A conductivity system designed to meet USP<645> for the Pharmaceutical Industry incorporating automatic Stage 1 test

- Meets USP<645> requirements — ensures compliance with pharmaceutical PW and WFI processes subject to US Pharmacopeia 24
- Fully automatic Stage 1 Test — eliminates manual interpretation of results
- Measurement of uncompensated conductivity — performs in-line test of soluble impurities
- Additional temperature output option — enables continuous record of compliance to USP<645>

- Certificated assurance of performance — guaranteed adherence to USP<645> criteria
- 2 in. Tri-clamp stainless steel cell — industry-standard ease of hygienic connection
- Portable validator — permits process samples to be verified for USP<645> compliance
Models 4623 & 4628 Conductivity Analyzers

The Models 4623 & 4628 Series Conductivity Analyzers and Model 2278 Cell have been developed specifically with the guidance of major leading pharmaceutical manufacturers to produce a system fully compliant to USP<645>.

The US Pharmacopeia has replaced off-line qualitative test of water impurities, such as chloride, with a composite in-line Stage 1 Test based on conductivity.

The Models 4623 & 4628 Series Conductivity Analyzers provide the operator interface and communications to other devices. The signal from the sensing system is converted by the analyzer and the information is presented on a large, easy-to-read, back-lit liquid crystal display (LCD). The measurement units are μS/cm.

A process retransmission signal and two alarm relay outputs are provided as standard. An optional RS485 Modbus serial interface allows the analyzer to be easily incorporated into the ABB PC30 supervisory system.

Available in a wall-mounting, or 1/4 DIN panel-mounting version, the analyzer is protected to IP66 (NEMA 4X), ensuring reliable operation in the most demanding situations. The same level of protection is maintained during programming and calibration.

Confidence in Service

To complement the well-proven design, unrivalled accuracy and reliability in service of the conductivity cell, the entire sensing loop is regularly self-monitored for short circuits and temperature element faults. The instrument includes a nonvolatile memory, eliminating the need for battery backup, and line voltage supply filtering to minimize the effects of mains-borne interference.

Automatic Stage 1 Test

Maximum acceptable impurity levels are expressed by USP<645> as uncompensated conductivity at 5°C increments. The Stage 1 test of PW and WFI requires both parameters to be checked against the set limits.

The Stage 1 conductivity/temperature limits are stored within the analyzer and can be activated on limit alarm contact A2. The alarm can be configured to initiate at a safe working distance from the Stage 1 limit. This permits assurance of operation to Stage 1 without manual intervention.

USP<645> Requirements

<table>
<thead>
<tr>
<th>Specification</th>
<th>USP Requirement</th>
<th>Models 4623 &amp; 4628 and 5999/980</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conductivity Cell Constant</td>
<td>Verified to within ±2%</td>
<td>Traceable verification to ±2% with certificate. (Normal accuracy ±1%) Re-verifiable</td>
</tr>
<tr>
<td>Resolution of Display</td>
<td>0.1μS/cm</td>
<td>0.01μS/cm</td>
</tr>
<tr>
<td>Instrument Accuracy</td>
<td>±1.0%; ±0.1μS/cm</td>
<td>Max. ±1.0% of f.s.d. Min. 0.01μS/cm to max. 0.1μS/cm Traceable verification with certificate</td>
</tr>
<tr>
<td>Temperature Compensation</td>
<td>Uncompensated</td>
<td>Uncompensated and compensated</td>
</tr>
<tr>
<td>Measurement Range</td>
<td>0.2 to 4μS/cm</td>
<td>0 to 1μS/cm to 0 to 10μS/cm Fully user configurable</td>
</tr>
</tbody>
</table>
Second Current Output
An additional current output (optional) permits both conductivity and temperature to be externally recorded as a permanent record of compliance.

Certification
To conform to USP<645>, the accuracies of the instrument display and the sensor’s cell constant are assured below specified limits. Each Model 4623/28 Analyzer and Model 2278 cell is supplied with a traceable test certificate.

Revalidation Facility
The Company provides a revalidation facility for the Model 2278 cell. The cell may be returned periodically for re-certification of the validity of the cell constant. This quick turnaround facility fulfills the stringent certification requirements of today’s pharmaceutical industry.
**Specification**

**Display**
- **Measured value**
  - 5-digit x 7-segment back-lit LCD

**Information**
- 16-character, single line, dot-matrix, back-lit LCD

**Range**
- Configurable 0 to 1μS/cm up to 0 to 10μS/cm

**Measurement units**
- μS/cm

**Accuracy**
- ±1.0% f.s.d., ±1 digit

**Linearity**
- ±0.1% f.s.d.

**Temperature measuring range**
- –10°C to 110°C (14°F to 230°F)

**Temperature compensation**
- Non-compensated (Off) or automatic –10°C to 110°C (14°F to 230°F)

**Temperature coefficient**
- Fixed at 2%/°C (2%/1.8°F) when set to compensation

**Temperature sensor**
- Pt100 resistance thermometer

**Reference temperature**
- 25°C (77°F)

**Outputs and Set Points**

**No. of relays**
- Two

**Relay contacts**
- Single pole changeover
  - Rating
    - 250V AC
    - 250V DC max.
    - 3A AC
    - 3A DC max.
    - 750VA
    - 30W max.
    - (inductive)
    - 750VA
    - 3W max.

**Insulation**
- 2kV RMS contacts to earth (ground)

**No. of set points**
- Two (2nd set point can be configured for USP<645>)

**Set point adjustment**
- Fully configurable

**Set point hysteresis**
- ±1% of set point

**Local set point annunciation**
- Red LED

**USP<645> Safety Alarm**
- Configurable 0 to –0.50 μS/cm in 0.01 μS/cm increments from USP limit

**Environmental Data**

**Operating temperature limits**
- –20°C to 55°C (~–4°F to 131°F)

**Storage temperature limits**
- –25°C to 55°C (~–13°F to 131°F)

**Operating humidity limits**
- Up to 95% RH non-condensing

**Power Supply**
- Voltage requirements
  - 100 to 130V, 200 to 260V, 50/60Hz

**Power consumption**
- < 6VA AC

**Error due to power supply variation**
- Less than 0.1% for +6% –20% variation from nominal supply voltage

**Insulation**
- Mains to earth (line to ground) 2kV RMS
Retransmission

No. of retransmission signals
One fully isolated supplied as standard
Second output optional

Output current
0 to 10mA, 0 to 20mA or 4 to 20mA programmable

Accuracy
±0.25% f.s.d. ±0.5% reading

Resolution
0.1% at 10mA, 0.05% at 20mA

Max. load resistance
750Ω (20mA max.)

Serial communication
RS485 Modbus (optional)

Mechanical Data

Model 4623
Wall mounting
Protection – IP66
Dimensions – 160mm (6.30 in.) wide x 214mm (8.43 in.) high x 68mm (2.68 in.) deep.
Weight – 2kg (4.5 lb).

Model 4628
Panel mounting
Protection – IP66 front
Dimensions – 96mm (3.78 in.) x 96mm (3.78 in.) x 191mm (7.52 in.)
Protection – IP66 front.
Panel cut-out: 92 ±0.8 mm x 92 ±0.8 mm (3.62 ±0.03 in. x 3.62 ±0.03 in.)
Weight – 1.5kg (3.25 lb)
Overall Dimensions

Model 4623 Wall-mounting Version

Model 4628 Panel-mounting Version
Electrical Connections

Model 4623 Wall-mounting Version

Model 4628 Panel-mounting Version
Model 2278 Stainless Steel Conductivity Cell
A high accuracy, traceable conductivity cell with 2 in. Tri-clamp hygienic fittings. Designed to meet the needs of the pharmaceutical industry.

- Accurate cell constant guarantees <±1% of cell constant
  - ensures accurate performance
- 2 in. Tri-clamp fitting
  - industry standard ease of hygienic connection
- Tested against traceable standards
  - assured performance
- Validation service available
  - enables on-going performance assurance
- Designed to meet USP<645> requirements

Validation of Accuracy
All ABB stainless steel cells, including the Model 2278, are guaranteed better than ±1% of stated cell constant to ensure high precision, high accuracy performance. Because of the importance attached to conductivity measurement in the pharmaceutical industry, certificates of tests against traceable standards are available.

Tested in a temperature controlled environment, using both traceable standards and traceable test equipment, the cells are supplied with documented evidence of performance.

Revalidation Service
To ensure the on-going optimum performance of the equipment, the Company offers a revalidation service, whereby in-service equipment is efficiently tested under controlled conditions and returned to site on a rapid turnaround basis.

Specifcation
**Operating range**
0 to 10μS/cm

**Cell constant**
0.05

**Cell constant accuracy**
<±1%

**Certificated accuracy**
<±2% according to USP<645>

**Type**
Insertion

**Cell body**
316 stainless steel

**Fixing details**
2 in. Tri-clamp

**Maximum pressure**
10.5 bar (150 psig)

**Maximum temperature**
110°C (230°F) constant
130°C (266°F) for short periods (sterilization)

Overall Dimensions

![Dimensions in mm (in.)](image)
Model 5999/980 Portable Conductivity Unit

The Model 5999/980 is a completely portable unit designed to allow simple validation of process waters to USP<645>. The system is a fully certificated unit comprising the Model 4623 analyzer and a Model 2278 cell, with flow chamber, all mounted and ready for use in a lightweight carrying case.

- **Portable Unit**
  - permits many process samples to be checked for USP<645> validity

- **Automatic Stage 1 Test**
  - visual confirmation of pass/fail

- **Certificated assurance of performance**
  - guaranteed adherence to USP<645>

The Model 5999/980 provides all the benefits of the Model 4623 instrument in a portable system. The unit is used close to a process tap-off point and a continuous sample is passed through the flow cell. The process temperature and uncompensated conductivity can be noted and checked for Stage and Test compliance. A visible indication of pass/fail is given by the front panel A2 alarm l.e.d. when configured for USP<645> automatic Stage 1 test.

Revalidation Service
A revalidation service is available as indicated on page 5.

Specification

**Mechanical Data**

**Model 5999/980**
- Dimensions – 370mm (14.6 in.) wide x 460mm (18.1 in.) high x 160mm (6.3 in.) deep.
- Weight – 8kg (17.6 lb).

**Integral Model 4623 Analyzer**
See specification on page 3.

**Integral Model 2278 Stainless Steel Cell**
See specification on page 6.
Schematic Layout

- **4600 Conductivity Transmitter**
- **Conductivity Cell**
- **Mains cable connected to 115/230V AC supply**
- **Conductivity Validation Unit**
- **Case**
- **Bulkhead Connector**
- **Tri-clamp**
- **Press to release connector**
- **Quick Release Connector – Sample Out**
- **Quick Release Connector – Sample In**
- **Flow Chamber**
- **To waste water drain**
- **From grab sample valve (conditioned to a safe temperature and pressure)**
- **Locking Arm**
- **4623 Conductivity Analyzers**
- **Models 4623, 4628 & 5999/980 DS/4623/28–EN Rev. I**
Ordering Information
To order a 4600 Conductivity Analyzer System select the Analyzer, Conductivity Cell and Connection Cables from the following information.

Analyzer

<table>
<thead>
<tr>
<th>USP&lt;645&gt; Models 4623 &amp; 4628 Conductivity Analyzers</th>
<th>462</th>
<th>X</th>
<th>X</th>
<th>0</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range 0 to 10μS/cm, power supply 110V/240V 50/60Hz, high and low alarms *</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Case</th>
<th>3</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wall-mounting IP66</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Panel-mounting IP66 front</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Output</th>
<th>5</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single isolated current output</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two isolated current outputs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modbus serial data interface</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Second alarm can be configured to USP<645> Automatic Alarm

Conductivity Cell
Order Model 2278/305 cell as standard for any of the above analyzers

<table>
<thead>
<tr>
<th>Stainless Steel Hygienic Conductivity Cell</th>
<th>2278 /</th>
<th>3</th>
<th>0</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cell constant</td>
<td>k = 0.05</td>
<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hygienic fitting</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 inch Tri-clamp</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Temperature compensation</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pt100</td>
<td></td>
</tr>
</tbody>
</table>

Connection Cables
Cell connection cable part no. 0233-811
Temperature compensation connection cable part no. 0233-819
(Maximum length 50m (162ft) when using cell Model 2278/305)

Portable Conductivity Unit
Model 5999/980

The 4600 Series Analyzers are so user-friendly and easy to program that they are normally supplied with standard factory settings. However, if specific programming requirements are stated at the time of ordering, units can be despatched suitably customized. Please apply to the nearest Company office for details.