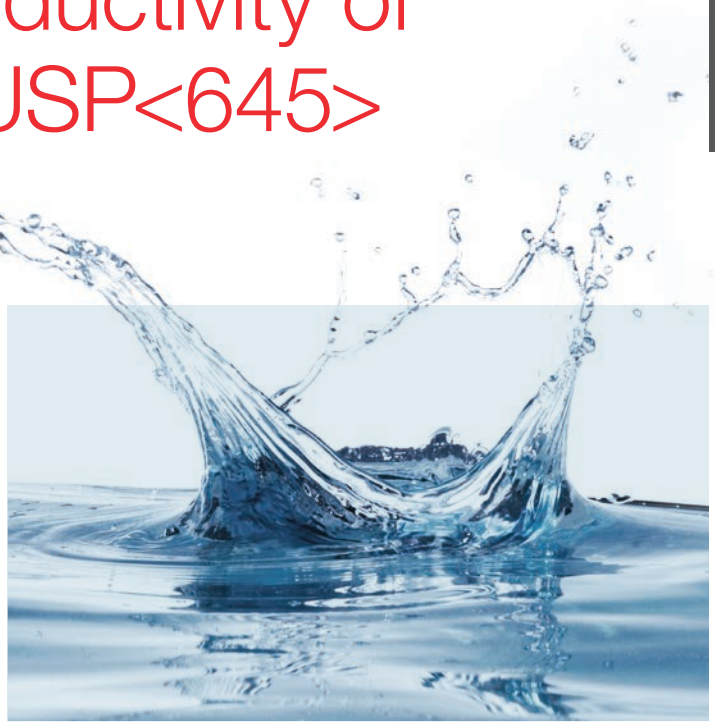
APPLICATION NOTE

Measuring the Conductivity of Pure Water Using USP<645>

Water Analysis Instruments,
Thermo Fisher Scientific



Key Words
Water conductivity, ultrapure water (UPW), USP<645>, water quality, dissolved ions, USP Purified Water (PW), Water for Injection (WFI), conductivity calibration kit, meter for conductivity.

Goal

The following application note describes the three stages of USP<645> water conductivity testing. It also includes sections on cell constraint calibration, meter calibration verification, and helpful measuring hints.

Key Markets and Industries

Pharmaceutical and biomedical, food and beverage, R&D, drinking water, consumer products, environmental.

Introduction

Water conductivity is used as a measure of purity for bulk USP Purified Water (PW) and Water for Injection (WFI) in the pharmaceutical industry. Conductivity measurements are a useful indicator of the amount of dissolved ions present in a water sample and can serve as a measure of water quality. Conductivity testing is more reliable and more convenient than the wet chemistry tests that were previously used to test for water purity.

Three stages of conductivity testing are described in USP <645>, each more involved than the last. If the requirements of Stage 1 are met, the water meets the requirements of the test. It is only necessary to proceed to the next stage, if the prior stage testing fails.
Only if the water fails all three stages is the sample judged noncompliant.

Recommended Equipment

- Thermo Scientific™ Orion™ meter for conductivity and pH (Thermo Scientific™ Orion™ Versa Star Pro™ pH and conductivity benchtop meter, catalog number VSTAR50, or equivalent Orion meter)
- Conductivity electrode (Orion 013016MD) and flow cell
- Orion pH electrode (such as Orion 8102BNUWP)
- Conductivity calibration kit for meter (Orion 1010001)
- Printer (Orion 1010006) – optional
- Thermo Scientific™ Orion™ Star Com™ or equivalent data capture software – optional (free download available with compatible Thermo Scientific™ Orion™ Star™ A and Versa Star Pro meters)
- Thermo Scientific™ Orion™ Navigator Pro™ computer software

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Required Solutions

- Stage 1 or Stage 2
  - 100 µS/cm conductivity standard (Orion 011008)
  - Deionized water (DI) of conductivity <1 – 2 µS/cm
- Stage 3
  - pH 4.01 buffer (Orion 910104)
  - pH 7.00 buffer (Orion 910107)
  - Thermo Scientific™ Orion™ ROSS™ fill solution (Orion 810007)
- Cell Constant Recalibration (if required)
  - 100 µS/cm conductivity standard (Orion 011008)
  - 1413 µS/cm (0.01 M KCl) conductivity standard (Orion 011007)
  - Deionized water (DI) of conductivity <1 – 2 µS/cm

• Stage 1 Testing •

Sample Preservation and Preparation

For Stage 1 testing, no sample preservation is necessary. If the sample will be stored, it is common to store refrigerated. No sample preparation is required for Stage 1 testing. The sample is tested at temperature without stirring, preferably as soon as possible after collection or in real-time by use of the provided flow cell.

Meter Setup

Connect the electrode onto the meter. Set measurement mode to conductivity. In Setup mode, set temperature compensation to off, conductivity cell type to USP, read type to auto, cell constant to 0.100 (nominal), and reference temperature (tREF) to 25.

Electrode Storage and Soaking

For overnight or longer, store electrodes clean and dry. Soaking in DI is acceptable between measurements. Before testing, rinse the electrode thoroughly with DI water and shake off excess water.

Electrode Setup and Calibration (Enter Calibrated Cell Constant)

The calibrated cell constant is printed on the conductivity electrode cable. In calibration mode, set the cell constant (K) to match the cell constant from the cable. The cell is now calibrated.

Calibration Verification

To verify cell constant, rinse electrode with 100 µS/cm conductivity standard and then test a fresh portion of the standard. Record the measured value and temperature.

Compare to the conductivity standard table (see Table 1 below). If results are within 2 % of expected, calibration is met. If not, see Corrective Actions, below. To verify meter calibration, refer to **Meter Calibration Verification** section of this application note (on the following page).

Analysis

Place conductivity electrode (which has been rinsed and shaken dry) into the sample bottle. Gently and briefly (e.g., 3 seconds) stir with the probe. Tap electrode, if necessary, to dislodge any bubbles. Alternately, insert the electrode into the provided flow cell and connect the flow cell to the water line to be tested. Allow the flow cell to flush with several volumes of the test water. Press “measure” and wait for the reading to stabilize. This value is automatically logged and/or printed.

Table 1: Chart of Standard Values in µS/cm at Specified Temperatures for Orion 011008

Deg C	0	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9
18	86.4	86.6	86.8	87.0	87.2	87.4	87.6	87.8	88.0	88.2
19	88.3	88.5	88.7	88.9	89.1	89.3	89.5	89.7	89.9	90.1
20	90.3	90.5	90.7	90.9	91.0	91.2	91.4	91.6	91.8	92.0
21	92.2	92.4	92.6	92.8	93.0	93.2	93.4	93.6	93.8	94.0
22	94.2	94.4	94.6	94.7	94.9	95.1	95.3	95.5	95.7	95.9
23	96.1	96.3	96.5	96.7	96.9	97.1	97.3	97.5	97.7	97.9
24	98.1	98.3	98.5	98.7	98.9	99.1	99.3	99.5	99.7	99.9
25	100.1	100.3	100.5	100.7	100.9	101.1	101.3	101.5	101.7	101.9
26	102.1	102.3	102.5	102.7	102.9	103.1	103.3	103.5	103.7	103.9
27	104.1	104.3	104.5	104.7	104.9	105.1	105.3	105.5	105.7	105.9
28	106.1	106.3	106.5	106.7	106.9	107.1	107.3	107.5	107.8	108.0
29	108.2	108.4	108.6	108.8	109.0	109.2	109.4	109.6	109.8	110.0
30	110.2	110.4	110.6	110.8	111.0	111.2	111.4	111.6	111.9	112.1

To use Table 1 (above), read down and across to the measured temperature for the standard value at that temperature.
For example, at 25.4 °C, the standard should read 100.9 µS/cm ±2 %.

Compare the measured temperature and conductivity readings to the Stage 1 values (see Table 2 below). Find the temperature value that is just lower than the measured value. If the measured conductivity is not greater than the value in the table, the water meets the requirements of the test for conductivity. If the conductivity is higher, conduct **Stage 2** testing.

Table 2: Temperature and Conductivity Requirements for USP <645>

Temperature °C	Conductivity Requirement (µS/cm)
0	0.6
5	0.8
10	0.9
15	1
20	1.1
25	1.3
30	1.4
35	1.5
40	1.7
45	1.8
50	1.9
55	2.1
60	2.2
65	2.4
70	2.5
75	2.7
80	2.7
85	2.7
90	2.7
95	2.9
100	3.1

Quality Control (QC)

Recommended QC procedures include: verification of cell constant, meter calibration checks, and temperature measurement accuracy[i].

Corrective Actions

If the calibration verification fails to meet criteria, try one or more of the following corrective actions:

1. Check the meter setup to ensure all modes are set properly.
2. Tap the cell to dislodge bubbles trapped inside.
3. Rinse thoroughly and soak the electrode in DI water for 5 minutes.
4. Rinse the electrode with a portion of the 100 µS/cm standard, then test a fresh bottle of 100 µS/cm conductivity standard.
5. Clean the electrode with warm water and alkaline detergent for 10 to 30 min with stirring, then rinse and soak as in Step 2 above, then rinse and test as in Step 3 above.
6. Only if Steps 1 thru 5 fail, recalibrate the electrode as described in the **Cell Constant Recalibration** section of this application note.

• Stage 2 Testing •

Sample Preservation and Preparation

For Stage 2 testing, no sample preservation is necessary. If the sample will be stored, it is common to store refrigerated. Place about 100 mL of sample into a clean container and stir vigorously to equilibrate with CO_2. Bring temperature to 25 ±1 °C.

Meter Setup, Electrode Setup and Calibration

Use the same meter setup, electrode setup, and calibration as Stage 1.

Calibration Verification

The calibration verification procedure is the same as in Stage 1.

Analysis

Place conductivity electrode (which has been rinsed and shaken dry) into the stirring sample. Tap electrode, if necessary, to dislodge any bubbles. Press “measure” and wait for the reading to stabilize. This value is automatically logged and/or printed.

Take measurements every 5 minutes (or set up meter to read type timed, 5 minute intervals) until the conductivity remains stable to within 0.1 µS/cm per 5 minutes and the temperature is between 24 – 26 °C.

If the measured conductivity is not >2.1 µS/cm, the water meets the requirements of the test for conductivity. If the conductivity is higher, conduct **Stage 3** testing within 5 minutes.

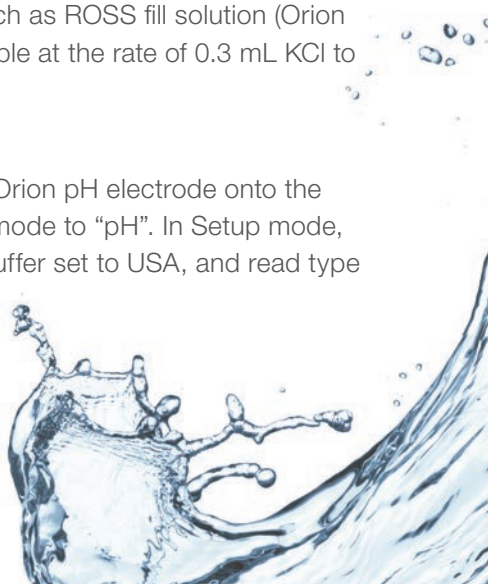
• Stage 3 Testing •

Sample Preparation

Once a sample has failed Stage 2 test requirements, Stage 3 should begin within 5 minutes. (Sample is CO_2 equilibrated and held at 25 ±1 °C in Stage 2). Add a saturated KCl solution, such as ROSS fill solution (Orion 810007) to this same sample at the rate of 0.3 mL KCl to 100 mL of sample.

Meter Setup

For Stage 3, connect the Orion pH electrode onto the meter. Set measurement mode to “pH”. In Setup mode, set pH resolution to 0.1, buffer set to USA, and read type to auto.



Electrode Storage, Soaking, and Rinsing

See electrode manual for storage 1) between measurements, 2) overnight, and 3) for long periods of time. Between measurements, rinse the electrode with DI and blot lightly.

Calibration

pH Buffers must be used at 25 ±2 °C. Perform a two point calibration using pH 4.01 and 7.00 buffers, then read back the buffers. Repeat until the observed pH values agree within 0.02 pH units of the expected values. If readings are not acceptable after a few iterations, consult the troubleshooting section of the electrode manual.

Quality Control (QC)

Recommended QC procedures include: calibration and calibration verification. See USP <791> pH for details[ii].

Analysis

Place pH electrode (which has been rinsed and lightly blotted) into the stirring sample. Press “measure” and wait for the reading to stabilize. This value is automatically logged and/or printed. Find the observed pH reading (see Table 3 below), and compare the associated conductivity value in the table to the value determined in Stage 2. If the conductivity from Stage 2 is higher than the tabulated value, or if the pH is outside the range of 5.0 to 7.0, then the water does not meet USP <645> requirements.

Table 3: pH and Conductivity Requirements for USP <645>

pH	Conductivity Requirement (µS/cm)
5.0	4.7
5.1	4.1
5.2	3.6
5.3	3.3
5.4	3.0
5.5	2.8
5.6	2.6
5.7	2.5
5.8	2.4
5.9	2.4
6.0	2.4
6.1	2.4
6.2	2.5
6.3	2.4
6.4	2.3
6.5	2.2
6.6	2.1
6.7	2.6
6.8	3.1
6.9	3.8
7.0	4.6

Cell Constant Recalibration

This section describes the process for recalibration of the conductivity cell constant.

Meter Setup

The meter setup is the same as Stage 1 and 2 testing.

Standard Preparation

No standard preparation is required for the Orion 100 µS/cm standard. The conductivity of this standard at any temperature is programmed into the meter. For preparation of the 147 µS/cm standard, dilute 1413 µS/cm (0.01 M KCl) standard 1:10 as follows:

1. All glassware must be scrupulously clean and dry.
2. Pipette 10.0 mL of 0.01 M KCl into a 100 mL volumetric flask.
3. Dilute to the mark with DI water of conductivity less than 1 – 2 µS/cm.
4. This 0.001M KCl standard has a conductivity at 25 ±0.2 °C of 147 µS/cm.

Recalibration of Cell Constant

Only if prior corrective actions have failed to bring the cell constant into ±2 % of the expected value for the standard at the measured temperature, then recalibrate the probe as follows:

1. Rinse electrode with two portions of 100 µS/cm conductivity standard.
2. Shake off excess drops.
3. Insert the probe into a brand new, freshly opened, previously unused Orion 100 µS/cm standard bottle.
4. Tap the electrode to dislodge any bubbles.
5. Recalibrate the electrode using AutoCal function (rather than entry of the cell constant, K).
6. Record the new cell constant.
7. Verify the new cell constant one time using the freshly prepared 0.001 M KCl standard.
8. Rinse a small beaker with two portions of the 0.001 M KCl standard then fill with standard.
9. Rinse the electrode with two portions of the 0.001 M KCl standard and place into the beaker.
10. Adjust the temperature of the standard to 25 ±0.2 °C using a water bath or slightly warm hot plate.
11. The standard should read 147 µS/cm ±2 % (144 to 150 µS/cm) at 25.0 °C. If not, take corrective action as detailed in Stage 1. If corrective actions fail, contact our Technical Support Specialists (see Reference section for contact information).
12. Once the new cell constant has been verified, record the new cell constant on the electrode cable.

Meter Calibration Verification

As part of USP <645>, meter calibration must be verified by replacing the conductivity cell with NIST-traceable precision resistors (accurate to ±0.1 % of the stated value). The Certificate of Analysis provided with each Orion conductivity calibration kit documents the NIST-traceability, the 0.1 % tolerance, and actual conductance values for each resistor. Meter readings must agree with actual conductance values to within ±0.1 µS/cm.

Meter Setup

The meter setup is the same as for Stage 1 and Stage 2 testing – no changes are required in setup mode. However, in calibration mode, set the cell constant to 1.000 cm^{-1}, rather than entering the cell constant from the conductivity electrode cable.

Meter Calibration

To verify meter calibration, use resistors A, B, C (nominal conductance values of 1, 10, 100 µS/cm) in the conductivity calibration kit. Plug the resistor into the meter in place of the conductivity electrode. Align the tabs on the resistor and meter and push the resistor firmly in place. (Improper alignment can damage the resistor and/or meter). Press “measure” and wait for the stable reading. Compare the displayed value to the actual conductance of the resistor, as documented on the Certificate of Analysis that comes with the kit. The displayed value should agree with the actual value within ±0.1 µS/cm.

Corrective Actions

If the calibration verification fails to meet criteria, try one or more of the following corrective actions:

1. Check the cell constant (in calibration mode) to verify that it has been set to 1.000 cm^{-1}.
2. Check the meter setup to ensure all modes are set properly, especially that the temperature compensation is off and the reference temperature is set to 25 °C.
3. Repeat the testing, pushing the resistors firmly into place and taking new measurements.
4. If the displayed readings are still out of range, contact our Technical Support Specialists (see last page).

Helpful Measuring Hints for USP <645> Water Conductivity Testing

Glassware and Equipment Cleaning

Measuring conductivity in ultrapure water is a trace analysis and best results are obtained when attention is paid to the process of cleaning and rinsing all glassware and equipment that touches the sample. Sample collection bottles should be clean and free from contaminants. The same applies to any beakers or test tubes used during testing or calibration.

Electrode Storage and Soaking

For overnight or longer, store electrodes clean and dry. Although soaking in DI is acceptable between measurements, prolonged storage in DI is not recommended, since 1) biofouling or other films can occur over time, even in clean water, and 2) the ionic pull of ultrapure water can eventually leach metals from the surface of the stainless steel probes.

Electrode Rinsing

Between measurements, rinse the conductivity electrode thoroughly with DI water and shake off excess. For best results, rinse also with a separate portion of the solution to be tested (sample or standard) before measuring the sample or standard itself.

Electrode Cleaning

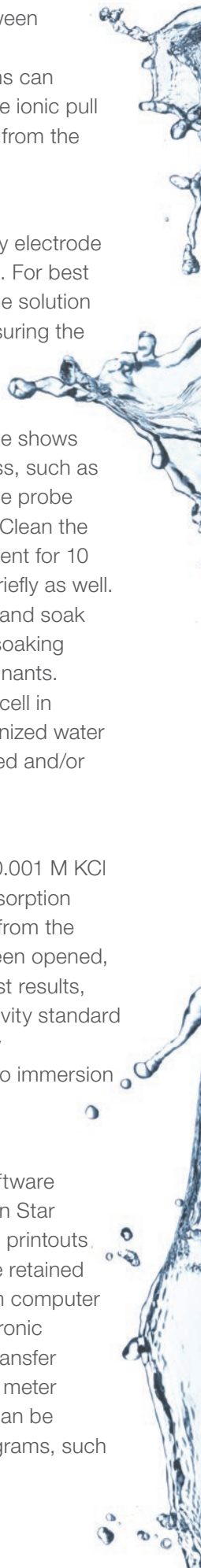
If the cell constant of the conductivity electrode shows significant drift, it is possible that some process, such as biofouling or metals leaching, has disturbed the probe surface sufficiently to affect the performance. Clean the electrode with warm water and alkaline detergent for 10 to 30 minutes. The probe may be sonicated briefly as well. After cleaning the electrode, rinse thoroughly, and soak in DI water for 5 minutes. Repeat rinsing and soaking until the electrode is clean and free of contaminants. If contaminants cannot be removed, soak the cell in 0.1 M HCl for 10 minutes, followed with a deionized water rinse. It is recommended that the cell be verified and/or recalibrated after cleaning.

Low Level Conductivity Standards

Aqueous conductivity standards of less than 0.001 M KCl (~149 µS/cm) are subject to change due to absorption of atmospheric CO_2. Protect these standards from the atmosphere. Once a bottle of standard has been opened, it should be used as soon as possible. For best results, use a new bottle of Orion 100 µS/cm conductivity standard for each calibration verification. Use previously opened bottles for rinsing the electrode prior to immersion in new standard.

Documentation of Results

Meter data may be captured to a printer or software for documentation of sample results. The Orion Star Series inkjet printer, catalog number 1010006, printouts provide a durable record of results that can be retained as hardcopies. Alternately, the Orion Star Com computer software can be used to capture data to electronic files. Orion Star Com software facilitates the transfer of measurement and calibration data from the meter to a computer. This data is easily stored and can be downloaded into spreadsheets and other programs, such as LIMS, for easy handling.



Linearity of Cell Constant

As noted above, aqueous conductivity standards of less than 0.001 M KCl are subject to change due to absorption of atmospheric CO_2 and are susceptible to contamination during handling. These are essentially trace-level standards. Although low-level conductivity standards <100 µS/cm are available from various manufacturers and are claimed to be accurate, NIST conductivity standards at levels from 5 to 25 µS/cm have listed uncertainties ranging from ±8.3 to 2.4 %. Thus low-level standards are not recommended for calibration of the cell constant, which must be known to ±2 % for USP <645>. If the conductivity electrode response is linear over the range of testing, a one-point calibration at >100 µS/cm will yield accurate results, even when measuring ultrapure water. Thermo Scientific™ Orion™ DuraProbe™ conductivity electrode response is linear over the range of testing. If calibrated at 100 µS/cm, it will read flowing ultrapure water to within 0.002 µS/cm of expected values. This demonstrates excellent accuracy over the range of measurement, well within the ±0.1 µS/cm readings required in Stage 1 and 2.

Accuracy of Low Level Conductivity Readings

This section contains a procedure and experimental data to demonstrate the accuracy of pure water conductivity measurement when using the Thermo Scientific Orion 100 µS/cm conductivity standard for calibration/verification of the Orion 013016MD stainless steel conductivity cell.

Overview

Many laboratories are monitoring the quality of pure water by measuring its conductivity. One question to consider is how to choose the appropriate standard for calibration/verification of the cell constant. There are conductivity standards available with conductivities lower than 100 µS/cm (down to 5 µS/cm) from various manufacturers. However, low-level standards are not recommended for calibration of the cell constant, which must be known to ±2 %. Due to the high uncertainties of atmospheric and container surface contamination, direct cell calibration with standard solutions below 100 µS/cm is not recommended[iii]. For example, NIST conductivity standards at levels from 5 to 25 µS/cm have listed uncertainties ranging from ±8.3 to 2.4 %. However, low-level standards are not required or recommended for calibration. When the Orion 013016MD stainless steel conductivity probe is calibrated and verified with the Orion 100 µS/cm standard, the response is accurate down to ~0.055 µS/cm (the conductivity of ultrapure water).

Meter Setup

The meter setup is the same as Stage 1 and 2 testing, except set the read type to continuous.

Electrode Setup and Calibration

The electrode setup and calibration is the same as Stage 1 and 2 testing.

Table 4: Accuracy of the Orion 013016MD Calibrated with 100 µS/cm Standard

Sample	Probe ID/ Read Time, Min.	Cell Constant	Temp	Cond Rdg (µS/cm)	Expected (µS/cm)	Delta (µS/cm)	Error
Pure Water	Probe # A/1 min.	0.093	22.5	0.046	0.0481	-0.002	<0.1 µS/cm
	Probe # A/2 min.	0.093	22.5	0.046	0.0481	-0.002	<0.1 µS/cm
	Probe # B/1 min.	0.094	22.8	0.049	0.0489	0.000	<0.1 µS/cm
	Probe # B/2 min.	0.094	22.8	0.049	0.0489	0.000	<0.1 µS/cm
100 µS/cm	Probe # A/1 min.	0.093	21.7	92.4	93.6	-1.172	-1.3%
	Probe # A/2 min.	0.093	21.8	92.5	93.8	-1.268	-1.4%
	Probe # B/1 min.	0.094	21.7	93.5	93.6	-0.100	-0.1%
	Probe # B/2 min.	0.094	21.8	93.6	93.8	-0.200	-0.2%
0.001 M KCl NIST	Probe # A/1 min.	0.093	21.3	136.1	136.7	-0.610	-0.4%
	Probe # A/2 min.	0.093	21.3	136.1	136.7	-0.200	-0.2%
	Probe # B/1 min.	0.094	21.2	136.0	136.4	-0.400	-0.3%
	Probe # B/2 min.	0.094	21.2	136.2	136.4	-0.206	-0.2%

Equation for Calculation of the Expected Ultrapure Water Readings

Coefficient	a0	a1	a2	a3	a4	a5
Pure H_20	4.45656	-7.33E-02	5.03E-04	-2.58E-06	6062E-09	7.05E-13

$$1/K = \exp (a0 + a1*T + a2*T^2 + a3*T^3 + a4*T^4 + a5*T^5)$$

Sample Preparation

Use the provided flow cell and flowing ultrapure water (UPW) with a resistivity of 18.0 Megohms-cm or more.

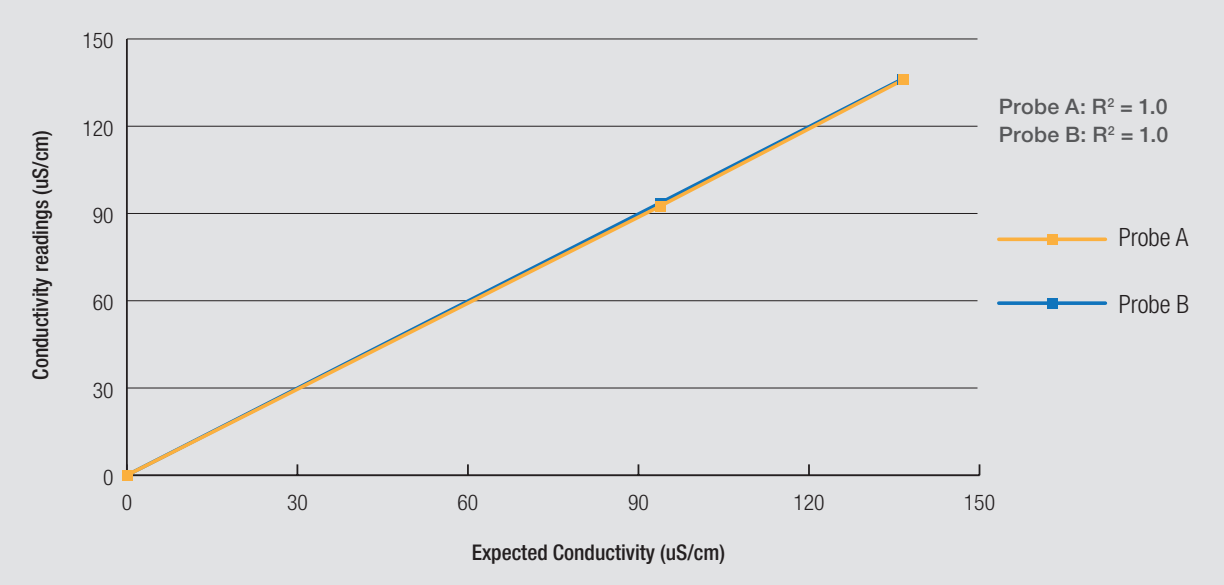
Calibration Verification

The calibration verification procedure is the same as in Stage 1 and 2 testing.

Analysis

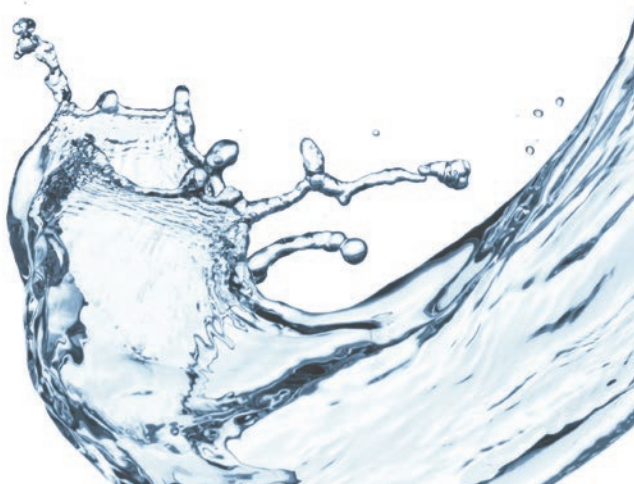
Insert the electrode into the provided flow cell and connect the flow cell to the UPW line. Allow the flow cell to flush with several volumes of the test water and ensure that there are no air bubbles in the flow cell or lines, as aeration will increase the conductivity value. Wait for the temperature and conductivity reading to stabilize. Evaluate the measurement accuracy by comparison to the expected theoretical conductivity of the UPW at that temperature (use the Equation for Calculation of the Expected UPW Readings)[iv].

Linearity of the Orion 013016MD Calibrated with 100 µS/cm Standard



Conclusions

1. Both probes read within -0.002 µS/cm or closer to the expected theoretical reading of UPW at measured temperature.
2. Probes calibrated at 100 µS/cm are accurate down to ~0.055 µS/cm (expected pure water reading at 25 °C).
3. Calibration/verification of the cell constant to 2 % is achieved by reading the Orion 100 µS/cm standard. Linearity to low levels is verified by reading UPW to 3 decimal places and by observing a correlation coefficient (R2) of >0.99. The measuring system is shown to be satisfactory for reading conductivity to ±0.1 µS/cm as required by USP <645>.



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References

i USP <645> Water Conductivity, United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, MD 20852-1790, USA. www.usp.org.

ii USP <791> pH, United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, MD 20852-1790, USA. www.usp.org.

iii "Standard Test Method for Electrical Conductivity and Resistivity of a Flowing High Purity Water Sample," ASTM D5391, www.astm.org.

iv Thornton, R.D., Morash, K.R., Light, T.S., Saunders, C.H., and Bevilacqua, A.C., "Measurement of the Resistivity of High-Purity Water at Elevated Temperatures," Ultrapure Water, Vol. 11, No. 9, December 1994, pp. 18 – 24.

For any questions or if you require assistance, contact our Technical Support Specialists:
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Within the United States, call 1-800-225-1480
Outside the United States, call +1-978-232-6000 or fax +1-978-232-6031

Visit www.thermofisher.com/water for additional information on Thermo Scientific Orion products, including laboratory and field meters, sensors and solutions for pH, ion concentration (ISE), conductivity and dissolved oxygen analysis plus spectrophotometry, colorimetry and turbidity products.

To purchase Thermo Scientific Orion conductivity meters, electrodes and other related products, please contact your local equipment distributor and reference the part numbers listed below.

Ordering Information

Product	Description	Part Number
Meters	Orion Versa Star Pro Conductivity Benchtop Meter Kit	VSTAR22
	Orion Star A212 Conductivity Benchtop Meter Ultra Pure Water Kit	STARA2126
	Orion Versa Star Pro pH and Conductivity Benchtop Meter Kit	VSTAR52
Sensors	Thermo Scientific Orion 2-Cell Conductivity Probe for Ultra Pure Water	013016MD
	Thermo Scientific Orion ROSS Ultra pH Electrode with Glass Body	8102BNUWP
	Thermo Scientific Orion ROSS Ultra pH Electrode with Epoxy Body	8156BNUWP
Accessories	Conductivity Calibration Kit for Orion Star A and Versa Star Pro Conductivity Meters	1010001
	Orion Star Series Inkjet Printer	1010006
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