2018- ENG

KW APPARECCHI SCIENTIFICI

Plasma & Stem Cell Thawer

Series WPFD-WSCFD Smart Version

BLOODline

Medical devices for transfusion centres

MEDICAL DEVICE

www.kwkw.it - kw@kwkw.it

BloodLine

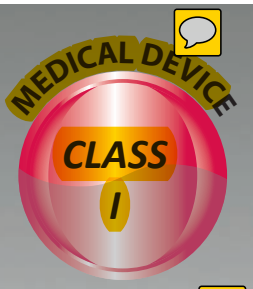
Plasma & Stem Cell Thawer model WPFD - WSCFD

W-PFD® Plasma Fast Thawer WSCFD® Stem Cell Fast Thawer

Medical Device - CEE 93/42

Smart Version:

With sensors, connectible via USB and ethernet, advanced control software (user identification, temperature cycle and whole process registration, diagnostic and alert).



Clinically Validated

USER FRIENDLY

2 MODELS

for 4 and 6 plasma bags

NEW SOFTWARE

NEW DESIGN

CONNECTIVITY

ANTIBACTERIAL

SICURITY

Model WPFD 3/6

Model WPFD 2/4

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The thawer line has been developed thanks to partnership work, in which KW involved different skills, right from the start of the project: from clinical and medical competence to industrial and scientific research, combining them with its thorough manufacturing know-how.
And it has been patented by KW.
W-PFD (or W-SCFD) is a completely innovative machine, both from the point of view of the choice of materials and in the way it works.
In fact, using this thawer it is possible to trace every step of the process; by reading the bar code or other forms of identification, the machine can recognise the operator, the type of bag and then from the bag trace the donor.
Through the electronic control unit with touch screen it is possible to transfer the information in the user's local network or file all the defrosting plan data on SD cards.
Unlike other appliances on the market, which only measure the temperature of the water, the KW thawer, which has several sensors in each pocket, continuously keeps the temperature of each bag under control, ensuring:

- Total traceability of everything that has occurred during defrosting.
- Validation of the entire defrosting process.
- Perfect homogeneity of the plasma defrosted with Hydro_pump_massage® i.e. the machine can subject the bag to a hydromassage treatment, so that at the end of defrosting the plasma is homogenised reaching a better quality.
- Asynchronous defrosting of several units of fresh frozen plasma or of several units of stem cells; the thawer is fitted with different independent heating units, so it is possible to activate the heating processes asynchronously and in a fully independent way.
- No stoppage of laboratory activity, except for exceptional events. Should any problems arise in a defrosting pocket, or if a bag breaks, the contents would in any case remain inside the pocket without contaminating the heating fluid. The pocket can easily be removed, washed under running water and then refitted without stopping the heating process of the other pockets.
- High machine productivity due to all the reasons mentioned above.

The W-PFD, W-SCFD line is a veritable challenge to common sense in terms of size, structure and information available. The KW fast defrosting system for plasma and stem cells represents the new point of reference for the user interface and for the functions of medical equipment, where a high visual impact is combined with sophisticated management of the bag preparation unit.

Asynchronous and uniform thawing.

Independent pockets

The independent pockets allow you to enable heating processes in a totally autonomous and asynchronous way.

Massage

Uniform thawing is guaranteed by the continuous water massage system.

Dry Thawing

No contact between water and external enviroment.

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Features:

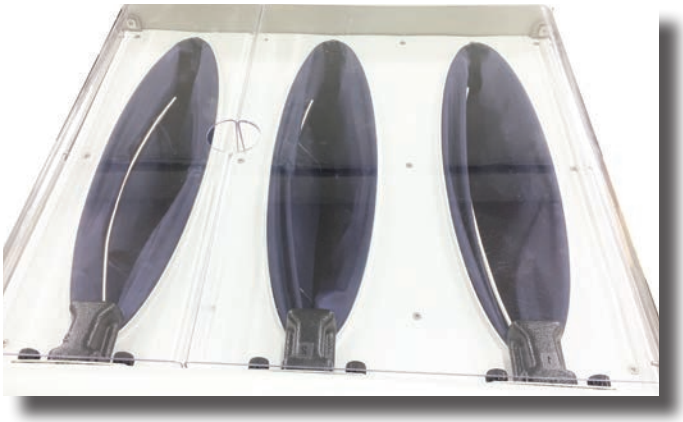
• Compact, made of **3 macro-groups:**

- **ABS Antibacterial frontal part** with control panel and electronic components.
- **Water tank in antibacterial HDPE** internal/external in one piece rotomoulding technology without any pre-post assembly. Complete with lids in Antibacterial methacrylate. Water drain from the bottom for maximum hygiene.
- Functional block, pumps, resistences, probe arms.

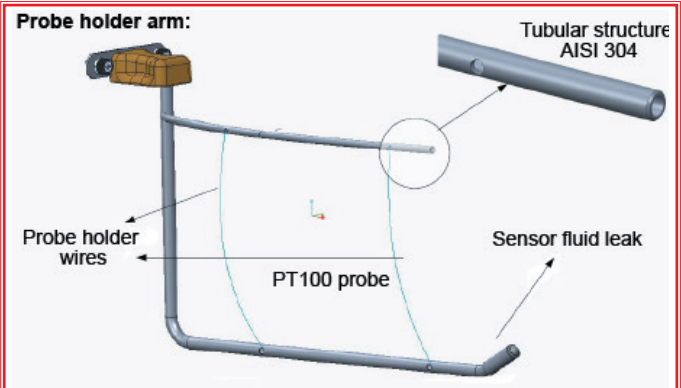
EASY FAST RELIABLE

- **Easy to use and to maintain.**
- **Easy Assembly and fast replacement of any faulty part.**

• **The system is easy to use, compact and economic,** easy to implement into blood banks or external departments.



Pans and all the sensors and actuators are fixed on the upper floor. And 'present between the upper floor and a cash insulation in insulating sheet.



New arrangment of the temperature sonsors and liquid presence not sensitive to condensation water by the defrost bags.

The electromechanical and electronic part is made up of:
- No. 1 power heater for the water bath,
- No. 2 PT100 probes for water tub temperature control,
- No. 2 water level sensors,
- No.1 independent safety thermostat;
- No. 1 water recirculation pump in the bath.

In each pocket, there are:
- No. 2 PT100 probes for the reading of the surface temperature of the plasma bag.

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Plasma & Stem Cell Thawer model WPFD - WSCFD

W-PFD® Plasma Fast Thawer WSCFD® Stem Cell Fast Thawer

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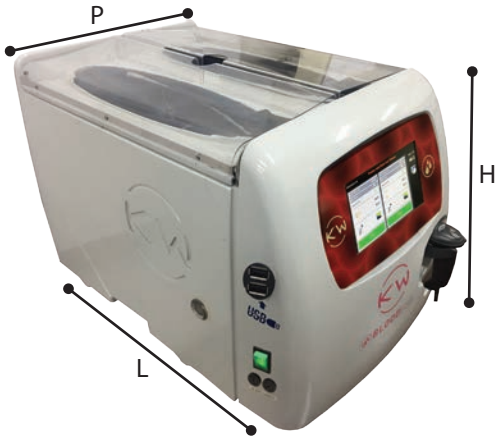
Models:

Mod. WPFD 2/4 (Smart)	
MODEL	**WPFD 2/4**
POCKETS	2
DEFROSTING CAPACITY	**up to 2 (1000 ml) bags or up to 4 (460 ml) bags**
ADJUSTMENT RANGE	Up to +40°C and more
EXT. DIMENSIONS (lxpxh)	640x396x420 mm
NET WEIGHT (Kg)	20
CAPACITY (lt)	25
INTERFACE	N.2 USB ports and Ethernet port
POWER SUPPLY	230 Vac-50 Hz 800W
CONTROLLER	TOUCH SCREEN 7"



Model WPFD 2/4
(2 pockets)

Mod. WPFD 3/6 (Smart)	
MODEL	**WPFD 3/6**
POCKETS	3
DEFROSTING CAPACITY	**up to 3 (1000 ml) bags or up to 6 (460 ml) bags**
ADJUSTMENT RANGE	Up to +40°C and more
EXT. DIMENSIONS (lxpxh)	640x555x420 mm
NET WEIGHT (Kg)	40
CAPACITY (lt)	38
INTERFACE	N.2 USB ports and Ethernet port
POWER SUPPLY	230 Vac-50 Hz 800W
CONTROLLER	TOUCH SCREEN 7"

Model WPFD 3/6
(3 pockets)

-Also available a Stem Cell Thawer model **WSCFD 1/2** with one pocket.
Defrosting capacity: 1 stem cell bag of varying capacity

N. Patent: 0001404653
29 November 2013

BloodLine

Plasma & Stem Cell Thawer model WPFD - WSCFD

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Innovation of the user interface with "touch screen "display

DISPLAY 7.0" **WIDE 165x105 mm**

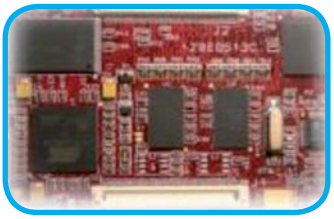
Display	TFT Touch screen 7.0" wide
Power Supply	from Power Board
Dimensions	197x122x50 mm
Frontal ports	n.2 USB ports
Port	Ethernet
Slot	per modem GSM (optional)
CPU	Atmel® at91 sam9261 256 Mb flash
	Sistema Operativo Linux 2.6.33

USB

ETHERNET

SIM/CARD

Touch Technology



CPU board

• Functions :

Thus system has up to three different defrosting pockets, each fitted with two temperature sensors, which allow the corresponding cycles for the preparation of blood bags to infusion temperature to be carried out simultaneously.

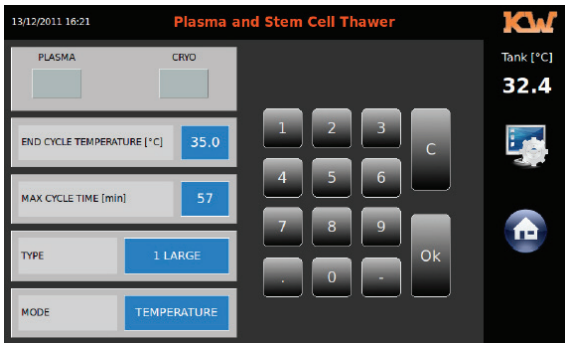
The following operating parameters can be defined for each pocket:

- **End of cycle temperature**
- **End of cycle time**
- **Bag mode**
- **Plasma mode**
- **Cell stem mode**
- **WARMER MODE**

Warmer Mode:
for warming of blood, blood products and infusion solutions.

Therefore each cycle can be controlled **in temperature** (when it is reached, the cycle ends automatically) and in any case within the set time limit, or **by time.**

WARMAP



POCKET WARMAP

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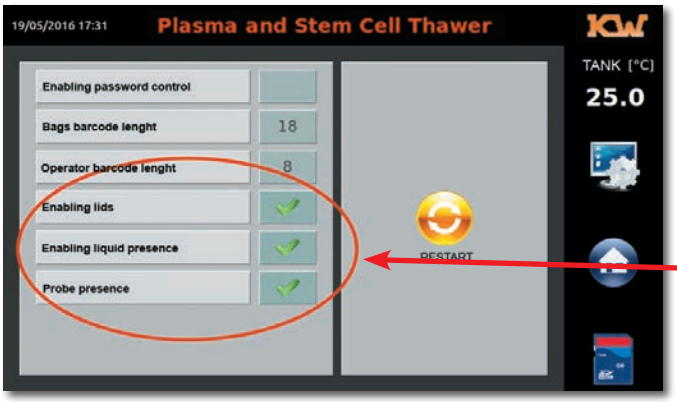
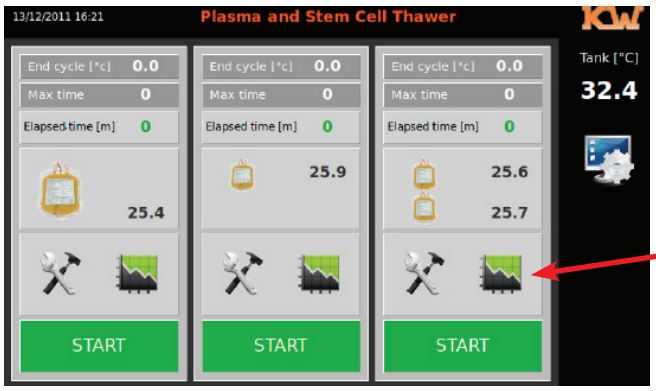


SETUP

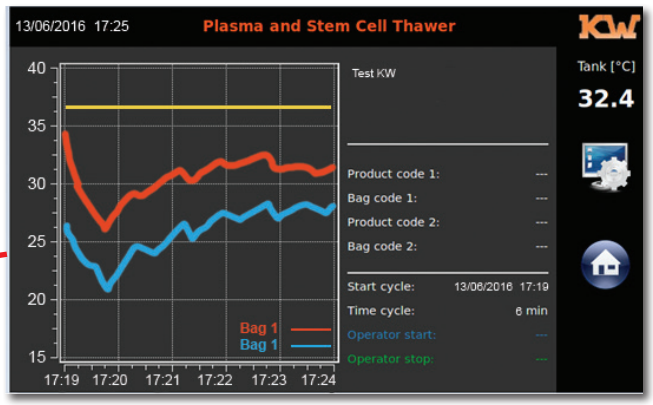
- **Alarms:**
  - **End Cycle.**
  - **Liquid leakage.**
  - **Temperature Alarm.**
- **Probe holder arm**
- **Bar code reader**

• Cycle Start:

When the set water temperature (default 40 ° C) of the tank is reached, a defrosting cycle can be started in one or more of the three available pockets, using the START key after having carried out the previous set-up operations. The defrost cycle can be started independently in all three pockets, even at different times.



CYCLE START



CYCLE MONITORING

Each of these processes are constantly monitored and recorded with the possibility of tracing the defrosting curve on the screen throughout the cycle time.
Every single defrosting cycle is stored in the memory to allow the historic retrieval of the various cycles according to the date, bag, addressee and the user who has performed the actual cycle.
Also all the operating variables are monitored in real time. At any non-conformity event, the screen shows an alarm warning. Therefore, the user can view the detail of the alarm in progress and decide the corrective action to be taken. Clearly, the system also stores the cycles interrupted due to an alarm.
A sensor warns the operator of breakage of the bag. The end of a bag preparation cycle is indicated on the screen, the pocket door is released and the user can take out the bag ready for use.

BloodLine

Plasma & Stem Cell Thawer model WPFD - WSCFD

W-PFD® Plasma Fast Thawer WSCFD® Stem Cell Fast Thawer

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Total traceability and real time monitoring.

Thanks to its intuitive interface and the bar code reader, WPFD provides the user with fast defrosting time and full traceability, as well as the ability to track the cycle in real time.

Barcode Reader

Integrated in the system, it is used for identification of the bag and the operator.

Monitoraggio continuo

Possibility of continuous monitoring of the entire defrost cycle.

Process recording and data traceability with SW Tracerand HW: *WiFi, USB, SD card and Ethernet*

Data of thawing cycles are recorded and stored on the intergrated SD card, and can be transferred to computers and servers through USB and Ethernet.

• Cycle recording/identification:

The thawer stores the cycle operating data once a minute on an internal SD Card.
Through an optional bar code every cycle can be allocated the identification of the bag, operator, etc.
These can be viewed in graphic and table form on the display itself or transferred to a PC via USB pen drive for further processing.
Or the appliance can be included in the user LAN via Ethernet port (also Wi-Fi)

N.2 USB PORTS

ETHERNET PORT

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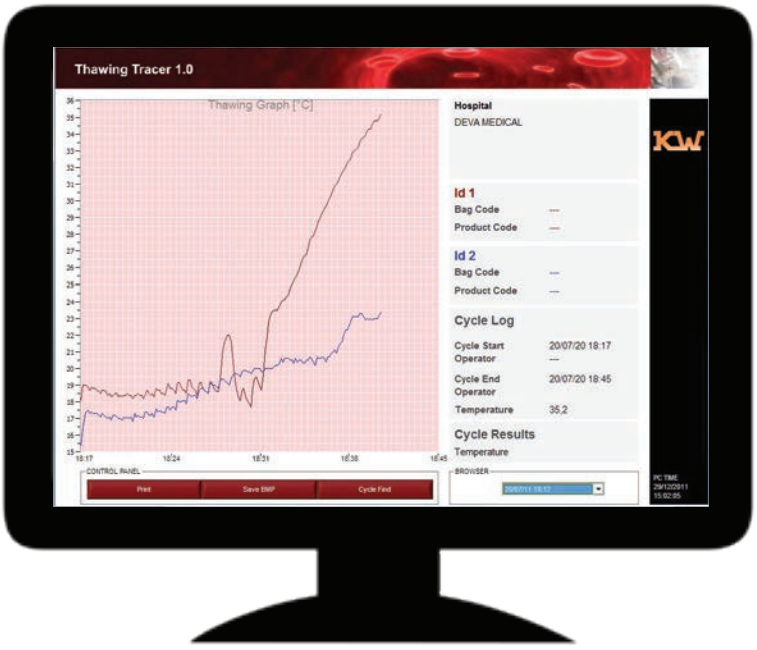
• Access control:

Each user can be associated with a password that allows access to one or more system functions:

- Cycle start
- Operating parameter setting
- Mode choose
- Date/time setting
- Turning off
- Etc...

A dedicated window shows the cycles performed on the day selected for every user.

• Included accessories:



Software THAWING TRACER

READER BARCODE

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TEST PLASMA BAGS THAWING

Figure 1: To thaw o**ne 260 ml bag**, cycle time can be set between 15 and 18 minutes with tray temperature of 40°C.

The graph shows a representative case of the recording of a 260 ml bag thawing cycle.
In this step, we performed a total of 9 tests, detecting a mean bag core temperature of 26°C and assessing that the minimum cycle duration is **equal to 15 minutes.**

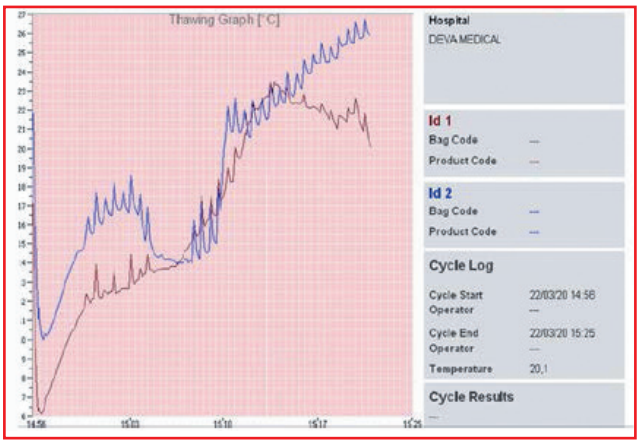

Figure2: To thaw **one or more 600 ml bags,** cycle time can be set between 25 and 27 minutes, with tray temperature of 40°C.

The graph shows a representative case of the recording of a 600 ml bag thawing cycle.
In this step, we performed a total of 12 tests, detecting a mean bag core temperature of 24.9°C and assessing that the minimum cycle duration is **equal to 25 minutes.**

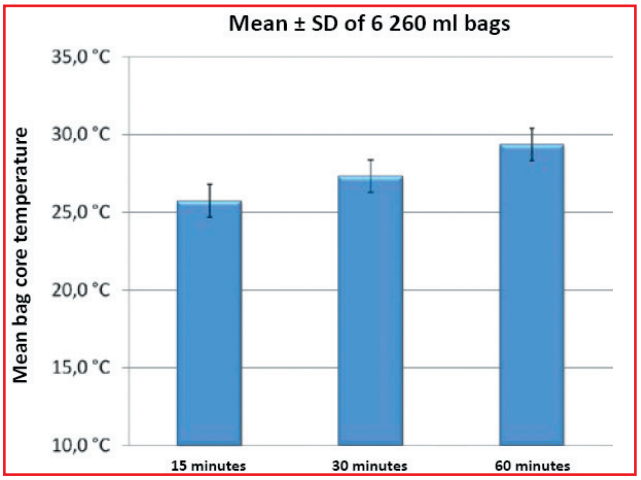

Figure 3: Even in case of negligence on the part of the operator, the mean temperature of the thawed bags does not reach potentially dangerous levels.

Worst-case simulation: after a normal 15 minute thawing cycle, the 260 ml bag was left inside the thawer and bag core T was measured after 30 and 60 minutes.
We assessed that bag core T increases by an average of approx. 2°C every 30 minutes, but does not reach potentially dangerous levels for product integrity even after 60 minutes.

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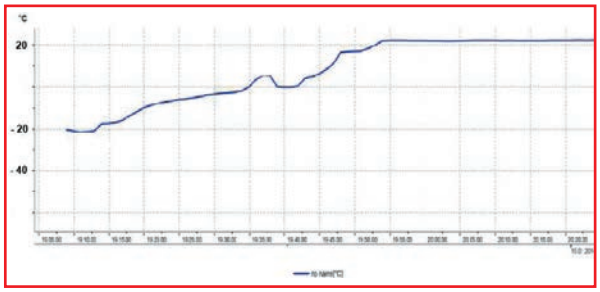
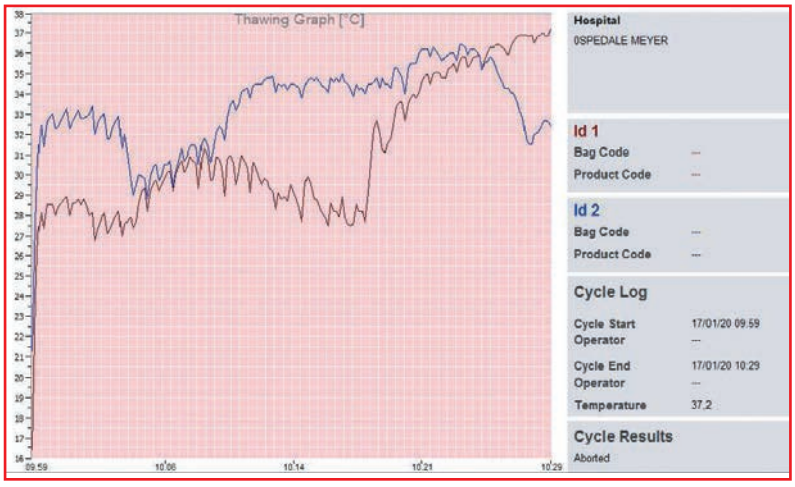
TEST N.9 PLASMA BAGS THAWING

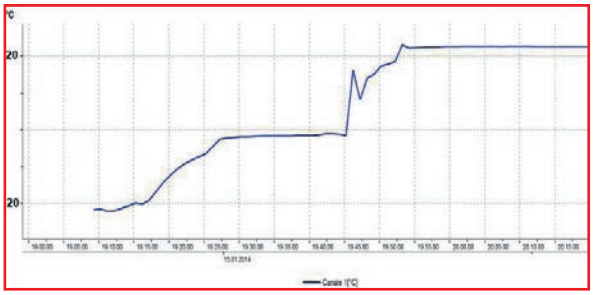
For emergency situations.

To thaw 9 plasma bags with cycle time of 35 minutes. Below - Graph of thawing 2 plasma bags (for each pocket) + Graph of the third plasma bag and detected with internal probe.

(Clinically Validated)







Plasma bags position inside pocket

BloodLine

Plasma & Stem Cell Thawer model WPFD - WSCFD

W-PFD® Plasma Fast Thawer WSCFD® Stem Cell Fast Thawer

Medical Device - CEE 93/42

New features compared with state of the art

- The plasma bag does not directly contact the thermostatic bath, therefore it remains completely dry and protected against contamination.
- The pocket material is guaranteed to remain intact even after repeated insertions of the frozen bag, which might have cutting edges.
- The temperature sensors inside the pocket allow recording the trend of the heating process for each bag.
- The machine version with three trays allows the fully independent and asynchronous activation of 3 heating processes.
- Alarm in the case of plasma bag breakage.
- The temperature of the thermostatic bath can be higher than the final temperature required for the plasma bag, as the temperature sensors in contact with the bag indicate that heating has taken place to the set temperature and the control system interrupts the process emptying the tray in just seconds.
- It is possible to activate the function for massaging the bag and homogenising the plasma by quickly filling and emptying the operating tray of the individual defrosting pocket.

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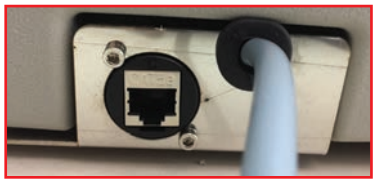
• Simple to use:

There is no need to indicate the defrosting time in relation to the bag size, as the machine interrupts the process when the required temperature is reached.

- The user can see the surface temperature reached by the bag in real time on the display.
- The whole process is recorded automatically.
- Total connectivity.

• Simple to clean:

If the bag is broken the contents remain inside the pocket without contaminating the thermostatic bath; the pocket can easily be removed, washed under running water and then refitted.
The bath water is treated with sterilising substances according to the maintenance procedures.



Ethernet Port

SD CARD INTERNAL

SLOT FOR SIM GSM

Tap for water drainage

Switch ON/OFF and N.2 USB Ports

BloodLine

Plasma & Stem Cell Thawer model WPFD - WSCFD

W-PFD® Plasma Fast Thawer WSCFD® Stem Cell Fast Thawer

Medical Device - CEE 93/42

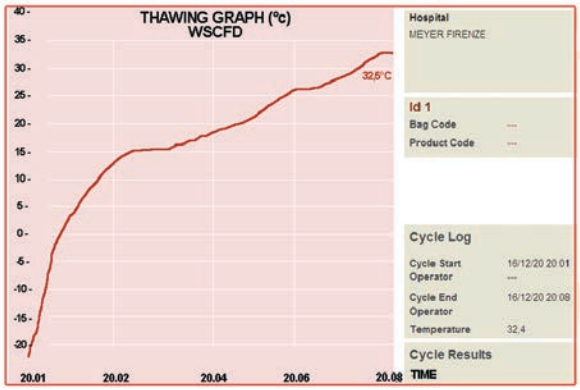
MEDICAL DEVICE CLASS I

Stem Cell Thawer model WSCFD

(Clinically Validated)

Experiences thawing of hematopoietic stem cells in the context of autologous or allogeneic, conducted in laboratory with **WSCFD**, showed that:

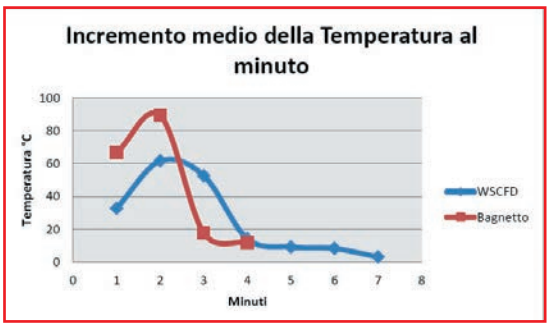
- The graphs of thawing and subsequent heating of the stem cells, are perfectly superposable to those made with the classic method of thawing in use, in most laboratories, which involves the use of the bath + 37°C; and also there are benefits about the greater linearity of the average of the T cell and the consequent lower thermal shock.



- The recovery, post thawing, CD34 + cells and leukocytes is similar or even better with the KW thawer, compared to traditional process until now in use.

- The safety of the process in the handling CSE is decidedly superior and supported by a traceability documented, especially useful in view of the evolution of the laboratories in terms of quality management processes.

By activating the massage *hydro massage pump*, there is an increase in the average temperature of the cells stem more linear compared to classic bath, ensuring a lower thermal shock to the cells.



Mean increase in temperature per minute.

BloodLine

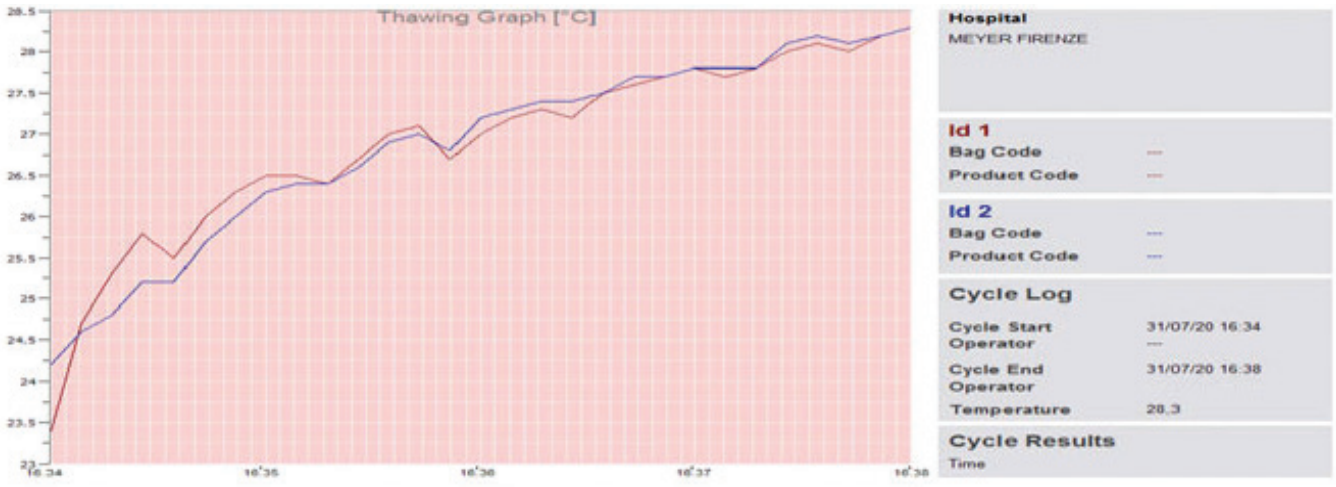
Warmer WB&BP® Warming Blood and Blood Products

Medical Device Classe I - CEE 93/42 e s.m.i.

WARMING MODE

(Clinically Validated)

for warming of blood, red blood cells, blood products and infusion solutions warming. It is very useful for intensive care, resuscitation, first aid, thalassemia and emophilia planned transfusions



Example of red blood cell bags warming; 270-290 ml. capacity for bag, initial temperature +5°C ± 2°C, bath temperature +32°C ; maximum warming time 10 minutes.

Infusion solution stored at ambient temperature ; 500 ml. capacity for bag, bath temperature +37°C , maximum warming time 8-10 minutes

2016
Frigoematica (Smart Blood Bank)

2014
New controller and new KW image

2006
Rapid freezer for plasma -85°C

2002
Control **NEW ICE AGE KW CONTROL®**

2001
Medical Project® series

1990
Biological Bank -85°C®

1985
KW Apparecchi Scientifici S.r.l

Anni '70
First **vertical** freezer **-85°**

1961
First **horizontal** freezer **-85°**

1953
KW (kalt/warm) **Officine Meccaniche**

ISO 13485:2012 ISO 9001:2008 ISO 14001:2004

Made in Italy

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