

- **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



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

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 $\mu\text{S}/\text{cm}$.

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

Specification	USP Requirement	Models 4623 & 4628 and 5999/980
Conductivity Cell Constant	Verified to within $\pm 2\%$	✓ Traceable verification to $\pm 2\%$ with certificate. (Normal accuracy $\pm 1\%$) Re-verifiable
Resolution of Display	$0.1\mu\text{S}/\text{cm}$	✓ $0.01\mu\text{S}/\text{cm}$
Instrument Accuracy	$\pm 1.0\%$; $\pm 0.1\mu\text{S}/\text{cm}$	✓ Max. $\pm 1.0\%$ of f.s.d. Min. $0.01\mu\text{S}/\text{cm}$ to max. $0.1\mu\text{S}/\text{cm}$ Traceable verification with certificate
Temperature Compensation	Uncompensated	✓ Uncompensated and compensated
Measurement Range	0.2 to $4\mu\text{S}/\text{cm}$	✓ 0 to $1\mu\text{S}/\text{cm}$ to 0 to $10\mu\text{S}/\text{cm}$ Fully user configurable

Second Current Output

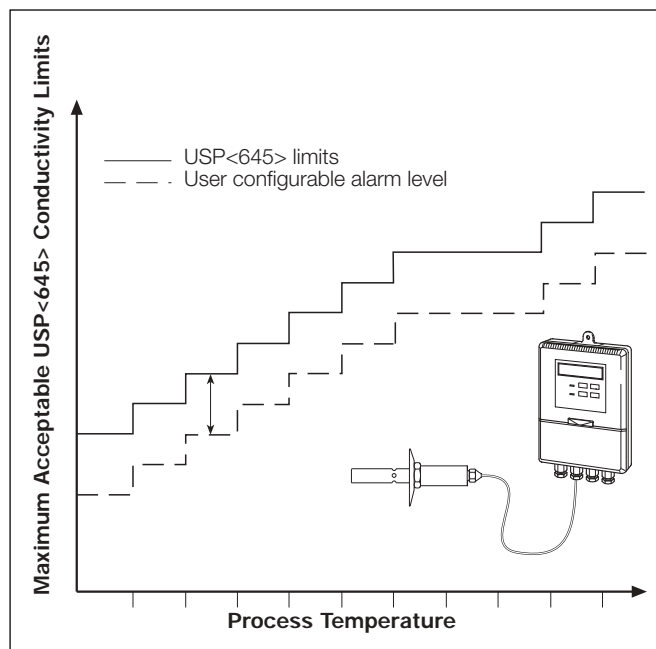
An additional current output (optional) permits both conductivity and temperature to be externally recorded as a permanent record of compliance.

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 fulfils the stringent certification requirements of today's pharmaceutical industry.



Automatic Stage 1 Test

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 1 μ S/cm up to 0 to 10 μ S/cm

Measurement units

μ S/cm

Accuracy

$\pm 1.0\%$ f.s.d., ± 1 digit

Linearity

$\pm 0.1\%$ f.s.d.

Temperature measuring range

-10°C to 110°C (14° to 230°F)

Temperature compensation

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

Temperature coefficient

Fixed at $2\%/^{\circ}\text{C}$ ($2\%/1.8^{\circ}\text{F}$) when set to compensation

Temperature sensor

Pt100 resistance thermometer

Reference temperature

25°C (77°F)

Environmental Data

Operating temperature limits

-20° to 55°C (-4° to 131°F)

Storage temperature limits

-25° to 55°C (-13° 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

Outputs and Set Points

No. of relays

Two

Relay contacts

Single pole changeover		
Rating	250V AC	250V DC max.
	3A AC	3A DC max.
Loading (non-inductive)	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

$\pm 1\%$ of set point

Local set point annunciation

Red LED

USP<645> Safety Alarm

Configurable 0 to $-0.50\mu\text{S/cm}$ in $0.01\mu\text{S/cm}$ increments from USP limit

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

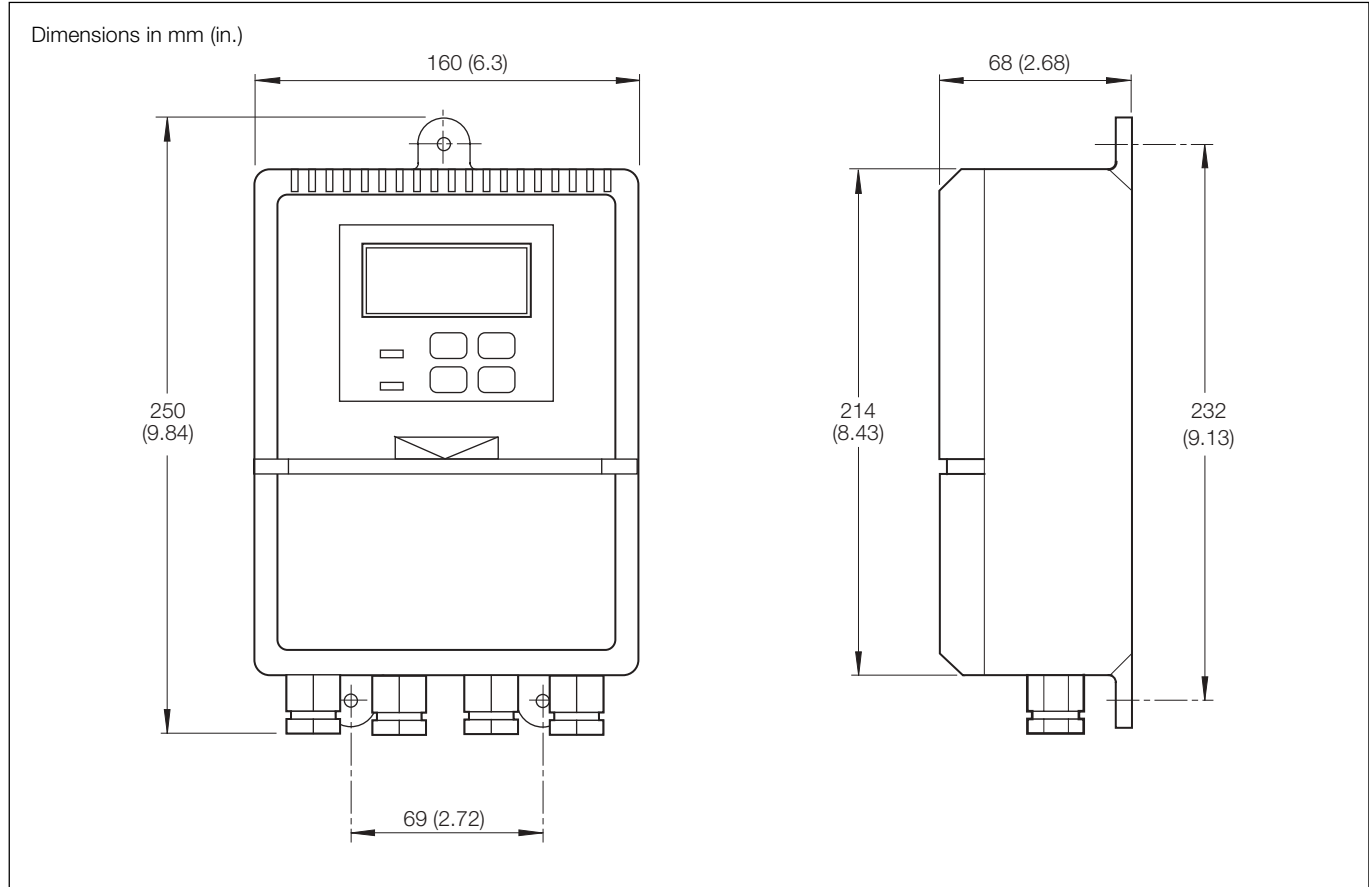
Model 4623

- 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).

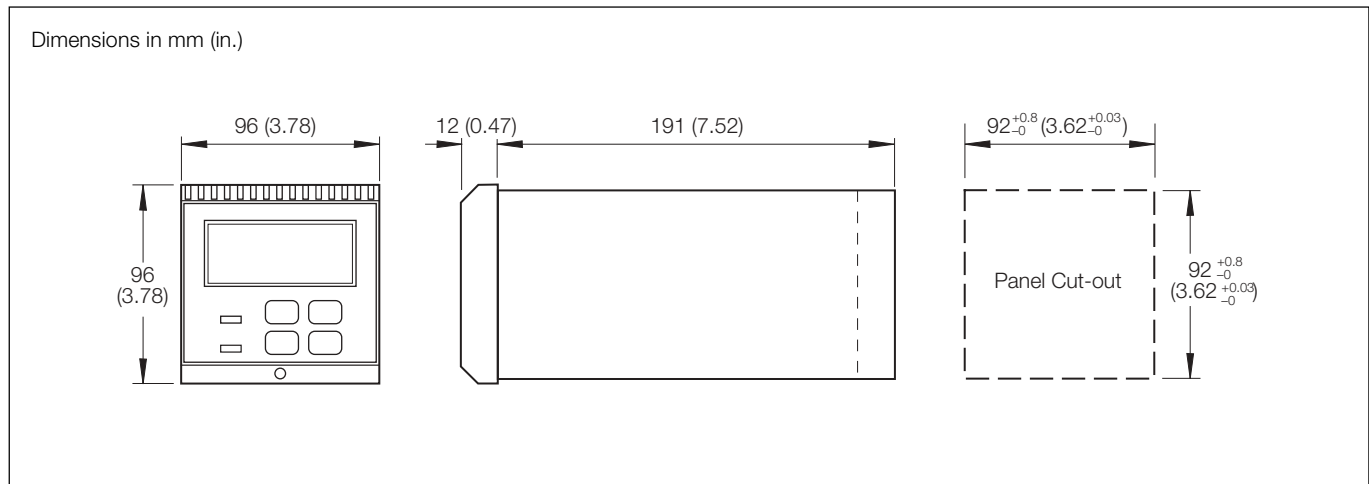
Model 4628

- 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: $92^{+0.8}_{-0}$ mm x $92^{+0.8}_{-0}$ mm
($3.62^{+0.03}_{-0}$ in. x $3.62^{+0.03}_{-0}$ in.)
- Weight – 1.5kg (3.25 lb)

Overall Dimensions

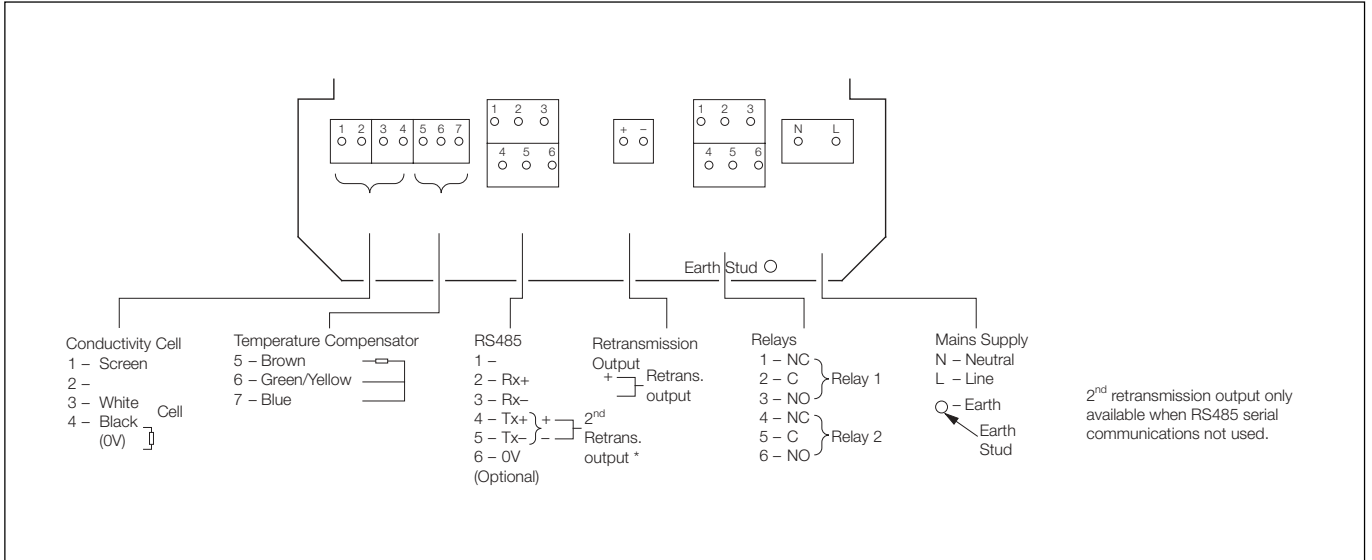


Model 4623 Wall-mounting Version

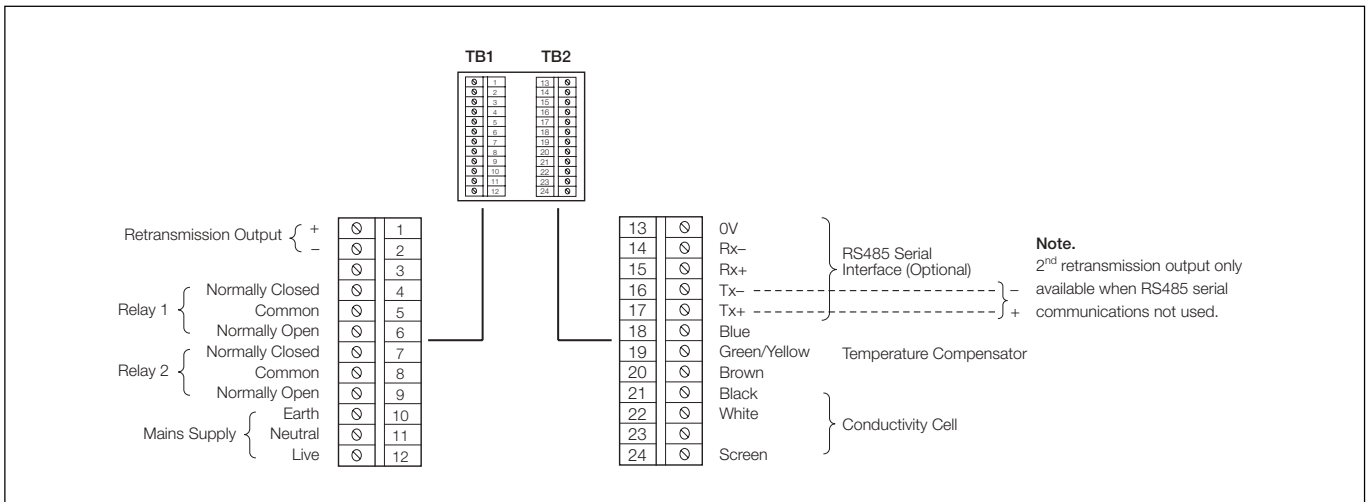


Model 4628 Panel-mounting Version

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 $<\pm 1\%$ 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 $\pm 1\%$ 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.



Model 2278 Conductivity Cell

Specification

Operating range

0 to 10 μ S/cm

Cell constant

0.05

Cell constant accuracy

$<\pm 1\%$

Certificated accuracy

$<\pm 2\%$ according to USP<645>

Type

Insertion

Cell body

316 stainless steel

Fixing details

2 in. Tri-clamp

Maximum pressure

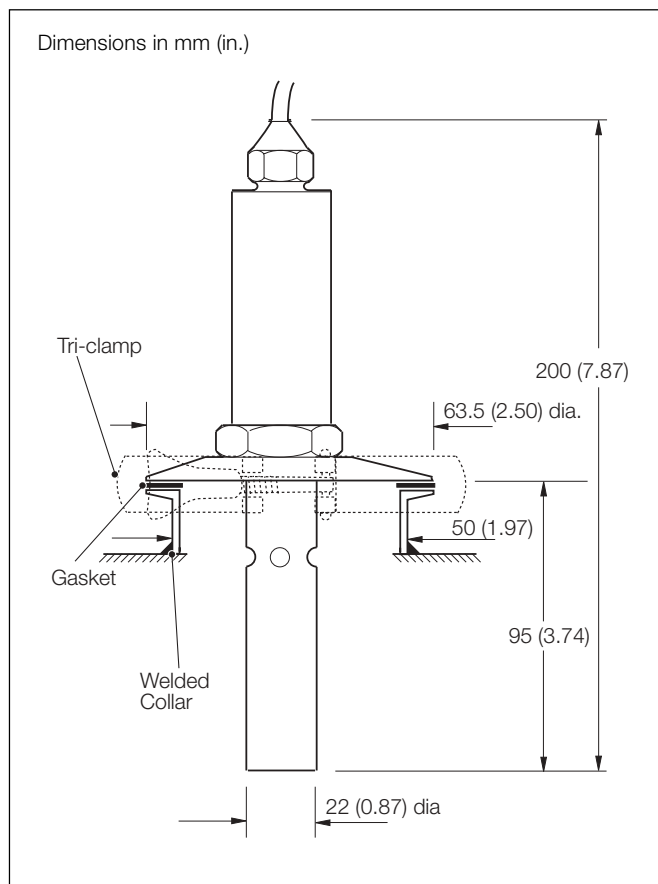
10.5 bar (150 psig)

Maximum temperature

110°C (230°F) constant

130°C (266°F) for short periods (sterilization)

Overall Dimensions



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).



Model 5999/980 Portable Conductivity Unit

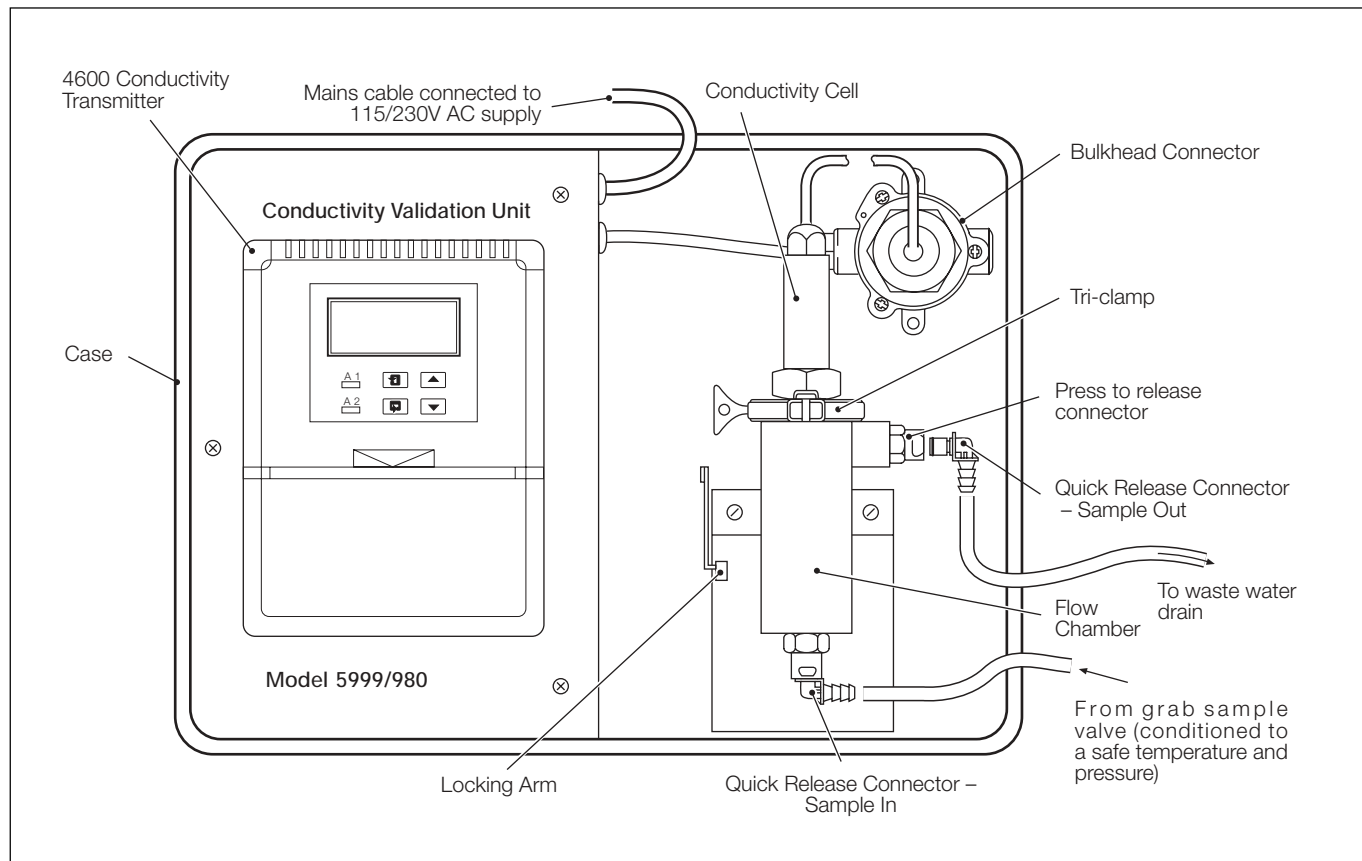
Integral Model 4623 Analyzer

See specification on page 3.

Integral Model 2278 Stainless Steel Cell

See specification on page 6.

Schematic Layout



Ordering Information

To order a 4600 Conductivity Analyzer System select the Analyzer, Conductivity Cell and Connection Cables from the following information.

Analyzer

USP<645> Models 4623 & 4628 Conductivity Analyzers Range 0 to 10µS/cm, power supply 110V/240V 50/60Hz, high and low alarms *	462	X -	X	0	0
Case					
Wall-mounting IP66		3			
Panel-mounting IP66 front		8			
Output					
Single isolated current output			5		
Two isolated current outputs			8		
Modbus serial data interface			7		

* 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

Stainless Steel Hygienic Conductivity Cell	2278 /	3	0	5
Cell constant				
k = 0.05		3		
Hygienic fitting				
2 inch Tri-clamp			0	
Temperature compensation				
Pt100				5

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.

ABB has Sales & Customer Support
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