



BloodLine

Plasma
&
Stem Cell Thawer

model WPFD - WSCFD

WPFD® Plasma Fast Thawer
WSCFD® Stem Cell Fast Thawer
Medical Device - CEE 93/42



Conformity with:

GMP
CNT
JACIE
FACT



The WPPD – WSCFD product is a registered and patented model





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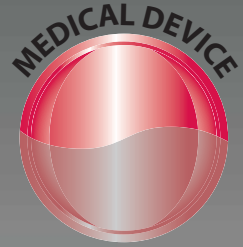
Plasma & Stem Cell Thawer model WPFD - WSCFD

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"TOUCH SCREEN" DISPLAY



Slot for USB



Slot per SIM Card



Model WPFD - WSCFD



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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 bath, **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.





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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
Front ports	USB - Slot per SIM Card e SD Card
Ports	Ethernet
Slot	for modem GSM (optional)
CPU	Atmel® at91 sam9261 256 Mb flash Operating System Linux 2.6.33



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.

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

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Cycle recording/identification

The thawer stores the cycle operating data once a minute on an 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)



Figure 1: To thaw one 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.



Figure 2: 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.



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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.

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.



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Models and specifications

Model	Defrosting capacity	Dimensions l x p x h (mm)	Net weight
WPFD 3/6 (3 pockets)	Up to 3, 1000 ml bags or 6, 460 ml bags	516x600x562	30 Kg
WPFD 1/2 (1 pocket)	1, 1000 ml bag or 2, 460 ml bags	540x370x562	20 Kg
WSCFD 1/2	1 stem cell bag of varying capacity	243x314x442	8 Kg

Specifications shared by models WPFD-WSCFD

Power supply	230 Vac-50 Hz 800W
Adjustment range	Up to +40°C and more
Interface	Bar code scanner, USB, SIM card, SD card, outside PT100 sensor, Ethernet port (also Wi-Fi)





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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. This way the process time can be reduced.
- 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.

• 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.

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WARMING MODE

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



Hospital	
MEYER FIRENZE	
Id 1	
Bag Code	---
Product Code	---
Id 2	
Bag Code	---
Product Code	---
Cycle Log	
Cycle Start	31/07/20 16:34
Operator	---
Cycle End	31/07/20 16:38
Operator	---
Temperature	28.3
Cycle Results	
Time	---

Example of red blood cell bags warming; 270-290 ml. capacity for bag, initial temperature $+5^{\circ}\text{C} \pm 2^{\circ}\text{C}$, bath temperature $+32^{\circ}\text{C}$; maximum warming time 10 minutes.



Infusion solution stored at ambient temperature; 500 ml. capacity for bag, bath temperature $+37^{\circ}\text{C}$, maximum warming time 8-10 minutes



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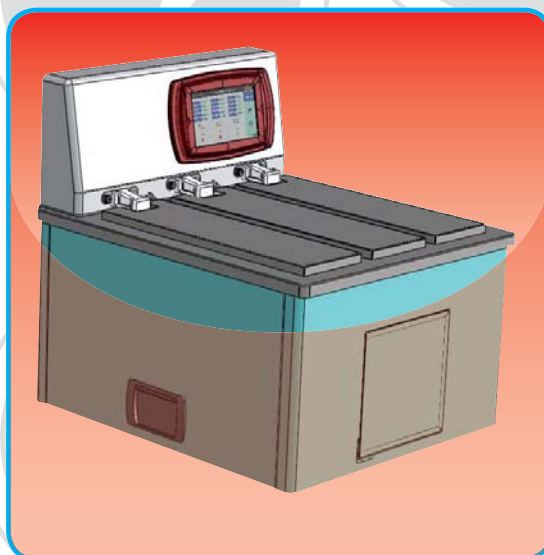
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model WPDF - WSCFD



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ISO 14001:2004



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DATA LOG

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