

Rapid plasma freezers  
**Plasmafrost ITeM® Series**



# OUR COMMITMENT

## in the world of quick plasma freezing



**ANGELANTONI LIFE SCIENCE** has a range of plasma freezers (Plasmafrost ITeM® 3 and 4) intended to meet the needs of small, medium and large Transfusion Centers, Hospitals, Nursing Homes and Test Laboratories.

Fresh Plasma (FFP) is a blood component prepared from whole blood by separation or from specific plasma collection by apheresis (plasmapheresis) and frozen with the aim of adequately preserving labile coagulation factors (Factor VIII).

FFP can be used to address coagulation disorders, especially in those clinical situations where multiple coagulation disorders coexist.

Its main use is to obtain the various purified factors as pharmaceutical specialities through an industrial chromatographic fractionation process.

Plasma freezing is subject to Recommendation no. (95) 15, which mandates to reach  $-30^{\circ}\text{C}$  in the center of the bag in less than 60 minutes.

The temperature must be measured in the bag core. In all Plasmafrost ITeM® models, the shelves act as freezing elements: the refrigerant flows within the shelf to optimise freezing efficiency and the contact plates press the bags, lying horizontally, for even temperature distribution. The contact plate is pre-refrigerated with empty machine (i.e. between two cycles).

The bags are frozen by conductivity through direct thermal exchange. There is a close relationship between the temperature of the contact plate and the temperature in the core of the bag. It is therefore possible to measure the temperature of the contact plate to reliably and precisely measure the temperature of the underlying plasma bag.

All the equipment is certified according to the Medical Devices Directive 93/42/EEC.



Notified body No. :  
0051

## PLASMA TEMPERATURE PULLDOWN PROCESS

• **THE DESIGN OF PLASMAFROST ITeM\* TAKES INTO ACCOUNT:**

• **Recommendation no. (95) 15:**

• When plasma is frozen, the cooling speed should be as fast as possible.

• In the optimal scenario, the core of the bag should reach the temperature of  $-30^{\circ}\text{C}$  in less than 60 minutes.

• The horizontal freezing of the plasma involves a homogeneous distribution of the proteins contained in it with uniform thermal exchanges over the entire surface of the bag

• **OBJECTIVE:**

Maximise the content of active factors and albumin in frozen plasma bags.

• **WHAT IS NEEDED TO VALIDATE A FREEZING PROCESS?**

- ▶ Identify (code reading) all the loaded bags;
- ▶ Evidence the proper performance of the freezing cycle;
- ▶ Record and store these data;
- ▶ Print and file reports.

\*ITeM®: Indirect temperature measurement



Hyperimmune plasma transfusion



Plasma tube centrifuge processing



**TEMPERATURE CONTROLLER (COLD-BRAIN)**  
To set up/edit the functional parameters



**COOLING SYSTEM**  
Equipped with 2 compressors in cascade to rapidly freeze bags



**CONTROL AND MONITORING SYSTEM**  
To carry out the bag loading/unloading activities and interface to the BBMS



**12" COLOUR LCD PANEL**  
For the user to interact with the device

## TECHNICAL FEATURES

The structure is made of phosphate and epoxy powder coated steel sheet, fitted with wheels for easier movement. The inside of the freezer is made of AISI 304 stainless steel with rounded corners for easy cleaning. The door is closed with lock and key and has silicone seals.

• **Thermal insulation** is achieved with the “sandwich” technique, using CFC and HCFC-free polyurethane foam, it has an average thickness of 125 mm.

• The **ergonomic design** allows plasma bags to be frozen in a horizontal position, for easier storage and, above all, to minimise the phenomenon of factor VIII precipitation.

• The **control panel** of the freezing unit, Cold-brain, is found on the front of the equipment and has:

- ▶ On/off switch with light signal;
- ▶ audible and visual indicator of freezing cycle end;
- ▶ high pressure alarm for the high/low stage refrigerant circuit;
- ▶ digital display to view the internal temperature;
- ▶ master switch located on the left side of the machine.



Horizontally placed bag

### VALUE TO SAFETY AND ERGONOMICS

The shelves placed **horizontally** make it easy and convenient to load and unload the bags and allow the operator to work **ergonomically**, limiting the back strain that would instead occur when loading vertically.

Special care was also paid to **safety** with the absence of sharp corners and edges.

### LOCKED DOOR

During the freezing cycle **it is not possible to open the door**, preventing the freezing process from being interrupted and untracked bags from being added to those that have already started the cycle.

## DISTINCTIVE FEATURES

### 1. ITeM® system: Management and validation of the freezing cycle

The I.Te.M.® (Indirect Temperature Measurement) system supplied with the freezer is based on an exclusive Angelantoni proprietary system that ensures:

- A. Management/recording** of frozen plasma bags;
- B. Monitoring the freezing cycle** with no need to use dummy bags;
- C. Full control** and traceability of the freezing process of every batch of processed plasma bags.

The system, having a **user-friendly and intuitive interface**, is **password-protected** and supported by a voice guide. It ensures controlled access and requires operator authentication via **PIN** or **barcode reading**.

#### Plasmafrost ITeM® makes it possible to:

- ▶ Identify all the plasma bags in a freezing batch;
- ▶ Record and track all the freezing process data;
- ▶ Protect the freezing process data from any tampering;
- ▶ Share the freezing data with the management systems of the hospital/blood bank.



Freezing process progress

The **validation of the freezing process** takes place by measuring the temperature of the bag placed in the ITeM® position by using a specific **algorithm**.

Measuring the temperature of the bag in that position ensures all the bags in the batch had the same or better freezing profile.

The specific I.Te.M. position, which contains the probe of the same name, is where the last bag must be placed.

All the data can be transferred via:

- ▶ Ethernet Connection;
- ▶ USB Port.

**Note:** Plasmafrost I.Te.M. freezes plasma bags of any shape and volume. However, the freezing batch must consist of bags having the same shape and volume.

### 2. Control user interface

The user interacts with **Plasmafrost ITeM®** via a 12" colour LCD touch-screen panel.

The simple and functional **interface** guides the operator through bag loading and unloading operations.

**On-board PC:**

Integrated computer with touch screen display for simple and straightforward use of the **Software ITeM®** controls in English and voice-guided procedure.

**Barcode reader:**

Built-in, in the lower left-hand corner of the computer box.

**USB Port:**

Located behind the freezer, used to connect a printer for printing out the freezing report.

**Ethernet Port:**

Located behind the freezer, used to transfer all data concerning the freezing process.



### 3. Cold-brain controller – proprietary microprocessor control system

Located on the front of the equipment, it comes with:

- ▶ On/Off switch with light signal;
- ▶ Audible and visual indicator of freezing end;
- ▶ Digital display indicating the internal temperature;
- ▶ Data log;
- ▶ Measured temperature graphs.

**Manages and signals the following alarms:**

- ▶ Minimum and maximum temperature;
- ▶ Mains power outage;
- ▶ Door open;
- ▶ Battery must be replaced;
- ▶ Probe fault;
- ▶ Compressor fault.



Cold-brain Controller

## FREEZING PROCESS

The freezing process according to the logic of the ITeM® system.



Detail of refrigerated internal shelves



Bag freezing specifications

The **cooling circuit** is designed with a powerful system of two semi-hermetic **compressors** working 'in cascade' combined with an air **condenser**.

The operating **temperature** is **-75°C**. This extremely powerful cooling system supports continuing freezing cycles without long waits between cycles (10 minutes approximately).

The plasma bags are placed in a horizontal position on **refrigerated shelves**. Within these shelves, built in aluminium alloy to achieve better thermal conductivity, a **refrigerating fluid** flows constantly through a refrigerated coil, which keeps the temperature of the plates at **-75°C**.

In addition to promoting **faster freezing**, the design of Plasmafrost ITeM® makes it possible to **compress** the bags so that at the end of the freezing cycle they are perfectly flattened.

This exclusive freezing method ensures the best contact on both sides and makes it possible to extract heat from the plasma in an extremely effective manner (**freezing by conduction**).

Horizontal freezing involves homogeneous distribution of the plasma and the proteins it contains with consistent heat exchanges over the entire surface of the bag.

**HOW ITEM® WORKS**

The ITeM® system makes it possible to validate freezing of all bags in the batch, without using “dummy bags”.

All available shelf positions can be used to freeze the plasma bags.

ITeM® measures the temperature of the bag placed in a specifically designed point of the machine.

It determines when a freezing cycle has ended through an **algorithm**, developed in collaboration with the Department of Industrial Engineering of the University of Salerno.

The freezing cycle is **monitored** and **recorded** by the machine’s PC, which produces a **report** of the freezing process.

**PLASMA BAGS CAPACITY AT FULL LOAD AND FREEZING TIMES**

Bag type	Plasma quantity	Bags per freezing cycle	Maximum freezing time	Arrangement of the bags on the shelf
400 ml	250 ml	Max 40	35"	Figure 1
400 ml	300 ml	Max 40	55"	Figure 1
450 ml	250 ml	Max 40	30"	Figure 2
450 ml	300 ml	Max 40	45"	Figure 2
1000 ml	650 ml	Max 16	45"	Figure 3
1000 ml	800 ml	Max 12	55"	Figure 4

**EXAMPLES OF POSITION OF PLASMA BAGS ON A SHELF**

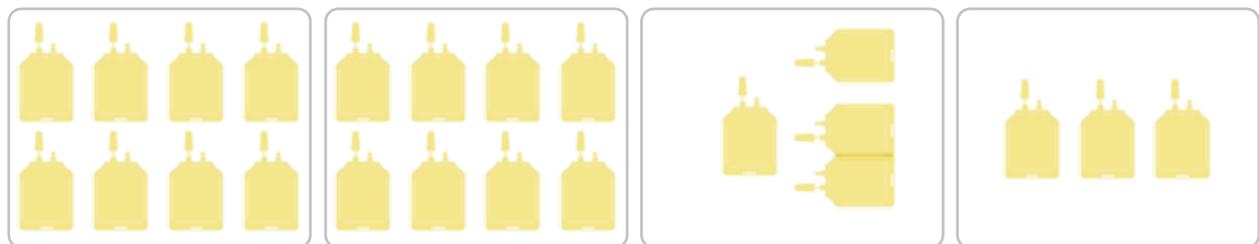


Figure 1

Figure 2

Figure 3

Figure 4

**STREAMLINING TIME AND PRODUCTIVITY**

**Real-time** monitoring of the cycle through the integrated probe allows the system to stop freezing as soon as the target temperature (**-30°C**) is reached, with time frames that allow even several cycles to be performed in one hour, with a consequent increase in the daily output.



User authentication

## PLASMAFROST ITeM®: STRENGTHS

### ..... PLASMAFROST PERFECTLY MEETS ALL REQUIREMENTS TO VALIDATE THE FREEZING PROCESS:

**Identify the batch of loaded bags** ⇨ Barcode reader built into the machine

**Display correct freezing cycle** ⇨ ITeM® probe built into the machine

**Record the data of the entire freezing cycle** ⇨ PC built into the machine

**Print out reports when the cycle is completed** ⇨ Printer or network folder as chosen by the customer

### ..... WINNING QUALITIES

▶ Improved throughput

▶ No "dummy bags"

▶ Freezing bags of different shapes and volumes

▶ Full traceability of the operations

▶ Option to connect with the databases of hospitals/blood banks

▶ User-friendly

▶ Every freezing batch is validated

▶ Utmost access safety: only authorised/registered personnel can operate the device

▶ Maintenance of the storage temperature until the bags are unloaded

### ..... STORAGE MODE FEATURE

In the event the freezing cycle has been completed, but the operator is unable to manually unload the bags of the batch, Plasmafrost ITeM® goes into a "Storage Mode" status, changing the Set Point from -75°C to -60°C.

This feature enables high energy savings and allows a stable temperature to be maintained so that all plasma bags are perfectly stored until the time of manual unloading.

		Plasmafrost Item 3	Plasmafrost Item 4
Outer Dimensions WLxDxH)	mm	950 x 1490 x 1890	
Outer dimensions with open arm (WxDxH)	mm	1300 x 1490 x 1890	
Volume	l	250	
450/400 ml bag capacity	N.	24	40
1.000 ml bag capacity	N.	12	16
Daily freezing cycles	N.	10	
Weight	Kg	660	690
Refrigerated shelves/Contact plates	N.	3	4
Shelf dimensions (WxD)	mm	550 x 590	
Through hole		Optional	
Operating Temperature	°C	-75 °C	
Voltage	V / Hz	230 V – 50 Hz	
Noise level (*)	Db(A)	< 62	
Maximum power input	A	16	12
Thermal dissipation	Kcal/h	3000	4000
1st Stage Refrigerant Gas		R452a	
2nd Stage Refrigerant Gas		R23	
Conditions of use			
Temperature	°C	10 ~ 32	
Relative humidity	%	30 ~ 80	

#### List of Accessories

Supplementary PT 100 probe with 3 calibration points

Chart recorder with microprocessor

Through hole diam. 23 mm with rubber cap

Class A PT 100 probe with 3 calibration points (-25°C; -30°C; -35°C)

Supplementary probe PT 100 class A (three wires)

Canon I-Sensys Ibp252DW printer

Class A PT 100 probe with 3 calibration points (-60°C; -70°C; -80°C)

Cryogenic gloves

AS

AG

STERIL

AIC

**Angelantoni Life Science (ALS)** is a world leader in the supply of refrigeration equipment and in the design of technological solutions in the biomedical sector, constantly engaged in innovation and safety, both biological and environmental.

**AS** brand provides for a wide range of refrigerators cabinets, ultra-low temperature freezers, blood banks refrigerators, freezers to preserve blood components, mortuary prefabricated rooms, stability tests and plant growth chambers, refrigerators and freezers for COVID-19 vaccines.

**AG** brand supplies standardized brine chilling units for pharmaceutical and chemical applications or pharma process, manual or automated solutions allow to reach  $-70^{\circ}\text{C}$  for special walk-in chambers and shelters to storage vaccines or other farmaceutical products.

**STERIL** brand provides for equipment able to meet any product protection need, as well as the product, operator and environment safety requirements, for any level of concentration and for any kind of substance (horizontal and vertical laminar flow cabinets, biohazard and cytostatic safety cabinets, laminar flow pass boxes with UV, sanitized hydrogen peroxide pass boxes, weighing, sampling and dispensing cabinets and isolators designed in accordance with the latest international standards (GMP).

**AIC** brand provides Waster, and an automated treatment system for hospital and contaminated waste.



Angelantoni Plants



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