RFID
Experience of a blood bag manufacturer
Bracknell, 12th March 2008

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COMPANY PROFILE

- French Private company
- Founded in 1977 in Tourcoing near Lille (France)
- More than 1800 employees
- 5 manufacturing plants: France – Poland & Tunisia
- International organisation > 55 countries
- CE marked products (Class I, IIb and III)
- FDA approval for blood bags with in-line filter

3 main activities

MASKS
- Respiratory Protection Masks
- Surgical masks

INFUSION
- I.V fluids
- Irrigation
- Chemotherapy

TRANSFUSION & BIOTHECHNOLOGY
- Filtration
- Safety of Blood Products
- Equipment
- Blood bags
- Biotechnology
PRODUCT DEVELOPMENT STRATEGY

- The continuous quest, through partnerships, for improved safety, efficacy and quality of Transfusion, Infusion and Biotherapy.
- The development of integrated closed systems
- To ensure a complete traceability of our products from MacoPharma to end-users
Traceability on a blood bag is done with:

- Reference Number
- Batch Number
- Individual numbers printed on each bag
- Tools codes engraved on plastic parts.

On a blood pack, you will find a lot of eye-readable traceability data.

Why not having them on an electronic format?

- RFID could be useful to increase the transfer of traceability
- First development of a RFID chip in 2001 for transfusion
RFID & MacoPharma

Radio Frequency Identification in Transfusion Medicine

RFID Tag

- Chip + antenna
- Transmits data over RF range
RFID Validation

• Internal validation in order to select an appropriate RFID tag for blood bags
  – Labelling
  – Sterilization
  – Pasteurization
  – Centrifugation
  – Freezing (-30°C & -80°C) & defrosting
  – Storage & stability (up to 3 years)

RFID bag

• Omron Cooper RFID chip (more reliable for our use than Aluminium)
• Withstands sterilisation process and centrifugation
• The RFID Tag used is an I-code2 conform to ISO 15693
• Memory Capacity - 128 bytes
• Placed under a standard PVC label
• Define a mapping for the use in Transfusion
### RFID Chip MacoPharma mapping

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<th>Byte 1</th>
<th>Byte 2</th>
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</table>

#### RFID within the Transfusion chain

- Filtration
- Centrifugation
- Separation
- Quality Control
- Collection
- Hospital
- Distribution
RFID could be useful in Transfusion

- To ensure a complete traceability from manufacturer to patient
- To secure a process (viral inactivation, bedside blood match…)
- To speed up data exchange in the different processes of blood transfusion & simplify blood inventory management
- To avoid blood bags to be used on the black market (China)

Target of the RFID

- Traceability manufacturer
  - Lot Number
  - Product reference
  - Expiry Date
  - …

- Traceability Blood banks
  - Blood group
  - Donation Data
  - Process Data
  - Temperature
  - …

- Traceability Hospitals
  - Data Storage
  - Blood Type
  - Temperature
  - …
Blood Bags Manufacturer

- Initialization
- Lot number
- Product Reference
- Expiry Date
- Goods Release
- Logistics Control

Receipt of goods in a blood bank

- Control and release of medical devices
- Logistics and storage
- Traceability of temperature and humidity in storage
Processes

- Control of Donation
- Control of Transport
- Control of Separation
- Control of Filtration
- Control of Centrifugation
- Control of Inactivation

Storage

- Receipt of blood products
- Release of blood products
- Control of transport conditions
- Delivery of blood products
- Control of storage conditions
- Random storage
Plasma Storage

- Random storage possible
  (Every unit is equipped with RFID and can be found with a mobile Reading Device)
- Selection of the right product by RFID
- Cluster-reading of incoming systems
- Goods income inspection for fractionation

Hospital

- Bedside cross matching with wristband
- Temperature Monitoring (from Blood Bank to patient)
MacoPharma
RFID Achievements

- RFID chips (13.56 MHz) integrated to blood bag systems: under PVC label, tamper proof – irremovable
- RFID chip can be integrated to any of our blood bags depending on the customer request (WB, Plasma, RBC…)
- RFID bag systems provided with:
  - pre-registered manufacturer information (product reference, lot number, expiry date…)
  - RFID tags functionality 100 % controlled
  - global system qualified as non toxic product
RFID options within MacoPharma Equipment

Whole Blood Collection
RFID reader/writer integrated within the ABC machine

Theraflex
Methylene Blue
Plasma Treatment
RFID reader integrated within the MacoTronic system with 4 multiplexed antennae (one under each bag location)

MacoTrace System

Macotrace™ Editor
- Reading and writing station for controlling RFID tags at different stages of the process
- Used to describe the mapping of the RFID tag memory (MacoTronic, ABC...)

Macotrace Editor
Technology used

- Reading
- Writing
- Modification
- Erasure
- Saving

RFID Gate/Tunnel
Read more than 50 bags at the same time

of data by R/W devices

Web pad version

Hand version

Macopharma RFID Experience

- Experience with different blood centers within different European countries (Spain, England, France, Austria, Italy…)
- Experience with several 13.56Mhz RFID tag manufacturers (different standards, size, memory capacity…)
- More than 10 000 RFID blood bag systems manufactured
RFID Pilot Studies

- Implementation of pilots application with RFID technology in order to:
  - Evaluate the reliability of different RFID tags through the blood processes: sterilization, pasteurization, centrifugation, freezing (-40°C)
  - Secure and trace blood components treatment process: viral inactivation of plasma by TheraFlex-MB Plasma™ system
  - Perform traceability and data transfer on MacoPharma ABC™ blood collection device with RFID technology
  - Secure autologous transfusion (routine use)
  - Evaluate the interest of using an active RFID tag to monitor temperature of red blood cells.

Secure a process

TheraFlex
Viral inactivation of Plasma
Using Methylene Blue & Light
Theraflex MB Plasma

- Light exposure stage critical to activation of Methylene Blue
- Not possible to use light sensitive indicators to confirm illumination
- Light exposure system must be a GMP compliant controlled process
- Development of RFID chip technology was done to increase security and confirmation of illumination
The RFID/Macotrace Process

RFID/Macotrace Validation Protocol (England)

- Validation of Macotrace system
- Verification of chip functionality
- Validation of Theraflex packs with chips/Macotrace
  - Normal run
  - Interrupted run
  - On top of illumination lid
RFID/Macotrace Validation Protocol

Macotrace
- Web Pad
- Detection Pad
- Password protection
- Product code entry
- Donation No Entry

Theraflex Pack
- Chip readability
- Correct Information entry
- Entry overwrite

Macotronic
- Illumination status
- PASS
- FAIL
- NO DETAILS

A simple system to Control inactivation
From donor to patient

Vein to vein RFID system

RFID Pilot Study in Valencia

Evaluation of RFID data transfer between collection, blood component separation & inactivation
Collection Bag

- Quadruple Top & Bottom Bag with 2 RFID chip integrated on the RCC & plasma bags
- Production of one Leucoreduced Red Cell Concentrate & one Fresh Frozen Plasma

Pilot Study Valencia (Spain)

- Traceability
- Securization
- Automation

Donation data: Donation Number, ABO group, Nurse ID, Donor Number, ABC SN, Date, Time, Duration, Errors...

Data Control

Sterile docking: Data Transfer

Illumination Data
Illumination Status, MacoTronic SN, User, Energy, Date, Time, Duration...
RFID Pilot Study in Graz

Evaluation of RFID data transfer between collection, blood component separation & transfusion to patient

Pilot Studies Graz (Austria)

- Test on 1500 blood bags equipped with passive RFID labels from blood donation to red cells transfusion.
  - 13 defective labels after centrifuge without specific folding.
  - No defective bags after training
- Test on active RFID
Tests with passive RFID at UBT/LKH Graz
From donation to the hospital

13/1466 failures = 0.88%

Control points:
- Good incoming/distribution to mobile team
- before centrifugation
- after centrifugation, separation & filtration
- after labeling
- after cross match before distribution
- withdrawal

1 bar code scanning ~ 40 sec
10 scanning steps x 40 sec x 1500 systems = 167 h

Discard of blood products in Austrian Hospitals 1996-2001 (Öbig Study)

transfusion medicine today:
transfusion medicine today:

Reasons for loss (Öbig-Study)

- Expired
- Discontinuance of the cooling chain
- Defect of fridge
- Incorrect Handling
- Other reasons

SIEMENS

in cooperation with

UNIV.-KLINIK FÜR BLUTGRUPPENSEROLOGIE UND TRANSFUSIONSMEDIZIN, GRAZ
transfusion medicine in/of the future:

Temperature monitoring with RFID
Conclusion

- RFID tags could be easily included to blood bags.
- RFID tags are useful to ensure traceability, secure processes & improve data acquisition.
- Large scale use should confirm the Return Over Investment for passive and active RFID tags in Transfusion Medicine.

Thank you for your attention.