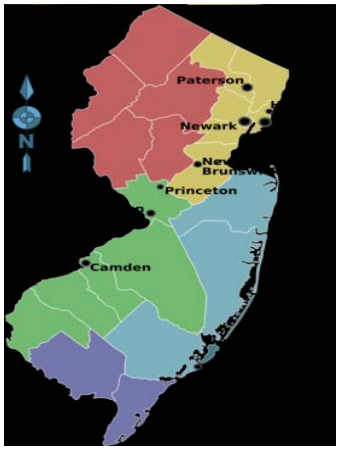


What Am I Signing my Name To?

Safety Without Compromise, Understanding Critical Sterilization Parameters

December 2, 2019

Presented by Fred Alston, CSPDT

Director of Clinical Sales and Services,
Eastern Region

healthmark™

Disclosure

- I am an employee of Healthmark Industries Fraser, Michigan USA
- I am involved with the manufacture and distribution of medical products to healthcare facilities and healthcare professionals
- No compensation has been received for this presentation
- All opinions are those of the presenter

Healthmark Policy

Healthmark's Policy is to provide our customers and the healthcare community with the highest quality, state of the art medical products and support services in a timely and cost effective manner.

This goal is supported by a staff committed to individual accountability, professionalism, mutual respect, collaboration and service excellence. **This presentation is part of that commitment, educating our customers.**

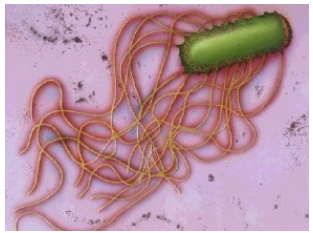
Agenda

- Understanding How/Why Steam is used
- Different types of Sterilizer Cycles
- Sterilization Parameters
- Dissecting Load Release Criteria
- Putting it all together

Definitions:

Sterilization: *A process by which all forms of microbial life including bacteria, viruses, spores, and fungi are destroyed*

- **Note:** In a sterilization process, the nature of microbial death is described by an exponential function. Therefore, the presence of microorganisms on any individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero. (ANSI/AAMI ST46)



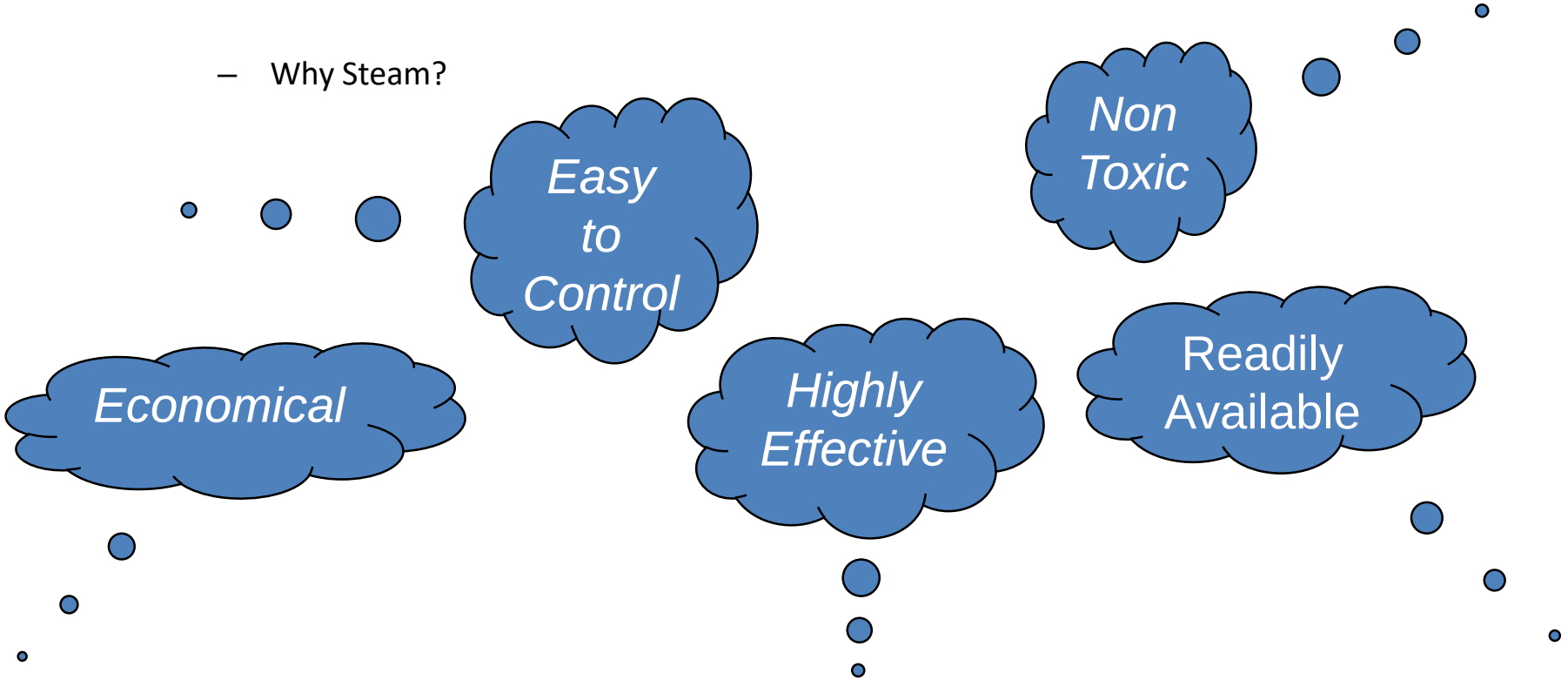
Why is infection prevention important?

- Critical to patient safety and clinical outcomes
- Continued concerns with HAI's
- MRSA kills 19,000 annually
  - Sepsis and pneumonia estimated kill 48,000 annually
  - C. Diff (chlostridium difficile) a growing concern
    - 15,000 deaths annually
    - Very hardy - has been incubated in hospital rooms 40 days after infected patient was discharged
  - Hand washing and room disinfection seen as a major contributors to Infection Reduction
  - Increasing focus on Infection Control

Steam sterilization

- Temperatures ranging from 250 - 275°F (121-135°C) at pressures of 15-30 psi are generally recommended to sterilize wrapped or unwrapped surgical instruments.

- Why Steam?



Steam sterilization

- Steam is a simple and inexpensive sterilization method with many benefits:
  - It produces little waste
  - Is a very effective way to kill microbial organisms.
  - Steam sterilization is the oldest, safest, cheapest, and most understood method of sterilization available to health care facilities.
- Steam sterilization is more effective than other methods because brief exposure to steam destroys most resistant bacterial species due to the heat transfer as steam condenses

Key factors affecting sterilization

Three factors are critical to ensure steam sterilization:

- **Time**
- **Temperature**
- **Moisture**

Surfaces to be sterilized must be heated to, and maintained at a high enough **temperature** with adequate **moisture** present for a prescribed **time**.

All sterilization failures can be traced to one or more of these factors not being adequate.

To ensure that these factors are achieved, guidelines and techniques have been established and standardized for preparation and packaging of items, as well as loading the sterilizer and releasing its contents.

Factors of sterilization

Steam Temperature and Pressure

Saturated Temperature		Saturated Pressure	
°F	°C	Absolute (psia)	Gauge (psig)
250.0	121.1	29.8	15.1
270.0	132.2	41.9	27.2
275.0	135.0	45.4	30.7
285.0	140.6	53.3	38.6

Absolute pressure, or pounds per square inch absolute (psia), is the steam pressure relative to a perfect vacuum.

Gauge pressure, or pounds per square inch gauge (psig) is the pressure relative to local atmospheric pressure.

psig = psia - Patmosphere

Pressure

- Atmospheric Pressure at Sea Level is typically 14.7 psia
- Gauge pressure typically begins at 0 psig
- Gauge pressure at 0 is actually 14.7 psia
- Simple Math:
  - When the Gauge shows 32 psig, add 14.7 and the sum is Atmospheric pressure.
  - **32** psig + **14.7** (atm at sea level) = **46.7**psia

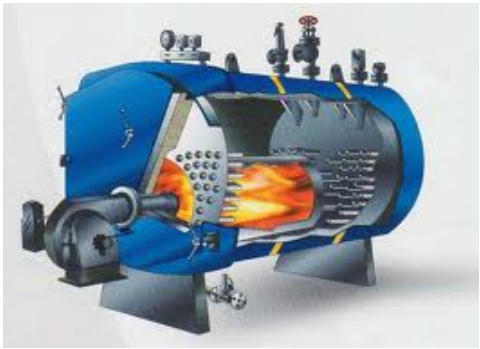
Pressure con’t

Why should I care?

- Modern electronics in sterilizers use psia to determine pressure levels when running cycles. Some manufacturers print this information on the sterilizer printout.

Factors of sterilization

- Steam Quality
  - Wet Steam
    - Dryness value should be between 97% - 100%
    - i.e. 98% steam 2% water
    - Excess moisture can cause wet packs and uneven temperature distribution on non-porous loads
  - Superheated steam
    - May occur during sterilization of extremely dry packs
    - Causes dry heat conditions
    - Hampers sterilization
    - Can damage textiles
  - Presence of non-condensable gases
    - Inhibits steam penetration



Types of sterilization

ETO (Ethylene oxide)
Gas Plasma
VHP
Formalin
Ozone

} Low temp.

Moist Heat (Steam)
Dry Heat

} High temp.

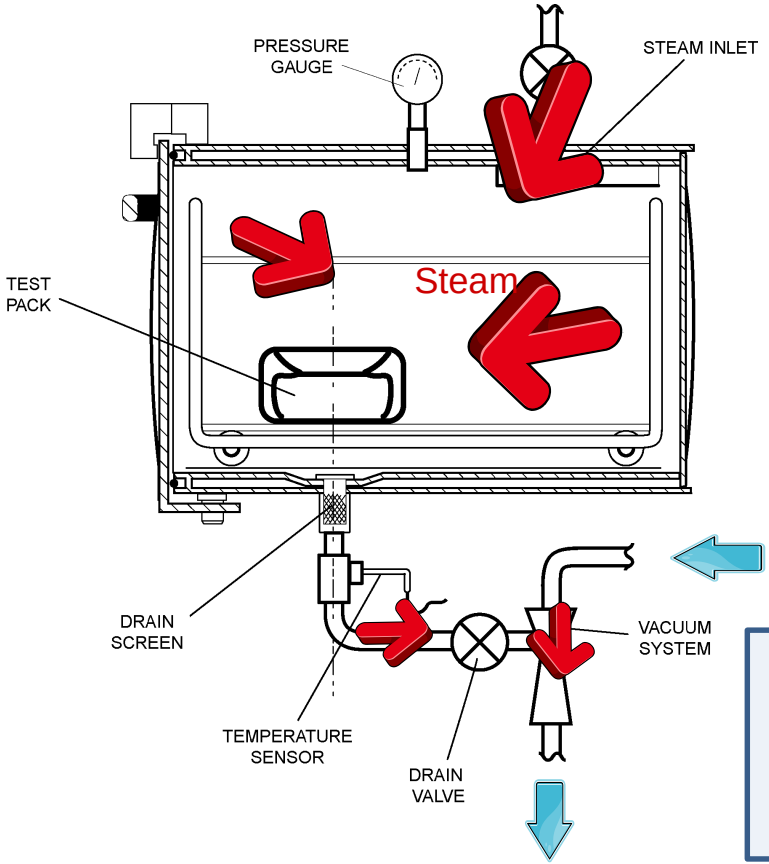
Steam sterilizers

- Although the principles of steam sterilization haven't changed during the past century, steam sterilizers and sterilization technologies have dramatically changed.

Sterilizer basics

- ASME Pressure Vessel
- Jacket
  - Keeps Chamber hot to reduce Steam Condensation during cycle
- Air Removal
  - Air is an insulator
  - Unless steam touches an item, it does not receive the correct amount of Time, Temperature (Heat) and moisture to provide sterilization.
- Steam
  - Saturated steam (97%)
  - Sterilant
- Water
  - Cools Sterilizer discharge (<140°F)
  - With an ejector, is the mechanism for active air removal and “Pulling a Vacuum”.

How does a sterilizer work?



Can be a Water Venturi (shown) or Vacuum Pump

Sterilizer sizes

Small: (17” / 21”)

Mid:
(26.5”x26.5”)

Medium:
(26.5”x36”)

Large: (26.5”x62”)

Most common sterilizer types

Vacuum:

- Used for large volumes of wrapped surgical instruments

Gravity:

- Typically used for individual unwrapped surgical instruments

Cycle phase diagram

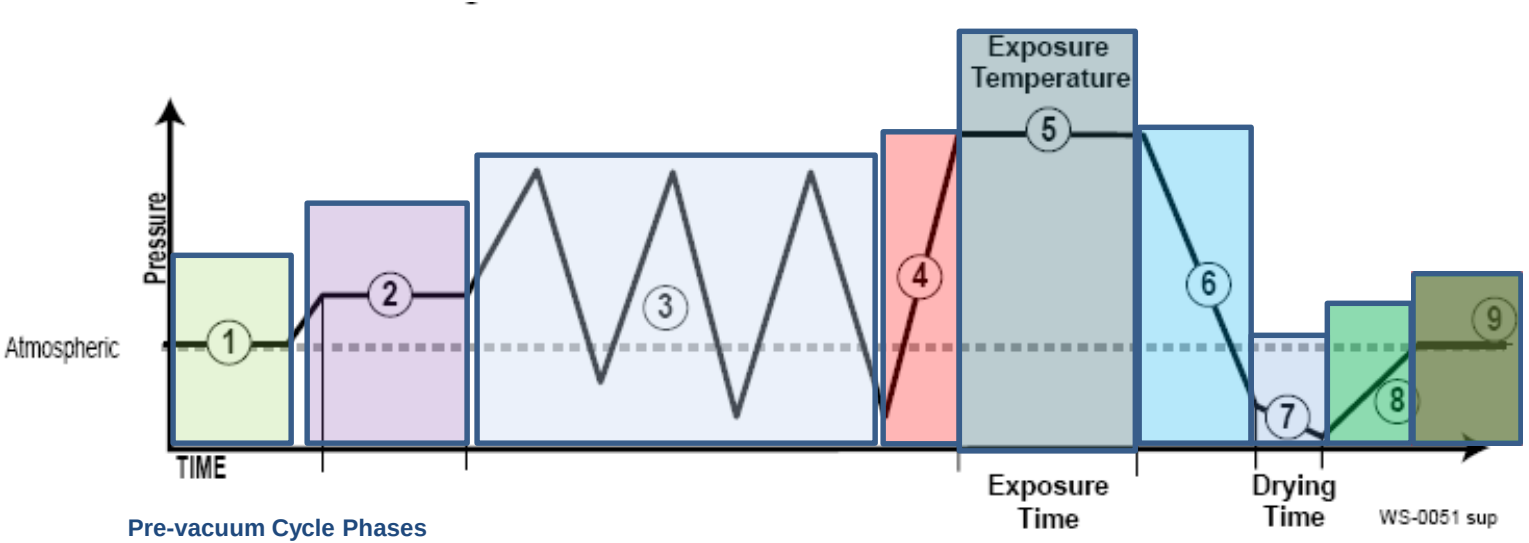
- For Each Sterilizer Type, there is a typical cycle phase that it follows to achieve preset parameters that remove air, allow steam penetration and drying.
- The cycle phase diagram varies from manufacturer to manufacturer.
- Original Sterilizer cycles were only Gravity, meaning air is removed without going below atmosphere (0 psig).
- Variations of the Gravity cycle phase diagram include “Flash”, “Express” and “Gravity Wrap”
- In some ways the SFPP cycle is another variation of a Gravity cycle in that air is actively removed without ever going below atmosphere.

Removing air?

- Why is air removal important?
  - Air is 1.6 times denser than steam
  - Air and steam do not mix
    - Impedes steam penetration
    - Inhibits steam contact
  - Loading and load type
  - Instrument design (lumens)

- Results in inadequate temperature, and moisture conditions at the desired sterilization sites.
  - Steam condenses on cool goods
  - Packs must be dry

Typical pre-vacuum cycle phase diagram



Pre-vacuum Cycle Phases

1. **Start** – door seals, jacket warms chamber
2. **Purge** – steam enters chamber, while air is purged through the chamber drain
3. **Conditioning** – positive pressure and negative vacuum pulses continue to heat load and purge air
4. **Heat Up** – steam pressure builds to selected exposure temperature and pressure
5. **Exposure** – timing begins for selected exposure time and temperature
6. **Exhaust** – chamber drain opens and ejector water creates vacuum in chamber to exhaust steam
7. **Drying** – ejector water controls vacuum in chamber for selected dry time
8. **Air-in** – chamber returns to atmospheric pressure
9. **Cycle Complete** – door can be opened

The magic box

All this activity occurs behind a solid door.
Maybe if I could see what is happening, I could better understand.

Your wish has been granted…

Click your heals three times and say after me,

Enough already, get to the point!!

Enjoy

Sterilization

May I have your autograph?

- Every reprocessing facility has Load Release Protocols in place and I would venture to guess that close to if not 100% of those protocols require the operator who pulls the items out of the sterilizer to “Initial” the printout.

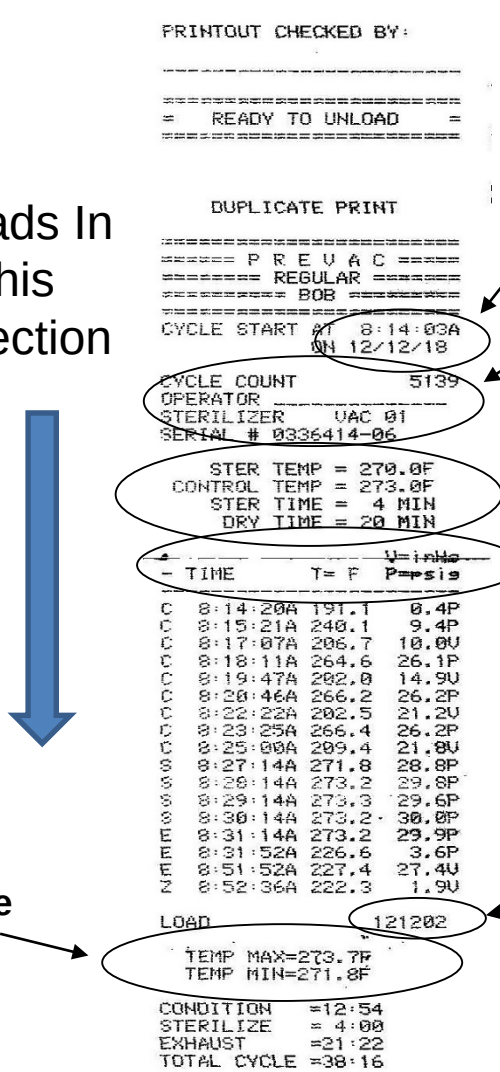
- Do you know what you are signing?

- Do you understand why?

Load Release

AMSCO Sterilizer Printout Load Release Information Locations

Reads In this Direction



PRINTOUT CHECKED BY:

READY TO UNLOAD

DUPLICATE PRINT

P R E V A C
REGULAR
BOB

CYCLE START AT 8:14:03A
ON 12/12/18

CYCLE COUNT 5139
OPERATOR
STERILIZER VAC 01
SERIAL # 0336414-06

STER TEMP = 270.0F
CONTROL TEMP = 273.0F
STER TIME = 4 MIN
DRY TIME = 20 MIN

	TIME	T= F	V=inHg P=psig
C	8:14:20A	191.1	0.4P
C	8:15:21A	240.1	9.4P
C	8:17:07A	206.7	10.0V
C	8:18:11A	264.6	26.1P
C	8:19:47A	202.0	14.9V
C	8:20:46A	266.2	26.2P
C	8:22:22A	202.5	21.2V
C	8:23:25A	266.4	26.2P
C	8:25:00A	209.4	21.8V
S	8:27:14A	271.8	28.8P
S	8:28:14A	273.2	29.8P
S	8:29:14A	273.3	29.6P
S	8:30:14A	273.2	30.0P
E	8:31:14A	273.2	29.9P
E	8:31:52A	226.6	3.6P
E	8:51:52A	227.4	27.4V
Z	8:52:36A	222.3	1.9V

LOAD 121202

TEMP MAX=273.7F
TEMP MIN=271.8F

CONDITION =12:54
STERILIZE = 4:00
EXHAUST =21:22
TOTAL CYCLE =38:16

Verify Correct Date

Signature

Verify Cycle Parameters

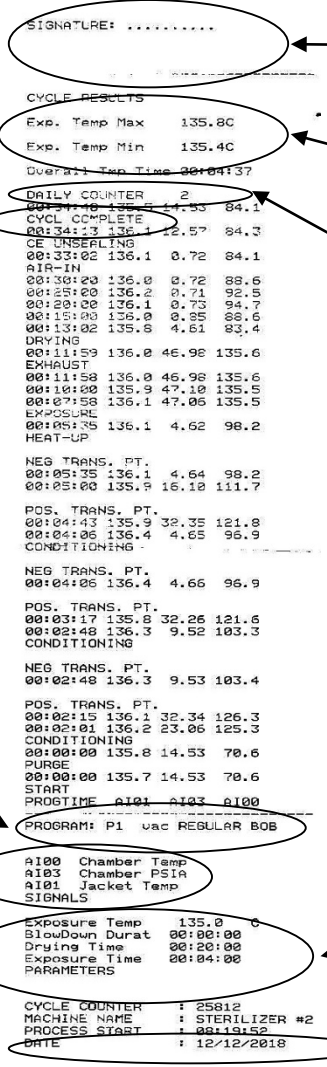
Column Header

Cycle Load Number

Verify Exposure Temperature

Load Release

GETINGE Sterilizer
Printout Load Release
Information Locations



Signature

Verify Exposure Temperature

Verify Complete Cycle

Cycle Load Number

Read in this Direction

Verify Correct Cycle Selected

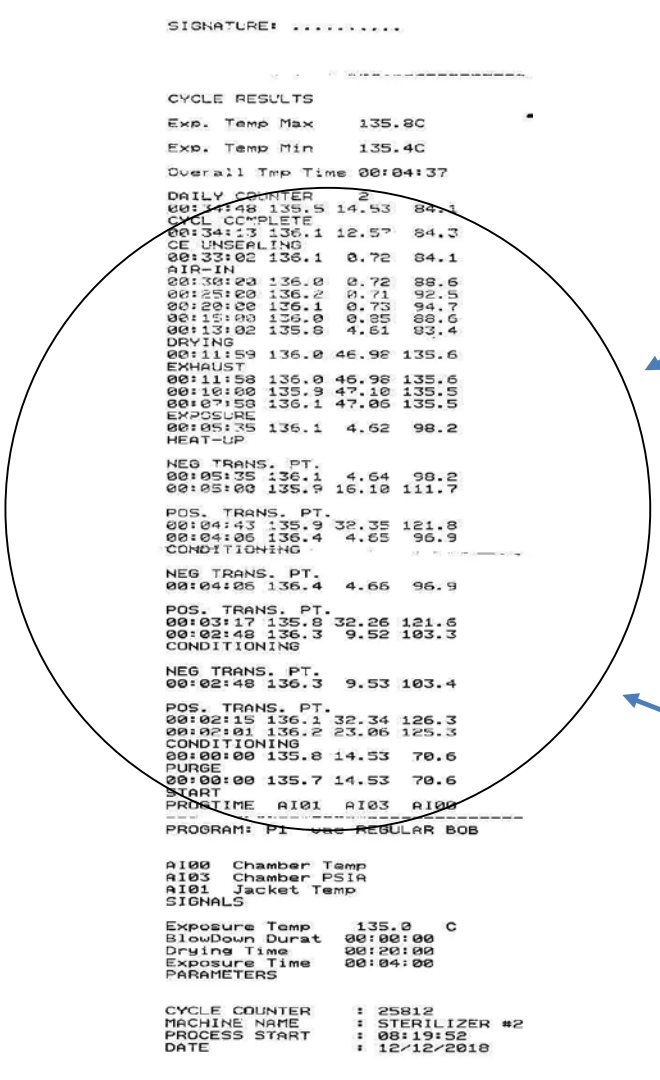
Column Header

Verify Cycle Parameters

Verify Correct Date

Load Release

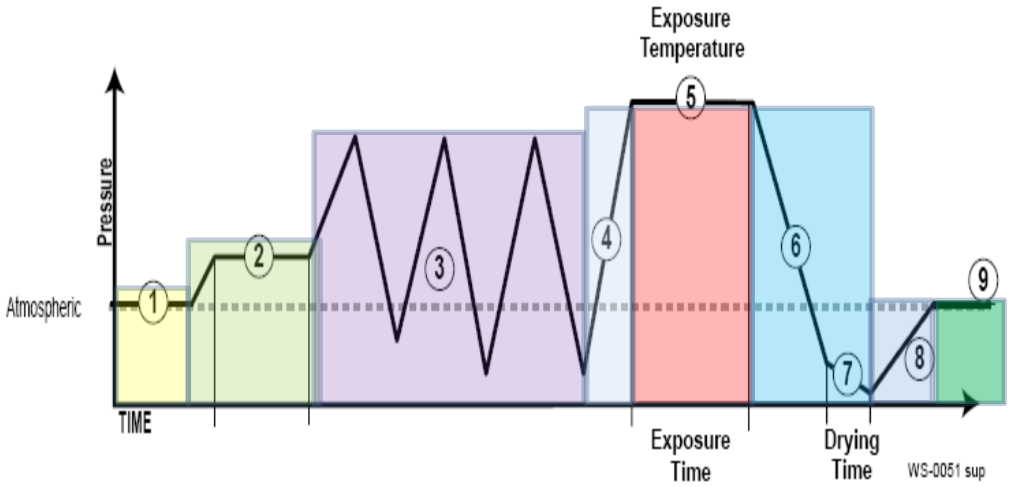
Sterilizer Printout



```
SIGNATURE: .....

CYCLE RESULTS
Exp. Temp Max     135.8C
Exp. Temp Min     135.4C
Overall Tmp Time 00:04:37

DAILY COUNTER     2
00:14:48 135.5 14.53  84.1
CYCL COMPLETE
00:34:13 136.1 12.57  84.3
CE UNSEALING
00:33:02 136.1  0.72  84.1
AIR-IN
00:30:23 136.0  0.72  88.6
00:25:20 136.2  0.71  92.5
00:20:00 136.1  0.73  94.7
00:15:00 136.0  0.85  88.6
00:13:02 135.8  4.61  93.4
DRYING
00:11:59 136.0 46.98 135.6
EXHAUST
00:11:58 136.0 46.98 135.6
00:10:00 135.9 47.10 135.5
00:07:58 136.1 47.06 135.5
EXPOSURE
00:05:35 136.1  4.62  98.2
HEAT-UP

NEG TRANS. PT.
00:05:35 136.1  4.64  98.2
00:05:00 135.9 16.10 111.7

POS. TRANS. PT.
00:04:43 135.9 32.35 121.8
00:04:06 136.4  4.65  96.9
CONDITIONING

NEG TRANS. PT.
00:04:06 136.4  4.66  96.9

POS. TRANS. PT.
00:03:17 135.8 32.26 121.6
00:02:48 136.3  9.52 103.3
CONDITIONING

NEG TRANS. PT.
00:02:48 136.3  9.53 103.4

POS. TRANS. PT.
00:02:15 136.1 32.34 126.3
00:02:01 136.2 23.06 125.3
CONDITIONING
00:00:00 135.8 14.53  70.6
PURGE
00:00:00 135.7 14.53  70.6
START
PROGTIME  AI01  AI03  AI00
PROGRAM: P1  use REGULAR BOB

AI00  Chamber Temp
AI03  Chamber PSIA
AI01  Jacket Temp
SIGNALS

Exposure Temp     135.0   C
BlowDown Durat  00:00:00
Drying Time     00:20:00
Exposure Time   00:04:00
PARAMETERS

CYCLE COUNTER     : 25812
MACHINE NAME      : STERILIZER #2
PROCESS START     : 08:19:52
DATE              : 12/12/2018
```

What about all this stuff??

```
SIGNATURE: ..........


CYCLE RESULTS

Exp. Temp Max     135.8C

Exp. Temp Min     135.4C

Overall Tmp Time 00:04:37

DAILY COUNTER     2
00:34:48 135.5 14.53  84.1
CYCL COMPLETE
00:34:13 136.1 12.57  84.3
CE UNSEALING
00:33:02 136.1  0.72  84.1
AIR-IN
00:30:00 136.0  0.72  88.6
00:25:00 136.2  0.71  92.5
00:20:00 136.1  0.73  94.7
00:15:00 136.0  0.85  88.6
00:13:02 135.8  4.61  83.4
DRYING
00:11:59 136.0 46.98 135.6
EXHAUST
00:11:58 136.0 46.98 135.6
00:10:00 135.9 47.10 135.5
00:07:58 136.1 47.06 135.5
EXPOSURE
00:05:35 136.1  4.62  98.2
HEAT-UP

NEG TRANS. PT.
00:05:35 136.1  4.64  98.2
00:05:00 135.9 16.10 111.7

POS. TRANS. PT.
00:04:43 135.9 32.35 121.8
00:04:06 136.4  4.65  96.9
CONDITIONING

NEG TRANS. PT.
00:04:06 136.4  4.66  96.9

POS. TRANS. PT.
00:03:17 135.8 32.26 121.6
00:02:48 136.3  9.52 103.3
CONDITIONING

NEG TRANS. PT.
00:02:48 136.3  9.53 103.4

POS. TRANS. PT.
00:02:15 136.1 32.34 126.3
00:02:01 136.2 23.06 125.3
CONDITIONING
00:00:00 135.8 14.53  70.6
PURGE
00:00:00 135.7 14.53  70.6
START
PROGTIME  AI01  AI03  AI00
PROGRAM: P1  vac REGULAR BOB


AI00  Chamber Temp
AI03  Chamber PSIA
AI01  Jacket Temp
SIGNALS

Exposure Temp     135.0   C
BlowDown Durat  00:00:00
Drying Time     00:20:00
Exposure Time   00:04:00
PARAMETERS


CYCLE COUNTER     : 25812
MACHINE NAME      : STERILIZER #2
PROCESS START     : 08:19:52
DATE              : 12/12/2018
```



1. Start
2. Purge Conditioning
3. Conditioning
4. Heat Up
5. Exposure
6.&7. Drying
8. Air-in
9. Cycle Complete

Load release policy

Basic example of a load release protocol

1. Review the data on the print-out.
   - Was the cycle run at the correct temperature?
   - Was the sterilize time correct for the device being run?
   - Operator initials and dates to document check.

2. Check indicators on outside of packages
   - Did the tape or monitor change to a pass indication (i.e. white to black change)?

3. Look for any blown packs or other rejects.
   - Are the packs wet or damp?

4. Open any PCDs used:
   - Does the chemical integrator show a pass reaction?
   - Incubate the BI (if there is one included)

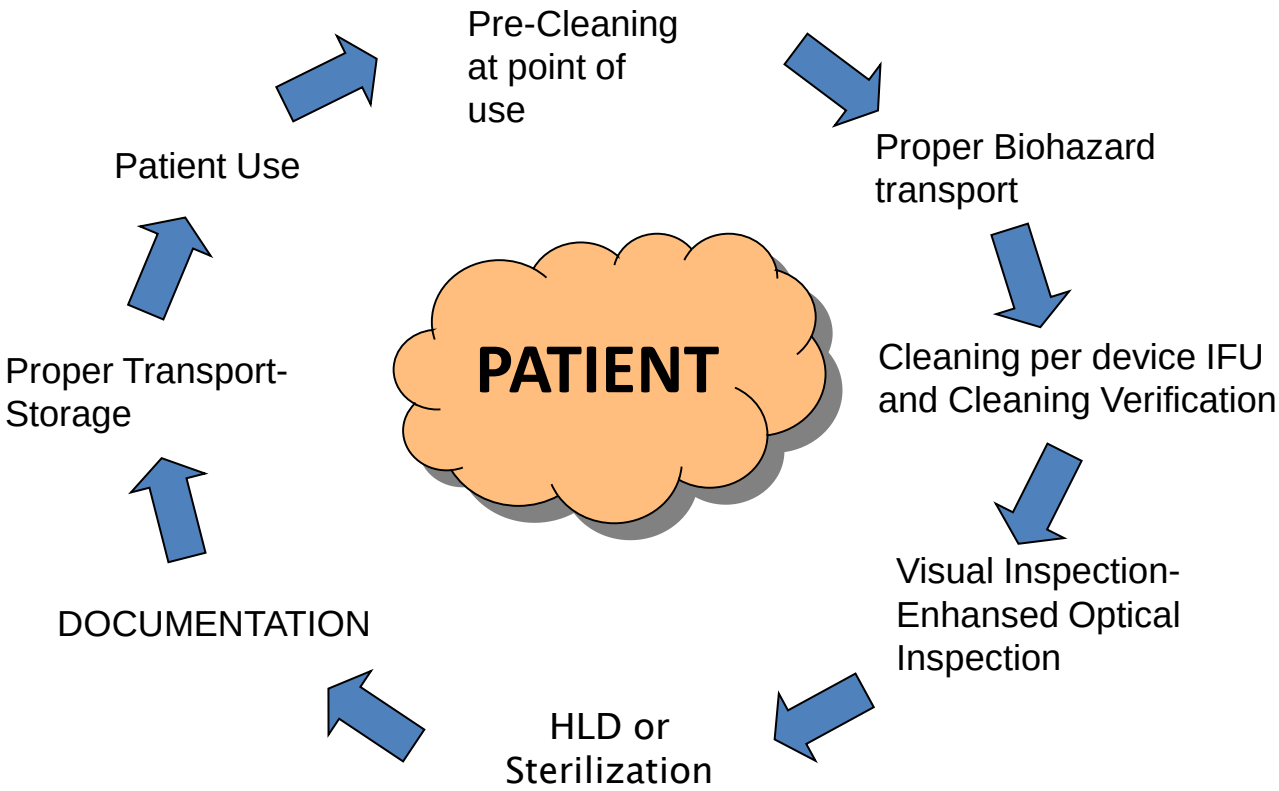
5. Sign off and release the load if all criteria are satisfied

6. **DOCUMENT, DOCUMENT, DOCUMENT**

Record Keeping – for each cycle

- The lot/load number
- Specific contents of the lot/load including quantity, department, towel packs, type/name of instrument sets
- Exposure time and temperature
- Name or initials of operator
- The results of BI testing, if applicable
- The results of Bowie-Dick test, if applicable
- The response of the CI placed in a PCD, if applicable
- Any reports of inconclusive or non-responsive CIs found later in the load
- **Document, Document, Document.**

The circle of life



Questions?

On behalf of Healthmark, I would like to thank you all for the opportunity to be here today.

THANK YOU!

Thank you so much!

Your healthmark™ Team

Chris Morrisey
Cell: 908.399.0938
Email: chris@morriseymedical.com

Fred Alston
Cell: 724-448-4121
falston@hmark.com

1969 • 2019 50 YEARS

www.hmark.com

www.healthmarkgi.com