain the approval of the Reviewer and the Manager.

Revision Code: Enter an alphabet character starting from A. Assign the same revision code to changes that are performed at the same timing.

Change No: Enter the change number assigned in sequence from 1 onwards in accordance with "1.3 Entries and Revisions". Even if the revision code is different, assign the next number for the change number without returning the change number to 1.

Page: _____ Enter the page number in which the change, deletion or addition was made.
Reason: _____

Reason: Enter the reason for the change, deletion or addition.

Date: _____ Enter the date on which the change, deletion or addition was made.

Revision Code	Change No.	Page	Reason	Date	Performer	Reviewer	Manager
							

5. Attached Documents

Attached	Item	Description		Page
☒	3-2	Electronic Balance Inspection Record	Evaluation data	16-A-
☐				

* Appended performance protocol and data shall be numbered by adding letters in sequence from A to the final page number of this document (e.g. 16-A-1/3 – A-3/3) and appended to this document after entry in the list above.

Performer (signature) *R. [Signature]*

Date: 18 / 07 / 2019

Reviewer (signature)

Date: / /

Certificate

No. 612112023

The following personnel is authorized to install and operate in
compliance with GLP/GMP (IQ/OQ)

**Instruments : LC, LCMS, GC, GCMS, TOC, UV, AA,
FTIR**

Approved on :

Issued on : December 2023 Valid until : December 2025

Name : Ruth Mega Hati

PT DITEK JAYA



PT DITEK JAYA
JAKARTA-INDONESIA

Setyawan H

Branch Manager



Certificate No. 62162/ENBPAQ
Date: November 23, 2023



Issuing Office:
Jl. Arteri Tol Cibitung No. 1, Cibitung Bekasi 17520, Indonesia
Phone/Facs: +62 21 88321176/021 88321166
Email: cs.cbt@sucofindo.co.id

CERTIFICATE OF CALIBRATION

CLIENT : PT. DITEK JAYA
ADDRESS : JL. PANJANG KEDOYA ELOK PLAZA BLOK DA/11-12-13 R
KEDOYA SELATAN - KEBON JERUK JAKARTA BARAT

NAME OF EQUIPMENT : ANAK TIMBANG

SERIAL NO. / CODE : S1905267 / 2190079

MATERIALS : STAINLESSS STEEL

WEIGHT / CLASS : (1~200) g / E2

MANUFACTURER : SHIMADZU

The Attachment available is an integral part of this certificate.

This calibration result (s) related to the sample (s) submitted only and the certificate cannot be reproduced in any way, except in full context and with the prior approval in writing from Sucofindo Laboratory.

This Certificate/report is issued under our General Terms and Conditions, copy of which is available upon request or may be accessed at www.sucofindo.co.id

CBT38012000529923

Sub Dept. Calibration

SUCOFINDO
Dedy Rahman Armen



4648873

SCI-2007A

Attachment
To Certificate No. 62162/ENBPAQ
Date: November 23, 2023



Page 2 of 2

Issuing Office:
Phone/Facs: +62 21 88321176/021 88321166
Jl. Arteri Tol Cibitung No. 1, Cibitung Bekasi 17520, Indonesia
Email: cs.cbt@sucofindo.co.id

CERTIFICATE OF CALIBRATION

TESTING CONDITION,
- TEMPERATURE : (19.4 ± 0.1) °C
- HUMIDITY : (53 ± 2) %
STANDARD & EQUIPMENT : CALIBRATED MASSES CLASS E1
Serial No. G1319257
Certificate of Calibration No. Cal. 1911/25/KAL/04/2022
: THERMOHYGROMETER
Serial No. TGH-01
Certificate of Calibration No. Cal. 009492023
The measurement is traceable to International System of Units (SI) through LK-045-IDN
CALIBRATION METHOD : PO / LAB-MS / 05
RECEIVED ON : November 7, 2023
DATE OF CALIBRATION : November 9, 2023

RESULTS :

NOMINAL	CODE	CONVENTIONAL MASS	UNCERTAINTY OF MEASUREMENT at 95% Confidence Level	k =
g		g	mg	
200	(ZD26D)	200.00023	0.058	2.00
200	(ZD25D)	200.00002	0.058	2.00
100		99.99965	0.043	1.99
50		49.99986	0.026	2.00
20	(ZD76B)	19.99982	0.020	1.99
20	(ZD75B)	19.99991	0.020	1.96
10		9.999927	0.018	2.00
5		4.999877	0.016	2.00
2	(ZD77C)	1.999962	0.011	2.00
2	(ZD76C)	1.999984	0.011	1.99
1		0.999980	0.010	2.00



2322601

SCI-2007P