LEAD THE WAY IN BLOOD SAFETY

THERAFLEX MB-Plasma
For more than 30 years, Macopharma has had the highest concern regarding BLOOD, which is the most precious component in the world.
The vocation of Macopharma is to always provide you with new products and new technologies improving blood processing from collection to transfusion.
Controlling the whole transfusion chain is part of Macopharma’s know-how; an expertise that has increased and expanded along the years, developing good practices and allowing a better care for patients.
That spirit has been translated by Macopharma into 3 words: the 100% project.
Macopharma’s aim today is to be able to provide to its greatest number of customers, efficient and relevant tools for each step of the transfusion chain.
This is the goal which Macopharma is willing to reach together with all the stakeholders in transfusion, with the greatest commitment aiming to improve, adapt and enhance more and more altogether the process of the whole transfusion chain.
It is a daily basis commitment in order to achieve a real goal: every collected and treated drop of blood should be transfused.
Today, Macopharma is implementing new tools and new processes within the blood safety range of products: the THERAFLEX Processing Platform, including RFID technology, which is an important step in securing and optimising blood safety processes.
Traceability, an ultimate concern

Traceability is an ultimate concern for all products related to human healthcare. Food and medical industries are the most involved sectors in traceability and safety of the different processes and nowadays, safety is the major interest with regards to globalisation.

RFID, an approved technology

RFID is part of the technologies which is already known by all of you without being really conscious of what it could be. RFID allows the identification of an object or a product by radio waves principle. This identified object or product will be afterwards recognized by a protocol which is shared at an international level. The product is identified by a chip or a tag; it is read by an RFID reader.

Already integrated into the passports, used for the identification and the traceability of animals, employed in the financial field or in the industrial production, RFID is an approved and reliable technology which is already present for years in all production, logistics and exchanges processes.

RFID, either recommended or required, is a must in the medical field

Many recommendations and requirements from international organisations aim to provide you with a reliable traceability system known by all. The acceptance of such traceability systems is globally ensured but its implementation is still not totally employed in the medical field. As a result from its research, Macopharma provides you with a full traceability system for blood products and especially related to the therapeutic and inactivated plasma from its collection until its transfusion.

RFID, in the core of traceability

It is important to know that a product could not be used when it is defective, but it is even more important to be able to monitor the life cycle of a product from its creation until its delivery and therefore to be able to know better at which step of the process the defect occurs.
By using the THERAFLEX Processing Platform from Macopharma, we can improve together the traceability of blood safety processes, and especially the process related to Plasma Pathogen Reduction technology: the THERAFLEX MB-Plasma.

Together with you, customers, this project will begin and will guide us to implement a complete solution which fits perfectly to your needs. Now comes the time to work hand in hand in order to constantly enhance the liability and the quality of transfusion processes, to finally improve the daily work for staff in blood banks, in hospitals and most importantly to increase transfusion safety for the final patient.

Macopharma can provide you with RFID chips already integrated to the labels:
- The RFID chip is always fixed on the storage bag
- The RFID chip is not in contact with the plasma
- The RFID chip contains at least donation data and product information
- Macopharma RFID chip complies with ISO 15693 and with ISBT 128 standards:
  - 2k-Bytes Memory
  - Passive RFID (no battery)
  - Flexible construction
  - Steam sterilised together with the plasma inactivation bag system
- The THERAFLEX MB-Plasma kits including RFID have been validated to resist to very low temperatures (up to -80°C) and to thawing processes.

Finally, the RFID chip contains donation data and process related information (illumination data etc.). The use of RFID will further strengthen the safety of the process (avoiding possible manual errors) and reinforce traceability level.

The heart of the THERAFLEX Platform is the MacoTrace. It is a user-friendly Data Management System (DMS) connected to the illumination devices (MacoTronic B2 for plasma inactivation) and optionally to the Blood Bank Information System (BBIS), and designed:
- to provide full traceability of inactivation procedures
- to secure the critical steps of the product workflow avoiding possible human errors
- and to increase cost-effectiveness of the inactivation processes

By using the THERAFLEX Processing Platform from Macopharma, we can improve together the traceability of blood safety processes, and especially the process related to Plasma Pathogen Reduction technology: the THERAFLEX MB-Plasma.
An open design technology

The MacoTronic B2 can operate with standard barcodes and/or with RFID (due to internal RFID readers). It could also be designed to be compatible with 2D barcodes (Datamatrix).

The MacoTronic B2 are RFID-ready and can be upgraded. Alternatively, the machines can be ordered with RFID readers already integrated. However, the implementation of RFID on B2 machines in routine use will require an upgrade of both hardware and software.

New features suiting with your working environment

The MacoTronic B2 is a small device (54kg) with the following dimensions 47 x 68 x 44 cm (width x depth x height). It could be installed in a small room (no need to have big spaces) and it integrates a cooling system. MacoTronic B2 can treat 2 plasma bags simultaneously per cycle.

It is a user-friendly machine operated by a touch screen. It integrates dedicated software with internal settings and an internal memory (to store illumination files). Data can be exported via 4 USB ports.

The MacoTronic B2 can exchange data with your BBIS (Blood Bank Information System) via the MacoTrace = the heart of the THERAFLEX Processing Platform.

Flexibility

MacoTronic B2 is a class IIb medical device using visible light (Light-Emitting Diode or LED). It is a flexible technology that could be used with or without RFID. It is a small, user-friendly and fast machine that has been especially designed to improve the efficiency of the process; it offers as well a high safety profile.
The MacoTrace, a flexible tool
- The MacoTrace software is available in several languages with multilevel users’ access.
- It could be optionally connected to the BBIS (import/export process-related data) and it complies with all laboratory organisations.
- Thanks to a bidirectional communication between the MacoTronic B2 and the MacoTrace, the risk of mixing bags and illuminating the wrong plasma bag is minimized. The MacoTronic B2 exchanges regularly with the MacoTrace about the bags to be treated (“Can I?”), does the treatment (when the MacoTrace gives the authorisation), and transfers to the MacoTrace all the information related to the illumination data.
- It can read/write data through RFID or barcode.

Designed to secure the product workflow
By using the MacoTrace, safety of processes is increased by eliminating the risk of treating the wrong bag, by preventing a second treatment and by generating alerts based on user-defined criteria.

Compatible with different identification systems
Today the MacoTrace is barcode and RFID compatible. If necessary, it will become compatible with other identification systems such as Datamatrix etc. and this will require an update of the software.

Designed to provide full traceability
The MacoTrace, if connected to the BBIS, can import the list of the products to be processed, can centralise illumination data, generate reports and export critical data to the BBIS.
The clinical indications for THERAFLEX MB-Plasma are in most cases the same as for standard FFP. Plasma quality is maintained after treatment:

- No influence on complement system, inhibitors of coagulation, fibrinolysis markers or ADAMTS13.
- Coagulation factors and activation are only moderately affected (Fibrinogen, Factor V, VIII, XI) and remain within the specifications set by the Council of Europe Guidelines.
- Moderate enhanced thrombin time and aPTT.
- Very little effect on the strength of clot formation as assessed by thrombelastometry (Cardigan et al., Transfusion 2009).

The product workflow is secured thanks to a bidirectional communication between the MacoTronic B2 and the MacoTrace:

- The risk of treating the wrong bag is eliminated by cross-checking with the to-do list of the MacoTrace.
- The MacoTrace prevents second treatment of processed products: bags cannot be illuminated twice.
- Validations or alerts based on user-defined criteria are automatically generated.

The THERAFLEX processing platform could be directly connected to the BBIS or the LIS: Importing to-do lists from the BBIS (products to be processed).

- Thanks to the MacoTrace GMP workflow is controlled according to SOP.
- The THERAFLEX processing platform centralizes the illumination data from a park of machines.
- Illumination and customizable activity reports could also be generated through the THERAFLEX Platform.
- Critical data about processed products could also be exported to the BBIS or the LIS thanks to this THERAFLEX Processing Platform.
The THERAFLEX MB-Plasma used with RFID technology allows Macopharma to enter into a new age by improving traceability and safety of the whole inactivation chain which represents a major and crucial step.

The aim of the 100% project is to share with our faithful customers’ new technologies such as RFID used together with the MacoTrace Datamanager within the THERAFLEX processing platform. This project will guide you through implementing a complete solution which fits perfectly to your needs. This solution starts with the improvement of the daily work of staff in blood bank and ends at the hospital with improving transfusion safety practices.

Jointly with you and thanks to your personal feedback regarding the THERAFLEX Processing Platform with RFID, we will be able to improve this platform and therefore to build together custom-made solutions.

The THERAFLEX MB-Plasma is a user-friendly technology designed for the treatment of single units of plasma collected from whole blood or aphaeresis. This pathogen reduction technology developed and commercialised by Macopharma incorporates a dockable dry set and the latest generation of illumination machine, the MacoTronic B2.

The MacoTronic B2 is a small, user-friendly and fast illumination machine that has been especially designed to improve the efficiency of the THERAFLEX MB-Plasma process; it offers as well a high safety profile especially when it operates with RFID (due to internal RFID readers).

RFID is an approved and reliable technology which has already been present for years in all production, logistics and exchanges processes. Today Macopharma is able to provide you with RFID chips already integrated to the labels of MB kits and with MacoTronic B2 machines already equipped with RFID readers. The RFID chip contains donation data and process related information (illumination data etc.); the use of RFID will further strengthen the safety of the process and reinforce traceability level.

The MacoTrace is at the heart of the THERAFLEX Processing Platform. It is a Data Management System (DMS) that has been designed to be connected to the MacoTronic B2 and to the BBIS of the blood bank in order to provide full traceability, to secure the critical steps of the process and to increase the cost-effectiveness.

The THERAFLEX Processing Platform has been designed to provide the highest quality, the highest safety and the highest traceability in order to reach our aim of 100% satisfaction.

Together with you, this 100% project will be initiated and will move forward to its definitive target: Every drop of inactivated plasma should be treated in good conditions and should be transfused to patients.