Temperature Mapping and Practical Sessions common loads

A. Kerr, Technical Support Manager, SteriTech Ltd

Temperature Sensors

Thermocouples

Platinum resistors, Pt100

Pt 100

Pt100
Structure and Mechanism

- Platinum resistor inside stainless steel sheath packed with MgO for insulation.
- Platinum resistance varies with temperature very uniform over a large temperature range.
- At 0°C the resistance is 100 Ohms, (Pt 500 or Pt 1000 also available)

Pt100
Where do we use them

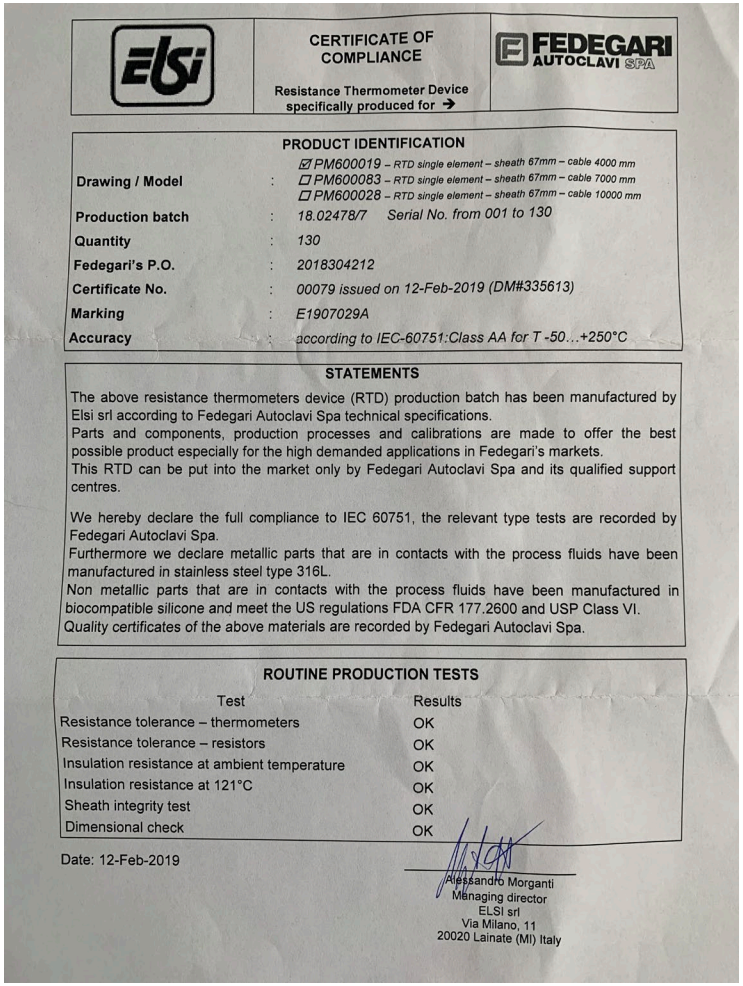
- Fedegari uses Pt 100 probes for controlling sterilization cycles
- Hold their calibration very well
- Very robust

Pt100 Accuracy

Tolerance class	Temperature range of validity °C		Tolerance values[a] °C
	Wire wound resistors	Film resistors	
AA	–50 to +250	0 to +150	± (0.1 + 0.0017 | t |)
A	–100 to +450	–30 to +300	± (0.15 + 0.002 | t |)
B	–196 to +600	–50 to +500	± (0.3 + 0.005 | t |)
C	–196 to +600	–50 to +600	± (0.6 + 0.01 | t |)
(a) | t | = modulus of temperature in °C without regard to sign.			

- Different accuracies of Pt 100
- Fedegari uses AA

Pt100 compliance



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CERTIFICATE OF COMPLIANCE

Resistance Thermometer Device specifically produced for →

FEDEGARI AUTOCLAVI SPA

PRODUCT IDENTIFICATION

Drawing / Model	:	☑ PM600019 – RTD single element – sheath 67mm – cable 4000 mm ☐ PM600083 – RTD single element – sheath 67mm – cable 7000 mm ☐ PM600028 – RTD single element – sheath 67mm – cable 10000 mm
Production batch	:	18.02478/7 Serial No. from 001 to 130
Quantity	:	130
Fedegari's P.O.	:	2018304212
Certificate No.	:	00079 issued on 12-Feb-2019 (DM#335613)
Marking	:	E1907029A
Accuracy	:	according to IEC-60751:Class AA for T -50…+250°C

STATEMENTS

The above resistance thermometers device (RTD) production batch has been manufactured by Elsi srl according to Fedegari Autoclavi Spa technical specifications.
Parts and components, production processes and calibrations are made to offer the best possible product especially for the high demanded applications in Fedegari's markets.
This RTD can be put into the market only by Fedegari Autoclavi Spa and its qualified support centres.

We hereby declare the full compliance to IEC 60751, the relevant type tests are recorded by Fedegari Autoclavi Spa.
Furthermore we declare metallic parts that are in contacts with the process fluids have been manufactured in stainless steel type 316L.
Non metallic parts that are in contacts with the process fluids have been manufactured in biocompatible silicone and meet the US regulations FDA CFR 177.2600 and USP Class VI.
Quality certificates of the above materials are recorded by Fedegari Autoclavi Spa.

ROUTINE PRODUCTION TESTS

Test	Results
Resistance tolerance – thermometers	OK
Resistance tolerance – resistors	OK
Insulation resistance at ambient temperature	OK
Insulation resistance at 121°C	OK
Sheath integrity test	OK
Dimensional check	OK

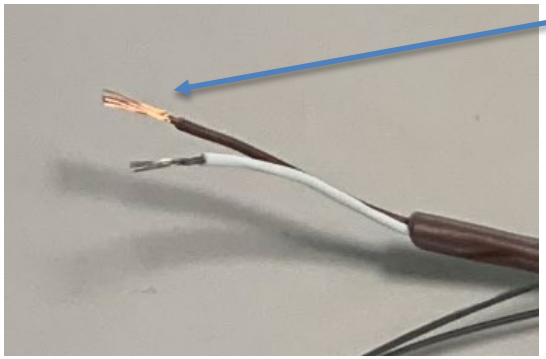
Date: 12-Feb-2019

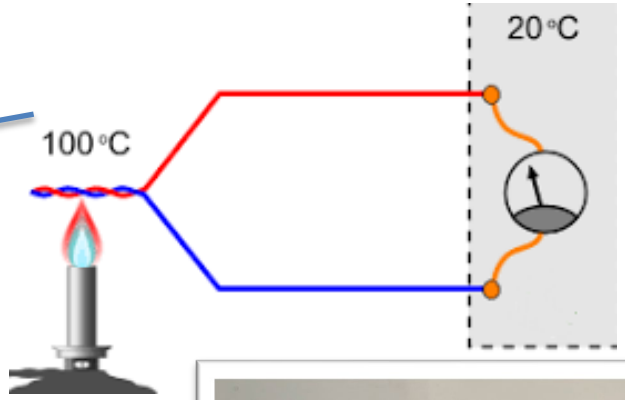
Alessandro Morganti
Managing director
ELSI srl
Via Milano, 11
20020 Lainate (MI) Italy

Thermocouples

Thermocouples

Hot junction,
inside chamber

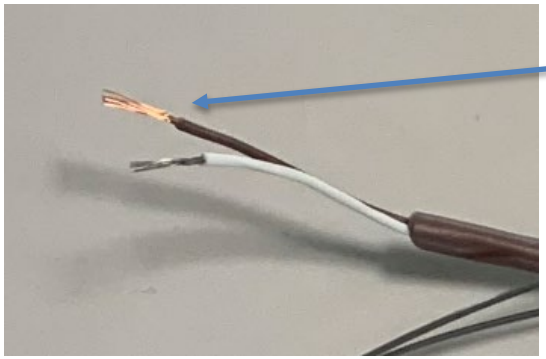


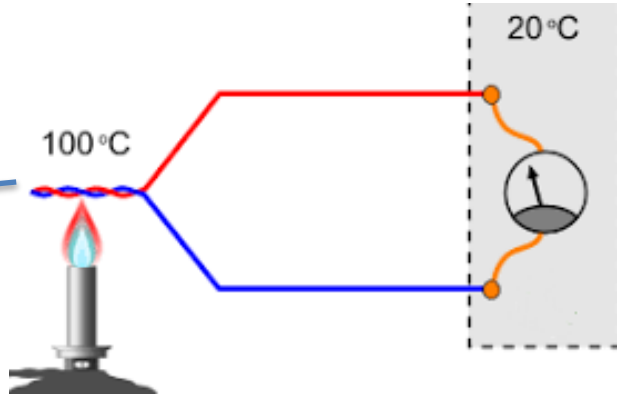


Cold junction,
outside chamber

Thermocouples

Hot junction,
inside chamber



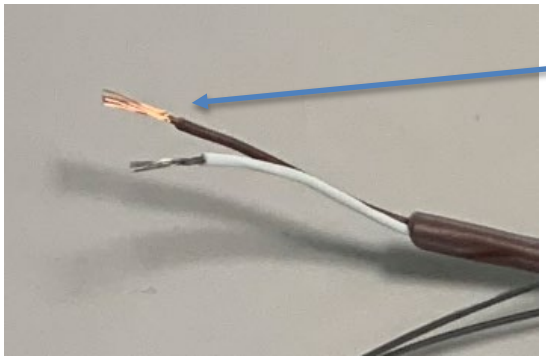


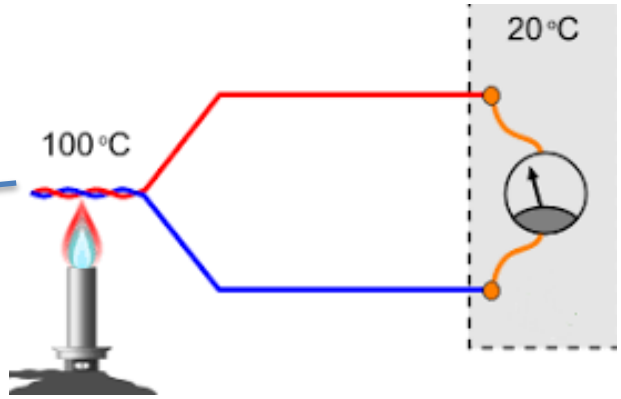
Cold junction,
outside chamber

- Two wires of two different metals.
- Connected at two points, the ‘Hot Junction’ and ‘Cold Junction’.
- Heat hot junction flow of electrons between two metals.
- Voltage is proportional to the difference in temperature between the hot and cold junction

Thermocouples

Hot junction,
inside chamber





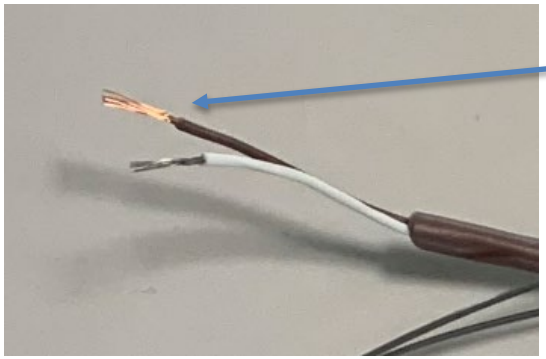
Cold junction,
outside chamber

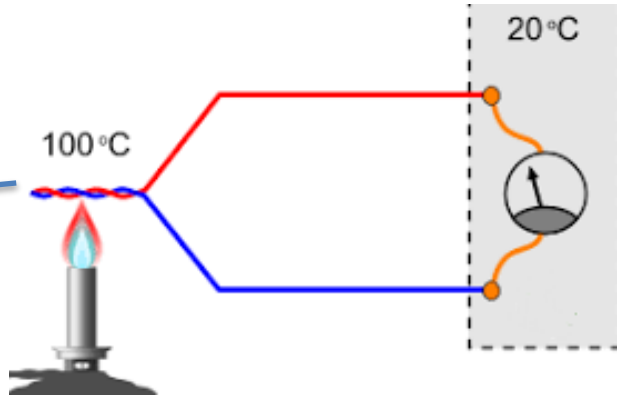
Disadvantages

- Calibration required before use.
- Verification required after use.
- May not hold calibration for a long time due to change in purity of metals.

Thermocouples

Hot junction,
inside chamber





Cold junction,
outside chamber

Advantages

- Very flexible/easily manipulated to get into load
- Can measure temperature in a very precise place
- More affordable

Tolerance classes

Tolerance classes for thermocouples according to IEC 60584:2013
The American ASTM E230/E230M-12 is a parallel standard, but be aware that both tolerances and temperature ranges could be different from those of the IEC standard. Note that prescribed tolerances are valid for unused thermocouple material only.

Thermocouple	Tolerance class 1 (°C)	Tolerance class 2 (°C)	Tolerance class 3 (°C)
Type R and S			
Temperature range	0 ≤ T ≤ 1600	0 < T < 1600	
Largest value is to be used.	±1 *för T<1100*	±1,5	-
	[±1+0,003·(T-1100)] *för T > 1100*	±0,0025·T	
Type B			
Temperature range		600 < T < 1700	600 < T < 1700
Largest value is to be used.	-	±1,5	±4
		±0,0025·T	±0,005·T
Type J			
Temperature range	-40 < T < 750	-40 < T < 750	
Largest value is to be used.	±1,5	±2,5	-
	±0,004·ITI	±0,0075·ITI	
Type T			
Temperature range	-40 < T < 350	-40 < T < 350	-200 < T < 40
Largest value is to be used.	±0,5	±1	±1
	±0,004·ITI	±0,0075·ITI	±0,015·ITI
Type E			
Temperature range	-40 < T < 800	-40 < T < 900	-200 < T < 40
Largest value is to be used.	±1,5	±2,5	±2,5
	±0,004·ITI	±0,0075·ITI	±0,0075·ITI
Type K and N			
Temperature range	-40 < T < 1000	-40 < T < 1200	-200 < T < 40
Largest value is to be used.	±1,5	±2,5	±2,5
	±0,004·ITI	±0,0075·ITI	±0,0075·ITI
Type C			
Temperature range	-	426 < T < 2315	-
Tolerance		±0,01·T	
Type A			
Temperature range	-	1000 < T < 2500	-
Tolerance		±0,01·T	
Reference junction 0°C			
Updated 2014-09-22			

IEC 60584-2013

- Type T , Class 1
- Most suitable temperature generally
- Most accurate class

Thermocouples Applications

- Temp. Distribution Exercise
- (Thermal mapping)
- During OQ – empty chamber

- Temp. Penetration Exercise
- During PQ – with the load for cycle development
- Generally used to qualify and re-qualify loads

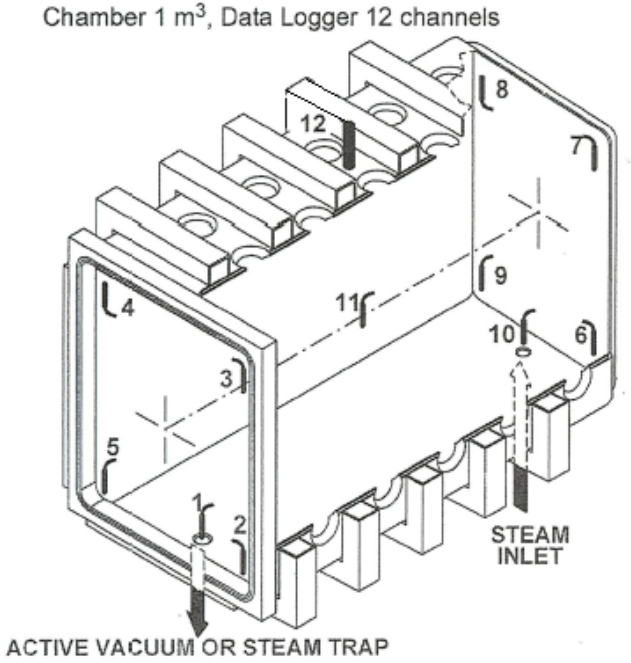
Thermocouples FAQ, How many have to be used ?

- There is no right or wrong answer
- Generally you will use enough TCs to distribute around the load leaving some contingency incase of failure. It's good practice to have 2 TCs at your reference point generally the in the drain for porous load programs.
- Typical 'rule of thumb'
- 12 for all chambers up to 2000 liters.
- Plus two for every extra 1000 liters

Thermocouples FAQ, Where do you locate them ?

- There is no right or wrong answer
- Looking for the coldest point during the exposure
- Looking for the slowest point to reach minimum Sterilization temperature
- Enough to cover all critical points within chamber and load

Thermocouples FAQ, Where do you locate them ?



Summary

	Pt 100	Thermocouple
How they work?	Resistance across a platinum resistor	Voltage created between two wires of different metals
When do we use them?	Sterilization process control	OQ and PQ procedures for thermal distribution and thermal penetration
Advantages	Hold calibration well Robust	Easily manipulated Measure temp in a precise point
Disadvantages	Large and harder to manipulate	Have to frequently recalibrate

Equilibration Time

Definition of Equilibration time:

EN285: 1996

- Clause 3.15 – Equilibration time
- “Period which elapses between the attainment of the sterilization temperature in the sterilizer chamber and the attainment of the sterilization temperature at all points within the load.”

As the statement “in the sterilizer chamber” was unclear, the definition was modified and has remained unchanged till now:

Definition of Equilibration time:

EN285: 2015 Latest Revision of EN285.

- Clause 3.10 – Equilibration time

"Period which elapses between the attainment of the sterilization temperature at the ***reference measurement point*** and the attainment of the sterilization temperature at all points within the load."

- Clause 3.24 – Reference measurement point

"Point where the temperature probe used for the operating cycle control is located."

Definition of Equilibration time:

Actual Definition

"The period that elapses between the attainment of the minimum exposure temperature at the reference measurement point (typically the drain) and the attainment of the sterilization temperature at all points within the load. This period is an indication of the ability to properly remove air and heat the load items; consequently, it is typically only evaluated by placing heat penetration probes in porous/hard goods loads."

Equilibration time Requirements:

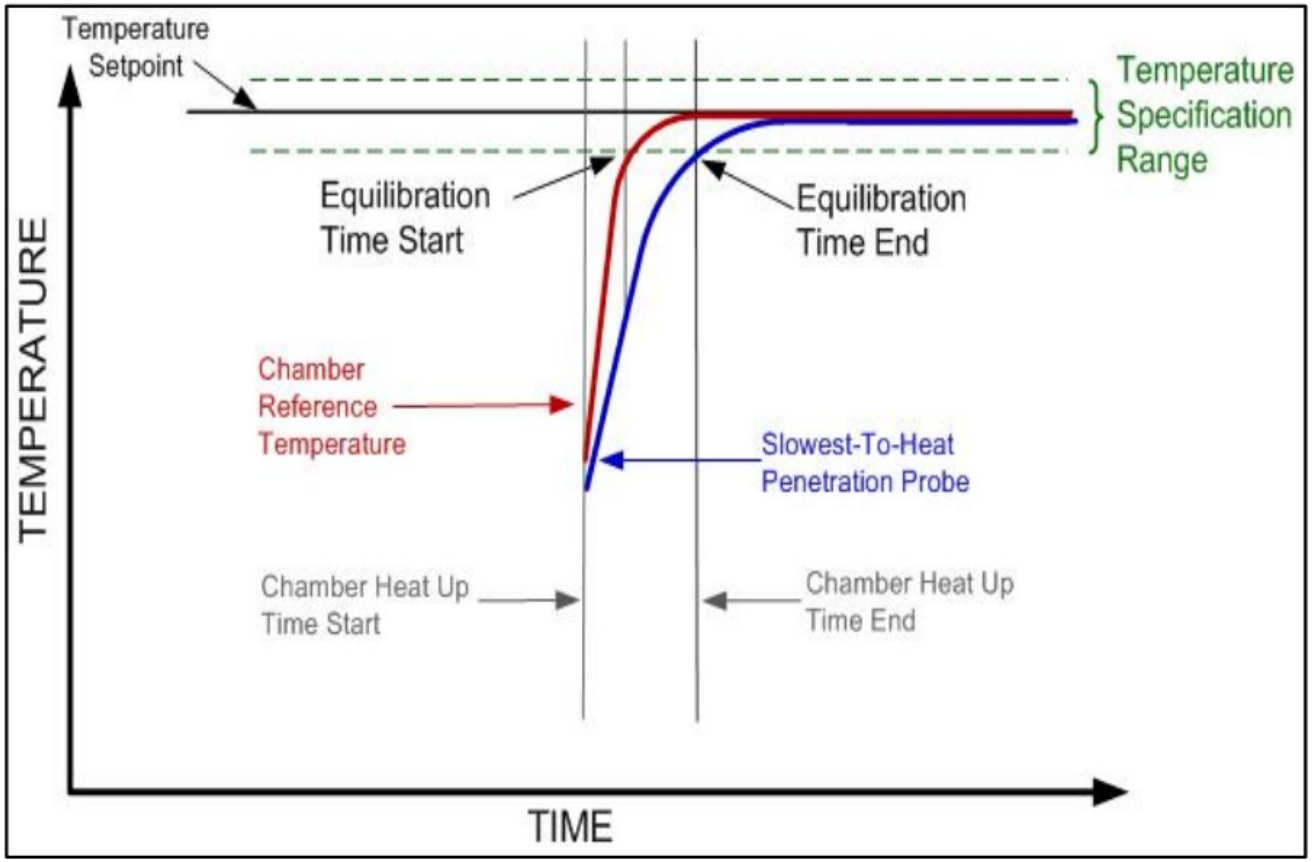
EN285: 2015

Clause 8.2.1.2.1 (Small load) & 8.2.1.3.1 (Full load)
“The equilibration time shall not exceed 15 s for sterilizer chambers up to 800 l usable space and 30 s for larger sterilizer chambers .”

PAY ATTENTION !

The requirements for **equilibration time not exceeding 30 (or 15) seconds** are referred to **test loads!!** The requirement on equilibration time duration is part of specification of the sterilizer and has the aim to demonstrate, by mean of **the standard test load**, that the sterilizer is compliant with the Standard.

Equilibration time:



Equilibration Overview:

Equilibration time is a variable parameter that shall be minimized during the cycle development and its maximum shall be included among the acceptance criteria for any actual sterilization process.

The following can be used to reduce the equilibration time

- Load orientation
- Increase number of vacuum pulses
- Increase number of positive pulses
- Add hold phases during steam/vacuum pulses to increase air removal
- Increase depth of vacuum pulses
- Increase heating time