Autoclave Validation

TOP FIVE TIPS

Time and Money Saving Validation Strategies

1 Create & Maintain Clear Validation Protocols

2 Begin Your Regimen with a Bowie-Dick Test

3 Use Autoclave-Friendly Data Loggers

4 Use Devices with Report Generating Software

5 Combine Heat Distribution & Penetration Study

MADGETECH
WE BUILD DATA LOGGERS

1 CREATE & MAINTAIN CLEAR VALIDATION PROTOCOLS

If you purchase an autoclave for laboratory, medical or industrial use, regulators will require you to submit a master validation plan before putting it into use. If you work in an industry where this is not the case, creating validation protocols for in-house use is still a must.

Clear, repeatable validation protocols are the first line of defense when it comes to autoclave validation.

Be sure to develop a plan that answers at least these three questions:

Who is responsible for validating your autoclave?

An in-house equipment engineer? A compliance officer? Any user?

How often will you validate?

Monthly? Weekly? Have you consulted your autoclave manufacturer about recommended hours of use between each validation cycle?

What are your qualifications?

What temperatures do you need to reach? Which biological indicators are you using to validate?

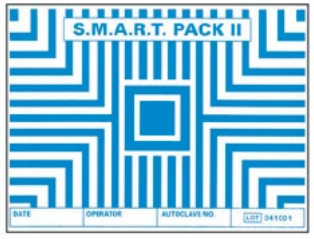
2 BEGIN YOUR REGIMEN WITH A BOWIE-DICK TEST

The Bowie-Dick test should always be one of the first, if not the first, steps in your autoclave validation protocol.

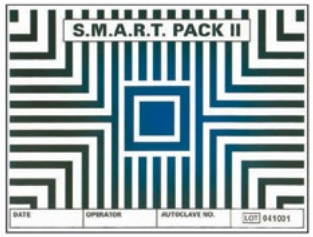
The Bowie-Dick test demonstrates the autoclave's ability to successfully remove air. In addition to being part of a regular validation protocol, many sterilization experts recommend starting each day of autoclave use with a Bowie-Dick test.

The simple test requires placing a specialized sheet covered in air and steam barriers and containing chemical sterilization indicators inside the autoclave and subjecting it to a normal cycle. When the test is complete, the appearance of the sheet will clearly tell users whether or not a proper vacuum was achieved for sterilization.

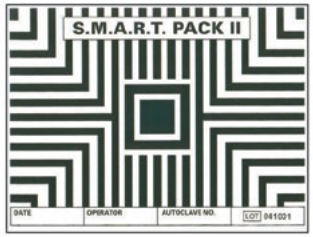
Putting this step at the top of your protocol can potentially save you wasted time. If your autoclave fails the Bowie-Dick test, you have either a vacuum or steam production issue which you must resolve before moving any farther. Contact your autoclave's manufacturer or a maintenance engineer for guidance on fixing the machine.



New Test Paper
(all blue)



Failed Test Result
(half blue/half black)



Passed Test Result
(all black)

3 USE AUTOCLAVE-FRIENDLY DATA LOGGERS

If you're threading thermocouple wires into your autoclave, stop right now!

Verification of high temperature is crucial to validating your sterilization cycles, but traditional thermometers and measurement devices can't do the job nearly as well as a set of data loggers.

Placing leads and wires can interfere with the seals needed to guarantee your autoclave works as designed. Wrangling wiring and getting probes into position also adds considerable time to the task of validation, which means more time your autoclave is unusable.

A data logger designed for autoclave validation should be small and able to withstand the temperatures and pressures of sterilization. Data loggers don't just measure temperatures, they simulate the journey of your autoclaved items from contamination to sterility.

These devices are often packaged together as an Autoclave Validation System, which contains both temperature and pressure sensors to provide second-by-second readings of conditions within your chamber. Such a kit will also make autoclave chamber mapping a snap, as data loggers can be placed by hand within the chamber to provide true temperature readings for every nook and cranny within the machine.

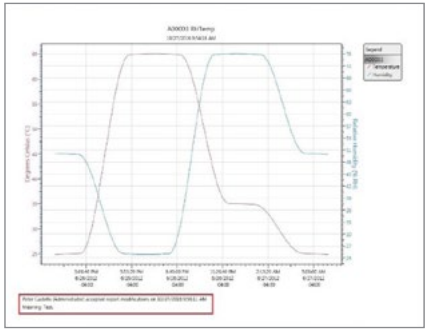
4 USE DEVICES WITH REPORT GENERATING SOFTWARE

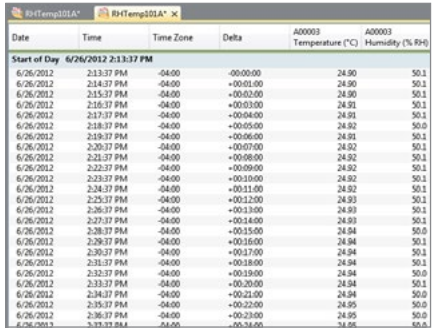
Before you purchase your data loggers for autoclave validation, make sure you have seen the loggers' proprietary software upon data download.

While all manufacturers' data loggers will record accurate temperatures, only some will create full color graphs and tables upon data upload. These time-saving, pre-generated graphics provide detailed documentation for regulators without creating any additional work for the end user.

You should also ensure that the logger software can be programmed to calculate sterilization units (F0), which will simplify reporting and save energy. With precise F0 calculation, you will know the exact time at which your autoclaved items have achieved sterility. This will help you refine your validation protocol and prevent energy waste caused by overkill (sterilizing longer than is necessary).

Software-generated graphs demonstrating lethality are the perfect compliment to internal reports and regulatory compliance documentation. Strong software simplifies validation by providing precise, easy-to-interpret data and taking the guess work out of reporting.





Date	Time	Time Zone	Delta	A00003 Temperature (°C)	A00003 Humidity (% RH)
Start of Day 6/26/2012 2:13:37 PM					
6/26/2012	2:13:37 PM	-04:00	-00:00:00	24.90	50.1
6/26/2012	2:14:37 PM	-04:00	+00:01:00	24.90	50.1
6/26/2012	2:15:37 PM	-04:00	+00:02:00	24.90	50.1
6/26/2012	2:16:37 PM	-04:00	+00:03:00	24.91	50.1
6/26/2012	2:17:37 PM	-04:00	+00:04:00	24.91	50.1
6/26/2012	2:18:37 PM	-04:00	+00:05:00	24.92	50.0
6/26/2012	2:19:37 PM	-04:00	+00:06:00	24.91	50.1
6/26/2012	2:20:37 PM	-04:00	+00:07:00	24.92	50.1
6/26/2012	2:21:37 PM	-04:00	+00:08:00	24.92	50.1
6/26/2012	2:22:37 PM	-04:00	+00:09:00	24.92	50.1
6/26/2012	2:23:37 PM	-04:00	+00:10:00	24.92	50.1
6/26/2012	2:24:37 PM	-04:00	+00:11:00	24.92	50.1
6/26/2012	2:25:37 PM	-04:00	+00:12:00	24.93	50.1
6/26/2012	2:26:37 PM	-04:00	+00:13:00	24.93	50.1
6/26/2012	2:27:37 PM	-04:00	+00:14:00	24.93	50.1
6/26/2012	2:28:37 PM	-04:00	+00:15:00	24.94	50.0
6/26/2012	2:29:37 PM	-04:00	+00:16:00	24.94	50.1
6/26/2012	2:30:37 PM	-04:00	+00:17:00	24.94	50.1
6/26/2012	2:31:37 PM	-04:00	+00:18:00	24.94	50.1
6/26/2012	2:32:37 PM	-04:00	+00:19:00	24.94	50.0
6/26/2012	2:33:37 PM	-04:00	+00:20:00	24.94	50.1
6/26/2012	2:34:37 PM	-04:00	+00:21:00	24.94	50.0
6/26/2012	2:35:37 PM	-04:00	+00:22:00	24.95	50.0
6/26/2012	2:36:37 PM	-04:00	+00:23:00	24.95	50.0

5 COMBINE HEAT DISTRIBUTION & PENETRATION STUDY

Any validation protocol requires both a loaded chamber heat distribution study and loaded chamber heat penetration study.

The goal of the heat distribution study is to confirm that your autoclave is reaching desired temperature and pressure throughout the chamber during sterilization cycles. The heat penetration study is designed to verify that sterilizing steam is reaching wrapped or packaged items.

The good news is you can complete both these studies at once! Keep in mind, however, you will still need to perform an empty chamber distribution study.

Again, autoclavable data loggers will make these studies much easier. Place loggers throughout the chamber to satisfy the distribution requirement, then place one inside your load's wrap or packaging to measure heat penetration.

Once your sterilization cycle is complete, you can extract your data loggers and download their readings to your PC for analysis.

To learn more about how data loggers can simplify autoclave validation, call (603) 456-2011 or email info@madgetech.com.