Supervitri device validation in the mouse model. Part I

Calculation of cooling and warming rates: RESULTS

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Results

Calculation of cooling and warming rates

Cooling rates

Supervitri cooling rates were compared with a similar surface open system available on the market (Figures 3-4). The mean cooling rate obtained for the Supervitri device was -30246ºC/min. Significant differences were not found between both groups (t-test > 0.05).

COOLING			
	Replicas	**Mean Cooling rate (°C/min)**	**SD**
Control	3	-30670	730
Supervitri device	3	-30246	2032

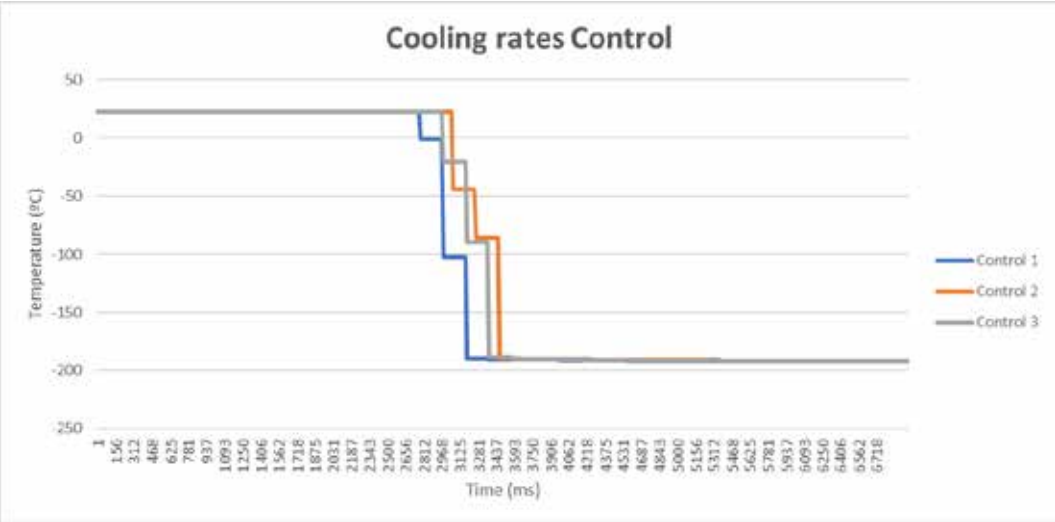

Figure 3. Graph with cooling ramps obtained in a surface open system used as a control. The results obtained in the three replicas are shown in different colours.

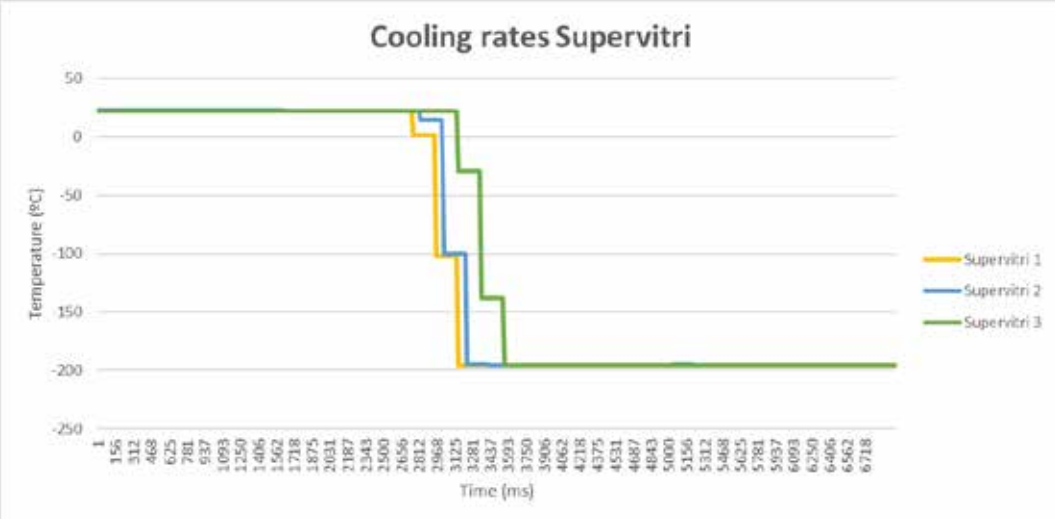

Figure 4. Graph with cooling ramps obtained with the Supervitri device. The results obtained in the three replicas are shown in different colours.

Results

Warming rates

Supervitri warming rates were compared with a similar surface open system available on the market (Figures 5-6). The mean warming rate of the Supervitri device was +55456°C/min. Significant differences in the cooling rates were not found when compared to the control device (t-test > 0.05).

WARMING			
	Replicas	**Mean Warming rate (°C/min)**	**SD**
Control	6	+57062	4927
Supervitri device	6	+55456	5820

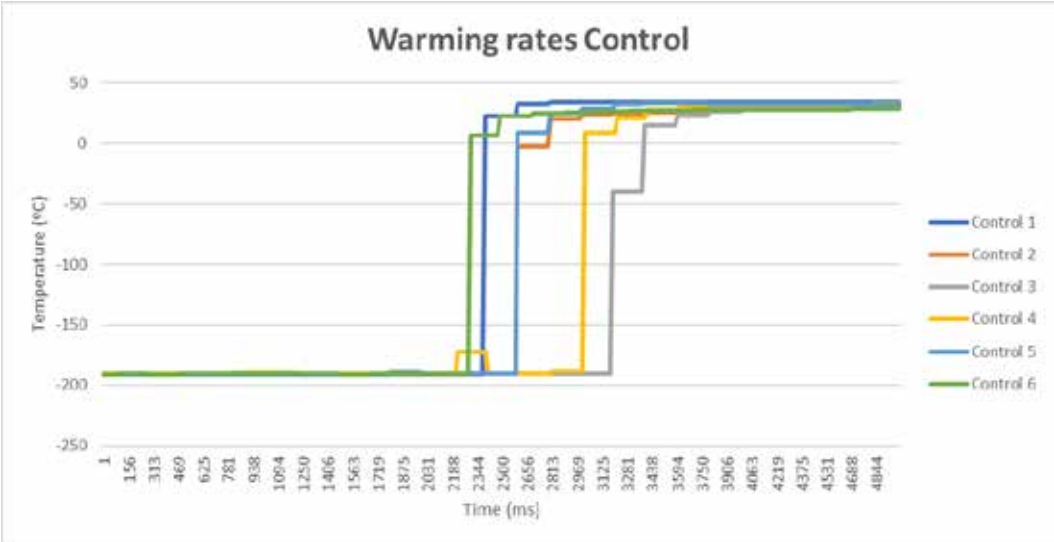

Figure 5. Graph with warming ramps obtained in a surface open system used as a control. The results obtained in the six replicas are shown in different colours.

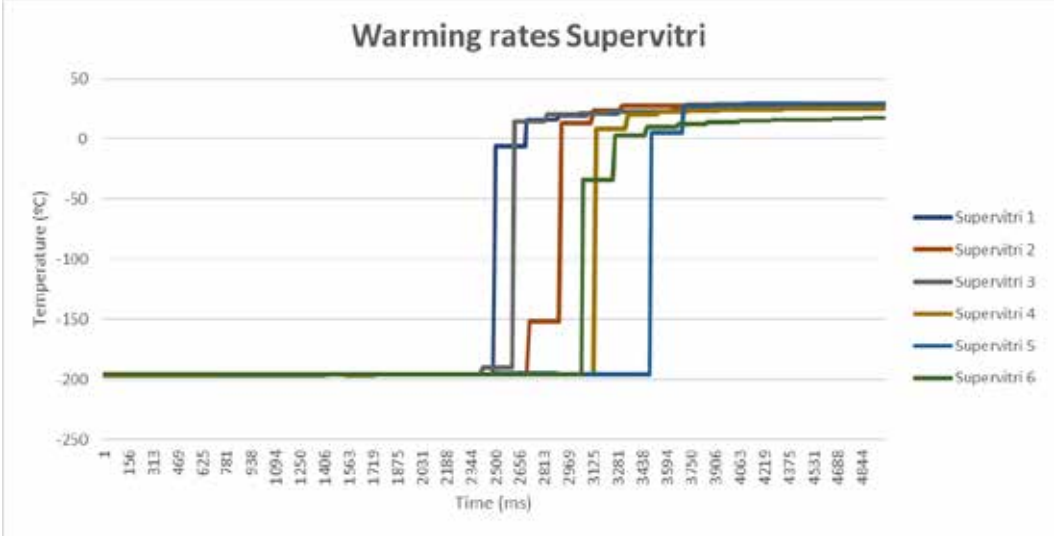

Figure 6. Graph with warming ramps obtained with the Supervitri device. The results obtained in the six replicas are shown in different colours.

Results

Warming rates (1 vs. 4ml)

The warming rate for the Supervitri device was assessed for two different set-ups. The Supervitri was plunged into 4ml or 1ml of the first warming solution at 37ºC (Figures 7-8).A lower warming rate was observed when performing the warming procedure in 1ml of warming. Although the differences between both set-ups did not reach statistical significance (t-test, p= 0.17), a higher consistency in warming rates is achieved when higher volumes of medium are used in this step of the vitrification protocol (lower standard deviation).

WARMING (1 vs. 4ml)			
	Replicas	**Mean Warming rate (°C/min)**	**SD**
Supervitri device (1ml)	6	+49799	7581
Supervitri device (4ml)	6	+55456	5820

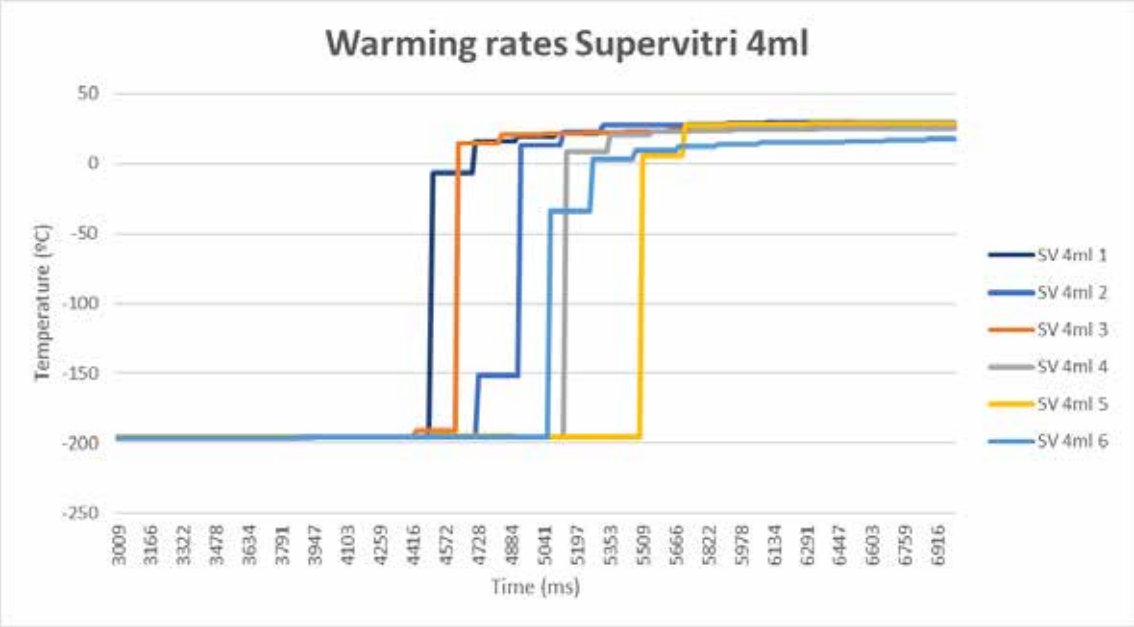

Figure 7. Graph with warming rates of the Supervitri device plunged in 4ml. The results obtained in the six replicas are shown in different colours.

Results

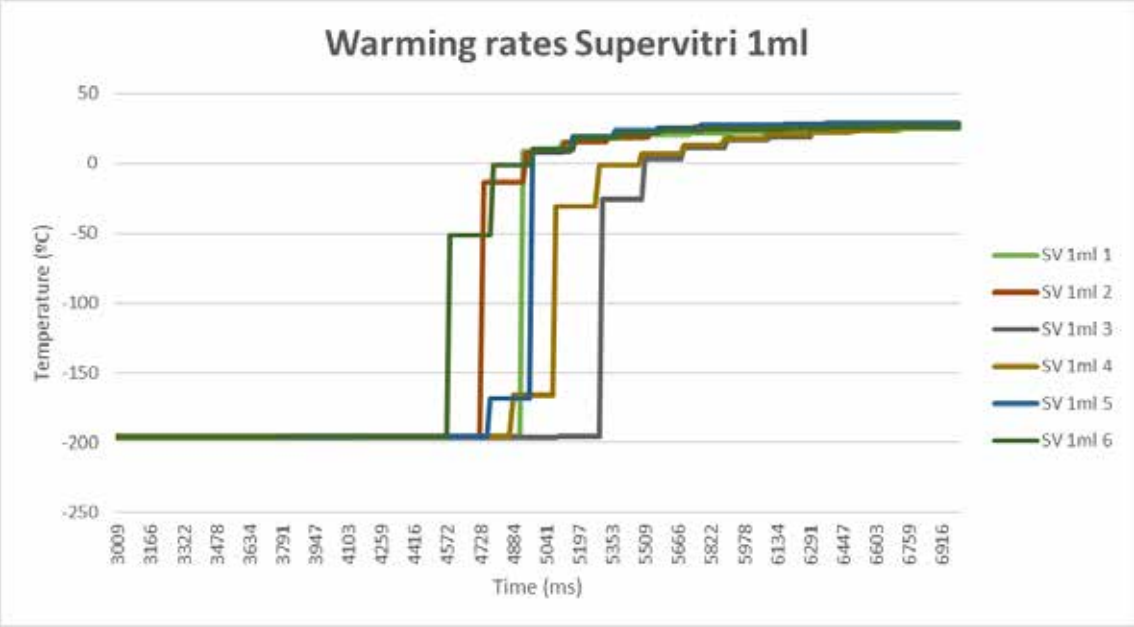

Figure 8. Graph with warming rates of the Supervitri device plunged in 1ml. The results obtained in the six replicas are shown in different colours.

CONCLUSIONS

- Macroscopic and microscopic features are evaluated positively for the Supervitri device. However, it is recommended to add a black mark on the caps of the devices to make it easier to visualise and use them under the LN2. In addition, if the mark is aligned with the black mark of the device body it will facilitate the insertion of the cap in the right position so that it fits tightly and seals the tip of the device properly.
- The labelling area is wide enough to write the sample identification with both markers and stickers.
- It is recommended to load the specimens for vitrification with a minimum volume (approximately 0.1 µl) to ensure the best cooling and warming rates possible, taking care not to leave the samples completely dry before plunging them in LN2.
- Supervitri cooling and warming rates were -30246ºC/min and +55456ºC/min, respectively. The results are comparable to those obtained with a similar surface open system available on the market.
- It is recommended to use big volumes when performing the first step of the warming protocol as there is a tendency to achieve better warming rates when using 4 ml than when 1 ml is used. Similarly, a higher consistency can be achieved when using 4 ml compared to when 1 ml is used.

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Our company

BPB MEDICA™ is an Italian manufacturing company specialized in the design, production and marketing of high qualitative healthcare products for medical use and medical-surgery devices.

BPB MEDICA™ was founded in 1999 by the Bellini family, boasting thirty year's experience in the biomedical sector. The founder, Carlo Bellini Sr., started the business in 1968 and has passed down to his heirs ethics, integrity and spirit of sacrifice. Today BPB MEDICA™ has leveraged its 50 years experience to develop new innovative product lines, growing the company on international level.

50 YEARS EXPERIENCE

1968 — MEDICAL BUSINESS BEGINNING:
The founder, Carlo Bellini Sr, started his business in the medical field, founding some of the most important companies of our medical district

1999 — BIOPSYBELL S.R.L. FUNDATION:
Carlo Bellini Sr's daughter founded Biopsybell srl: "Biopsy" as the initial core business and "Bell" as Bellini family name.

2008 — THIRD GENERATION OF THE FAMILY:
Carlo Bellini, founder's nephew, joined the company and focused on export sales development.

2012 — THE EARTHQUAKE:
The company was damaged by an heavy earthquake: the family worked hard to keep the production open. After only 2 weeks from the EQ was back in business.

2014 — SPINE SURGERY:
Development and launch of Spine product line.

2015 — EXPORT EXPANSION:
Export success: 41 foreign countries served (35%TNR).

2016 — NEW SITE:
The intensive growth of the last few years required a new and bigger production site.

2018 — A.R.T. LINE:
Development and launch of Assisted Reproduction product line.

2019 — EXPORT ORIENTED:
70 country served (70% TNR).

2019 — REGENERATIVE & ORTHO-BIOLOGICS:
Development and launch of Regenerative Medicine & Ortho-Biologics product line.

2020 — SURGICAL MASKS:
New production line of Surgical Masks in response to COVID-19 emergency.

Our company

BPB MEDICA's™ philosophy is to grow alongside the needs of patients, doctors and hospital staff in general. Backed by the experience acquired by the company's specialized technical personnel and thanks to newly-adopted technologies, BPB MEDICA™ has quickly managed to make a name for itself on the domestic and international markets.

70

COUNTRIES SERVED

BPB MEDICA™ provides painstaking service to its clientele and its primary aim is product quality. The **internal Regulatory and Quality Departments** conducts rigorous tests, from the raw materials to the equipment and the finished product. This allowed the company to obtain CE, ISO 13485 and the establishment registration by FDA.

BPB MEDICA™ operates with high qualitative standards aimed at increasing customer satisfaction through a continuous improvement regime. We conduct multiple quality tests during the entire production process: this allows to reduce the production waste and grant high quality products.

Thanks to the **internal R&D Department** BPB MEDICA™ conducts constant research in the reference pathologies with an aim to ever better qualifying and improving its production standards and aiding the development of new products.

TÜV SÜD

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OUR PRODUCT LINES

- SPINE SURGERY
- ORTHO-BIOLOGICS
- ASSISTED REPRODUCTION
- BIOPSY
- INTENSIVE CARE
- PERSONAL PROTECTION

Our company

METAL REFINISHING DEPARTMENT
Cutting, grinding, sharpening, cleaning, echogenic marking, sealing, reduction.

CLEAN ROOM
Manual & automatic assembly, packaging.

MOLDING DEPARTMENT
Vertical and horizontal molding.

OUR SERVICES

PRODUCTION PROCESS CONTROL
Complete manufacturing process carried out internally, from design to final packaging.

RESEARCH & DEVELOPMENT
Constant research in order to increase production and quality standards while developing new products.

OEM & PRIVATE LABEL SERVICES
A la cart production, with customer's brand name and custom colour.

MARKETING SUPPORT
Video tutorial, case report, presence at the major medical congresses, organization of training and courses.

QUALITY & REGULATORY DEP.
Our primary aim is product quality and provide painstaking service. Our regulatory and quality teams conduct rigorous tests for this purpose.

FOUR WEEKS DELIVERY
Thanks to the optimization of the production process, we satisfy our customers orders within 4 weeks.

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