DEVELOPMENT OF A PROCESS CONTROL DEVICE (PCD) FOR USE IN MONITORING THE EFFECTIVENESS OF AN AUTOCLAVE PROCESSING INFECTIOUS/BIOHAZARDOUS WASTE

Edward Krisiunas[1], Charles Dippolito Jr.[2], Joseph Dippolito[2],

[1] WNWN International, Inc., Burlington, Connecticut, United States, [2] Future Healthcare Systems, Mt. Vernon, New York, United States

Abstract

Objectives: Develop a safe and practical approach to periodically evaluate the treatment parameters of an autoclave treating infectious/biohazardous waste using a biological indicator and thermal couple.

Method: A commercially available Process Control Device (PCD) was evaluated and modified to reflect the density of infectious/biohazardous waste being processed in a commercial autoclave (currently permitted to process 2,000 lbs per cycle).Baseline tests included modifying the PCD to also contain a wireless thermocouple in addition to a biological indicator. The thickness of the PCD was increased by adding additional material (5x8 index cards) to determine what density provided the best challenge. Thermocouples were also placed in the waste stream for comparative purposes.

Results: The standard thickness of the commercially available PCD proved easy to penetrate with steam as compared to temperatures in the heterogeneous waste loads. Two times (2x) the normal thickness proved more challenging. Three times (3x) the normal thickness proved the most challenging for the particular waste streams being processed. Testing was repeated and the 3x PCD demonstrated reproducible results as being the most challenging.

Conclusion: A PCD used to monitor the effectiveness of an autoclave processing infectious / biohazardous waste was developed based upon a trial and error method. The density of the PCD for testing was validated with the use of a biological indicator and a wireless thermocouple, the latter which provides an actual thermal record of the temperature attained and a measure of the margin of safety of microbial inactivation.

Outcomes: A safe and simple system for monitoring the treatment of infectious / biohazardous waste in an autoclave process. The PCD can also be used for regulatory compliance as thermocouple data can we retrieved within minutes of the completion of a cycle or in real time depending the on the thermocouple used. Facilities can modify the PCD to suit their own individual needs in addition to providing a more realistic metric as to the efficacy of their process when treating infectious/biohazardous waste.

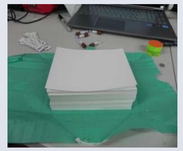
Introduction: Autoclaves are one of the most common technologies currently used non-incineration technologies around the world to treat infectious waste generated from a healthcare facilities. While the conducting periodic challenge or Quality Control (QC)tests for the treatment of surgical instruments has been established for many years, standards for testing autoclaves processing infectious waste is not as well documented. Since the inception of the medical waste management regulations in the United States as well as other parts of the world, vendors have also developed larger autoclaves to process the increasing volumes of waste. Some of these commercial autoclaves can hold over 3,000 lbs of waste. While challenging an autoclave with a capacity of 25 lbs may be easy, there are numerous challenges including occupational health and safety issues.

Some facilities utilize various carriers to place in the waste stream to hold biological indicators as well as thermocouples. These can be made of a variety of material such as wood or Teflon tubes . These are then placed into the waste stream which can be hazardous to staff. Retrieval can also be challenging as material may have melted around the carrier.

Carriers for Biological Indicators

Teflon Carriers in waste stream

Methodology: Standard Process Control Devices (PCD) purchased from 3M (photos below) were modified by adding a MesaLabs Date Trace Thermocouple to monitor temperature during the treatment process in a commercial medical waste autoclave (Bondtech 6 x 20 foot unit capable of handling 2,000 lbs per cycle. Paper cards the comprise the major component of the PCD were also doubled and tripled in two different PCDs. Baseline testing using a standard PCD in which only a thermocouple was added was conducted on a hospital based autoclave that demonstrated the density of a single pack was easily penetrated by steam relative to the rest of the waste steam being treated (Chart 1). The packs for the commercial autoclave were therefore constructed to be two and three times the density. For the analysis, standard carriers (Teflon tubes) with biological indicators were placed into bins of waste with MesaLabs DataTrace thermocouples . In addition, the PCDs with increased density were also placed inside of the autoclave near the exit door along with a baseline thermocouple to confirm autoclave processing temperatures.



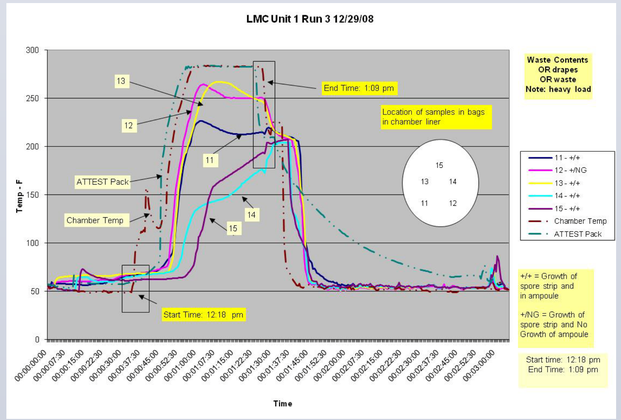
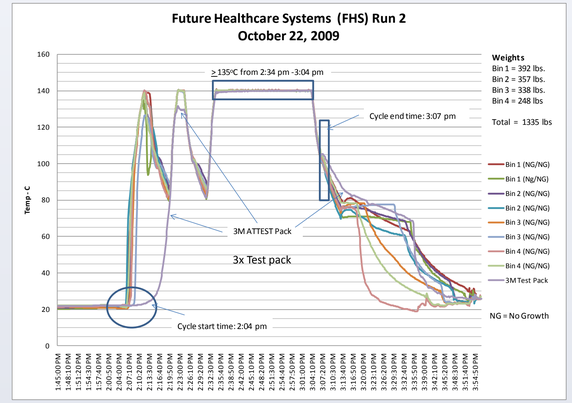
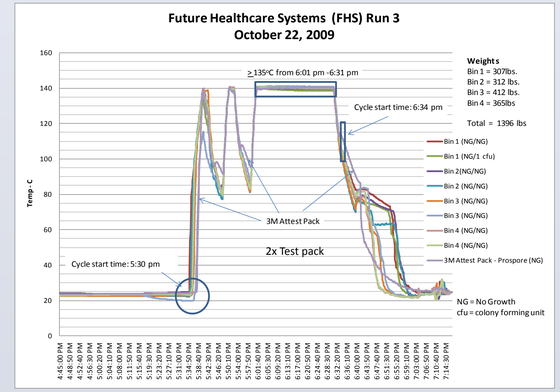


Chart 1

Results: The double thickness test pack demonstrated minimal resistance to steam penetration as had the single thickness pack in the hospital medical waste autoclave and temperatures were comparable to those of other thermocouples placed in the waste stream. The triple thickness test pack proved to be more challenging as the thermocouple data lagged the other thermocouple data obtained during testing (Charts below).





Conclusions: A PCD used to monitor the effectiveness of an autoclave processing infectious / biohazardous waste was developed based upon a trial and error method. The density of the PCD for testing was validated with the use of a biological indicator and a wireless thermocouple, the latter which provides an actual thermal record of the margin of safety of microbial inactivation. This approach can be applied to other autoclaves processing infectious waste. The waste to be processed will always present a heterogeneous waste stream that will require some baseline testing to determine the best PCD density for the waste streams to be processed.

Conflict of interest statement: Future Healthcare Systems underwrote the cost of testing at their treatment facility in Mt. Vernon, New York.