HEMOSAFE® 2.0

The only fully automated blood bank system for the remote management of blood bags

CE
2460

Hemosafe® 2.0 is part of ALS's professional range of automatic refrigerators designed to meet the strictest standards for the storage and management of blood bags.

With Hemosafe® 2.0 Software, reliability and continuous performance monitoring is guaranteed, <u>as well as being enabled for connection to whatever Blood Bank Management System (BBMS)</u>

Designated use:

It is used when there is the need to store and distribute packed red blood cells (erythrocytes) or plasma in compliance with the Directive 93/42/EEC – Medical Devices.

Applications:

Placed in the peripheral facilities of Transfusion Centers — Private Clinics — Remote Hospitals where blood is distributed and stored and then assigned remotely by the Blood Bank doctors.

It can also be placed at the Blood Bank itself in order to enable a fast loading of the collected red blood cells and a fast and efficient distribution to the peripheral centers.
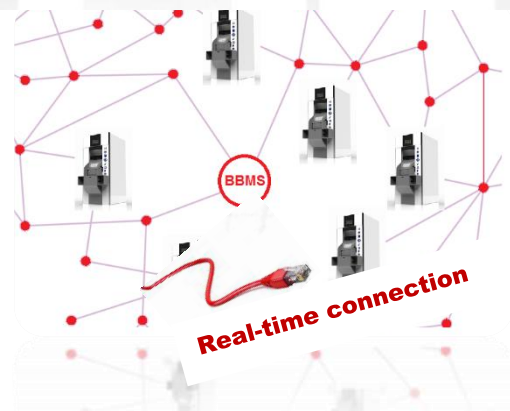
Hemosafe® 2.0 peculiarities

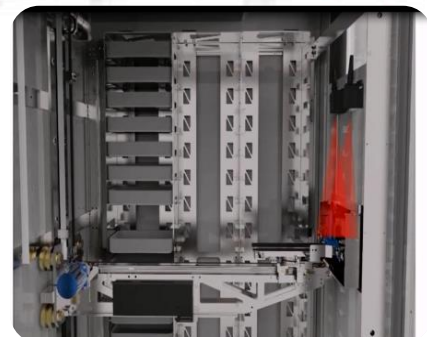### Automatic reading of bag codes

The reading of the bag codes during the loading and unloading phases takes place inside the device without any operator's intervention, thus avoiding possible human errors. Only the required bags can enter/exit from the device eliminating the possibility to load and unload wrongly one bag for another and ensuring the identification of the moving bags.

Safe storage area

The main door is always locked in conditions of normal use. For this reason, the storage compartment is inaccessible to the operators (except for the device breakdown and in any case by authorized personnel).

Real-time connection

Bar code reader inside the refrigerated compartment

Automatic drawer for loading and unloading

The loading and unloading of the bags take place through the mechanical drawer located on the front of the machine and controlled by the device.

Users can load and unload one blood bag at a time.

The automation system, together with the drawer, **minimizes the air inlet from the outside maintaining the best storage conditions of the blood bags stored inside** HEMOSAFE 2.0.

Drawer for loading and unloading

High storage capacity

Hemosafe® 2.0 consists of a refrigerated area at 4°C that houses an automated warehouse composed of 2 shelves with a capacity of 90 bags of 450 ml.

The two shelves and the plastic container

Blood spillage prevention system

The device is equipped with 90 plastic containers capable of containing blood bags and preventing possible blood spillages due to bags already damaged and accidentally introduced in the device.

Blood availability H24 7/7

Hemosafe® 2.0, located in operating rooms, emergency rooms or other strategic place for blood distribution, makes the withdrawal of the blood bags possible at any time and it is always controlled by BBMS.

Emergency 0NEG bags management

Hemosafe® 2.0 can be configured to stores ten (10) red plastic containers which can hold exclusively 0NEG bags. Hemosafe software manages this configuration helping customer finding this kind of bags in the fastest way. Moreover, in case of emergency, 0NEG bags can be manually retrieved in an easy way due to the red color of the plastic containers..

Access only to authorized personnel

The access to the device is allowed using username and password. All the operations executed by the user are logged in a log file that enables to establish at any time the right sequence of the activities carried out. The level and the number of users are free and configurable by the administrator, who can grant or deny the permissions to carry out each individual procedure to different users.

External bar code reader

The device has an external bar code enables an easy user authentication.

This reader can be used to carry out the triple security check when internal procedures require it.
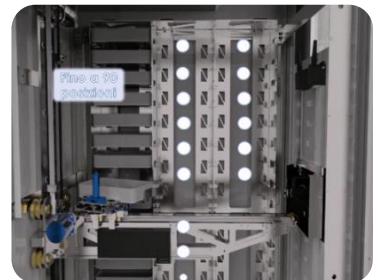

Label printer

Label printer

Hemosafe® 2.0 has an integrated printer to print assignment labels at the end of the withdrawal phase (unloading).

Construction features

Hemosafe® 2.0 is managed by an information system that includes:

1) **10-inch color LCD panel** enabling the user to interact with the device

2) **management software** enabling users to carry out the loading and unloading of the blood bags and the interface of the device with the BBMS (Blood Bank Management System)

3) **latest generation controller (ACP7)** allowing users to set/monitor the functional parameters of the device (Regulation – Alarm)

1. User interface

Users interact with Hemosafe® 2.0 through **10-inch color LCD *Touch-screen* panel**. The easy and functional interface shows to users only the allowed commands by preventing them, in fact, from taking those decisions already remotely set by BBMS.

2. Management software

The management software installed on Hemosafe® 2.0 integrates the functions for control of the storage automation with the management and identification functions relating to the blood bags stored in the unit.

It enables a rapid storage of the bags' identification data and a consequent and easy operation of loading/unloading of them.

In accordance with the main international standards (AABB, ISBT) all this guarantees:

- ✓ TRACEABILITY of the operations carried out on board machine by authenticated users
- ✓ SAFE and RAPID management of blood bags
- ✓ OPTIMIZATION of blood stocks (method first in / first out)
- ✓ REDUCTION OF OPERATING COSTS (ROL)
- ✓ REMOTE MANAGEMENT and INTEGRATION of the device with the reference BBMS*

*In this case, each procedure is based on the medical and scientific data in the BBMS in a completely transparent way for the user by guaranteeing safety and protection of sensitive data. If the integration with the reference BBMS doesn't exist already, it will be built following a technical meeting between the parties (ALS and Customer) on the basis of the specifications of Hemosafe® 2.0 and BBMS. *(Except quotation)*

Moreover, the software is integrated by:

- ❖ Direct connection to a printer for the immediate printing of the activity reports (printer optional)
- ❖ UPS to ensure the operations of loading/unloading even in case of a lack of primary power supply
- ❖ Ethernet port for the connection to MMBS

3. **_ACP7 controller: consumption optimization and continuous monitoring_**

It guarantees high performances, maximum safety and ease of use through:

- Internal **micro SD card** (not removable) allowing the recording of operating data every 30 seconds for up to 10 years
- Frontal **integrated USB**
- **7-inch touch-screen display** with simplified or graphical interface
- Intuitive **icon surfing**
- **Warning** for alarms and breakdowns

The **SMART DIAGNOSTIC function** ensures constant monitoring of the wear of the main components. When the preset maximum wear threshold has been reached, an alarm will prompt the replacement of the component reducing the risk of machine downtime.

The ULT freezer is equipped with **_BACK-UP BATTERY_** that provides periodic tests on the state of charge. _In case of a power failure, the battery has a 36-hour operating time._
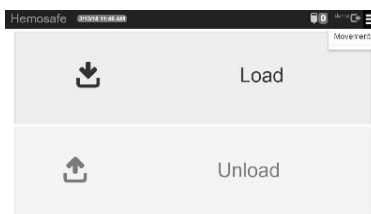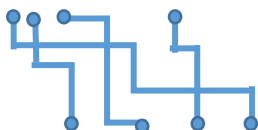
...connection

Thanks to the close connection between the **ACP7 controller** and the **management software,** the latter gathers, records and stores locally all the information related to the intrinsic functioning of the device and to the activities carried out by users.

All this information can be made available through the latest technologies directly to the person responsible for the device identified in the customer's facility through

The identification of an address on the local network where telemetry and traceability data can be sent

Examples of information that can be sent by the device:
- Current temperature of the refrigerated compartment (at predefined intervals)
- Event messages related to bag loading and unloading operations
- Event messages for alarms of the cooling system
- Event messages for automation-related alarms
- Event messages for device malfunction or problems of power supply

Each event message can also be sent by email to a configurable address list (after verification of the configuration in the customer's network)

Technical specifications

Brand		**Angelantoni Life Science**
Model		**HEMOSAFE® 2.0**
Commercial Code		**14214**
CND code		**Z121701**
RDM code		**1769889/R**
External dimension	Mm	**810(L) x 1215(P) x 2077(H)**
Bag capacity	N°	**90 (450 ml)**
Weight	Kg	**350**
Range of temperature	°C	**+2 / +10**
Working temperature	°C	**+4**
Temperature uniformity	°C	**± 2***
Supply voltage	V / Hz	**230 V – 50 Hz**
Noise level	dB(A)	**< 45**
Energy consumption	KWh	**0,45****
Refrigerant Gas		**R290**
Plug		**Schuko**
Conditions of use		
Temperature	°C	**10 ~ 38**
Relative humidity	%	**20 ~ 60**
Dimensions with packaging	Mm	**1200(W) x 1600 (D) x 2077 (H)**
Weight with packaging	Kg	**600**

*Guaranteed with setpoint of 4°C and at an ambient temperature of 20°C.
**Measured at an ambient temperature of 32°C and fully loaded machine.

Codes and available configurations

Code	Description
14214	* HEMOSAFE 2.0 (230V/50 HZ)
	Mandatory Configuration options (one exclude the other)
14412	Base configuration: 90 black boxes
14413	Configuration 0Neg: 80 black boxes + 10 red boxes
	HEMOSAFE accessories
14414	7 days temperature chart recorder
12279	Kit for chart recorder (100 discs and 2 pens)

* Is included: Hemosafe 2.0 software license, label printer mod. Zebra complete with paper sheet model ETI.-ULTIMATE 3000T WHITE 25MM and one roll of RIBBON 84x74 Resin 5095

Certifications

- CE marking as Medical Device in accordance with the Directive n.93/42 and subsequent variation
- Machinery Directive **2006/42/EC**
- Low Voltage Directive **2014/35/EU**
- Electromagnetic Compatibility Directive **2014/30/EU**
- **2011/65/UE** ROHSS II
- **EN 60601-1:2006 excluded 8.7**
- **EN 61010-1:2009 for leakage current 6.3**
- **EN 60601-1-2:2015**
- **EN 60601-1-8:2006/AC:2010**
- **EN 62304:2006**
- **EN 62366-1:2008**

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