Dr. Harris’s Presentation 2009
AALAS

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Good morning.
The dry heat sterilizer is the greatest thing to happen in lab animal science since the introduction of the Microisolator in the early 1980’s. I believe it will revolutionize how we prepare rodent cages.
Rutgers has installed a dry heat sterilizer for processing microisolation cages. This is a new application of an established technology. To my knowledge there are 3 dry heat sterilizers in use in animal facilities today. Ours is the best design.
What dictates autoclave size?

The widespread acceptance of cage-level barrier housing has led to facilities using larger and larger steam autoclaves. Dry heat sterilization is a practical, cost-effective adjunct to steam sterilization which will allow you to operate your facility with a smaller autoclave used less frequently and with smaller energy bills.
Our dry heat sterilizer is built by the Gruenberg Division of Thermal Product Solutions or TPS.
Neither I nor Rutgers have any financial relationship with the company. I am here to sell you an idea, not to sell you an oven.
Over 25 years ago, Bob Sedlacek at Mass General converted a steam autoclave so that steam only heats the jacket surrounding the pressure vessel. This created in effect, a static dry heat sterilizer. This sterilizer has a large capacity but the cycle time is 6 hours.
The “Rutgers” dry heat sterilizer

- Cabinet interior: 139 cu ft
- Wall and door construction
  - Welded heavy-duty steel frame
  - Non-continuous struts from inner to outer walls
  - 4” FibreEx® insulation
  - Chamber interior 304L stainless steel, 18 and 20 ga.
  - Exterior 304 stainless, 18 and 20 ga.
- Floor: 3/16” plate, 304L stainless, beveled front edge, uninsulated
- Chamber interior dimensions
  - 62” wide
  - 54” deep
  - 70” high

The Rutgers design has a process chamber that accepts open, rolling carts.

- The cabinet interior has a volume of 139 cu ft.
- We designed custom carts, but ...
- The floor is level with the facility floor, so that you could use any cart designed to withstand heat
• The inner side walls of the oven are removable perforated panels, computer-designed to provide a uniform flow of air.
• These panels create a plenum on each side of the process chamber.
• The walls and door have 4 inches of insulation.
• The chamber ceiling is removable.
• It separates the oven chamber from the heater plenum.
• Removal allows access to the heating elements and circulation fan from the inside.
On top of the upper section,

- a 2-speed exhaust blower provides up to 290 CFM
- Both intake and exhaust air are HEPA filtered

Since the exhaust filter is on the oven, air is PUSHED through the chimney or exhaust duct under positive pressure.
• We designed custom loading carts.
• Each cart has 3 cantilevered, removable shelves.
• Four carts can fit in the oven.
• Allowing for space between cages to allow air circulation:
  • Each shelf will take 15 assembled mouse cages or 25 nested cage bottoms
  • With 4 carts, a load is 180 assembled cages or 300 nested bottoms.
  • NESTED CAGES heat more slowly than ASSEMBLED CAGES
  • Our plan is to cover nested cages with “toaster cover” style fabric covers
  • We have only recently acquired the covers
  • We are using POLYSULFONE cages
We validate our sterilizer using $10^6$ spore strips placed in cages. Ampoules won’t work for dry heat or ethylene oxide. After exposure, strips are aseptically transferred to media similar to that in the ampoules. A color change indicates growth.
A sterilization cycle has 3 phases.
• During the RAMP UP phase, the electric heaters are on constantly until just before operating temperature is reached. This is the period of highest energy consumption, using about 60 kW of power.
• During the SOAK phase the set temperature is maintained with heat on intermittently. Power consumption drops from 60 to less than 12 kW.
• During the COOL DOWN phase, the heat turns off, the circulating fan continues to provide alternating air, and the exhaust fan increases speed to provide cooling to a designated temperature. Power usage drops to 4 kW.
• Although the active cooling phase is optional, the load continues to be at a high temperature for part of this phase, and this contributes to killing bugs.
Measured Energy Consumption
300° F  Soak: 60 minutes

<table>
<thead>
<tr>
<th>Stage</th>
<th>Time (min)</th>
<th>Power (kW)</th>
<th>Energy (kWh)</th>
<th>Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ramp up</td>
<td>20</td>
<td>61</td>
<td>20.3</td>
<td>$2.64</td>
</tr>
<tr>
<td>Soak</td>
<td>60</td>
<td>12</td>
<td>11.7</td>
<td>$1.53</td>
</tr>
<tr>
<td>Cool</td>
<td>100</td>
<td>4</td>
<td>5.4</td>
<td>$0.83</td>
</tr>
<tr>
<td>Total</td>
<td>180</td>
<td>37.4</td>
<td>4.99</td>
<td></td>
</tr>
</tbody>
</table>

USER CONTROLLABLE PARAMETERS are:
• The SET POINT operating temperature of the oven
• The PROCESS TIME during which the set point is maintained
• A COOL DOWN cutoff temperature, and
• An OVERHEAT cutoff temperature
• And the INTERVAL for changing air direction
We are currently running tests with a MULTICHANNEL RECORDER to learn more about how the sterilizer works with different load configurations.
• Here we see probes in the HEATING PLENUMS.
• The temperature oscillates as AIR DIRECTION is reversed every 5 minutes.
• The phases of operation are easily identifiable on the graph.
• Note how little the temperature changes after the cycle if the oven is left closed.
• Here we have added a probe in the oven chamber and one measuring the temperature of a stainless steel shelf.
• Unfortunately, metal heats up faster than plastic
• The 3 slower tracings are in a single cage.
• Probes are positioned on the outside cage wall, on the inside cage wall, and in airspace inside the assembled cage.
• They heat up in that order.
• Heating of the cage interior is primarily by conduction through plastic, not by convection into the cage.
Here we see probes in 5 different cages with probes on the inside cage bottom under bedding. The cage heating up the most quickly was monitored on the side wall and not under the bedding. Otherwise, the cages heat reasonably uniformly.
Air circulation is the key to assuring even heating and minimizing cycle time.
• Our oven’s unique design uses horizontal, alternating air flow and we have reduced the cycle time to about 3 hours.
• Important is that the airflow is parallel to the shelves
• A circulation fan provides 6,600 cfm
• On startup, the heating elements come on.
• The exhaust fan runs at low speed to remove moisture but not to remove too much heat.
• The circulation fan blows air upward and down one side of the oven
• The air passes from side to side, recirculating and increasing in temperature.
• Every 5 minutes, dampers move and the air direction is reversed.
• [CLICK TO NEXT SLIDE]
- RAMP UP is the shortest phase but uses the most energy
- When air in the far side plenum, the coolest air, reaches target temperature, timing starts for the designated soak period.
  - During the SOAK PERIOD the heating elements provide sufficient heat to maintain temperature
At the end of the soak period, the cooling phase begins

- The heating elements shut off
- The exhaust fan shifts to high speed drawing room-temperature HEPA filtered air into the chamber and exhausting HEPA-filtered hot air
- Cooling continues until a pre-set temperature of 150 F is reached
- The cycle is over. Everything shuts off
Our oven was installed in an existing building. Rutgers quoted $750,000 just to bring steam to this site for a steam autoclave ½ the size of our dry heat sterilizer.
The oven opens into a former procedure room. The exhaust chimney runs in the interstitial space above the ceiling. It exhausts to the side of the building.
Because the sterilizer does not have a one-piece pressure vessel, parts can be assembled on site. A big advantage for renovations.
• All components had to fit through a 42” doorway
• The cabinet is in 2 halves.
• The heater plenum sits on top.
Advantages of steam sterilization under pressure

- Effective sterilization
- Short cycle times
- Penetration of surgical packs, assembled cages or stacks of nested cages
- Ability to sterilize liquids
- Decontamination
- Inexpensive “process indicator” (autoclave tape)

Advantages of STEAM STERILIZATION under pressure are

- effective sterilization,
- short cycle times,
- penetration of LARGE LOADS
- the ability to sterilize liquids
- and the ability to decontaminate infectious material in a closed, sealed autoclave chamber
Disadvantages of steam autoclaves include:

- the INITIAL COST of the equipment
- The high initial COST OF PROVIDING UTILITIES such as steam, electricity, compressed air, high volumes of cold water, a floor pit and drain
- the weight of an autoclave which may limit where it can be used
- the complexity of the equipment and the high cost of maintenance
- the high cost of producing steam
- the heat and moisture load to the room
- for installation in existing facilities, the one-piece pressure vessel determines the MAXIMUM size. It may not be possible to get through doorways, elevators and hallways.
- Even hi-vac autoclaves may leave bedding damp
- The high pressure vessel should not be left unattended and should be shut off before the end of the work day
- Steam, heat and impurities may damage plastic cages
Advantages of dry heat vs. steam

- Purchase price ~ 60%
- Cheaper to install
  - No steam, no water, no pit, no drain
- Less expensive to maintain
- No moisture added to workplace
- Minimal heat load to workspace
- No apparent damage to plastic cages

Dry heat sterilization addresses many of these issues.

For equipment with comparably sized chambers:

- A dry heat sterilizer will be less costly to purchase. TPS estimates 60-70% of the cost of a steam sterilizer
- A dry heat sterilizer will be less costly to install
  - It will require no steam, no pit, no water, no drain
  - Ours sits on a flat floor
- The dry heat sterilizer should be less expensive to maintain.
- Bedding is dry at the completion of a cycle
- The dry heat sterilizer will not add humidity to the workspace
- Our oven seems to contribute almost no heat to the workplace. The walls are so well insulated it is hard to tell a difference when the oven is on
- [CLICK]
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Based on experience at Rutgers, Mass General and at the TPS factory, repeated exposure to dry heat seems to cause no visible damage to plastic cages.

Dry heat kills as effectively as moist heat:
- Steam transfers heat more readily than air, but
- Pressure, in and of itself, does not contribute to killing microbes
- It is possible in fact to safely and affordably attain higher temperatures with dry heat
Let’s compare the Rutgers oven with a similar hi-vac steam autoclave. I chose an autoclave manufacturer at random for this comparison.

• A dry heat sterilizer needs less space
• This large an autoclave requires a pit. The dry heat sterilizer sits on a flat floor.
• An autoclave this size will have a sliding door, and the pit footprint will actually be almost twice the footprint of the autoclave, 3 times the size of the dry heat sterilizer.
• In addition to a pit, the autoclave will require cold water, steam and a drain

[SAME SLIDE – CLICK]
• For the cycle we are using now, calculated energy usage is 32 kW hours. At Rutgers, the total energy cost is $5.00 per cycle.

• The steam autoclave will use a whopping 700 gallons of water per cycle.

• The steam autoclave will cost $8.20 per cycle, over 60% more.

• The steam autoclave does have a shorter cycle.
Limitations of dry heat sterilization include:

- The chamber is not a sealed chamber. This design not intended for disinfection of biohazardous material.
- The chamber is not pressurized. Do not attempt to sterilize liquids
- Oven operates at higher temperature than standard steam autoclave cycles. Do not attempt to sterilize materials that cannot withstand the operating temperature
Limitations of dry heat sterilizers

- Cycle times for dry heat sterilizers will be longer than those for steam sterilization.
- If your dry heat sterilizer runs for more than 4 hours, call an authorized repair technician.
- There is no cost-effective “process indicator” for dry heat comparable to autoclave tape for denoting that individual cages have been sterilized.

No such thing as dry heat autoclave tape”
In summary:

- **Dry heat sterilization:**
  - Cost-effective alternative to steam autoclaves
  - Established, proven technology
  - Kills microbes as effectively as steam

- **Cycle length:**
  - Minimize with convection oven technology
  - Larger capacity in same footprint and lower cost can offset

In SUMMARY:

Dry heat sterilization is a cost-effective alternative or adjunct to large steam autoclaves.

Dry heat sterilization is an established, proven technology.

Dry heat kills microbes, including spores, as effectively as steam.

The hit on dry heat has been prolonged cycle times.

This can be minimized with convection technology.

It can be offset by being able to afford a larger capacity in a smaller footprint.

Our design works:

- It will lend itself to a pass-through configuration.
- It could easily be made twice as long or half as wide.
- New designs will allow for decontamination of BSL-1 and 2 material.

- **OH! Did I mention it’s GREEN!!**
I would like to acknowledge the many people who have helped me in acquiring and getting our sterilizer working. A number of people were also very helpful in putting my talk together.

Thank you.