DS1922F

Digital Sterilization Monitor for Autoclave Applications

General Description

The DS1922F* is a complete solution for real-time digital indication and data recordkeeping for autoclave sterilizers.

The device is a precision, electronic-based solution designed to monitor and record the applied temperature profile during an autoclave sterilization cycle. The DS1922F, when placed inside an autoclave, measures and logs temperature by recording data into the device memory. Once the sterilization cycle is complete, the DS1922F is simply removed from the sterilization chamber and docked into the USB reader accessory to download the captured data to a PC. Companion software then displays the temperature measurements, indicates whether the sterilization cycle was successful, and keeps a record of the data to satisfy regulatory and liability requirements.

DS1922F Autoclave Sterilization Logger



*FDA and CE certifications pending.

Benefits and Features

- Verifies Autoclave Sterilization Time and Temperature
- Automatically Measures and Stores Temperature and Time Readings
- If the Cycle Fails, Indicates at What Time the Failure Occurred
- If the Cycle Fails, Indicates the Failure Reason and Maximum Temperature Reached by Autoclave
- · Withstands Harsh Autoclave Sterilization Cycles
- Simplifies Recordkeeping by Eliminating Paper Log Books and Printouts
 - Programmable Operation and Results Uploading Using Companion PC Software
 - PC Software Securely Prevents Tampering, Modification, or Addition of Spurious Records
- Precalibrated and Easy to Use
 - · Precalibrated to NIST Traceable References
 - Compatible with Any Steam-Sterilization Autoclave Cycle Duration with Temperature Up to +140°C
 - · Typically 150 Uses Before Replacement
- Supplement to Biological Indicators
 - Use the DS1922F as an Instant Proxy Indicator While Waiting on Spore Test Results

DS1922F Docked in USB Reader Accessory





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Absolute Maximum Ratings

Operating Temperature Range+15°C to +140°C Storage Temperature Range-25°C to +140°C

Stresses beyond those listed under "Absolute Maximum Ratings" may cause permanent damage to the device. These are stress ratings only, and functional operation of the device at these or any other conditions beyond those indicated in the operational sections of the specifications is not implied. Exposure to absolute maximum rating conditions for extended periods may affect device reliability.

Electrical Characteristics

(Limits are 100% tested at $T_A = +25^{\circ}$ C. Limits over the operating temperature range are guaranteed by design and characterization.)

PARAMETER	SYMBOL	CONDITIONS	MIN	TYP	MAX	UNITS
Autoclave Cycle Endurance	N _{CY}	Cycle = ramp from +25°C to +135°C and back to +25°C, total cycle duration = 20 minutes		150		cycles
Operating Temperature	T _A		15		140	°C
Temperature Accuracy	T _{ERR}	+115°C < T < +140°C		±1%		°C
Weight				17		g
Diameter				25		mm
Height				23		mm

Note: Not for use outside of autoclave steam sterilizer applications. This product has not been tested to work with other types of sterilizers including, but not limited to, chemiclaves or steam sterilizers that operate over 140°C and 2atm. As the product does not record humidity or pressure, the user shall periodically assure that the autoclave is running properly and in accordance with regulatory or trade group guidelines by using recommended tests that measure temperature, time, humidity, and pressure. Per each sterilizer cycle, the user shall assure that redundant, or other primary, methods of testing and determining the compliance of the sterilization cycle are implanted to mitigate risk. Data-logger products are 100% tested and calibrated at time of manufacture by Maxim to ensure that they meet all data sheet parameters, including temperature accuracy. User shall be responsible for proper use and storage of this product.

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Detailed Description

The DS1922F is ruggedized monitor that is designed to measure and log temperature in an autoclave chamber during a steam-sterilization cycle. It is specifically designed to withstand and operate in high temperature, pressure, and steam during a sterilizer cycle. After configuring with separate PC software, the DS1922F is ready to monitor a sterilization cycle and record data. The DS1922F does not record the temperature data if it has not been configured prior to running a sterilization cycle.

To set up the DS1922F and accessories for initial use as well as complete instructions for use, refer to the separate document *Instructions for Use*. The following is an abbreviated process for using the DS1922F:

- Configuring: The DS1922F is placed into its PC-connected USB reader accessory. The PC software prompts the user to enter the parameters for the specific type of sterilization cycle to monitor and record.
- Placement in autoclave: The DS1922F is placed into the sterilization chamber along with other instruments to be sterilized.
- 3. After the sterilization cycle is complete, the DS1922F is placed into its USB reader accessory to download the captured temperature data. The PC software graphically displays the recorded time versus temperature data with other relevant information including whether the sterilization was successful. The cycle data is automatically saved in a database for long term record keeping.

If a cycle fails due to temperature, then the companion PC software indicates at what point in the cycle the failure occurred. Once the measured results are downloaded to the PC, the data is automatically saved by the PC software. For regulatory reasons or liability reasons, it may be

necessary to provide proof of sterilization data. This total solution with the DS1922F, USB reader accessory, and software enables long term record keeping of the cycle data through use of a database. Paper log books and printouts are no longer needed, yet the proof of sterilization cycle data is available in the event of an audit.

The DS1922F is set up for use at the Maxim factory and is calibrated/validated against NIST traceable reference devices. End users do not have to perform professional installation or calibration.

Maxim provides a complete solution for DS1922F use. A USB reader accessory is available for sale separately; see the <u>Companion Products</u> section for the part numbers of the accessories. Maxim also offers a PC software utility to operate the DS1922F and to display, print, and store data from autoclave sterilization cycles. Each DS1922F is factory programmed with a unique and unalterable serial number that is used to electronically identify the device and provide strong use-traceability using the PC software. For every cycle record downloaded to the PC software database, the serial number of the corresponding DS1922F is always included.

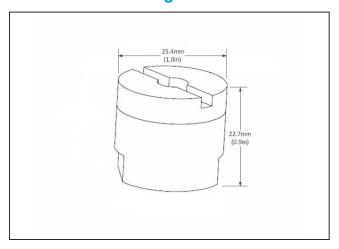
Certifications and Compliance

The following is a comprehensive list of the certifications and industry regulations to which the DS1922F adheres:

- UL 913, 5th Ed. Rev. 1997-02-24; Intrinsically Safe Apparatus: Approved Under Entity Concept for Use in Class I, Division 1, Group A, B, C, and D Locations
- RoHS compliance
- Calibrated/validated against NIST traceable reference devices

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Dimensions Drawing



Ordering Information

PART	DESCRIPTION
DS1922F#	Autoclave high temp logger

#Denotes RoHS compliant.

Companion Products

PART	DESCRIPTION
DS9490R#	USB to 1-Wire/iButton Adapter
DS1402-RC3+	Reader for DS1922F

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Revision History

REVISION NUMBER	REVISION DATE	DESCRIPTION	PAGES CHANGED
0	12/14	Initial release	_
1	1/15	Revised content	1–4
2	6/15	Updated temperature accuracy condition	2

For pricing, delivery, and ordering information, please contact Maxim Direct at 1-888-629-4642, or visit Maxim Integrated's website at www.maximintegrated.com.

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