KW APPARECCHI SCIENTIFICI

MANUAL
OPERATION AND MAINTENANCE

PLASMA THAWER WPFD

DIRECTIVE 93/42/CEE
AND SUBSEQUENT AMENDMENTS AND ADDITIONS (2007/47/CE)
CLASS IIA, RULE 2, ANNEX V

SERIAL NUMBER N°……..

Original instructions

Vers. 3/10/2022

IMPORTANT: Read this instruction manual. Failure to read, understand and follow the instructions in this manual could result in damage to the unit, injury to operating personnel, and poor equipment performance.

ATTENTION: All internal adjustments and maintenance operations must be carried out by qualified technical personnel.

The data and instructions given in this manual refer to the models currently in production; KW reserves the right to make any changes that will be deemed useful for the technical improvement of the products at any time.

Business presentation

KW APPARECCHI SCIENTIFICI S.r.l., bearing the prestigious "KW" brand, whose creation and diffusion dates back to 1953, operates in the biomedical and scientific research sector.
Since 1979, the Company's management has concentrated all activities (commercial, administrative, production and the technological research laboratory) in the current headquarters located in Via della Resistenza 119 - Le Badesse-53035 Monteriggioni -Siena.
Currently the company has a staff of about 30 units, including specialized technicians, employees, workers, consultants in engineering and biology and is present both in Italy and abroad with a sales network composed of scientific collaborators and resellers, as well as with a qualified assistance network.
KW's commitment to the construction of machines at the service of new biological techniques is achieved through the synergistic effect of innovations in manufacturing and marketing processes, the use of microelectronics, constant investments in applied thermodynamic research and integrated regulation systems; this allows us to offer users a decidedly ergonomic range of products with a high technological content; and to have a high dynamism of the KW structure, with particular reference to:

- company quality-product safety
- product reliability
- eco-compatibility of the product.

The company's activity consists of the creation, marketing and installation of the products currently in the catalog, which can be divided into 5 distinct sectors:

1) refrigeration

- freezers with operating temperatures down to –130 ° C, both horizontal and vertical, suitable for storing any biological material and for cold tests of various types;
- efrigerated cabinets (also with combined T) for storing sera, vaccines, various biological materials, drugs, etc.;
- refrigerated cabinets for gelfiltration and cold chromatography techniques;
- Blood cells;
- control units for liquid refrigeration;

2) controlled T environments

- stoves with a range of T up to + 250 ° C;
- stoves with paraffin;
- refrigerated thermostat cabinets with forced air circulation and thermal water flywheel;
- growth chambers with T-control and photoperiod and germination chambers;
- CO_2 incubators with% CO2 control (air jacket and water jacket) both with flow meters and with TC electronic analyzer;
- precision thermostatic baths;
- water bath with oscillating / linear stirring;

3) sterilization

- ventilated dry sterilizers with automatic control of the thermal cycle;
- glassware-drying cabinets;
- cabinets for sterile storage;

4) laboratory accessories

- accessories for completing the above equipment: tube holders, pipette holders, tube rotators, bottle rotators, etc.;

5) engineering-apparecchi speciali

- special equipment and systems on specific design for GMP, FDA, etc. certification

KW Apparecchi Scientifici has been certified for many years according to the company quality standards:

- ISO 9001: 2015 ***Quality Management Systems***
- ISO 13485:2016 ***Quality Management Systems for Medical Devices***
- ISO 45001:2018 ***Occupational health and safety***
- ISO 14001:2015 ***Environmental management system***

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1. General warnings

The recommendations, shown below, must be read carefully by the user, as they provide important information regarding the safety of installation, use and maintenance and possible dismantling.

Furthermore, before using the equipment, the operators must be trained on the contents of this instruction, use and maintenance manual.

Keep this booklet carefully for any further consultation.

After removing the packaging, check the integrity of the appliance. If in doubt, do not use the appliance and IMMEDIATELY contact the KW central technical assistance service (tel. 0577/309144).

1.1 Symbols used in the manual

The following symbols and conventions are used inthis manual:

	**ATTENTION** Important operating instructions that reduce the risk of injury, even serious, or of possible damage or insufficient performance of the unit.
	**NOTICE** Situations where dangerous voltages exist and the risk of electric shock
	Obligation to use gloves
	Read these instructions before use
	Particular requirements related to the presence of low temperatures
	Prohibition

	Prescription or recommendation
	Recyclable materials
	Obligation to use protective goggles
	Obligation to use safety shoes

1.2 Symbols present on the device

	CE Mark
	Read the enclosed instructions before use
	Grounding point
	**NOTICE** Situations where dangerous voltages exist and the risk of electric shock
	Danger of explosion

1.3 General advices

	The recommendations, shown below, must be read carefully by the user, as they provide important information regarding the safety of installation, use and maintenance and possible dismantling.
	This manual is an integral part of the machine/equipment and must be consulted by the operator, the maintenance worker, and the safety manager and possibly by the department manager before making the machine/equipment available.
	Before using the equipment, the operators must be trained on the contents of this instruction, use and maintenance manual.
	Keep this booklet carefully for any further consultation. It must be stored in a protected, dry place, away from the sun's rays and must always be present, for consultation, near the machine.
	This information is the property of KW Apparecchi Scientifici. It is strictly forbidden to reproduce them or communicate them to third parties without explicit authorization.
	This manual cannot be altered or changed in any of its parts by the buyer on pain of forfeiture of the guarantee granted and the assumption by the buyer of all civil and criminal liability arising from damage caused to people and/or things.
	The machine/equipment cannot be put into service, or made available without having read the attached documentation, under penalty of forfeiture of the guarantee granted and the assumption by the purchaser of all civil and criminal liability deriving from damage caused. to people and/or things.
	If some photos or drawings are not consistent with what was delivered, it is likely that the photos or drawings refer to a different machine configuration, contact the assistance center.
	This manual reflects the state of the art at the time the machine / equipment was placed on the market, as well as the national and international legislative requirements for safety and hygiene in force at the time it was placed on the market; any subsequent technological innovation will not affect its validity as long as the owner always checks the compliance of the system with the provisions of future laws.

1.4 Terms and definitions

In compliance with the Machinery Directive, this documentation contains important information whose knowledge we believe is essential for both the operator and the service assistant, in order to be able to operate in safe conditions.

Precisely because they are widely used terms, we believe it is essential to clearly explain the meaning attributed to:

Terms	***Description***
Operator	Person in charge of operating, regulating, carrying out, providing for routine maintenance, cleaning the machine.
Assistance attendant	Specialized employee, specially trained and authorized to carry out extraordinary maintenance interventions as well as repairs that require in-depth knowledge of the machine, of its operation, of the safety devices and related intervention methods.
Dangerous zone	Any area inside and / or near the machine in which the presence of an exposed person constitutes a risk for the safety and health of the same.
Exposed Person	Any person who is wholly or partially in a dangerous zone.

1.5 Safety

The device/equipment in question has been built taking into account the possible risks that it can cause during its operating life.

The staff must be aware of the presence of residual risks, the precautions to be taken and the general accident prevention rules to be followed and respected, therefore the operator:

- It must be properly trained;
- Must read and learn these instructions; if he does not have reading skills, he must be verbally informed of the information relating to this manual;
- Must have a clear understanding of the concept of responsibility and competence.

	The machine/equipment must be driven and managed exclusively by operators who have read and learned the instructions. Comply fully with the instructions, procedures, warnings and general rules to be followed in this manual. Unauthorized tampering/replacement of one or more parts of the machine/equipment, the use of accessories, tools, consumables other than those indicated by the manufacturer, can constitute a real danger of injury.

In order to maintain safety conditions, the operator must always pay attention to:

- Do not tamper with any of the parts of the machine for any reason;
- Avoid the presence of people not related to the operation of the machine.

	In order to avoid the risks present, the operator and all the machine operators are required to familiarize themselves with the machine/equipment in order to better evaluate its correct functionality and promptly report any anomalies; not to be distracted during the execution of maneuvers and/or other activities on the machine itself and/or in parts of it, in order to guarantee the safety of oneself and any other exposed persons, while preserving the machine/equipment from possible damage.

1.6 Intended use of the equipment

Questa apparecchiatura deve essere destinata solo all'uso per il quale è stata espressamente concepita: ovvero per lo scongelamento di plasma fresco congelato, di cellule staminali e di materiale biologico congelato, in genere, comunque non infiammabile, esplosivo, etc.

Ogni altro uso è da considerarsi improprio e quindi pericoloso.
La KW Apparecchi Scientifici non può essere considerata responsabile per eventuali danni derivanti da usi impropri, erronei ed irragionevoli.

1.7 Allacciamento elettrico

The machine is equipped with protections and safety devices for the prevention of accidents at work in compliance with the laws in force.

The electrical safety of this equipment is only ensured when the equipment is correctly connected to an efficient grounding system, as required by current electrical safety standards. It is necessary to verify this fundamental safety requirement and, in case of doubt, request an accurate check of the system by professionally qualified personnel. KW App. Scientifici cannot be held responsible for any damage caused by the lack or inefficient grounding of the system.

	**Connect the power cable to a 2P + T Schuko power socket. The appliance is already set up to be powered with 230V / 50Hz. The installation category referred to overvoltages is II.** After placing the equipment in the designated place, carefully remove any adhesive films that may cover some steel or sheet metal parts. If glue residues remain, eliminate them with suitable substances, with a low flammability rate. Never use abrasive substances.
	The removal or tampering of the protective barriers causes the operator or assistance assistant to assume all responsibility for the dangers that may arise and/or derive from them.
	The removal or tampering of the safety devices is not allowed and **KW Apparecchi Scientifici** is released from any liability or legal involvement in the event of an accident.

1.8 Residual risks present during the various work phases

During the design and manufacturing phases, all measures were taken to eliminate or reduce the risks for the user of the machine, however only the use provided for in this manual can make these measures effective.

The risks that cannot be eliminated, or residuals, are those deriving from incorrect use of the machine whose probability of occurrence is limited only with the correct training and information of the operators.

2. Techical Data: description series WPFD-WSCFD

The line of defrosters was developed thanks to a partnership work, in which KW, from the first design phase, was able to involve different skills: from clinical-medical ones to those of industrial and scientific research, combining them with its deep know- how of constructor. And it is the subject of a patent, owned by KW.

The WPFD - WSCFD machines are totally innovative devices, both from the point of view of the choice of materials and in its operation. Using this plasma thawer it is, in fact, possible to trace each phase of the process: the machine, by reading bar codes, or other forms of identification, can recognize the operator, the type of bag and then trace back to the donor from the bag.

The electronic control unit with touch screen display then allows the information to be transferred to the user's local network or to archive all the data of the defrosting plan on SD card support. The machine is equipped with a USB device and WiFi and is therefore designed to be entered into the data network of the hospital.

Connection protocols are possible (on request) with the software installed in the hospital company server, so that the central server can query the KW device at a set frequency and automatically for complete traceability of the operations related to the machine in question.

Unlike other equipment on the market, which only measure the temperature of the bath, the KW defroster, thanks to multiple sensors inserted inside each cell, continuously monitors the temperature of each bag, ensuring:

- Total traceability of everything that occurred during defrosting, complete with Temperature - Time curve;
- The validation of the entire thawing process;
- The perfect homogeneity of the plasma thawed with Hydro_pump_massage®, ie the machine has the ability to subject the bag to a hydromassage treatment, so that the plasma, at the end of thawing, is homogenized reaching a better quality.
- The asynchronous defrosting of several units of fresh frozen plasma, or of several units of stem cells;
- The defroster is equipped with several independent heating units, and can activate the heating processes in a totally independent and asynchronous way.
- No downtime at the laboratory, unless exceptional events occur. Should problems be encountered in a defrosting cell, or should a plasma bag break, the contents would still remain inside the bag, thus without contaminating the heating liquid. The bag can be easily disassembled, washed under running water, possibly sanitized with disinfectants and then reassembled, without stopping the heating process of the other bags.
- A high productivity of the machine, for all the above reasons.

The W-PFD / W-SCFD line constitutes a real challenge to common sense due to the size, structure and information available. The KW rapid defrosting system for plasma and stem cells represents the new reference for the user interface and for the functionality of medical equipment, where a sophisticated management of the bag preparation unit is combined with a high visual impact.

2.1 Technical characteristics

Model	External Dimensions** (mm) LxPxH	Capacity (l)	Tub	Capacity THAWING	Rated installed Power	Net weight
WPFD 2/4	380 x 620 x 420	25	2	up to 2 bags of 1000ml or up to 4 bags of 460ml	685 W	Kg 35
WPFD 3/6	550 x 620 x 420	38	3	up to 3 bags of 1000ml or up to 6 bags of 460ml	750 W	Kg 40

Power supply: 110/230 Vac, 50/60 Hz
Temperature range: from + 5 °C above Tambiente to +50 °C
- User interface via 7.0” wide adjustable Touch Screen display on adjustable support.
- Front USB 2.0 ports - SD Card slot - SIM slot - Wi - Fi system.
- Atmel® 256 Mb flash CPU with Linux 2.6.33 Operating System.

2.2 Structure and system

Compact execution, easily interchangeable for maintenance purposes, consisting of **3 macro-groups**:

- Front shield in antibacterial ABS with control panel and electronic components.
- Internal/external antibacterial HDPE bathtub group in one piece with rotomoulding technology without any pre-post assembled parts, complete with antibacterial transparent methacrylate doors.
- Functional monobloc unit, pump, resistors, probe holder arms etc.

The trays and all the sensors and actuators are fixed to the upper level: between the upper level and the box there is an insulating plate insulation. Each defroster is equipped with a Touch Screen display, for thermoregulation and machine controls. The electromechanical and electronic part consists of a power resistor for heating the bathroom, 2 PT100 probes for controlling the water temperature, two water level sensors, an independent safety thermostat, and a pump for water recirculation in the basin; for each bag there are 2 PT100 probes for the surface reading of the plasma bag, a plasma loss sensor and a water filling pump.

3. Installation

3.1 PPE mandatory for installation

	The clothing and PPE (personal protective equipment) of those who work or carry out maintenance on the machine / equipment must comply with the essential safety requirements in force in their country, as indicated in the EEC directive 89/656 and 89/868 relating to use of personal protective equipment.

During the product installation phases, the use of the following PPE is mandatory:

	Gloves against mechanical agents
	Safety goggles
	Safety shoes

3.2 Transport and unpacking

The product is packed in KW Apparecchi Scientifici to guarantee its integrity during transport.
The packaging is customized for the various models while ensuring protection of the surfaces by means of cardboard and/or polystyrene coating, corners and a wrapping with stretch film of polyethylene and strap.
If the appliance is not equipped with wheels, it is placed on a pallet that facilitates its movement by means of mechanical aids (transpallet, forklift). If there are wheels, they are used for handling.

	Handling on wheels is however not recommended for long stretches and on uneven surfaces.

In no case are sockets or eyebolts provided because it is not allowed to move in a different way from the aforementioned. The transport takes place with an authorized courier trained on loading, transport and unloading procedures, in particular on the need to always keep the appliance in a vertical position. In the event that it is necessary to transport the instrument, the original packaging (or equivalent) must be requested from KW APPARECCHI SCIENTIFICI SRL. KW is not liable for any damage resulting from the transport of the instrument in unsuitable packaging.
After removing the packaging, make sure the appliance is intact. in case of doubt, do not use the

appliance and contact the KW central technical assistance service - tel. 0577/309144.

	All the packaging materials used for the new device can be disposed of safely. Cardboard can be crushed and destined for wastepaper; the sheets are in polystyrene free from fluoro-hydrochloric hydrocarbons and the wrapping is in branded nylon: these substances can be recycled, if delivered to a relative collection center (ask the Municipal Administration).

3.3 Safety and accident prevention

The machine was designed and built with appropriate measures to ensure the safety and health of the user.

- *Stability*: the machine has been designed and built in such a way as to ensure stability in all expected operating conditions if positioned flat with the help of the adjustable feet;
- *Surfaces, edges, corners*: within the limits allowed by their functions, the accessible parts of the machine are free of sharp corners and sharp edges.
- *Movable elements*: all the elements with the possibility of movement have been designed, built and arranged in such a way as to avoid risks.
- *Electricity*: the machine has been designed and built in such a way as to prevent the risks deriving from electricity, in compliance with the specific legislation in force. The electrical safety of this equipment is ensured when the equipment is correctly connected to an efficient grounding system, as required by current electrical safety standards.
- *Noise*: the machine was designed and built in such a way as to minimize the risk of noise pollution.

	The use of any electrical equipment requires the observance of some fundamental rules: - do not touch the appliance with wet or damp hands or feet; - do not use the appliance with bare feet; - do not use extension cables, except with particular caution (and with prior notification and authorization from the CENTRAL TECHNICAL ASSISTANCE SERVICE);

	- do not pull the power cable, or the appliance itself, to remove the plug from the socket; - do not leave the equipment exposed to atmospheric agents; - do not allow the equipment to be used by incapable persons, without supervision;

	- the fixed guards (fixed protections solidly connected to the structure), if present, must remain in their seat, correctly fixed and in perfect integrity during all operations relating to normal operation; - do not put explosive materials or cans/containers with flammable substances into the device; in contact with the electrical parts, any gas leaks (flammable) can ignite. Do not store different materials that are incompatible and/or not clearly separated or materials that require different storage temperatures; - do not allow children to play with the appliance and / or it is within their reach; - use the appliance only in the temperature range for which it is built and tested; do not use at different temperatures; - do not try to alter - in any way - the configuration and adjustment parameters of the electronic instrument of the control panel; - do not modify the electrical wiring or mechanical connections in any way.

	Since the freezer has the purpose of keeping the material contained in it at a very low temperature, whenever you ask to open the door, it is recommended to always wear gloves with adequate thermal protection.

	Before carrying out any cleaning or maintenance operation, disconnect the appliance from the power supply by pulling out the plug.

3.4 Posizionamento e allacciamento elettrico

	The installation must be carried out according to the instructions of KW Apparecchi Scientifici S.r.l. by professionally qualified personnel. Incorrect installation can cause damage to people, animals or things, for which KW Apparecchi Scientifici cannot be held responsible.

At the time of installation by the user, the device is moved in the manner described above, unpacked and positioned flat (level).
If the appliance is equipped with adjustable feet, rotate them to compensate for any unevenness in the ground. If the appliance is equipped with wheels, engage the brake for maximum stability.

	Check that the electrical capacity of the system and of the power sockets are adequate for the maximum power of the appliance indicated on the plate. If in doubt, contact professionally qualified personnel.
	During the installation of the Incubator, make sure that EASY EXTRACTION OF THE PLUG FROM THE ELECTRIC POWER SOCKET is always allowed.

The device is suitable for installation in a dry and airable environment.
The place must not be exposed to direct sunlight and must not be near a heat source such as a radiator, stove, other heat-dissipating equipment (sterilizer, autoclave, etc.).
If flammable gases are present inside the appliance, it must finally be installed in a compartment that has a sufficiently large volume to avoid dangerous concentrations in the event of leaks. The minimum volume that the room must have can be calculated using the lower flammability limit (LFL) of the gas and the quantity of the same gas present in the circuit, using the following formula:

V_{min}= (gas charge in Kg) / (0.2 x LFL)

For example, if there are 0.15 kg of R290 in the circuit which has an LFL value of 0.038 kg/m^3, the minimum volume will be 19.7 m^3.

	Particular attention must be paid to localization

Under no circumstances must the ventilation space between the appliance and the wall or the ventilation grille be obstructed.
The appliance must be installed in a fixed and level way.
Any unevenness in the floor must be compensated for, at the user's discretion.
The room where the instrument is located must have air exchange, through a natural circulation or, better, a forced circulation; if the T is close to + 30 °C it is necessary, for the hottest periods, to use an air conditioner/conditioner to remove the condensation heat from the freezer, which varies from model to model; average reference value about 700/800 W; this must be multiplied by the number of machines present in the same room or zone.
KW declines all responsibility for any damage occurring in the use of the equipment produced or marketed by it, if the recommendations made have not been observed exactly and scrupulously by the user.

4. Technical assistance service

	In the event of breakdown and/or malfunctioning of the equipment, contact the authorized technical assistance center: for any repairs, request the use of original spare parts. Failure to comply with the above can compromise the safety of the equipment.

The technical assistance of the equipment present on the national territory is made through a maintenance service, both direct and with authorized technical assistance centers distributed throughout all regions of Italy.
The center operating in Monteriggioni (Siena), Via della Resistenza n.119 -53035.
tel. 0577-309143-5 **fax 0577-309142** e-mail: assistenza@kwkw.it
For a copy of the manual, send a request to qa-red@kwkw.it

5. Installation and start-up instructions

5.1 Filling

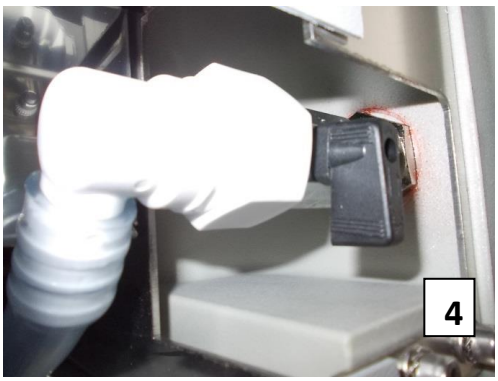
Before any operation, the defroster must be filled with demineralised water.

This operation must be carried out manually and the machine must be switched off. The procedure is as follows:

1. Move the defroster in order to have access to the underlying part where the water tap is located (Photo 1).
2. Open one of the doors on the deck.
3. Unscrew the two screws that secure the sleeve to the body of the device and gently extract it from its seat (Photo 2).

4. Remove the bag from its seat by gently squeezing the side edges towards the center (Photo 3).

5. Open the flap located on the left side of the machine (Photo 1) containing the drain hose.
6. 6. Open the tap located under the defroster (it is open longitudinal to the tube) (Photo 4).



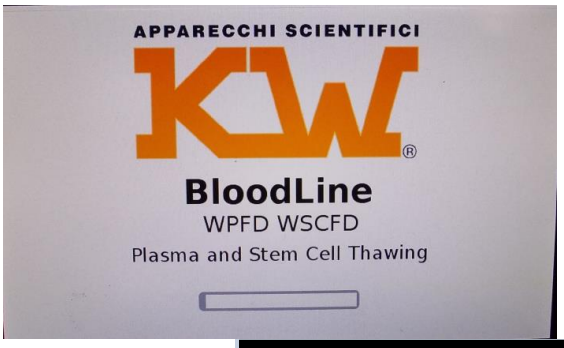
7. Pour water into the compartment of the extracted bag, until you see the water rising along the drain pipe and reaching an intermediate level between MIN and MAX.
8. Close the tap and the flap, reposition the bag in the tray and fix the sensor sleeve in reverse order to those described in the previous points.
9. Return the defroster to its original position.
10. Turn on the machine.
11. Use the same procedure in case of topping up the quantity of water: this eventuality is identified by a special sensor and is signaled by the device (see dedicated paragraph).

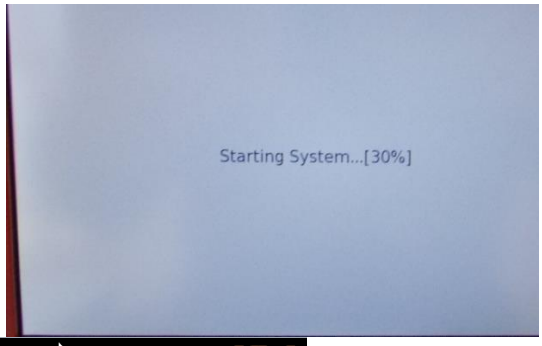
This operation must be done the first time with KW personnel at the time of testing, the same procedure will be used for cleaning the bag in case of breakage of the plasma bag.

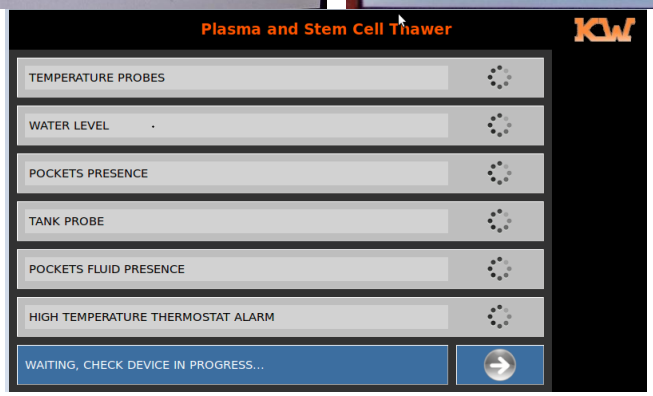
6. Instructions for use

6.1 Power on

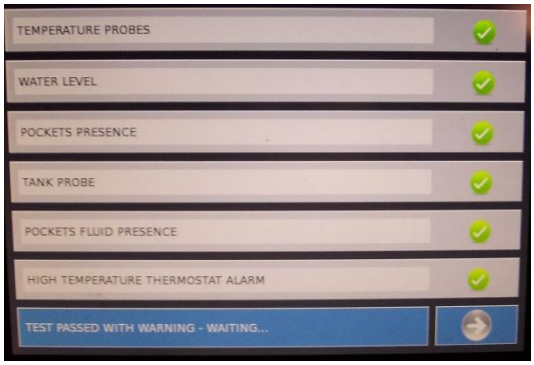
To turn on the defroster, use the green general rocker switch, located to the right of the machine body. It is advisable to always keep the device switched on in the user since, once it is switched off or in Stand-by, the necessary time must elapse to bring the tank temperature to the operating value and allow the start of a defrosting cycle.
When turned on, the display shows the following windows in sequence for the startup time of the operating system.

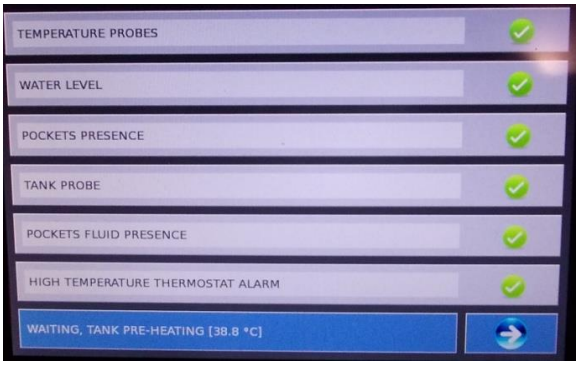






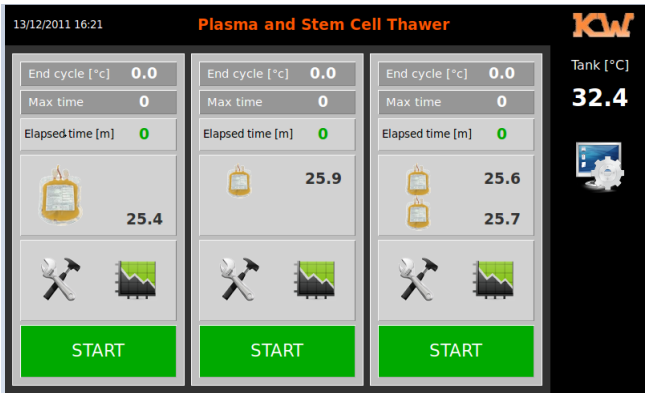
Immediately after switching on, the self-test phase is automatically started; once completed successfully (all green icons) the preheating period begins. Otherwise, turn off the defroster using the green switch previously used for ignition and remove the cause that generated the test failure.





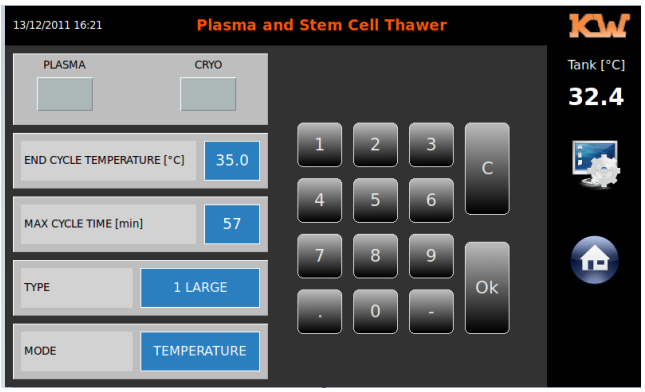
6.2 Preheating phase

During the preheating phase, the display will remain on the self-test screen, indicating, in the bar at the bottom of the screen, the gradually increasing temperature of the water inside the tank. However, it is possible to go to the main screen by pressing the arrow at the bottom right of the screen. In this phase, as long as the bath temperature reaches the default value (40.0 ° C or higher), no cycle should be started.



6.3 Setting the tank parameters

Before carrying out a cycle make sure that you have set the correct parameters for the cycle by pressing the symbol  : the following screen will appear.



Through it it is possible to set, by pressing on the blue field concerned and confirming with OK:

1. Surface temperature at the end of the defrosting cycle;
2. Maximum cycle time;
3. Type of bag to defrost (1 large, 1 small, 2 small);
4. End defrost mode by time or by temperature. Even in timed mode, the device will interrupt the defrosting cycle if the temperature set in the previous point is reached, before the set time has expired (this provided that the "Presence of probes" has been enabled in the Setup Menu (see corresponding paragraph).
5. The display of the temperatures relates to the two probes inside the relative tank. With two bags, the temperature at the top (image on the right) identifies the bag closest to the operator.

NB: When we activate the cycle of a single small bag, it must always be inserted in the part closest to the operator.

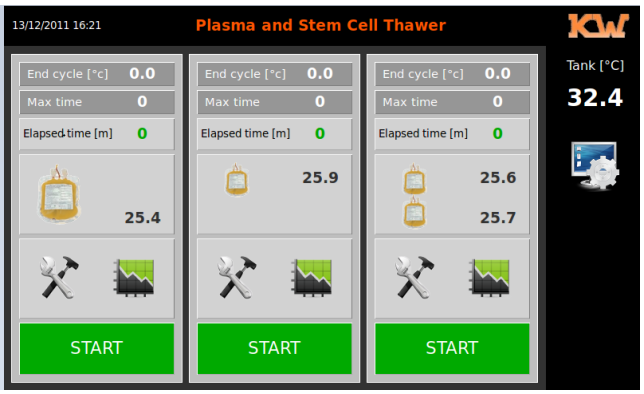
KW Recommend setting for one or two 260ml bags 37 ° C and max cycle time 25min with the Temperature mode, while with 600ml bag 37 ° C and max cycle time 35min (with bags frozen at -40 ° C).

Connect any Bar Code reader to the USB port on the side of the defroster.

6.4 Starting a cycle

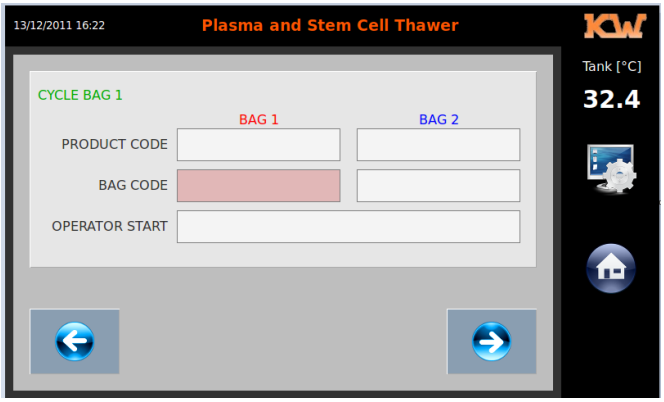
Upon reaching the set water temperature (default 40 ° C), a defrosting cycle can be started in one or more of the three available trays, using the key START.

The defrosting cycle can be started independently in all three trays, even at different times. The bath water is kept continuously at the set temperature and a tray is activated by starting the defrosting cycle relating to the compartment used, by pressing the **START** button after having carried out the previous set-up operations.



At this point, if the use of a barcode reader has been set in the WARMUP MENU (see dedicated paragraph), the screen as in the figure will appear, below where you can enter the various codes of the PLASMA bag.

- PRODUCT CODE: PRODUCT CODE (EX. PLASMA TYPE B FROZEN) (OPTIONAL)
- BAG CODE: BAG CODE 1 and 2 (depending on the choice) (OPTIONAL)
- OPERATOR START: OPERATOR CODE (IF PRESENT (OPTIONAL)



With the arrow at the bottom right you confirm the set data (or you start the cycle even without

having entered any code), while with the arrow at the bottom left you go back to the previous screen and the cycle is not started.

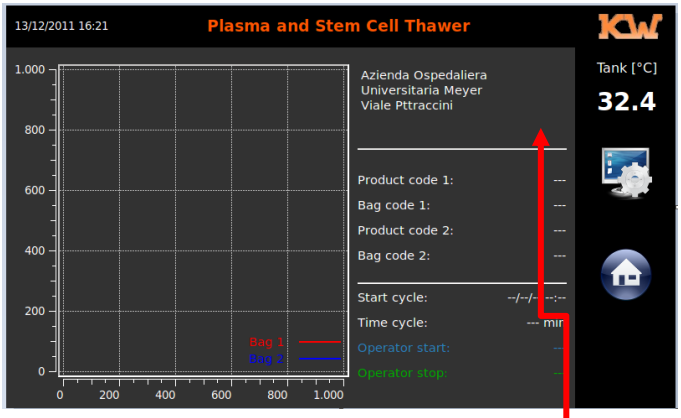
During the course of the cycle or cycles, the process variables are displayed for each zone:

- End of cycle temperature set by the operator before starting the cycle;
- Maximum cycle time;
- Duration of the cycle, in progress, with resolution in minutes from start;
- Type of bag and relative surface temperature; for a large bag two surface sensors are used.

The keys enabled are those for accessing the graphic display of the temperatures and the STOP cycle key.

6.5 Cycle monitoring

Using the key  on the main screen, it is possible to monitor the temperature trend of the bags in the individual tanks in real time through a screen like the one below.

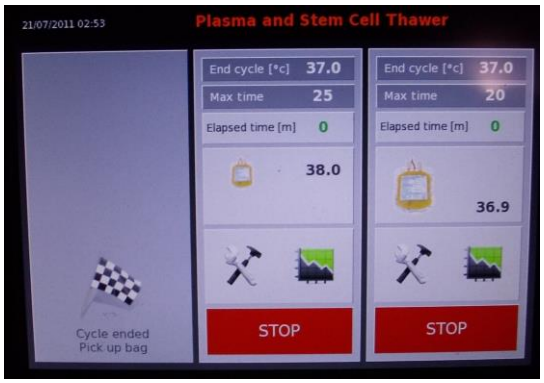


It is possible to enter personal data from the USER MENU from TEXT.

In addition, the defroster stores the functional cycle data on SD Card for consultation on a PC using the dedicated application.

6.6 Fine del ciclo

The regular end of the cycle will appear on the screen with the finished cycle  figure as shown in the photo.

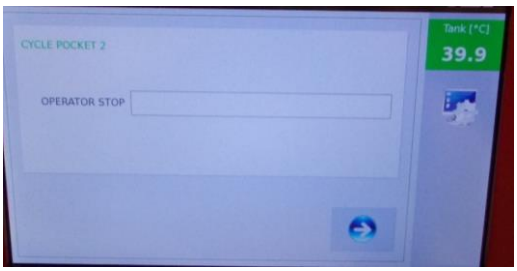


In the event that a cycle ends while the graph and other window are displayed, the display will automatically return to the Console Panel.

6.7 End of cycle operations

At the end of the cycle, the following manual operations must be performed:

- Press on the checkered flag (see previous figure);
- Entering the operator identification via BARCODE, if present, otherwise type on the right arrow;
- Opening the door;
- Removal of the bag from the bag.



7. User Menu

From any position, you can access the user menu by pressing the icon:

From the USER MENU you can access the following functions:

1) INFO STATUS
2) USB
3) LANGUAGE/TIME
4) SETUP
5) TEXT
6) PARAMETERS
7) WARMUP
8) PASSWORD

1. INFO STATUS

View all parts of the defroster in operation.

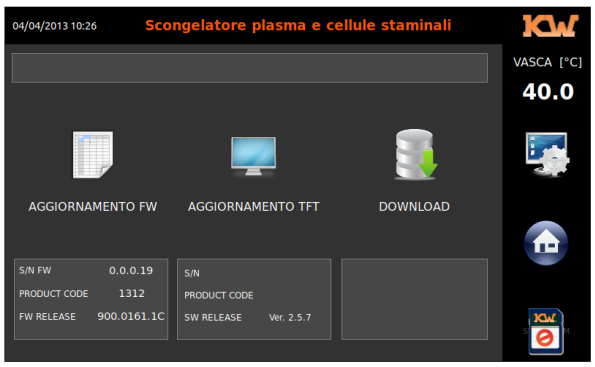
This option is very important because it has the function of checking and evaluating the status of all the equipment, allowing you to understand if and where there may be a possible malfunction of the device.

- The first eight items show the values of the probes (from S1 to S8) present in the freezer: the probes from S1 to S6 are the 2x3 probes present inside the 3 tanks for detecting the

temperature of the bags to be thawed, the last two (S8 and S9) are the two water temperature probes inside the machine body;

- The compartment door items indicate the status of the doors (if the door closing sensor is present and active);
- The **presence of the bag** and the **presence of liquid** indicate respectively if the probe holder sleeves are present (1 = presence is the correct value) and if there is liquid inside the bag (0 = no liquid is the correct value);
- **HW protection** indicates if there are any malfunctions in the electronic control board; therefore, it must always be 0;
- **H2O refill** goes to 1 when there is an alarm in progress of low water level in the machine and it is necessary to top up (see);
- **Thermal** indicates if the safety thermostat has tripped and therefore in normal conditions it is equal to 0;
- **Agitator** indicates if the water recirculation pump is running; therefore, it is normally at 1;
- **Heating** indicates whether the heating resistance is on or off and therefore can be either at 1 or at 0;
- **Mixer failure** indicates a malfunction related to the power supply and therefore must be equal to 0;
- **Low water level** is a second level of water level alarm: it indicates that the topping up was not done when the first alarm was signaled and now the level is too low: this generates an alarm and the machine is blocked ;
- **High temp. water** is normally equal to 0 and will go to 1 only in case of water temperature over the limit (and therefore thawing alarm in alarm);
- **Pumps** 1, 2 and 3 give the status of the pumps (0 = in stand by; 0 or 1 = during a defrosting cycle);
- **Alarm** S indicates if there is an alarm in progress linked to the probes, so they are normally all at 0;
- **Fault** S has the same logic as the previous one, linked to a possible malfunction of the probes;
- **Machine status** must be 3, any other value is an anomaly and KW assistance must be called.

2. USB



By pressing the USB icon you access the menu in the figure above, to allow three activities through the use of a pen-drive:

a) **UPGRADE FW**

Allows you to update the firmware via a USB key.

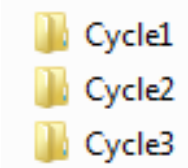
b) **UPGRADE TFT**

To update the user interface software.

N.B. The updates listed above must be carried out at the request of KW Apparecchi Scientifici srl and by staff.

c) **DATA DOWNLOAD**

To transfer the defrosting process recording files to a USB pen drive or SD CARD, for consultation on a PC using the dedicated software Thawing Tracer application (supplied by KW). Inside the used support we will find three folders, one per bag, with all the data relating to all the defrosting cycles carried out with that bag.

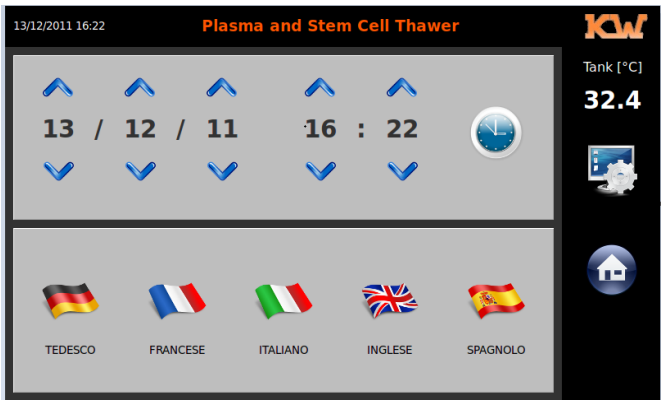


Inside there is a series of csv files that can be read either with the optional dedicated software "Thawing Tracer" or managed with any spreadsheet (as excel shown below).

1	Kw Apparecchi Scientifici				
2	---				
3	---				
4	---				
5		09/11/2011	14:59	37.7	36.5
6		09/11/2011	14:59	40	39.2
7		09/11/2011	14:59	40.4	39.7
8		09/11/2011	14:59	40.8	40.1
9		09/11/2011	15:00	39.8	39.3

For the “Thawing Tracer” software, refer to the dedicated manual if present.

3. DATE/TIME AND LANGUAGE SETTING



This panel is accessed by pressing the LANGUAGE / TIME icon in the main user menu, for setting the system date and time and for selecting the language of the entire user interface.

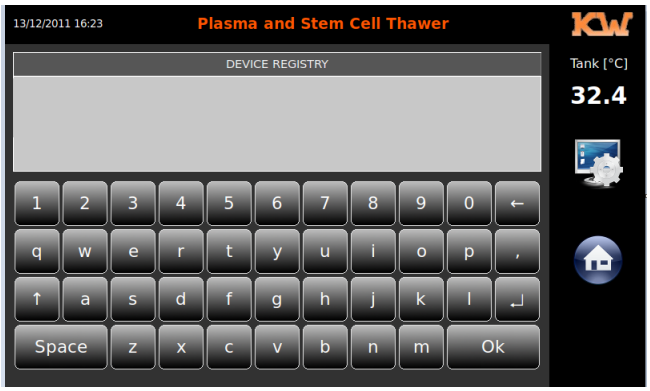
Each time the date/time is changed, a new folder is created where the daily process files are saved;

this allows to obtain folders with data that is always consistent in terms of time. The folder search function retrieves the requested day's backup from the most recent. However, it is advisable not to change the system date / time frequently as it could generate the double day condition if a new date is defined prior to the current one.

4. SETUP

1. Enable Password Control By activating each setting change, the password will be requested (1111);
2. Bag barcode length;
3. Operator barcode length;
4. Enabling doors;
5. Enabling the presence of liquid: by deselecting the cycle is allowed, even with the breakage of the bag;
6. Presence of probes: by deselecting the probes of the “sleeves” are no longer taken into consideration”.

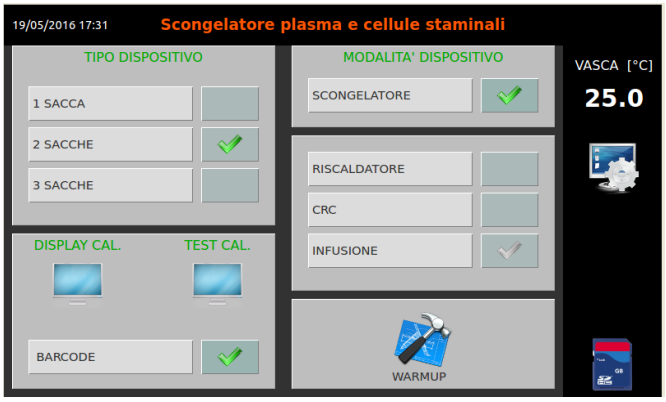
5. TEXT



It is accessed by pressing the TEXT icon.

It allows you to edit the registry of the defroster's residence site via keyboard and / or barcode.

6. WARMUP



Allows functionality for use in Single, Two or Three Bags, for Plasma or Stem Cells. It is possible to recalibrate the Display by pressing on **DISPLAY CAL** with further confirmation with **TEST CAL**.
We recommend performing the calibration after contacting KW Apparecchi Scientifici or enabling the Barcode function.
In the column on the right you can switch to different device operating modes: **Heater** *, **CRC** and **Infusion**.
<u>* modification to be carried out with KW Technician or with authorization from KW Apparecchi Scientifici, as functions are enabled that may make the defroster no longer suitable for the use for which it was purchased.</u>

7. PASSWORD

By pressing the PASSSWORD icon it is possible to change the panel password.

8. Alarms and faults

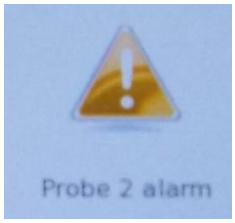
8.1 Cycle block due to failure

During operation of the defroster, the following are monitored:

1) The temperature sensors in their consistency and exceeding of limit values;
2) The responses of the probe 1 and 2 of the sleeve according to the temperature of the bag;
3) The responses of the sensors for the presence of plasma in the bag (rupture of the bag);
4) The perfect connection and communication of the tub sleeve with the control board.

In the event of a discrepancy event, the cycle relating to the tank in alarm or fault is blocked immediately and an acoustic warning is given and the red triangle appears on the display.

Point 1 Alarm

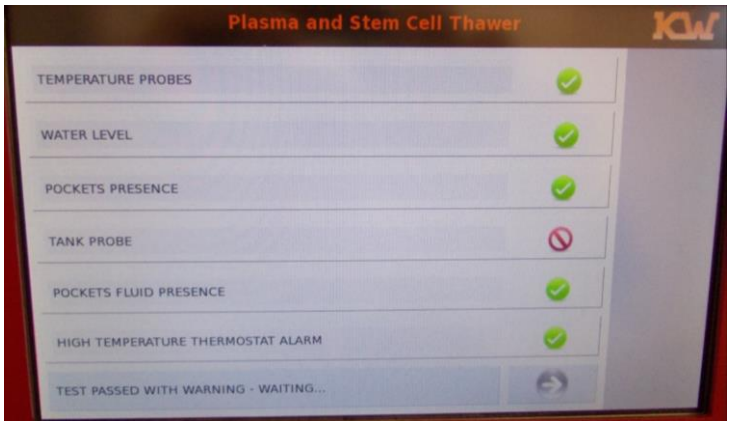


Point 2 Alarm

Point 3 Alarm

Point 4 Alarm

And consequently the tray empties, avoiding damage to the bag caused by the T of the water.



When the prohibition icon in red appears on any test, the defroster does not allow its functionality: it is therefore necessary to CALL KW ASSISTANCE by telephone 0577-309142 or 0577-309144 or through a COMMUNICATION VIA E-MAIL at the address assistance@kwkw.it

LIST OF FAULTS AND ALARMS

Faults detected

Sensors monitored with recording of the date / time of the event:

- Bathroom probes
- Probes A and B trays 1 - 2 - 3
- Insufficient water level with stopped cycles
- Bag and / or bags 1 - 2 - 3 leakage sensor intervention
- Recirculation pump failure detected due to the temperature differential of the bathroom probes
- Safety thermostat intervention

Alarms detected

- Temperature cycle finished for max
- High temperature bag surface sensors
- High bath temperature
- Minimum water level in operation
- Opening the door during the cycle
- End of cycle

FAULT CODES

COD. Description

35.0: Door 1 open
35.1: Door 2 open
35.2: Door 3 open
35.3: Presence of compartment 1 bag
35.4: Presence of compartment 2 bag
35.5: Presence of compartment bag 3
35.6: Low water level HW protection
36.0: Presence of liquid 1
36.1: Liquid presence 2
36.2: Liquid presence 3
36.3: Magnetothermic intervention
39.0: Probe 1 alarm - Compartment 1
39.1: Probe 2 alarm - Compartment 1
39.2: Probe 1 alarm - Compartment 2
39.3: Probe 2 alarm - Compartment 2
39.4: Probe 1 alarm - Compartment 3
39.5: Probe 2 alarm - Compartment 3
39.6: Tank 1 probe alarm
39.7: Tank 2 probe alarm
40.3: High temperature alarm
40.4: Absence of compartment 1 bag
40.5: No compartment bag 2
40.6: No compartment bag 3
41.0: Fault in probe 1 compartment 1
41.1: Compartment 1 probe 2 fault
41.2: Fault in probe 1 compartment 2
41.3: Compartment 2 probe 2 fault
41.4: Fault in probe 1 compartment 3
41.5: Compartment 3 probe 2 fault
41.6: Tank 1 probe failure
41.7: Tank 2 probe failure
42.0: Mixer failure
42.1: Low water level fault

9. Maintenaince

9.1 Top up water

Two special sensors inside the device signal the shortage of water in the tank; in this case it is necessary to top up:

- follow the procedure described in the ignition paragraph for disassembling a sleeve and the relative tank;
- add a quantity of demineralized water necessary to reach the level between MIN and MAX on the control tube, inside the door located to the left of the machine body;
- check that the water shortage message is no longer present..

9.2 Emptying/changin the water

In case of emptying the machine, proceed as follows:

1. Turn off the appliance using the switch located to the right of the machine body;
2. Move the appliance in such a way as to have access to the underlying part of the defroster itself where the tap is present [5];
3. If necessary, place the machine on a table or in any case in a slightly raised position with respect to the ground: a container or a water conveyance system must be placed under the loading / unloading door;
4. Open the door on the left of the machine body;
5. Position the inlet hose [1] downwards facing the water conveyance system and rotating it thanks to the swivel fitting [4];
6. Open the tap [5] (it is open in a horizontal position), the water will begin to flow outwards;
7. Continue until no more water comes out of the tube;
8. Close the tap, reposition the tube inside the compartment and close the door;
9. Return the defroster to its original position.

Note: A small amount of water will remain on the bottom of the tank as it cannot be emptied completely but the amount is not such as to be a problem. It is possible to dry this quantity with a common sponge for the home.

It is advisable to have an AUTHORIZED KW Technician to carry out the operations indicated above.

The complete water change can be done every 6 - 12 months depending on the use and any breakages of plasma bags, following the procedure described above for emptying the water and then the instructions described in the paragraph on filling. : before approaching this procedure, we recommend an analysis of the water inside the tank (molds, etc ..).

9.3 Washing of containment bags

The bags containing the plasma bags are fixed to the upper mouths of the filling trays. These bags can be removed from their location in order to be washed and disinfected in case of leakage from the plasma bag. Additionally, the bags are sturdy enough to withstand the cutting action of the

hard, sharp edges of the frozen bag.

9.4 Preset thermal bath temperatures

The bath temperature is defined through password access to the configuration parameters of the defroster, which can only be carried out by authorized personnel. This temperature will have a definition range from 30 ° C to 42 ° C and the factory value is set at + 40.0 ° C. Extending the temperature above 37 ° C means significantly reducing the thawing and heating times of the plasma bags.
The bath is kept at a constant temperature by means of a feedback control, which uses two PT100 type thermo sensors according to IEC 60751, precision class B. The first sensor is used to control the tank temperature, the second to control consistency (redundancy) which is managed at the software level.
The temperature tolerance is established at 0.1 ° C even if, after the insertion of frozen plasma bags, the tank temperature could undergo a temporary and natural decrease in the maintenance value.

10. List of parameters and wiring diagrams

10.1 Parameter setting

It is accessed by pressing the PARAMETERS icon with the Service password and allows the manual setting of each configuration parameter.

	Name	Description	Min	Max	Step	Def	Units
0	**ADR**	Address	1	1	1	1	NUM
1	**TBT**	Time between two water level tests	1	24	1	24	HOURS
2	**CPR**	Proportional correction of hot action	0	100	1	45	NUM
3	**CIN**	Full correction of hot action	0	100	1	0	NUM
4	**SPT**	Water temperature setpoint	0	50,0	0.1	40,0	DEGREES

5	**DTV**	Maximum temperature delta between the tank probes	0	10,0	0.1	2,0	DEGREES
6	**OF0**	PT100 probe offset channel CH0	-10,0	10,0	0.1	0	DEGREES
7	**OF1**	PT100 probe offset channel CH1	-10,0	10,0	0.1	0	DEGREES
8	**OF2**	PT100 probe offset channel CH2	-10,0	10,0	0.1	0	DEGREES
9	**OF3**	PT100 probe offset channel CH3	-10,0	10,0	0.1	0	DEGREES
10	**OF4**	PT100 probe offset channel CH4	-10,0	10,0	0.1	0	DEGREES
11	**OF5**	PT100 probe offset channel CH5	-10,0	10,0	0.1	0	DEGREES
12	**OF6**	PT100 probe offset channel CH6	-10,0	10,0	0.1	0	DEGREES
13	**OF7**	PT100 probe offset channel CH7	-10,0	10,0	0.1	0	DEGREES
14	**OF8**	PT100 probe offset channel CH8	-10,0	10,0	0.1	0	DEGREES
15	**AD1**	Compartment 1 high temperature alarm delay	0	60	1	10	SECONDS
16	**AD2**	Compartment 2 high temperature alarm delay	0	60	1	10	SECONDS
17	**AD3**	Compartment 3 high temperature alarm delay	0	60	1	10	SECONDS
18	**HT1**	Compartment 1 high temperature alarm limit	-10,0	50,0	0.1	37,0	DEGREES
19	**HT2**	Compartment 2 high temperature alarm limit	-10,0	50,0	0.1	37,0	DEGREES
20	**HT3**	Compartment 3 high temperature alarm limit	-10,0	50,0	0.1	37,0	DEGREES
21	**TM1**	Compartment 1 bags massage start temperature	-40,0	50,0	0.1	20,0	DEGREES
22	**TM2**	Compartment 2 bags massage start temperature	-40,0	50,0	0.1	20,0	DEGREES
23	**TM3**	Compartment 3 bags massage start temperature	-40,0	50,0	0.1	20,0	DEGREES
24	**PO1**	Bag massage on time (0 = disabled) compartment1	0	60	1	0	SECONDS
25	**PO2**	Bag massage on time (0 = disabled) compartment2	0	60	1	0	SECONDS
26	**PO3**	Bag massage on time (0 = compartment3 disabled	0	60	1	0	SECONDS
27	**MHT**	Maximum time for reaching the water set point	10	240	1	60	MIN
28	**WDT**	Maximum allowable decrease in water temperature	0	50	1	2	DEGREES
29	**WOD**	Maximum allowable increase in water temperature	0	50	1	2	DEGREES

11. KW C.A.T. authorized in Italy

The technical assistance of the devices present on the national territory is done through a maintenance service, either directly or with authorized service centers spread across all regions of Italy.

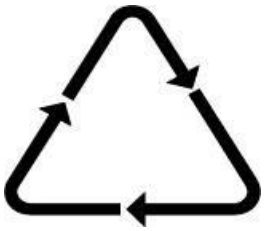
FOR ACTIVATION OF THE INTERVENTION FOR ADMINISTRATIVE AND TECHNICAL CENTER TO ACTIVATE THE SERVICE AREA MUST BE OTHERWISE A FAX TO REQUEST THE SEAT KW ASS. 0577-309142 OR COMMUNICATION VIA TEL. 0577-309144.

FOR EACH REPORTING ALWAYS INDICATE:

- YEAR OF CONSTRUCTION.
- MODEL.
- SERIAL NUMBER OF THE APPLIANCE.

12. Waste disposal and machine demolition

12.1 Refrigerated appliance

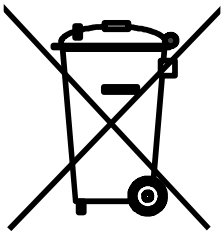


The appliance needs to be scrapped according to local regulations for waste disposal.
Make it useless by cutting the power cord, also remove the door. For the disposal of metal parts, plastics, electronic boards, lead batteries, compressor oil and freon, follow the local disposal regulations.

12.2 Electric and electronic waste disposal instruction

In accordance with the European Directive 2012/19/EC, this device when it is no longer used must be disposed of Refusal Electrical Appliance and Electronic Equipment (**WEEE**).

The abovementioned Directive and the laws that prohibit WEEE is disposed of as "household waste" because they must be disposed of as "**separate collection**" in accordance with the provisions of local collecting or delivering it to the dealer or distributor in the case of purchase of a new similar apparatus.



The symbol of the container out wheeled bin, shown here, and affixed to the equipment or its packaging states this prohibition.

By ensuring this product is disposed of correctly you will help:

- prevent potential negative consequences for the environment and health caused by the dispersion of the pollutants contained within the equipment;
- recycle part of the materials of which the appliance is made, reducing the use of natural resources and the amount of waste to be disposed of.

Failure to comply with such laws on the disposal is punishable by fine.
The manufacturer of this equipment, identified by the label affixed to each unit and is committed to the management of treatment and recovery of WEEE under Dl.gs 152/2005.

12.3 Packing

The packaging materials are recyclable and made from paper, cardboard, polystyrene and plastic. For disposal, observe local legislation. The packaging materials (plastic bags, polystyrene, etc.). Should be kept out of reach of children as a potential source of danger.

12.4 Dangerous material

There are no dangerous substances on this equipment, as required by current laws and in particular by the Rohs 2011/65 / EU directive.
The only attention should be paid if there are flammable gases inside the appliance such as ethane or propylene. Even if present in small quantities, avoid releasing these substances in the presence of open flames and without adequate ventilation of the room.

During disposal, plastic, ferrous and non-ferrous metal components, glass, lead and lithium batteries, electronic boards with their components, lamps, polyurethane foam and mineral oils will be treated.

WARNING

This appliance is not suitable for the storage of corrosive substances or whose vapors are corrosive.

13. CE Plate

14. Declaration of conformity CE Mark

CE 0051

THE MANUFACTURER: **KW APPARECCHI SCIENTIFICI S.R.L.**

Via della Resistenza 119 53035 Monteriggioni (SI) –ITALIA
Tel.0577/309144, Fax.0577/309143
e-mail: kw@kwkw.it, web: www.kwkw.it
Trademark: KW APPARECCHI SCIENTIFICI S.R.L.

DECLARES THAT:

The device: **Model: _____** **Serial numer _____**

CONFORM TO THE FOLLOWING DIRECTIVES:

- MEDICAL DEVICES	**93/42/CEE** modified by 2007/47/CE Class IIa, rule 2, annex V
- MACHINERY DIRECTIVE	**2006/42/CE**
- ELECTROMAGNETIC COMPATIBILITY	**2014/30/UE**
- LOW VOLTAGE DIRECTIVE	**2014/35/UE**

TECHNICAL STANDARDS APPLIED:

- EN 61010-1:2010/A1:2019
- EN 61326-1:2013

Name: Ing. Fabiani Stefano
Status: CEO & President

Monteriggioni, ……

15. Warranty rules

This appliance is guaranteed for the period of:

☐ **12** months ☐ **24** months ☐ **36** months ☐ other _____

from the date of the sales invoice. Within this period, the buyer has the right in the case of imperfect operation, the free replacement of parts due to effective material defect, provided that they are returned to KW defective parts, and it is detected the defect.
The warranty does not cover parts subject to normal wear such as gaskets, light bulbs, battery. Does not cover faults and/or malfunctions resulting from failure to periodically clean the condenser (where present), also does not cover cases of block machine, due to the intervention of the safety pressure switch with manual reset (KP5) (for refrigerated versions).
This warranty is void if the products are used in a manner inconsistent with the instructions given in the manual of the company or if they are modified, repaired or dismantled outside the workshop of the company or by people who did not authorize this in writing to the repairs. And especially in the case of incorrect operation on the controller general of temperature.
In this regard, KW disclaims any responsibility for their electrical faults they had a certain cause or probable in the alleged improper installation of the device, specifically in connection to the power supply of the laboratory.
This also applies in cases where the destination environment of the equipment is not fulfilled the safety rules.
The warranty is void in the event of failures and / or malfunctions attributable to the case where the local location is not guaranteed air exchange.

For KW Apparecchi Scientifici

User/customer signature

_____

Failure to comply with the information described in this publication will result in the immediate forfeiture of the granted guarantee and the assumption by the purchaser of all civil and criminal liability in the event of injury to property and/or persons.

16. Instructions for transport and packaging

The product is packed in KW Apparecchi Scientifici to guarantee its integrity during transport.

The packaging is customized for the various models while ensuring protection of the surfaces by means of cardboard and / or polystyrene coating, corners and a wrapping with stretch film of polyethylene and strap.
If the appliance is not equipped with wheels, it is placed on a pallet that facilitates its movement by means of mechanical aids (transpallet, forklift). If there are wheels, they are used for handling.
In no case are sockets and eyebolts provided because it is not allowed to move in a different way from the above.
The transport takes place with an authorized courier trained on loading, transport and unloading procedures, in particular on the need to always keep the appliance in a vertical position.

At the time of installation by the user, the device is moved in the manner described above, unpacked and positioned flat (level). The packaging materials are collected by the courier himself.

In the event that it is necessary to transport the instrument, the original packaging (or equivalent) must be requested from KW APPARECCHI SCIENTIFICI SRL. KW is not liable for any damage resulting from the transport of the instrument in unsuitable packaging.

KW APPARECCHI SCIENTIFICI