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TOP 5 CAUSES OF STEAM STERILIZATION FAILURE

AUTOCLAVE VALIDATION: ONE DEVICE CAN SOLVE THE PROBLEM

THE SIMPLICITY OF STEAM STERILIZATION

In This Issue

Distributor Highlight

WessexPower

LS Technology©

A loyal distributor for more than 15 years, **Wessex Power Technology** is a premier supplier of monitoring instrumentations located in the United Kingdom. Established in 1979, Wessex Power specializes in the supply and calibration of GxP compliant solutions, mapping and monitoring in storage areas, distribution, laboratories and appliances. Wessex is dedicated to selling a variety of MadgeTech loggers to meet the needs of several industries, applications, and customers.

Features

Products

Connections

Services

MADGETECH
WE BUILD DATA LOGGERS

MadgeTech has set the standard for excellence and is proudly known as the industry expert and leading manufacturer of data loggers on the market today. MadgeTech performs all data logger engineering, manufacturing and servicing in the USA — with products sold in more than 100 countries worldwide.

Top 5 Causes of Steam Sterilization Failure

Autoclaves are valuable tools that benefit a wide range of industries. In healthcare settings, autoclaves protect patients by eliminating pathogens from tools and equipment. In the laboratory, autoclaves provide scientists with assurance that they have eliminated biological factors that may interfere with their results. In manufacturing facilities, autoclaves are used in a variety of innovative ways to create new products and materials such as aerated concrete.

When autoclaves don't work properly, however, they're not benefiting anybody. Here are some of the most common reasons that steam autoclave sterilization cycles fail:

Choosing the Wrong Cycle for Autoclave Contents

Nobody wants to hear that they're the problem, but human error is at the root of many cases of sterilization failure.

While a steam autoclave can process a variety of different objects, not all materials can be sterilized in the same manner. For example, if you are sterilizing wrapped medical tools using your autoclave's gravity cycle, sterilizing steam may not be reaching every part of your instruments.

If you experience a sterilization failure, begin by looking back at where you started and consider if you chose the correct cycle for the autoclave's contents. You can learn more about which sterilization cycles are appropriate for different materials by checking out our "What Kind of Autoclave Cycle Do I Need for My Work?" post at **madgetech.com**.

Inappropriate Packing or Loading

While some objects, such as large glassware, may go into the autoclave completely uncovered, many smaller objects must be packed or wrapped prior to sterilization. Wrapping ensures that sterilizing steam reaches all materials in an even manner.

When a packet of materials is not wrapped correctly, though, it may interfere with your autoclave's ability to sterilize. This is another example of how human error may be interfering with your sterilization cycle.

Additionally, when loading the autoclave chamber, technicians should place materials based on the equipment manufacturer's guidance. If your autoclave is not loaded the way the manufacturer intended, it may not work properly.

Proper wrapping and loading protocols should be part of training for medical and dental assistants, sterilization engineers, laboratory technicians or any other professionals who may be responsible for preparing materials to be placed into an autoclave.

Poor Steam Quality

If you're seeing wet packets and materials after a sterilization cycle, your autoclave may be suffering from poor steam quality.

Low steam quality can be created by a variety of factors. If the "weight" (water content) of the steam is outside of desired parameters, it may interfere with the autoclave's ability to function as designed. Superheated steam—steam heated above the point at which all liquid has vaporized—is also considered low quality for sterilization.

To understand your steam production, it's important to have a clear picture of both temperature and pressure within the autoclave chamber. Measurement devices, such as data loggers, are useful in creating these profiles.

Vacuum Failure

If you're sterilizing small, porous or irregularly-shaped materials, you need to be using a vacuum sterilization cycle. In a vacuum cycle, all air is forcibly removed from the autoclave during preconditioning. This allows sterilizing steam to reach every nook and cranny of your contents.

If your autoclave is not able to create adequate vacuum conditions, your sterilization cycle will fail. The most straightforward way to learn if you have a vacuum failure is to use a Bowie-Dick test. The Bowie-Dick test is a specialized test sheet that uses steam and air barriers to validate that your autoclave is producing the proper vacuum environment for steam production and sterilization.

Continued on page 11…

Product Spotlight

AVS140-6
Autoclave Validation System

Conducting temperature mapping studies and validating autoclave cycles has never been easier! The **AVS140-6** has all the tools needed to ensure continuous consistency and proper operation, while assisting with 21 CFR Part 11 compliance.

The AVS kit includes (Standard Package):

- (5) HiTemp140 High Temperature Data Loggers with 1 inch probe, all with Calibration Certificates
- (1) PR140 Pressure Data Logger with Calibration Certificate
- IFC406 Multiplexer interface
- MadgeTech Secure Data Logger Software, with IQ/OQ/PQ validation protocols and workbook
- Aluminum Storage Briefcase

The HiTemp140 high precision, temperature data logger can withstand temperatures up to 140 °C with an accuracy of ±0.1 °C. To assist with validation, the PR140 pressure 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.

The AVS140-6 can be custom configured with any combination of HiTemp140 data loggers with a wide variety of probe lengths to choose from.

Product Guide

Temperature and Pressure

HiTemp 140 Rigid
Rigid Probe

Robust
Submersible in enviroments between -40 and +140°C up to 5 bar pressure

Accurate
0.1°C between 20°C and +140°C. Supported with calibration certificate and internal electronic record

Easy to use
Self contained operation with optical interface and user friendly software. 21 CFR Part 11 compliance and GxP documentation available.

HiTemp 140 PT
Bendable Probe

Adaptable
A durable probe that can be spiraled, bent or angled in any direction, making it easy to use in hard to reach places.

Accurate
±0.1 °C (20 °C to +140 °C)
±0.3 °C (-20 °C to +19.99 °C)
±0.4 °C (-40 °C to -20.01 °C)

Easy to use
Self contained operation with optical interface and user friendly software. 21 CFR Part 11 compliance and GxP documentation available.

HiTemp 140 X2
Dual Probe

Dual configuration
Dual probe with rigid, mineral insulated and flexible temperature probe configurations with +/- 0.1°C accuracy

Selection of ranges
[TD] Rigid Probe: -200 °C to +260°C
[PT] Bendable Probe: -200 °C to +350°C
[FP] Flexible Probe: -60 °C to +260°C

Easy to use
Self contained operation with optical interface and user friendly software. 21 CFR Part 11 compliance and GxP documentation available.

HiTemp 140 FP
Flexible Probe

Narrow and lightweight
Ideal for placement within small vials, tubing, test tube and other small diameter or delicate applications.

Accurate
0.1°C between -60°C and +260°C. Supported with calibration certificate and internal electronic record

Easy to use
Self contained operation with optical interface and user friendly software. 21 CFR Part 11 compliance and GxP documentation available.

Product Guide

Temperature and Pressure

PR 140
Pressure Datalogger

Robust
IP68 submersible at temperatures from +20 to +140°C

Accurate
Record 0 to 5Bar pressure with calibrated accuracy of +0.003 Bar

Easy to use
Self contained operation with optical interface and user friendly software. 21 CFR Part 11 compliance and GxP documentation available

Interface and software

IFC406
Multi-logger Interface

Rapid
Configuration and data extraction from 140 and 1000 series data loggers

Intuitive LED
Individual port light system shows you the status of your action

Scalable
Connect multiple IFC406 to manage multiple 140 and 100 series data loggers

IFC400
Logger Interface

Rapid Communication
Optical > USB interface for setting up and downloading 140 and 1000 series IP68 data loggers

MT4 compatible
Enables batch configuration then graphical, statistical and tabular analysis

LED
Power and connection status reporting via integral lights.

Product Guide

Accesories

Vented Shield
Thermal Protection

Time-Temperature protection
Temporarily extends the operating range of a HiTemp140 data logger to -200 ~ +250°C

Vented shield
Offers protection to exposed probes when travelling through a process

Simple installation
Screw thread enables the rapid deployment and removal of installed data logger.

Mag Mount
Temporary Mounting Point

Magnetic mount
Suitable for mapping, validation studies

316 stainless steel
Durable, built to last.

Compatible
Use with dataloggers HiTemp140, PR140, PRTemp140, Temp1000EX-/RHTemp1000EX

Flush Shield
Thermal Protection

Time-Temperature protection
Temporarily extends the operating range of a HiTemp140 data logger to -200 ~ +250°C

Fast response
Fully exposed probes react faster to temperature changes

Simple installation
Screw thread enables the rapid deployment and removal of installed data logger.

Multi-mount Z
Anchoring Mounting Point

Versatile mount
Suitable for mounting on any flat surface even inside an autoclave at 150°C

316 stainless steel
Durable, built to last.

Compatible
Use with dataloggers HiTemp140, PR140, PRTemp140, Temp1000EX-/RHTemp1000EX

Product Guide

Packages

HiTemp 140 DHS
DRY Heat Sterilisation

Includes thermal shield
ThermoVault MAX temporarily extends the operating range to -200 ~ +400°C

Includes HiTemp 140-M12
Data logger with interchangeable M12 probe, rapid recording rate includes calibration certificate

Supplied with M12 probe
36" glass braided RTD depyrogenation probe with flat tip

AVS140 1
Autoclave Validation System

USB Interface
Supplied with IFC400 single data logger reader station.

Supplied with...
1x Calibrated HiTemp140-1 data logger inc. ISO17025 certificate

21 CFR Validated Software
Supplied with MadgeTech Secure Data Logger Software, IQ/OQ/PQ Validation Protocols and Workbook.

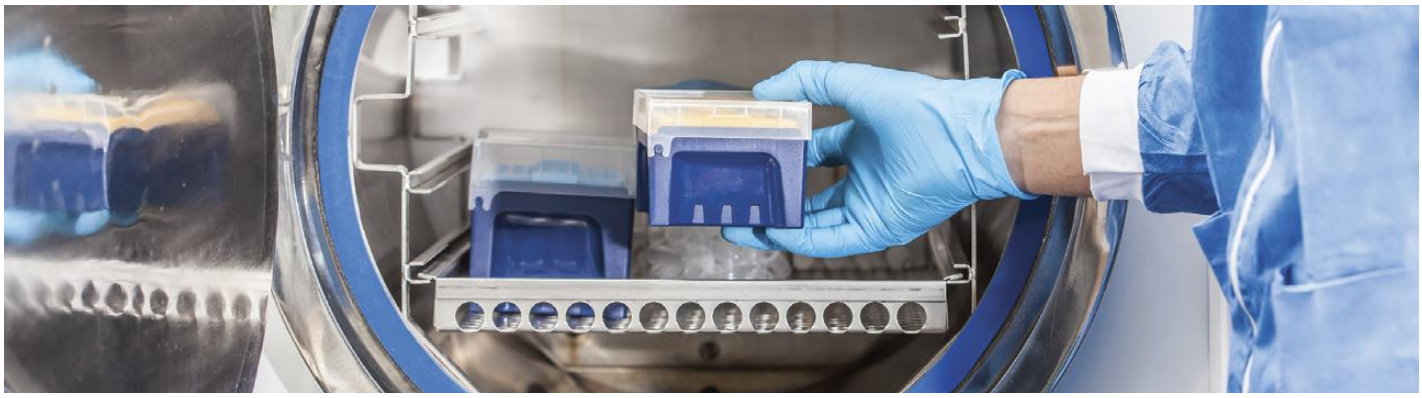
AVS140 6
Autoclave Validation System

USB Interface
Supplied with IFC400 single data logger reader station.

Supplied with...
5x Calibrated HiTemp140-1 and 1x Calibrated PR140 data loggers inc. ISO17025 certificate

21 CFR Validated Software
Supplied with MadgeTech Secure Data Logger Software, IQ/OQ/PQ Validation Protocols and Workbook.

Promedica Turns to Madgetech for Autoclave Validation



Background

Founded in 1987 and based in Oldsmar, Florida, Promedica is a leading designer and manufacturer of custom, high value medical carts, consoles and assemblies. With products ranging in level of complexity and FDA classifications, Promedica has attracted some of the largest medical device companies in the world as customers.

Challenge

As with any medical application, it is of the utmost importance to ensure that devices and equipment have been properly sterilized. Promedica uses an autoclave for steam sterilization and were interested in using data loggers to validate that the autoclave is compliant with industry standards.

The autoclave records and prints a summary of each load, however, there's no guarantee the results are correct. Validating that temperature and pressure thresholds are being met within the autoclave chamber provides confirmation that contaminated items are in fact being properly sterilized.

Solution

Using MadgeTech's AVS140-6 Autoclave Validation System, Promedica can obtain a complete profile of the autoclave to ensure it's operating as intended. Included in the AVS140-6 are five HiTemp140 high temperature data loggers, as well as one PR140 pressure data logger.

The HiTemp140 can withstand temperatures up to 284 °F, which is needed to ensure the autoclave chamber reaches 270 °F for four minutes during the sterilization cycle. The PR140 was designed for high temperature applications and applies during the drying phase when pressure is used to draw out moisture from the item(s).

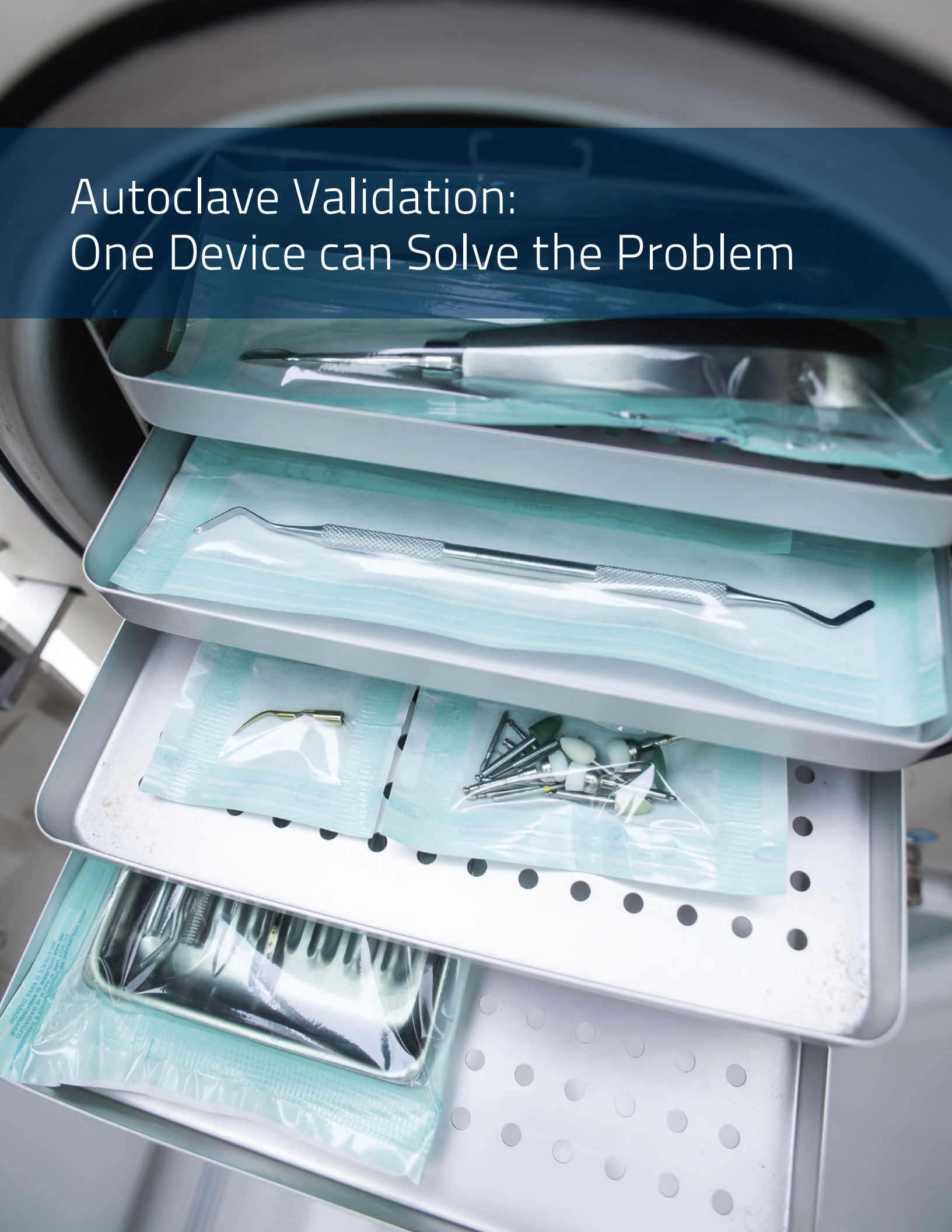
By using the AVS140-6, Promedica can analyze the data in the MadgeTech 4 Secure Software. The software even meets the criteria to assist with 21 CFR Part 11 compliance. Promedica was impressed with the ease of use of the AVS140-6 as well as the software. They say they can now easily view the data and compare it to the autoclave findings.

For more information on data loggers used in autoclave validation, contact us today at info@madgetech.com.

For more information on the AVS140 Autoclave Validation System or to find the right data logging solution for your needs, contact us today at **sales@wpls.co.uk**

Since this case study, Promedica was acquired by TouchPoint Medical.

Autoclave Validation:
One Device can Solve the Problem



Picture you're in a laboratory and notice there's an autoclave. You slowly approach the device when suddenly it flashes, "CAUTION: HIGH TEMPERATURES". It can't be that hot, right? Then, you lean a bit closer, only to discover the temperature logger reading 135 degrees Celsius! While 135 °C may seem absurdly hot, autoclaves are in fact built to withstand these scorching temperatures for several reasons.

One of the autoclaves most relevant purpose includes sterilization validation. This is necessary to ensure the accuracy of the sterilization process. The autoclave utilizes steam heat in order to kill any potential bacteria on certain goods that could present contamination into a sensitive environment such as hospitals, laboratories, or food facilities.

To kill the bacteria, the temperature of the autoclave must be adjusted to the point where the bacteria can break down and evaporate. Therefore, autoclaves are set to very high temperatures. To ensure the instruments or goods are sterile, the autoclave process and temperatures must be monitored very closely.

Data loggers can play a significant role in monitoring the autoclave validation and sterilization process. For example, the HiTemp140 data logger is a stainless steel submersible device that can withstand temperatures up to 140°C, or 284 °F. Once the sterilization cycle is complete, just connect the logger to a computer and the data will load onto MadgeTech's free software, which will allow you to view all the reading and even create reports.

The HiTemp140 is sold individually or as a Validation Data Logging System which includes an interface cable, licensed software corresponding with the logger, and a calibration certificate.

To learn more about the sterilization and validation process, visit **wessexpower.co.uk** or call +44 (0)1929 459 459

Top 5 Causes of Steam Sterilization Failure continued…

Inadequate Temperatures

Steam sterilization simply doesn't work without high temperatures. The specific temperature at which you will be sterilizing will depend on a variety of factors such as the materials you're sterilizing, the nature of your work and good manufacturing or laboratory practices.

Temperatures within the autoclave can be double-checked or validated using a temperature data logger or similar device. If your autoclave isn't reaching 100 °C, it can't produce steam at all! If it's not reaching 121 °C, it isn't reaching the threshold required for sterilization.

Create a study of autoclave temperatures throughout your sterilization cycle to determine if you're reaching adequate conditions for sterilization.

Whether it's human error or equipment malfunction, sterilization failures can cost businesses and laboratories valuable time and money. To keep this from happening to you, make sure you have an autoclave validation plan in place and train any autoclave users in proper preparation and use of the device.

The Simplicity of Steam Sterilization

Despite the many sterilization methods available today, steam sterilization continues to rise as a top choice because of its simple yet effective decontamination method. Through the use of an autoclave, this process involves four parameters: steam, pressure, temperature and time. A successful cycle directly exposes the contaminated items to steam at the required temperature and pressure for the specified time.

Steam sterilization is typically carried by using a high-pressure chamber, known as an autoclave. Once the chamber is sealed, steam is pumped into the top and sides of the chamber, forcing the air out. Steam is then pumped into the chamber at a higher pressure than normal to create temperatures ranging between 121 °C (250 °F) to 132 °C (270 °F) to kill microorganisms. According to the CDC, for the sterilization of wrapped healthcare instruments, these temperatures must be maintained anywhere from 4 to 30 minutes depending on the type of autoclave. Sterilization occurs when the saturated steam touches the instrument causing a condensation and immediate transfer of heat.

Time and temperature are important factors in the process, but pressure is the driving force behind it. Without the presence of pressure, steam would not be able to reach the high temperatures necessary to destroy harmful pathogens. Standard temperature and pressures values include 121 °C at 15 psi and 132 °C at 27 psi.

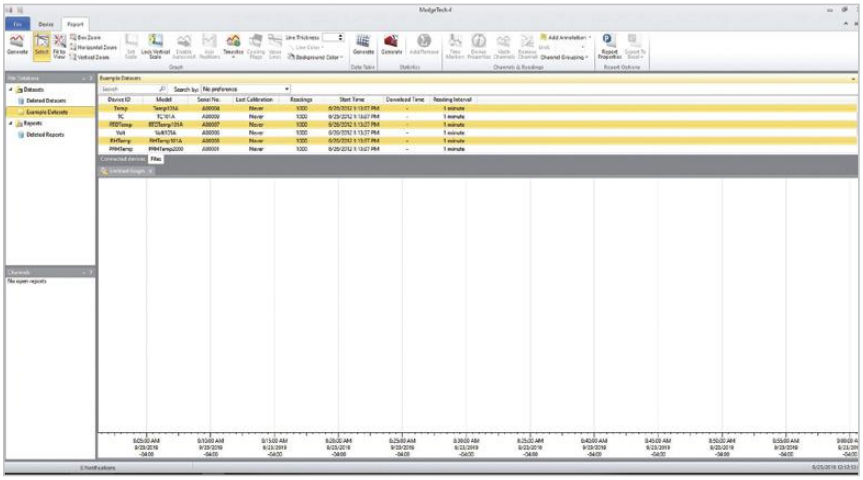
Data loggers are often used to monitor, record and validate each sterilization cycle. With the capability to withstand temperatures up to 140 °C and high-pressure environments, MadgeTech data loggers offer an easy way to ensure accuracy and safety. A MadgeTech top-seller, the Autoclave Validation System, provides users with the tools needed not only to perform autoclave validations, but also create reports to assist with the 21 CFR Part II requirements.

To check out the complete line of data loggers for a variety of sterilization methods, **wessexpower.co.uk** or call +44 (0)1929 459 459

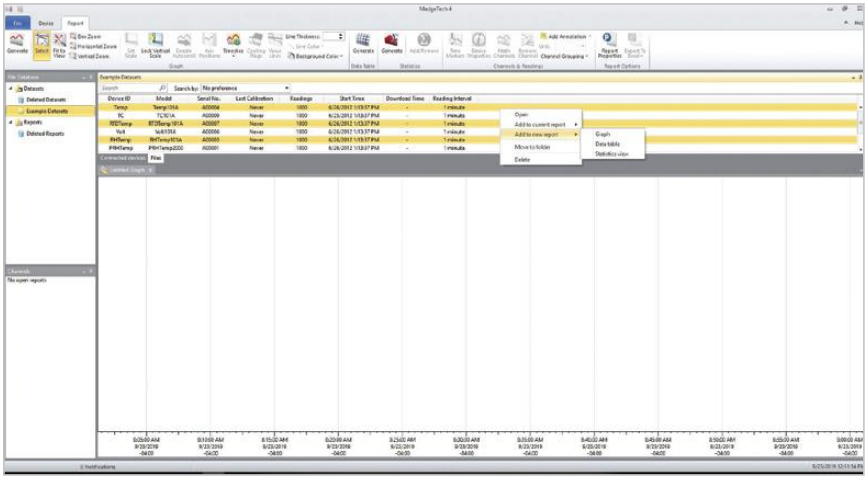
Can I combine the data from all my loggers into a single report?

Yes !

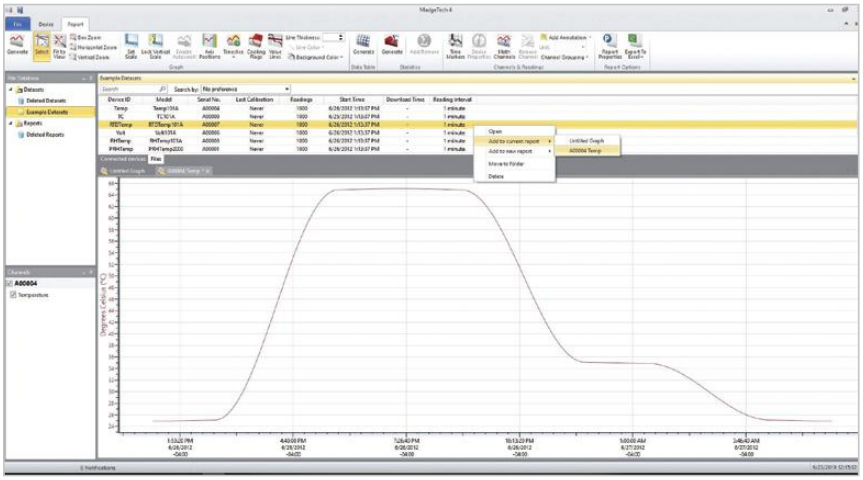
The **MadgeTech 4 software** allows users to easily create reports that include datasets from multiple loggers. If the loggers are downloaded simultaneously, then a composite report of all of the downloaded data will be generated automatically.



It is also easy to combine datasets into reports after the fact. Simply find the datasets within the Datasets folder of the File Database. Highlight the datasets desired, then right-click and select **Add** to new report and select the report type (Graph, Data Table, Statistics View).



Alternatively, right click and select **Add** to current report and select an open report to add the dataset(s).



IQ/OQ/PQ

Let us do the dirty work

On-site IQ/OQ/PQ services

IQ INSTALLATION QUALIFICATION

We make sure our data loggers meet required specifications and are installed correctly.

OQ OPERATIONAL QUALIFICATION

We get your data logging system up and running according to process parameters and assess worst-case scenarios.

PQ PERFORMANCE QUALIFICATION

We put our loggers to the test to ensure proper performance and provide a comprehensive qualification report upon completion.

MadgeTech Cloud Services

Access Data Instantly and Securely from Anywhere in the World

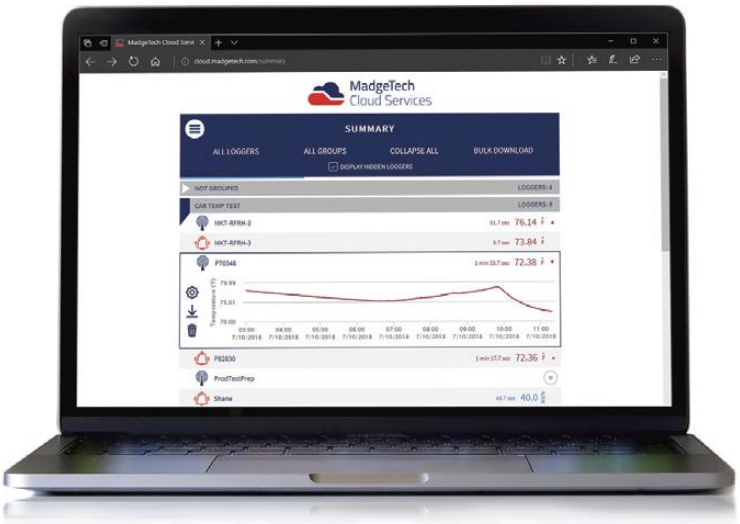
The **MadgeTech Cloud** is compatible with all MadgeTech wireless data loggers, providing users with instant access to real-time data from any location. With the MadgeTech Cloud, data loggers can securely transmit data to be viewed on any Internet enabled device such as a computer, tablet or smartphone.

Quick and Easy Setup

View Data From Anywhere

Access Data Instantly

Email and Text Notifications



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