



## Shock freezer for Plasma on contact

**KPFF Series**

 **BLOODline**

Medical devices for  
transfusion centres



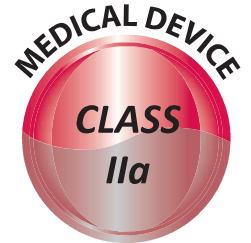


# BloodLine

## Shock freezer for Plasma on contact



manages in the  
 MONTERIGGIONI (SI) - VIA DELLA RE  
 assurance system ensuring the conformity of the  
**Blood bank refrigerators**  
 K-Lab BBR Type ref. As to annex document dated 05/09  
 provided with IMQ stamp.  
 Trade mark KW  
 Type ref. SBB5 HPL  
 Trade mark KW  
**Plasma freezer (fast freezing)**  
 Series: KPFF Type ref. KPFF 24B; KPFF 48B  
 Trade mark KW  
**Freezer**  
 Line PL-PLL Type ref. As to annex document d  
 valid only if provided with IMQ stamp.  
 Trade mark KW  
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 with IMQ st



DIRECTIVE 2007/47 CE

CLINICALLY  
VALIDATED



■ PFF 48B  
Plasma Shock Freezer



# BloodLine

## Shock freezer for Plasma on contact

The plasma bags, to be frozen, are immersed, vertically, in wells in which the walls are at  $-70^{\circ}\text{C}$ .

The geometry of the wells is conical, to simplify extraction and formation of the solid bag, without any impediment for the increase in volume which happens when there is a passing in state from liquid to solid.

### RAPID FREEZING

the bag is in contact with the surfaces of the wells and intense extraction of thermal energy is obtained in this manner, minimizing in this way the freezing time: **<45' for 24 or 48 (450 ml.) nominal standard bags, with a net content of plasma of at least 230 cc. and an initial temperature between  $+25^{\circ}\text{C}$  and  $+30^{\circ}\text{C}$  (KW has undertaken tests with bags with a mass of 260 gr. each).**

**The storage solution in vertical encounters**, in fact, all the freezing advantages of the horizontal freezers, leaving the vertical placement of the plasma bags salvaged.

The surface of the wells is smooth and in inox steel, without edges, and therefore permit the safe storage against accidental breaks or bumps of the bags; permits furthermore the eventual download of liquids exiting due to breakage, from the bottom, or the successive condensation to a freezing and maintenance stop, by means of outlets (one for each well), all gathered and leading to a single external tube.

Furthermore, the solution of the horizontal freezer maintains the following advantages:

### • TEMPERATURE UNIFORMITY

**minimum alteration of the internal T during the loading phase of the plasma bags seeing as the movement is minimal from the internal cold air, that tends to remain on the bottom of the wells guaranteeing good cooling – freezing during the bag contact – well walls.**

### • VERTICAL FREEZING

**simplifies the bag immersion seeing as the operator does not feel the intense coldness from the wells and no air bubble inside the bags, with minimum breakage risk of the bags; the shape of frozen bag is like a tile, so the following phase of storage is easier.**

### • SPATIAL DISTRIBUTION of BAGS

In conventional freezer, with horizontal shelves, the plasma bags are often stored on one another and air distribution is not perfect. It follows that freezing of the individual pockets varies considerably. In contrast, the freezing procedure proposed by KW guarantees identical conditions of freezing for each individual bag, with consequent higher yields of factor VIII and more reliable.

**The shape of the bag is very compact, in the form of a thin parallelepiped, and allows easy storage.**

### • AUTOMATIC STORAGE (option on request)

**when the door is closed, the deflectors move automatically compressing pockets in the wells for optimum freezing. (increased safety and ease of use)**

### • MINIMUM MAINTENANCE

**no ice formation in the area around the wells and in the retention gaskets, for minimum maintenance and an absolute guarantee of the maintenance of a constant T of  $-75/-80^{\circ}\text{C}$ .; no necessity of defrosting, possibility of continuous freezing.**





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### • MAX ERGONOMICS

An handy load height eases the operator, without the introduction of any addition to a very low T and without contact with the cold air.

### • ENERGY SAVING

minimum energy consumption in addition to the thermodynamic performance, thank to the high insulation and to the horizontal positions of the -70°C wells.

### • PROCESS TRACEABILITY

It's possible to equip the freezer with an electronic recorder and a bar code reader; the user can set a work schedule for single freezing batch, determining a) the single plasma units b) the operator c) the pulling down curve of T: all data are exportable whether in paper format or in digital format, which guarantee the full traceability of the freezing batch.

### • QUALITY OF FROZEN PLASMA

The quality was evaluated through the values of concentration of fibrinogen, before and after freezing, and concentration of VIII factor post freezing.

The recovery of 96% of fibrinogen and 81% of concentration of VIII factor post, are very good results.

### STRUCTURE:

Internal case, made of **6 wells** (in the **KPFF24B** model) and of **12 wells** (in the **KPFF48B** model) in inox AISI 304 steel (AISI 316 on request) with BA polished finishing, with rounded corners for easy cleaning.

**The external structure is in glazed inox AISI 304 steel sheet;** the insulation is in polyurethane CFC and HCFC free, expanded in situ, with density of 40 Kg./mc. and with a **minimum mean width of 175 mm.**

The door is mounted on the hinges with ABS cover, **auto balanced.**



**Triple gasket** (absolute retention guarantee against air entry) in silicon rubber with welded joints, warmed up by the refrigerant and of unlimited duration.



The handle has a very ergonomic design and has a key lock.

The freezer has pivoting wheels for easy transportation and internal movement in the laboratories.

**KW's guarantee on the steel parts of the structure is for life.**

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## Shock freezer for Plasma on contact

### REFRIGERATION:

The refrigerant system is completely sealed up; **it uses a cascade circuit, innovative in its components and in the fluids to follow, together with, maximum reliability and maximum performance cooling;** with 2 hermetic compressors (of more than 2 HP of power) silent (the Leq dB (A) value < 65; at more than 3 metres < 55), at high capacity refrigerant, having magnetic-thermal protection and of a manostat of maximum/minimum pressure on both circuits: total reliability and absence of failures 1st stage.

**The condensation surface of the 1st stage (air and thermal yield superior to 5000-10000 Watt,** with environment T of about + 25° C), are very ample (with exchangers in tubeless execution) to overcome the most severe environmental and work conditions (functioning guarantee of environment T ≤ +35°C); this is also for the second stage, with more exchangers, both air, and counter current, between the two fluids in bi-phase conditions.

The expansion of the refrigerating fluids is obtained using special thermostatic valves; the evaporators made up of serpentine tube in cooper thermally connected – to the entire external peripheral surface of the freezing wells. The solution, together with the use of tanks for refrigeration, guarantees:

- **a great reserve of liquid, a consecutive fast response to the cold request in the act of introducing the bags and therefore a high refrigerant capacity (very rapid freezing)**
- **high internal temperature uniformity.**

The entire thermofluidodynamic circuit is made in order to have maximum functionality (efficiency, reliability) and of maximum ease on the maintenance operations, and furthermore for maximum safety to the environment and operators, by means of inter-stage thermostats, of HP and LP manostats, etc. etc.

The refrigerants used are not toxic, inflammable, not explosive and ecological (maximum respect for the environment) HC free, CFC free, HCFC free (ODP=0 OZONE POTENTIAL DEPLETION).

R404A in the first refrigeration stage

R508B in the second refrigeration stage

### TERMOREGULATION AND CONTROLS:

The electrical command installations enabled by a switch under key (extractable in both conditions) for maximum safety in the management of the machine; and furthermore is present a light to signal the power supply. The internal T regulation is managed by a control panel that includes:

- **digital electronic control with  $\mu P$ , having led display with both T set and actual -T values, with changeable hysteresis, with ON/OFF action.**

The thermal probes used are thermo resistant RTD Pt 100 Ohm, placed in the air. The user may read the process T (the actual one in the freezing wells) in the display above, with in the inferior may verify the predefined set point value.



**KPFF 24B  
Plasma Shock Freezer**



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On the side of the display mentioned, there are functional leds:

- **COOLING** indicates that the refrigerator installation is working
- **ALARM** indicates the process value is out of acceptable range of T, with respect to the set point; having to do with the min /max alarm T default T set  $\pm 10^{\circ}\text{C}$ ., this alarm is both optical and visual and may be turned off by acting on the BUZZER OFF. indicates the visual alarm (red led turned on) persists until the system does not exit from the alarm conditions.

- **TIMER** indicates that there is in act the counting of time (setted by the user) of freezing. The lab technician may read the count down (in minutes) on the lower display, while on the upper one remains the T indication of the process inside the wells. When the cycle is finished, i.e. when the time set by the user is over, the following visual signal appears End on the lower display. And an acoustic buzzer is activated to signal the end of the cycle; it may be turned off by pressing the RUN or FUNC buttons.

### POWER FAIL

The rapid plasma freezer also has an energy acoustic alarm independent power supply (estimated battery life span of about 3 years) 12 Vdc 1.2 Ah that recharges automatically on the return of the electrical power supply, via a switching supply. the buzzer may be turned off, by pressing the BUZZER OFF button.

### SIGNAL REMOTING

All the alarms are integrated and connected to distance signal repeating unit, having a plug and relative socket (5A), ready for cabling according to the user (sounders and visual signalling devices in the laboratory, tele– alarm unit, etc.).

**ACCESSORIES:** (available on request)

- open door alarm

### • **BAGS TEMPERATURE RECORDER (RTS SYSTEM)**

**Automatic recording of the pockets of fresh plasma or by bar code reader or by RFID reader**

The “Bag Temperature Recorder” device, from now on called RTS System, use the tab **touch TFT display 7”** with dedicated software and the quick freezer board with dedicated firmware, as acquirer of temperature together with the compatibility of the application for PC Freezing Tracer for reading the graphs of the freezing process and the codes of pockets Functionality:

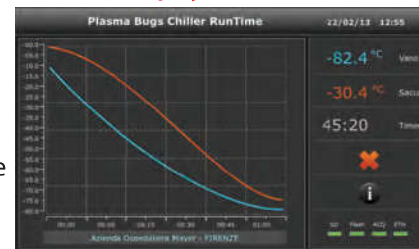
- **Reading and recording up to a maximum of 8 PT100 channels** (6 + 2);
- **Selection through display of the probe of active registration;** with exclusion of the visualization and tracking of the remaining probes excluded, with the exception of the probe in the cabinet that remains always enabled.

Association of barcodes relative to the bags in abatement related to the circuit temperature air/sample bag (there is a differentiation of the air probe and probe pockets sample)

- **Ability to select, along with the bar code, the type of bag:** large 650ml plasmapheresis or small by donation 260 ml.
- **Enabling a clean digital input for synchronizing the start of recording with the start of the unit abatement.**
- Enable output on/off switch to stop the cycle of freezing when the pre-set temperature is reached in all pockets connected during the test cycle of freezing data management
- **Historization cycles/codes on SD Card - Export of cycles/codes via USB port**
- Reading and printing cycles/codes through the application Freezing Tracer RTS
- Installing and configuring FTP server embedded on each machine



7" TFT Display Touch Screen



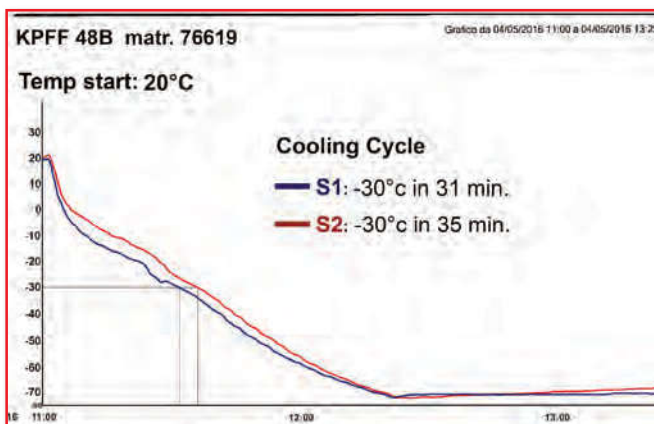
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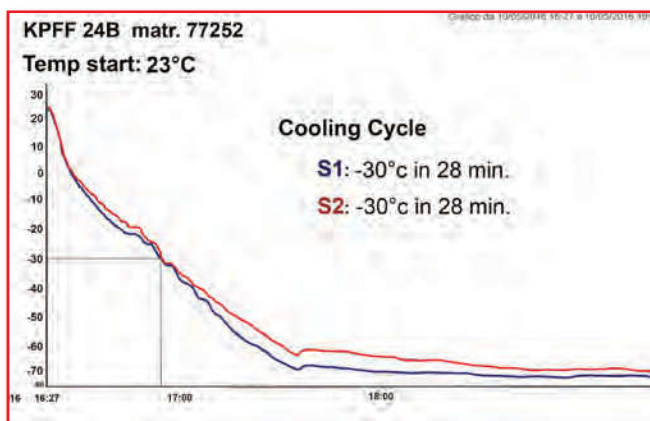
Internal case of the rapid freezer with standard 450 ml. bags in freezing



Standard 450 ml. bags after freezing



Cooling curve in the freezing weels (model. **KPFF 48B**) with external registration system. N.48 standard bags (260/280 ml.) with start temperature of +20°C.



Cooling curve in the freezing weels (model. **KPFF 24B**) with external registration system. N.24 standard bags (260/280 ml.) with start temperature of +23°C.

**NOTE:** Test performed with **S1** and **S2** probes placed inside the warmer wells.





# BloodLine

## Shock freezer for Plasma on contact

*Internal case of the rapid freezer with standard 1000 ml. bags in freezing*



*Standard 1000 ml. bags after freezing*



*Standard 1000 ml. bags after freezing*



### NEW SYSTEM AUTOMATIC STORAGE KW (option on request)

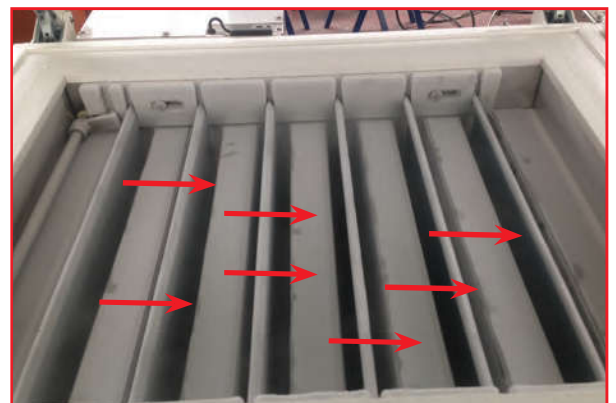
Opened door, wells free for introduction and/or extraction of plasma bags

**OPEN**



When the door is closed, the baffles automatically move, compressing plasma bags inside the wells, for the best freezing

**CLOSED**





# Shock freezer for Plasma on contact



**KPFF 24B**  
Plasma Shock Freezer

## AUTOMATIC DATA DOWNLOADING

Possibility of automatic data downloading to the end of each cycle of freezing and availability/traceability of the plan of freezing on the internal laboratory network. At the same time of the refrigeration system action, time count on the digital electronic recorder is activated, without any further intervention by the operator



Touch Technology



## GUARANTEED TRACEABILITY

With the recording of the procedure all operative phases, by a digital system touch screen and by a bar code reader, with many possibilities for the connection to the transfusion centre network.



■ PFF 48B

## Rapid freezers for Plasma on contact

K= Kalt P= Plasma F= Fast F= Freezer 24 - 48 (number of 450 ml. standard bags or 1000 ml.) B= Bags

Model	Max external dimensions (lxwxh)	Plasma bags shelf level	Internal wells	Used refrigerants	Power supply	Weight
<b>KPFF 24B</b>	cm. 120x84x126 h	117 cm	n.6 (to 4 bags cad.)	R404A ed R508B	V 230/1/Hz 50 max absorption 15 A	Kg. 250
						<i>(on request, execution 400V/3/50Hz+N+T)</i>
<b>KPFF 48B</b>	cm. 179x84x126 h	117 cm	n.12 (to 4 bags cad.)	R404A ed R508B	V 400/3/Hz 50 +N+T max absorption 10 A	Kg. 400



o 2015

New controller and new KW image

o 2006

Rapid freezer for plasma -85°C

o 2006

Control **NEW ICE AGE KW CONTROL®**

o 2001

**Medical Project®** series

o 1990

Biological Bank -85°C®

o 1985

**KW Apparecchi Scientifici S.r.l**

o Anni '70

First **vertical** freezer -85°

o 1961

First **horizontal** freezer -85°

o 1953

**KW** (kalt/warm) **Officine Meccaniche**



ISO 13485:2012



ISO 9001:2008



ISO 14001:2004

Made in Italy

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