



ELECTRONIC BALANCE

Operational Qualification

Operational Qualification Report

System Name Sehi Micro Analytical Balance AP-225 WD
System ID No. Timbangan 2
Installation Site Pt. Mersifarma Tirmatu Mercusana

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

• Performer

Signature Pt. DITEK JAYA
Print Robiansyah Alabuari
JAKARTA-INDONESIA

Date

11 / 06 / 2025

Title Customer Support Engineer

Certificate No.
(Shimadzu-certified Performer only) 512112023

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. 2FMD-2003 A). 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, Depok.
(Company): PT. Mersipharma Timbaku Mercusana
(Department): RnD
(Installation Site): Instrument Room
(System ID No.): Timbangan 2
(Product Model Name): AP-225 WD

Performer (signature)

Date: / /

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: Roziansyah AlanuariDate: 11 / 06 / 2025Title: Customer Support EngineerCompany name: Pt. Ditet JayaCertificate No.: 512112023Signature: [Signature]

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: _____

NA

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: _____

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

<u>Performer</u>	
Name: _____	Date: ____/____/____
Title: _____	
Company name: _____	
Signature: _____	
NA 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-225 WD	D3163100 26

We hereby approve the system configuration specified above.

Performer (signature)

[Signature]

Date: 11 / 06 / 2025

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.	☒	☐
3-2	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: 1 / 06 / 2015

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>E2/SW05267</u>	Certificate No. <u>29-10067A</u>
☐ Weight(s)	Article No. <u>NA /</u>	Certificate No. <u>NA /</u>
☐ Weight(s)	Article No. <u>0</u>	Certificate No. <u>NA</u>

☐ When the customer uses their own calibrated controlled instruments

* Weights

Weights that are traceable to national standards are required.

☐ Weight(s)	Article No. <u>NA</u>	Certificate No. <u>NA</u>
☐ Weight(s)	Article No. <u>NA</u>	Certificate No. <u>NA</u>
☐ Weight(s)	Article No. <u>NA</u>	Certificate No. <u>NA</u>

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

Performer (signature) [Signature]

Date: 11 / 06 / 2025

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-225 WD
Serial No. (S/N)	D 3 1 6 3 1 0 0 2 6
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)

2/24

Date: 11 / 06 / 2025

Reviewer (signature)

Date: / /

Test 4 TARE function

☒ Applicable ☐ Not Applicable

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

Test 5 Clock

☒ Applicable ☐ Not Applicable

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

Performer (signature)



Date: 11 / 06 / 2025

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	± 0.0010 g or less		0.0003 g	☒	☐
Eccentric error	100	± 0.0010 g or less		Max. 0.00005 g	☒	☐
Linearity	No.1 (smallest) observation point	0 g	± 0.0000 g or less	0.00000 g	☒	☐
	No.2 observation point	5 g	± 0.0005 g or less	0.00008 g		
	No.3 observation point	10 g	± 0.0005 g or less	0.00005 g		
	No.4 observation point	50 g	± 0.0005 g or less	0.00014 g		
	No.5 observation point	100 g	± 0.0010 g or less	0.00008 g		
	No.6 observation point	200 g	± 0.0010 g or less	0.00020 g		

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

Performer (signature)	<i>[Signature]</i>	Date:	11 / 06 / 2025
Reviewer (signature)		Date:	/ /

4. Change List

When changing or deleting the contents of this document, or adding new information to this document, record revision code, 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

5. Attached Documents

Attached	Item	Description		Page
☒	3-2	Electronic Balance Inspection Record	Evaluation data	16-A- 1/1
☐				

* 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)	Date: / /
Reviewer (signature)	Date: / /

* Repeatability test

14:00:35 2025/06/11

Shimadzu Corporation
Model:
S/N:
Date: 2025/06/11
Start Time: 14:01:58
Sample No. 00000001869

001: 0.000009
002: 200.0003 9
003: 200.0003 9
004: 200.0003 9
005: 200.0003 9
006: 200.0003 9
007: 200.0003 9

Date: 2025/06/11
End Time: 14:05:45

Signature:

* Eccentric test.

Shimadzu Corporation
Model:
S/N:
Date: 2025/06/11
Start Time: 14:06:47
Sample No. 00000001870

001: 100.000109
002: 100.000099
003: 100.000159
004: 100.000159
005: 100.000149
006: 100.000109

Date: 2025/06/11
End Time: 14:14:40

Signature:

* Linearity test.

Shimadzu Corporation
Model:
S/N:
Date: 2025/06/11
Start Time: 14:15:15
Sample No. 00000001871

001: 0.000009
002: 5.000009
003: 10.000059
004: 50.000149
005: 100.000009
006: 200.0002 9

Date: 2025/06/11
End Time: 14:21:09

Signature:



SERTIFIKAT KALIBRASI CALIBRATION CERTIFICATE

Nomor Seri : 24.10067A

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Page 1 of 2

IDENTITAS ALAT

Instrument Identity

Nama : ANAK TIMBANGAN
Name :
Merk Pabrik : ZWIEBEL
Manufacturer :
Tipe / Nomor Seri : E2 / S1905267
Type / Serial Number :
Kapasitas / Ketelitian : Kapasitas : 1 mg - 200 g
Capacity / Resolution : Ketelitian : -

IDENTITAS PEMILIK

Owner Identity

Nama : PT DITEK JAYA
Name :
Alamat : JL. PANJANG KEDOYA ELOK PLAZA BLOK DA/ 11-12-13 R
Address : KEDOYA SELATAN, KEBON JERUK, JAKARTA BARAT, DKI
JAKARTA

IDENTITAS STANDAR

Reference Identity

Nama : WEIGHT SET, MASS COMPARATOR
Name :
Keterelusuran : SNSU - BSN, LK-008-IDN
Traceability :

PENGESAHAN

Authorization

Pejabat : Kepala Balai Kalibrasi
Authoring Officer : Head of Calibration Laboratory
Nama : Basa Sianipar
Name :
Tanggal Pengesahan : 20 November 2024
Date of Issue :



Sertifikat ini diterbitkan melalui sistem pelayanan secara elektronik pada Direktorat Jenderal Perlindungan Konsumen dan Tertib Niaga Kementerian Perdagangan yang tidak membutuhkan cap dan tanda tangan basah.

This certificate issued by Directorate General of Consumer Protection and Trade Compliance's electronic services system. No signature or seal is required.

Sertifikat ini berlaku untuk alat dengan nama, merk dan tipe/
nomor seri yang dinyatakan diatas
This Certificate applies only for the item specified above

Sertifikat ini dilarang dipertukarkan. Sebaiknya secara lengkap dan atas
persetujuan dari Balai Kalibrasi Direktorat Standardisasi dan
Pengendalian Mutu.
This Certificate shall not be produced except in full without approval
from Calibration Laboratory Directorate of Standardization
and Quality Control

Direktorat Jenderal Perlindungan Konsumen Dan Tertib Niaga
Direktorat Standardisasi Dan Pengendalian Mutu

BALAI KALIBRASI

Jalan Raya Bogor Km 26, Cincas, Jakarta Timur 13740
Tel. 021-8703960, 8710321-3 Fax. 021-8702781

DIREKTORAT JENDERAL PERLINDUNGAN KONSUMEN DAN TERTIB NIAGA
Directorate General of Consumer Protection and Trade Order
DIREKTORAT STANDARDISASI DAN PENGENDALIAN MUTU
Directorate of Standardization and Quality Control
BALAI KALIBRASI
Calibration Laboratory

No. Seri : 24.10067 A

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NAMA ALAT : ANAK TIMBANGAN
TEMPAT KALIBRASI : LAB. KALIBRASI DIT. STANDALITU
TANGGAL DITERIMA : 04 NOVEMBER 2024
TANGGAL KALIBRASI : 20 NOVEMBER 2024
PETUGAS KALIBRASI : ALIEF SETIAWAN
SUHU RUANGAN : 20.2 ± 0.0 °C
KELEMBABAN : 56.3 ± 0.9 %RH

HASIL KALIBRASI

Nomor	Massa nominal (g)	Massa Konvensional (g)	U_{95} (mg)	Nilai k
1	1 (ZD63A)	0.999995	0.010	2
2	2 (ZD76C)	1.999995	0.013	2
3	2 (ZD77C)	2.000014	0.013	2
4	5 (H960Z)	5.000036	0.016	2
5	10 (ZC56L)	10.000094	0.020	2
6	20 (ZD76B)	20.000029	0.025	2
7	20 (ZD75B)	20.000017	0.025	2
8	50 (ZD10B)	50.00000	0.038	2
9	100 (ZD43C)	99.99984	0.054	2
10	200 (ZD26D)	200.00011	0.095	2
11	200 (ZD25D)	200.00010	0.095	2

Alat tersebut dikalibrasi dengan standar Weight Set kelas E1 111134096, tertelusur ke SI melalui SNSU - BSN dan menggunakan Mass Comparator CC 111, MCM 1005, tertelusur ke SI melalui LK - 008 - IDN.
Metode kalibrasi : IKM - 05 (OIML R - 111 - 1 - 04).

Diverifikasi Oleh : Wahyu Nurhamsah
Tanggal Verifikasi : 20 November 2024
Disetujui Oleh : Henu Lumoko
Tanggal Persetujuan : 20 November 2024

==== Akhir Sertifikat/End of Certificate ====

Certificate

No. 512112023

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 : Robiansyah Alanuari

PT DITEK JAYA



P. DITEK JAYA
JAKARTA-INDONESIA

Setyawan H
Branch Manager