



OM-CP-AVS140-6 Autoclave Validation Data Logging System

**INSTRUCTION
SHEET**

MQS5775/0117

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Autoclave Validation System

The OM-CP-AVS140-6 is a complete system used to perform autoclave validations. The OM-CP-AVS140-6 consists of five high temperature (OM-CP-HITEMP140) and one pressure data logger (OM-CP-PR140), an OM-CP-IFC406 Multiplexer Interface and the OMEGASOFT Secure Software providing tools to users to assist with FDA 21 CFR Part 11 compliance.

Hardware

OM-CP-HITEMP140 Product Overview

High Temperature Data Logger

The OM-CP-HITEMP140 data logger is Omega's solution for high precision, rugged temperature monitoring. It can withstand temperatures from -40 °C to 140 °C and has an accuracy of ± 0.1 °C.

The OM-CP-HITEMP140 can store up to 32,700 readings, and features a rigid external probe capable of measuring extended temperatures, up to 260 °C (500 °F). Custom probe lengths up to 7 inches are available. Also available, is the OM-CP-HITEMP140-PT that features a 24 inch flexible stainless steel probe for measuring extended temperatures up to 350 °C (662 °F). The probe is durable and can be spiraled, bent or angled in any direction, making it easy to log temperatures within bottles, vials or other hard to reach places.

OM-CP-HITEMP140 Specifications

Description	OM-CP-HITEMP140
Temperature Sensor:	100 Ω Platinum RTD
Probe Measurement Range:	OM-CP-HITEMP140: -200 °C to +260 °C (-328 °F to +500 °F) OM-CP-HITEMP140-PT: -200 °C to +350 °C (-328 °F to + 662 °F)
Temperature Resolution:	0.01 °C (0.02 °F)
Calibrated Accuracy:	± 0.1 °C/ ± 0.18 °F (20 °C to +140 °C/68 °F to +284 °F) ± 0.3 °C/ ± 0.54 °F (-20 °C to +19.99 °C/-4 °F to +67.98 °F) ± 0.4 °C/ ± 0.72 °F (-40 °C to -20.01 °C/-40 °F to -4.02 °F)
Reading Rate:	1 second up to once every 24 hours
Memory:	32,700 readings
Battery Life	1 Year Typical (1 Minute reading rate at 25 °C/77 °F)
Time Accuracy:	± 1 minute/month at 20 °C to 30 °C (68 °F to 86 °F) (Stand alone mode)
Operating Environment:	-40 °C to +140 °C (-40 °F to +284 °F), 0 %RH to 100 %RH
Dimensions (Body):	1.6 in x 0.970 in dia. (40 mm x 24.6 mm dia.)
Submersible:	Yes (IP68)
Weight:	4.2 oz (120 g)
Material:	316 Stainless Steel
Approvals:	CE



Hardware

OM-CP-PR140 Product Overview

Pressure Data Logger

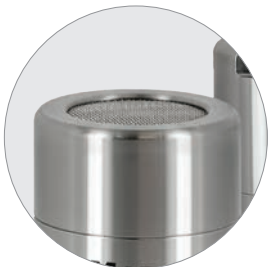
The OM-CP-PR140 is a data logger designed to validate if appropriate pressure levels have been achieved during the steam sterilization cycle. It is built with a precision stainless steel pressure gauge, the data logger has an accuracy of ± 0.03 Bar (± 0.435 PSI), which can be achieved over a wide temperature range, from 20 °C to +140 °C (68 °F to 284 °F). The OM-CP-PR140 is available in either a Flush Top or NPT Pressure Port Top design, with an optional female luer fitting accessory.



OM-CP-PR140 Specifications

Description	OM-CP-PR140
Pressure Sensor:	Semiconductor (Strain Gauge)
Pressure Range:	0 to 5 Bar (0 to 72.5 PSIA)
Pressure Resolution:	0.1m Bar (0.0015 PSIA)
Calibrated Accuracy:	± 0.03 Bar (± 0.435 PSI) (20 °C to +140 °C/68 °F to 284 °F)
Response Time:	0.1 ms (10 %FSR to 90 %FSR)
Reading Rate:	1 second up to once every 24 hours
Memory:	32,700 readings

Description	OM-CP-PR140
Time Accuracy:	± 1 minutes/month at 20 °C
Operating Environment:	-20 °C to +140 °C (-4 °F to +284 °F), 0 %RH to 100 %RH Note: The OM-CP-PR140 may be used above 60 °C for up to 8 hours, per 24 hour period.
Dimensions:	2.3 in x 1.0 in dia. (58.2 mm x 25.4 mm dia.)
Submersible:	Yes (IP68)
Weight:	3 oz (85 g)
Material:	Stainless Steel
Approvals:	CE



Flush Top



NPT Pressure Port Top



Luer Fitting



Hardware

OM-CP-IFC406 Product Overview

Multiplexer Data Logger Interface

The OM-CP-IFC406 Multiplexer Data Logger Interface allows for multiple devices to be connected into one interface. Each OM-CP-IFC406 allows for 6 data loggers to be connected. Up to 3 OM-CP-IFC406 units may be daisy-chained together to communicate with a total of 18 devices through 1 USB port. To connect multiple OM-CP-IFC406 Interfaces together, simply join the units side by side, making sure the spring pin contacts are connected and magnetically joined.



OM-CP-IFC406 Specifications

Description	OM-CP-IFC406
Operating Environment:	+10 °C to +35 °C; 0 %RH to 95 %RH non-condensing
Connection Type:	USB (to PC)
Weight:	1.65 lb (750 g)
Material:	6061 Aluminum (PTFE impregnated hard anodized coating), ABS Plastic
Dimensions:	9.5 in x 1.95 in x 1.75 in (241.3 mm x 49.5 mm x 44.5 mm)
Maximum Input Voltage:	6 Volts (V)
Approval:	CE
Battery:	This device does not use a battery

LED Indicators

Blue: Indicates unit has power.
Amber: Channel is busy or searching for a device
Green: Operation successful or complete

Dust Cover

Be sure to remove the dust cover from the spring pin contacts to ensure the devices communicate properly.



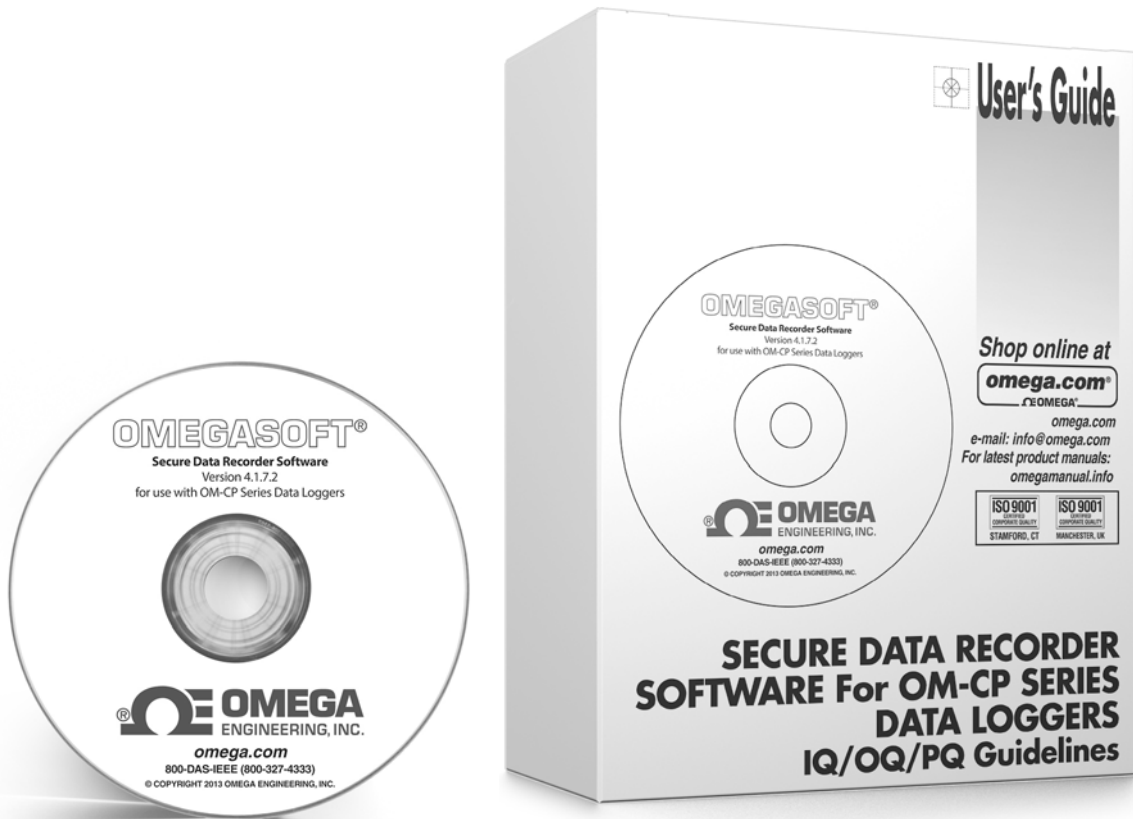
To connect multiple OM-CP-IFC406 Interfaces together, simply join the units side by side, making sure the spring pin contacts are connected and magnetically joined. An optional AC Power adapter is included, recommended for three or more daisy-chained OM-CP-IFC406 Interfaces.



Software

OMEGASOFT Secure Software

The OMEGASOFT Secure Software aids customers in compliance with 21 CFR Part 11 requirements. The software ensures standards in which electronic files are considered equivalent to paper records, saving time and effort. OMEGASOFT Secure Software contains criteria such as electronic signatures, access codes, secure data files, and an audit trail which meet the requirements of 21 CFR Part 11 and help provide data integrity.



IQ/OQ/PQ

IQ/OQ/PQ Validation Protocol

Meeting compliance with regulations for the FDAs Good Manufacturing Practices, or those set forth in Quality Plans, has become increasingly complex. Omega has simplified this process by including IQ/OQ/PQ protocols with its Omega Secure Software package.

This enormous time and money saving feature eliminates the need to develop in-house software validation procedures. The Omega IQ/OQ/PQ protocol is in support of FDA and cGMP guidelines. In addition, Omega offers a Software Validation Workbook to help the user verify the functionality of the software.

Installation Qualification (IQ)

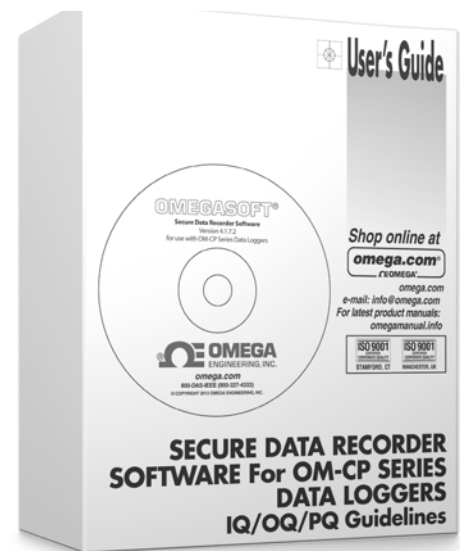
- A description of the OMEGASOFT system
- Verification that all OMEGASOFT system equipment, software and accessories are received in good condition
- A check for complete documentation
- Verification that the installation of Omega equipment is completed properly
- Verification that OMEGASOFT Secure Software is installed properly on the target workstation
- Verification of basic communication between Omega data logger(s) and the target workstation(s)

Operational Qualification (OQ)

- Functional verification of Omega data loggers
- Handling and maintenance information for the use of Omega equipment
- Omega operating procedures for primary functions
- Verification of proper communication between the Omega data logger(s) and the workstation(s)
- Verification that the data logger hardware is operational

Performance Qualification (PQ) Recommendation

- Additional handling precautions for maintaining the accuracy of Omega equipment
- Periodic maintenance information for the use of Omega equipment
- Periodic calibration verification in the field
- Comparison of the reported values to a known good standard
- Verification of acceptable performance in the target system





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WARRANTY/DISCLAIMER

OMEGA ENGINEERING, INC. warrants this unit to be free of defects in materials and workmanship for a period of **13 months** from date of purchase. OMEGA's WARRANTY adds an additional one (1) month grace period to the normal **one (1) year product warranty** to cover handling and shipping time. This ensures that OMEGA's customers receive maximum coverage on each product. If the unit malfunctions, it must be returned to the factory for evaluation. OMEGA's Customer Service Department will issue an Authorized Return (AR) number immediately upon phone or written request. Upon examination by OMEGA, if the unit is found to be defective, it will be repaired or replaced at no charge. OMEGA's WARRANTY does not apply to defects resulting from any action of the purchaser, including but not limited to mishandling, improper interfacing, operation outside of design limits, improper repair, or unauthorized modification. This WARRANTY is VOID if the unit shows evidence of having been tampered with or shows evidence of having been damaged as a result of excessive corrosion; or current, heat, moisture or vibration; improper specification; misapplication; misuse or other operating conditions outside of OMEGA's control. Components in which wear is not warranted, include but are not limited to contact points, fuses, and triacs.

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CONDITIONS: Equipment sold by OMEGA is not intended to be used, nor shall it be used: (1) as a "Basic Component" under 10 CFR 21 (NRC), used in or with any nuclear installation or activity; or (2) in medical applications or used on humans. Should any Product(s) be used in or with any nuclear installation or activity, medical application, used on humans, or misused in any way, OMEGA assumes no responsibility as set forth in our basic WARRANTY/DISCLAIMER language, and, additionally, purchaser will indemnify OMEGA and hold OMEGA harmless from any liability or damage whatsoever arising out of the use of the Product(s) in such a manner.

RETURN REQUESTS / INQUIRIES

Direct all warranty and repair requests/inquiries to the OMEGA Customer Service Department. BEFORE RETURNING ANY PRODUCT(S) TO OMEGA, PURCHASER MUST OBTAIN AN AUTHORIZED RETURN (AR) NUMBER FROM OMEGA'S CUSTOMER SERVICE DEPARTMENT (IN ORDER TO AVOID PROCESSING DELAYS). The assigned AR number should then be marked on the outside of the return package and on any correspondence.

The purchaser is responsible for shipping charges, freight, insurance and proper packaging to prevent breakage in transit.

FOR **WARRANTY** RETURNS, please have the following information available BEFORE contacting OMEGA:

1. Purchase Order number under which the product was PURCHASED,
2. Model and serial number of the product under warranty, and
3. Repair instructions and/or specific problems relative to the product.

FOR **NON-WARRANTY** REPAIRS, consult OMEGA for current repair charges. Have the following information available BEFORE contacting OMEGA:

1. Purchase Order number to cover the COST of the repair,
2. Model and serial number of the product, and
3. Repair instructions and/or specific problems relative to the product.

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