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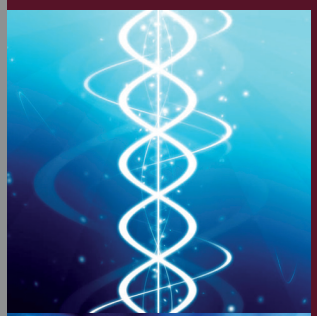
Angelantoni Life Science

Plasma blast freezers
PlasmaFrost ITeM Series



Lab Automation

- → Comply to EU Reccomandation n° R (95) 15.
- → Certified Freezing Process.
- → Medical Device, class IIa, according to EU Directive 93/42, Registered into the Medical Device Repertory at the Italian Ministry of Health
- → Comply to the European Plasma Master File (PMF)

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CE
Notified Body No.:
0434

Background

The Fresh Plasma (FP) is a blood derivative obtained by centrifugal separation or directly trough apheresis (plasmaferesis) and frozen (FFP) to correctly preserve the coagulation factors (factor VIII). The FFP is used in therapy to correct the coagulation disorders namely in presence of multiple coagulation deficiencies.
These factors are purified as dosage forms through an industrial chromatographic separation.

I.Te.M Indirect Temperature Measurement

The EU Recommendation n° R (95) 15, tells that the temperature in the core of the bag must reach -30C in 60 minutes or less.
In all Plasmafrost ITeM models, the shelves act as freezing elements: the refrigerant flows inside the shelves for the best freezing efficiency while the uniformity plates press the bags to evenly distribute the temperature. The uniformity plates are pre-refrigerated with the chamber empty (i.e. between two freezing cycles). The bags are frozen by conductivity through a direct thermal exchange. The strict relationship between the temperature of the uniformity bag and the one in the core of the bag.
The temperature profile of the uniformity plate gives a reliable and precise measure of the temperature of the bag below.

The ITeM's operation principle (patented)

The process detects the bag temperature in the I.Te.M. location trough a specific algorithm.
The temperature of the bag in that position assures that all the other bags of the batch have exactly the same freezing profile.
The I.Te.M. position contains the I.Te.M. probe. The last bag of the batch loaded into the Plasmafrost MUST be place in that position.
The freezing cycle is controlled, monitored and registered. At the end, the PC on board prints a certificate of conformity or non conformity according to the results.
The bags are loaded on the shelves of the Plasmafrost I.Te.M. after the reading of the bags barcodes. The certificate of conformity contains the codes of all the bags of the batch.

The ITeM Probe

- I.Te.M. is an integrated probe that certifies the freezing profile of all the bags of the batch.
- "dummy bags" are not needed and all the positions available on the shelves are usable to freeze the plasma bags.

← Uniformity plate

← Plasma bag

← Freezing plate (-75°C)

Embedded PC and SW

At the end of the freezing cycle Plasmafrost I.Te.M. ptints a certificate stating:

- Batch freezing Time.
- Plasma bags barcodes.
- Details of any step of the process.
- Operator ID.
- Date and time.
- Signature of the validating operator.

Plasmafrost I.Te.M. Has a panel PC touch-screen, a barcodes reader and a proprietary SW to:

- Identify all the bags of the freezing batch.
- Detect the temperature of each plasma bag of the freezing lot.
- Store and trace back all the data of the freezing processes.
- Protect all data fron any external action.
- Share the data with the Hospital/Blood Center databases.

Easy-to-use Interface

- → Access control
- → PIN Code protected
- → Plasmafrost I.Te.M. freezes soft plasma bags of any volume and shape
- → The freezing lot must process plasma bags of the same shape and volume

Technical specification

Structure /fosfatated and epoxy painted carbon steel. Mounted on wheels for an easy moving. AISI 304 inner structure with round corners for an easy cleaning.
Door /equipped with a key lock and silicone gasket.
Thermal insulation /"sandwich" technique and polyfoam CFC- HCFC free. Insulation tickness: 125 mm.
Contro Panel /located in the front of the unit; on/off switch with light; acoustic and visual signal of end-cycle high pressure refrigerant high/low stage alarm; digital display of the internal temperature; main switch on the left size.

Models	PlasmaFrost ITeM 3	PlasmaFrost ITeM 4
Internal shelves (n°)	3	4
Bags capacity (450ml)	24	40
Working temperature (°C)	-75	-75
Supply voltage (V)	230V / 50 Hz/1+N+T(G)	400V / 50 Hz/3+N+T(G)
Maximum absorbed current (A)	12	12
External dimensions (mm) (W,D,H)	1300x1490x1830	1300x1490x1830
Neat weight (kg)	660	690
Noice level (dBA)	62	62

Plasma blast freezers /PlasmaFrost ITeM Series

- ✓ **Plasma Blast Freezer where the freezing process is certified (Patented)** brings the plasma bags temperature to -30°C in less than 60 minutes. According to the international norms and procedures to safeguard the active principles present into the plasma according to the n° R (95) 15 Reccomendation and to the European Plasma Master File.

- ✓ **Medical Device certified according to the EU Directive 93/42/CEE.**
- ✓ **Complete back traceability of each freezing cycle.**
- ✓ **Maximum freezing efficiency due to the innovative uniformity plates.**
- ✓ **Horizontal freezing for the best temperature uniformity.**
- ✓ **Possibility to freeze any kind and shape of soft plasma bags.**
- ✓ **Increased productivity due the optimized freezing times.**
- ✓ **Ergonomic easiness of use.**

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Laboratory automation and biomedical equipment for storage at low temperatures (+4°C/-180°C) and chambers for stability tests.

Refrigerating systems for industrial processes.

acotec

Project design and implementation of controlled contamination environments (clean rooms).

STERIL

Laminar flow equipment for laboratory and non contamination industrial equipment.

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