Medical Device 93/42/EC

PLASMAFROST 3 I.Te.M.

Plasma Shock Freezer

Shock freezer specially designed to freeze Fresh Plasma bags at a temperature below -30°C in less than 60 minutes in accordance with the international standards for the protection of the active principles present into plasma. Equipped with a dedicated software (I.T.e.M.) that allows certifying the successful result of the plasma freezing process.

Designated use:

(It is used to) freeze Fresh Plasma bags at a temperature of at least -30°C in 60 minutes.

Applications:

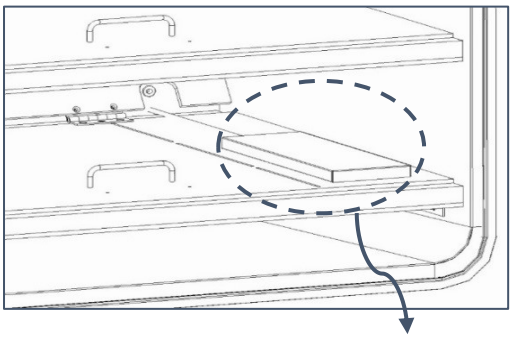
(It is used in) blood establishments for quick plasma freezing.

Peculiarities of Plasmafrost I.Te.M

Validation of the freezing process

The integrated control and monitoring system (I.Te.M.) to detect, record and certify the temperature of the plasma bag (not dummy bag) located in a specially designed position inside the freezer (I.Te.M. position).

Through an algorithm developed together with the Industrial Engineering Department of the University of Salerno, it **establishes when a freezing cycle is over.**



I.Te.M. position

Productivity increase

Thanks to the temperature monitoring system, the duration of the freezing cycle is limited to the absolute minimum necessary. Therefore, it allows increasing the freezing cycles throughout the working day (e.g. Bags of 450 ml filled at 250 ml freeze in 35 minutes).

Horizontal freezing

The ergonomic design enables the horizontal freezing of plasma bags that makes the following storage easier and it especially minimizes the factor VIII phenomenon.

Full traceability of operations

Access control

Only authorized users can access and use the device thanks to the identification through username and password.

Batch identification

Information about bags is gathered and stored by the integrated bar code reader.

Recording of freezing data

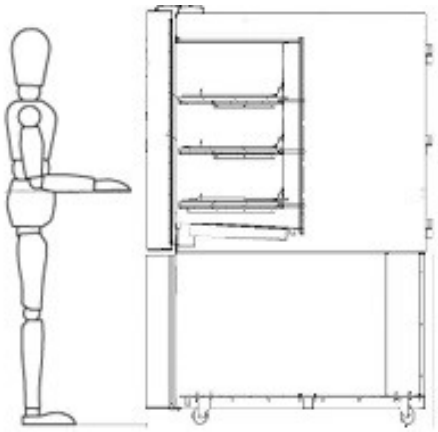
The onboard machine software records the duration and temperature data of the freezing.

Printing of reports

All the data related to the freezing cycle, the batch of the loaded bags, the user and the duration are organized in a report that users can file or print.

Data exchange of the management software

The device can be interfaced with the management software in used at the facility (BBMS) and it shares data about the batch freezing.



Value to safety and ergonomics

Horizontal shelves make the loading and unloading phases of the bags easier and allow users to work in improved working conditions by limiting stress on their back that would occur during a vertical loading.

Particular attention has also been paid to safety through the lack of sharp corners and edges.

Locked door

During the freezing cycle, it is not possible to open the door by preventing to interrupt the freezing process and add not tracked bags to those that have already started the freezing process.

Intuitive and easy to use

Touch-screen display

A color touch-screen display combined with easy and intuitive commands guarantees the maximum convenience of the operator and offers an easy and rapid use of the freezer.

Turn-by-turn voice option

The device is equipped with speech synthesizer that guides users during the loading and unloading phases by reducing the probability of error.

Construction features

Plasmafrost I.Te.M. is managed by an information system that includes:

1) ***12-inch color LCD panel*** enabling the user to interact with the device

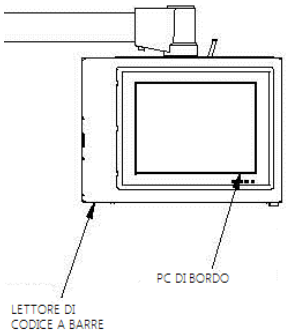
2) ***temperature controller (Cold Brain)*** allowing users to set/monitor the functional parameters of the device (Regulation – Alarm)

3) ***the control and monitoring system integrated to the device (I.Te.M.)*** allowing users to carry out the operations of loading/unloading of plasma bags and the interface of the device with the BBMS (Blood Bank Management System)

4) ***cooling system*** composed of two cascade compressors allowing freezing plasma bags quickly

1. *User interface*

Users interact with Plasmafrost I.Te.M. through **12-inch color LCD *Touch-screen* panel**. The easy and functional interface guides the operator during the loading and unloading of the bags.



On-board PC: integrated PC with touch-screen display for an easy and immediate use of the Software I.Te.M. commands in Italian and procedure with turn-by-turn voice option.

Bar code reader: integrated in the bottom left corner of the box computer.

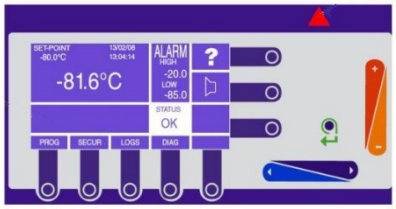
USB port: Located on the back of the freezer. It is possible to connect a printer for the printing of the freezing report.

Ethernet port: Located on the back of the freezer. All the data related to the freezing process can be transferred thanks to it.

2. *ColdBrain controller: proprietary microprocessor-based control system*

It is located on the front of the device and is equipped with:

- ✓ On/Off switch with light signal
- ✓ Noise and visual indicator for the end of the freezing
- ✓ Digital display with the internal temperature indication
- ✓ Archive of collected data
- ✓ Graphs of recorded temperatures



Alarms

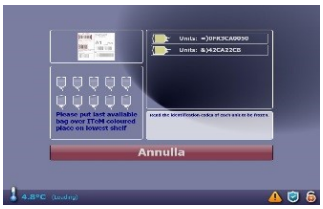
- ✓ Minimum and maximum temperature
- ✓ Lack of electrical grid
- ✓ Door ajar
- ✓ Battery to be replaced
- ✓ Probe breakdown
- ✓ Compressor failure

3. *Software I.Te.M.: Management and validation of the freezing cycle*

The I.Te.M.® (**I**ndirect **Te**mperature **M**easurement) software issued with the freezer is based on an exclusive Angelantoni proprietary system that enables:

A. The management/recording of frozen plasma bags
B. **The elimination of the need to use dummy bags** to certify the successful result of the rapid freezing cycle.

A. It allows the full management and traceability of the freezing process of every batch of plasma bags.
The system with an easy and intuitive user interface is password-protected and supported by an Italian turn-by-turn voice.
At the end of each freezing cycle, a report (PDF file) is released with all the relevant data such as the plasma bag ID, the date and when the bag freeze. Each cycle is activated with the identification of the operator and the ID of every plasma bag loaded inside the freezer.



B. The validation of the freezing process takes place trough the temperature measurement of the bag located in the I.Te.M. position thanks to a specific algorithm.
The temperature measurement of the bag in that position guarantees that all the other frozen bags (of the batch) have the same or a better freezing profile. The I.Te.M. position that contains the probe of the same name is in a specific position where users have to insert the last bag loaded.

All the data can be transferred through:

- ✔ Ethernet connection
- ✔ Txt file
- ✔ USB port

4. *Cooling system*

Designed with a powerful system of two hermetic cascade compressors together with an air-cooled condenser that allows working at -75°C.

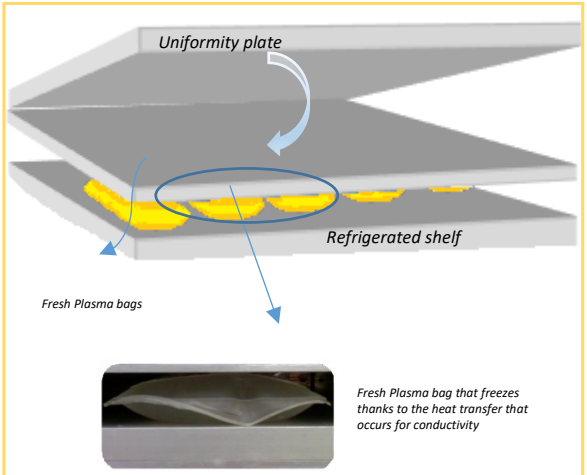
Highly efficient cooling system that enables to freeze plasma bags rapidly and carry out ongoing freezing cycles without long waiting periods between one cycle and the following (about 10 minutes).

Plasma bags are positioned **horizontally** on **refrigerated shelves**. A refrigerant that keeps the temperature at -75°C flows constantly through a cooling coil inside these shelves made of aluminum alloy to get a better thermal conductivity.

To guarantee the best heat transfer on both bag sides there is an **upper uniformity plate** made of aluminum that has the function of making the heat transfer efficient and creating a kind of "sandwich" effect on the bags.

This exclusive freezing method guarantees the best contact on both sides and allows extracting heat very efficiently from the plasma.

FREEZING METHOD



Refrigeration circuit that works with refrigerants not prohibited by the Montreal Protocol and not considered as harmful substances in the London review.

- CFC Free refrigerant gas

HORIZONTAL FREEZING FOR THE BEST FREEZING

The **EU Recommendation R (86) 6** suggests the horizontal freezing because it increases the factor VIII yield after the freezing.
The horizontal freezing enables a homogenous and "light" distribution of the plasma and proteins in it through uniform heat transfers over the whole bag surface.

Capacity of fully loaded plasma bags and freezing time

Bag type	Plasma quantity	Bags for the freezing cycle	Maximum freezing time	Bag position on the shelf
400 ml	250 ml	Max 24	35"	Figure 1
400 ml	300 ml	Max 24	55"	Figure 1
450 ml	250 ml	Max 24	30"	Figure 2
450 ml	300 ml	Max 24	45"	Figure 2
1000 ml	650 ml	Max 12	45"	Figure 3
1000 ml	800 ml	Max 9	55"	Figure 4

Examples of plasma bag position on a shelf

Figure 1

Figure 2

Figure 3

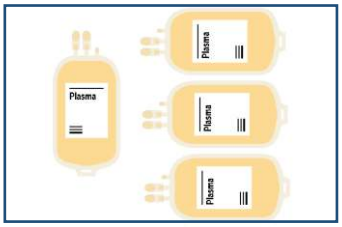


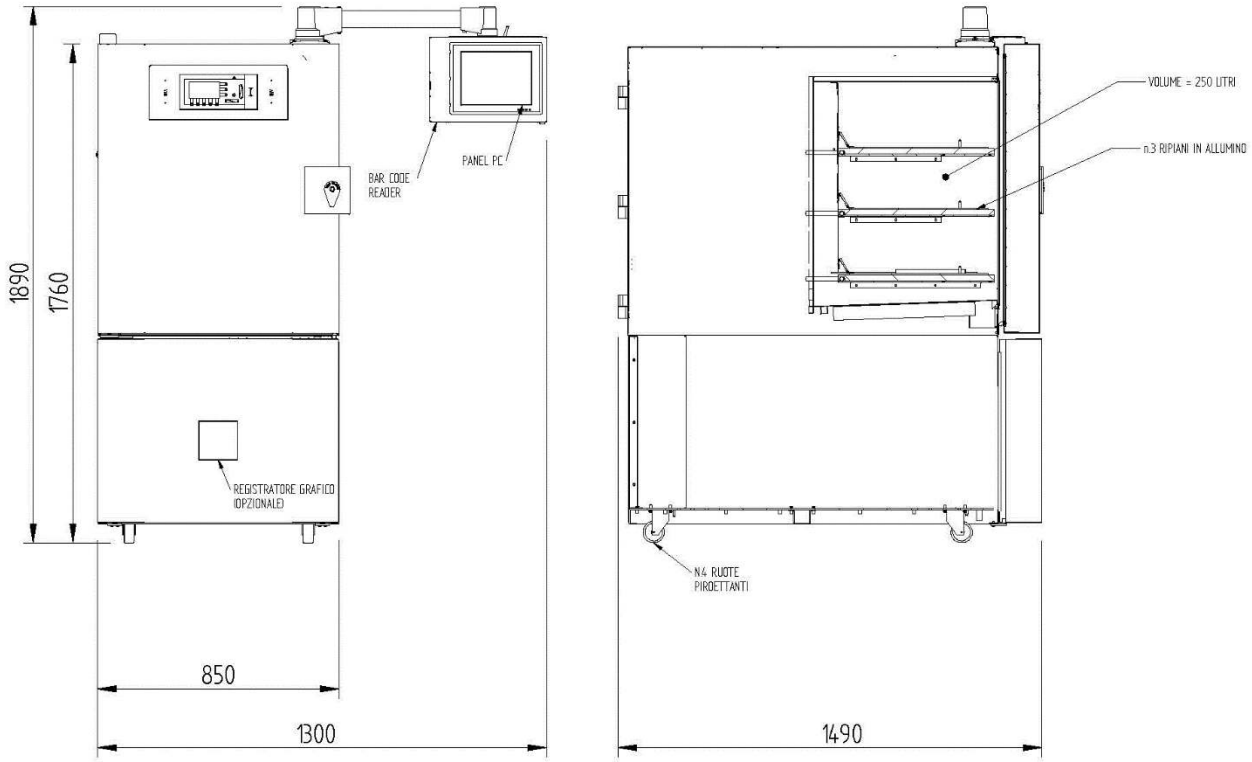
Figure 4

Technical specifications

Brand		**Angelantoni Life Science**
Model		**PLASMAFROST 3 I.Te.M.**
Commercial code		**13368**
CND code		**Z121702**
RDM code		**853634/R**
External dimensions (WxDxH)	mm	**950 x 1490 x 1890**
External dimensions with open arm (WxDxH)	mm	**1300 x 1490 x 1890**
Volume	l	**250**
Bag capacity (450/400 ml)	Nr	**24**
Bag capacity (1.000 ml)	Nr	**12**
Daily freezing cycles	Nr	**10**
Weight	kg	**660**
Refrigerated shelves/Uniformity plates	Nr	**3**
Shelf dimension (WxD)	mm	**550 x 590**
Port hole		**Optional**
Working temperature	°C	**-75°C**
Supply voltage/Frequency	V / Hz	**230 V – 50 Hz**
Noise level (*)	dB(A)	**< 62**
Maximum absorbed power	A	**16**
Refrigerant gas		**CFC Free**
Conditions of use		
Temperature	°C	**10 ~ 32**
Relative humidity	%	**30 ~ 80**

(*) the sound pressure level is measured in front of the source at a distance of 1m, at a height of 1.6 m and in a not reverberation area in accordance with EN ISO 11201 regulation.

Layout



Certifications

The freezer has the **CE marking** as Medical Device in accordance with the EU-Directive n.93/42 and subsequent

- Machinery Directive **2006/42/EC**
- Low Voltage Directive **2014/35/EU**
- Electromagnetic Compatibility Directive **2014/30/EU**
- **EN 61010-1** Electrical Safety
- **2011/65/EU** ROHSS II

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