Microbiological Efficacy Report

Biological and Physical Evaluation of the Sterilization Process of Newster® Sterilizers NW5 – NW15 – NW50

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Summary

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1 Abstract

A microbiological validation test was carried out in May – June – July 2019 to demonstrate the microbiological efficacy of a Newster Sterilizer (model NW15) installed at the Private Clinic "Sol et Salus", Rimini (Italy).

The test involved three different targets:

A. Proof of the inner sterilization temperature as declared by manufacturer (150 °C) with an external temperature sensor calibrated by an accredited third-party laboratory;

B. Proof of the sterilization process with a Bio-indicator Vial with Log6 concentration of thermos-resistant G. Stearothermophilus spores according to STAAT Level IV;

C. Proof of the sterile conditions of the residue with an initial spiking of Log6 of six different kinds of bacteria per kg according to STAAT Level IV;

D. Proof of the constant sterile conditions of the residue held at 25°C for 28 days, according to the dedicated French Law.

Newster technicians (Runs 1-2) and an accredited third-party laboratory technician (Run 3) carried out the samples for the microbiological analysis in accordance with international standard methods:

1) Incubation of the bioindicator vial (G. Stearothermophilus spores with log6 concentration) at 55 °C for 48 hours;
2) Incubation of the plates of each kind of bacteria with specific agar and temperature.

The Newster sterilizer meets the international standard requirements for the sterilization of infectious solid medical waste.

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2 Brief Description of Newster® Sterilization Cycle

Newster®sterilizer is a patented technology for the processing of infectious solid waste, based on frictional heat treatment (FHT)[1]in a blade-equipped vessel, under slightly negative pressure (the treatment chamber is never under pressure unlike autoclave). The residue obtained is sterilized, finely ground, dry and reduced in weight and volume

A patent sensor detects the real-time temperature inside the vessel. The cycles allows to reach the sterilization temperature of 150 °C after which the waste is automatically sprinkled with tap water in order to cool down the residue until 95°C. The cycle is over and the dehydrated product is unloaded automatically. Newster® machines are equipped with a heat-exchanger to cool down the vapour coming out from the vessel. The water from the heat-exchanger and condensable vapours, with values within legally established limits, are discharged into the sewer. Each cycle lasts approximately 30-40 minutes depending on the quantity of liquids present in the waste.

[1]Compendium of Technologies for Treatment/Destruction of Healthcare Waste, UNEP, 2012 (see p 64-66)

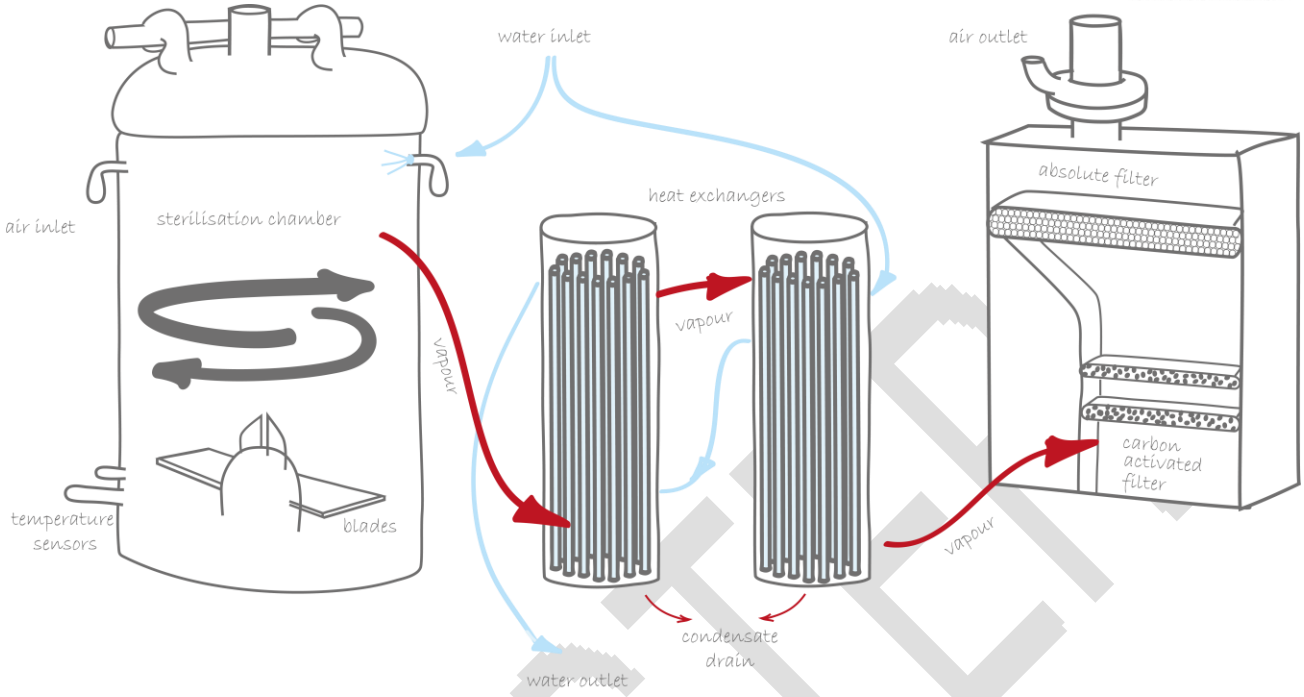

Figure 1: Frictional Heat Process Scheme

2.1 Sterilization Process in Newster® NW Series

The process, in automatic mode with the final printing of the report, follows these stages:

1. Waste is loaded into the sterilization vessel, the lid is closed and the treatment process is started by pressing a button. The engine starts, filters are activated and resistances are turned on.
2. The rotor turns faster and the temperature starts to rise rapidly and the materials are finely pulverized.
3. When 96 – 100°C is reached, the temperature remains stable until the water present in the waste has completely evaporated. The vapours are cooled down in the heat-exchangers and discharged into the sewage system;
4. After the water has evaporated the temperature starts to rise rapidly again, reaching 150°C. The sterilization phase is finished.
5. The residue is sufficiently moistened by a spray of water to cool down to 95°C.
6. The sterilization cycle has now been completed. The hatch is opened, and the product is extracted and collected in the stainless steel integrated waste collector.

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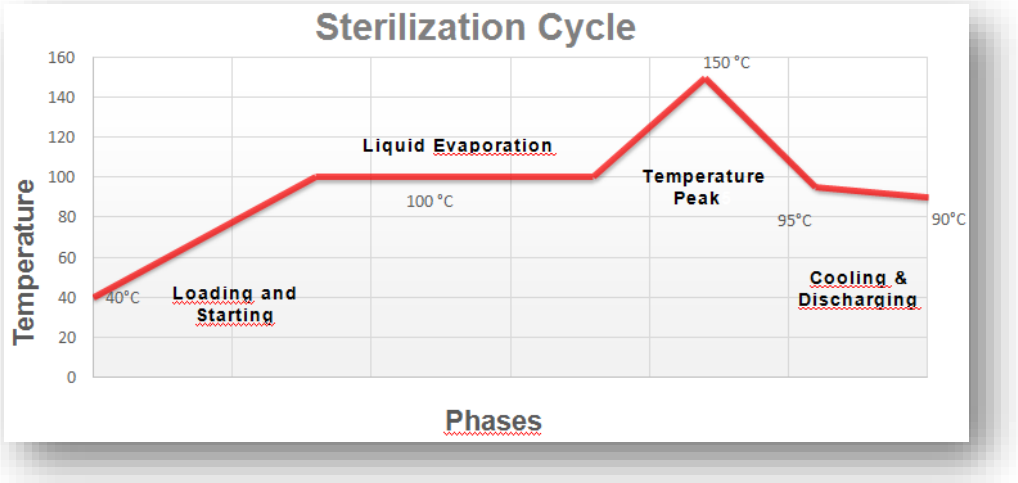


Figure 2: Frictional Heat Temperature Diagram

3 Efficacy Validation Testing

In order to meet the target of the present microbiological study, *Newster® Technical and R&D Departments* decided to realize a scientific research in collaboration with the *CSA Institute of Research*, located in Rimini (Italy), in order to evaluate the efficacy of the sterilization process according to the following analysis template:

1. Newster® Physical Validation Protocol;
2. Newster® Biological Bio-Indicator Test;
3. Newster® Microbiological Efficacy Test Protocol;
4. Newster® Evaluation of Bacterial Re-Growth Test.

3.1 Newster® Physical Validation Protocol

Considering the sterilization process as described above, the first target is the validation of the physical sterilization agent represented by the temperature. According to the Italian technical protocol *UNI 10384*, the temperature sensor used during the physical validation test is a certified sensor, controlled by an accredited third-part laboratory:

ITEM: Digital Thermometer;

Manufacturer: TESTO S.p.a.

Model: TESTO 925

Serial Number: 34794905/705/A

Certification Date: 2019 – 03 – 05

Laboratory Register: BCSGL/15408

Calibration Certificate: LAT 238 0749-19

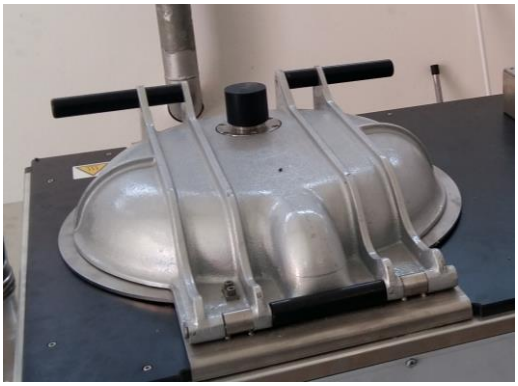
In attachment there is the validate certificate.

The temperature control must be carried out at this set-point:

a) 150 °C

It is necessary to write down the start time of the cycle and the time of each survey.

***HOW TO PROCEED*:** Prepare a determined load of waste (according to the treatment capacity of Newster® Machines). Load the waste into the vessel and close the lid. Prepare the temperature sensor, close the inlet tap water and start the cycle in automatic mode. When the temperature on the touch panel arrives at the indicated set point, stop the machine, remove the closure nut and insert the sensor in the vessel. Measure the temperature in the three different points indicated in the following figure:



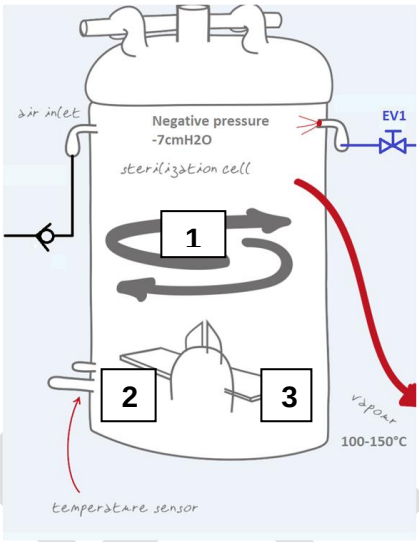


Figure 3: Sensor Position in Sterilization Vessel

The temperature is controlled in three different points of the vessel according to UNI 10384:

1. The upper part of mass waste (Point 1 – Critical Point);
2. The bottom part of the mass waste, left side (Point 2);
3. The bottom part of the mass waste. Right side (Point 3)

Write down on the specific form the temperature indicated on the machine's touch panel and the temperature measured with the certified sensor.

NOTE: use all the personal protective equipment (glasses, gloves, mask, overalls…) indicated in the user manual.

3.2 Newster® Biological Bio-Indicator Test

The usual Newster® sterilization process efficacy protocol is based on the use of *Geobacillus Stearothermophilus spores* ampoules. According to STAAT (*State and Territorial Association on Alternative Treatment Technologies)*, non-combustion devices for moist heat treatment of

health care waste must achieve a 4Log10 or greater reduction of *Geobacillus Stearothermophilus* bacterial spores (ATCC 7953) – Level III.

Never-less, to assure a higher microbial inactivation level, we using a biological indicator containing 6Log10 of *Geobacillus Stearothermophilus* spores (ATCC 7953), in order to follow the Level IV[2].

***HOW TO PROCEED*:** Take a glass ampoule bio-indicator consisting of a 1 ml vial containing a suspension of thermo-resistant *Geobacillus Stearothermophilus* spores (ATCC 7953), at 6Log10 concentration, in culture soil with pH indicator.

Take off the ampoule's label and place the test vial in the dedicated vial holder inside the vessel of the NW machine just before the loading of the health care waste (HCW).

At the end of the sterilization process, recover the vial and incubate it at 56±1°C for 48 hours.

The colour change of the biological indicator from purple to yellow confirms the vitality of the

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[2]2. Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies. A Report of the State and Territorial Association on Alternative Treatment Technologies (STAATT) (see p 21, p34)

Table 2-1

Levels of Microbial Inactivation (STAATT I)

Level I: Inactivation of vegetative bacteria, fungi, and lipophilic viruses at a 6 Log10 reduction or greater;

Level II: Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log10 reduction or greater;

Level III: Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log10 reduction or greater; and inactivation of B. stearothermophilus spores or B. subtilis spores at a 4 Log10 reduction or greater;

Level IV: Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, mycobacteria and B. stearothermophilus spores a 6 Log10 reduction or greater.

spores. If no colour change takes place, the spores are no longer vital, therefore the sterilization process has been successful.

Figure 4: Vial Incubation at 55 ± 2 °C for 48 hours

PRE-INCUBATION	*TEST VIAL* 	*CONTROL VIAL* 
POST-INCUBATION (after 48h at 55-56 °C)	*TEST VIAL* 	*CONTROL VIAL* 

Figure 5: Bioindicator Test

NOTE: After the cycle the vial's original purple colour could have changed to dark-purple or brown. The colour variation before the 48h incubation doesn't have an effect on the validity test.

NOTE: Use a vial unexposed to the sterilization cycle as positive control.

3.3 Newster® Microbiological Efficacy Test Protocol

In order to demonstrate the effective sterile conditions of the residue, Newster® Microbiological Efficacy Protocol contemplates a direct analysis of the residue after the cycle. Before starting the cycle, each kilogram of the waste is spiked with an amount of 6Log10 of Geobacillus

Stearothermophilus spores with the possibility to include other different kinds of bacteria. The choice of different types of bacteria depends on the most reliable bacteria that it is usually possible to find in solid healthcare waste, including the biological indicator and at least spore-forming bacteria like *G. stearothermophilus.*

The bacteria usually used are *Escherichia coli, Pseudomonas aeruginosa, Legionella pneumophila, Staphylococcus aureus, Clostridium perfringens, Salmonella enteritidis and Geobacillus stearothermophilus* with an initial concentration of 6log10.

The 6log10 concentration choice depends on STAATT (*State and Territorial Association on Alternative Treatment Technologies*) Level IV criteria, non-combustion devices for moist heat treatment of health care waste.

The protocol includes for each automatic cycle a sample in a sterile bag. Inside the laboratory, the samples can be stored in a refrigerator at 4°C up to 24 hours maximum before performing the microbiological analyses.

HOW TO PROCEED:

1) PREPARATION OF BACTERIAL COLTURE AT 6LOG10

Resume microbial strains in selective agar media. From the culture growth, transfer a single isolated colony to a nutrient agar broth (NB) and incubate until they reach the desired concentration as indicated above.

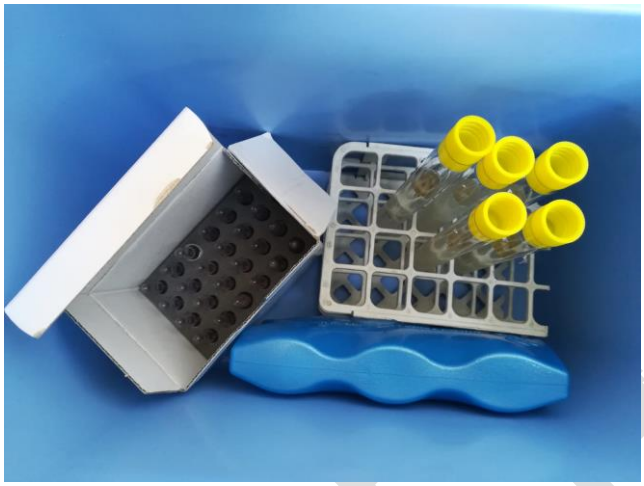


Figure 6: G. Stearothermophilus Ampoules and Vials with specific bacterial concentration

2) WASTE SPIKING

Prepare a predetermined quantity of actual medical waste (not surrogate medical waste or solid waste) considering the capacity of the machine.

Figure 7: Microbiological Contamination of Waste

3) SAMPLING AND STORAGE

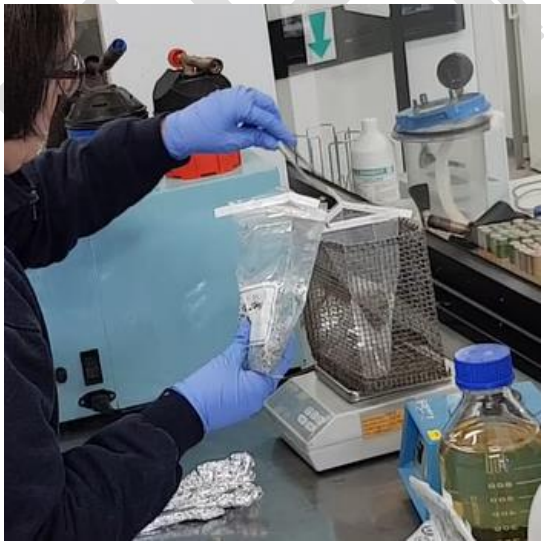
After sterilization, one sample is put in sterile plastic bags measuring 25x30 cm by using sterile gloves. Divide the sample in two parts and put into the correct storage temperature system (for only bacterial re-growth evaluation).

Figure 8: Sampling of the residue

4) MICROBIOLOGICAL ANALYSIS

Dilute each 10 gram sample with 90 ml of water peptone solution and put it in a stomacher for a few minutes (or shake it on a stir for 30 minutes at room temperature).

1,0 ml of supernatant in a 90 mm petri dish (trying to avoid touching the walls), each containing specific agar as listed in the Table below.



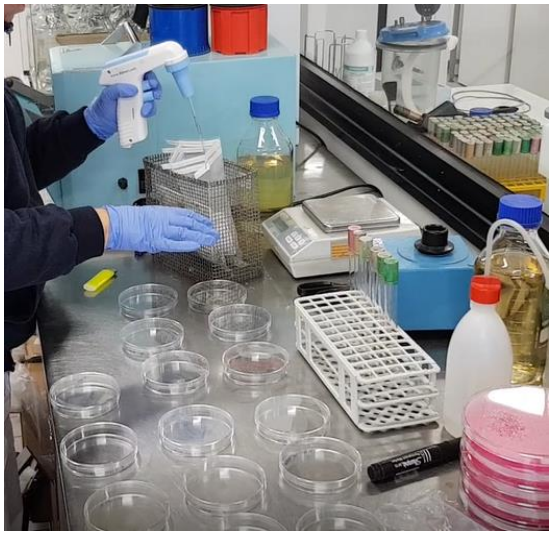


Figure 9: Microbiological Analysis– Particular 1 and 2

Aerobically incubate the plates for 24-48 hours at the temperatures reported in the table below.

Count the number of colonies in each plate and calculate the CFU per gram of waste residue considering the dilution and the weight of the initial waste residue.

Figure 10: Microbiological Analysis – Particular 3

Microorganism	***Growth media***	***Incubation Temp.***	***Method***
Escherichia Coli	TBX	44±1 °C for 24±2h	ISO 16649-2:2001
Stafilococcus Aureus	Baird parker agar	37±1 °C for 48±4h	UNI EN ISO 6888-1:2018
Pseudomonas aeruginosa	Pseduomonas CN agar	36±2°C for 48±4h	UNI EN ISO 16266:2008
G. Stearothermophilus	Dextrose Tryptone Agar	55±1 °C for 48±4h	Internal method
Clostridium perfringes	TSC agar	37±1°C for 24±2h	UNI EN ISO 7937:2005
Salmonella enteriditis	XLD agar	37±1°C for 96h	UNI EN ISO 6579-1:2017

Legionella pneumophila	Legionella BCYE-MWY Agar	36±2°C for 10 days	ISO 11731:2017

Table 1: Microbiological Analysis of Waste Residue

If the plate contains less than 10 colonies, consider the count as not representative. Report the result "**<10 CFU/g**" as '**estimated number of microorganisms per gram'.**[3]

3.4 Newster® Evaluation of Bacterial Re-Growth Test

To prove the efficacy of the sterilization process and evaluate any possible bacterial regrowth after the usual 48 hours of maximum storage time, the Newster® Microbiological Efficacy Test protocol includes a dedicated section for the evaluation of the possible bacterial re-growth until the 28th day.

The schedule of this section follows the French Law "*Order of 2019, 28th March on the implementation of an experiment on the recovery of waste from pre-treatment by disinfection of infectious and related health care waste*" (JORF n ° 0082 of April 6th, 2019 Text n ° 14),

The residue is maintained in a sterile bag at a temperature of 20 ° C.
The specific bacterial indicators are *Staphylococcus aureus, Enterobacteriaceae, Pseudomonas aeruginosa.* Newster® Protocol also considers *Escherichia coli, Legionella pneumophila, Clostridium perfringens, Salmonella enteritidis and Geobacillus Stearothermophilus.*
For each cycle, the protocol contemplates the microbiological analysis at 24 hours intervals for 5 days and the last one at the 28th day:

[3] **ISO 7218:2007(E) - 10.3.2.4.1 Case when one dish (test sample or initial suspension or first dilution) contains less than 10 colonies (see p. 40-41)**

- T0 = 0 hours from sampling
- T24 = 24 hours from the sampling;
- T48 = 48 hours from the sampling;
- T72 = 72 hours from the sampling;
- T96 = 96 hours from the sampling;
- T672 = 672 hours from the sampling.

HOW TO PROCEED: Follow paragraph 1.3

4 Validation Testing

The following paragraphs describe, as an example, the tests conducted according to the Newster Protocols on 4 different runs and the related results, in order to demonstrate the microbiological efficacy (>log10 6 reduction of bacterial spores) of a Newster Sterilizer (model NW15) installed at the "Sol et Salus" Private Clinic, Rimini (Italy).

Unit Tested:	NW15 – Serial Number 364
Onsite Test Manager:	*Gianluca Magrini –Accredited Chief Waste Officer* *R&D Department, Newster System Srl*
Operations Manager:	*Laura Trevisson – Quality, Health, Safety and Energy Manager* *R&D Department, Newster System Srl*
Third-Part Laboratory Technician:	*Sara Lazzarini – Microbiologist* *Laboratory Unit, CSA Group - Institute of Research*

For the validation testing, actual medical waste (not surrogate medical waste or solid waste) was delivered to the area where the NW15 Sterilizer is located. In four different days, four runs were processed:

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- **RUN 0**: Temperature Validation according to *Newster® Physical Validation Protocol*

- **RUN 1**: Microbiological Efficacy Test according to *Newster® Biological Bio-Indicator Test* and *Newster® Microbiological Efficacy Test Protocol* (the waste was spiked only with *Geobacillus stearothermophilus)*with the evaluation of the possible bacterial re-growth until the 28th day;

- **RUN 2**: Microbiological Efficacy Test according to Newster® Biological Bio-Indicator Test and Newster® Microbiological Efficacy Test Protocol (the waste was spiked only with *Geobacillus stearothermophilus)*with the evaluation of the possible bacterial re-growth until the 28th day*;*

- **RUN 3**: Microbiological Efficacy Test according to Newster® Biological Bio-Indicator Test and Newster® Microbiological Efficacy Test Protocol with the evaluation of the possible bacterial re-growth until the 28th day.

4.1 RUN 0

On April 1,2019 a run with 17 kg of waste (intensive care unit, sub-intensive care unit, operation theater, orthopedic dept., sharp boxes) was processed. The machine worked in automatic until the 150 °C temperature.

When the printer, printed out the line with 150°C temperature, the machine is stopped and the temperature sensor is inserted inside the vessel. The three different points were controlled.

Figure 11: Temperature Measured inside the vessel

POINT "1": 151,1 °C

POINT "2": 152,2 °C

POINT "3": 152,8 °C

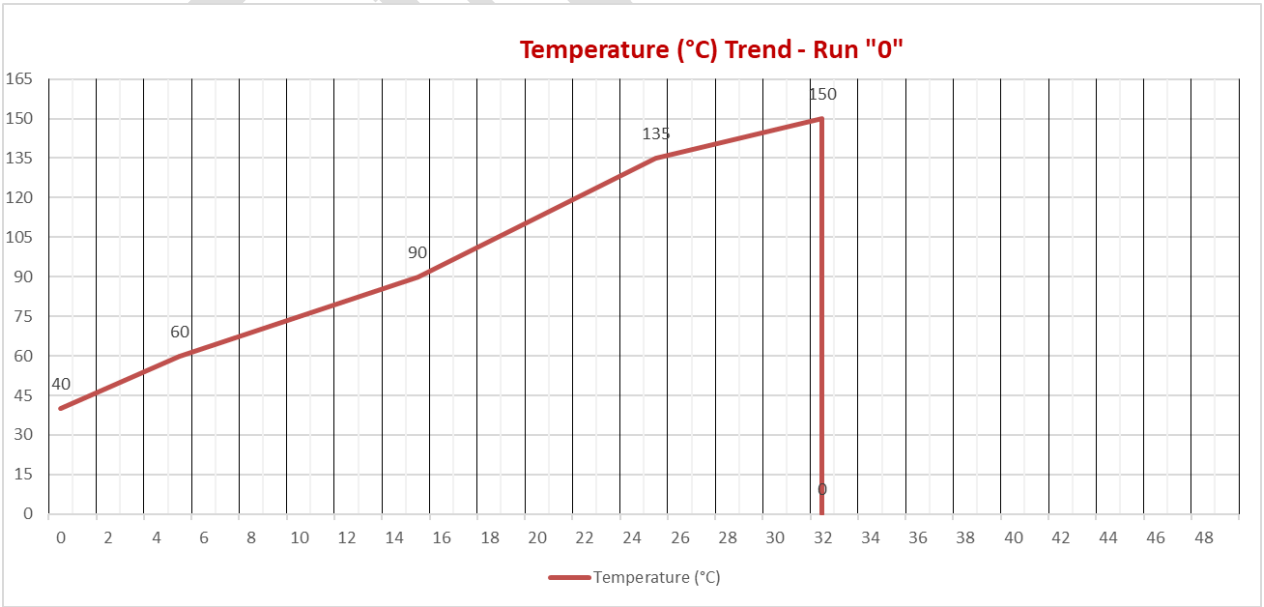

Figure 12: Temperature Trend Run "0"– Duration Cycle 29 minutes

4.2 RUN 1

On April 8, 2019 a run with 18 kg of waste (intensive care unit, sub-intensive care unit, Operation Theatre, orthopaedic department, sharps boxes) spiked with a log10 6 concentration of *Geobacillus stearothermophilus* spores, was processed (18 ampoules).

Before starting the cycle in automatic mode a vial containing a suspension of thermo-resistant *Geobacillus stearothermophilus* spores (ATCC 7953) at 6 Log_{10} concentration was also placed in the dedicated vial holder inside the vessel of the NW machine.

After the end of the cycle (35:02 minutes), with sterile gloves, a sample of the residue was taken out of the unloading box and placed in a sterile plastic bag to be analysed at the certified laboratory.The following table summarizes the microbiological analysis results from the test performed on *Geobacillus Stearothermophilus* at 24 hour intervals for the first 5 days and the last one the 28th day.

ID Sample	Temp.	T0	T24	T48	T72	T96	T360	T672	Newster Protocol
(#)	[°C]	[CFU /ml]	[CFU /ml]	[CFU /ml]	[CFU /ml]	[CFU /ml]	[CFU /ml]	[CFU /ml]	(#)
3.1_SW2_08042019	5 ± 3 °C	**<10**	-	-	-	-	-	-	**Microbiological Efficacy Test Protocol**
3.1_SW2_08042019	25 ± 1 °C	-	**<10**	**<10**	**<10**	**<10**	**<10**	**<10**	**Evaluation Bacterial Re-growth**

Table 2: Microbiological Analysis Report on Geobacillus Stearothermophilus

None of the results show *Geobacillus stearothermophilus* re-growth (the original analysis are available upon request). The following pictures show the result of the Bio-Indicator Test after the treatment. After 48 h of incubation the vial did not change colour, meaning that the sterilization was successful.

Figure 13: Bio-Indicator before incubation (on the left) and after incubation at 55-56 °C for 48 h (on the right)

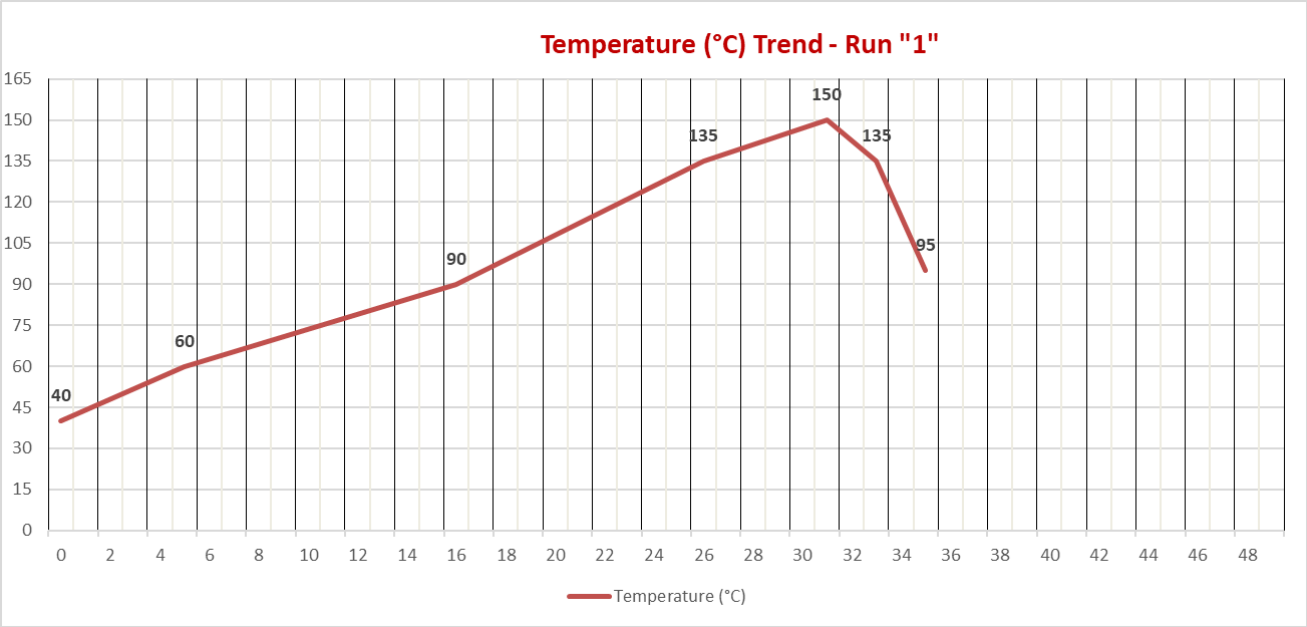

Figure 14: Temperature Trend Run 1 – Duration Cycle 35:02 minutes

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4.3 RUN 2

On 2019 April 14th a run with 15 kg of waste (intensive care unit, sub-intensive care unit, operation theatres, orthopaedic department) spiked with log10 6 concentration of *Geobacillus stearothermophilus* spores, was processed (15 ampoules).

Before to start the cycle in automatic mode a vial containing a suspension of thermo-resistant *Geobacillus stearothermophilus* spores (ATCC 7953) at 6 Log_{10} concentration was also placed in the dedicated vial holder inside the vessel of the NW machine.

After the end of the cycle (39:25 minutes), with sterile gloves, a sample of the residue was taken out the unloading box and placed in a sterile plastic bag before to be analyzed at the certified laboratory.The following table summarizes the microbiological analysis results from the test performed on *Geobacillus Stearothermophilus* at 24 hours intervals for the first 5 days and the last one at 28th day.

ID Samples	Temp.	T0	T24	T48	T72	T96	T360	T672	Newster Protocol
(#)	[°C]	[CFU/ml]	[CFU/ml]	[CFU/ml]	[CFU/ml]	[CFU/ml]	[CFU/ml]	[CFU/ml]	(#)
3.1_SW2_15042019	5 ± 3 °C	<10	-	-	-	-	-	-	Microbiological Efficacy Test
3.1_SW2_15042019	25 ± 1 °C	-	<10	<10	<10	<10	<10	<10	Evaluation of Bacterial Re-growth

Table 3: Microbiological Analysis Report on Geobacillus Stearothermophilus

None of the results shows *Geobacillus stearothermophilus* re-growth. The following pictures show the result of the Bio-Indicator Test after the treatment. After 48 h of incubation, the vial did not change colour, meaning that the sterilization was successful.

Figure 15: Bio-Indicator before incubation (on the left) and after incubation at 55-56 °C for 48 h (on the right)

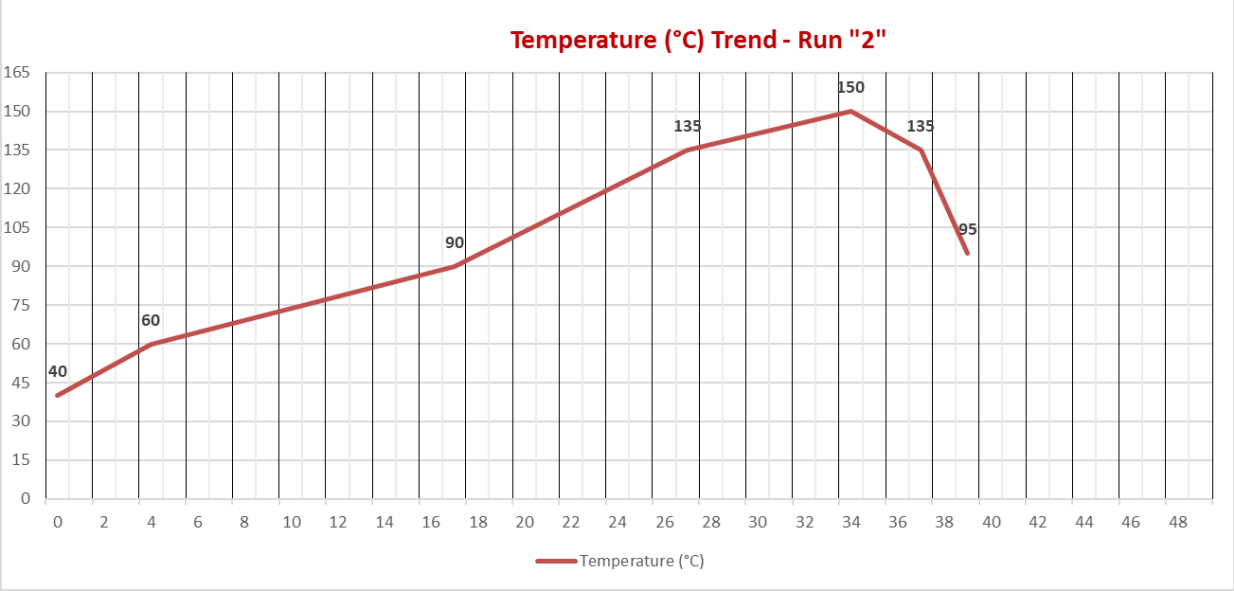

Figure 16: Temperature Trend Run 2– Duration Cycle 39:25 minutes

4.4 RUN 3

On June 10, 2019, a run with 15 kg of waste (intensive care unit, sub-intensive care unit, operation theatres, orthopaedic department, sharps boxes) spiked with log10 6 concentration of *Escherichia coli, Pseudomonas aeruginosa, Legionella pneumophila, Staphylococcus aureus, Clostridium perfringens, Salmonella enteritidis and Geobacillus stearothermophilus,* was processed.

Before starting the cycle in automatic mode a vial containing a suspension of thermo-resistant *Geobacillus stearothermophilus* spores (ATCC 7953) at 6 Log_{10} concentration was also placed in the dedicated vial holder inside the vessel of the NW machine.

After the end of the cycle (38:25 minutes), while wearing sterile gloves, a sample of the residue was taken out the unloading box and placed in a sterile plastic bag before being analysed at the certified laboratory.

The following table summarizes the microbiological analysis results from the test performed on the six bacteria at 24 hours for the first 5 days and the last one at the 28th day.

ID Samples	Temp.	Analysis	T0	T24	T48	T72	T96	T672	Newster Protocol
(#)	[°C]	(Type)	CFU /ml	CFU /ml	CFU /ml	CFU /ml	CFU /ml	CFU /ml	(#)
2.1_SW2_10 062019	5 ± 3 °C	G. Stereothermophilus	<10						Microbiological Efficacy Test
		Stafilococcus Aureus	<10						
		Pseudomonas Aeruginosa	<10						
		Clostridium Perfrigens	<10						
		Salmonella Enteridis	<10						
		Legionella Pneumophila	<10						
		Escherichia Coli	<10						
2.1_SW2_10 062019	25 ± 1 °C	G. Stereothermophilus	<10	<10	<10	<10	<10	<10	Evaluation of Bacterial Re-growth
		Stafilococcus Aureus	<10	<10	<10	<10	<10	<10	
		Pseudomonas Aeruginosa	<10	<10	<10	<10	<10	<10	
		Clostridium Perfrigens	<10	<10	<10	<10	<10	<10	
		Salmonella Enteridis	<10	<10	<10	<10	<10	<10	
		Legionella Pneumophila	<10	<10	<10	<10	<10	<10	
		Escherichia Coli	<10	<10	<10	<10	<10	<10	

Table 4: Microbiological Analysis Report on six different bacteria

None of the results show bacterial re-growth (original analysis certificate are available upon request). The following pictures show the result of the Bio-Indicator Test after the treatment. After 48 h of incubation the vial did not change colour, meaning that the sterilization was successful.

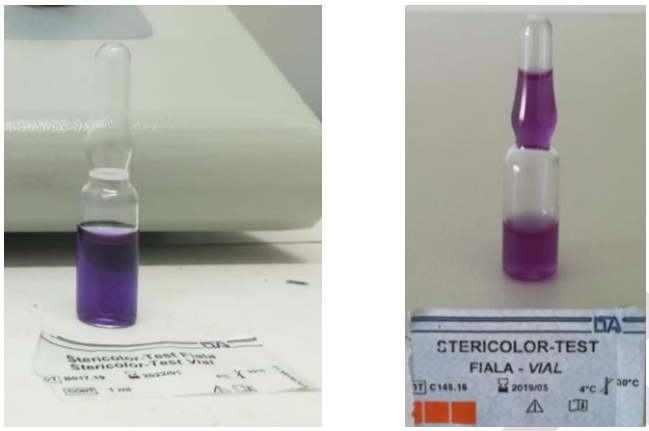

Figure 17: Bio-Indicator before incubation (on the left) and after incubation at 55-56 °C for 48 h (on the right)

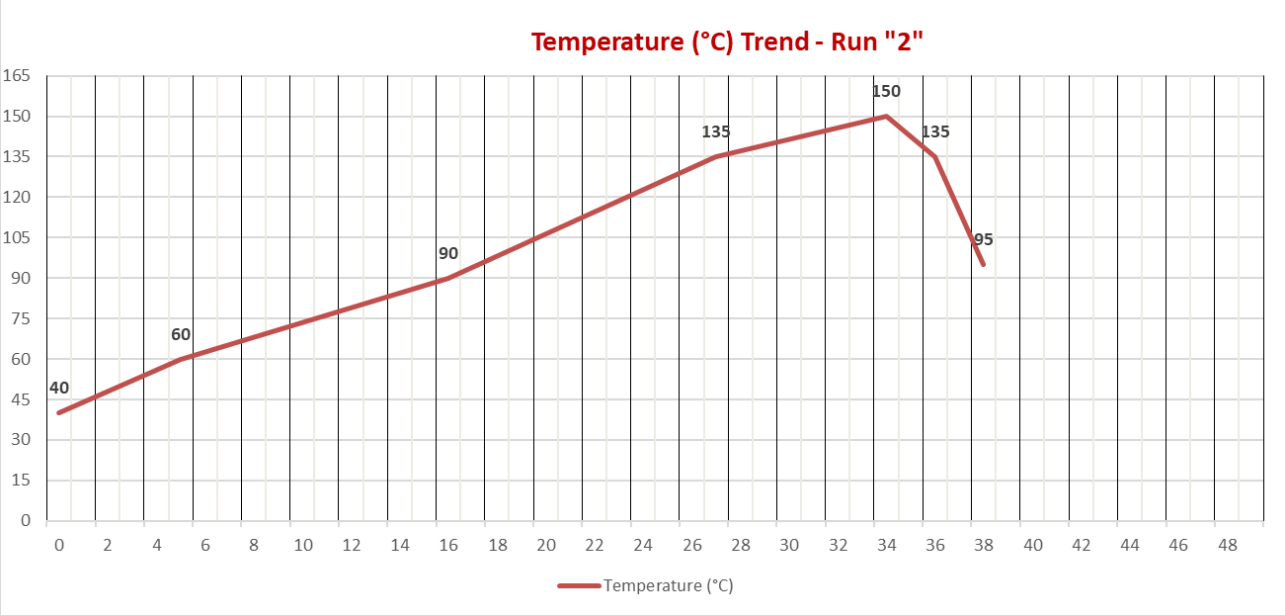

Figure 18: Temperature Trend Run 3– Duration Cycle 38:24 minutes

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5 Conclusions

The present report was developed in order to demonstrate that Newster® Sterilizers can meet all objectives and requirements requested by a typical Autoclave homologation test.
Most of the methods used for this scope are different from Autoclave's, because of the differences in terms of process of the two technologies.
Nevertheless, the analysis and the studies of the present document show that with Newster® Sterilizers it is possible to meet and overcome the Level IV criteria of sterilization according to the State and Territorial Association on Alternative Treatment Technologies (STAATT).

Moreover RUN 3 points out a sterilization level greater than 6Log10. In fact, before the treatment, the actual waste was spiked with an additional concentration of 6Log10 of six different bacteria.

The sterilized material of all RUNS, described in the present report, show the sterilization status at least until 28th day after the treatment at STD condition. This feature is not usually requested in typical commissioning and validation tests, but Newster R&D department submitted also to this evaluation in order to prove the high qualitative level of the Newster Sterilizer treatment.

The original CSA laboratory certificates are available under request.