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# **3200 Series Meters**

## **Installation Qualification**

## **Operation Qualification**

## **Performance Verification**

## **Reference Document**



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## 1. Introduction

### 1.1 General Information

This standard operating procedure (SOP) defines the procedure for the installation qualification, operation qualification and performance verification (IQ/OQ/PV) of Agilent 3200 series meters. This procedure provides a guideline to generate the data necessary to validate or qualify the Agilent 3200 series meters.

This SOP is applicable to all Agilent 3200 series meters that are used in a regulated lab. And this SOP can be used as a reference for customer to develop their own IQ/OQ/PV documents. It's customers' responsibility to develop and maintain the IQ/OQ/PV SOP for their specific applications.

### 1.2 Meter Information

Installation qualification and operation qualification are required for all new meters used in a regulated environment. The meters will not be released for regulated use until the installation qualification and operation qualification have been performed with passing result.

Part Number	Description	Measurement Function
G4383-64000	Agilent 3200P Benchtop pH Meter	pH,ORP
G4384-64000	Agilent 3200C Benchtop Conductivity Meter	Conductivity
G4385-64000	Agilent 3200D Benchtop Dissolved Oxygen Meter	Dissolved Oxygen
G4386-64000	Agilent 3200I Benchtop Ion Meter	ISE
G4387-64000	Agilent 3200M Benchtop Multi-Parameter Analyzer	pH, ORP, Conductivity, Dissolved Oxygen, ISE

### 1.3 Required Material

The following materials are required to perform the IQ/OQ/PV on Agilent 3200 series meters

- Short circuit plug, PN: G4383-40000, shipped with 3200P/3200M/3200I
- Conductivity diagnostic tool, PN:5185-8391, shipped with 3200C/3200M
- ATC temperature diagnostic tool, PN: 5185-8390, shipped with 3200P/3200M/3200I/3200C/3200D
- Manuals/User Guide

For 3200P/3200M with pH function:

- pH electrode or pH combination electrode or pH triode combination electrode, with BNC connector
- pH buffers

Option	Agilent Standard Solution	Part Number	Package	Shelf Life
1	pH4.001 buffer (NIST)	5190-0535	3 x 250ml	15 months
	pH7.00 buffer (NIST)	5190-0537	3 x 250ml	15 months
	pH10.01 buffer (NIST)	5190-0536	3 x 250ml	15 months
2	pH4.00 buffer (GB)	5190-0538	3 x 250ml	15 months
	pH6.86 buffer (GB)	5190-0539	3 x 250ml	15 months
	pH9.18 buffer (GB)	5190-0540	3 x 250ml	15 months
3	pH buffer package (4.01、7.00、10.01) (NIST)	5190-0533	3 x 250mL	15 months
4	pH buffer package (4.00、6.86、9.18) (GB)	5190-0533	3 x 250mL	15 months

Select one option from the list. Each option contains three standard buffers.

For 3200I/3200M with ISE function:

- Ion selective electrode (ISE) with BNC connector
- Certified ISE standards appropriate for ion selective electrode, for example, NaF for fluorion measurement with I9111 Fluoride combination ISE. Agilent don't supply ISE standards.

For 3200C with conductivity function:

- Conductivity probe with 3 pin mini DIN connector
- Certified conductivity standards appropriate for conductivity probe. Agilent don't supply conductivity standards.

For 3200D with DO function:

- Dissolved Oxygen probe with 4 pin miniDIN connector
- Zero Oxygen solution for Zero Oxygen Calibration, freshly prepared by customers.

## 1.4 Meter Keys



## 1.5 Meter Connections



### 1 Ground

### 2 Reference electrode socket

3 pH Combination electrode / ISE electrode socket BNC Connector

4 DO Probe socket 4 pin MiniDIN

5 Conductivity probe socket 3 pin MiniDIN

6 USB port

7 Power (DC 9 V, 800 mA)

All connectors on 3200M are listed above. 3200P/3200I/3200D/3200C will have fewer connectors. For example, 3200P with all these listed connectors except Conductivity 3 pin MiniDIN connector.

## 1.6 Qualification Scope

### 1.6.1 Installation Qualification

Verify and document that a system is installed according to written and pre-approved specification. Provide assurance that the system specified for a particular function was received, installation procedures were followed and the system was installed according to customer/manufacturer's specifications.

### 1.6.2 Operation Qualification

Verify and document that a system operates according to written and pre-approved specification throughout. Provide assurance that the system operates according to

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customer/manufacturer's specifications.

#### **1.6.3 Performance Verification**

Verify and document the measurement accuracy and precision according to specifications.

## **2. Installation Qualification**

### **2.1 Overview**

Before performing the IQ/OQ/PV, examine the meter for abnormal conditions such as corrosion, deterioration, loose components, broken parts and environmental conditions. Correct any of these conditions before installation.

Installation qualification of new meters includes verifying meter information, reviewing pre-installation requirements and confirming environment conditions.

### **2.2. Meter Information**

- 2.2.1 Record the start date.
- 2.2.2 Record the location of the meter.
- 2.2.3 Record the person responsible for the meter.
- 2.2.4 Describe the meter appearance.
- 2.2.5 Describe the application or purpose of the meter.

### **2.3 Environmental Conditions**

Inspect the site prior to installation and verify that all the meter operating conditions are met. Check the electrical/power supply. Inspect the equipment for abnormal conditions. Record and correct all abnormal conditions.

### **2.4 Documentation Inspection**

- 2.4.1 Obtain all manuals supplied with the meter.
- 2.4.2 Record the part number and title of theses manuals.
- 2.4.3 Check the certificate of the meter.

### **2.5 Component Check**

- 2.5.1 Give a detailed description of all meter components.
- 2.5.2 Record the information for all components including the component type, serial number and firmware version.

### **2.6 Reference Standards Information**

- 2.6.1 Record the last calibration data and calibration due date
- 2.6.2 Check the Standards shelf life

## **3 Operational Qualification**

Operation qualification of new meters demonstrates correct meter operation by verifying the

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meter self-test and pH, ORP, ISE, DO and conductivity functionality.

For detailed calibration procedures refer to the User Guide of 3200 series meters.

### **3.1 Meter Power Supply**

Check the power adapter input and output.

They should meet: Input 240 VAC, 1 A

Output 9VDC, 800mA

### **3.2 Meter Self-Test**

#### **3.2.1 Temperature test for all meters**

- Connect the ATC temperature diagnostic tool (PN:5185-8390) to the Temp. socket of meters;
- Turn on the meter to enter into measurement state.
- The meter should display a temperature reading between 49.0 to 51.0 °C.

#### **3.2.2 Check the potential (mV) value for 3200P/3200I/3200M**

- Disconnect the pH electrode.
- Connect the short circuit plug (PN:G4383-40000) to the pH socket.
- Turn on the meter.
- Start measuring pH.
- The meter should display a potential (mV) reading between -0.5 to 0.5 mV (also called mV Zero).

#### **3.2.3 Check pH value for 3200P/3200M**

- Disconnect the ATC probe if plugged.
- Set the temperature to 25 °C manually.
- Connect the short circuit plug (PN:G4383-40000) to the pH socket.
- When the potential (mV) is zero, the meter should display pH 7.00 ( $\pm 0.01$ ).

#### **3.2.4 Check pX value for 3200I/3200M**

- Disconnect the ATC probe if plugged.
- Set the temperature to 25 °C manually.
- Connect the short circuit plug (PN:G4383-40000) to the pH socket.
- When the potential (mV) is zero, the meter should display pX 2.00 ( $\pm 0.01$ ).

#### **3.2.5 Check for current Response for 3200D/3200M**

- Connect the meter with the ATC temperature diagnostic tool (PN:5185-8390) shipped with the meter.
- Turn on the meter. Enter the measurement state.
- The meter should display a current between 680 to 720 nA.
- When the diagnostic tool is unplugged, the meter should display a current from 0 to 5 nA.

#### **3.2.6 Check conductivity for 3200C/3200M**

- Disconnect the ATC temperature diagnostic tool if plugged and manually set the temperature to 25°C.
- Connect the meter with conductivity diagnostic tool (PN:5185-8391) shipped with the meter.
- Turn on the meter. Enter the measurement state.
- It will display:  
Conductivity: nearly 100  $\mu$ S/cm

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Resistance: nearly 10 kΩ·m

### 3.3 Manual Temperature Verification

- Disconnect all of the electrodes and probes from the meter.
- In the measurement mode, the temperature display should be 25.0±0.1°C

### 3.4 pH Electrode Calibration (Meters with pH function)

The calibration points should cover the expected pH range of the samples to be measured. The calibration points should be not less than 1 pH unit apart and not more than 4 pH units apart. Fresh buffers should be used for each calibration.

- Prepare the electrode and ATC probe (if necessary). Connect the electrode and ATC probe to the meter.
- Select appropriate standard solution and press **[Calibration]** key from the meter interface.
- Clean pH electrode, reference electrode (if separated) and ATC probe (if separated). Put them in the buffer to be calibrated.
- When the reading becomes stable, press **[Enter]** key and the meter will display 'Storing.....' and save calibration data.
- Repeat until all buffers are calibrated.
- After calibration, you could review the actual electrode slope, in percent. The slope must be in the range of 90% to 102%.

### 3.5 ISE Electrode Calibration (Meters with ISE function)

The calibration standards should cover the expected concentration of the samples to be measured and the calibration range should be at least ten times greater than the lowest calibration point. Control the calibration solution and sample solution at the same temperature. If not, the measuring accuracy and reproducibility will be affected. Calibrate ISE in these solutions from low concentration to high concentration. Fresh standards should be used for each calibration.

- Prepare the ISE and ATC probe (if necessary). Connect the electrode and ATC probe to the meter.
- Select ion mode and press **[Calibration]** from the meter interface.
- Clean ISE and ATC probe (if necessary). Put them in standard solutions to be calibrated in order from low to high concentration.
- When the reading becomes stable, press **[Enter]** key and the meter will display 'Storing.....' and save calibration data.
- Repeat until all buffers are calibrated.
- After calibration, you could review the actual electrode slope, in percent. The slope must be in the range of 90% to 102%.

### 3.6 DO Probe Calibration (Meters with Dissolved Oxygen function)

- Prepare the DO probe and connect it to the meter.
- You may select either 'Zero Oxygen Calibration' or 'Full Scale Calibration' from the meter interface.
- Full Scale Calibration:

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Thoroughly rinse the DO probe with DI water; Dry it with a soft tissue on the membrane surface. To calibrate with air, put the probe in a well-ventilated area.

**OR** calibrate with water saturated with air as below,

Swirl the probe at a speed of 20–80 cm/s or stir the water to produce a similar linear speed. Keep the flow speed constant during calibration. Ensure there is no air bubble trapped under the membrane.

From the initial state or while measuring, press **[Calibrate]**; Select **Full Scale**. Press **[Enter]**; when reading becomes stable, press **[Enter]** to automatically record the Full Scale response. This ends Full Scale Calibration.

- Zero Oxygen Calibration

Prepare zero-oxygen water by dissolving 12.5 g AR grade anhydrous sodium sulfite in 250 mL DI water; Soak the measuring tip in zero oxygen water and gently shake the probe to remove bubbles on the gas permeation membrane surface; From the initial state or while measuring, press **[Calibrate]**; Select **Calib Zero**; Press **[Enter]** to select Zero Point Calibration. When reading becomes stable, press **[Enter]** to automatically record the Zero Point value. This ends Zero Oxygen Calibration.

### 3.7 Conductivity Probe Calibration (Meters with Conductivity function)

#### 3.7.1 Prepare the conductivity probe and connect it to the meter.

#### 3.7.2 Calibrate the cell constant

- Prepare a standard solution (KCl) according to page 37 of 3200C User Guide.
- Ensure the meter is connected with both a conductivity probe and an ATC probe. Record the actual temperature of sample solution.
- Disconnect the ATC probe. The meter will display 25.0 °C by default. Pay attention to: If the temperature is set at 25.0 °C manually, conductivity displayed is without temperature compensation.
- Rinse the conductivity probe with distilled or DI water. Soak the conductivity probe in the standard solution.
- Press **[Calibrate]**. Select Cell Const.
- Press **[Setup]** to enter a Standard Solution Value (STD Value). You could find the proper STD value on page 39 of 3200C User Guide with the temperature recorded.
- When the reading stabilizes, press **[Enter]**. The meter will calculate and set the new cell constant. The calibration is done.

#### 3.7.3 Calibrate the TDS

- Select a proper standard solution according to the nature and conductivity range of sample.
- Set the cell constant to the value written on the probe label or recalibrate the probe to get a new cell constant in 3.7.2.
- Press **[Calibrate]** and select **TDS Factor**. Press **[Enter]** to enter Calibration mode.
- Rinse the conductivity probe with DI water.
- The temperature of the calibration solution should be  $25.0 \pm 0.1$  °C.
- Soak the conductivity probe in the standard solution.
- Press **[Setup]**.
- Enter an STD value (mg/L) given in Table 6 on page 41 of 3200 C User Guide.
- When the reading becomes stable, press **[Enter]**.

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- The meter automatically calculates and sets a new TDS factor. Calibration is done.

## 4. Performance Verification

For performance verification, evaluation of accuracy, inter-assay RSD and intra-assay RSD will consist of at least three measurement sets. Each set will measure pH of three test samples representing low, medium and high pH value. The test buffers were the same as the standard buffers. To evaluate precision of the inter-assay and the intra-assay, three measurement sets must be conducted in three different days. The acceptance criterion is bracketed in the table in appendix document.

The accuracy and the precision of pH meter should be validated. Measure three testing buffers. Each buffer is measured six times continuously. Repeat the procedure three times; each repeat should be at least 24 hours apart. Calculate intra-day and inter-day RSD%.

## 5. Appendix

### 5.1 Change history

Date	Author	Reason For Change

### 5.2 IQ - Mete Information

Start Date		Responsible Person	
Location			
Model			
Description			
Application			

### 5.3 IQ – Environmental Conditions

Environmental Conditions	Ambient
Temperature	0-40 °C
Relative Humidity	5-85%
Power Supply	Power Adaptor
Voltage	Power input: 100 to 240 VAC, 1 A Power output: 9 VDC, 1 A
Frequency	50/60 Hz

### 5.4 IQ - Component Information

Available	Not Available	Model	Firmware Version	Serial No.
<input type="checkbox"/>	<input type="checkbox"/>			
<input type="checkbox"/>	<input type="checkbox"/>			
<input type="checkbox"/>	<input type="checkbox"/>			
Checked by			Date	
Verified by			Date	

## 5.5 IQ - Documentation Inspection

Document	Provided Number	Accept Number
Vendor's Manual		
Manufacturer's Specification		
Certificate		
Conclusion		
Checked by	Date	
Verified by	Date	

## 5.6 Buffers Used in the Qualification

The standard buffers were purchased from \_\_\_\_\_.

Lot No.	pH value	Expiration Date	Remark
Performed by		Date	
Verified by		Date	

## 5.7 OQ – Meter Self-Test

Self Test \_\_\_\_\_ Passed \_\_\_\_\_ Failed

Observations: \_\_\_\_\_

## 5.8 OQ – Manual Temperature Verification

Temperature: \_\_\_\_\_ Passed \_\_\_\_\_ Failed

Specification:  $25.0 \pm 0.1$  °C

Observations: \_\_\_\_\_

## 5.9 OQ – pH Electrode Calibration

pH Electrode Calibration \_\_\_\_\_ Passed \_\_\_\_\_ Failed

pH Electrode Information (Model/Lot/Serial Number) \_\_\_\_\_

Lot No.	pH Buffer Value	Expiration Date
Calibration Result		
Slope (in percent)		

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E0		
Calibration Specification		
Performed by		Date
Verified by		Date

### 5.10 OQ – ISE Electrode Calibration

ISE Electrode Calibration \_\_\_\_\_ Passed \_\_\_\_\_ Failed

ISE Electrode Information (Model/Lot/Serial Number) \_\_\_\_\_

Lot No.	pH Buffer Value	Expiration Date
Calibration Result		
Slope (in percent)		
E0		
Calibration Specification		
Performed by		Date
Verified by		Date

### 5.11 OQ – DO Probe Calibration

DO Probe Calibration \_\_\_\_\_ Passed \_\_\_\_\_ Failed

DO Probe Information (Model/Lot/Serial Number) \_\_\_\_\_

Calibration Result		
Zero Oxygen Calibration		
Full Scale Calibration		
Calibration Specification		
Performed by		Date
Verified by		Date

### 5.12 OQ – Conductivity Probe Calibration

Conductivity Probe Calibration \_\_\_\_\_ Passed \_\_\_\_\_ Failed

Conductivity Probe Information (Model/Lot/Serial Number): \_\_\_\_\_

Lot No.	Conductivity Standard Value	Expiration Date
Calibration Result		
Cell Constant		

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TDS		
Calibration Specification		
Performed by		Date
Verified by		Date

### 5.13 PV– Accuracy and the Precision Test

Assay Date							
Criteria		pH	SD (<5%)	pH	SD (<5%)	pH	SD (<5%)
Low pH	1						
	2						
	3						
	4						
	5						
	6						
Intra-assay RSD (<5%)							
Inter-assay RSD (<10%)							
Medium pH	1						
	2						
	3						
	4						
	5						
	6						
Intra-assay RSD (<5%)							
Inter-assay RSD (<10%)							
High pH	1						
	2						
	3						
	4						
	5						
	6						
Intra-assay RSD (<5%)							
Inter-assay RSD (<10%)							
Performed by				Date			
Verified by				Date			