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)

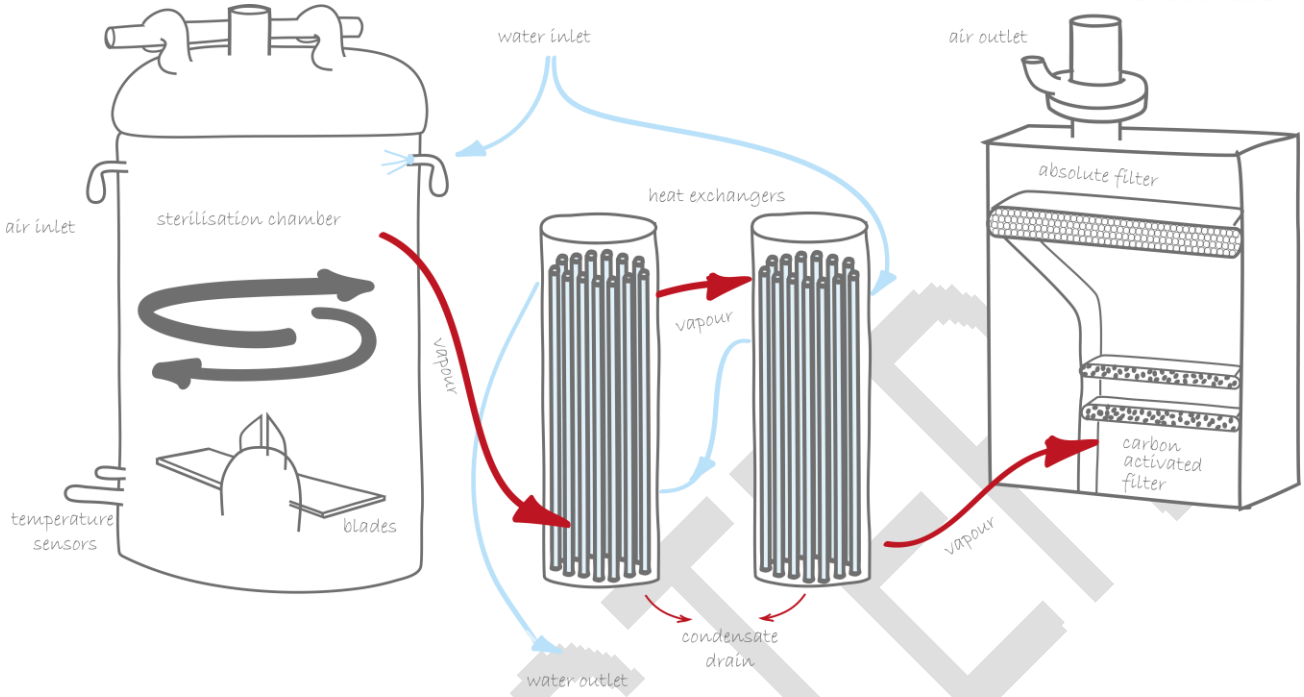

Figure 1: Frictional Heat Process Scheme

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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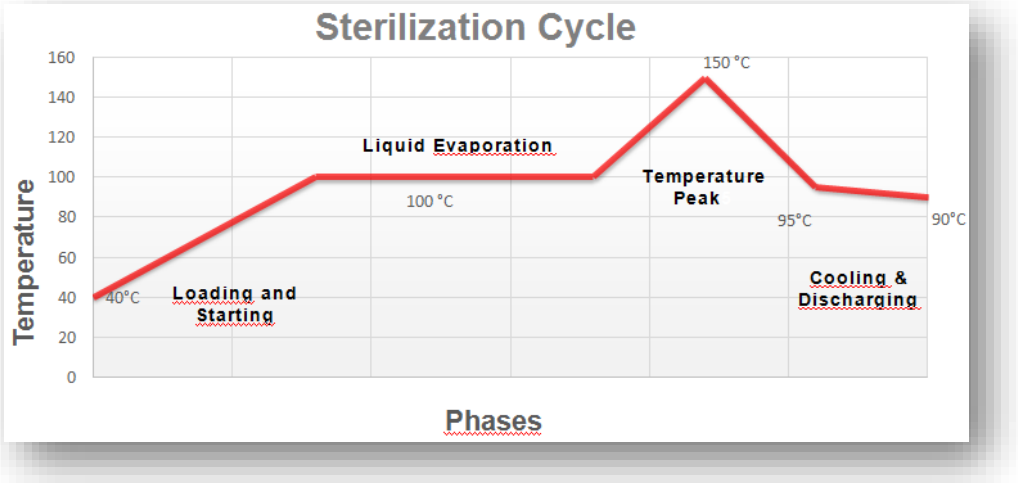


Figure 2: Frictional Heat Temperature Diagram

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

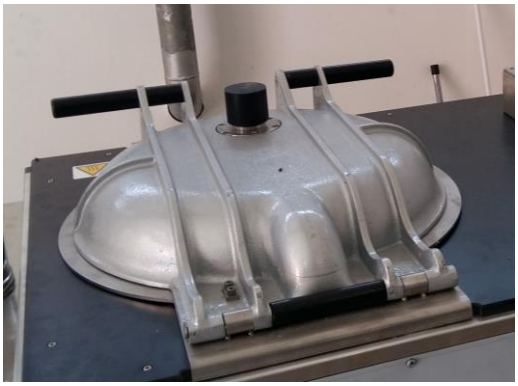
In attachment there is the validate certificate.

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:



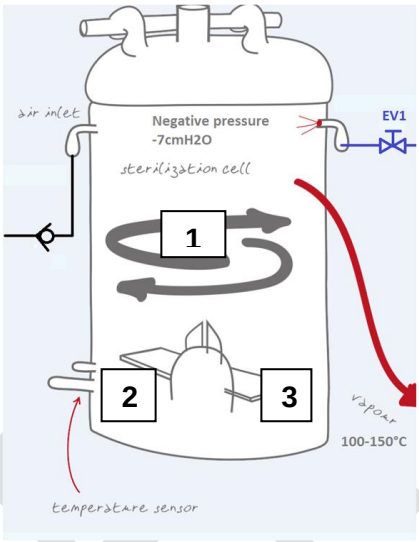


Figure 3: Sensor Position in Sterilization Vessel

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.

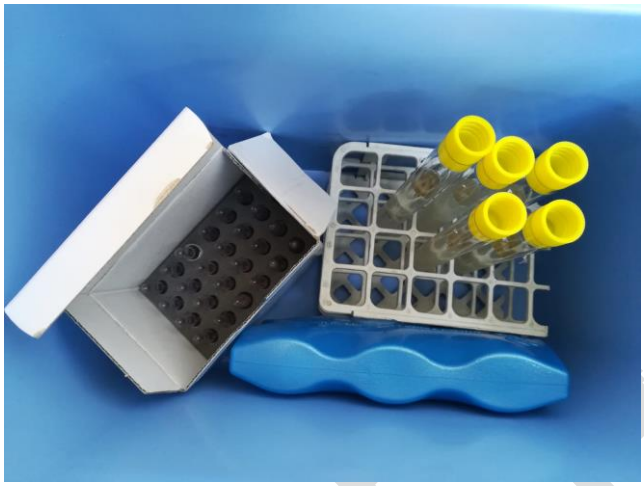


Figure 6: G. Stearothermophilus Ampoules and Vials with specific bacterial concentration

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

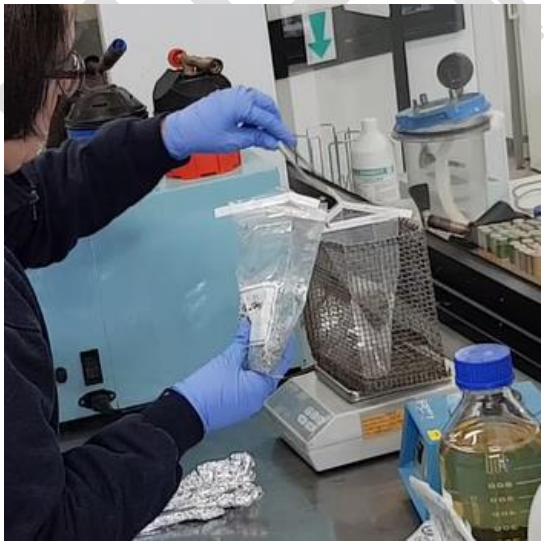
After sterilization, one sample is put in sterile plastic bags measuring 25x30 cm by using sterile gloves. Divide the sample in two parts and put into the correct storage temperature system (for only bacterial re-growth evaluation).

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.



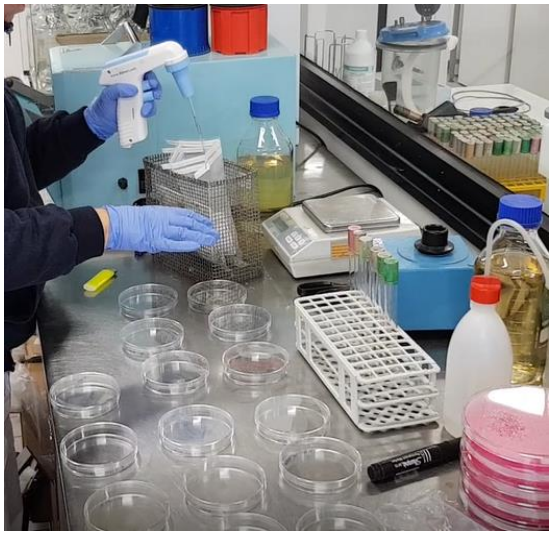


Figure 9: Microbiological Analysis– Particular 1 and 2

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

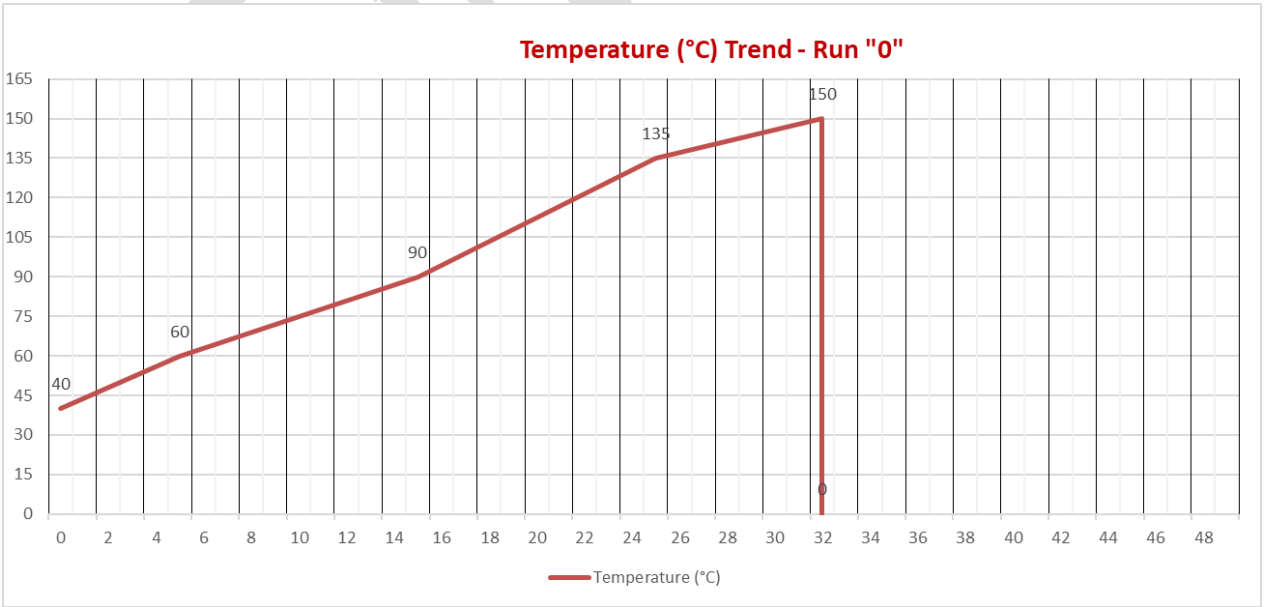

Figure 12: Temperature Trend Run "0"– Duration Cycle 29 minutes

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)

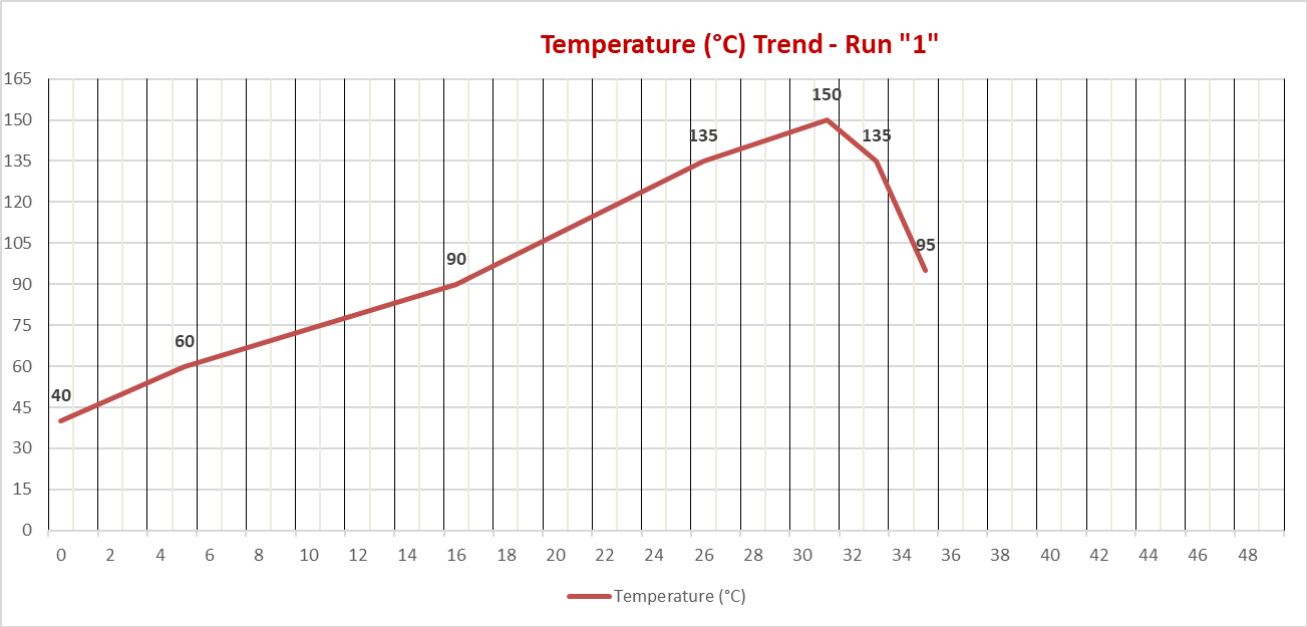

Figure 14: Temperature Trend Run 1 – Duration Cycle 35:02 minutes

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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)

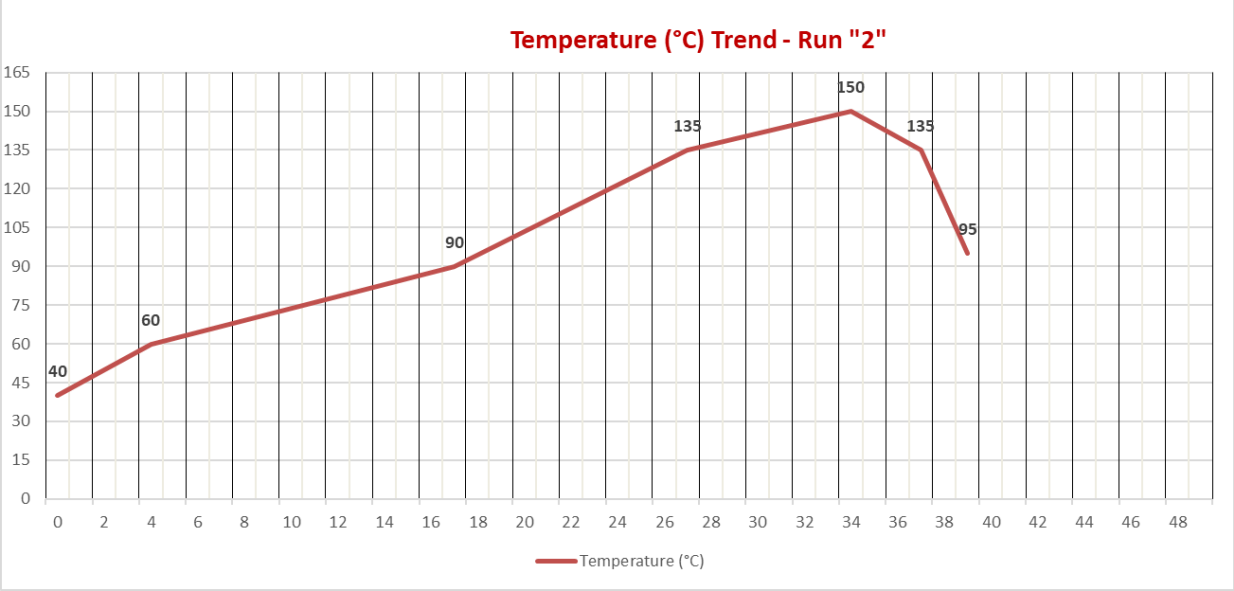

Figure 16: Temperature Trend Run 2– Duration Cycle 39:25 minutes

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.

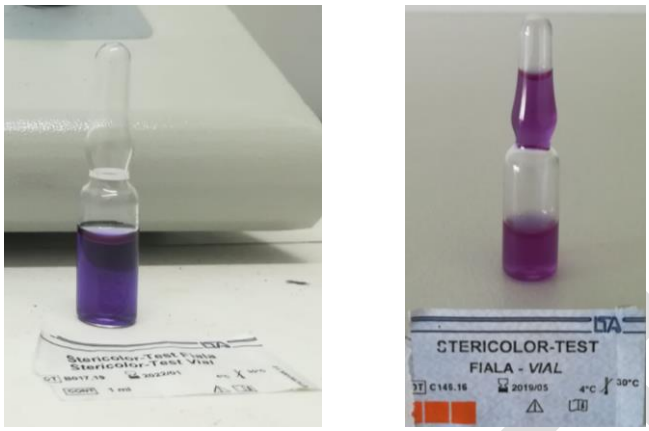

Figure 17: Bio-Indicator before incubation (on the left) and after incubation at 55-56 °C for 48 h (on the right)

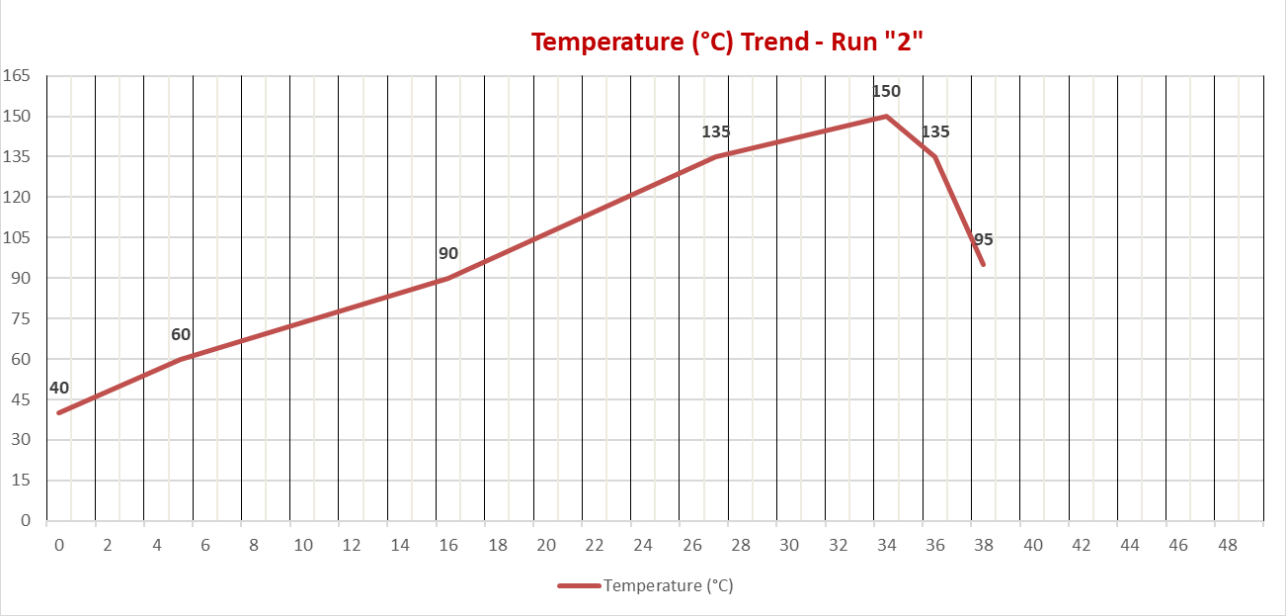

Figure 18: Temperature Trend Run 3– Duration Cycle 38:24 minutes

HEADQUARTER & MANUFACTURING

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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.

Proving the efficacy of sterilization treatment of potentially infectious solid waste

Medical waste: from sterilization to the End of Waste

sterilization

Solid infectious waste

hospitals

microbiological analysis

Gruppo C.S.A. S.p.A. has defined and executed in collaboration with Newster System s.r.l. the validation tests of the efficacy of the sterilization process of Newster sterilizers:

- Physical validation test, based on the verification of the sterilization temperature according to the Italian technical standard UNI 10384
- Biological indicator test, based on the use of Geobacillus Stearothermophilus spore vials and verification of the achievement of a level higher than that defined by the State and Territorial Association on alternative treatment technologies, for non-combustion devices for wet thermal treatment of healthcare waste
- Microbiological efficacy test, based on the execution of microbiological analyzes to verify the sterile conditions of the medical waste residual produced by the sterilizer
- Bacterial regrowth test, based on the execution of microbiological analyzes up to the 28th day from sampling.

Specialization AREA

Health and wellness - Safety in wellness and healthcare infrastructures

Platform and catalogue section

Energy and Environment – tools and methods for sustainability, Industrial symbiosis: use, reuse, enhancement and substitution of matter

Microbiological analysis preparatory activity: plate inoculation

GRUPPO CSA ISTITUTO DI RICERCA

Gruppo C.S.A. S.p.A.

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Proving the efficacy of sterilization treatment of potentially infectious solid waste

PRODUCT DESCRIPTION

C.S.A. helped Newster to define a protocol to verify the sterilization effectiveness of Newster sterilizers, designed for the on-site treatment of potentially infectious medical waste.
C.S.A. provided the study and planning of the steps and methods to evaluate the Newster sterilization process and then performed the tests, including microbiological analysis activity on the residue of the sterilization process.

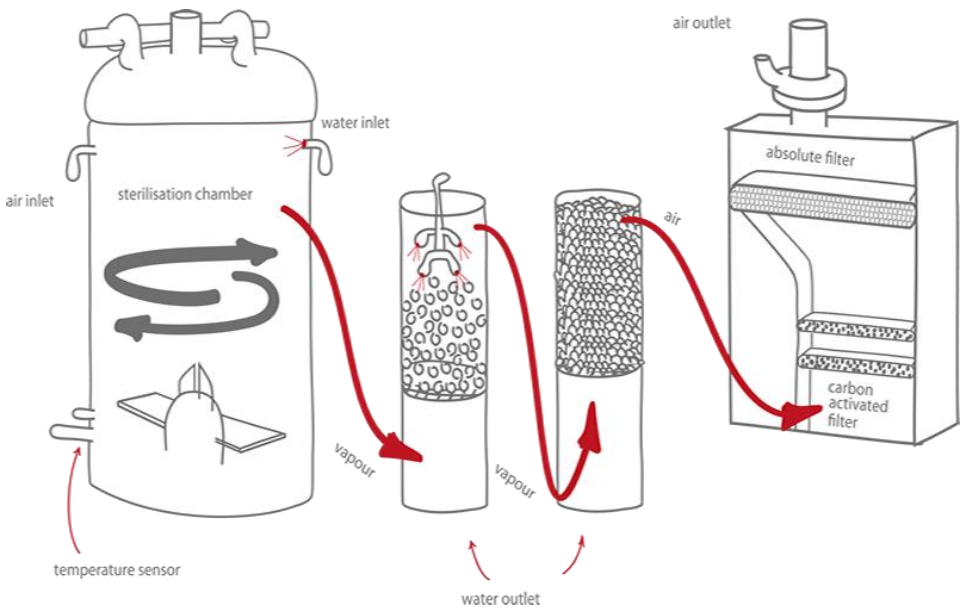
INNOVATIVE ASPECTS

The results obtained from the laboratory tests and analyses demonstrated that Newster sterilizers comply with the international requirements for the sterilization of medical waste, represented by STAATT level IV. for the evaluation of the efficacy of the sterilization processes which corresponds to the inactivation of bacteria, fungi, lipophilic and hydrophilic viruses, parasites, mycobacteria and spores of Geobacillus Stearothermophilus with a concentration equal to or greater than 6log10.

POTENTIAL APPLICATIONS

Newster sterilizers can be used by public or private hospitals, of various sizes, for the disposal of solid waste, through the installation of the system on site for the treatment of potentially infectious waste generated by the structure itself. The installation does not require authorization from the competent PPAA, but a simple communication pursuant to the Decree by the President of the Republic n. 254, 15 July 2003. Thanks to its characteristics, the residue can be considered as RDF or assimilated to the undifferentiated municipal waste.

Scheme of the sterilization flow using Newster friction heat treatment technology



Proving the efficacy of sterilization treatment of potentially infectious solid waste

APPLICATION EXAMPLE

Treatment of waste from small hospitals

APPLICATION DESCRIPTION AND RESULTS

Newster NW5 machine was designed for use in small hospitals.
On-site sterilization significantly reduces the costs of disposal of healthcare facilities, increases hygiene standards by improving staff safety and helps to reduce both the quantity of waste produced and the environmental impact thanks to the 30% reduction of CO_2 emissions due avoided transport.
The sterilization process involves 6 stages:
1. Loading of waste and start in automatic mode.
2. The rotor starts to rotate faster and faster, changing the direction according to needs. The temperature begins to rise as the materials are finely pulverized.
3. When 96 - 100 °C is reached, the temperature remains stable until the moisture in the waste has completely evaporated. The vapors are cooled in the heat exchangers and discharged into the sewage system in compliance with the discharge table pursuant to the legislative decree n.152/06 and as amended.
4.The temperature starts to rise rapidly, reaching 150 °C. Sterilization is reached in a few seconds.
5. By using tap water, the waste is cooled down to 95 °C before unloading.
6. Once the sterilization cycle is completed, the hatch can be opened and the product extracted and collected in the integrated stainless steel box.

INVOLVED PARTNERS

Newster System s.r.l.

IMPEMENTATION TIME

6 months

TECHNOLOGY READINESS LEVEL

TRL9 - Actual system proven in operational environment

EXPLOITATION

The Newster "FHT" sterilizer is covered by an international patent and has been available on the market for 25 years. The project implemented in collaboration with C.S.A.Group allowed to validate the sterilization efficacy of the machine through an objective and scientifically proven verification protocol.

Newster NW5 machine was designed for use in small hospitals

Gruppo C.S.A. S.p.A.

LABORATORY DESCRIPTION

Gruppo C.S.A. S.p.A. is an analysis laboratory and a private research institute specializing in the management of complex environmental monitoring plans, and capable of guiding and supporting a mainly application activity by research and development and following and coordinating complex and interdisciplinary projects that require a high level of professionalism and experience. The chemical-physical-microbiological analysis laboratory accredited according to ISO/IEC 17025 with number L0181, and equipped with a quality, safety and environmental management system certified according to ISO 9001, ISO 14001 and ISO 45001, is equipped with modern analytical systems that allow you to deal with a very wide range of investigations, ensuring reduced times and high quality standards. The high professional profile, the skills acquired in over thirty years of activity, and the continuous updating of staff, allow Gruppo C.S.A. S.p.A. to integrate sampling and analytical determination on various environmental and agri-food matrices, with high-level consultancy providing innovative and interdisciplinary solutions to complex problems, developing existing services and creating new ones, and thus representing a reliable partner. Always at the forefront in methodological, instrumental and technological applications of applied research in the environmental field.

REFERENCES

Altroconsumo Edizioni S.r.l., Celli S.p.A., Eco Pets Italia s.r.l., Hen food group s.r.l., ALIA S.P.A. OCU - Organización de Consumidores y Usuarios, Romagna Acque s.p.a., Arcadis Italia S.r.l., AECOM URS Italia S.p.A., The It Group Italia S.r.l., Tamoil Italia S.p.A., Ecotherm S.r.l., Sogepu S.p.A., Sogliano Ambiente S.p.A., GESENU S.p.A., HERAtech S.r.l., Planeta Studio Associato, Saipem S.p.A., Alia Servizi Ambientali S.p.A., Yara Italia S.p.A., Italferr S.p.A., A2A Ambiente S.p.A., Api Raffineria di Ancona, Caviro Distillerie S.r.l., Golder Associates S.r.l., Comune di Sant'Antioco, Jacobs Italia S.p.A., Enomondo S.r.l., Enel Produz. S.p.A, Consiglio Naz.le delle Ricerche, Conai, Tamoil Raffinazione S.p.A., Project Automation S.p.A., Cesi S.p.A., FERONIA S.r.l., Water & Soil Remediation S.r.l., Stantec S.p.A., Kuwait Petroleum Italia S.p.A., Consorzio Naz. Riciclo e Recupero Imb. Acciaio, Newster System srl, Regione Emilia-Romagna

Gruppo C.S.A. S.p.A. headquarters in Rimini

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RETE ALTA TECNOLOGIA EMILIA-ROMAGNA HIGH TECHNOLOGY NETWORK
POR FESR EMILIA-ROMAGNA 2014/2020
UNIONE EUROPEA Fondo europeo di sviluppo regionale
Regione Emilia-Romagna

Sterilization Theory

It has been experimentally shown that, under the above conditions, the reaction of thermal degradation of the micro-organism at issue obeys the laws of chemicalreactions.

Using N to indicate the number of micro-organism present in the system at a given moment, the variation of this number as the function of a chosen time t of exposure to the selected sterilization temperature can be writtenas:

$$\frac{dN}{\quad} = -KN\,dt$$

where **k** is a constant which is typical of the species and conditions of the chosen microorganism.

The degradation reaction, i.e. the sterilization reaction, therefore develops like a first order chemical reaction (i.e. like a chemical decomposition reaction) in which the reaction rate is proportional, in each moment, only to the amount of product still to be degraded (or decomposed).

The above expression can be developed as follows:

$$\frac{dN}{N} = -Kdt \qquad (1)$$

$$\int \frac{dN}{N} = -K \int dt$$

and, by converting to base 10 logarithms, the following is obtained:

$$log\ N = -kt + constant$$

where k = K/ 2.303 due to the shift from base e logarithms to base 10 ones.

At time zero, the following is true:

$$t = 0$$

$$N = N_0$$

therefore

$$\log N_0 = \text{constant}$$

From which

$$\log N = -k \cdot \Delta t + \log N_0 \qquad (2)$$

Which leads to

$$\log \frac{N}{N_0} = -kt$$

And therefore

$$\frac{N}{N_0} = 10^{-kt} \qquad (3)$$

Where

N_0= initial number of microorganism

t = elapsed exposure (=sterilization) time

N = number of micro-organism after the exposure time t

k = reaction rate constant which depends on the species and conditions of the microorganism.

Expression (3) shows that the number of micro-organism decreases exponentially depending on the sterilization time. If this expression is converted into a chart, with log N as the function of t, Diagram 1 is obtained:

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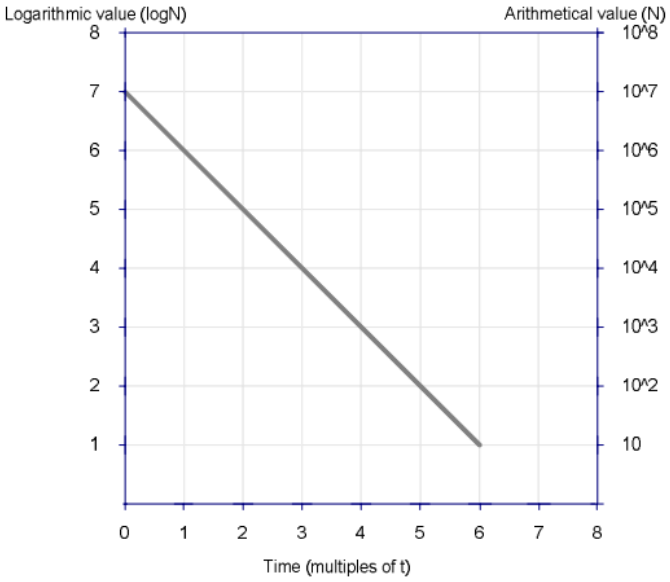

Diagram 1

Here we see that a constant percentage reduction of the concentration of viable microorganism occurs for each arbitrary time interval t. We can therefore draw a firstconclusion:

The time required to reduce the micro-organism concentration to any pre-set value is the function of its initial concentration.

The sterilization reaction is therefore neither an "all-or-nothing" process nor a "potential barrier" process as was once thought.

D-VALUE OR DECIMAL DECAY TIME

The D-value is defined as the decimal (or decadal) decay (or reduction) time: i.e. it is the time required, at a specified temperature T, to reduce the microbial population being considered by one logarithmic value, i.e. from 100% to 10% of the initial value.

It is very easy to calculate the D-value on the base of the above expression (3): it is the reciprocal of the reaction rate k, since if t = k-1, it is N = 0.1N0.

At the temperature of 121°C, the D-values generally oscillate between 0.2 and 2 minutes: very often D121 = 1 is assumed in the absence of more specific experimental data. It is immediately evident that the result of sterilization at constant temperature can be very different depending on the D-

value of the contaminating microbial species (or on the largest D-value, in case of mixed contamination). The following graph shows that a residual contamination of 10-6 is achieved in eight minutes, starting from an initial unit contamination of 102, at 121°C if D = 1. Sixteen minutes are required for the same result if D = 2 and 4 are sufficient if D = 0.5 (see Diagram 2).

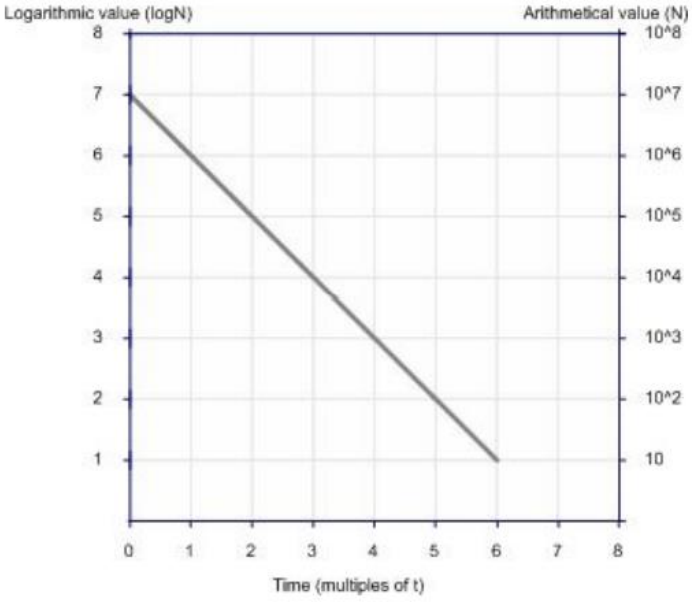

Diagram 2

STERILITY AS "PROBABLE EFFECT" OF EXPOSURE TIME

Let us now consider what happens within a batch of items (vials, bottles or others) with an initial constant unit contamination of 100 micro-organisms.

If the D-value at 121°C is assumed to be 1, after one minute at 121°C, the reduction t0 101 = 10 microorganisms is achieved; after another minute, only 10^0= 1 micro-organism is still surviving. After another minute the surviving microbial population would be 10^{-1} = 1/10 micro-organism.

A contamination of 1/10 must not be understood to mean that each unit contains 1/10 of a microorganism, which is biologically meaningless (in this case the unit would probably be sterile...) but that there is a probability of having 1/10 of the units still contaminated within the batch of sterilized units.

In fact, three minutes would be the necessary time to reduce the microbial population to a single surviving micro-organism if the initial population were ten times larger than the one at issue. This higher initial contamination could be regarded either as a ten times larger number of micro-organism in the same unit, or as the initial contamination of a ten times larger unit.

If the unit is not considered any longer as the single object, but as the whole of all the items produced over a period of time, the initial number of micro-organism present in each item has to be multiplied by the number of items produced, and the exposure time to achieve the reduction to the same number of viable micro-organism left in the whole of the items produced, has to be correspondingly increased.

The following example will be helpful to focus the matter. A new sterile product in ampoules has to be launched; the number of ampoules to be produced over all the life period of the product is expected to be 10^{10} . The maximum number of contaminated ampoules deemed to be acceptable is 10^0 = 1: this obviously means that the probability of having non sterile ampoules after the sterilization must not exceed -10.

Let us also suppose that the microbial population within each ampoule after the filling and the sealing does not exceed 10^3 micro-organisms: these must be destroyed by mean of heat terminal sterilization at 121°C. The applicable D-value is 1 minute. The total number of micro-organism to be destroyed during the life of the product will be:

$$10^{10+3} = 10^{13}$$

If this whole microbial population were exposed to moist heat at 121°C over a period of thirteen minutes, it would be reduced to 10^{-13} times it initial number, i.e. to $10^{13-13} = 10^0 = 1$.

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The exposure time of thirteen minutes would thus be sufficient (under all the other above hypotheses) to prevent the total number of contaminated ampoules from exceeding the value of one.

From the point of view of each single ampoule, thirteen minutes of exposure would reduce the microbial population to the theoretical value of:

$$10^{3-13} = 10^{-10}$$

To interpret this numeric value as the probability of still having one contaminated ampoule in ten thousand million sterilized ampoules means that a single ampoule will still be contaminated out of a whole of 10^{10} (or ten ampoules out of a whole of 10^{11}).

This probability value is defined as PNSU (Probability of Non Sterile Unit).

z-VALUE OR TEMPERATURE COEFFICIENT

All the above considerations have been developed under the basic assumption that the temperature is kept constant during all the exposure time. It seems rather obvious that the D-value will change as the temperature changes. If the D-values experimentally obtained for a given microbial species are plotted on a semi logarithmic chart as the function of the temperature T, a path similar to Diagram 4 is obtained:

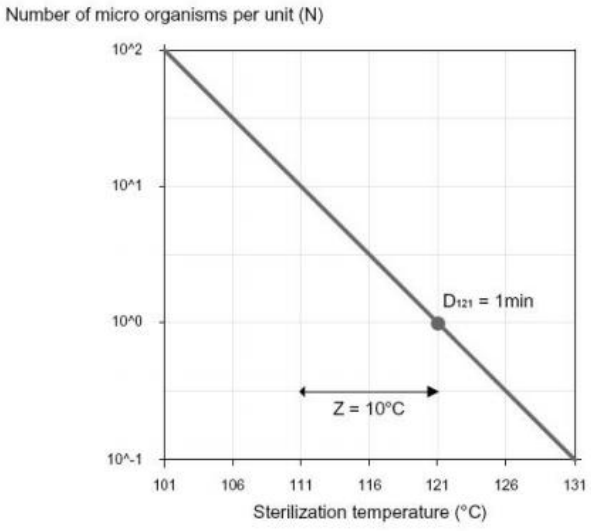


Diagram 4

In this case, it can be seen that D-value is 1 minute at 121°C (i.e. the average value which is very often assumed to be acceptable in the absence of more exact experimental data). It can also be seen that D - value varies by a factor of 10 if the temperature varies by 10°C.

The z-value is defined as the temperature coefficient of microbial destruction, i.e. as the number of degrees of temperature which causes a 10-fold variation of D (or, more generally, of the sterilization rate).

Z-value is often assumed to be equal to 10 in the absence of more precise experimental data. The fact that D-value varies by 10 times for a variation of 10°C when z = 10 must not lead to the false assumption that D varies by one time (i.e. doubles) for an increase of 1°C; obviously this is not true. It is actually a matter of finding the number which yields 10 when raised to the tenth power. This number is 1.24.

Therefore a variation of 1°C entails a variation of D-value of 24%

As can be seen, this is quite a considerable value which illustrate the dramatic effects which are generated when the sterilization temperature is also only a few degrees lower than the expected value, perhaps only in some point of the load.

Table 1 lists "average" D-values and z-values for some "typical" micro-organism; in fact the actual D-values and z-values depend to a large extent on the medium which contains the micro-organisms and on their history.

Table 1

AVERAGE VALUE OF D AND z FOR SOME TYPICAL MICRO-ORGANISMS		
Micro-organism	D_{121} (minutes)	z (°C)
Clostridium botulinum	0,2	10
Bacillus stearothermophilus	2,0	6
Bacillus subtilis	0,5	10
Bacillus megaterium	0,04	7
Bacillus cereus	0,007	10
Clostridium sporogenes	0,8 - 1,4	13
Clostridium histolyticum	0,01	10

Actually, at 121°C no micro-organism has exactly D = 1 and z = 10. However, the combined use of these two parameters in calculating F0 and PNSU provides ample margins of safety as regards the micro-organisms which are commonly dealt with.

F_0 OR EQUIVALENT EXPOSURE TIME AT 121°C

As seen above, D is thus a different function of the exposure temperature T for each different microorganism:

$$D = D(T)$$

On the basis of the definition of coefficient z it has also to be:

$$D(T - z) = D(T) \times 10$$

With the obvious condition that $D = D_0$ if $T = T_0$, the mathematical function which satisfies the above relationship is (see further explanation in the note at the end of this paragraph):

$$D = D_0 10^{\frac{T_0 - T}{z}} \qquad (4)$$

where D_0 is the value of D at the temperature T_0 and for a given micro-organism.

Let us now calculate the time interval required to obtain at a constant temperature T_0 the same reduction of a microbial population obtained at the actual exposure temperature T, continuously variable over a certain time interval t. It has obviously to be:

$$\int_0^{t0} \frac{dN_{T_o}}{N} = \int_0^t \frac{dN_T}{N}$$

and recalling expression (1) and the definition of D-value:

$$\int_0^{t_0} \frac{dt_0}{D_0} = \int_0^t \frac{dt}{D}$$

D-value is variable with the actual exposure temperature and is given by expression (4), but Do is a constant, so we may write:

$$t_0 = \int_0^t 10^{\frac{T - T_0}{z}} dt \qquad (5)$$

It is thus possible to calculate the lethal effect of the exposure of a microbial population to a variable temperature T by relating it to an hypothetical sterilization performed at a constant temperature $T_o$for the time t_o. If the constant reference temperature is assumed equal to 121.11°C

(originally 250°F) and the z-value equal to 10, the equivalent time given by expression (5) is named F_o:

$$F_0 = \int_0^t 10^{\frac{T-121.11}{10}} dt \qquad (6)$$

F_o is the equivalent exposure time at 121.11°C of the actual exposure time at a variable temperature, calculated for an ideal micro-organism with a temperature coefficient of destruction equal to 10.

F_o means the equivalent amount of time, in minutes at 121°C or 250°F, which has been deliveredto a product by the sterilization process. For its calculation, "a z-value of 10°C or 18°F is assumed; the term z-value means the slope of the thermal death time curve and may be expressed as the number of degrees required to bring about a tenfold change in the death rate". In practice, the knowledge of the temperature values as the continuous function of elapsing time is not available, and F_o is calculated as follows:

$$F_0 = \Delta t \sum 10^{\frac{T-121}{z}} \qquad (7)$$

Δt = time interval between two following measurements of T
T = temperature of the sterilized product at time t
z = temperature coefficient, assumed to be equal to 10°C

If we assume a sterilization lasting 15 minutes, constantly at 121°C, we obtain:

$$F_0 = 15 \cdot 10^{\frac{121-121}{10}} = 15 \cdot 10^0 = 15 \text{ minutes}$$

indeed according to the definition of F_o.

If we assume sterilization lasts 15 minutes, constantly at 111°C, we instead obtain:

$$F_0 = 15 \cdot 10^{\frac{111-121}{10}} = 15 \cdot 10^{-1} = 1.5 \text{ minutes}$$

Therefore, a 15 minutes sterilization at 111°C is equivalent, in terms of lethal effect, to 1.5 minutes at 121°C; this can be easily expected if z = 10.
Similarly, if we assume a 15 minutes sterilization constantly at 124°C, we have:

$$F_0 = 15 \cdot 10^{\frac{124-121}{10}} = 15 \cdot 10^{0.3} = 29 \text{ minutes}$$

STERILIZATION AT 135°C

Suppose to sterilize the unit decreasing the concentration of 10^{40} times at the temperature of 135 °C.

T_0 [°C]	z	temp+z	D_{121}	D_{temp+z}	T [°C]	$D_{tperm.}$ [sec]	N_0	PNSU
121	10	131	120	12	135	4,8	1,E+34	1,E-06

Table 2

Temperatura [°C]	ΔT	z [°C]	D [min]	N_0/N	Δt [min]
121	**0**	**10**	**2**	1,E+40	80
122	1	10	1,59	1,E+40	64
123	2	10	1,26	1,E+40	50
124	3	10	1,00	1,E+40	40
125	4	10	0,80	1,E+40	32
130	9	10	0,25	1,E+40	10,1
135	**14**	**10**	**0,080**	**1,E+40**	**3,2**
140	19	10	0,025	1,E+40	1,0
145	24	10	0,008	1,E+40	0,32
146	25	10	0,006	1,E+40	0,25
147	26	10	0,005	1,E+40	0,20
148	27	10	0,004	1,E+40	0,16
149	28	10	0,003	1,E+40	0,13
150	**29**	**10**	**0,0025**	**1,E+40**	**0,10**

The results are better described by the diagram below:

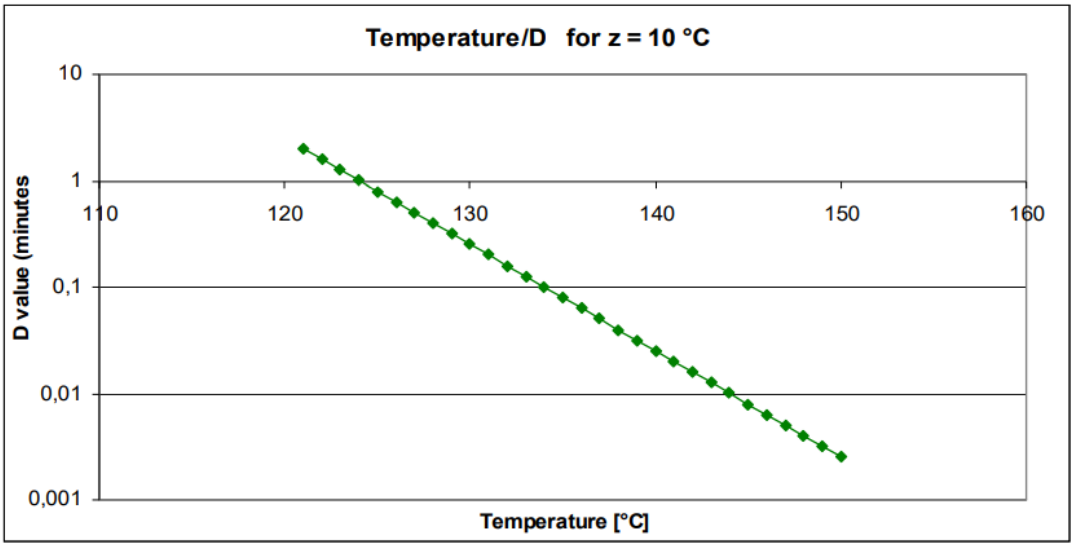


Diagram 5

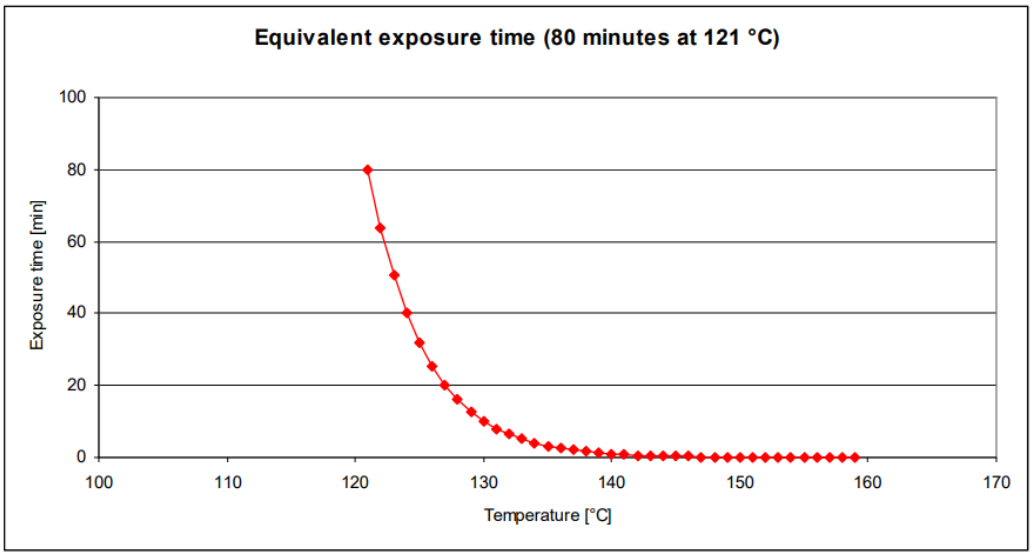


Diagram 6

SYMBOLS AND DEFINITIONS USED IN STERILIZATION TECHNOLOGY

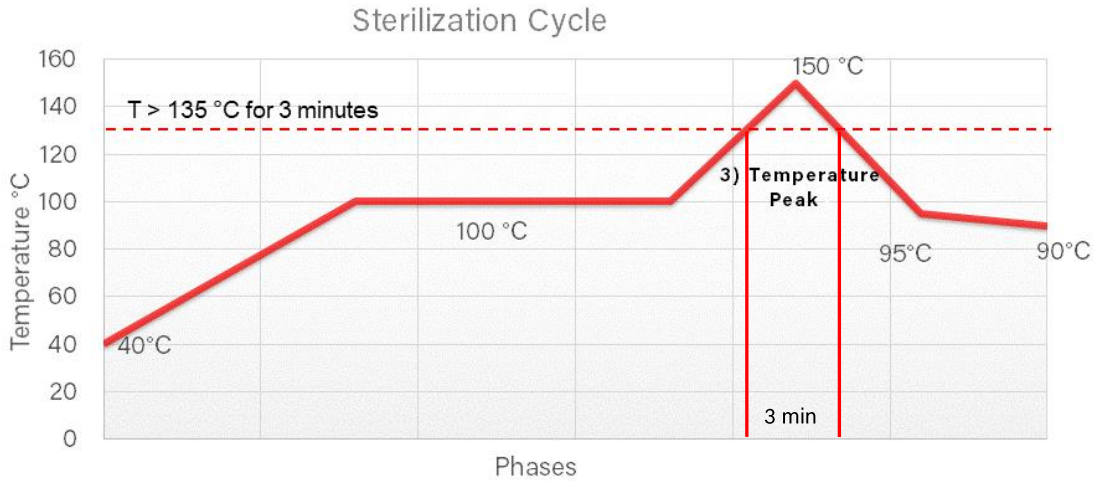
Table 5 summarizes the symbols and associated descriptions of the terms most frequently used in moist-heat sterilization technology.

Table 3

SYMBOL	PHYSICAL DIMENSION	DEFINITION	DESCRIPTION
D_T	Time	D-value (Decimal decay time)	The time required, at a given temperature T, to reduce the number of micro-organisms of a given species to 10% (1 logarithmic reduction)
F(z,T)	Time	Equivalent exposure time	Equivalent exposure time related to the specific temperature T and to the specific value of z indicated
F_O	Time	"Reference" exposure time, "F zero"	Equivalent exposure time related to the temperature of 121°C and to z = 10
N_O	None	Initial biological load	Number of viable micro-organisms contained in a unit before sterilization
N_U	None	Surviving biological load	Number of micro-organisms contained in a unit, surviving a sterilization of U minutes at a given temperature
z	Temperature difference (°C)	z-value (Temperature coefficient)	Number of degrees of temperature variation which causes a 10-fold variation in the value of D_{121}
PNSU	None	Probability of Non Sterile Unit	Number which expresses the probability of finding 1 non-sterile unit in a certain number of sterilized units (batch)

NW STERILIZATION AT TEMPERATURE HIGHER THAN 135 °C

Once the humidity has been eliminated, the temperature starts to rise reaching **a temperature higher than 145 °C(with a maximum peak temperature value of 150 °C for a few seconds)**, as required for a complete sterilization according to STAATT Level IV. **Despite this, NW sterilizer guarantees a temperature higher than 135 °C for a time range greater than 3 minutes.**



BIBLIOGRAPHY

-National Canners Association, "Laboratory Manual for Food Canners and Processors", Vol. 1, AVI Publishing Co., Westport, CT, 1968.

- F. D. A., "Current Good Manufacturing Practice in Manufacture, Packing or Holding of LVPs", Proposed Rules for 21 CFR Part 212, Federal Register, Vol. 41, No. 106,June 1, 1976.

-Stumbo, C. R., Thermobacteriology in Food Processing, Academic Press, 19732.

-"Validation of Steam Sterilization Cycles", Technical Monograph No. 1, Parenteral Drug Association, Philadelphia, PA, 1978.

- Akers, M. J., "Dynamics of microbial growth and death in parenteral products" , Journal of Parenteral Drug Association, 33 372 (1979).

- Pflug, I. J., Textbook for an Introductoty Course in the Microbiology and Engineering of Sterilization Processes, University of Minnesota, 19825. -United States Pharmacopeia, XXI, 1985, p. 1351.

-"Guideline for Industrial Moist Heat Sterilization of Medical Products", American National Standard, Association for the Advancement of Medical Instrumentation, Arlington, VA, 1987.

Verifica dell’efficacia di trattamenti di sterilizzazione per rifiuti solidi a rischio infettivo

Rifiuti sanitari: dalla sterilizzazione all’End of Waste

Sterilizzazione

Rifiuti solidi infettivi

Ospedali

Analisi microbiologiche

C.S.A. ha progettato ed eseguito in collaborazione con la società Newster System i test di convalida dell'efficacia del processo di sterilizzazione degli sterilizzatori Newster:
- test di validazione fisica, basato sulla verifica della temperatura di sterilizzazione secondo lo standard tecnico italiano UNI 10384;
- test del bioindicatore biologico, basato sull'uso delle fiale di spore di Geobacillus Stearothermophilus e verifica del raggiungimento di un livello superiore a quello definito dall’Associazione statale e territoriale sulle tecnologie di trattamento alternative, per i dispositivi di non-combustione per il trattamento termico umido dei rifiuti sanitari;
- test di efficacia microbiologica, basato sulla esecuzione di analisi microbiologiche per la verifica delle condizioni di sterilità del residuo di rifiuti sanitari prodotto dallo sterilizzatore
- test di ricrescita batterica, basato sull’esecuzione di analisi microbiologiche fino al 28 ° giorno dal campionamento.

Area di Specializzazione

Salute e Benessere – Salubrità nelle strutture wellness e sanitarie

Piattaforma e sezione catalogo

Energia - Ambiente – Strumenti e metodi per la sostenibilità, Simbiosi industriale: uso, riuso, valorizzazione e sostituzione di materia

Attività preparoria di analisi microbiologica: inoculo in piastra

GRUPPO CSA ISTITUTO DI RICERCA

Gruppo CSA SpA

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Verifica dell'efficacia di trattamenti di sterilizzazione per rifiuti solidi a rischio infettivo

DESCRIZIONE PRODOTTO

C.S.A. ha affiancato la Newster per la definizione di un protocollo di verifica dell'efficacia di sterilizzazione dello sterilizzatore Newster, studiato per il trattamento on-site dei rifiuti sanitari a rischio infettivo.
Il servizio svolto da C.S.A. si è sviluppato in una attività di studio e progettazione delle fasi e delle modalità di verifica del processo di sterilizzazione ed in una successiva attività di esecuzione dei test, comprensiva dell'attività di analisi microbiologica sul residuo del processo di sterilizzazione.

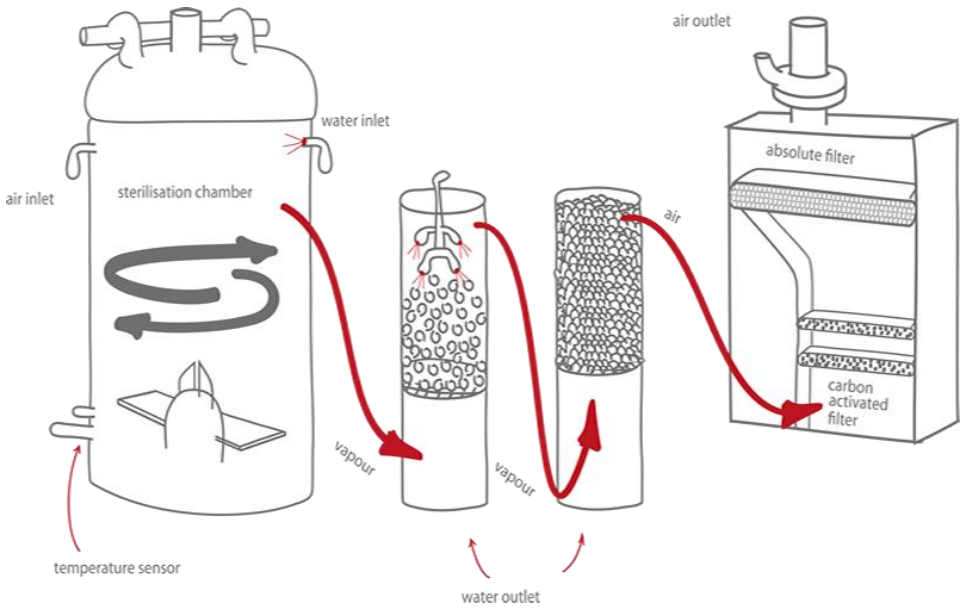
ASPETTI INNOVATIVI

I risultati ottenuti dalle verifiche e dalle analisi di laboratorio condotte sul ciclo di sterilizzazione degli sterilizzatori Newster e sui campioni di residuo prodotti dallo sterilizzatore hanno permesso di dimostrare che gli sterilizzatori Newster rispettano i requisiti internazionali per la sterilizzazione dei rifiuti sanitari, rappresentato dal IV livello STAATT per la valutazione dell'efficacia dei processi di sterilizzazione che corrisponde all'inattivazione di batteri, funghi, virus lipofili e idrofili, parassiti, micobatteri e spore di Geobacillus Stearothermophilus con un concentrazione pari o superiore a 6log10.

POTENZIALI APPLICAZIONI

Lo sterilizzatore Newster può essere utilizzato dalle strutture ospedaliere pubbliche o private, di varie dimensioni, per lo smaltimento di rifiuti solidi, attraverso l'installazione dell'impianto sul sito stesso per il trattamento dei rifiuti a rischio infettivi generati dalla struttura stessa.
L'installazione non richiede autorizzazione dalle PPAA competenti, ma una semplice comunicazione ex Decreto del Presidente della Repubblica n 254, 15 Luglio 2003.
Grazie alle proprie caratteristiche, il residuo può essere considerato come CDR o assimilato alla frazione indifferenziata del RSU.

Schema del flusso di sterilizzazione tramite tecnologia di trattamento termico per attrito Newster.



Impianto per la sterilizzazione e ossidazione dei reflui di laboratorio di analisi

ESEMPIO DI APPLICAZIONE

Trattamento dei rifiuti di piccole strutture ospedaliere

DESCRIZIONE APPLICAZIONE E RISULTATI

La macchina Newster NW5 è progettata per l'uso in piccoli ospedali. La sterilizzazione on-site consente una notevole riduzione dei costi di smaltimento delle strutture sanitarie, aumenta gli standard igienici per la sicurezza del personale, e contribuisce a ridurre sia la quantità di rifiuti prodotti che l'impatto ambientale grazie alla riduzione del 30% di emissioni di CO_2eq dovute al trasporto evitato.
Il processo di sterilizzazione prevede 6 fasi:
1. Caricamento dei rifiuti e avvio automatico
2. Il rotore inizia a girare sempre più velocemente invertendo il senso di marchia in funzione dei consumi. La temperatura inizia a salire mentre i materiali vengono polverizzati finemente.
3. Raggiunti i 96 - 100 ° C, la temperatura rimane stabile fino a quando l'umidità presente nei rifiuti non è completamente evaporata. I vapori vengono raffreddati negli scambiatori di calore e scaricati nel sistema fognario nel rispetto della tabella per lo scarico ex D. Lgs 152/06 e s.m.
4. La temperatura riprende a salire rapidamente, raggiungendo i 150 ° C. In pochi secondi viene raggiunta la sterilizzazione.
5. Tramite l'utilizzo di acqua di rete, il rifiuto viene raffreddato fino a 95 ° C prima dello scarico.
6. Il ciclo di sterilizzazione è stato completato. Il portello viene aperto e il prodotto viene estratto e raccolto nel box integrato in acciaio inossidabile.

PARTNER COINVOLTI

Newster s.r.l.

TEMPI DI REALIZZAZIONE

6 mesi

LIVELLO MATURITA' TECNCOLOGICA

TRL 9 – Sistema reale testato in ambiente operativo

VALORIZZAZIONE

Lo sterilizzatore Newster "FHT" è coperto da brevetto internazionale ed è disponibile per il mercato al oltre 25 anni. Il progetto attuato in collaborazione con C.S.A. ha permesso di avvalorare l'efficacia di sterilizzazione della macchina attraverso un protocollo di verifica oggettivo e scientificamente provato.

La macchina Newster NW5 è stata progettata per l'uso in piccoli ospedali.

Gruppo CSA SpA

DESCRIZIONE LABORATORIO

Il Gruppo C.S.A. S.p.A. è un laboratorio di analisi ed un istituto di ricerca privato specializzato nella gestione di piani complessi di monitoraggio ambientale, in grado di guidare e supportare un'attività di ricerca e sviluppo di tipo prevalentemente applicativo e di seguire e coordinare progetti complessi e interdisciplinari che richiedono un elevato livello di professionalità ed esperienza. Il laboratorio di analisi chimiche–fisiche–microbiologiche accreditato ai sensi della ISO/IEC 17025 con numero L0181, e dotato di un sistema di gestione qualità, sicurezza e ambiente certificato ai sensi della ISO 9001, ISO 14001 e ISO 45001, è equipaggiato con moderni sistemi analitici che consentono di affrontare un vastissimo range di indagini garantendo tempistiche ridotte ed elevati standard qualitativi. L'alto profilo professionale, le competenze acquisite in oltre trent'anni anni di attività, l'aggiornamento continuo del personale, consentono al Gruppo C.S.A. S.p.A. di integrare l'attività di campionamento e determinazione analitica su varie matrici ambientali ed agroalimentari, con una consulenza di alto livello fornendo soluzioni innovative e interdisciplinari a problematiche complesse, sviluppare servizi esistenti e crearne di nuovi, e rappresentare così un partner affidabile e sempre all'avanguardia nelle applicazioni metodologiche, strumentali e tecnologiche della ricerca applicata in ambito ambientale.

REFERENZE

Altroconsumo Edizioni S.r.l., Celli S.p.A., Eco Pets Italia s.r.l., Hen food group s.r.l., ALIA S.P.A. OCU - Organización de Consumidores y Usuarios, Romagna Acque s.p.a., Arcadis Italia S.r.l., AECOM URS Italia S.p.A., The It Group Italia S.r.l., Tamoil Italia S.p.A., Ecotherm S.r.l., Sogepu S.p.A., Sogliano Ambiente S.p.A., GESENU S.p.A., HERAtech S.r.l., Planeta Studio Associato, Saipem S.p.A., Alia Servizi Ambientali S.p.A., Yara Italia S.p.A., Italferr S.p.A., A2A Ambiente S.p.A., Api Raffineria di Ancona, Caviro Distillerie S.r.l., Golder Associates S.r.l., Comune di Sant'Antioco, Jacobs Italia S.p.A., Enomondo S.r.l., Enel Produz. S.p.A, Consiglio Naz.le delle Ricerche, Conai, Tamoil Raffinazione S.p.A., Project Automation S.p.A., Cesi S.p.A., FERONIA S.r.l., Water & Soil Remediation S.r.l., Stantec S.p.A., Kuwait Petroleum Italia S.p.A., Consorzio Naz. Riciclo e Recupero Imb. Acciaio, Newster srl, Regione Emiiia-Romagna

Sede Laboratorio CSA

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POR FESR EMILIA-ROMAGNA 2014/2020
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