

Automated blood bank refrigerator
Hemosafe® 2.0



OUR DEDICATION

in the world of transfusion services

ANGELANTONI LIFE SCIENCE has developed the only completely automated blood bank refrigerator for remote management of blood bags.

Hemosafe® 2.0 belongs to the professional line of automatic refrigerators by Angelantoni Life Science. It is designed to meet the most stringent standards for blood storage and management.

The Hemosafe® 2.0 software controls and manages the blood bank safely and reliably by interfacing and connecting in real time to the external management system (BBMS) of any Transfusion Medicine Service.

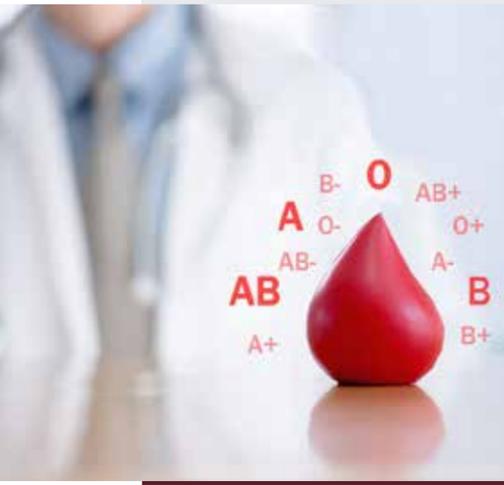
It is ideally suited for all situations where concentrated red blood cells (erythrocytes) and plasma need to be stored in compliance with Directive 93/42/EEC - Medical Devices. Located in the peripheral facilities of the S.I.M.T. (Immunohaematology and Transfusion Medicine Service), private clinics, peripheral hospitals, operating theatres and emergency rooms, where blood is distributed and stored then allocated remotely by S.I.M.T. doctors.

It may also be located at the S.I.M.T. itself for quickly loading the RBC collected and for quick and convenient distribution to the peripheral centers.

The equipment is certified according to the Medical Device Directive 93/42/EEC, evidencing the company's great commitment to high quality and reliability.



Notified body No. :
0051



THE BLOOD PRODUCT SUPPLY CHAIN

Let's get to know the entire supply chain of the **BLOOD** product.

SCENARIO:

A transfusion center generally supplies blood bags to several departments or to several peripheral hospitals, which do not always have specialised personnel available.

REQUEST:

Following a request by the peripheral hospital, the blood bank selects the blood units required for a specific patient. The various units are allocated, labelled and prepared at the blood bank.

TRANSPORTATION:

The blood units are transferred from the blood bank to the peripheral hospital and subsequently placed in a blood refrigerator.

SELECTION AND MANUAL UNLOADING OF THE BAG:

The bags are manually unloaded from the blood refrigerator and transfused.

UNUSED BAGS:

Sometimes, the allocated bags are only partly transfused, therefore the remaining ones are sent back to the blood bank for their integrity to be analysed so that they can be released and made available again for future requests.



Selection of the blood bags from the blood bank



Blood transportation



Manual unloading



Transfusion



QUALITY SPECIFICATIONS

The user interacts with **Hemosafe® 2.0** via a colour LCD touch-screen panel. The simple and functional interface only shows the user the permitted controls, effectively preventing the user from making those decisions that have already been set remotely by the BBMS (Blood Bank Management System).

- The software supplied with **Hemosafe® 2.0** integrates the functions related to storage automation control with
- those related to the management and identification of the stored bags.
- The software enables **quick filing** of bag identification data and consequently simple loading/unloading
- of bags.

••••• **ALL THAT ENSURES:**

- ▶ **TRACEABILITY** of operations carried out on the machine by authenticated users;
- ▶ **SAFE** and **FAST** blood bag management;
- ▶ **STREAMLINING** blood stocks;
- ▶ **REDUCTION** of operating costs;
- ▶ **REMOTE MANAGEMENT** and **INTEGRATION** of the device with the reference BBMS.

••••• **THE SOFTWARE IS ALSO INTEGRATED WITH:**

- ▶ **Direct connection** to a printer provided by the customer for immediately printing out the activity reports;
- ▶ **UPS** to assure the loading/unloading procedures even in the event of primary power failure;
- ▶ **Ethernet** output for BBMS connection.

••••• **ELECTRONIC CONTROLLER:**

The state-of-the-art **Temperature controller** (ACP7) ensures high performance, utmost safety and ease of use thanks to:

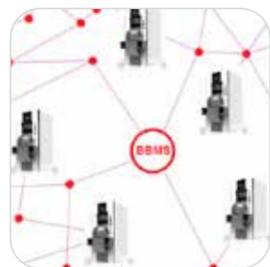
- ▶ **Internal MicroSD** (non removable) that records the functional data every 30 seconds for 10 years;
- ▶ Integrated **USB** at the front;
- ▶ **7"** touch screen with simplified view;
- ▶ User friendly navigation by icons;
- ▶ Alarms and fault warnings;
- ▶ Smart Diagnostic feature;
- ▶ Back-up battery with 36-hour autonomy.



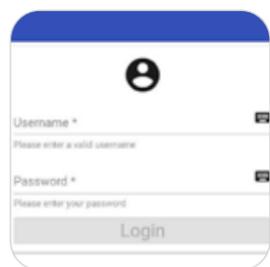
Front view of Hemosafe® 2.0

OPERATING SCENARIO

How does the blood supply change with Hemosafe® 2.0?
In order to fully understand the economic and safety advantages offered by Hemosafe®, let's analyse the processes that take place within the blood supply chain.



Real-time connection



User authentication display

- A **Hemosafe® 2.0** is installed at every peripheral center and department managed by the transfusion center, connected in real time with its management software.
- The transfusion center periodically ships to the peripheral hospital a stock of available blood units. For the time being, the blood units contained in Hemosafe® 2.0 are not allocated to any patient.
- The peripheral hospital requests blood bags to be unloaded for a given patient, consequently the transfusion center checks availability of the bags for allocation. After that, the unloading authorisation is sent to the peripheral center.
- **UNLOADING BAGS FROM HEMOSAFE® 2.0:**
- Access to the device is allowed by **Username/Password**.
- All operations carried out by the user are recorded in a **LOG** file, which allows the exact sequence of activities carried out and sent to the BBMS to be determined at any time.
- The number of users authorised to use the machine is free and can be set up by the administrator.



According to user privileges, it will be possible to unload the blood bags by entering the operation in the display, the drawer opens automatically and the bag codes are read. Once identified, the bag is unloaded and the **Hemosafe® 2.0** database is updated, consequently the information is sent to the BBMS. When the action is completed the management software is updated as well.

..... **BLOOD BAG STORAGE AND HANDLING:**

The bags are stored in the **internal compartment** until a request is received.

The **mechanical arm** moves the drawer, after which the identification codes are read automatically.

After reading the request-code, **Hemosafe® 2.0** shows a list obtained from the management software. The bag codes are read automatically also during unloading, obviously.

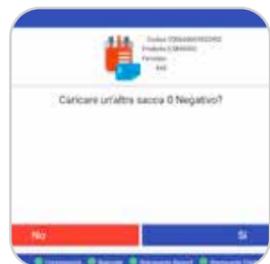
Upon unloading, the allocation label is printed out, which is used to perform the **triple check** procedure. After unloading has been carried out correctly, the delivery **report** is printed out, containing all the information deemed significant by the transfusion center.

..... **SAFETY AND RELIABILITY:**

The entire process is constantly monitored by the **Management Software**, which authorises any action.

SETUP FOR ONeg MANAGEMENT

Management of extremely urgent transfusion requests, with a designated system bypassing the unit allocation procedure.



0 Negative loading action



0 Negative unloading action

Hemosafe® 2.0 can also be set up to manage **ONeg bags**, as well as to manage the delivery of units allocated with extra urgent procedure by the **SIMT**.

In this case the system operates according to the "standard" mode and also makes it possible to collect 0 negative units in the event of an emergency without prior unit allocation.

IN THIS EVENT, THE SYSTEM:

- ▶ Operates according to a specific procedure shared with the SIMT;
- ▶ Unloading can only be carried out by an authorised operator;
- ▶ It is not possible to collect a number of units exceeding a preset limit, according to the setup.

All this information can be made available with the most up-to-date technologies directly to the person in charge of the equipment identified in the customer's facility, by identifying an address on the local network where telemetry and traceability data are sent.

THE LATEST GENERATION OF CONTROLLER

Taking the lead thanks to its reliability, performance and user-friendliness and developed after years of experience and leveraging the latest technologies, it ensures high performance and the utmost safety.



The **controller** comes with a **simple and functional** operator interface that allows you to monitor the function and adjust the settings.

Access to the parameters is password-protected with **3 privilege levels**: user, service and administrator. The increasingly sophisticated **display** is easy to use with intuitive **icon-based navigation**, a **touch screen**, and **multilingual instructions**.

It is of a convenient size (7") for easily and immediately viewing the menu and identifying the colour-coded alarms.

The controller has **3 separate microprocessors** that communicate with each other via the **CAN-BUS** connection system, known for its high reliability and immunity to electrical noise.

ENVIRONMENTALLY FRIENDLY:

The cooling system uses **natural refrigerants** (HC) with extremely low GWP (Global Warming Potential) offering high energy efficiency and protecting the environment.



HEMOSAFE® 2.0: STRENGTHS

THE RIGHT BAG, AT THE RIGHT TIME, TO THE RIGHT PATIENT

- | | |
|--|--|
| ▶ Fully automated system | ▶ Waste reduction |
| ▶ Automatic reading of bag codes on loading and unloading, therefore the possible human error, reading a bag and loading another, is reduced to zero | ▶ Reduction of transport costs for the transfusion center |
| ▶ ONeg bag management with designated area within the storage compartment | ▶ Real time connection with the SIMT management system |
| ▶ Single access point for loading and unloading the bags. It is not necessary to open the main door, thereby ensuring excellent thermal consistency | ▶ Full traceability of operations performed on the machine |
| | ▶ Remote bag allocation (Electronic Cross-match) |



Touch screen display

RETURN OF UNUSED UNITS

If the collected unit is not transfused, it can be loaded into Hemosafe® 2.0 again. The bag reloaded into Hemosafe® 2.0 goes into quarantine status and it cannot be unloaded for any patient. Only the intervention of authorised SIMT personnel can release the quarantine status and make the bag available again for another patient.

SAFETY FEATURES

In the event of system failure, the blood bags can be picked manually by opening the main door of the machine, the keys of which are held by the person in charge.

HEMOSAFE® 2.0		
Sales code	14214	
CND Code	Z121701	
RMD Code	1769889/R	
Outer dimensions	mm	810 (W) x 1215 (D) x 2077 (H)
Bag capacity	N.	90 (450 ml)
Weight	Kg	350
Temperature range	°C	+2 / +10
Operating temperature	°C	+4
Temperature consistency	°C	±2*
Voltage	V / Hz	230 V - 50 Hz
Noise level	dB(A)	< 45
Energy consumption	Kwh	0,45**
Refrigerant gas	R 290	
Plug	Schuko	

Conditions of use		
Temperature	°C	10 - 36
Relative humidity	%	20 - 60
Dimensions with packaging	mm	1200 (W) x 1600 (D) x 2077 (H)
Weight with packaging	Kg	600

Code	Description
14214	Hemosafe® 2.0 (230 V/50 HZ) ***
Mandatory configuration options (one excludes the other)	
14412	Basic bag configuration (90 black boxes)
14413	ONeg bag container configuration (80 black boxes + 10 red boxes)
Accessories for Hemosafe® 2.0	
14414	Weekly chart temperature recorder
12279	Chart recorder kit (100 diagrams and 2 pens)

* Guaranteed with set point at +4°C and room temperature of 20°C.
 ** Measured at 20°C room temperature considering 40 robotic actuations.
 *** Machine supply includes:
 Software licence of Hemosafe® 2.0 - label printer mod. Zebra supplied with paper model ETI.-ULTIMATE 3000T WHITE 25MM - one roll of RIBBON 84x74 Resin 5095.



Internal compartment for bag storage



AS

AG

STERIL

AIC

Angelantoni Life Science (ALS) is a world leader in the supply of refrigeration equipment and in the design of technological solutions in the biomedical sector, constantly engaged in innovation and safety, both biological and environmental.

AS brand provides for a wide range of refrigerators cabinets, ultra-low temperature freezers, blood banks refrigerators, freezers to preserve blood components, mortuary prefabricated rooms, stability tests and plant growth chambers, refrigerators and freezers for COVID-19 vaccines.

AG brand supplies standardized brine chilling units for pharmaceutical and chemical applications or pharma process, manual or automated solutions allow to reach -70°C for special walk-in chambers and shelters to storage vaccines or other farmaceutical products.

STERIL brand provides for equipment able to meet any product protection need, as well as the product, operator and environment safety requirements, for any level of concentration and for any kind of substance (horizontal and vertical laminar flow cabinets, biohazard and cytostatic safety cabinets, laminar flow pass boxes with UV, sanitized hydrogen peroxide pass boxes, weighing, sampling and dispensing cabinets and isolators designed in accordance with the latest international standards (GMP).

AIC brand provides Waster, and an automated treatment system for hospital and contaminated waste.



Angelantoni Plants



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