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Life-cycle information management and acquisition for blood products

by

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Declaration

No part of the material described in this thesis has been submitted for the award of any other degree or qualification in this or any other university or college of advanced education

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Abstract

Ten of thousands patients die every year because of medical errors. Many more patients suffer permanent damage and have to be medicated for the rest of their life. In the context of a blood donation, blood production and blood transfusion process, a lack of consistent and complete trace and tracking of individual blood bags has been identified as a source of medical errors. This research aims to address this challenge to help organisations such as blood banks to track the donation, manufacture, distribution and in-use of blood products, to remove/minimise the potential medical errors. Although the major goal of this research study is to increase patient security, reduction of wastage is also part of the research aims because donated blood is a scarce resource. Nowadays, up to 20% of the blood bags are put to scrap without use and each of the blood bag costs 220 Euro to produce (i.e. from collection, production and storage until it is consumed/discarded). In Austria alone, 5.6 million Euros could be saved each year if the wastage can be removed. Besides the economic issue, donated human blood is a scarce resource and always gives a poor psychological response from the general public when preventable wastage occurs.

This research study approaches the challenges through a life-cycle point of view because it sees the goal can only be achieved through 'real-time' life-cycle information that governs the quality and life-span of such products. As a result, a new RF based semi-active transponder (13.56 MHz, ISO 15693 compatible HF interface) with integrated data storage and temperature sensor, which is able to sustain high g - forces have been developed to provide the 'real-time' temperature data and other related information support.

The developed life-cycle information system has been trialled at the University Clinic of Graz not only to test its effectiveness, but also used as a case study for this research study. Due to the resources constraints (e.g. time), the case study does not create sufficient data to establish any statistical significance to quantify the benefits of the proposed systems. However, all the involved persons including both the operational and professional staff at University Clinique of Graz, have agreed the proposed RFID transponders, together with its lifecycle management system provides better decision support to handle individual blood bag at any stage of its lifecycle. They believe the proposed system will improve patients'

safety and reduce the wastage of blood bags. During the trail, it happened that two blood bags ready for transfusion were detected to be below 0°C somehow during their life-cycle. A blood transfusion would have been 100% mortal to the patients. The detection of this fatal mistake did save at least the life of one human being and illustrated the importance of an objective, overarching and complete life-cycle system for blood products.

Although this research is focused on blood products for blood banks and medical environments, the benefits of the system approach and methodologies could also apply to other types of sensitive and fragile goods that require life-cycle information support.

Acknowledgement

As an ‘off shore’ student it is not easy to set up a relationship to his University. However, I still remember the first day when I entered the Queens Building and asked for Dr. Wong; I will never forget that I was welcomed with open arms. The DMU from my point of view is a specialist for part-time students, as everybody there brings a wide understanding about what it means to do both: to work and to study. For this I like to thank all the personnel at the DMU I was in contact with for their friendliness, correctness and the great job they do every day.

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Acronyms and Abbreviations

137Cs	Caesium 137 (radioactive Element)
2,3-DPG	2,3-Diphosphoglyzerat
51Cr	Chrome 51 (radioactive Element)
AABB	American Association of Blood Banks
ACD	Adenine Citrate Dextrose
AFI	Application family identifier
AIDS	Acquired Immunodeficiency Syndrome
AS	Additive Solution
ATP	Adenine Tri Phosphate
BG	Blood Group (ABO-blood groups A, B, AB and O)
CJD	Creutzfeldt Jacob Disease
CPD	Citrate Phosphate Dextrose
CP2D	Citrate Phosphate 2xDextrose
CPDA1	Citrate Phosphate Dextrose Adenine
CRC	Cyclic redundancy check
DSFID	Data storage format identifier
EOF	End of Frame (File)
F.VIII	(Coagulation-) Factor VIII
FDA	Federal Drug Association
FFP	Fresh Frozen Plasma
GAMP4	Good Automated Manufacturing Practice, Version 4
GMP	Good Manufacturing Practice
HAV	Hepatitis-A Virus
HAL	Hardware Abstraction Layer
Hb	Haemoglobin
HBV	Hepatitis-B Virus
HCV	Hepatitis-C Virus
HIV	Human Immunodeficiency Virus
HCT	Haematocrit

ISBT	International Society of Blood Transfusion
LSB	Least significant bit
MSB	Most significant bit
NaCl	Natrium-chloride
PC	Personal Computer
PCR	Polymerase Chain Reaction
RBC	Red Blood Cells
RFID	Radio Frequency Identification
RFU	Reserved for future use
RF	Radio Frequency
Rh	Rhesus
SHOT	Serious Hazards of Transfusion
SOF	Start of frame
TA-GVHD	Transfusion associated - Graft vs. Host Disease
TMS	Temperature Monitoring Sheet
TRALI	Transfusion Related Acute Lung Injury
TRD	Temperature Recording Device
UID	Unique Identifier
VCD	Vicinity coupling device (reader)
VICC	Vicinity integrated circuit card
WHO	World Health Organization
WNV	West Nil Virus

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Publications

1. Noemi Kozma, Harald Speletz, Ursula Reiter, Gerhard Lanzer and Thomas Wagner, “Impact of 13.56-MHz radiofrequency identification systems on the quality of stored red blood cells”, Transfusion, Volume 51, Issue 11, pp 2384–2390, November 2011
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5. D. Jansen, H. Speletz, B. Fleiner, D. Bau, A. Kreker and A. Riske, “Active RFID Sensor with Integrated File System for Logistic Applications”, European Workshop on Smart Objects: Systems, Technologies and Applications (RFID Sys Tech), ISBN: 978-3-8007-3282-1, 15-16 June 2010
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Patent

1. H. Speletz, D. Jansen and T. Volk, “Anordnung zur Organisation von Daten auf einem RFID-Transponder”. Deutschland Patent 10 2012 008 147.2, 24 April 2012.

1 Introduction

'To err is human' [1] published by the Institute of Medicine (USA) has alarmed the medical branches by stating that 44,000 up to 98,000 people will die every year in the USA alone because of medical faults[1]. This report was critically discussed but last not least agreed by the honourable New England Journal of Medicine. [2]

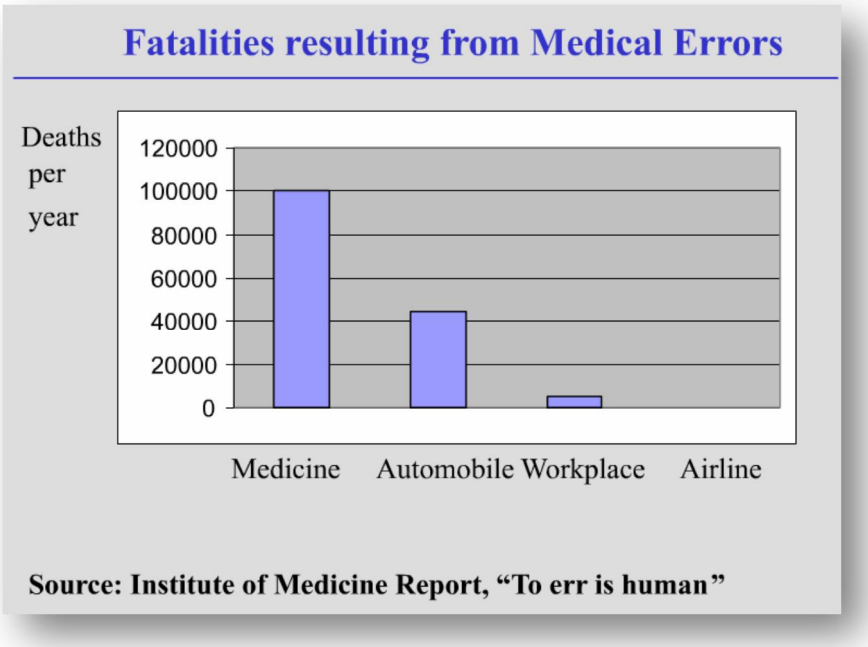


Figure 1: Fatalities resulting from medical errors [2]

Most of the experts today have agreed that information technology could significantly reduce medical errors and therefore improve patient security. [3] [4] In transfusion medicine, this issue was identified quickly and barcode systems have been implemented to improve patients' safety. [5] The necessity to improve safety at blood transfusion has been recognized even much earlier due to a significant number of viral transfers in last few decades. [6] Nowadays, various improved test systems come to use indeed the risk of infection by blood transfusion has decreased.

[1] Medical faults are often described as human errors in healthcare although this definition is subjected to debate

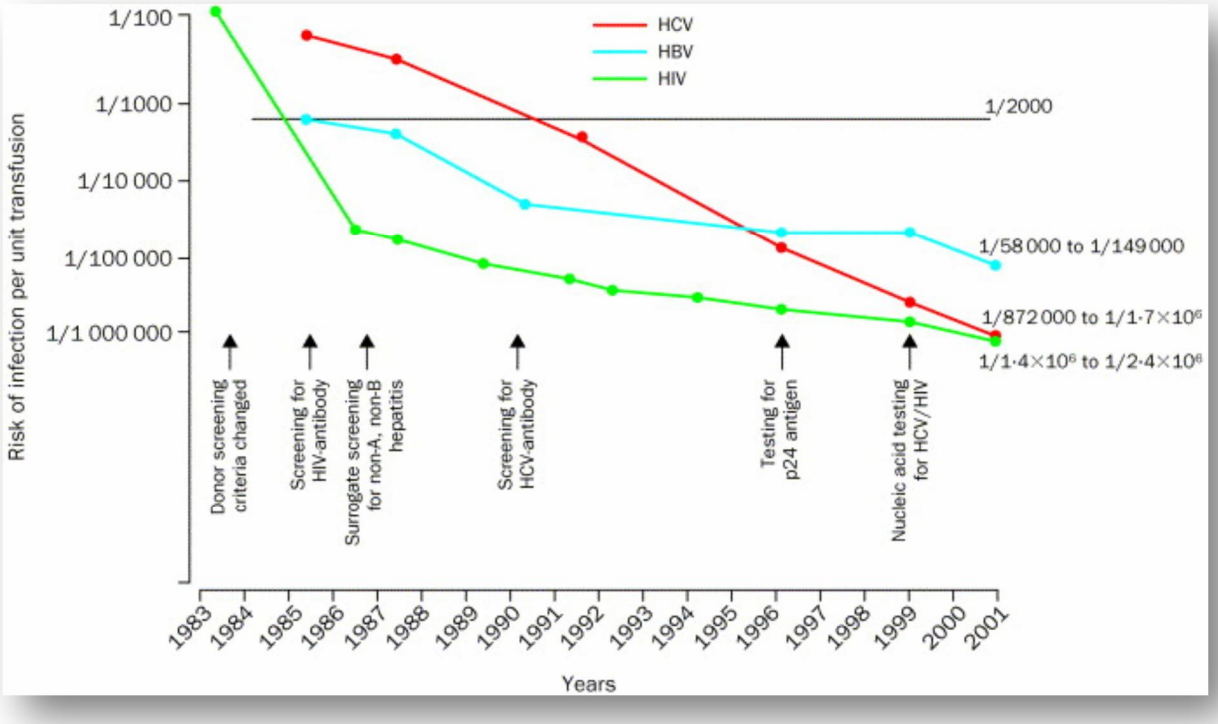


Figure 2: Risk of infection per unit transfusion [6]

Two recent research studies have proved the major risks of blood transfusions today are not caused by viral infection but the confusions in the ABO blood types system (see figure 3). [7] [8]

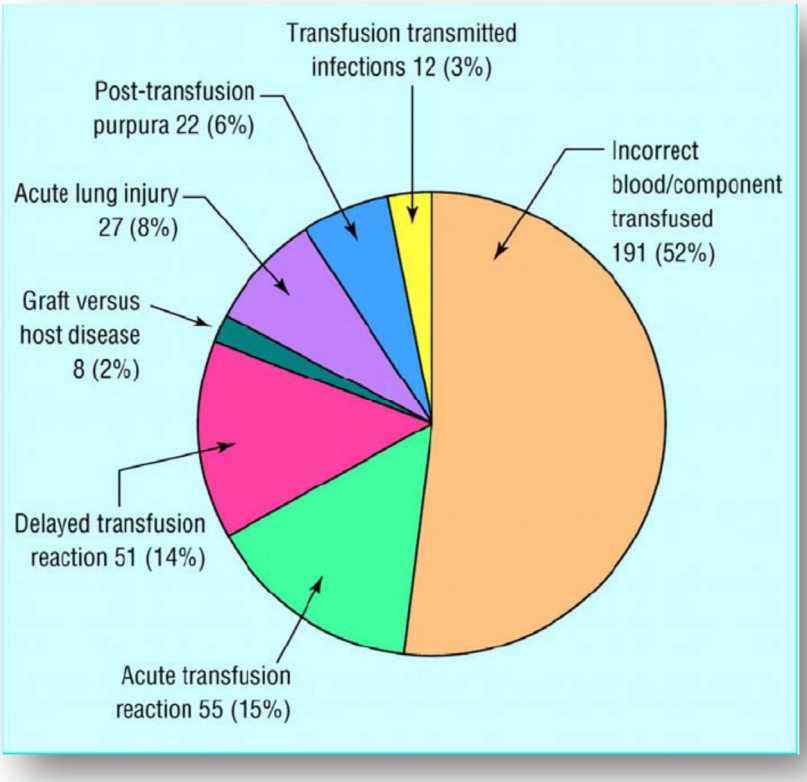


Figure 3: Hazardous due to blood transfusion [7]

Another step towards quality improvement was the implementation of a system to manage so called 'almost or nearly – errors'. This system would help to discover risks within the blood production procedures and estimate their probabilities, which led to establish procedures and/or steps to avoid these risks in the future. [9] However, this proposed system demands a new 'error culture' in order to succeed - a new way of thinking about how to handle errors. Reports of human error must not lead to personal sanction or persecution even it is based on gross carelessness; it could deter the reports of errors. The declaration of errors must result in a constructive review that leads to improvements within the blood production process itself. [10] One recent publication raised a question 'Transfusion safety: Where we are today?' [11]. The report not only discussed infection risks such as Creutzfeldt-Jacob disease (CJD) and West Nil Virus in blood transfusion, but also non infection based risks such as insufficient blood transfusions or mistaken blood transfusions.

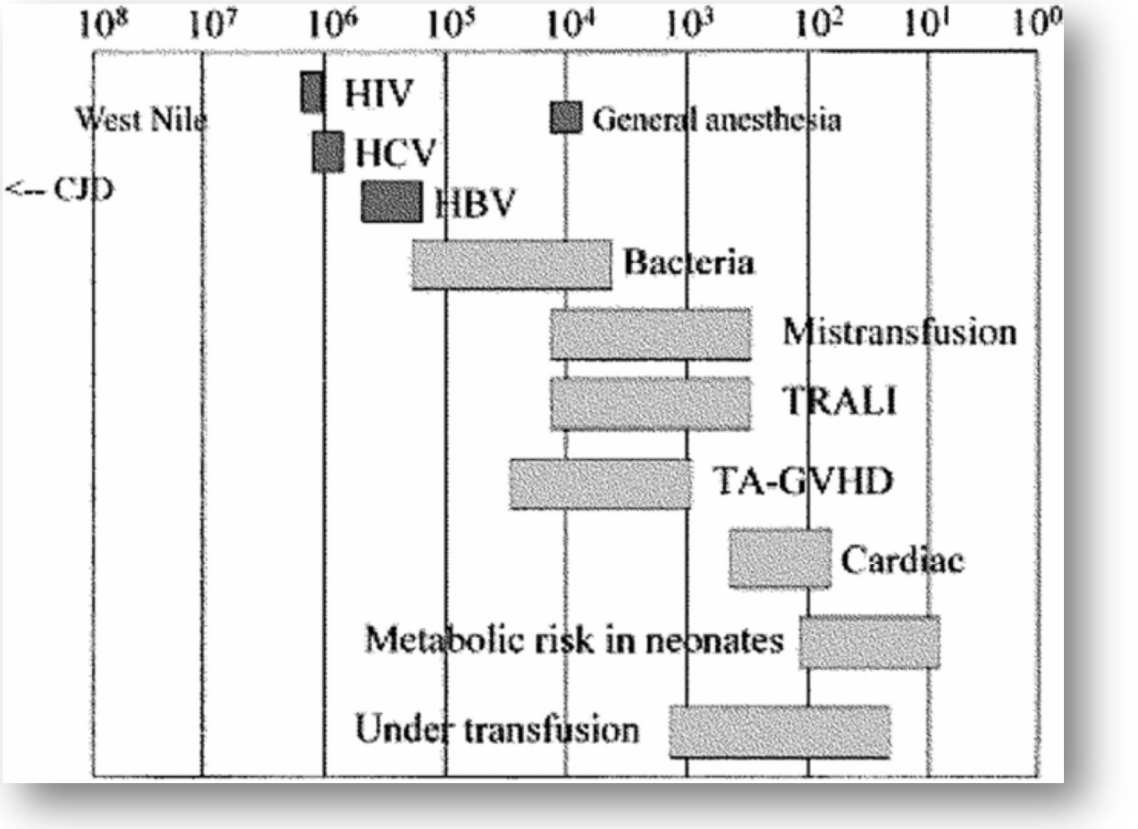


Figure 4: Risks in transfusion medicine [11]

Classical risks like HIV or HCV are estimated with a risk of 1:1 million (10^6) which is small when compared to the probability of a blood transfusion failure of $1:10^2$ - 10^3. Today, due to the improvement of test procedures, the risk to get HIV because of a blood transfusion is 1:5.54 million, for HCV is 1:4.4 million and HBV is 1:620 000. [12] [13]

TABLE 1. Kinds of adverse transfusion events

	Estimated risk
Serious	
• Mistransfusion	1:14.000 to 1:19,000
• ABO-incompatible transfusion	1:38,000
• Death due to ABO-incompatible transfusion	1:1.8 million
• Acute hemolytic transfusion reaction	1:12,000
• Delayed hemolytic transfusion reaction	1:4,000 to 1:12,000
• Transfusion-related acute lung injury	1:20,000 to 1:5,000 (5–10% fatal)
• Anaphylaxis	1:20,000 to 1:47,000
	l:150,000
	1:1,600 (platelets)
	1:23,000 (RBCs)
• Graft-vs.-host disease	1:1 million (Canada)
• Post-transfusion purpura	1:143,000 to 1:294,000
• Fluid overload	1:708 to 1:3,200
	1:7,000 to 1:15,000
Less serious	
• Febrile nonhemolytic transfusion reaction	1:500
• Allergic (urticaria)	1:250

Figure 5: Kinds of adverse transfusion events [11]

Computer and IT systems have an important role in blood transfusion medicine as it is almost impossible to handle the huge amount of blood bag data via human and paper-based systems, without adverse effect on patients' safety. For example, blood tests results which have to be carried out for each blood bag could not be easily tracked/linked to its blood bag in a secure way. Although computer and IT systems are popular and gaining momentum in the supply-chain of blood products, there still some parts within the blood production process that are not adopting any means of electronic systems. In the blood transfusion medicine, the mix-up of blood bag and recipient is still the most dangerous and deadly [14] [15] risk. Many pilot projects have been conducted worldwide to seek methods on improving the patients' safety in blood transfusion. In Oxford (UK) [16] and Hong Kong, [17] patient wristbands came to use and have a degree of success regarding improvement of patients' safety. Many countries in Europe have started a so called haemovigilance – system. [18] [19] This control system supervises the blood transfusion procedures, registers

and analyses all unwanted effects before, during and after blood transfusion. All events are collected in a national haemovigilance registry.

The European Commission Directive 2003/63/EC [EU 2003], amending Directive 2001/83/EC, requests all companies that deal with human blood products must have a system to monitor environmental data. This led to a proliferation of incompatible approaches and solutions, partly because the nature of the directive and partly because the diversity of the legal and social background. Due to the diversity of the approaches, attempts have been made to categorise these approaches for supporting the selection process to identify the best approach for specific and/or identified needs. Research has also been carried out to tackle such diversity using advanced information and communication technology and has producing some promising results. However, a number of questions still remains to be answered (e.g. interoperability issue).

Previous research studies also revealed incompatible blood transfusion or identification errors could be avoided with the aid of an integrated sensing and environmental information system. Such system would also improve the recirculation of unused blood bags.

1.1 Aims and Objectives

The principal aim of this study is to investigate the design of an integrated sensing and environmental information system, which involves collecting and analysing environmental lifecycle data for blood products. The aim is not only to help organisations such as blood banks to track in manufacture, distribution and in-use of the blood products, but also reduce wastage of the blood products significantly through 'real-time' lifecycle information that governs the quality and life-span of such products. Furthermore, this information would help to improve the future design of processing and distribution of these products. The following objectives were setup to facilitate the realisation of the defined aim.

- Literature survey and review to identify what previous and current related work has been done and its relationship to the proposed investigation.
- Identify appropriate enabling technologies.

- Produce a generic specification, design guidelines and reference architecture for the proposed system
- Design and implement system prototypes for supporting a field trial and case study

2 Literature Review

Approximately 95 million blood donations are collected worldwide annually from all type of blood donors (volunteers, family and paid). Each blood bag is linked to a unique donator number, which allows follow-up from donor to patient to ensure safety and security. Today, validated procedures and technical treatments[2] transform the raw blood product into one erythrocyte concentrate and one plasma unit due to medical considerations. In some cases, platelet concentrates are also produced.

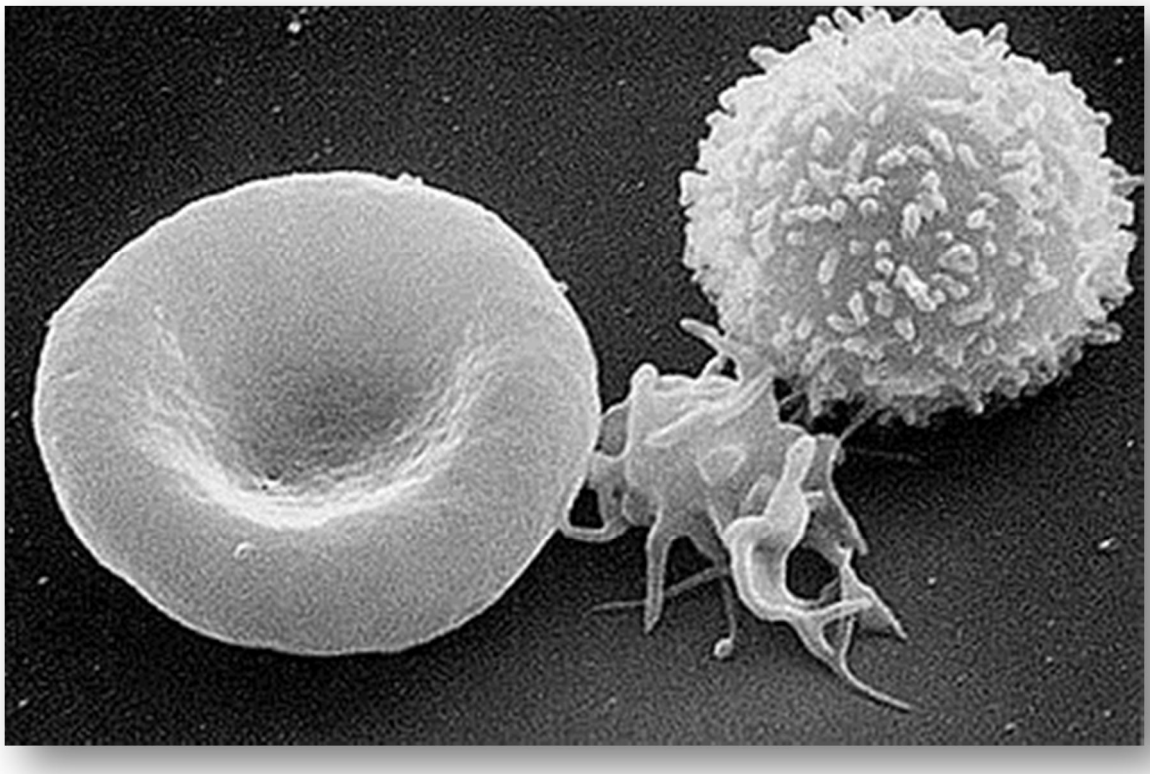


Figure 6: From left to the right - Red Blood Cell, Platelet, White Blood Cell (Erythrocyte, Thrombocyte, Leucocyte) [Source: Wikipedia]

Majority of blood banks are adopting proprietary software to store information according to their national judicial directives. [20] All blood bags are registered and controlled throughout their life-cycle (i.e. from donation to transfusion) for safety and security. [21]

[2] The common method of blood production is to centrifuge the whole blood with an acceleration force of around 4000g. After this the different products are pressed into specific bags of the blood bag system.

Any donation is required to be tested in accredited laboratories [3]where all blood products must not be used before confirmation. [22] After laboratory confirmation, the blood products will be labelled and released for subsequent use. The majority of the blood products are delivered to hospitals. In compliance with EU regulations[4], each hospital has to have a blood depot for storage and internal distribution of blood products. This regulation has been led to national laws in majority of the EU member states. [5] The EU directive (article 11) also notes that each depot has to comply with the Good Manufacturing Practice (GMP). Therefore, a quality assurance system must be established and standards are defined according to the needs of individual member state to meet this EU directive. The business of blood depots is more than just a blood warehouse. They guarantee the availability of blood products for the hospital and also responsible for blood quality issues. Blood depots have to avoid becoming the bottlenecks in their supply-chain. Therefore, the blood depots have to estimate their future demand and place the orders accordingly to avoid short-supply of blood products. Both the shelf life of red blood cells (RBC's) (a maximum of 42 days) and occasionally volatile consumption have imposing complexities of forecasting on the demand of blood products.

The following sections describe the blood production process in detail to provide better understanding on information which required for supporting the blood products management throughout their life cycle. It also describes the influence of life cycle management methods. These methods are based on the use of active RFID transponders with temperature and data recording facilities.

2.1 The life cycle of blood products from donation to transfusion

2.1.1 The Blood Bag System

Transfusion of whole blood is obsolete since centuries. Only in case of own blood transfusion or in situations caused by catastrophes, whole blood transfusion could come to use. Separating whole blood into blood components allows the doctor transfuses only

[3] The laboratories test all parameters for HIV, HCV, HBV, syphilis (TPHA-test), HAV and ParvoB19. Additionally GPT and neupterin as well as immune- hematological parameters like ABO, Rhesus, Kell and anti-body search test are performed.

[4] Guideline 2002/98/EG article 6: blood depots

[5] E.g. in Austria §8f and §65 national law for medical institutions

required blood component(s), which would maximise and efficiently use of human blood. The basic requirement of blood transfusion is a donation set that meets all the quality criteria, for example, the materials used must be free from pyrogenic germs. In 1950, Carl Walter developed and patented a special plastic bag that has been commercialized by Baxter. [23] [24] This bag is the forerunner of all the blood bag systems used today. Plastic bags have many advantages to former used glass bottles. They are virtually unbreakable; they can stay closed and therefore sterile throughout their whole lifetime and allow higher rotation rates in the centrifuge. Main disadvantage of plastic bags is the volume determination. Material damages will only be recognized after filling. Today a blood bag is a closed multiple bag system consisting of three or four blood bags. All systems are equipped with adapters, equipment and test tubes.

There is no universal design of blood bag systems and their design are depending on individual supplier, however, the basic components remain as the same. CDP/SAG-M system, a name which resemblance to the use of the additive solution, is an exemplar of modern blood bag system design. The primary bag of this system (the one that takes the whole blood) is equipped with a 63ml Citrate- Phosphate- Dextrose- Adenine (CPDA-1) solution [23] to enable the anticoagulation of the donor blood. CPDA-1 solution is a stabilizer which replacing CPD solutions that have been used since the 1970. It stretches the shelf life of whole blood from about 21 to 35 days. [25] Two other bags are used to hold the buffy coat (platelets and leucocytes) and plasma after fragmentation. The final bag that takes the erythrocytes after separation is filled with a SAG-M (Sodium Adenine Glucose – Mannitol) solution. This solution allows a shelf life of 42 days for red blood cells when stored at a temperature around 4°C (+/- 2°C). [26]

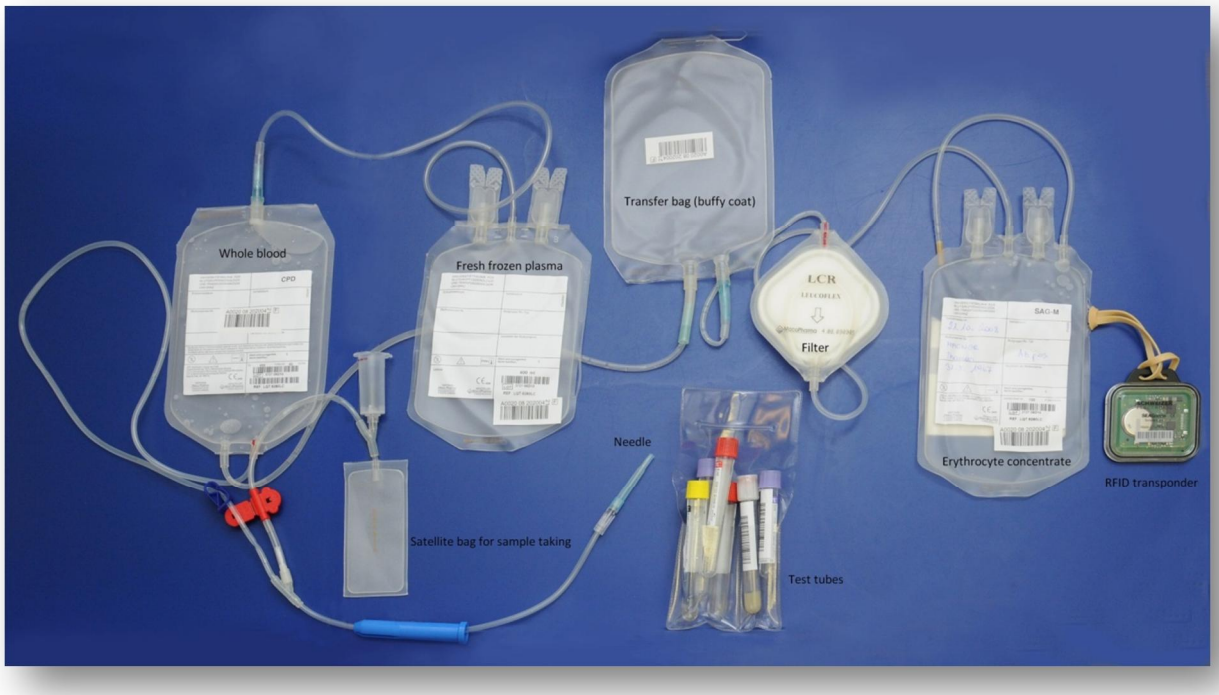


Figure 7: Multi bag system from 'MacoPharma' used at the blood bank of Graz

2.1.2 Whole Blood Donation

The prospective donor will have to answer a questionnaire with questions about health condition and life style before the donation. This is followed by a medical check of blood pressure, pulse; haemoglobin etc. is examined by a physician to ensure safety for both donor and patient. This procedure is usually not supported by electronic systems. Data is hand written onto a paper document. According to European regulations, questionnaire and medical check records must be kept for a minimum of 30 years.

The Donor ID will be linked to the number of the blood bag system received. This data could be stored electronically if software system is available. After cleaning and disinfection of the donor's skin, the punctuation will be carried out by a phlebotomist. The blood bag system will be positioned on a special weighting and mixing machine to ensure the right amount of blood is collected.

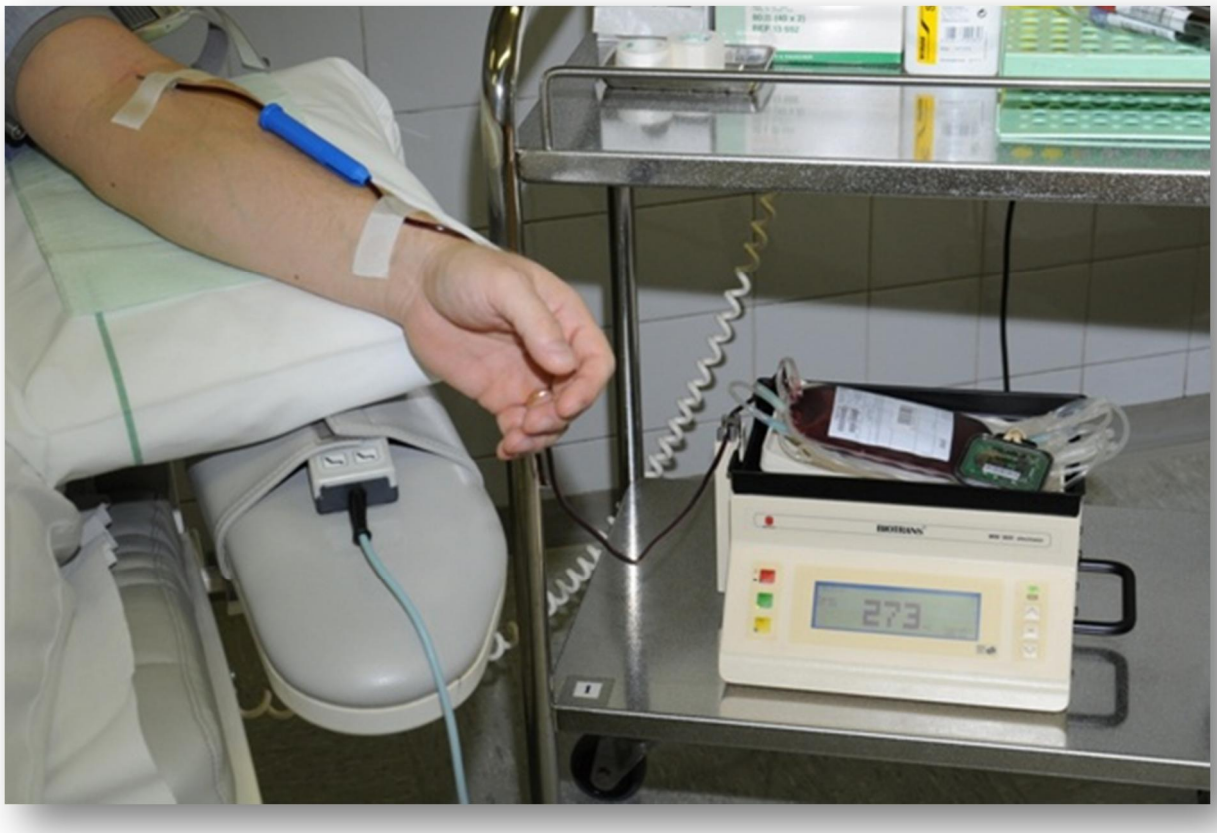


Figure 8: Donation process. The blood bag is placed on the mixing and weighting machine

The bag that takes the whole blood is pre-filled with 63ml of an anti-coagulation[6] liquid. This citrate phosphate dextrose and adenine (CPDA-1) must be approved by the FDA[7].

For a good mixing of the whole blood with the pre-filled anti-coagulator, the weighting machine also shakes the blood bag gently backwards and forwards to avoid blood coagulation.

[6] Anti-coagulation means to avoid blood coagulation with help of appropriate substances. This is essential in case blood comes in touch with materials that are foreign to the body.
[7] FDA: Food and Drug Association is the regulatory authority of the USA.

Figure 9: Weighting and Mixing of Whole Blood

A blood sample is taken before donation for subsequent laboratory tests to ensure the donated blood is free from any dangerous infections such as HIV, and viral hepatitis. Best practice guidelines such as arm cleaning must be followed to ensure this pre-donation sample is free from contamination, as the small piece of skin that was punched out during punctuation could be infected by bacteria. [27] The blood sample is collected with sample test tubes and these tubes are equipped with a barcode for identification. Today, test tube number, blood bag number and donor ID are linked together with the aid of appropriate software.

The volume of donated blood will be approximately 450ml +/-10% (405 – 495ml). The American Association of Blood Banks (AABB)[8] recommends the maximum level of donation

[8] Especially for the North American countries the AABB defines and publishes regulation for transfusion medicine. The AABB is also publisher of the peer – reviewed professional journal 'Transfusion'. This journal is accepted as one of the world - wide most important publication for transfusion medicine.

at 10.5 ml/Kg body-weight of the donor. [28] The blood drawing process must not exceeds 10 minutes, although a research study has found the quality of platelets and plasma would not be infected within 15 minutes time period. [29]

The tubes to the whole blood bag are multiple welded right after the donation process to ensure free of contamination in the subsequent processes. A final health check on the donor will be carried out to complete the donation procedures. Results of the health check as well as other data like the donation time, the amount of taken blood and the ID of responsible blood donation team will be recorded onto a paper document.

2.1.3 Storage and Transportation of Whole Blood

The storage of donated whole blood bags starts immediately after removal of the needle from the donor's vein and the welding of the blood bag tubes. The whole blood is cooled down to 22°C +/- 2°C with the aid of butane-1, 4-diol filled special cooling plates. The cool down period lasts for approximately 15 minutes. This temperature reduction ensures the functionality of the platelets and maintains the quality of the coagulators. It also maintains the quality of the erythrocytes [30] and allows delay of further processing up to 24 hours. [31] [32] Immediate cooling down to 4°C +/- 2°C would lead to a total loss of platelet functionality. Furthermore, the quality of plasma-factors is reduced and the phagocytosis[9] of bacteria [30] [33] would be complicated. The storage of whole blood over a period of 24 hours leads to a degeneration of granulocytes[10] (white blood cells). This may also lead to liberation of phagocytized bacteria's. [34]

Whole blood will be transported to the institution for further processing. In most cases, this will be the blood bank. However, other institutions such as Red Cross are also able and allowed for blood separation. There are no universal regulations or recommendations to guide when and how the whole blood is transferred; such procedures would be different from country to country (even worst from institution to institution within the same nation).

[9] Phagocytosis: The absorption of solid particles to the inside the cell. Also called eating activity of cells
[10] Granulocytes: White blood cells. These scavenger cells are most important for the human immune system.

The following procedure is an illustrative example on how it is practicing at the University Clinique of Graz (Austria).

Most of the blood will be collected by mobile teams that travel from village to village. The teams are organized by the Red Cross and are legalized to carry out the procedures of collecting blood donations. Under normal circumstances, donated blood will be delivered to the local blood bank in the afternoon or in the evening. The blood bags are transported with special cooling boxes.

Figure 10: Whole Blood Transportation

Each blood bag will be inspected and registered at the goods reception. It is checked up against damages such as due to failure of cooling system during transportation. The temperature is measured with special loggers which are put inside the boxes. These temperature values can be retrieved via a computer system when the blood bags arrive to their destination.

Nowadays, whole blood will not be transfused directly. Therefore, whole blood must be seen as base product (raw material) for the production of blood components.

2.1.4 Component Separation

Before the collected whole blood pass by 24 hours at 22°C +/- 2°C, the separation process starts by centrifugation of the whole blood at 4000g for approximately 7 minutes[11] (also at 22°C +/- 2°C). This process will separate different blood components according to their density.

Figure 11: Centrifuge at the University Clinique of Graz

Blood component	Density (g / ml)	
Plasma	1.026	Plasma
Platelets	1.058	

[11] The duration time is different and depends on the planned results. E.g.: A 30 minutes centrifugation time leads to a higher separation rate and therefore an almost total separation of white and red blood cells.

Monocytes	1.062	Buffy Coat
Lymphocytes	1.070	
Granulocytes	1.082	
Erythrocytes	1.100	Red Blood Cells

Table 1: Medium Density of Blood Components [34]

Sedimentation of the cells can be calculated according the Svedberg formula:

$$V = \frac{\frac{2}{9} * W^2 * R * [d_{cells} - d_{plasma}] * r^2}{n_t}$$

- V Centrifugation speed
- W Angular speed
- R Distance from the blood cell to axis of rotation
- d Density
- r Radius (blood cells)
- n_t Viscosity of medium at t°C

The density of the blood components increases starting with plasma, platelets, monocytes, lymphocytes, granulocytes and ends with erythrocytes. According to the size of the cell, their sizes increase from platelets, erythrocytes, granulocytes, monocytes to leucocytes. At the beginning of centrifugation, sedimentation is affected by the component sizes (cell radius). Therefore, leucocytes settle down faster than platelets or red blood cells. When most of the red blood cells reach the bottom of the bag during the centrifugation, the enclosed leucocytes and plasma is pressed in the upper areas between erythrocytes and plasma. At the end of centrifugation, red blood cells, leucocytes, platelets and plasma are stacked due to their density.

Figure 12: Blood bag after centrifugation

With the aid of special technical instruments called pressing machines, the blood components will be extracted. First fresh plasma (200 – 250 ml) will be put into the transfer bag of the blood bag system. Afterwards, a buffy coat, approximately 2 cm thick level below the plasma will be separated from the red blood cells. Buffy coat consist of 70% of the leucocytes and 90% of the platelets that can be found in the whole blood composition. [35] [36] Plasma will be shock frozen, which means the plasma should be frozen to -30°C within an hour. After this process, the frozen plasma is permanently stored at a temperature of -23°C. [37]

Figure 13: Component extraction and filtering at the University Clinique of Graz

For a red blood cell production (also for thrombocyte production), depletion of the white blood cells is one of the major production quality indicators. The key reason is when contamination of blood products occur, the white blood cells can lead to unwanted effects that could harm the recipient. These undesirable effects could be febrile non-haemolytic reactions or the transmission of leucocyte–based pathogens like HTLV, CMV, EBV, etc. Most of these unwanted effects could be avoided by reducing the white blood cell counts below 5 x 10^7 for each red blood cell concentrate. Therefore, the regulations of the AABB [38] advise that each erythrocyte and each thrombocyte concentrate must not consist of more than 5 x 10^6 leucocytes. The European Council is much stricter in this issue and recommends a rate of below 1 x 10^6 cells. [39] Effective reduction of leucocytes will be carried out with the aid of special filters. [37] The separation of whole blood (especially the separation of buffy coat) leads to a higher success of filtration of leucocytes, as most of the leucocytes are bounded in the buffy coat. [40] [41] Best filtration results can be obtained when filtration process is carried out after 6 hours storage of whole blood at ambient temperature.

Figure 14: Storage of red blood cells at the University Clinique of Graz

Due to the separation of plasma, a nutrient solution for erythrocyte concentrates has to be added to improve the storage behaviour. An additive solution (AS) which consist of NaCl (Natrium chloride), dextrose, adenine and other substances allows viability and functionality of red blood cells for up to 42 days. In general, a volume of 450ml (500ml) whole blood requires 199ml (110ml) additive solution to be added. [42] [43] The additive solution must be added to the erythrocyte concentrate within 72 hours. [44] [45] Recently, novel additive solutions like AS-3 allow (according to actual research study) storage periods up to 56 days. [46]

2.1.5 Laboratory Tests of Whole Blood Donations

Various regulation and laws (slightly different from country to country) are not only providing guidelines for testing blood product against different pathogens, but also defining a valid method to identify the blood groups. In the European Union, published directives are the forerunners for national laws. [47]

A safety blood transfusion must not be seen as a medical action but rather as a process. All blood bags have to pass this process in the same way. The first stage of this process; donation, production and testing that have been described in previous sections, are well monitored with the current practices. The critical and most error prone processes beginning at correct labelling of the patient sample, the pre-tx testing[12], the release and delivering of the blood bag and end up at the administration of the bedside test. The major driving forces behind this 'Life-cycle information management and acquisition for blood products' research project is to improve and enhance the patient safety for these later parts of the process.

When discussing safety in blood donation and blood transfusion, general public will automatically associate the major threat with virus infection such as HIV, hepatitis B or C. And indeed, until a few years, almost any international initiatives for blood safety are focused on the non-transmission of infectious agents. Today, research studies have been proved that virus infection is possible through blood donation and transfusion.
Figure 16 describes the detection of viruses and the implementation of specific test systems.

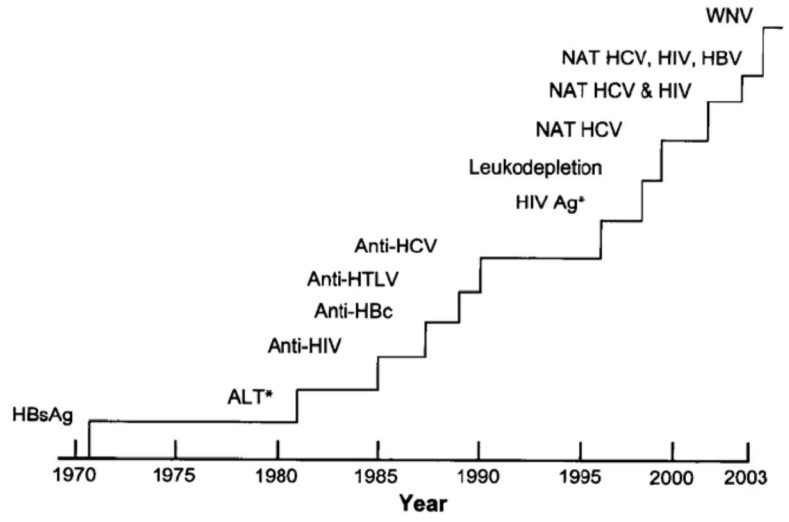


Fig 2. Approximate timeline (1970-2003) for the introduction of various interventions to improve transfusion safety. This timeline may not apply to all countries. The y-axis indicates the magnitude of the number of tests done annually. *No longer in use.

Figure 15: Implementation of Test Systems [48]

[12] Pre-tx Test: Repeat of AB0, Rh and Ab (antibody) screening.
Post-tx Test: Repeat of AB0, Rh, Ab, DAT, CBC, UA, bilirubin, BUN, CR and coagulation screening

Blood test at the laboratories and blood production are parallel processes. This means that the result of the laboratory will be received after blood separation. Therefore red blood cells are stored in a ‘quarantine store’ until the laboratory results arrive. When the laboratory results arrive, the blood bag will either be finally labelled and released to the common store, or disposed properly.

2.1.6 Clearance of Blood Products

Receiving the blood test results from the laboratory the blood bag will be labelled. The clearance process must be computer based and controlled by precise clearance procedure. This procedure must comply with the national laws and have to be validated. The computer based clearance of erythrocyte concentrates will be carried out by labelling the RBC bag after production and if all results of the blood tests are available. Depending on the test results the label indicates if the RBC bag is disposed or not. In case the test results show no contamination the label includes the following information (minimal version):

- Unique bag ID (barcode and letters)
- Donation date
- Expiry date (and time)
- Product description (e.g. erythrocyte concentrate)
- Product code (e.g. ISBT 128)
- Summary of laboratory tests (e.g. HIV, HBV, HCV negative)
- Volume and additive (e.g. 230 ml + 100ml SAGM AS Haemoglobin > 51g)
- Blood group and rhesus (e.g. barcode and letter e.g. B +)
- Kell factor
- Location of Production
- Name and location of blood bank

If the test results shown contamination exist and disposal is required, the blood product will be labelled with the following information:

- Unique bag ID (barcode and letters)
- Product description (e.g. erythrocyte concentrate)
- Eye caching text that the product as to be disposed

- Donation date and time
- Reason for disposal (e.g. Anti – HIV ½ doubtful)

2.1.7 Transport and Distribution

Temperature of the blood product during transportation is fixed at 2 – 10°C. This practical approach due to the fact that such stricter temperature conditions adopted in controlled cooling stores (4°C +/- 2°C) cannot be easily (or economically) realized during transportation, especially in a long journey.

In general, the shelf life of erythrocytes has to be re-estimated if their temperatures reach above 10°C during transportation, especially if the blood bag is returned into the 4°C +/ -2°C cooling area. [49] Such shelf life re-estimation is due to the threat of bacterial growth, which gets worsen at a higher temperature. A guideline called “30 minute rule” which designed for the operators has implemented in the USA. This rule states when the blood bag stays at an ambient temperature of 22°C +/- 2°C for less than 30 minutes, the core temperature of blood bag will not exceed 10°C. In cast the blood bag stays at ambient temperature for more than 30 minutes it has to be disposed. This rule is based on a study reported in 1971 by Pick et.al. [50]. A more up to date study critically rates the bacterial growth [51] and this core message has been reconfirmed. [52]

In Germany, any responsibility for transportation issues is under the liability of the producer. This is also valid for complying with the cold chain restrictions. [53] In Austria, the governmental department for public health defined minimum standards for blood depots. For the transportation of blood products, it is pointed out that the organization of transports for blood products to the depots is under the control of the blood bank. During transportation, criteria such as distance and temperature must be considered and deal with appropriate measures. Transports are part of a validated process.

2.1.8 Manipulation of Blood Bags

Within its life cycle of approximately 42 days, each blood bag will be taken out of temperature controlled areas. Main reason is the cross matching of blood compatibility that will be carried out 3 to 5 times (in smaller blood depots even more often). In average, each blood bag will be cross matched for 2 times before it is delivered to the station. During blood separation, the tube of the blood bag is segmented where each segment holds 2-3ml of blood.

Figure 16: Segmentation of the Tube at the University Clinique of Graz

One of the segments will be required for each cross matching. During the life-cycle, each blood bag has to be taken out of controlled areas to carry out all the laboratory screenings and handlings for a minimum of 4 times.

During the cross matching, the compatibility of the donors' blood and the recipient is examined. Here a probe of the patients' blood is needed and has to be correctly labelled in letters and as a barcode. This data will be transferred to a blood bank software application for data record. In some circumstances (e.g. if no technical instruments for automatic data recording is available), this data will be edited manually. The laboratory results of the cross matching will be manually transferred to the blood bank system. When positive cross matching occurs, a supply note is printed and attached to the blood bag. The supply note includes the following information: Personal data of the recipient, station where the blood bag will be transferred, blood group, result of the cross matching and duration of validly.

Manipulating blood bags the time each single blood bag stay out of temperature controlled areas cannot be foreseen or reproduced. The lack of a temperature control of each single blood back is the major reason why blood depots do not take back blood bags. Therefore already delivered blood bags that remain unused (e.g. during an operation) are discarded.

2.1.9 Blood Transfusion

Before blood transfusion, the data label on the blood bag will check against the patient data. Furthermore, a last screening of compatibility test will be carried out at the bedside to ensure patient safety is maintained.

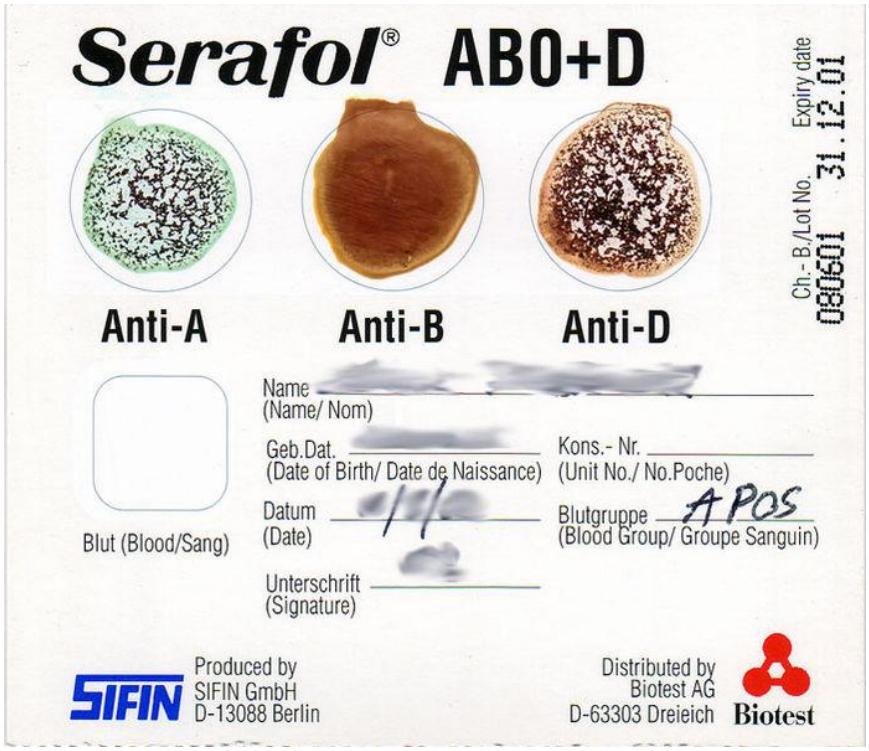


Figure 17 Bedside Test Card (Source: Wikipedia, April 17 2012; "http://de.wikipedia.org/wiki/Bedside-Test")

As the blood within the blood bags are preserved at a temperature ranged between 4°C and 10°C, it has to be warmed up to 37°C just before transfusion. Any adverse reactions that arise during or due to blood transfusion will be manually documented. These documents should be returned to the blood depots, however, many of them get lost. It is on the transfusion personnel to return the documentation of adverse reactions at transfusions. There exists no regulation for this. In hospitals like the University Clinique of Graz the return rate is at 30 – 40% of approximately 55,000 transfusions the year.

In most cases, dispatched blood bags that are not used will be disposed. Unfortunately, the exact figure of such wastage are treated as internal data and not publicly available. Therefore, an official figure does not exist. The blood bank of Graz takes back unused blood

bags when the criteria are met. Out of a one year production of 55,000 erythrocyte concentrates, approximately 15,000 are returned [54] and will be reused.

If organisations are blood product producers only (like the Red Cross), they will not take back any kind of blood bag. In their annual report 2011, the General Account Office of Austria stated as follows (translated):
"The number of disposed blood preservations at the Public Hospital of Vienna in 2009 was around 3,000 (9.2%) and at the Public Hospital of Graz around 1,500 (7%). If only the production costs are taken into account, the monetary value of such wastage would be 390,000 Euro in Vienna and 181,000 Euro in Graz.

Such wastage is mainly due to lack of life-cycle temperature monitoring system, which cause huge difficulties (if not impossible) to track whether the blood bags are stored in an adequate way or not. …." [55]

2.2 Barcode Systems for Life Cycle Monitoring

2.2.1 Blood Bag Labelling

Barcodes have been used to identify blood products almost since its inception. For example, 'ABC Codabar' is the most popular system employed worldwide. In 2005, blood banks started to adopt the ISBT 128 barcode and today almost all the blood banks around the world have adopting this coding system to label their blood bags.
With the aid of this coding system, each blood product gets a unique identifier to ensure each blood bag is uniquely identified worldwide.

Figure 18: : Blood bag label used by the Austrian Red Cross based on ISBT128

The ISBT code is placed in the upper left corner of the 10cmx10cm label. The barcode must be equipped with 'readable' letters under the barcode. Technical details of the ISBT 128 code can be found on the ICCBBA homepage (www.iccbba.org).

The 13 numbers code consists of 3 parts. First part identifies the manufacturer, the second part represents the year of manufacturing, the last part represents the blood bag number itself.

At the end of the code a 2 digit flag (e.g. 44) is added. This flag indicates the use of the code. (e.g. <44> indicates a blood bag, <06> indicates a test tube).
The final letter ('Z') is the check sum.
The product specification consist of the primary product code followed by a letter (e.g. <V> for volunteer homologous donation). The final digits indicates the split number (e.g. for baby bags).

Product Spec	Description
E5258V00	Erythrocyte concentrate
E5262V00	Erythrocyte concentrate washed
E5260V00	Erythrocyte concentrate radiated
E5264V00	Erythrocyte concentrate washed and radiated
E5258100	Erythrocyte concentrate own blood
E4197100	Fresh Frozen Plasma own blood

Table 2: Example product specification

At each production step (described in chapter 2.1) the ISBT 128 code is used as a unique identifier for the information system. With the aid of a barcode reader system (stationary or LAN connected), additional information can be read from the information system.

Barcodes are sufficient to identify goods and can be read and interpreted with minor effort. Main disadvantage of barcodes is that they cannot store data and measure environmental conditions.

2.2.2 Patient Wristbands

Prof. Walter Dzik, head of the START (Saver Transfusion with Advanced Radio-frequency), investigated the use of special wrist bands to improve patient safety with focus on the patients who need blood transfusions. Patients' wristbands help the medical stuff to accurately identify a patient without confusion, which might lead to mis-handling of patients.

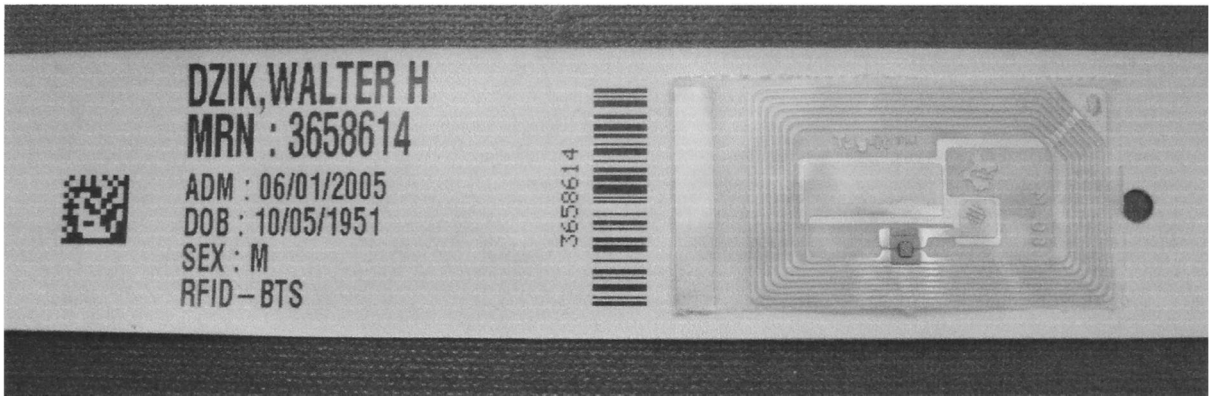


Figure 19: Example wrist band with one and two dimensional barcode and RFID [56]

Figure 20: Printing the wrist-bands [48]

Different options of barcode technologies (wristbands, labels, stickers) for transfusion patients have been evaluated in 2008 [57]. The wristband turned out to be the best way for patient identification. The most efficient way for identification of blood bags was the barcode label. The procedure of tracking transfusions is described as a flow chart in figure 25.

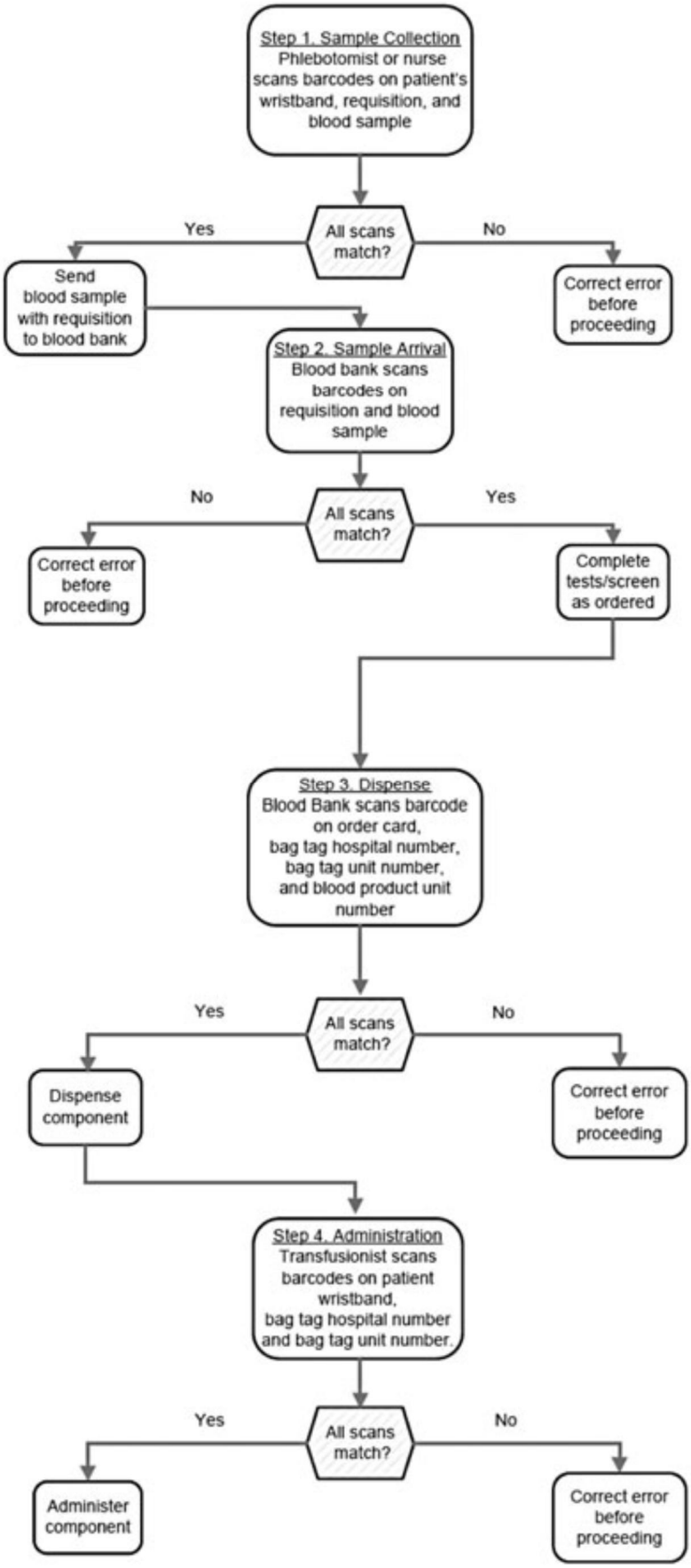


Figure 21: "Blood transfusion tracking" procedure

Medical personnel have been equipped with a hand held PC's [58], therefore, information is available directly at the patient's bed. The studies have taken place at the heart surgery department in Oxford [58] and reported a significant increase of patients' security when patients are equipped with appropriate barcoded wristbands.

2.3 RFID Systems for Life Cycle Monitoring

Macopharma, a manufacturer of blood bags, has added a passive RFID transponder on their blood bags.

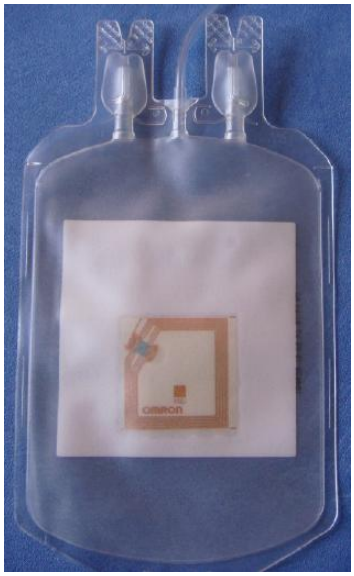


Figure 22: Ready implemented passive RFID [59]

The RFID system consists of an ISO 15693 compatible chip with a total memory of 128kB. Beside the serial number of the tag, the chip also carries information about application code, lot number, product reference, donation number and product code. Therefore it can be seen as an electronic version of a common barcode based paper label.

With help of this technology, the manufacturer can devise a trace back system. Blood bag can be traced back to each production step of the blood bag itself. Further armed with appropriate RFID equipment, medical institutions are able to use this chip to record information to further improve the safety and security of the blood bags.

2.3.1 Active RFID Systems

Active RFID system has the advantage of storing more information, which is vital for life-cycle information support. When such system integrated with the temperature sensors, more comprehensive life-cycle data of blood products can be monitored and logged. A study was conducted at the Shin-chon Severance Hospital in Seoul; a 2.4 GHz based temperature sensors was installed inside the cooling areas of the blood depot to record the room temperature. [60] A 13.56 MHz RFID tag integrated with temperature sensor is added on the blood bag system right after donation. Although the numbers of temperature measurements that could be saved in the tag at a time was limited to 64 values and frequent data retrieval must carry out throughout the life cycle of the blood bag, it does provide enormous benefits (e.g. wastage reduction) over the barcode and/or paper-based systems.

Another 2.4 GHz RFID based system integrated with temperature sensor is able to track temperature change at any stage of blood production. [61] This system is designed to hold significant blood bag data such as Rh-Factor, blood group, etc., and monitor the change of temperature throughout its life-cycle. Data transmitted by the tag are stored in an information management system and enables the user to get a clear history of the blood bag, from donation to the arrival in the blood bank. The measured temperature of this system is not sent in a regular interval but on demand to reduce the power consumption. The major disadvantage of this system is the acquisition of the life-cycle temperature profile is not guaranteed.

2.4 RFID / Barcode Combinations

Complex software solution, which integrates various database/functions to improve safety and efficiency of the care services has implemented in larger hospitals, including a mixture of barcode and RFID systems (marked red)

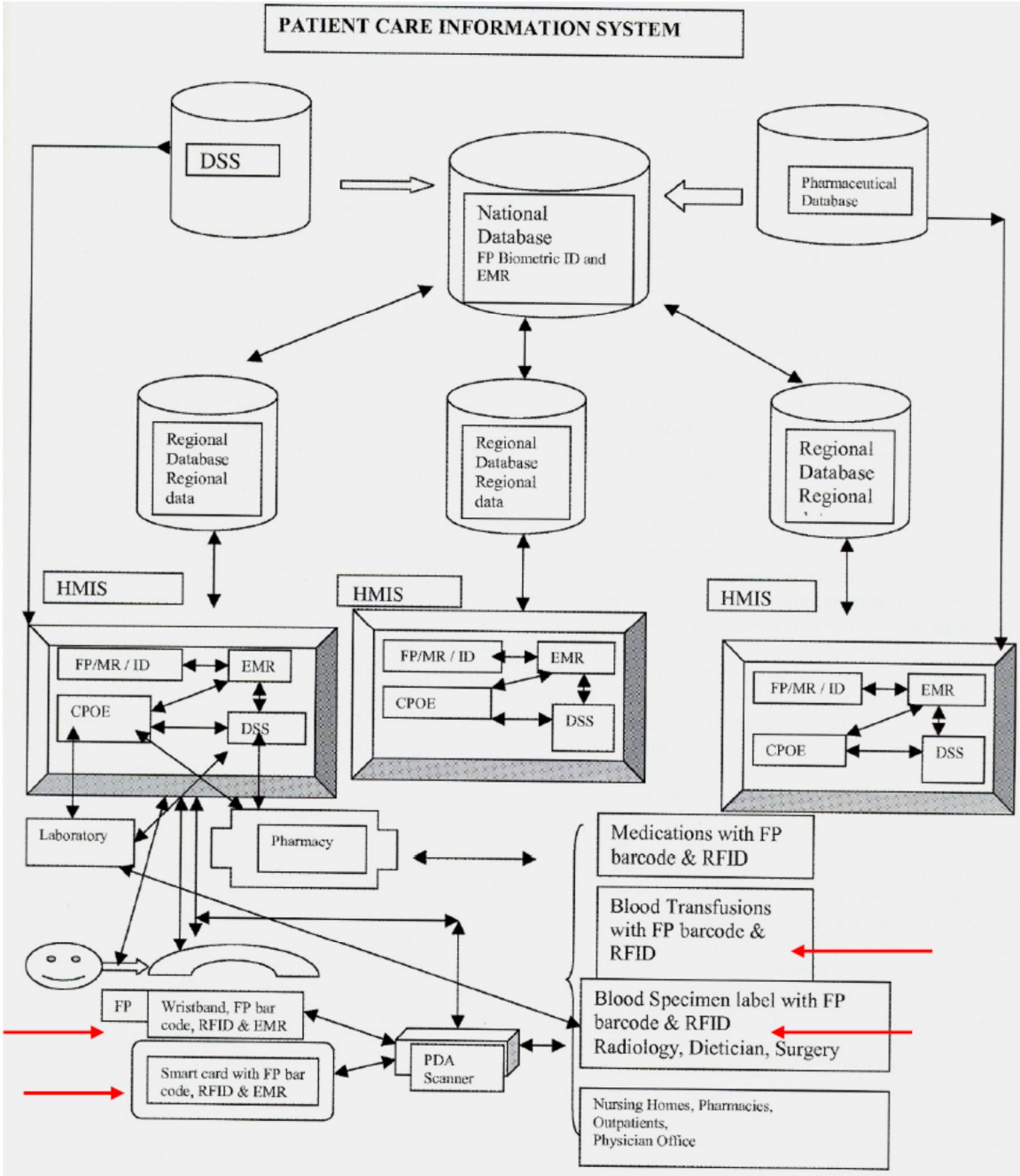


Fig. 6. FP = fingerprint; EMR = electronic medical record; MR = medical record; ID = identification. A total integrated patient care information network. The network, following biometric authentication of patient identification, accesses real time patient information through interface with healthcare provider database, regional and/or central database.

Figure 23: Computer based solution for safety improvement [62]

With reference to Figure 27, a network including all services of a hospital like blood handling, labelling of blood probes, blood transfusion control, etc. is implemented.

Equipped with RFID and barcode technology and the use of standard interfaces, communication between the medical IT systems can be enabled and significantly reduce human errors like mismatch. [62] Even this system includes only the transfusion part of a blood product's life cycle, it can be used as a base concept with which a life cycle system for blood products has to interact.

2.5 Radio Activators

The institute for integrated circuits at the Fraunhofer has developed and implemented activators or radio nodes onto the blood bags. The system consists of 'smart nodes', which are able to record environmental information such as temperature and location data. The collected information will transmit to an IT-system via the wireless network. The 'smart nodes' are integrated with power supply and work autonomously. The system is currently trialled at the hospital of Erlangen and could be ready for use within the next few years. [63]

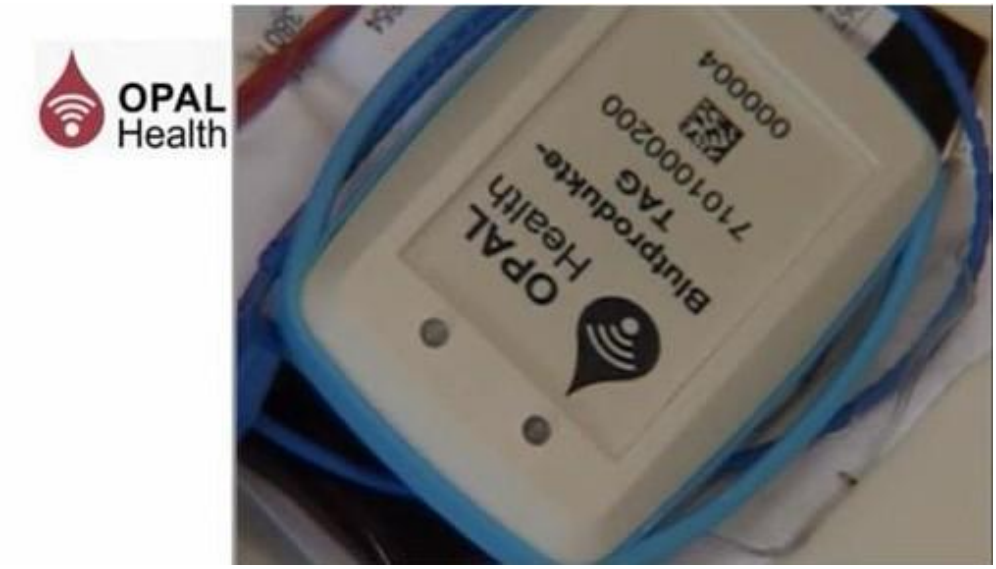


Figure 24: 'Smart node' (Opal – Health) system [63]

Main advantage of the 'smart node' system is minimising the interference of electromagnetic field. Interferences of medical equipment have to be taken in account when using electromagnetic waves greater than 13.56MHz. In 2008, the Journal of the

American Medical Association published the 'JAMA' studies. [64] It proofed interferences at medical instruments caused by electromagnetic waves. The active RFID tag used in 'smart node' system has an operational frequency of 868MHz and 2µW in power.

2.6 Conclusion

Many activities in the course of blood production still remain poorly recorded or completely undocumented. Data such as donors' questionnaire, donor medical test result, cross-check result, bedside test result, adverse reactions at transfusion are not electronically recorded and still hand written in paper forms. From donation to transfusion, blood bags will pass through different environments. Blood production, storage, testing, transport and transfusion will be carried out by different companies or interest groups. Blood bags will be transported between different places with diverse means of transportation. Blood bags will be taken out of temperature controlled areas number of times. There is no overarching method for tracing the life-cycle history of the blood products.

Different barcode technologies are used for blood bag and patient identification. Those systems are not able to store mass data such as life-cycle history of a blood bag. Active radio systems using frequencies greater than 13.56 MHz may risk to interfering with medical instruments. Radio activators send current data on demand to local servers without saving them to an on-board memory. Donation, production, storage, etc. is done on different places and by different interest groups. Data cannot be forwarded to the blood bank automatically. Therefore the blood bank depends on data input of many organizations. Within transportation, where most of temperature violations occur, no access to a server can be guaranteed.

As a result, blood bags remain uncontrolled in several stages throughout its life-cycle. This leads to the blood products such as erythrocyte concentrates that are prepared but not used for transfusion cannot be returned to the depot for reuse due to uncertainty and safety issues.

A life-cycle information system is required to capture the life-cycle data (e.g. temperature) of the blood products system, which allows high degree of transparency on the life-cycle. A high precise temperature sensor is needed as temperature variations are low (+/- 2°C).
Data transfer must be done with help of common RFID interface technology less or equal to 13.56MHz to avoid interferences to medical instruments. Also a frequency of 13.56MHz is able to transport data through blood. To ensure data completeness, memory capacity must be able to save more than 10,000 temperature / time values and other relevant blood production and handling data. A special firmware interprets each measured value and enables individual adjustments on the value - interpreting algorithm. This RFID label is integrated into a life cycle software application that interacts with existing medical IT-systems. With these identified functionalities, the identified problem will be tackle (i.e. reduce the wastage of blood products due to uncertainty).

3 Project Specification

3.1 Preconditions for implementation

3.1.1 The influence of thermal fluctuation on the quality of erythrocyte concentrates

Any blood bag stored at 37°C will cause a rapid deterioration of quality even if the blood is incubated just 2 hours after donation. [65] The question of the ideal storage temperature of whole blood has been discussed in an international forum. [66] Most of experts agreed that the storage of whole blood at ambient temperature should be limited to 24 hours. After this time period blood component separation should have been completed.

An issued but unused blood bag will shorten by a third of its remaining life time when it returns to the blood bank due to the fluctuation of the temperature it endured (i.e. from cool storage area to ambient temperature and then returning to cool storage area) [49] Monitoring of special cooling chambers and refrigerators for blood products are already regulated by international and national laws. Nevertheless, regulations or laws concerning the monitoring of individual blood bag throughout its life-cycle are still missing.

The current requirement of storing erythrocyte concentrates is at 4°C +/- 2°C in special cooling areas. Those areas must be free of vibration and all of them have an automatic temperature monitoring system today. These systems will alarm the personnel in case of any temperature violation. Temperature monitoring of individual blood bag is not mandated and unlikely carried out in the blood banks today. When the process of cross match has to carry out on the required blood bag, it will withdraw from its storage area and overarching temperature documentation is not possible with the current practices. The similar situation occurs when the blood bag is transported to other blood depots or recipient's station. This is the key reason why significant numbers of physicians in blood bank demand a monitoring system that is able to track and monitor the temperature of individual blood bag to ensure it is safe to use by the recipient. Procedural specification

As a best case scenario the SAG-M bag (The bag that holds the red blood cells after separation) of the blood bag system will be equipped with an active RFID transponder. The supplier of the systems saves the following information on the chip:

- Supplier ID
- Lot Number
- Date of expiry
- Specification like suggested from ICCBBA for ISBT 128 code. [67]

Each donor will be equipped with an RFID donor identification card. This card has a bank card size with the photo of the donor on it. Before donation the donor ID is written to the blood bag RFID system. The timestamp and donation number are also recorded into the RFID tag. The donors will sign with their ID-cards when they have completed the electronic questionnaire. The results of the medical check as well as the signature and clearance of the physician will also be transferred to the RFID based system.

Figure 25: Information Collection at the Donors Admission Area

Today many blood transfusion service centres support their donors with proprietary donor cards. Interoperable problem occurs when each service centre uses their own card system (i.e. blood service centres cannot exchange information electronically).

When each donor is equipped with an RFID based donor card, information will be saved in a standardized format which will facilitate electronic information exchange between blood service centres. Besides the common personal data like name, date of birth and address, other important data could also be recorded.

- ABO group and Rhesus factor
- Date and time and location of last donation
- Medical data of last donation (blood pressure, haemoglobin, pulse, …)
- Legal electronic signature

Each blood service centre is equipped with a special terminal. There and/or over the internet each donator takes a look to his/her medical data or latest laboratory results. As the card has an electronic signature included, the donor questionnaire can be easily signed by the donor.

Also the medical personnel are equipped with an RFID card. This card must also be equipped with a legal electronic signature which allows a paperless and easy admission of donors.
With help of the donor ID – card, the lapsed period after the last donation of blood can be checked. With the aid of a RFID reader, an unique link between donor, blood bag and test tubes can be guaranteed. The medical personnel are verified with their RFID card to ensure security and tracking. Data and their signature are also transferred to the RFID chip on the blood bag system.

The weighting and mixing machine is equipped with an RFID reader. In case any data is missing, the machine will not start and alerts the medical crew. Simultaneously the documentation of donation time, blood volume and the name of the phlebotomist will be carried out automatically.

When the donation process starts, the temperature will be recorded by the RFID chip on the blood bag system. As whole blood is expected to be around 37°C the threshold parameters are set as follows[13]:

Name of Category	Donation
Upper absolute limit	37.5°C
Upper relative limit	36°C
Lower relative limit	23°C
Lower absolute limit	21°C
Interval	30 seconds
Positive Threshold	2°C * min
Negative Threshold	3°C * min
Start Delay	60 seconds
Premature stop	0 seconds

Table 3: Temperature Parameters at Donation

Temperature recording is started immediately after punctuation. The start delay represents the time the medical personnel needs for filling the test tubes and redirecting the blood stream into the blood bag system.

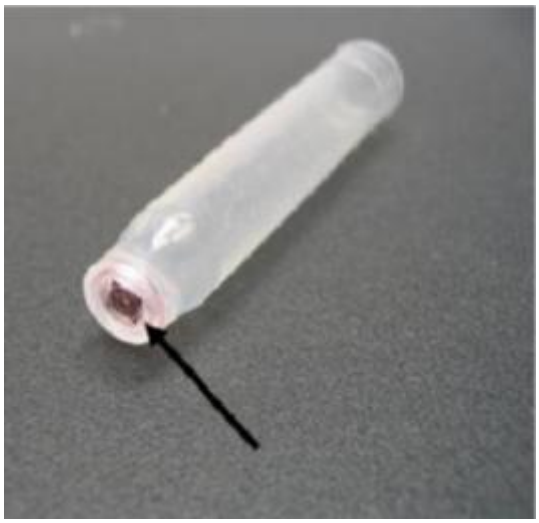


Figure 26: RFID chip on the bottom of the test tube

[13] A precise description of the RFID chip's measurement and parameter system will be described later in the technical part

Instead or in addition to a barcode, each test tube is equipped with a passive RFID transponder. The unique number of the tube is linked to the blood bag system and the donor number. The tube numbers will be saved on the RFID chip of the blood bag system.

The RFID tag can be used for unique identification of the blood bag within the laboratory environment. Today, the analysing machines are equipped with RFID readers and able to support fully automatic and paperless systems. Test data will be transferred back to the blood bank in an electronic way (like it is carried out today).

The most important data like donation duration time, volume taken and documentation of unwanted effects will be written to the RFID tag. The RFID tag will use the same technology as the one included into the scale system. In this case the ID-number of the scale and the donation data that is taken by the scale will be transferred to the RFID chip.

At this stage, a data transfer to the computer system could take place, as any important data of the donation is stored and carried by the RFID tag that is placed on the blood bag.
Before cooling down the blood bags and taking them into the transportation boxes a new temperature measurement is started. As the cooling down phase will be around 15 - 20 minutes the delay time is set to this value. The RFID tag must be placed on the top of the blood bag, when it is put on the cooling plate.

Name of Category	Whole Blood Transportation
Upper absolute limit	26°C
Upper relative limit	24°C
Lower relative limit	20°C
Lower absolute limit	18°C
Interval	1 minute
Positive Threshold	2°C * min
Negative Threshold	2°C * min
Start Delay	15 minutes
Premature stop	0 seconds

Table 4: Temperature Parameters for Whole Blood Transportation

The transportation box is equipped with a barcode or ideally with an RFID. The identification of the box will be written to each blood bag that is put into. When the number of the box is transferred, a timestamp is taken to enable transportation time tracking.

The goods reception is equipped with a barcode scanner, a RFID reader/writer and a computer system, where any persons who receive goods must log on with their identification and password. The computer is connected to the local blood bank software. When the blood bags arrived the blood depot, all the blood bags have to pass a visual quality check to avoid major damages or leakages on the blood bag system. Each blood bag will be put on a reader is now automatically registered to blood bank software. This means that first of all the unique number of the bag system; the RFID tag and the test tubes are transmitted. For validation issues the number of the blood bag is double checked by reading the label with the aid of a barcode scanner. Now any other data can be transferred to the blood bank software. The medical personnel also check the temperature curve of the RFID tag. Here the measured values must be in range, but also the parameters of the temperature curve have to be checked. This ensures quality of blood bag after the transportation. Finally the medical personnel signs with his/her electronic signature. Both, signature and timestamp will be saved on the RFID tag.

Within a minimal solution the temperature measurement will not be interrupted at the goods receipt, as the storage conditions have not changed. In normal cases whole blood will be stored at overnight (but with a maximum time of 24°C) at an ambient temperature of 22°C +/-2°C.

As the blood bags will now be transferred to a controlled area, a measurement interval of 1 minute is no longer necessary. Hence the whole blood transportation period will be stopped and a new measurement will be started. On the other hand the start delay can be set to zero.

Name of Category	Whole Blood Storage
Upper absolute limit	26°C
Upper relative limit	24°C
Lower relative limit	20°C
Lower absolute limit	18°C
Interval	15 minute
Positive Threshold	2°C * min
Negative Threshold	2°C * min
Start Delay	0 minutes
Premature stop	0 seconds

Table 5: Temperature Parameters for Whole Blood Storage

At the stage of component separation the number of the centrifuge used is documented and written to the RFID tag. Also the program selected as well as the personnel who started centrifugation and a timestamp is saved on the RFID transponder.

After centrifugation the number of the squeezing machine is documented on the RFID tag. The identification of the person in charge and a timestamp will be written to the RFID tag. Finally the filtration process will be documented by transferring the personnel ID, a timestamp and the duration to the RFID transponder. Ahead of each step of the production the temperature curve will be checked. Each bag is visually controlled if the treatment caused any damage onto the bag system.

Now the whole blood storage period is over and the measurement will be stopped. The erythrocyte concentrates will now be stored at a controlled cooling room within a temperature of 4°C +/-2°C. Hence a new measurement has to be started after the separation process.

Name of Category	RBC Storage
Upper absolute limit	10°C
Upper relative limit	6°C
Lower relative limit	2°C
Lower absolute limit	0°C
Interval	15 minute
Positive Threshold	2°C * min
Negative Threshold	2°C * min
Start Delay	20 minutes
Premature stop	0 seconds

Table 6: Temperature Parameters for RBC Storage

After separation the erythrocyte concentrates will be stored in an interim storage as in normal cases the results of the blood tests are not available at this time.

As any relevant data is saved on the RFID tag of the blood bag, any mismatch can be eliminated during the course of laboratory blood tests. After the label is fixed on the bag, the blood bag ID is read with help of a barcode scanner. At the same time the bag ID that is stored on the RFID is identified by a reader. In case of any mismatch the systems informs the operator with help of visual and acoustic signal.

During the labelling procedure any data that is written on the label will be transferred to the RFID tag. The cleared product is now ready for future use.

Before transport the temperature curve, the RFID has to be checked. The correctness of storage condition, as well as other quality issues (like e.g. the blood bag has no damages, haemolysis rate is ok …) has to be accepted by the recipient. Running measurements will be stopped and a new series is started with the following parameters:

Name of Category	RBC Transport
Upper absolute limit	10°C
Upper relative limit	4°C
Lower relative limit	2°C
Lower absolute limit	0°C
Interval	30seconds
Positive Threshold	2°C * min
Negative Threshold	2°C * min
Start Delay	0 seconds
Premature stop	0 seconds

Table 7: Temperature Parameter for RBC Transport

The sample probe of the recipient is equipped with a passive RFID tag which can be the same as the one used for the test tubes. Any patient data needed is saved on this tag before it is handed to the blood depot. At the depot the data resided in the RFID transponder is read and automatically transferred to the blood bank software which enables the selection of appropriate blood bags for cross matching.

When the blood preservation is taken out from the depot, its data is read out and an automatic linkage to the probes will be carried out. The result of the cross match will be written on the RFID tag of the blood bag. Now the RBC will be transferred to a special consignment stock which is specially designed to store cross matched blood bags. Here the temperature will be the same as in the blood depot (4°C +/-2°C). Before the blood bag is forwarded to the station or the operating room, the temperature recording is stopped. The system and the medical personnel check the data and the thermal correctness of any conditions the blood bag went through in the past. A delivery note will be produced and saved on the RFID as well as the electronic signature of the medical personnel who handed out the blood bag. A new temperature recording will be started with the following parameters:

Name of Category	RBC Delivery
Upper absolute limit	10°C
Upper relative limit	4°C
Lower relative limit	2°C
Lower absolute limit	0°C
Interval	30 seconds
Positive Threshold	5°C * min
Negative Threshold	5°C * min
Start Delay	0 seconds
Premature stop	20 minutes

Table 8 Temperature Parameters for RBC Delivery

Even for short transports like from the depot to the station a 4°C (+/-2°C) temperature condition cannot be guaranteed. The premature stop is set to 20 minutes that represents the warm up time of blood before transfusion.

Each patient who will receive blood carries an RFID based wristband, where all relevant patient data is stored. When the blood bags are arrived to the patient's bed and ready for transfusion, the patient's data on the RFID will be cross checked with this wristband. This will disable any confusions and each patient will receive the correct blood bag.
The result of the final ABO test will be saved on the RFID where the medical personal that performs this test will sign it with help of an electronic signature. The documentation of the transfusion is automatically transferred to the haemovigilance register.

The haemovigilance - register is a collection of any possible problems that might occur during or after a transfusion. It consists of the following error reasons:

- Near Miss Event
- Febrile non- haemolytic reaction
- Reaction due to allergies
- Haemolytic reaction
- Alloantibodies, delayed haemolytic reaction

- Bacterial contamination
- TACO (Transfusion associated circulatory overload)
- TRALI (Transfusion related acute lung injury)

After the transfusion, the blood bag's RFID transponder is stopped. All the data resided in the RFID tag is transferred to a central database.

Unused blood bags will be returned to the blood depot. They arrive at the receiving department and will be integrated to the life cycle again.

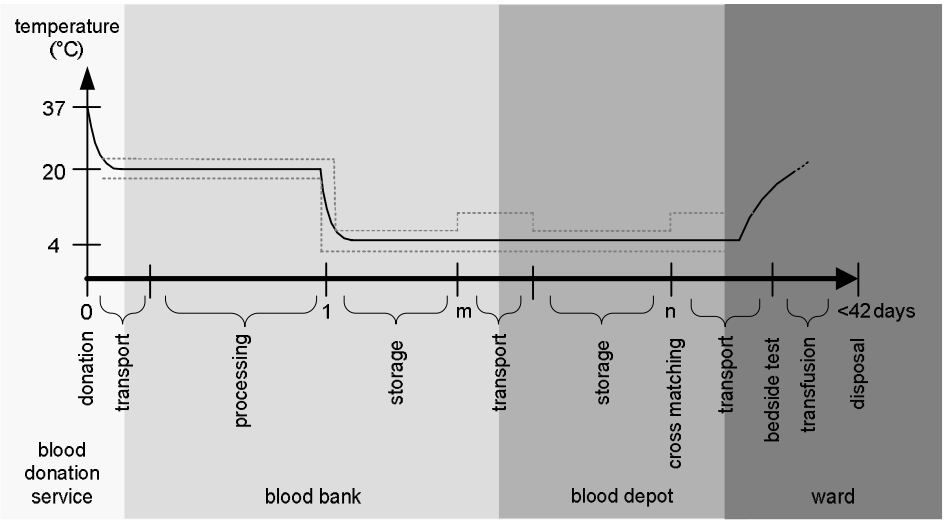


Figure 27: The ideal Temperature Course for RBCs

3.2 Technical Specification

3.2.1 Preconditions for implementation

3.2.2 Active RFID Transponder for RBC monitoring from vein to vein

Radiofrequency identification (RFID) technology is emerging as one of the most pervasive electronic technologies due to its broad applicability. The advantages of RFID technology and its potential benefits of improving safety, quality, productivity, and responsiveness in the delivery of care to patients have not gone unnoticed by the blood banking and transfusion medicine communities. [68] [69] [70] [71] [72] Blood centres, clinics, and industry are engaged in the investigation to research actively, develop, and introduce application of RFID for identification, tracking, and status monitoring of blood products in the supply chain from the point of collection (donation), through manufacturing to delivery of a product by a health care provider to patients. [73] Storage of red blood cells (RBCs) is a routine procedure worldwide. Due to on-going research in the past 100 years RBC storage was extended from hours to 6 weeks. [74] Depending on the additive solution (AS), RBCs in phosphate-adenine-glucose-guanosine-saline-mannitol or in other ASs could be stored at 4 - 2°C up to 49 days maximally. [75] According to European and American guidelines, transport temperature of RBCs should not exceed 10°C. [76] [77] [38]

Due to the lack of temperature monitoring and subsequent quality control the shipped RBCs cannot be returned to the blood depots. A unit is required that can do both: measurement of temperature and data acquisition of each RBC unit throughout the entire life cycle. [78] Based on the data saved the decision of discarding or further using the blood bag is supported.

4 Design and Implementation

Design and implementation of this project was done by several groups. All medical inputs came from the blood bank of the University Clinic in Graz (Austria). Hardware design and implementation was done by the University of Applied Science in Offenburg (Germany). The author was responsible of the overall project management and implementation of RFID firmware, RFID design, components/sub-systems selection, programming and implementation of the operator software. The author is also responsible of the design and management of the field trial.

4.1 Overview of the life-cycle management system

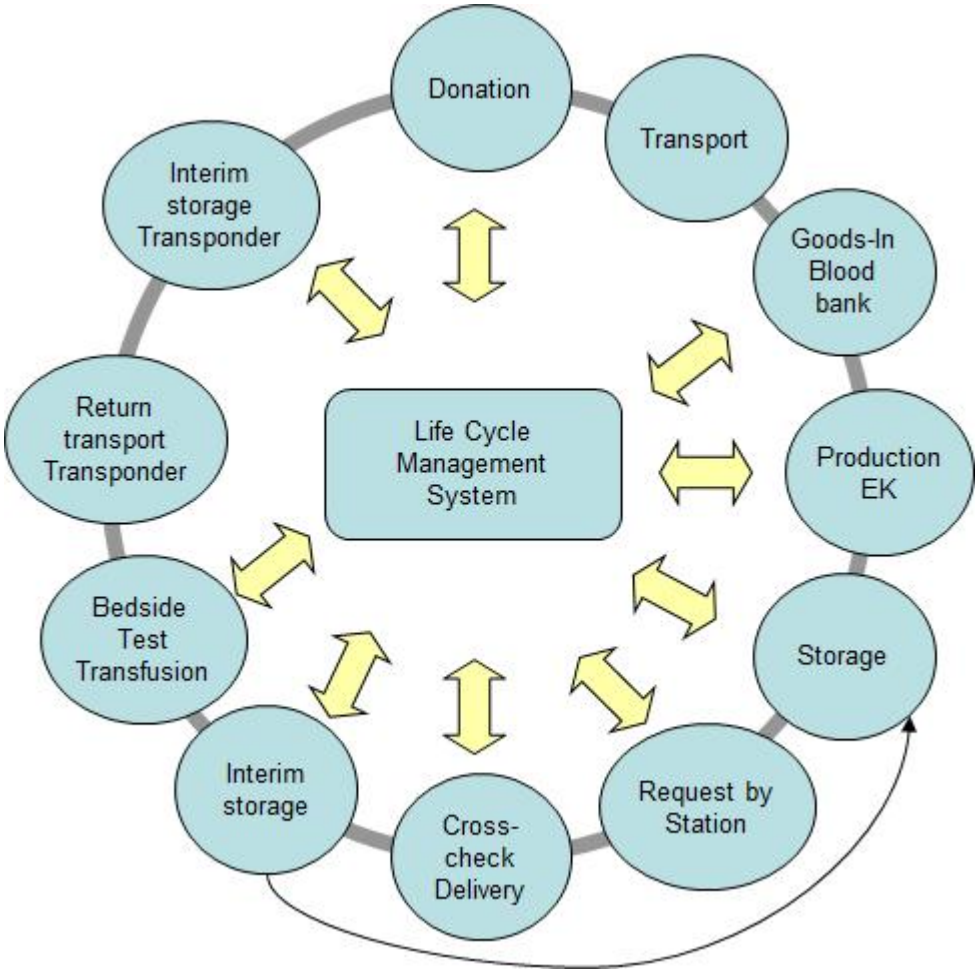


Figure 28: Stages of blood production

Core function of a life cycle management system is to receive and provide data to any stage of the blood supply-chain.

Each stage requires at least one mobile or stationary RFID reader to retrieve information from the active RFID tag that records environmental conditions, and also used as external data storage. This is a necessity as different stages of the life cycle are managing by different interest groups.

Process Stage	Interest group
Donation	Red Cross Blood Bank Third party hospital Third party provider
Transport	Red Cross Blood Bank Private forwarder Taxi ….
Good In / Blood Bank	Blood Bank
Production of erythrocyte concentrates	Blood Bank Third party provider
Storage	Blood bank
Blood requisition	Hospital (Surgery, Intensive station, …)
Cross Check Delivery	Blood Bank
Interim Storage	Blood Bank Hospital (Surgery, Intensive station, Pharmacy)
Bedside Test / Transfusion	Hospital (Surgery, Intensive station, …)
Return Transport of transponder	Hospital ((Surgery, Intensive station, …) Blood Bank Private forwarder …
Interim storage of transponder	Blood Bank

	Red Cross

Table 9: Interest groups within the blood production

Interest group refers not only different organisations, but also different departments or cost centres within an organisation such as a hospital. It also needs to point out, which most of these interest groups are employing different information systems without concern interoperability. The proposed life-cycle management system must able to interoperable with these information systems to enable data to be collected and analysed in the blood bank.

Each stage within the supply-chain will be equipped with a minimum of one PC / RFID Reader combination.

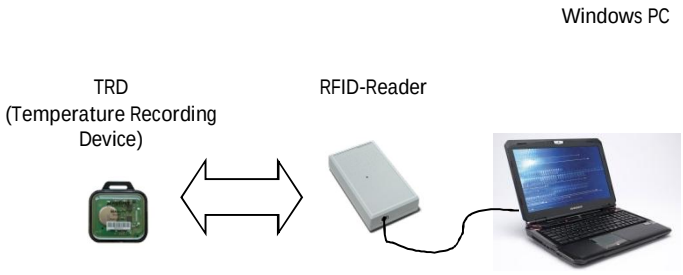


Figure 29: Minimum equipment for each station in various stages of the supply-chain

For a PC any common of the shelf PC or laptop may be used. The PC should at least have a hard disc capacity of 100GB and 2GB RAM. The life-cycle management system requires a standard Windows XP or Windows 7 operating system. The RFID reader can be any ISO15693 compatible reader. Similar combination in mobile devices can also be adopted such as handheld or tablet based PC with built in RFID readers.

4.2 Management System Architecture

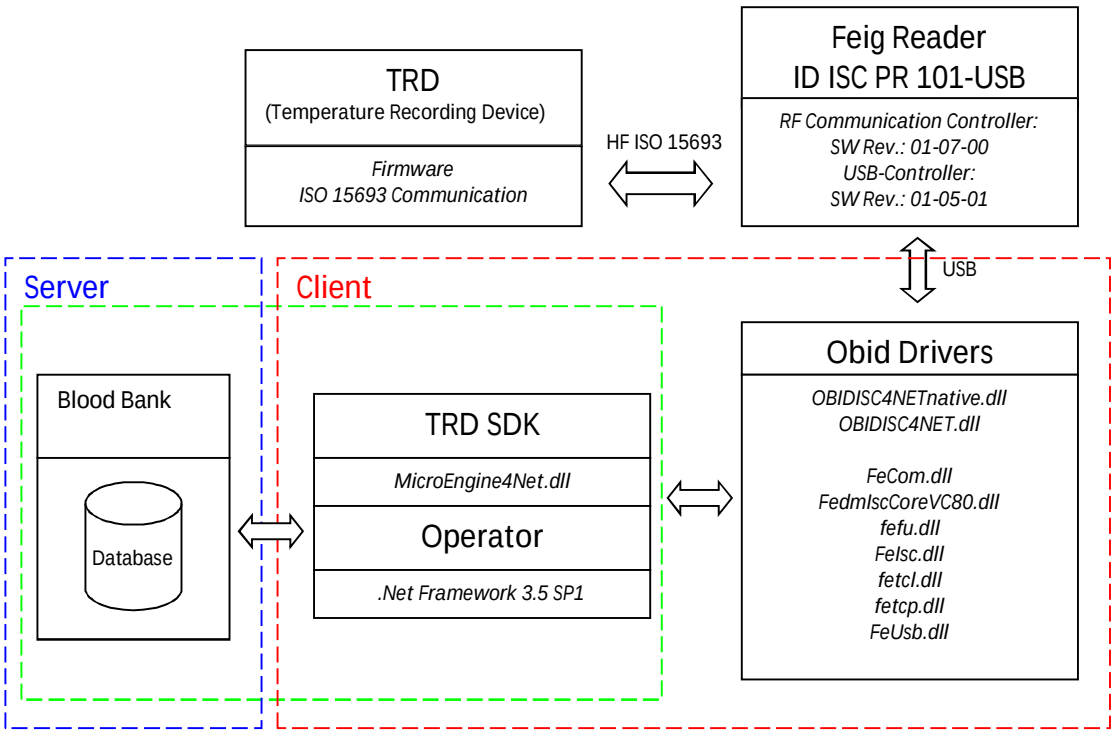


Figure 30: Management System Architecture

The key requirement of the proposed life-cycle management system is to retrieve information from the active RFID temperature sensor which is called 'Temperature Recording Device' (TRD). For this reason the client software called *Operator* is designed as a central element.

The life-cycle management system may interact with existing blood bank software systems like e.g. eProgesa®, Blues®, etc. The life-cycle management system then acts as client with direct access to the blood bank database.

4.2.1 RFID reader and OBID drivers

Figure 31: Feig RFID reader

Dimensions (W x H x D)	85 mm x 145 mm x 31 mm
Weight	200 g
Protection	IP30
Housing	Plastic ABS
Operating frequency	13.56 MHz
Transmitting power	0.5 W ± 2 dB
Supply voltage	5 V DC (via USB)
Current consumption	maximum 0.5 A
Power consumption	maximum 2.5 VA
Antenna	Integrated
Read range	maximum 18 cm
Interface	USB
Indicators, optical	1 LED multicolour
Supported transponders	ISO 15693 (ISO 18000-3 MODE 1)

A crucial factor of the selected RFID reader is the requirement of short reading distance. In medical application there are concerns about the issue that the electromagnetic field generated by RFID may lead to unwanted interactions with life sustaining machines. Therefore the reading distance (and therefore the radiation range) must be kept as short possible. A common off-the-shelf RFID reader (ID ISC PR 101-USB) is chosen for the development of system prototype to support the test and validation. The reader is a common RFID reader that complies with the ISO 15693 regulations.

4.2.2 Sensory RFID sensor with integrated file system

Blood is collected with great effort and stored in a Blood Centre and distributed until it enters the vein of another human body. In this logistic chain from “vein to vein“, the blood product must be kept in temperature controlled areas, until it is re-warmed and given to the appropriate patient. Most importantly, various identification data, date of production, type of blood, etc. must accompany the blood bag in all time to avoid any misuse. Currently, some of these data are printed on a paper and attached on the blood bag. A survey of existing RFID transponders with or without sensor logging capability showed that not one of them meets the requirements to sustain 5,000 g in the centrifuge process. Also the medical requirements on hermetical sealing, and skin compatibility and storage of complex data storage cannot be fit by stage of the art transponders. [79]

The life-cycle support for the blood bags require storing more than 30,000 temperature measurements and maintain for a long period of time. During its life-cycle, the blood bags will be influenced by different actions and their immediate environmental. The temperature sensor must provide accurate and precise measurements over a wide temperature range. A precise clock is necessary to maintain a correct and precise registration of violation events like exceeding temperature limits. Storage space for additional customer data has to be provided and secure access must establish to avoid unauthorised access. Methods and mechanisms are needed to assure the consistency of the data, methods that have moreover to comply with international standards. [80]

To ensure all this functionality a programmable embedded processor system must be used, containing a flash memory device and related peripherals. Using the RFID air interface standards, a frontend has to be added, which fulfils the detailed specified requirements of the ISO 15693 standard. [81] Complying with the standard allows the use of widely commercial available RFID readers (i.e. FEIG OBID i-scan HF or SIEMENS Moby D) to communicate with the transponder. [82] The system prototype is built with the following components:

- Front end [14](discrete or integrated)
- Processor
- Sensor and storage
- Firmware (embedded software)

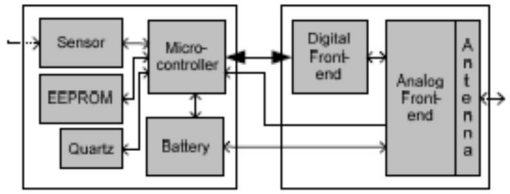


Figure 32: Transponder Hardware, Backend (left), Frontend (right)

The transponder can be divided into two parts: hardware and firmware. The hardware consists of a front end, connected to a microcontroller. The frontend complies with the ISO 15693 standard requirements [83] [84] and is carried out in a semi-discrete way with some analogue components and a CPLD (computer programmable logic device), containing the time critical digital circuitry. In future, it is possible to fully integrate the component into one single chip (ASIC) to improve the reliability and reducing the cost.

4.2.2.1 Components of Sensory RFID Sensor

4.2.2.1.1 HF Front end

- Voltage controller to maintain 1.8V (operating voltage of frontend): Linear LT1761-1.8 [85]
- Analogue front end
- Digital front end (CPLD): XC2C64A (Coolrunner 2) [86]

4.2.2.1.2 Microcontroller

ATMEL atmega164pv [87] has been chosen because its low power consumption, which is one of the most important requirements to the RFID system. It also equipped with a JTAG

[14] The front end is responsible for collecting input in various forms and processing it to conform to a specification the back end can use. The front end is an interface between the RFID reader and the back end.

interface that is used for inter-system communication. Other characteristics of the microcontroller are:

- High-performance, Low-power AVR® 8-bit Microcontroller
- Advanced RISC Architecture
    - 131 Powerful Instructions – Most Single-clock Cycle Execution
    - 32 x 8 General Purpose Working Registers
    - Fully Static Operation
    - Up to 20 MIPS Throughput at 20 MHz
    - On-chip 2-cycle Multiplier
- Nonvolatile Program and Data Memories
    - 16/32/64K Bytes of In-System Self-Programmable Flash Endurance
    - True Read-While-Write Operation
- JTAG (IEEE std. 1149.1 Compliant) Interface
    - Boundary-scan Capabilities According to the JTAG Standard
    - Extensive On-chip Debug Support
    - Programming of Flash, EEPROM, Fuses, and Lock Bits through the JTAG Interface
- Peripheral Features
    - Two 8-bit Timer/Counters
    - One 16-bit Timer/Counter
    - Real Time Counter with Separate Oscillator
- Special Microcontroller Features
    - Power-on Reset and Programmable Brown-out Detection
- Operating Voltages
- 1.8 - 5.5V for ATmega164P/324P/644PV
- Speed Grades
- ATmega164P/324P/644PV: 0 - 4MHz @ 1.8 - 5.5V, 0 - 10MHz @ 2.7 - 5.5V
- Power Consumption at 1 MHz, 1.8V, 25°C for ATmega164P/324P/644P
- Active: 338/398/TBD µA
- Power-down Mode: 0.035 /0.027/TBD µA
- Power-save Mode: 0.5 /0.5/TBD µA (Including 32 kHz RTC)

4.2.2.1.3 Battery

A modified Renata CR2430 3V, 285mAh lithium coin cell battery is used. The battery is modified by the supplier as it must sustain the blood centrifuge at 5,000g for up to ½ hour. Overall lifetime exceeds 3 years at a temperature range of -30 to +60°C.

4.2.2.1.4 Sensor

The DS620 digital thermometer and thermostat provides low-voltage (1.7V _ VDD _ 3.5V) temperature measurements with +/- 0.5°C accuracy from 0°C to +70°C and an operating temperature range of -55°C to +125°C. The DS620 communicates over a 2-wire digital interface. The DS620 has thermostat functionality with user defined thresholds stored in EEPROM, and it can be configured for standalone thermostat operation. The programmable output (PO) pin serves as the thermostat output, and this pin can also be configured to function as an active-low control for peripheral devices. [88]

Sensor features

Low-voltage operation: 1.7V to 3.5V

0.5°C accuracy from 0°C to +70°C operating temperature range: -55°C to +125°C

Temperature measurements require no external components

Resolution is user-selectable to 10-, 11-, 12-, or 13-Bits (0.5°C, 0.25°C, 0.125°C, and 0.0625°C (12 bit version is used)

Fast (200ms max) Temperature-to-Digital

Thermostatic Settings are User-Definable and non-volatile

Standalone Thermostat Capability

Data is read / written through a 2-wire serial interface

a) The key factors to choose this components are:The DS620 uses Band gap base emitter technology for measurement. Therefore no calibration is needed throughout the whole lifetime of the transponder
b) The linearity of measurements (see Appendix 5: Proof of Linearity) has been tested and remained accurate and precise over the temperature ranges where red blood cells are handled.

4.2.2.1.5 EEPROM

The Temperature Recording Device (TRD) has to store measurement data, common file data like measurements, blood bag id, etc. and system data like software version, transponder id, etc. Therefore, sufficient memory space must be implemented. The chip must have an I^2C to communicate with the microprocessor. The ST M24C512-R EEPROM [89] was chosen because of the following key characteristics:

- M24512-R: 512 Kbit EEPROM addressed through the I2C bus
- Supports the I2C bus modes:
    - 1 MHz Fast-mode Plus
    - 400 kHz Fast-mode
    - 100 kHz Standard mode
- Supply voltage ranges:
    - 1.8 V to 5.5 V
    - 2.5 V to 5.5 V
- More than 1 000 000 write cycles
- More than 40-year data retention

As the memory has to save measurement data, common ASCII data and system data; a novel data structure for transponders was designed and implemented on the prototype. Please refer to Appendix 4: Data organisation and structure for mass data on RFID transponders for detailed information.

4.2.2.1.6 Real-time clock

The real time clock used has the following features:

- Accuracy/Drift $+-10^{-4}$ (5min over 42d)
- External Quartz (Fox Electronics FX135 [8]) as input to Timer/Counter2
- 32768 kHz
- Accuracy +-20ppm

4.2.2.2 Firmware

The front end interface to the microcontroller runs the firmware and manages the data sampling of the sensor devices. The firmware implemented with the RFID communication protocol and it is not time critical. Time critical function will be handled by routines running on the CPLD or internal logic of the front end. Data is stored in a customised file-system. The command protocol is based on the standard ISO commands, using the basic commands like 'Inventory Request' and 'Select' for interoperable support. Any communication that exceeds the 'identification level' requires a login and special defined commands, which are known in the standard as 'customer defined extensions'. These commands can be transmitted, if the RFID reader is able to process the 'transparent command' which is supported by majority of commercial RFID reader in the market. Collision detection and processing according to the standard where up to 8 transponders or even more can be handled simultaneously. The identification process via the 'inventory request' command requires no additional software and will be sufficient for many intermediate read outs in the supply chain.

The communication protocol between the transponder and a (e.g.) PC is implemented in a .net DLL. This dynamic library can be integrated into a Microsoft Visual Studio project and supports the use of hardware independent programming languages such as Visual Basic and C#. Therefore, programmers will not require to have detailed knowledge about the communication process.

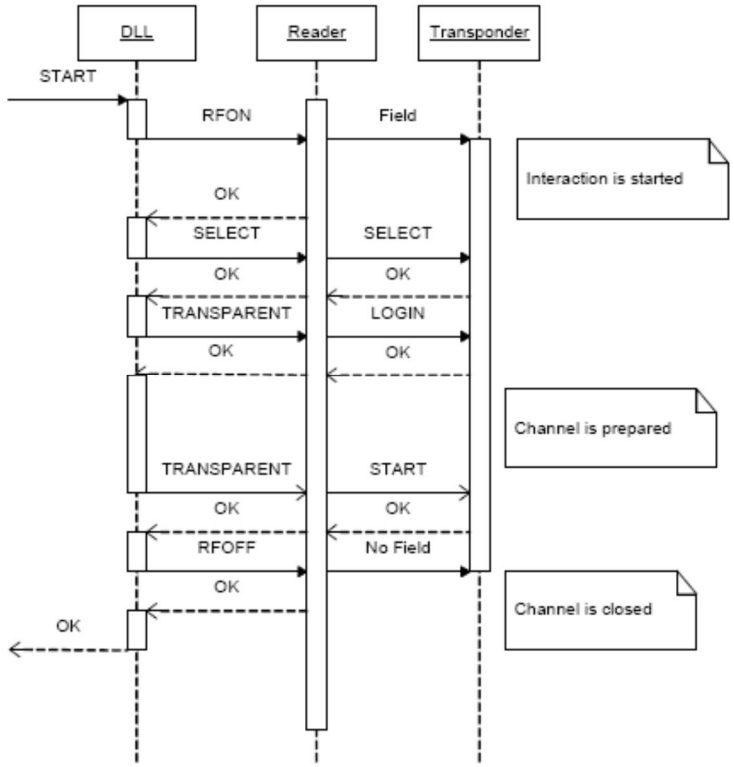


Figure 33 Basic Communication protocol between the transponder and RFID reader

The interface software sends a command sequence through a USB or serial interface to the RFID reader. The command sequence is followed by the 'Select' and 'Login' command, carrying predefined data. By acknowledging the successful login the connection between the PC and the transponder is established. Any further command sent via the RFID reader to the transponder will be served by the transponder. If any error encounter, an error message will be acknowledged. If the transponder moving away from the RF field, the RF field has switch off, or communication timeout, the communication channel will be closed. The DLL supports synchronous programming and manages all operations in time. Data transmission integrity is ensuring by CRC that is defined at the ISO standard.

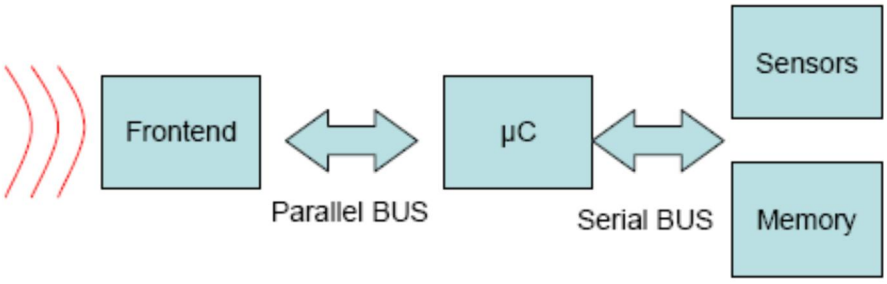


Figure 34 Block diagram of RFID transponder

The microprocessor controls all the connected peripheral components. A high precision sensor communicates with the microcontroller via a local serial bus system (SPI or I^2C bus). [90] This bus system also connects the microcontroller with the memory. The low data transfer rate of the ISO 14693 air interface standard of only 24kbit/s has to be taken into account when choosing memory capacity. Due to this low data rate, the data transfer time takes approximately 40 seconds for 64kByte. Hence, memory capacities higher than 64kByte will lead to unacceptable performance. The core RFID communication functionality is implemented in the front end. A mixed signal circuit design is used where the logical functions are implemented in a CPLD. The circuit is designed for very low power consumption. This is necessary as the transponder is reusable and can therefore be used for many years. RFID front end and microcontroller are connected with the aid of a proprietary parallel 8 bit bus.

Any real time access is processed in the digital part of the front end. Time non-critical protocol layers are implemented in the controller software. Time critical functionalities are implemented in the CPLD. There exists no first in – first out (FIFO) memory. Data transfer from the front end is carried out byte wise and interrupt controlled. Other protocol issues are performed by the firmware.

The firmware itself can be divided into four key parts:

- communication engine,
- file system,
- update loader and related,
- Hardware abstraction layer (HAL).

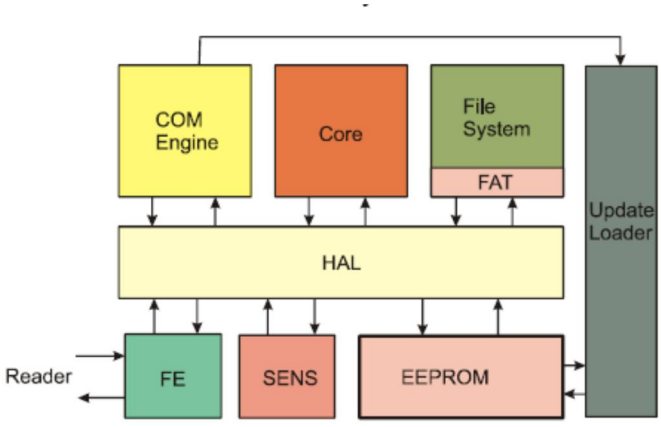


Figure 35 Firmware structure

The largest part of the program is used for the RFID communication, Communication Engine and the related HAL. The RFID front end device provides control signals, i.e. external interrupts, for the microcontroller. Events on the wireless interface will trigger processes in the firmware. To manage all these processes, an event queue is designed and implemented

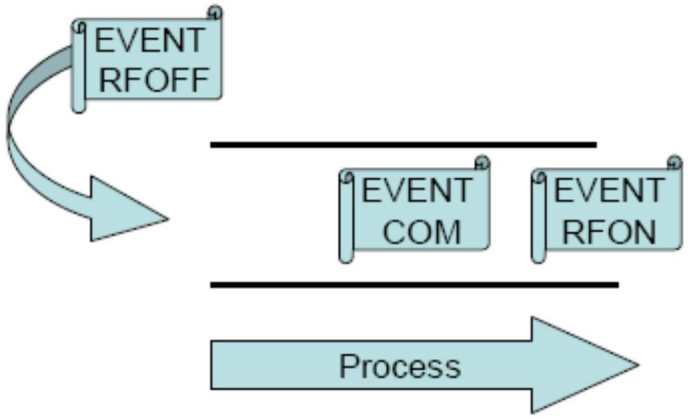


Figure 36 Event queue: working principle

All events from the front end are managed by an interrupt control mechanism throughout the communication.

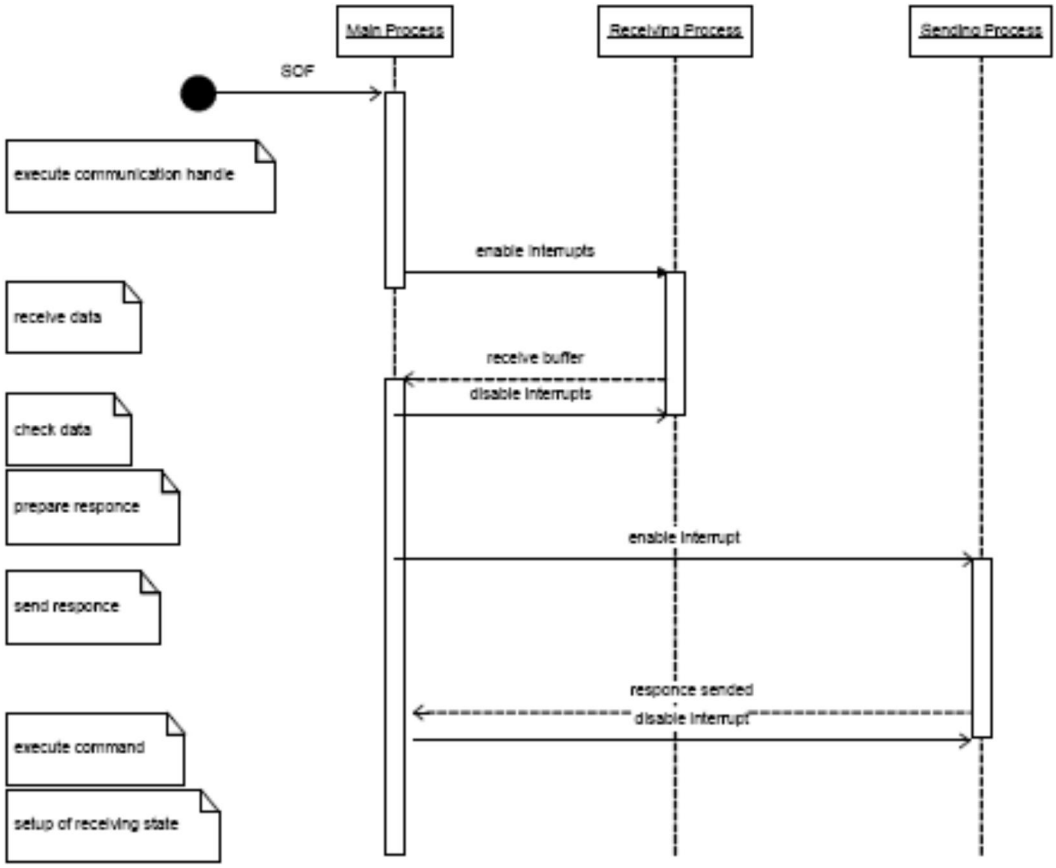


Figure 37 Communication model from the front end perspective

The communication process is operated by the main process with the aid of the event queue. Interrupts received and transmitted are represented by parallel threads with high priority. Using these threads, data will independently be sent and received. The communication process is separated into five threads:

1. Receive
2. Check
3. Interpretation
4. Execution
5. Respond

The receiving tread stores the incoming data into the input buffer. End of file (EOF) signals the end of the message. The message finally completed with a CRC number. The Check thread uses this CRC to check the message against any form of inconsistence and

compliances to the protocol requirements. Execution and Respond thread are executed 'in parallel'. That means that the respond thread will be started during the command is executed. This method helps to fit the timing specification described in the standard. The transmission process itself operates autonomous. Any data transmitted is taken from a buffer that is filled with data by the main process. Also the front end handles any real time conditions autonomously – means without any microcontroller support.

The memory is managed via a File Allocation Table (FAT). Writing, reading or deleting files can be done similar to the well-known USB memory devices that use standard Microsoft WINDOWS capabilities. All data, stored in the transponder, is organized in files with header, body and CRC protection. Configuration, measurement values and customer data are saved in special files where the header includes all information needed to interpret the data inside the file, including an file -identifying number. The body of any file contains the user data like e.g. measurement data. The file is protected by CRC, which allows detecting accidental changes to the data. Writing and reading of transponder data is protected by a three level authorisation system to avoid unauthorised manipulation of files or data. This is one of the most important legal requirements of high risk logistic transportation such as blood bags. The file system can be updated over the air interface. This allows the manufacturer to load different version of application firmware to the transponder to meet different business operating models and customized to different requirements.
(Refer to Appendix 3: Advanced Functionalities)

4.2.3 HF ISO 15693 Communication

The RFID-based sensing device (i.e. transponder) can only communicate via radio frequency (RF) interface with a carrier frequency of 13.56 MHz. A RFID reader is needed to initialize the communication channel, transfer commands and data, read out and maintain the transponder.
The transponder is used as a VICC complying to ISO 15693-2, and with a protocol in conformance to ISO 15693-3 but with the following limitations:

- ASK with modulation index 10% to 30% (RFID reader) only
- Data coding mode 1 out of 4

- Data Rate: High (only 26,48 Kbits/s)
- Dual sub carrier (FM-Modulation) or Single sub carrier (AM-Modulation)

The communication is asymmetric with different coding for RFID reader (VCD) to transponder (VICC) and transponder to RFID reader. ASK is used for bi-directional communication, with load modulation on the transponder side. To keep the technical effort in the transponder as low as possible, only a selected part of possible modulation schemes have been implemented.

Single or Double Subcarrier Modulation in the Response is indicated in the transmitted request flag. The transponder shall be able to communicate with both modulation schemes according to standard ISO 15693 readers.

4.2.3.1 Protocol

Data communication has designed to comply with ISO 15693-3 anti-collision and transmission protocol. The protocol is based on 'reader talks first' principle. A communication consists of a request by the RFID reader, answered by a response of the transponder if the conditions are fulfilled. Details can be referred to the standard.

4.2.3.2 Frame Format

A request is packed in a frame of the following format:

SOF	Flags	Command	Parameters	Data	CRC	EOF

A response of the transponder has the following format:

SOF	Flags	Data	CRC	EOF

All bytes are transmitted LSB first. Parameters start with the Manufacturing ID, which is:

SEAG = 0x32

4.2.3.3 Anti-collision Behaviour

The transponder behaves like a standard ISO 15693 inventory transponders under an anti-collision scenario. Selection of one distinct transponder out of a minimum of 16 different transponders in the RF field at the same time is possible.

4.2.3.4 Communication Time Out

If there is no new request after a maximum of 20 ms in the protocol sequence, the communication state of the transponder shall be reset to *ready* state. Before reception of new commands, the transponder has to be first selected again.

4.2.3.5 CRC Block Check

Two bytes CRC are appended to each request and response, within each frame, before EOF. The CRC is calculated on all bytes after SOF up to, but not including the CRC field. CRC is transmitted LSB first. Initial register content shall be '0xFFFF', the algorithm shall be in accordance with ISO 13239 with the following byte transmission rule:

Generation rule according ISO 13239 for 16 bits is:

LSB LSByteCRC 16 (8bits) MSB	LSB MSByteCRC 16 (8bits) MSB

P= X16 (+) X12 (+) X5 (+) 1

See Annex C in ISO 15693-3. CRC shall be checked for every transmission frame. This CRC block check is further related as CRC16 and shall be used where a block check is applicable.

4.2.3.6 Restore of Previous Mode

If the transponder is leaving the RF field, the transponder goes into that mode which has been used before entering the RF field. If the transponder is in *acquisition mode*, after leaving the RF field, *acquisition mode* shall be used, same as for *storage mode* etc.

(Appendix 2: RFID Operational Modes)

4.2.3.7 Data Structure

The Transponder includes a device (EEPROM) which provides the persistent data storage for storing the following information:

- File allocation table FAT of all stored information (FILETABL.SYS)
- Configuration data (CONFIG.CFG)
- History data (HISTORY.LOG)
- Multiple Customer data[1]
- Multiple Measurement data (TEMP_XX.DAT)[2]

- Multiple Executable Data (FIRMWARE.BIN)

The overall storage capacity is 64 kByte and this capacity can be easily expanded with larger capacity of EEPROM.

1. The file name is specified by user.

2. The field XX is filled with numbers. These numbers begin with 00 for the first record.

4.2.3.8 General File Structure

All data in the persistent storage area (EEPROM) is stored with a predefined file structure. A file consists of the following blocks:

- File header
- File body
- File CRC16

The file header starts with a 2 byte file identifier for direct file type recognition, the file header contains all information to describe the data stored in the file body. The file size shall always be a multiple of Blocks with 4 bytes each, including CRC16.

File Type	Identifier	Remarks
*.sys	0x3E47	File table information
*.cfg	0x3E57	Configuration data
*.log	0x3E67	History File
*.xxx	(0x3E77)	Customer Data[1]
*.dat	0x3E87	Measurement data
*.bin	0x3E97	Executable File[1]

Table 10 File identifier

The format of customer data file will not be examined by the firmware. The file body contains data in a raw data format. The CRC16 is a 2 byte 16 bit CRC at the header and body of the file and appended at the end of the file. With this feature, the consistency of a file can be verified in the receiving end. Writing the CRC16 to the transponder will be the last action before closing the file.

Since customer data will do no further CRC check by the firmware, consistency check must be carried out by the application software.

4.2.3.9 Memory Space Organization

The persistent memory (EEPROM) is organized in 2 main blocks:

Persistent Segment: This part of the memory contains the configuration data and the historical data as well as the file table (fixed size). Within the INIT command these data is written to the transponder and permanent stored to the transponder.

Data Segment: This part is used to store text files created by the users and life-cycle sensor data.

The memory is organized in blocks with 4 bytes in size (1 BU = 4 bytes). Memory addressing scheme is based on block addressing with 16 bit address space or an overall addressable space of 256 Kbyte. With the INIT command, data segment shall be physically erased.

4.2.3.10 File Names

File names are stored in the FILETABL.SYS file and conform to sub domain of the MSDOS-rules with 8 letters A ...Z (only uppercase), underscore '_', leading blanks, and the numbers 0...9. Filenames with less than 8 characters are filled up from left to right with leading blanks (justified to the dot). The dot is not part of the file name. The file types are limited to the above specified types.

4.2.3.11 File Allocation Table FAT

The file allocation table shall contain the following data:

Data	Size/byte	Contents
Handle	1	Identifier
Attributes	1	File Attributes
RFU	2	Reserved for further use
Name	8	File name
Dot	1	'.'
Type	3	File type
Time	4	Timestamp
Start address	2	Start address of the file in EEPROM in BU
Size	2	Physical size of the file including header and CRC in BU

Table 11 Structure of file allocation table (24 bytes for each entry)

The file table is always placed at the fixed EEPROM address (0x0000) and has the attribute:

'11000010'.

This indicates that only authorized users can read out or change the contents of the table.

The File attributes conform to the following table with:

Bit	7	6	5	4	3	2	1	0
meaning	VALID	READ	WRITE	EXEC	HIDD	RFU	ROL_1	ROL_0

Table 12 : File Attributes

These attributes are:

VALID: Only files with the VALID attribute exist in the memory.

READ: A file with this attribute is ready for reading.

WRITE: A file with this attribute is ready for writing.

EXEC: A file with this attribute is in an executable format (i.e. used for update process)

HIDD: A file with this attribute is hidden and only readable with the master role.

RFU: Reserved for further use

ROL_xx: Defines four level of Access rights (roles) as '00' indicates master role, '01 and '10' are referred as user roles USER_1 and USER_2 respectively, and '11' with the manufacturer role.

File Type	Attribute	Remarks
*.sys	1100.0010	File table information
*.log	1100.0010	History File
*.cfg	1100.0010	Configuration data
*.xxx	1111.0010	Customer Data
*.dat	1100.0010	Measurement data
*.bin	1111.0010	Executable File
default	0000.0000	Default

Table 13 Predefined attributes for file types

The file table has a fixed size of 16 entries, which is 98 memory blocks.

4.2.3.12 Date and Time Format

The transponder uses the following data format:

32 Bit Counter represents the number of seconds before midnight, January 1, 1970 until 19:14:07, January 18, 2038, UTC.

The adopted format is complies to the ANSI C Standard.

4.2.3.13 Persistent Data configuration

This data configuration is part of the production process of transponder. Format is subjected to implementation.

- Manufacturing UID
- Time stamp of manufacturing

- Version of the Hardware
- Version of the Firmware
- Version of the battery
- Calibration offset the sensor CALIBOFFSET
- Calibration scale factor of the sensor CALIBSCALE
- Additional data as needed

These data are designed against unintentional change with security measures.

The transponder can be first time initialized in the final test stage during production. The permanent data is copied to the CONFIG.CFG file during initialization (command INIT) process from secure storage (Processor FLASH-Memory).

4.2.3.14 Usage Profile Configuration

This profile will remain changeable with each usage of the transponder. The profile consists of:

- Minimal logging interval in 6 sec, TINTV (default 10 min).
- Minimum temperature threshold, MINTEMPINT, for time - temperature integral[15] (default 5°C).
- Maximum temperature threshold, MAXTEMPINT, for time - temperature integral (default 30°C).
- Minimum temperature threshold, MINTEMPABS, as absolute limit (default 0°C).
- Maximum temperature threshold, MAXTEMPABS, as absolute limit (default 60°C).
- Additional data for application specific requirements.

To evaluate if a measured temperature value exceeds will be done in two ways. On one hand with help of absolute limits. In case an absolute limit MAXTEMPABS (e.g. 60°C) is exceeded the temperature controlled blood bag would be indicated as to be discarded.

[15] See 'Acquisition Mode' at Appendix 5: RFID Operation Modes.

The second analysing method values the measured temperature within a time period. In case the door of the cooler is opened the measured value may be higher than e.g. the MAXTEMPINT (e.g. 30°C). But it is just a short time event and will not influence the blood quality. Therefore the temperature values before this event will be taken in account to indicate the blood bag to be discarded or not. This method is called ‘time-temperature integral’.

4.2.3.15 Transponder File Structure

Header:	<file identifying number>	2 Byte
Persistent configuration:	UID	8Byte
	Firmware Version	1Byte
	Hardware Version	1Byte
	Battery Version	1 Byte
	Timestamp of Manufacturing	4 Byte
	Size of EEPROM	2 Byte
	Size of File Table	2 Byte
	CALIBOFFSET	2 Byte
	CALIBSCALE	2 Byte
User Profile Configuration:	TINTV	2 Bytes
	MINTEMP	2 Byte
	MAXTEMP	2 Byte
	MINTEMPABS	2 Byte
	MAXTEMPABS	2 Byte
	T1	1 Byte
	T2	1 Byte
	TTINTTHRPOS	2 Byte
	TTINTTHRNEG	2 Byte
	Reserved	1 Byte
Footer:	CRC	2 Byte

4.2.3.16 Initialization

The initialization of the transponder is carried out with the INIT command. This command erases all the recorded data. The log (or historical) file that holds important system information (e.g. error messages, start and stop events, etc.) will remain intact. File allocation table information and the configuration file will set to blank. The initialization process is recorded as an INIT-Event in the HISTORY.LOG file. The clock of the transponder will also be initialised when the INIT command is carried out

4.2.4 Summary of performance characteristics

The transponder records temperature values with a resolution of 0.125°C and an accuracy of 0.5°C. Test in a calibrated liquid bath did show better results than expected. The transponder fully complies with the DIN EN 12830 regulation – temperature recorders for the transport, storage and distribution for chilled, frozen, deep frozen / quick frozen food such as ice creams. The transponder has enough capacity to hold more than 30,000 temperature (sensor) values. With sampling rate of 10 minutes intervals the transponder can operate autonomously for approximately 7 months. The device has to operate in the harsh conditions such as during transportation, environments of a blood bank and subjected to 5,000 g in the centrifuge. Therefore, the device is packaged with a robust housing and completely sealed. Other important characteristics for medical devices used in medical environments are the housing must not easily penetrate into the skin and must able to resist steam or chemical disinfection process. The transponder is also equipped with three LED's to indicate some important status and information.

Blue LED indicates sufficient RF field for communication

Red LED indicates data acquisition

Green LED indicates operation when flashing with a 6 sec. interval

Green LED indicates a temperature violation when successive flashing twice in 6 seconds interval.

With the aid of these LED's, the user is informed about the current state of the transponder and the monitored blood bag, without checking the temperature values.

4.2.5 Operator Software and SDK

In order to cater for different requirements of different users and user groups, the operator software application can be installed in different combinations.

Use case	Permanent Network Connection	Local Equipment needed
handling tags (start, stop)	yes	Reader
handling tags (start, stop) + managing logistic data	yes	Reader
interpret curves	yes	none
managing logistic data	yes	none
interpret curves + managing logistic data	yes	none
handling tags (start, stop)	no	Reader

Table 14: Environmental Requirements for different Use Cases

4.2.5.1 Stand - alone operation

In this operation mode, the user is able to configure measurement, to start and stop the temperature measurement, to view data stored on the TRD and export the data as a .csv text file to the file system of the computer. These exported measurement data can be imported to a different user database with the aid of each T.I.M.S Operator that is connected to the database.

Exported files are secured with the aid of a checksum and encryption to prevent accidental change or damage the exported measurement file.

4.2.5.2 Indicator LED on the Temperature Recording Device (TRD)

LED	Description
Blue	Device is located within the RF field of the RFID reader. Intensity of light indicates the field strength
Red	Device is calculating, or taking a measurement
Green - flashing once in 6 seconds interval	Device is working and no temperature violation took place
Green – successive flashing twice in 6 seconds interval	Device is working and a violation was raised

Table 15: Indicator LED on TRD

4.2.5.3 Identification of the Temperature Recording Device (TRD)

The TRD can be identified with the aid of two different unique ID's:

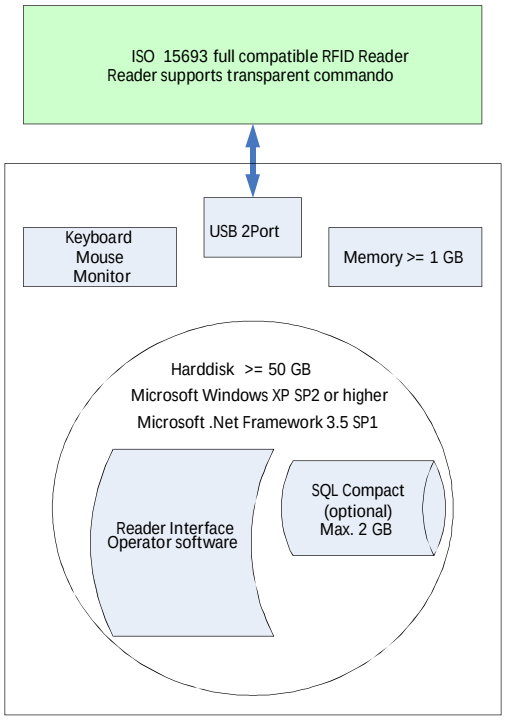
- Universal ID (UID): 16 digits alphanumerical – readable only with the aid of RFID-Reader
- BarCodeID: 7 digits alphanumerical - readable with the aid of Barcode-Reader (Code 39)

4.2.5.4 Maximum tags on reader

Depending on the physical and geometrical dimensions of the RFID reader used, it is possible to place a maximum of 4 TRD's within the electromagnetic field of the RFID reader. The limitation of 4 in handling TRD simultaneously is also due to the design of the application software

4.2.5.5 Operating system

The application software runs on any Windows XP (SP2) systems or higher with .NET framework (3.5 SP1) installed. Any functions, classes, etc. of the application software are developed with Microsoft Visual Studio .NET Version 2008. No further development tools have been used.



System Requirements:

RFID Reader (optional):
FEIG ELECTRONIC
ID ISC.PR101-USB

PC with:

Hardware:

- USB Port installed (optional)
- RAM minimum 1GB
- HD minimum 50 GB
- Monitor Resolution 1024*768
- Keyboard
- Mouse

Software:

- Windows XP SP2 or higher
- Microsoft .NET Framework 3.5 SP1
- Obid Driver V2.40.0.0 FEIG ELECTRONIC GmbH

4.2.5.6 Overview of the functions

Major topic	Group	Function
Application	Main window	Help
		Style
	T.I.M.S	About
		Login
		Connect Reader
Utilities	User Management	User
		User groups
		Change Password
	Program	Change Language
		Options
	TRD	Initialization
		Test
		TRD Values
		Show History
		Emergency Read
		Settings

Operator	Sensor	Start Measurement
		Stop Measurement
		TRD State
		State Overview
		Calibration Report
	Analyzer	Quick Analyzer
		Detailed Analyzer
	Common File Functions	New
		Open
		Save on Tag
		Save on Disk
		Delete
		Memory State
	Import/Export	Import
		Export
	Windows	Open Windows
		Title horizontal
		Title vertical
		Cascade

Table 16: Overview of Functions

Detailed functional descriptions can be found in Appendix 6: Operator Software Functions.

5 Test, Evaluation and Verification

This lifecycle management system with active RFID transponders was implemented and tested at the University Clinique of Graz and also used as a case study for this research study. The developed system was run parallel and independently with the existing system and procedures to avoid any potential risk to the use of involved blood products. The blood bank system is based on an off the shelf product called ePROGESA® and supplied by the French company MAK-Systems. Field staff such as blood transportation crew from Austrian Red Cross, are equipped with special laptops fitted with ePROGESA® module. The blood donation teams were equipped with RFID readers to write data to the RFID transponders. The RFID reader is also used to activate the temperature curve at the donation stage of blood production. All the blood donations involved in this case study were took place at the donation centre of the University Clinique of Graz.

When the blood bags delivered to the blood bank, each blood bag was identified by a barcode reader. Temperature and additional data on the RFID transponders were uploaded to the ePROGESA® system at this stage. An RFID infrastructure was needed at the goods receipt of the blood bank to facilitate this process.

After the procedures of labelling and clearance of the blood bag, the erythrocyte concentrate or thrombocyte concentrate is declared as medical product and can be used for transfusion. At the same time, data such as blood group, product code and date of expiry were written to the RFID transponder. RFID equipment was installed in the area where cross matching is carried out. When the blood bag has passed the cross matching procedures, patient data and test results were written to the RFID transponder. Just before delivered to the requesting station, a bill of delivery was produced and the correct thermal treatment of the blood bag was checked.

The case study is completed when the blood bags have passed the quality inspection and delivered to the receiving stations. The RFID transponders were removed from the blood bags and all the resided data also immediately erased when the case study was completed.

5.1 Case Study

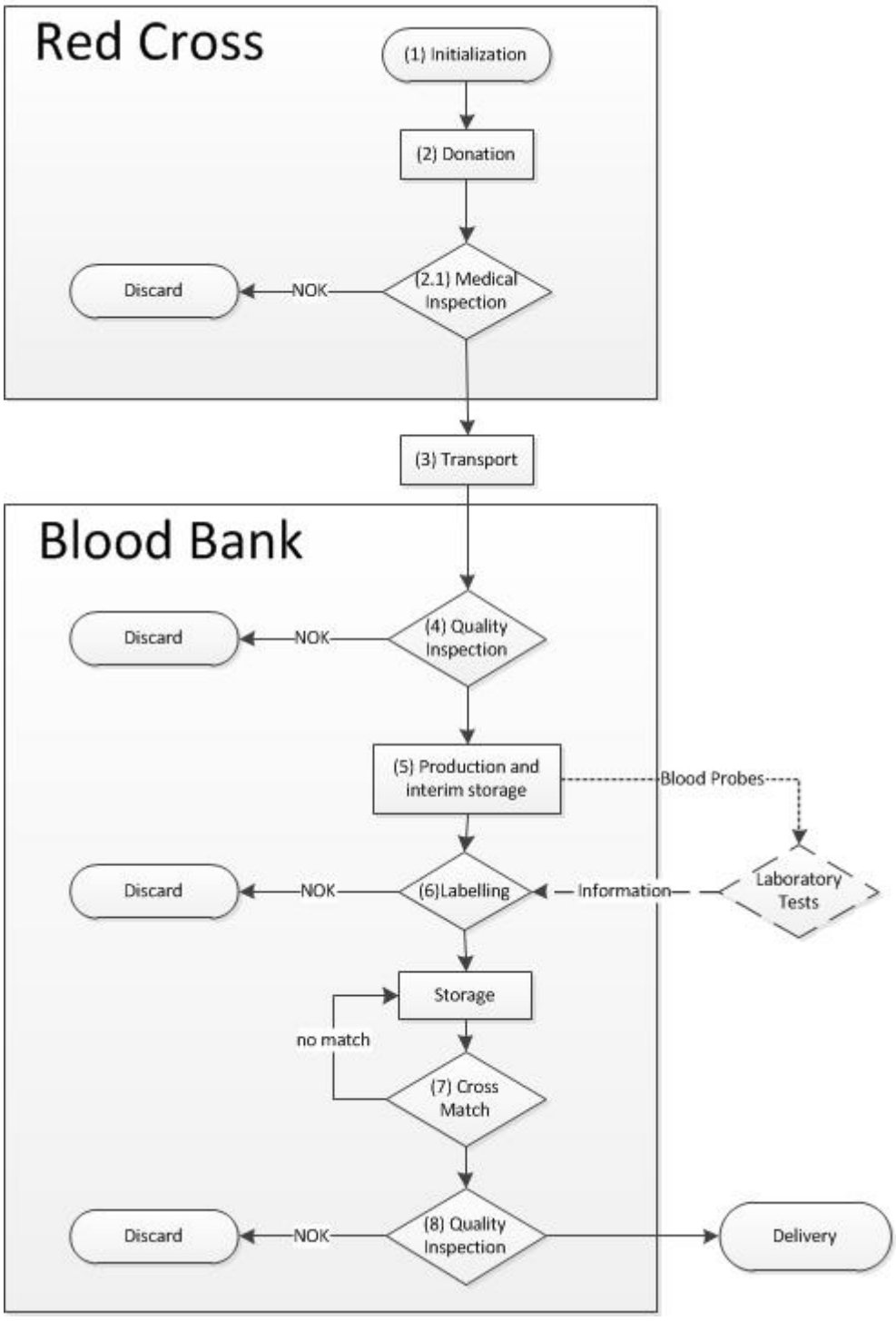


Figure 38: Life Cycle of Blood Bags in the Case Study

5.1.1 Initialization

The RFID transponder was mounted on the SAG-M bag of the blood bag system in the presence of the donor. Any old data (e.g. old temperature values) on the RFID transponder will be removed before the initialisation process. The blood bag ID and the donor ID will be recorded and copied to the RFID transponder.

5.1.2 Donation

Whole blood is expected to be around 37°C. The parameters for the analysing program of the RFID transponder were set to the following values:

Name of process stage	Donation
Upper absolute limit	37.5°C
Upper relative limit	36°C
Lower relative limit	23°C
Lower absolute limit	21°C
Interval	30 seconds
Positive Threshold	2°C * min
Negative Threshold	3°C * min
Start Delay	60 seconds
Premature stop	0 seconds

Table 17: Temperature Parameters set at Donation Stage

Temperature recording was started after punctuation of a new blood bag. The start delay time required for the medical personnel filled up the test tubes before the whole blood was started to fill the blood bag system.

5.1.2.1 Medical Inspection

Not only the most important data such as donation duration time and blood volume taken were copied to the transponder, but also any kind of side effects (e.g. nausea, dizziness, etc.) the donor suffers from will be documented and written to the RFID transponder.

During the medical inspection, a physician checked the temperature curve recorded on the RFID transponder. The physician responsible the decision whether the blood bag will be discarded or not when anomaly was discovered.

During the process of lowering the temperature of the blood bag with the aid of special cooling plates, the RFID transponder must be placed on top of the blood bag to continuously record its temperature. Once the process was completed, the blood bag was placed into a dedicated transportation box to be forwarded to the blood bank.

The parameters for the analysing program of the RFID transponder were updated to the following values:

Name of process stage	Whole Blood Transportation
Upper absolute limit	26°C
Upper relative limit	24°C
Lower relative limit	5°C
Lower absolute limit	0°C
Interval	1 minute
Positive Threshold	2°C * min
Negative Threshold	2°C * min
Start Delay	15 minutes
Premature stop	0 seconds

Table 18: Updated Temperature Parameters set for Whole Blood Transportation

5.1.3 Transport

Each transportation box was equipped with a unique ID number. This ID number and a time stamp represented the start of transportation were copied to the RFID transponders.

5.1.4 Quality Inspection

The goods receipt of the blood bank was equipped with a barcode scanner, a RFID reader/writer and a computer. The computer was connected to both the developed life cycle management system and the local blood bank software. When the blood bags arrived, the medical personnel checked the temperature curve by retrieval of the temperature records resided on the RFID transponder. When the blood bags passed through the quality

inspection, they will be transferred to a controlled area with a measurement interval of 1 minute is no longer necessary. The parameters for the analysing program of the RFID transponder were updated to the following values:

Name of process stage	Quality Inspection
Upper absolute limit	26°C
Upper relative limit	24°C
Lower relative limit	5°C
Lower absolute limit	0°C
Interval	15 minute
Positive Threshold	2°C * min
Negative Threshold	2°C * min
Start Delay	0 minutes
Premature stop	0 seconds

Table 19: Updated Temperature Parameters set for Whole Blood Storage

5.1.5 Production and Interim Storage

Blood production process is carried out at ambient temperature and change of temperature parameters of the analysing software is not necessary. During blood separation process, the RFID transponder was subjected to approximately 5000 g-force

After blood separation process, the temperature curves of each blood bag were checked for anomaly. Each blood bag was also visually checked for any damage due to the blood production process.

Erythrocyte concentrates will then be stored at a controlled cooling room within a temperature of 4°C +/-2°C. The parameters of the analysing program have to be changed to:

Name of process stage	RBC Storage
Upper absolute limit	10°C
Upper relative limit	6°C
Lower relative limit	2°C
Lower absolute limit	0°C
Interval	15 minute
Positive Threshold	2°C * min
Negative Threshold	2°C * min
Start Delay	20 minutes
Premature stop	0 seconds

Table 20: Updated Temperature Parameters set for RBC Storage

The cooling room is an interim storage as blood bags were ready for subsequent laboratory tests.

5.1.6 Labelling and Storage

Blood bags were labelled when they passed the laboratory tests and forwarded to the blood bank. The blood bag ID was read with the aid of a barcode reader. The blood bag ID which stored on the RFID transponder was retrieved with the aid of a RFID reader. When any mismatch was detected, the systems informed the operator with the aid of visual and acoustic signals.

Any data that was printed on the label of the blood bag was copied to the RFID transponder:

- Unique bag ID (barcode and letters)
- Donation date
- Expiry date (and time)
- Product description (e.g. erythrocyte concentrate)
- Product code (e.g. ISBT 128)
- Summary of laboratory tests (e.g. HIV, HBV, HCV negative)
- Volume and additive (e.g. 230 ml + 100ml SAGM AS Haemoglobin > 51g)
- Blood group and rhesus (e.g. barcode and letter e.g. B +)

- Kell factor
- Location of Production
- Name and location of blood bank

The blood product was ready for use when the labelling process was completed. Finally, the blood bags were transferred to the blood bank warehouse.

When the laboratory tests returned with the negative results, the relevant blood bag has to be disposed. Under this situation, the following information were added to the relevant blood bag:

- Unique bag ID (barcode and letters)
- Product description (e.g. erythrocyte concentrate)
- Eye caching text that the product as to be disposed
- Donation date and time
- Reason for disposal (e.g. Anti – HIV ½ doubtful)

Before disposal, all the data resided in the RFID transponder will be transferred to the blood banks lifecycle management system and all the data within the RFID transponder will be erased. The RFID transponder can then be reused again.

5.1.7 Cross Match

When request was raised, blood bag was taken out from the blood bank warehouse for the process of cross match. When the blood bag passed the cross match process, date and time, the patient ID (the receiver of the blood bag) and the test results (blood group, rhesus factor, kell factor - match) were written to the RFID transponder. The blood bag was then forwarded to the quality inspection. The blood bag was returned to the blood bank warehouse when it failed the cross match process; with only the date and time recorded into the RFID transponder.

5.1.8 Quality Inspection and Delivery

When the blood bag passed the cross match process without problem, further quality inspection was carried out before the blood bag was delivered to the recipient. During the quality inspection process, the temperature values recorded on the RFID transponder were read. Any test result or data recorded throughout the case study were checked by the medical personnel before these data were copied to the database of the lifecycle management system.

Although the 'real' lifecycle of the blood bag would not end at this stage; the case study was ended here due to various considerations. The RFID equipment used in this case study was not certified as approved medical equipment. This is the reason why RFID transponder and reader are not allowed to be used in operation rooms or intensive care stations in the hospital.

5.2 Results

5.2.1 Initialization

At the beginning of the lifecycle of a blood bag, the RFID transponder has to be fixed to the blood bag.

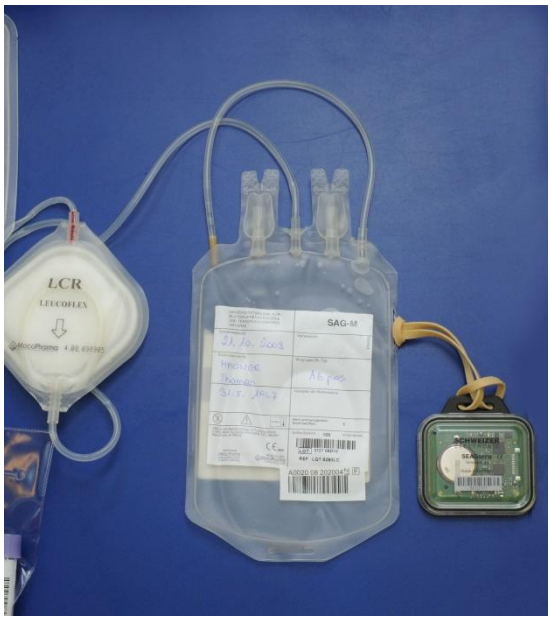


Figure 39: RFID Transponder attached to the blood bag

The blood bag system consists of many different blood bags. The RFID transponder must be mounted to the SAG-M bag only. Errors occurred at this stage as the personnel mounted the RFID transponder on other bags of the blood bag system. This resulted in the RFID transponder had to be taken off at the blood product separation stage and re-attached to the SAG-M bag. Some errors were based on inadequate mounting or simply non – mounting of the RFID transponder.

5.2.2 Donation

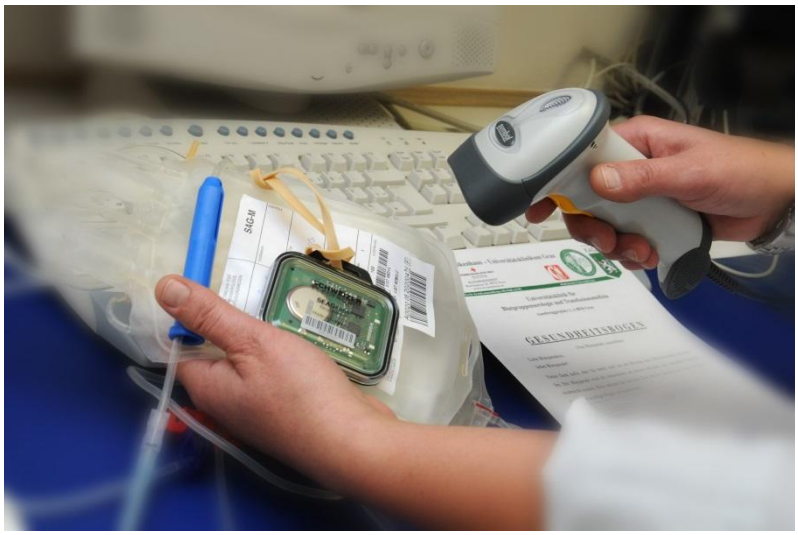


Figure 40: Initialisation of the RFID Transponder during the donation stage

During the donation stage, the RFID transponder was initialized with first temperature curve and associated parameters loaded. Soon it was clear that an automated data transfer has to be established to transfer data and parameter to the RFID transponder to avoid/minimise the human error.

5.2.3 Transport

Figure 41: Transportation of blood bags

Throughout the case study, blood donation and subsequent production process were took place at the same hospital. Therefore, no temperature problem due to transportation was expected.

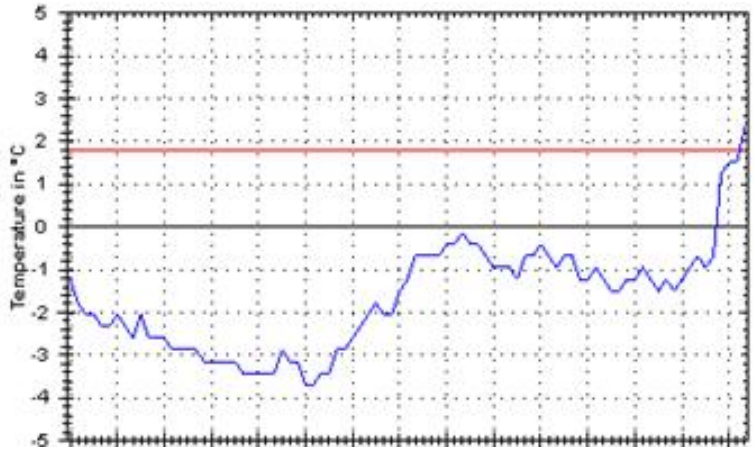


Figure 42: Transportation issue (7 hours during winter time)

However, even with the simple transportation conditions in this case study, errors still occurred more often than expected. The temperature curve shown in figure 67 revealed a situation where the blood bag was left for approximately 6.5 hours beyond 0°C. This case

has proofed negative temperature violations can hardly be recognized/detected by the medical personal without temperature data record.

5.2.4 Quality Inspection

During quality inspection stage, the same problems occurred as at blood donation stage. Manual input is prone to human error, for example, the inputs of the parameters of the temperature curve. The author strongly believe more automated the data input will avoid/minimise the human error.

5.2.5 Production and Interim Storage

Problems occurred during the case study when the blood bag system and the RFID transponder were placed into the centrifuge. It was found damages occurred to RFID transponder or blood bag when the RFID transponder was placed at the bottom of the box. The key reason is the centrifugal force of the centrifuge exerted heavy load on the housing of the RFID transponder, which led to broken housing. In some occasions (depended on the location of the RFID transponder), the blood bag was pressed so hard onto the edge of the RFID transponder which caused it damaged.

Figure 43: Packing the blood bag into the box of the centrifuge

With careful studies, the best location of the RFID transponder was found on the upper part of the box where approximately 1/3 of the RFID transponder should be protruded from the box. When the centrifuge is running, the blood within the blood bag is pressed towards the bottom of the box. When the RFID transponder is placed in the middle position, it cannot slip down rather it would be put on the front or back side of the box. No further damage of the blood bag or the RFID transponder has been detected when the improved packing procedure was introduced.

5.2.6 Labelling and Storage

The case study was not expected any major problem at the labelling and storage stages, however, the blood bags were taken out from the storage area because of various reasons and more often than expected.

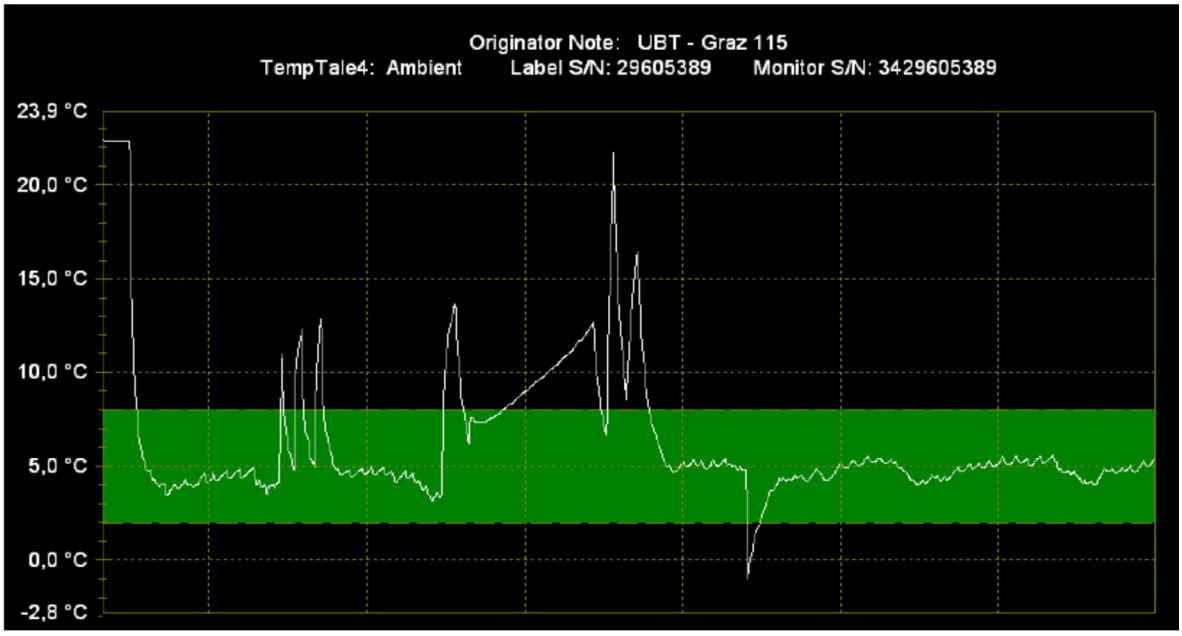


Figure 44: Temperature curve - storage period

According to the clinical requirements, the blood bag should stay in the temperature range between +2°C and +6°C. However, for various reasons, the blood bag was taken out of the storage area number of times and therefore warmed up for many times (see Figure 61). Reasons to take out the blood bag from the store are mostly due to quality checks, tests or simply mistakes made by the personnel. Obviously, temperature rise up will not only increase the chance of wastage, but also pose health risk to the patient if situations undetected. This case study show evidence to proof each single blood bag has to be tracked and controlled to ensure they are all safe and hazardous free. The existing guided statement stated all the blood bags should keep in a temperature controlled area is not sufficient to weed out all the risks associated with environmental temperature.

5.2.7 Cross Match

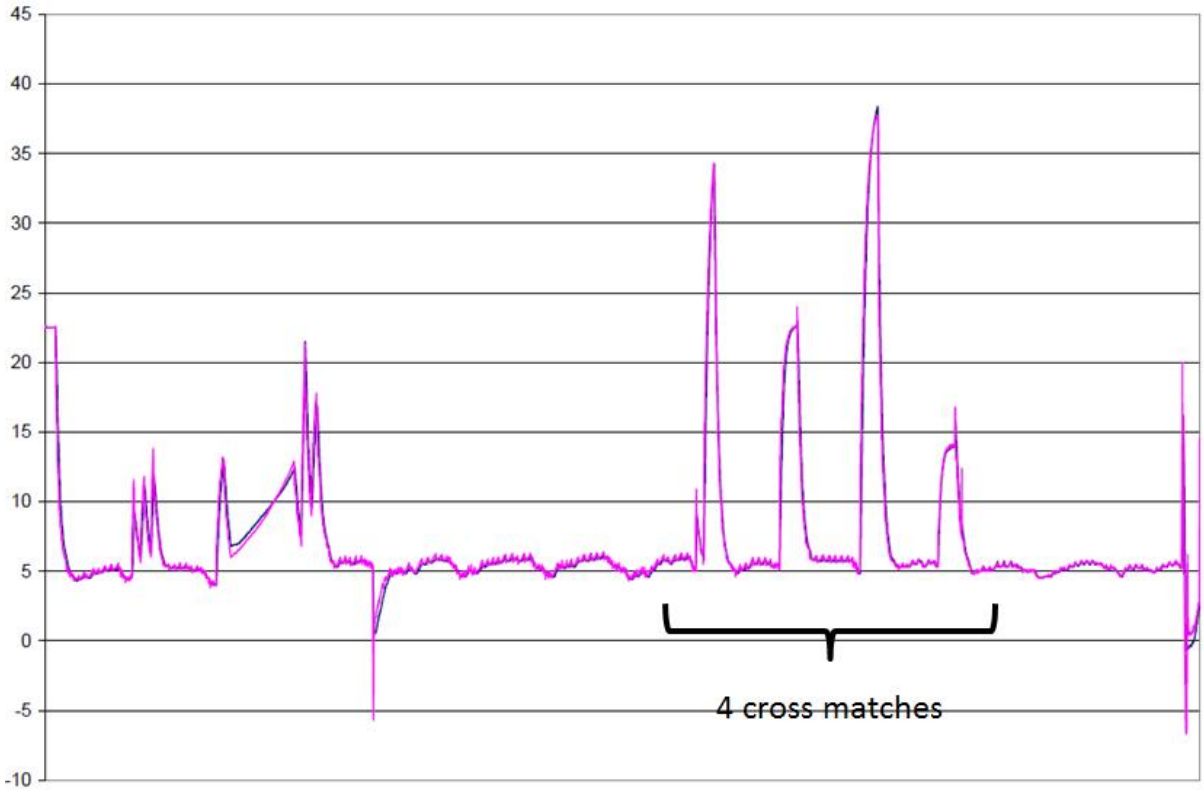


Figure 45: Storage and Cross Match

It cannot be foreseen how many times a blood bag will be taken out from the temperature controlled store for a cross check. According to the general guidelines, up to 8 cross checks are allowed on one blood bag before it has to be discarded due to health risk. The case study was initially estimated most of times the blood bag will be delivered to recipient after only one cross check. The result of the case study showed only in few cases the first cross check led to success of delivery. In most of the situations, more than one cross check was carried out on one single blood bag. The exact average number of cross check on blood bag is still remained unclear as the case study did not produce an enough number of blood bags to create statistical significance. However, the results of the case study showed only a small number of blood bags were consumed with only one single cross check.

5.2.8 Quality Inspection and Delivery

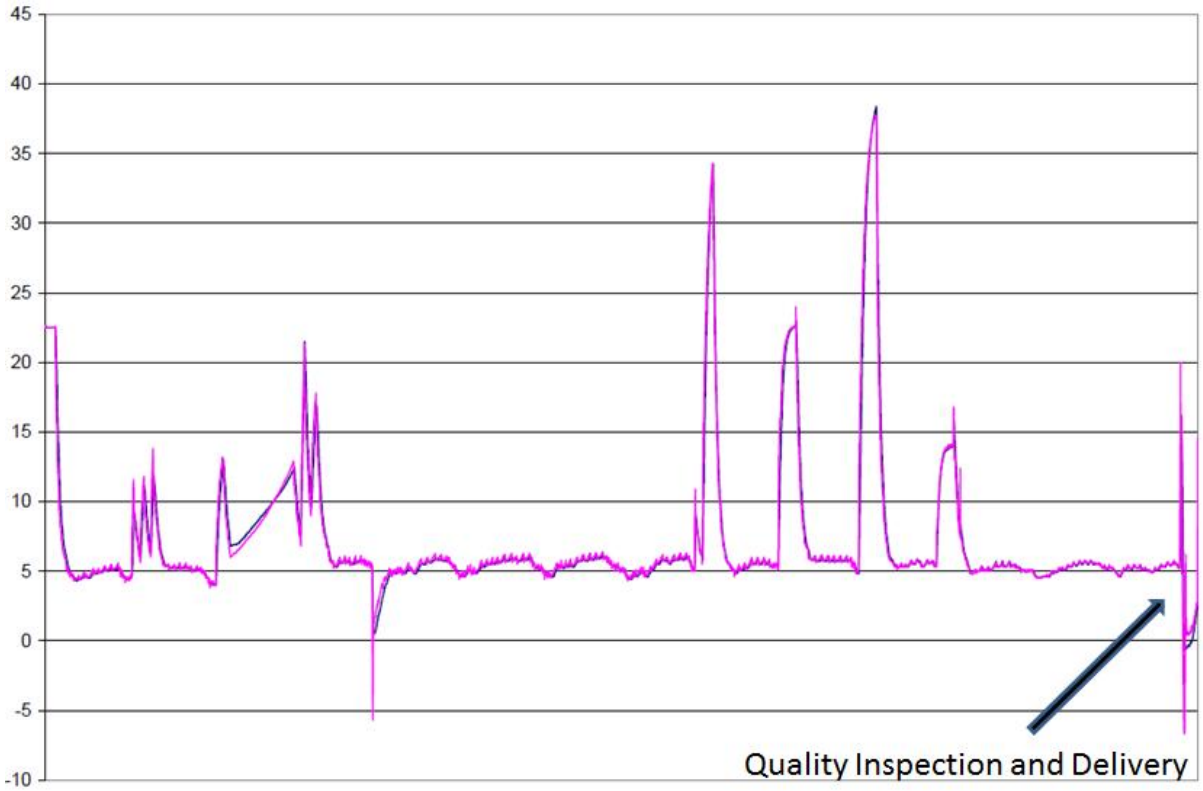


Figure 46: Quality Inspection and delivery

There is no major problems occurred within quality inspection throughout the period of case study. The figure 63 has showed a sudden decrease of the temperature down to -7°C. After the investigation, it found out the temperature dropped was a result of an opened window during the winter time in Austria. In this situation, the recorded temperature will not cause any harm on the quality of the red blood cells.

5.3 Result Evaluation

Due to the resources constraints (e.g. time), the case study hardly creates sufficient data to establish any statistical significance to quantify the benefits of the proposed systems. However, apparent benefits could be qualified with the collected data, opinions and comments/feedback from the involved professionals.

From a blood bank software point of view, the RFID system consists of two major parts:

The first one collects data from different stations and has to be seen like a trace and tracking system. Here the RFID transponder acts as a data transportation unit where data is collected and transmitted in a defined way. Data like donor number, blood bag number, blood group, date of expiry ... are permanent and must not be deleted or changed over the whole lifecycle. Other data that must not be kept throughout the whole process can be deleted when transferred to the host computer.

The second part concerns about collection, reprocessing and presentation of temperature data. Data representation will be presented in graph format. When the temperature interpretation finds any kind of violation, the blood bag will be marked as dismissed and future use must be avoided.

After the process of cross match and the delivery of the blood bag to the station of recipient, patient data will be written to the RFID transponder. The temperature curve will be checked just before the transfusion. IT-systems employed at different stages of blood production cannot assume same as the system used in the blood bank. Therefore, a tool has to be developed to enable the developed RFID transponder system interoperable with any of those applications. The IT system of the blood bank enables a secure assignment of blood bags with the patients and must also be able to track and control whether the blood bag has been transported and stored in a correct manner.

All the data concerning the transfusion like adverse effects or complications have to be communicated back to the blood bank system when the transfusion has completed. Not only a correct and complete haemovigilance file can be established with the aid of a complete lifecycle temperature data of a blood bag, but also enable it traced in an electronic way.

As a common opinion among all persons involved in this case study, the proposed RFID transponders, together with its lifecycle management system provides better decision support to handle a blood bag at any stage of its lifecycle.

Today only a visual quality control decides whether a blood bag is to be discarded or not. The current practices not only required well-trained medical staff to carry out the task, but also prone to human error.

It turned out that mounting the RFID transponder to the SAG-M bag was the most critical topic of this case study. The most promising way to avoid this problem is to place (or attach) the RFID transponder inside of the blood bag system during its production. Design and functionality of the blood bag system must be modified to adapt this new RFID transponder.

6 Discussion

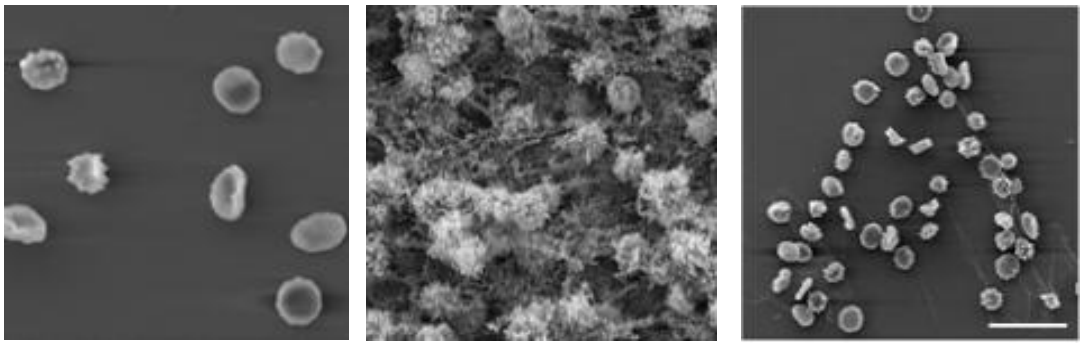
This research studies have proved the implementation of an overarching system to monitor and track individual blood bag throughout its life-cycle is possible. As tests and the case study carried out have proved the thermal influence on erythrocytes is lower than expected. Tests and the case study have also proved that HF radiation is harmless for red blood cells. Therefore, RFID systems can be used throughout the life-cycle of the blood products.

Significant research [7] [8] have revealed more than 50% of medical errors in blood transfusion process are due to incorrect blood transfusion (i.e. patient received an incompatible blood group or rhesus factor). Incorrect blood transfusion will cause serious health damage to the patient, if not a death penalty. The proposed life-cycle management system uses the blood bag integrated with a custom designed RFID transponder which carried all the essential data of the blood product to improve documentation and traceability; a vital support to avoid any mismatch between patient and the blood bag. There was no single mismatch that occurred throughout the trial period. Although the trial result did not provide any statistical significance in prevention of mismatch, it does show the potentials of the proposed system in prevention of mismatch during the blood transfusion process.

Throughout the trial, the proposed system has revealed two blood bags which ready for blood transfusion have temperature below 0°C during their life-cycle. A blood transfusion would have been 100% mortal to the patients if not caught by the proposed system. The ability of catching such fatal mistake during the trial not only proved the success of this research project, but also proved the necessity of the proposed system in patients' security.

6.1 Commenting on findings

In course of the experiments to investigate the impact of different temperature profiles on the quality and survival of stored RBCs, RBCs stored at 4°C were exposed to 22°C once a week for 24 hours. After 42 days of storage more crenate erythrocytes appear than after 3 days. Additionally, after 42 days a few fine filaments between erythrocytes were detected.
Additionally, experiments were done to compare surface and core temperature to establish a conversion factor necessary to program the RFID tag to get a quick response whether the RBC unit can still be used or not.
Due to the quality control of RBC units, it was in fact surprising to discover, that storage of RBC units for 14 days at a constant temperature of 22°C did not increase the haemolysis rate above the borderline of 0.8%. Additionally, storage at various temperature profiles with repeated cooling and rewarming periods (up to 22°C) had no significant impact to the haemolysis rate even on day 42 compared to correctly stored RBC units. These results were impressively confirmed by the electron microscopically pictures.



Left: Electron microscopic image of fresh RBCs on day 3 of storage

Middle: RBCs constantly stored at 22°C showed agglutinated erythrocytes on day 42. In SEM a lot of febrile material was found on and between the agglutinated cells

Right: RBCs stored at 4°C and exposed to 22°C once a week for 24 hours. After 42 days of storage more crenate erythrocytes appear than after 3 days. Additionally, after 42 days between erythrocytes a few fine filaments were detected.

Normally, RBC units will be discarded if warmed-up to room temperature which happens routinely in case of transfusion preparation. As a conclusion of the research, it can be assumed to restore these RBC's without quality loss or harm to any patient. Anyway it must be assured that these units have not exceeded any critical threshold and therefore the monitoring of each single blood unit can be stated as a precondition. Together with RFID wristbands the system will increase safety for patient due to avoidance of patient/RBC unit mix-up.

One objectives of this research was to complement a limit test study by assessing the biologic effect of 13.56-MHz RFID technology on blood product samples that might be caused by long-term exposure (0-42 days).
The maximum expansion of the electromagnetic field of the reader used was 160 mm; the operating distance was defined with 0 to 120 mm. This means that the optimal distance was up to 120 mm. The RBC had direct contact to the reader. Therefore a maximum of radiation power on the blood bag could be provided. To avoid any influence of possible operation heat the reader was placed on top of the RBC unit. The whole experiment was carried out in a cold storage room with a controlled temperature of 4°C (+/- 2°C). Room and surface temperature have been checked permanently and more than one time per day.

Significant differences in the levels of pH, lactate, Hb, and Hct that have been observed did not announce significant different developments of variables in time in the test and control groups and must therefore be interpreted as variances appearing in randomly selected samples. The haemolysis remained below 0.8%, which is the European guideline regulated, the maximum acceptable percentage. The glucose concentration was always higher than the lowest acceptable level of 90 mg/dL. In conclusion, all variables measured remained within the acceptable limits in both groups, without detecting any obvious adverse effects of RFID on RBCs; therefore, one can conclude that it is feasible to implement RFID-enabled processes.

6.2 Suggestions for future work

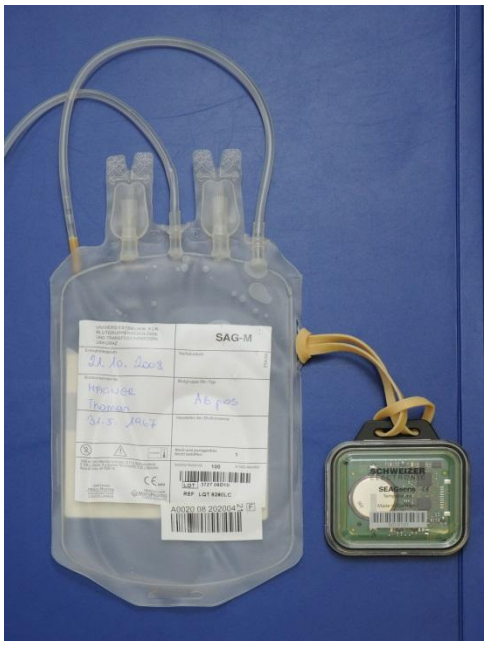


Figure 47: Correctly mounted RFID transponder

The RFID transponder must be mounted to the SAG-M blood bag at the donation stage to ensure a complete life-cycle data is captured. This procedure turned out to be error prone during the trial. The key reason is such procedure was not carried out by medical personnel rather than by people who was carried out his/her civilian service. In numbers of occasions, the transponder was fixed to other bags of the blood bag system. Medical personnel at the production stage had to correct this error which was at least double the efforts. Such human error could be avoided when the transponder is designed as an integral part of the blood bag system.

The transponder is equipped with a green LED indicating the product quality. In case of any violation the LED flashes 2 times every 6 seconds. This alarms the medical personnel to consult a physician to decide if the blood bag must be discarded or not. Although green colour is not common to adopt as a risk indicator, LED with very low power consumption were only available in green colour at the time of this research project. Maybe in the future

they are available in red colour which would fit the common understanding of signalling in alarms.

7 Conclusion

The European Commission Directive 2003/63/EC [EU 2003], amending directive 2001/83/EC, requests all companies that deal with human blood products must have a system to monitor environmental data. This led to a proliferation of incompatible approaches and solutions, partly because the nature of the directive and partly because the diversity of the legal and social background. Research also been made to tackle such diversity using advanced information and communication technology and does producing some promising results. However, numbers of question still remains to be answered (e.g. interoperability issue). Furthermore, the current approaches are lack of life-cycle perspective, resulting in incomplete monitoring and tracking the blood products. Without a life-cycle monitoring and tracking support for the blood products not only imposing security risk to their recipients, but also significantly increasing the wastage of the blood products. Due to the advancement of ICT and sensing technologies in recent years, life-cycle monitoring and tracking individual blood item is no longer cost prohibited and this research has successfully addressing this challenge: creative a life-cycle information management system with the aid of ICT and integrated sensing technology, to monitor and track individual blood item (i.e. blood bag). Such system is not only minimising the blood transfusion and/or identification errors, but also improving the recirculation of unused blood bags (i.e. reducing wastage).

Reduction of wastage is possible as blood bags that are not used for transfusion can be taken back by the depots or blood banks also because of the fact that the thermal influence of temperature > 0 °C to blood is lower than expected.

The issue was discussed at the IdTechEx at the University of Cambridge in 2011 and the Healthcare Conference at Stockholm in 2011. [92] [93] The interest of the committee was high, even the discussion how those systems can be consistently implemented is still on-going.

A prototyping system has been developed for supporting the research studies and a subsequent trialled at University Clinique of Graz, in Austria. The developed system prototype has chosen 13.56MHz RF for supporting its communication, mainly because a series of test has proved this frequency will not cause any radiation issue to erythrocyte concentrates. This non-influence property was proved and published in the Transfusion journal in 2011 by the author and his colleagues [93]. An active RFID-based sensing device

with an integrated file system was developed to support the life-cycle management system. The developed file system was the worldwide first approach to organize data on RFID transponders in an MSDOS® like way, this invention was applied for patent in 2012 and registered at the German Patent Office in 2014. [94]

The trial at the University Clinique of Graz was used as a case study for this research study. Although the trial has not create sufficient data to establish any statistical significance to quantify the benefits of the tested systems, all the involved persons including both operational and professional staff at University Clinique of Graz, have agreed the proposed RFID transponders, together with its lifecycle management system provides better decision support to handle individual blood bag at any stage of its lifecycle. They believe the proposed system will improve patients' safety, reduce the wastage of blood bags and also the administrative works. The Results were presented and published at the ISBT conference in Berlin (2010) and the DGTI conference in Graz (2013) [95].

The trial result has successfully proved the proposed life-cycle management system has the potential and ability in ensuring the high standard of patient security and significantly reducing the blood wastage.

7.1 Recommended Future Works

The RFID based life cycle management system was designed for supervising blood products with accelerations of up to 5,000 g over a time period of up to half an hour. Packaging and performance of the RFID system is generally acceptable. Only the size of the transponder is sub-optimal and too big as all components are built in discrete assembly.

With help of ASIC design the transponder could be miniaturized and therefore pre-packed into the blood bag by the manufacturer. As the shelf life of the system would not exceed 2 month an alternative to the coin cell battery (e.g. foil batteries) can be implemented. In mass manufacturing ASIC systems are very cheap to produce. The disadvantage that each transponder will be discarded after one production cycle can be compensated with cheap mass production. Also the complex and expensive housing of the RFID can be reduced.

The grade of integration leads to 3 possible versions:

Version 1: The concept is based on the actual design with a frontend ASIC

The design integrates the complete analogue and digital part of the frontend RFID. The backend stay more or less unchanged.

This version has the disadvantage that relative expensive devices (like the microprocessor) will not be integrated in the ASIC part. Advantage is that a redesign can be fast and easy done.

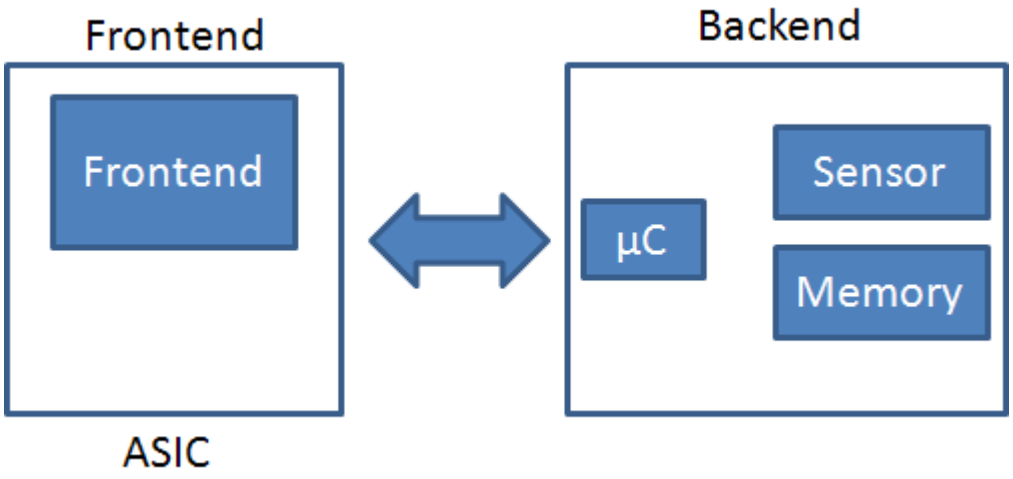


Figure 48: ASIC Integration Version 1

Version 2: Frontend and processer integrated

The design integrates the frontend like in version 1 as well as the microprocessor. This will replace the ATMEL microprocessor. Costs of production will not increase and smaller sizes can be reached.

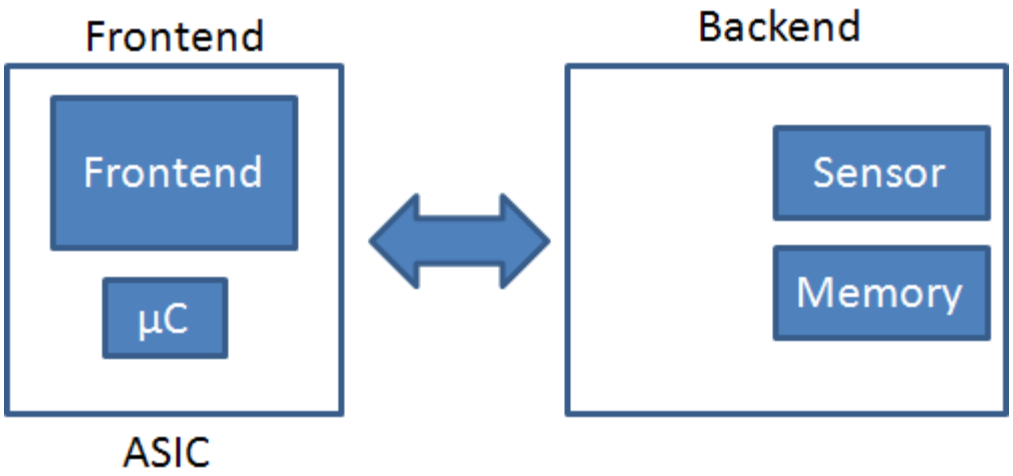


Figure 49: ASIC Integration Version 2

Version 3: Integration of frontend, processor and sensor:

Main disadvantage of this version will be that the sensor will have to be calibrated with each manufactured device. So there must be an individual calibration process during production.

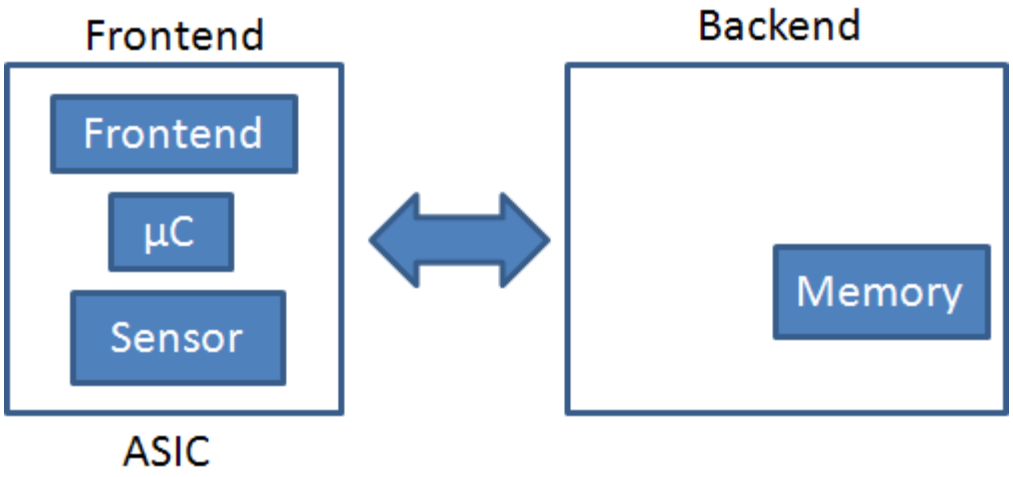


Figure 50: ASIC Integration Version 3

The current transponder has a very robust housing, consisting of two shells of grillamid – plastics hermetically sealed by laser welding. Considering a device to be smaller than 30mm in diameter it allows a different encapsulation concept. Direct grouting of electronics e.g. with epoxy or foaming with medical proofed PU-material is possible.

A tiny measurement instrument could be part of the blood bag system and the core temperature of blood could be monitored.

Temperature tracking by RFID may be interesting for any branches that handle temperature sensitive goods. Transportation of medical goods like diagnostics has to be performed under strict temperature regulations. But also forwarders that are specialized to ship temperature critical freight would benefit this easy to use system.

Today a big diagnostic company uses this life cycle system worldwide. Mayor reason was to improve transportation quality and finally product safety. RFID transponders are started at delivery. The goods are shipped to their destination by air, sea or land freight where after approaching the destination the temperature values are read. Those data is the only proof of product quality and therefore the only decision base weather to bring a product to the end user or not.

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Appendix

Appendix A: RFID Command Structure

The RFID transponder is listening for commands and sends responses after initialization. There exist three types of commands:

1. mandatory commands
2. optional commands
3. customer commands

Optional and customer commands are only accepted in the selected mode. Addressed commands are not supported.

Mandatory commands

See ISO 15693-3 for details.

ISO 15693 compliant anti-collision is implemented. Permission for this command is PUBLIC role.

	Name	Command	Parameters	Return Values
M1	inventory	0x01	Flags, mask	UID
M2	stay quiet	0x02	Flags, UID	--

Table 21 Mandatory Commands

Optional Commands

See ISO 15693-3 [1] for details. ISO 15693 compliant transponder selection is implemented. Additionally, a selected transponder returns to *ready state* if there is no communication for 100ms, or if a test command has been issued, or a measurement has been taken.

	Name	*Com-*	*Parameters*	*Return Values*	*Permission*
O1	select	0x25	Flags, UID	-	Public
O2	reset to ready	0x26	Flags, UID	-	Public
O3	Get System Information[1]	0x2B	-	Info-Flags, UID	Public

Table 22 Optional Commands

1. The address and select flag must be reset.

All commands are responded immediately (first slot) as defined in ISO 15693-3. Permission for these commands is PUBLIC role.

Customer Commands

These commands are custom to the transponder application and contain the manufacturing ID as part of the command structure.

	Name	*Com-*	*Parameters*	*Return Values*	*Permission*
C01	INIT	0xA0	Time Stamp	-	USER
C02	LOGIN	0xA2	Role	-	PUBLIC
C03	LOGOUT	0xA3	-	-	USER
C04	CONFIG	0xA8	TINTV MINTEMP MAXTEMP MINTEMPABS MAXTEMPABS	-	USER
C05	START	0xAA	Time Stamp	-	USER
C06	STOP	0xAB	-	-	USER
C07	RESUME	0xAC	Time Stamp	-	USER
C08	PUT <file>	0xD0	File	-	USER
C09	GET <file>	0xD1	File Name	File Address	USER
C10	READ LOG STATE	0xAD	-	RUNNING NBLOCKS CTIME NCNTPOS NCNTNEG	USER
C11	BATTERY TEST	0xC1	-	-	USER
C12	SENSOR TEST	0xC2	-		USER
C13	GET TEST RESULT	0xCF	-	Test_ID	USER
C14	MANUF. TEST	0xC3	Test_ID		MANUFACT

C15	READ SINGLE BLOCK	0xB2	Start block	Data of one	USER
C16	READ MULTIPLE	0xB3	Start block	Data of N	USER
C17	WRITE SINGLE	0xB4	block address,	-	USER
C18	WRITE MULTIPLE	0xB5	start block	-	USER
C19	ACCESS RIGHTS	0xA1	Permissions		MASTER
C20	REVIVE	0xBF	Time Stamp	Error ID	USER
C21	DEL <file>	0xD2	Filename	-	USER
C22	RUN <file>	0xD3	Filename	-	MASTER

Table 23 Customer commands

INIT Command

This command erases physically the custom memory, the log configuration and parameters, and the log state and restores any default values. Also the file table is set back to default. The access control permission and history is kept untouched.

INIT Command:

SOF	Flags(1)	0xA0	ICMfg(1)	Timestamp(4)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xA0 | 0x32 | 0xF3 0x5A 0x71 0x16 | 0x4D 0x72

Tag to Reader: 0x00 | 0x78 0xF0

(Date: 12/07/1981 00:00)

The execution depends on the system state. In logging and error mode the return value ‘invalid logical flow’ is raised.

Permissions are checked for this command. Users must be logged in and possess the authorization. Without adequate permission the error code ‘access denied’ will be returned.

This command cannot be executed when the log is started. Execution time shall be below 10 seconds.

SET ACCESS RIGHTS Command

This command sets the access permissions and password. The concerned role is selected with the permission flags.

ACCESS RIGHTS Command:

SOF	Flags(1)	0xA1	ICMfg(1)	Permission (4)	Password (4)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xA1 | 0x32 | 0x86 0x07 0x00 0x20 | 0x78 0x56 0x34 0x12 | 0x5B 0xEE

Tag to Reader: 0x00 | 0x78 0xF0

(Permission: Public Role)

(USER: 2)

(Password: 12345678)

Permission is made of Roles (4 bits) + Permission flags:

Predefined Roles:

0	Master role
1..2	User roles
3	Manufacturer role
4..15	Reserved for future use

The lowest bits of role define if USER_1 or USER_2 is defined. There are only 2 different USER with different permissions allowed at the same time.

Bit	Command	MANUF.	MASTER	USER	PUBLIC	Description
31	ROLE[3]	0	0	X		Role
30	ROLE[2]	0	0	X		Role
29	ROLE[1]	1	0	X		Role
28	ROLE[0]	1	0	X		Role
27	RFU	1	0	0	0	Reserved
26	RFU	1	0	0	0	Reserved
25	RFU	1	0	0	0	Reserved
24	RFU	1	0	0	0	Reserved
23	RFU	1	0	0	0	Reserved
22	RFU	1	0	0	0	Reserved
21	RFU	1	0	0	0	Reserved
20	RFU	1	0	0	0	Reserved
19	RFU	1	0	0	0	Reserved
18	RFU	1	0	0	0	Reserved
17	RFU	1	0	0	0	Reserved
16	RFU	1	0	0	0	Reserved
15	C16	1	X	X	0	Run file
14	C15	1	X	X	0	Delete file
13	C14	1	X	X	0	Revive after error mode entered
12	C13	1	X	X	0	Define access rights and user password
11	C12	1	0	0	0	Manufacturer test
10	C11	1	1	1	1	Get test result
09	C10	1	1	1	1	Sensor test
08	C09	1	1	1	1	Battery test
07	C08	1	1	1	1	Read log state
06	C07	1	X	X	0	Read multiple blocks (low level) Read single block (low level) Get file

05	C06	1	X	X	0	Write multiple blocks (low level) Write single block (low level) Put file
04	C05	1	X	X	0	Resume logging Stop logging Start logging
03	C04	1	X	X	0	Configuration
02	C03	1	1	1	0	Logout
01	C02	1	1	1	1	Login
00	C01	1	X	X	0	Initialization

Table 24 Permission Flags

A set bit indicates the permission to execute the command. The X marks that a command is changeable. The master can also change his permissions. A complete logged transponder needs the manufacturer role to reset passwords and permissions.

The execution is dependent on system state. In logging and error mode is the return value will be 'invalid logical flow'.

Permissions are checked for this command. Users must be logged in and possess the authorization. Without adequate permission the error code 'access denied' will be returned.

LOGIN Command

The login procedure must be passed before the user is able to send commands which are restricted by the access control.

The login state is kept until a logout command is received or the Transponder is removed from the RF-field.

With a repeated login command the user role can be switched.

LOGIN Command:

SOF	Flags(1)	0xA2	ICMfg(1)	Role(1)	Password(4)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xA2 | 0x32 | 0x00 | 0xEF 0xCD 0xAB 0x89 | 0xC7 0xE5

Tag to Reader: 0x00 | 0x78 0xF0

(Master Role Login)

An incorrect password will result in the error code ‘access denied’.

LOGOUT Command

This command clears the login state. The role returns to public role.

LOGOUT Command:

SOF	Flags(1)	0xA3	ICMfg(1)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xA3 | 0x32 | 0xE7 0x61

Tag to Reader: 0x00 | 0x78 0xF0

CONFIG Command

This command changes the logging and evaluation settings.

CONFIG Command:

SOF	Flags(1)	0xA8	ICMfg(1)	Config Data(16)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xA8 | 0x32 | 0x64 0x00 | 0x28 0x00 | 0xF0 0x00 | 0x00 0x00 | 0xE0 0x01 | 0x01 | 0x01 | 0x80 0x3E | 0x80 0x3E | 0x0C 0x9B

Tag to Reader: 0x00 | 0x78 0xF0

(Parameter: default settings)

Parameter descriptions:

Pos	bytes	Value	Meaning
0	2	TTINTV	Logging Interval in 6 sec steps
2	2	MINTEMP	Minimum Temperature Limit in sensor units (SU) for the time temperature integral
4	2	MAXTEMP	Maximum Temperature Limit in sensor units (SU) for the time temperature integral
6	2	MINTEMPABS	Minimum Temperature absolute Limit in sensor units (SU)
8	2	MAXTEMPABS	Maximum Temperature Limit in sensor units (SU)
10	1	TSTART	Ignore time after start in TTINTV
11	1	TSTOP	Ignore time before evaluation in TTINTV
12	2	TTINTTHRPOS	Time Temperature integral positive threshold in SU * TTINTV
14	2	TTINTTHRNEG	Time Temperature integral negative threshold in SU * TTINTV

A SU (sensor unit) must be seen as the raw data taken from the sensor. In the application software this value will be converted to °C by the following formula:

Temp [°C] = (CALIBSCALE * SU + CALIBOFFSET)/1000

Where CALIBSCALE is a positive 16 bit value and CALIBOFFSET is a signed 16 bit value.

The time temperature integral concerns a numeric integral. The time steps, TTINTV, are accepted as constant value, which are not stored in the transponder. The maximum value is 0xFFFF.

This command cannot be executed when the logging process is started. In this case the return value is ‘invalid logic flow’.

The permissions are checked for this command. Users must be logged in and possess the authorization. Without the permission the error code ‘access denied’ will be returned.

Also the value of TSTOP is limited to the range between 0 and 32. The error code ‘invalid parameter’ returns if the number is too large.

START Command

This command starts the logging process. Start time handed over by the time stamp is defined as seconds from 1.1.1970 (UTC). Configuration data is used for the logging configuration. The signature is set into the header of the measurement file for further identification.

START Command:

SOF	Flags(1)	0xAA	ICMfg(1)	Time Stamp(4)	Signature(4)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xAA | 0x32 | 0xF3 0x5A 0x71 0x16 | 0x01 0x02 0x03 0x04 | 0xAE 0xA0

Tag to Reader: 0x00 | 0x78 0xF0

(Date: 12/07/1981 00:00)

The execution is dependent on system state. In logging and error mode is the return value ‘invalid logical flow’.

The permissions are checked for this command. Users must be logged in and possess the authorization. Without the permission the error code ‘access denied’ will be returned.

STOP Command

STOP Command:

SOF	Flags(1)	0xAB	ICMfg(1)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xAB | 0x32 | 0x27 0xAF

Tag to Reader: 0x00 | 0x78 0xF0

This command stops the logging process.

The execution is dependent on system state. In sleep and error mode is the return value 'invalid logical flow'.

The permissions are checked for this command. Users must be logged in and possess the authorization. Without the permission the error code 'access denied' will be returned.

RESUME Command

This command allows resuming the logging process after a stop. Is there no logging process before, this command shall have the same effect than a start command, but the first measurement entry in the FAT and the current evaluation remain. For a detailed description of the parameters and responses see 'Start Command'.

RESUME Command:

SOF	Flags(1)	0xAC	ICMfg(1)	Time Stamp(4)	Signature(4)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xAC | 0x32 | 0xF3 0x5A 0x71 0x16 | 0x01 0x02 0x03 0x04 | 0x7C 0x48

Tag to Reader: 0x00 | 0x78 0xF0

READ LOG STATE Command

This command shall be executed in logging state.

READ LOG STATE Command:

SOF	Flags(1)	0xAD	ICMfg(1)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	Data (16)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xAD | 0x32 | 0x27 0xAF

Tag to Reader: 0x00 | 0x01 | 0x03 0x00 | 0x5F 0x5B 0xBE 0x4A | 0x00 0x00 | 0x00 0x00 | 0x00 0x00 | 0x00 0x00 | 0x00 | 0x77 0x75

This command delivers the actual log state. The data field contains the following information:

Pos	Bytes	Value	Meaning
0	1	RUNNING	Flag showing current logging mode (0 = not logging ; 0 ≠ logging)
1	2	NREC	Number of records in the actual file
3	4	CTIME	Last setted time stamp
7	2	CNTPOS	Pos. Number of positive Temperature Limit violations
9	2	CNTNEG	Pos. Number of negative Temperature Limit violations
11	2	TTINTPOS	Pos. Time Temperature Integral positive value in SU*TTINTV
13	2	TTINTNEG	Pos. Time Temperature Integral negative value in SU*TTINTV
15	1	VIOLATION	Flag showing violation of the predefined limits in the actual logging record (0 = o.k. ; 0 ≠ violation)

CNTPOS and CNTNEG count the exceeding over MAXTEMPINT and MINTEMPINT.

If the transponder is not running, all parameters remain. The evaluation values are reset by three events, start command, init command and microcontroller reset.
In error mode the return value is ‘invalid logic flow’.
The permissions are checked for this command. Users must be logged in and possess the authorization. Without the permission the error code ‘access denied’ will be returned.

READ SINGLE BLOCK Command

This command corresponds to the ‘Read Single block’ command in ISO 15693, but with an IC Mfg Code after the command byte and a 2 byte address. The respond starts in a later timeslot. 1 Block is 1 BU = 4 bytes. The block address field is 2 bytes, allowing to address a memory of 64k * BU = 256kbyte.

READ SINGLE BLOCK command:

SOF	Flags(1)	0xB2	ICMfg(1)	Block addr.(2)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	Data(BU)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xB2 | 0x32 | 0x01 0x00 | 0x9B 0x1F

Tag to Reader: 0x00 | 0x00 0x00 0x00 0x00 | 0x77 0xCF

(Address: 00 01)

Any non - matching block address results in the error code ‘block not available’. If the block address is not released by file system error code ‘access denied’ returned.
The permissions are checked for this command. Users must be logged in and possess the authorization. Without the permission the error code ‘access denied’ will be returned.
This command cannot be executed in error mode. In this case the return value is ‘invalid logic flow’.

READ MULTIPLE BLOCKS Command

This command corresponds to the ‘Read multiple blocks’ command in ISO 15693, but with an IC Mfg Code after the command byte and a 2 byte address. The respond starts in a later timeslot. N blocks of 4 bytes each are transferred.

READ MULTIPLE BLOCK Command:

SOF	Flags(1)	0xB3	ICMfg(1)	Block addr.(2)	N of Blocks(2)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	Data (N*BU)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xB3 | 0x32 | 0x01 0x00 | 0x01 0x00 | EF 1E

Tag to Reader: 0x00 |0xB8 0x69 0x0C 0x4A 0xB8 0x69 0x0C 0x4A |0x1A 0xBA

(Address: 00 01)

(Numbers of Blocks 2)

A not matching block address generates error code ‘block not available’. If the block address is not released by file system error code ‘access denied’ returned.

Numbers of blocks that are larger than 15 are receipted with error code ‘invalid parameter’.

The permissions are checked for this command. Users must be logged in and possess the authorization.. Without the permission the error code ‘access denied’ will be returned.

This command cannot be executed in error mode. In this case the return value is ‘invalid logic flow’.

WRITE SINGLE BLOCK Command

This command allows writing a single block of data (4 bytes) to an arbitrary position in external memory and corresponds to the related command in ISO 15693, but with an IC Mfg

Code after the command byte and a 2 byte address field. There shall be an acknowledge response after execution.

SINGLE BLOCK WRITE command:

SOF	Flags(1)	0xB4	ICMfg(1)	Block addr.(2)	Data (BU)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xB5 | 0x32 | 0x01 0x00 | 0x01 0x02 0x03 0x04 | 0x7B 0xEB

Tag to Reader: 0x00 | 0x78 0xF0

(Address: 00 01)

A not matching block address generates error code ‘block not available’. If the block address is not released by file system error code ‘access denied’ returned.

The permissions are checked for this command. Users must be logged in and possess the authorization. Without the permission the error code ‘access denied’ will be returned.

This command cannot be executed in error mode. In this case the return value is ‘invalid logic flow’.

WRITE MULTIPLE BLOCK Command

This command allows writing multiple blocks of data (4 bytes) to an arbitrary position in external memory and corresponds to the related command in ISO 15693, but with an IC Mfg Code after the command byte and a 2 byte address field. There shall be an acknowledge response after execution.

MULTIPLE BLOCK WRITE command:

SOF	Flags(1)	0xB5	ICMfg(1)	Block addr.(2)	N of Blocks(2)	Data (N*BU)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xB5 | 0x32 | 0x01 0x00 | 0x01 0x00 | 0x01 0x02 0x03 0x04 0x01 0x02 0x03 0x04 | 0x7B 0xEB

Tag to Reader: 0x00 | 0x78 0xF0

(Address: 00 01)

(Numbers of blocks:2)

A not matching block address generates error code ‘block not available’. If the block address is not released by file system error code ‘access denied’ returned.

Numbers of blocks that are larger than 5 are receipted with error code ‘invalid parameter’.

The permissions are checked for this command. Users must be logged in and possess the authorization. Without the permission the error code ‘access denied’ will be returned.

This command cannot be executed in error mode. In this case the return value is ‘invalid logic flow’.

REVIVE Command

This command revives a transponder which is in the error state. The user must be locked in. The response contains the reason of failure and error flag is reset when the command is accepted.

REVIVE command:

SOF	Flags(1)	0xBF	ICMfg(1)	Time Stamp(4)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xBF | 0x32 | 0xF3 0x5A 0x71 0x16 | 0x6E 0x03

Tag to Reader: 0x00 | 0xD2 | 0x78 0xF0

(Date: 12/07/1981 00:00)

(Error: Brown Out)

This command cannot be executed on normal modes. In this case the return value is ‘invalid logic flow’.

BATTERY TEST Command

The most tests are performed in a 2 step procedure:

- Start Test
- Get Test results

Between test start and getting test results may be some milliseconds as specified later. Test start activates an internal test procedure, which blocks any other requests from executing. If there is a communication request before the test is finished.

This command reads out the battery voltage:

SOF	Flags(1)	0xC1	ICMfg(1)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

The execution is dependent on system state. In logging and error mode is the return value ‘invalid logical flow’.

Example:

Reader to Tag: 0x12 | 0xC1 | 0x32 | 0x02 0x37

Tag to Reader: 0x00 | 0x78 0xF0

SENSOR TEST Command

This test reads out the temperature sensor. The command flow is similar to the battery test.

SOF	Flags(1)	0xC2	ICMfg(1)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xC2 | 0x32 | 0x6A 0x1D

Tag to Reader: 0x00 | 0x78 0xF0

The execution is dependent on system state. In logging and error mode is the return value 'invalid logical flow'.

MANUFACTURING TEST Command

This command is used during manufacturing and requires the MANUFACTORER permission. It is implementation in the operational firmware is optional. There may be a special firmware for testing downloaded before, which uses this test:

SOF	Flags(1)	0xC3	ICMfg(1)	Test_ID(1)	Parameter (4)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xC3 | 0x32 |0x01| 0x00 0x00 0x00 0x00 | 0xD3 0xFE

Tag to Reader: 0x00 | 0x78 0xF0

A not valid test ID has the return value 'invalid parameter'.

Test ID 5 to 8 needs an addition parameter. In test 5 the parameter represents a time stamp. In 6 the calibration data is handed over. The parameter in test 7 controls the time between two measurements. The parameter in test 8 switches the life beat indicator on, if the value is not zero.

Users without manufacturer role will receive a 'access denied' message.

The execution is dependent on system state. In logging and error mode is the return value 'invalid logical flow'.

GET TEST RESULT Command

GET TEST RESULT command:

SOF	Flags(1)	0xCF	ICMfg(1)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	Test_ID(1)	Result(2)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Table 3.2.6.3.18-1: Test ID definition

Test ID	Description of the Test
0x00	Battery Voltage Test
0x01	Temperature Sensor Test
0x02	Firmware integrity Test (optional in operational version)
0x03	EEPROM Test /Read/write/erase (optional)
0x04	RTC Test (optional)
0x05	Set Manufacturer Timestamp
0x06	Calibration
0x07	Power Test (optional)
0x08	Life Beat Indicator on/off (optional)

Test ID allows automatic interpretation of the test result. There may be a several (at about 6) seconds time interval between test start and the receipt of the test results. The login state and communication time out must be switched off.

Interpretation of the 12 bit raw values of sensor and battery read out see table below.

Results are of the form:

Test ID	Test result	Description
0x00	0x0000 0x0FFF	Battery voltage as a 12 bit raw value
0x01	0x0000 0x0FFF	Temp Sensor value as 12 bit raw data in SU
0x02 0x03	0x0000 0xFFFF	Successful Not successful

0x04 0x05 0x06 0x07 0x08		
0x09-0F		RFU

The permissions are checked for this command. Users must be logged in and possess the authorization. Without the permission the error code 'access denied' will be returned.
The execution is dependent on system state. In logging and error mode is the return value 'invalid logical flow'.

PUT File Command (high level)

This command allows transferring a complete file to the transponder. The protocol is:

1. Request of memory space for the transmitted file (filename includes dot):

SOF	Flags(1)	0xD0	ICMfg(1)	Filename(12)	N of Blocks(2)	Time stamp (4)	CRC16(2)	EOF

if space is available, respond is *start address* of the block:

SOF	Flags(1)	Block address(2)	CRC16(2)	EOF

If error flag is set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

If no space or no permission, command ends here.

1. if ok, write multiple blocks follow:

SOF	Flags(1)	0xB5	ICMfg(1)	Block addr.(2)	N of Blocks(2)	Data (N*BU)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xD0 | 0x32 | 0x20 0x20 0x20 0x20 0x74 0x6F 0x62 0x69 0x2E 0x74 0x73 0x74 | 0x00 0x01 | 0xF3 0x5A 0x71 0x16 |0xAF 0x27

Tag to Reader: 0x00 | 0xFF 0x3E | 0xF1 0xE1

With positive respond, the FAT is updated with the new file.

If there is no space for new record, error code 'no space' returned.

The permissions are checked for this command. Users must be logged in and possess the authorization. Without the permission the error code 'access denied' will be returned.

This command cannot be executed in error mode. In this case the return value is 'invalid logic flow'.

GET File Command (high level)

This command allows getting a complete file from the transponder:

GET FILE command

SOF	Flags(1)	0xD1	ICMfg(1)	Filename(12)	CRC16(2)	EOF

If file exist, respond is *start address* and *number blocks*:

SOF	Flags(1)	Block address(2)	N of Blocks(2)	CRC16(2)	EOF

If error flag is set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

If no space or no permission, command ends here.

If ok, READ MULTIPLE BLOCK follows:

SOF	Flags(1)	0xB3	ICMfg(1)	Block addr.(2)	N of Blocks(2)	CRC16(2)	EOF

Respond:

SOF	Flags(1)	Data (N*BU)	CRC16(2)	EOF

Respond if error flag set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xD1 | 0x32 | 0x20 0x20 0x20 0x20 0x74 0x6F 0x62 0x69 0x2E 0x74 0x73 0x74 | 0x6C 0x64

Tag to Reader: 00 | FF 3E | 00 01 | 99 8D

If the file name does not exist in file record, error code 'file not exist' is returned.

The permissions are checked for this command. Users must be logged in and possess the authorization. Without the permission the error code 'access denied' will be returned.

This command cannot be executed in error mode. In this case the return value is 'invalid logic flow'.

DEL File Command (high level)

This command deletes a file in the external memory of the transponder.

DEL FILE command:

SOF	Flags(1)	0xD2	ICMfg(1)	Filename(12)	CRC16(2)	EOF

If file is existent permission validated, respond is *ok:*

SOF	Flags(1)	CRC16(2)	EOF

If error flag is set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Example:

Reader to Tag: 0x12 | 0xD2 | 0x32 | 0x20 0x20 0x20 0x20 0x74 0x6F 0x62 0x69 0x2E 0x74 0x73 0x74 | 0x52 0xE7

Tag to Reader: 0x00 | 0x78 0xF0

FAT entry will be marked accordingly. There will be no physical erase of the file.

If the file name does not exist in file record, error code 'file not exist' returned.

The permissions are checked for this command. Users must be logged in and possess the authorization. Without the permission the error code 'access denied' will be returned.

This command cannot be executed in error mode. In this case the return value is 'invalid logic flow'.

RUN File Command (high level)

This command is used in the manufacturing- and update- processes and requires the existence of bin-files which are executable on the transponder.

RUN FILE command:

SOF	Flags(1)	0xD3	ICMfg(1)	Filename(12)	CRC16(2)	EOF

If file is existent and permission there, respond is *ok:*

SOF	Flags(1)	CRC16(2)	EOF

If error flag is set:

SOF	Flags(1)	Error code(1)	CRC16(2)	EOF

Only files which are corresponding to specifications of *.bin files, are executed. Behavior after that depends on the executable and is undefined.

Example:

Reader to Tag: 0x12 | 0xD3 | 0x32 | 0x20 0x20 0x20 0x20 0x74 0x6F 0x62 0x69 0x2E 0x74 0x73 0x74 | 0x8B 0x99

Tag to Reader: 0x00 | 0x78 0xF0

If the file name does not exist in the file record, error code ‘file not exists’ is returned.

The permissions are checked for this command. Users must be logged in and possess the authorization. Without the permission the error code ‘access denied’ will be returned.

This command cannot be executed in error or logging mode. In this case the return value is ‘invalid logic flow’.

Error Codes

Additionally to the standard ISO 15693 [1] error codes, the following custom error codes (marked in the table) are defined from 0xA0 on:

Error	Short Message	Description
0x01	Not supported	Command not supported
0x02	Not recognized	Command not recognized, format error
0x03	Option not	The required command option is not supported

0x10	Block is not	Requested block/blocks are not existing (out of range)
0xA0	Access denied	The currently logged-in role does not have the
0xA1	invalid logical	The command cannot be executed in the current system
0xA2	invalid parameter	The request contains an invalid parameter.
0xA3	response too long	The response length would exceed the response buffer
0xB0	No file exist	The requested file is not existent
0xB1	No memory space	There is not enough space for new customer file
0xC0	No memory	There is not enough space for more measurements
0xCD	Unexpected	Run Time Failure (A internal variable is corrupted)
0xCE	Unexpected mode	Run Time Failure (invalid logic flow)
0xCF	RAM failure	Non consistent data in RAM
0xD0	Internal Failure	Run Time Failure (unidentified)
0xD1	Frontend Failure*	Communication interface is damaged
0xD2	Brown Out	Brown Out or unexpected reset
0xD3	EEPROM Failure*	EEPROM Failure
0xD4	Sensor Com. Error	Sensor do not reacted on I2C-Communication
0xD5	EEPROM Com.	EEPROM do not reacted on I2C-Communication
0xD6	Internal EEPROM	CRC check does not pass for EEPROM
0xD7	Firmware Integrity	Firmware is not integer

* Failure does no excite a failure handling from tag.

Appendix B: RFID Operational Modes

Storage Mode (Off)

This Mode is entered after manufacturing after writing default configuration data, UID, calibration data, initial MASTER password, and basic data structure. Time and Date of entering this mode is registered in the transponder LOG file. No clocks are operating. A default configuration is stored. The transponder may be stored in this mode for a long time.

Operational Modes (On)

This mode is always entered when the transponder is in a RF field as defined. In this mode, data may be read from the transponder and written to the transponder. All clocks are running. Sub modes are:

Ready

This is the basic mode after RF- field is detected. The transponder is ready to response to requests.

Quiet

This mode is entered after receiving the 'stay quiet (UID)' command. The transponder does not respond to a request until the command 'reset to ready' is received.

Selected

The transponder enters the selected mode after the reception of a valid SELECT (UID) command. In this mode, data can be read from the transponder and written to the transponder. All optional and custom commands require this mode for communication. The mode is left after a 'reset to ready' command or by a select command to a different transponder (different UID), by a 'stay quiet' command, removing from field or after a defined timeout. See ISO 15693 -3 protocols for details.

Communication

The transponder answers to commands as defined. Communication during a measurement is rejected until measurement is finished (prioritized).

Active Mode

The transponder is activated after a START command and goes to active mode.

If the transponder enters RF Field, only the following commands are allowed (in active mode):

STOP,

GET LOG STATE,

GET file,

PUT file,

Del file,

Read/ Write Single Block,

Read / Write Multiple Block,

Login, Logout

Active mode ends with the STOP command

Acquisition mode

Measurements are requested from the temperature sensor and recorded. The real time clock is running. The acquisition mode is signaled to the user by an optical signal green LED (Life Beat) if Life Beat Indicator is switched on. The moment of sensor data acquisition is signaled by a red LED. Violation of specified limits is signaled by a double flash of the green LED (LB-Indicator). This function is inhibited if LB-Indicator is switched off. After acquisition, the transponder transfers to sleep mode.

Sleep Mode

In this mode, the transponder is waiting for the next wake up by the real time clock; the real time clock is active, allowing return to acquisition mode in regular intervals. All other functions are shut down. This mode can be interrupted by the communication mode.

Test Mode

This mode may be entered during communication mode (no active logging) and allows executing the TEST commands.

Error Mode

This mode is entered when a fatal internal error is detected and the error flag is set. The error flag contains information on the error source (implementation dependent). Acquisition is stopped. Error mode is similar to storage mode with all clocks turned off.

Error mode can be reseted by sending the command sequence

REVIVE

Examples: Brown Out, Sensor Com. Error, etc.

The reasons of entering the error mode shall be responded with the revive command. A communication error shall not trigger this mode and shall not be considered as fatal.

Appendix C: Advanced Functionalities

Configuration Process

Without downloading any configuration, the transponder uses the default values which are permanently stored. Configuration may be changed by using the CONFIG command after LOGIN, changing the related configuration parameters. The new configuration is valid until another configuration is received. Only a part of the configuration data can be changed by the user, but following parameters require LOGIN with the manufacturer password:

- Calibration of sensor,
- Manufacturing Time.

Permission status is not part of the configuration file and must be changed with the ACCESS RIGHTS command

Configuration may be checked by using the

GET CONFIG.CFG command

The retrieved file contains all related configuration data.

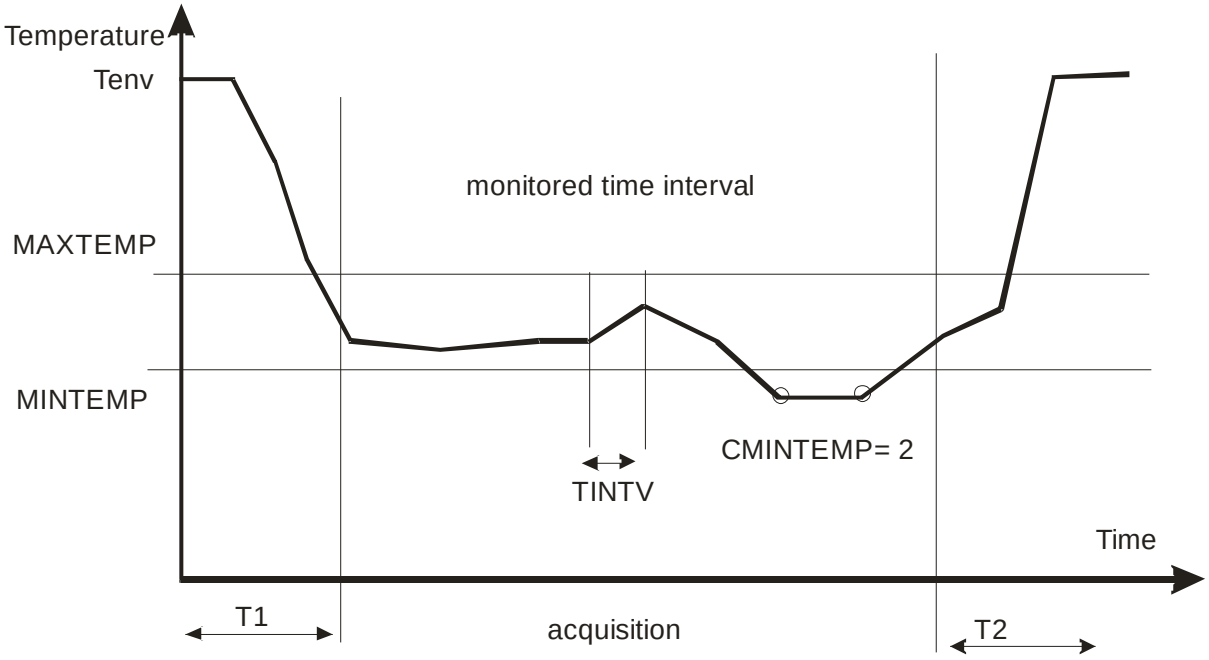
Data Acquisition

Data acquisition is started with the START command. A new file with the generated name TEMP_1.DAT is opened and a header with all information which is related to the acquisition process is written:

Header:	<magic number>	2 Byte
	SENSOR	1 Byte
	CALIBROFFSET	2 Byte
	CALIBRSCALE	2 Byte
	BATVALUE	1 Byte
	TINTV	2 Byte
	MINTEMP	2 Byte
	MAXTEMP	2 Byte
	MINTEMPABS	2 Byte
	MAXTEMPABS	2 Byte
	T1	1 Byte
	T2	1 Byte

	TTINTTHRPOS	2 Byte
	TTINTTHRNEG	2 Byte
	TIMESTAMP	4 Byte
	USER SIGNATURE	4 Byte
Body:	RAWDATA	n x 2 Bytes for each record
Footer:	CRC16	2 Byte

Measurement is taken by triggering the sensor and storing the data in a raw format. Sensor calibration is done in the application software by processing the raw data, using the calibration data from the header. The acquisition mode is signaled to the user by flashing a life beat indicator in a regular period (if this feature is switched on).



During acquisition, the sensor data is checked against MINTEMP and MAXTEMP.

If there is a violation, the counters CMINTEMP or CMAXTEMP are incremented and TTINTPOS or TTINTNEG are calculated (out of Range). TTINTPOS or TTINTNEG are the sum of positive or negative exceeding. By this there is a continuous monitoring of the recorded data.

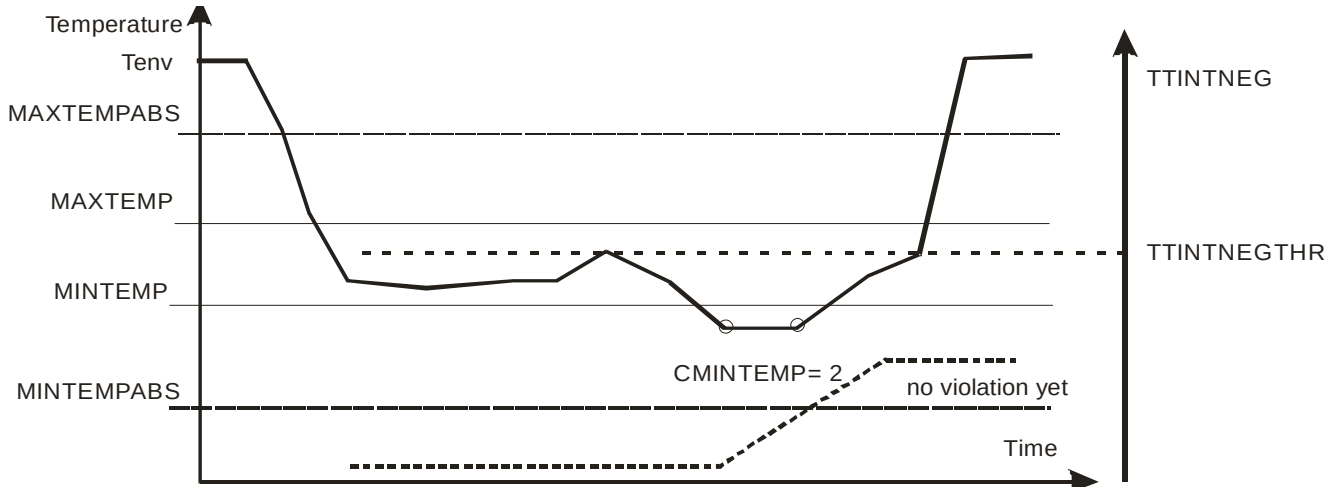


Figure 51 Time Temperature Integral Calculation TTINTEG

If TTINTNEG or TTINTPOS is larger than the time temperature integral threshold TTINTEGNEGTHR or TTINTPOSTHR, a TTINT_EVENT event is triggered and saved to the HISTORY.LOG file. As well a exceeding of the borders of MAXTEMPABS or MINTEMPABS generates a violation. A VIOLATION flag is set, which is used to change the life beat indicator behavior to double flashing.

The footer is written, when the file is closed, which happens when the command STOP is received or in case of a memory full event the file is closed automatically. The FAT is updated accordingly. This event is logged in history.

Data Evaluation

During the acquisition process, the recorded data can be checked with the

GET LOG STATE command

Return values are

- Number of recorded measurements
- Number of range violations (pos, neg. separately)
- Value of the accumulated TTINTEG (pos and neg.) as well as the status of the VIOLATION flag.

This command can be used any time during active mode. The status of the violation flag is signaled to the user by a double flash of the life beat indicator, if this feature is switched on.

Data Readout

Data is read out using the

GET FILETABL.SYS for getting a directory of the stored files

GET TEMP_01.DAT for downloading the recorded data.

The same process is used for text files with customer data, history or configuration files.

Resuming Acquisition

In case of resuming the acquisition process, a new TEMP_02.DAT file is created with the new time stamp and the actual configuration data by using the

RESUME command.

There may be as many resumes as storage space is available. With each RESUME, the number in the filename is incremented by 1. The application program is responsible for memory space allocation and supervision in the customer and measurement segment. The maximum number of files including the configuration, sys- and log-files must not exceed the maximum FAT size of 16.

Testing, Maintenance and Updating

There are tests integrated for field testing and manufacturing testing. Special tests used during manufacturing only may be an optional part of the firmware. Required tests in field application are

- Sensor Test and
- Battery Test.

These tests are triggered with the command

BATTERY TEST

or SENSOR TEST

All other tests are subject of manufacturing or maintenance and shall use by the command

MANUFACTURING TEST <test_ID>

The parameter contains information on the required test procedure. Because all these tests need some time to perform (may be some seconds), the test results are taken with the command

GET TEST RESULT

which ends the test-mode and transmits all related information. In the test mode, the transponder do not answer to commands. Testing is not allowed in the acquisition mode.

Maintenance and Life Update Procedure

The implemented file system is simple and is maintained by the application software. This program generates all related warnings and error messages when violating the hardware limits of the transponder, which can be found in the configuration file. Maintenance requires MASTER permission.

The program is able to update the firmware to a new version by using an update process. This procedure can will be performed like follows:

INIT <time stamp>	erase all data stored on the tag
PUT FIRMWARE.BIN	load the new firmware to the storage area
RUN FIRMWARE.BIN	execute the loader, which copies the firmware to the FLASH
INIT <time stamp>	reformat the memory area
CONFIG <data>	configure the new software

Details will be subject of implementation. During the update process, communication is interrupted and will be restored with the INIT command. During this time, the RF Field must be on and available.

History File

The HISTORY.LOG file is appended with each significant event. These events may be of the following types:

NOEVENT	(0x00)
MAN FIN TEST EVENT	(0xFF)
INIT EVENT	(0x01)
START EVENT	(0x02)
STOP EVENT	(0x03)
RESUME EVENT	(0x04)
REVIVE EVENT	(0x05)
VIOLATION EVENT	(0xE0)
ERROR EVENT GRADE 1	(0xF0)
ERROR EVENT GRADE 2	(0xF1)

ERROR EVENT GRADE 3 (0xF2)

ERROR EVENT GRADE x (0xFX)

There can be more types and subtypes defined. The error event shall contain the error number x, which triggers this registration.

For each event, there are eight bytes (2 blocks) written:

Event number (1) | Event Type (1) | Parameter (1) | Reserved (1) | Timestamp (4)

The log file is256 bytes long. The file starts with the

magic number 0x3E67 (2 bytes)

number of events (2 bytes)

n x EVENT (n x 8 bytes)

Reserved (2 bytes)

CRC16 (2 bytes)

CRC is calculated including the magic number with each entry in the file. If the maximum storage area of the file is reached, the entries are overwritten in a ring file manner. This ring buffer allows storing the last 64 events.

The HISTORY file can be read from the transponder using the high level commands

GET HISTORY.LOG

The permission to read this file may be defined in the role.

Security

Data Validity

Data stored on the transponder memory (files) is secured by using CRC16 as a part of the file. After transmission, data validity is checked in the application program by recalculation and comparing the CRC.

Data Transmission

All transmission of data is secured by using standard CRC procedures which is the case in using the ISO 15693 data transmission procedures.

Access Rights Management

There are a minimum of 4 roles defining the access rights to data and data handling. For each role, a password is defined:

MANUFACTURER role: Password is included in the Firmware and may be changed with a new update of the firmware. This role has permission to any commands.

MASTER role: Password is included in the persistent memory and may be changed with the ACCESS RIGHTS command. Default value is

'0x89ABCDEF'

Master role allows almost all commands to be executed.

USER role: The rights of the USER may be defined with the ACCESS RIGHTS commands, using the master password.

It is possible to store 2 different USER with different permissions. They are differentiated by the role number.

PUBLIC role: In the public role, only very restricted access to the tag is available. The public role is predefined.

Data Safety

Stored data on the transponder may be subject of data restriction. Initialization of the transponder shall physically erase (overwrite) the contents of the memory. Hence there is no possibility to reconstruct data from former records.

Safety against Data Manipulation

The low level commands are restricted in a way that there exists no possibility of data manipulation in the USER or MASTER role by replacing a file by a modified one. Device number and manufacturing date are protected in persistent memory and kept even under the update process. A singular manipulation of program data will be detectable by the firmware integrity check.

Appendix D: Data organisation and structure for mass data on RFID transponders

RFID transponders are electronic systems that can be used as an identifier for almost any kind of materials or products. Identification is unique and can be read with help of a radio interface which is widely standardized. [96] Beside this characteristic any RFID tag is able to store data that can be read or written over the radio interface. In most cases storage of data work with manufacturer depend standards

The number of data stored during a whole blood product life cycle is high. Therefore data storage must be significant greater than the one that can be found in common transponders. Data on the RFID tag has to be stored in an organized way. Those methods are already known. The most appropriate one is published in the US patent 2007 / 82613. [97] This patent describes the integration of RFID transponders to the directory of a data processing system (host) with help of a program (middleware). Files are not directly integrated into the file structure and the file allocation table is saved on the host and not on the RFID system.

In the publication 'The RFID files system whitepaper' [98] the author describes how data of a RFID transponder can be directly mounted into the file system of a processing system. Even here no autarkic file system on the tag itself exists. The RFID transponder is used as a cluster or a semi device of a data structure. This approach has been expanded by the international patent 2007/065747 [99] to the integration of multiple RFID tags to result into a distributed memory. Also in this case the organization of data will be performed on the host system. Similar concepts for external mass data storage to the file system of a processing unit are already known at other technologies than RFID. As an example the US patent 7039756 [100] describes an equipment that is widely called as USB stick.

Memory on common RFID transponders has more or less little data storage capacity. For the use within life cycle management a much higher data capacity is required. State of the art RFID systems do not organize their data on the tag itself. RFID transponders are integrated as data blocks to other systems. The file allocation table is (if it ever exists) located on an external host computer. The transponder itself has no knowledge about the current number of files or the current amount of used memory. It also has no control over the access rights

to this data. The way of data distribution to more than one unit turns out to be very risky when taking communication problems in account.

Using RFID transponders for a life cycle management is to simplify the organization of the mass data that will be received during the processes. Therefore a simple autarkic file system on the RFID transponder has been realized and [94] applied for patent. It needs a minimum of internal resources and is implemented in a way that the radio communication to the RFID tag can be done with already standardized RFID commands. (ISO 15693 part 1 -3, ISO/IEC 13239, ISO/IEC 13239 CRC calculation)

The data storage of the transponder can be used much more efficient and different data – types like system information, sensor data or any data that is transmitted via the interface can be saved in the same data segment. The transponder is able to organize data of different sources (e.g. internal sensors) without major changes to the standardized memory structure or the instruction set. The interface will no longer depend on the data type or data contents. Problems like restricted data access, data consistence can be put to an abstract level on the transponder. Consistence of data can be provided with help of checksums inside the files. Data can be equipped with headers that make any kind of interpretation easier. Restrictions to data access are solved inside the file level. Copy operations between the memory units on the transponder but also between the transponder and a computer system can be operated in a safe and easy way. Input data can be located to non – critical parts of the memory.

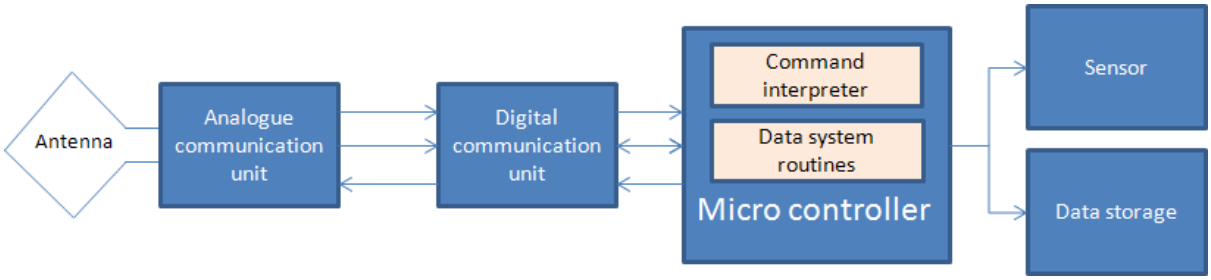


Figure 52 Application sample

With help of the inductive voltage of the antenna the analogue communication unit generates a clock pulse with the carrier frequency of the transmission medium. Also the amplitude modulated received signal will be transformed to a data signal (down – link). The other way round data to the transponder will be is transported by load modulation (up – link). This data will be decoded by the digital communication unit to be processed for later

use in the micro-controller. The digital unit can be implemented as a complex programmable logic device (CPLD) but also with help of discrete or application specific integrated elements. The command interpreter is implemented as a digital program and communicates with the routines of data system. Externals requests will be answered and data operations will be provided. The serial data - bus (I2C or SPI) provides connection to the digital sensor and to the mass data storage (EEPROM, Flash-PROM or FRAM).

The first sector of the electrically erasable programmable read-only memory (EEPROM) holds the file allocation table (FAT) which is saved as a file.

Index	Attribute	Name	Date/Time	Address	Size
0	0xC2	FILETABLE.SYS	0x00000000	0x0000	0x0062
1	0xC2	HISTORY.LOG	0x00000000	0x0062	0x0082
2	0xC2	CONFIG.SYS	0x00000000	0x00e4	0x000B
3	0xC2	TEMP_00.DAT	0x4C803C2C	0x00ef	0x0cb3
4	0xC2	TEMP_01.DAT	0xD1B6522	0xda2	0x112a
5	0x00		0x00000000	0x0000	0x0000
...					
13	0x00		0x00000000	0x0000	0x0000
14	0x00		0x00000000	0x0000	0x0000
15	0xF2	CUSTOMER.TXT	0x4CA2D838	0x3ff5	0x000A

Figure 53 File Allocation Table

Each table record holds information about the saved files.

- Index serial number of the file
- Attribute information about access and authorization
- Name filename and extension separated by a dot (.)
- Date/Time bit-field with decoded date/time according C – standard
- Address address in the EEPROM where the file starts
- Size size of the file in data block units

File access can be taken from the attribute – field. The filename is used to handle data requests to the file. Index, start -address and size describe the reserved data area for the specific file. Index and current read/write address can be put together to a single file pointer.

Two file pointers are located in the data storage of the microprocessor. Each of them allows the data system to open a file. Therefore telemetric data and sensor data can be transferred (read or written) in parallel into two different files.

Data fragmentation is prohibited as on one hand the electronic storage is strictly partitioned, on the other hand data access is regulated by the FAT. Lower sectors of the memory hold system relevant data that are protected against user access.

F	Telemetric (external) data
E	...
D	...
C	
B	
A	
9	
8	
7	...
6	...
5	
4	sensor data
3	
2	
1	system relevant data
0	

Figure 54 Memory segmentation

The next sectors are for the sensor data. Other data that is received by the interface is placed in the upper area of the memory. Data can be written until the file pointers overlap each other.

Each file consists of a header, user data and footer. The header starts at the lowest address. The header holds information that makes data interpretation easier for other data processing units. The footer holds a check sum according the system of a cyclic redundancy check (CRC). Changes on the file can be interpreted with help of this value. User data are placed in the middle part of the memory. User data are binary coded and can be encrypted if necessary.

The file system knows three types of files:

- System data: data is generated by the RFID transponder
- Measured data holds measured sensor data
- User data copied from another system to the transponder.

In normal case system data is read only for an external system. System data is information about the configuration, the assignment use of the transponder.

- File allocation table (*.SYS)
- Configuration file (*.CFG)
- History log (*.LOG)

The file allocation table is organized with 16 data records described in the table above. External systems will get immediate information about the file system by reading the file allocation table. This enables to easily implement a ‘DIR’ or ‘LIST’ command.

Data	Size/byte	Contents
Handle	1	Identifier
Attributes	1	File Attributes
RFU	2	Reserved for further use
Name	8	File name
Dot	1	'.'
Type	3	File type
Time	4	Timestamp
Start address	2	Start address of the file in EEPROM in BU
Size	2	Physical size of the file including header and CRC in BU

Table 25 Structure of file table, for each file

Transponder configuration is also saved in a file. Special commands that request information about the configuration can be handled this way. Static configuration values will not change throughout a transponder life-time. Those values are the ID-number of the transponder, the production status (version), structural information about the memory, sensor calibration and manufacturing data. Dynamic configuration data may change many times. In the course of an active transponder with a temperature sensor those dynamic values are e.g. the sampling interval of the sensor and the parameters for measurement interpretation.

The history log is a tabular log that holds important events. This file will give information about the use of the transponder.

Data of the sensor are saved in a measurement file (*.DAT). Those data can be interpreted without further context. Its header holds configuration information like the ID-number of the transponder, the sensor calibration data, measurement interval and parameters of the algorithm for measurement interpretation. Also process data will be saved at start up time of the logging. Here the date and time of the start of logging, and a special process number

is added. The data part of the file will be filled with raw data of the sensor which are continuously saved to the measurement file.

Data from an external system can also be saved on the transponder. Even any kind of data and any type of file could be transmitted (as long as data must not be interpreted), *.TXT type files will be preferred.

Data organisation is completely compliant to the ISO 15693 standard. The command set of the interface allows extensions to implement customer commands. This allows to include the following expansion set to the standard:

Login	Enables access to the RFID transponder
Init	Resets the transponder to its initial condition
Put File	Writes a file from an external system to the transponder
Get File	Sends a file from the transponder to an external system
Del File	Deletes a file on the transponder
Copy file	Copies a file inside the transponders file system. Data will not be sent over the interface
Update	Copies a file to the transponder and restarts the transponder
Logout	Ends a user session

All commands will be inserted to the optional command set according the ISO 15693 regulations. A prolongation of the response time for write operations is defined which accords to the standard. Any read / write access to the transponder is carried out as follows:

- The transponder will be selected
- The user logs in with help of a user – id and a password.
- A read or write – channel will be opened (The transponder response with a file pointer and the file size)
- A set of read or write commands will be performed with help of read multiple block and write multiple block until the complete file is received or sent.
- Logout or deselect ends the session

Appendix E: Proof of Linearity

Calibration

Before starting the tests all probes have been calibrated. Calibration was done with a 3 – point calibration at -5°C, 0°C and +5°C in liquid bath.

Reference:	Huber ministat 230-NR
Certificate No.	CN20100811
Equipment No.	112074/10
Calibration Date:	Oct. 15, 2010

The calibration has been performed according to the manufacturer's specifications. All tests have been performed using methods that preserve traceability for the instruments.

Test Procedure

Temperature was generated with the same equipment as described under 'Calibration'.
First the liquid was cooled down to -35°C.
The TRD was started with a measuring interval of 6 seconds.
The temperature was increased in steps of 5°C up to a temperature of 55°C.
In former tests a dwell time of 15 minutes has shaped up to be appropriate. Shorter intervals may disrupt the continuity of measurements at a specific temperature. Longer intervals would elongate the overall procedure. Hence the dwell time at each step was a minimum of 15 minutes.
After the temperature reached 55°C the liquid bath was cooled down to a non-dangerous temperature. After the probes were taken out of the liquid bath, the TRD were stopped.

Analyses

After stopping the logger, the temperature curve was analyzed. The smoothed areas within the dwell period where the temperature remained constant are checked out. As the bath temperature is known at any stage (of the dwell area) the deviation to the measured values could be calculated.

Documentation

All measured values where recorded into Excel sheet. Each line contains the values of one single device, as each column contains the measured values. With help of those values a chart could be produced that shows the overall linearity of all 50 probes.

Results

In the range or interest (between -10°C and 30°C) 100% of the probes where under a deviation of 0.5 °C.

100% of the probes have a deviation below 0.37°C in the range of -5°C and 30°C.

100% of the probes have a deviation below 0.25°C in the range of 5°C and 25°C.

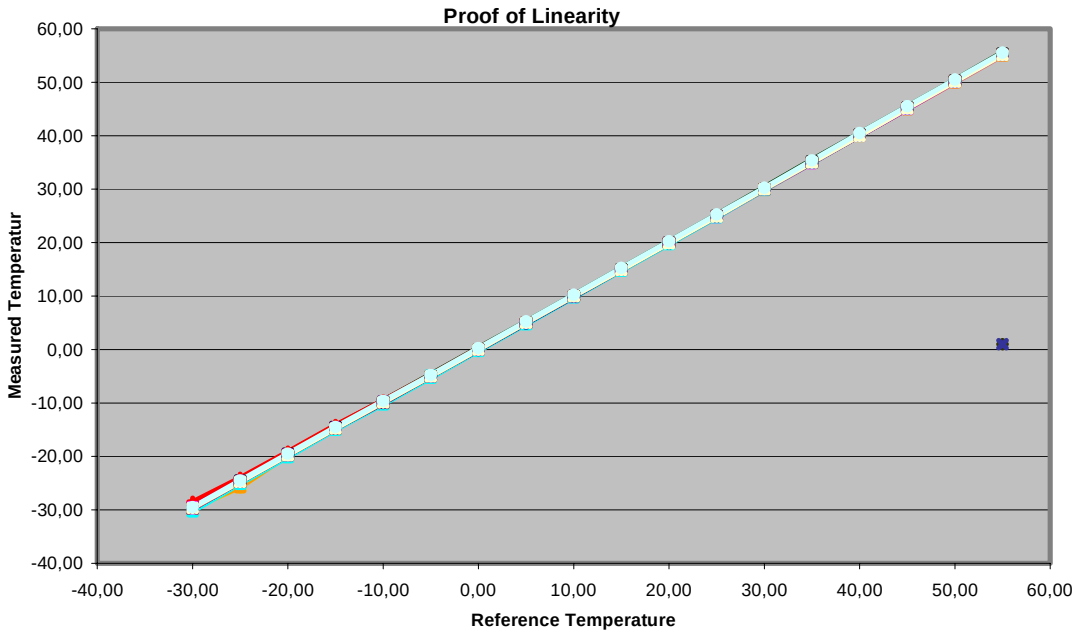
0°C	0.12°C	0.25°C	0.37°C	0.5°C	Deviation / Temperature In %
6	14	58	68	94	-30.00°C
4	20	72	88	96	-25.00°C
8	20	74	90	96	-20.00°C
4	12	68	86	96	-15.00°C
40	62	94	96	100	-10.00°C
76	88	98	100	100	-5.00°C
74	86	98	100	100	0.00°C
72	84	100	100	100	5.00°C
66	82	100	100	100	10.00°C
58	82	100	100	100	15.00°C
60	88	100	100	100	20.00°C
62	86	100	100	100	25.00°C
78	92	98	100	100	30.00°C
74	92	96	98	100	35.00°C
42	74	94	96	100	40.00°C
18	40	94	94	100	45.00°C
8	32	92	94	100	50.00°C
8	32	90	94	98	55.00°C

This table shows the percentage of the deviation at a particular temperature. E.g. 72% of the devices have maximum deviation of 0.25°C at a temperature of -25°C.

In absolute numbers:

Deviation / Temp. in absolute Numbers	0.00°C	0.12°C	0.25°C	0.37°C	0.50°C	0.62°C	0.75°C	1.00°C
-30.00°C	3.00	4.00	22.00	5.00	13.00	1.00	1.00	1.00
-25.00°C	2.00	8.00	26.00	8.00	4.00		1.00	1.00
-20.00°C	4.00	6.00	27.00	8.00	3.00		1.00	1.00
-15.00°C	2.00	4.00	28.00	9.00	5.00		1.00	1.00
-10.00°C	20.00	11.00	16.00	1.00	2.00			
-5.00°C	38.00	6.00	5.00	1.00				
0.00°C	37.00	6.00	6.00	1.00				
5.00°C	36.00	6.00	8.00					
10.00°C	33.00	8.00	9.00					
15.00°C	29.00	12.00	9.00					
20.00°C	30.00	14.00	6.00					
25.00°C	31.00	12.00	7.00					
30.00°C	39.00	7.00	3.00	1.00				
35.00°C	37.00	9.00	2.00	1.00	1.00			
40.00°C	21.00	16.00	10.00	1.00	2.00			
45.00°C	9.00	11.00	27.00		3.00			
50.00°C	4.00	12.00	30.00	1.00	3.00			
55.00°C	4.00	12.00	29.00	2.00	2.00	1.00		

This table shows the deviation at a specific temperature in absolute number of devices. E.g. 16 devices (out of 50) had a deviation of 0.25°C at a temperature of -10°C.


Proof of Linearity
Measured Temperatur
Reference Temperature
60,00
50,00
40,00
30,00
20,00
10,00
0,00
-10,00
-20,00
-30,00
-40,00
-40,00
-30,00
-20,00
-10,00
0,00
10,00
20,00
30,00
40,00
50,00
60,00

Appendix F: Operator Software Functions

The operator is an application to handle any activities concerning the logger. Main functions are to start and stop the logger and to read and analyse the current temperature curves as well as to store them in a database. At least some logger operations will enable the user to re-initialize the 'Temperature Recording Device' (TRD) as well as to set parameters.

To document the measurement data and quality decisions it is possible to add evaluation data in form of lines, boxes, borders and text to the chart of measurements (Detailed Analyser). Possibility to change temperature units (°C / °F) and possibility to change time zone (default is UTC – change is possible). This 'extended chart' can be stored in the database and is base for reports that can be stored and printed out (Reports).

The TRD cannot be started when guaranteed time of use is over. While starting a measurement user is informed about the end of use within a period of e.g. 60 (parameter) days before end of use.

Start

Only stopped devices can be started.
The procedure starts a temperature recording. The temperature category has to be selected before a real start is possible.

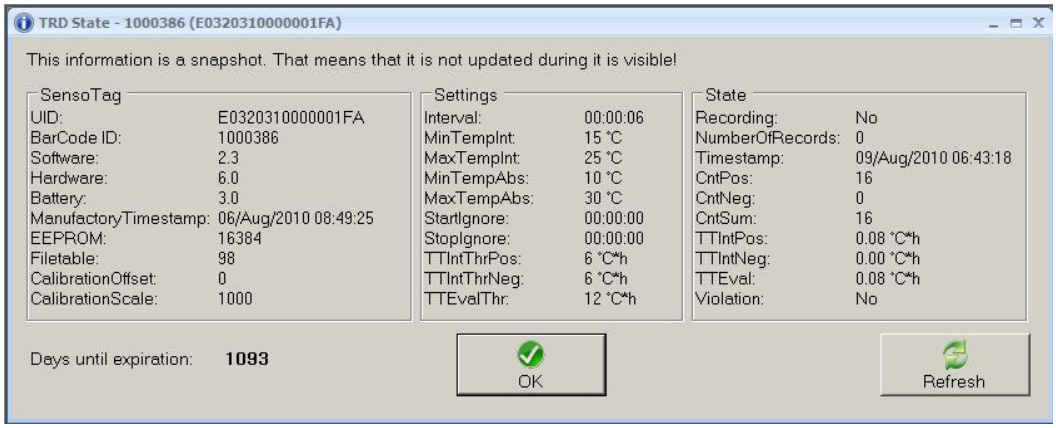
Stop

Only started devices can be stopped.

Stopping the device means also to save the recorded values to the database.

TRD State

This function informs the user about the current state of the TRD. The identification and system data, the current settings and a summary of the recorded data is listed



State Overview

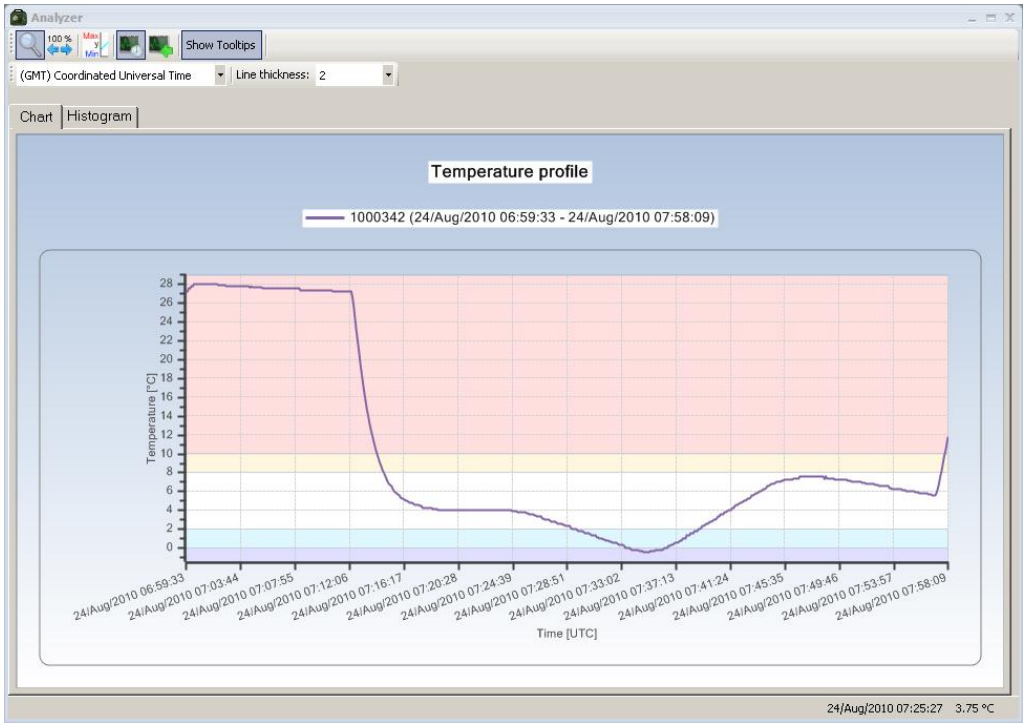
Informs the user weather the TRD's are stopped or started and if a violation occurred.

Calibration Report

On each device a calibration report is saved. The calibration is a 3 point calibration and can be listed with help of this function. The report can be printed or saved on disk in various formats.

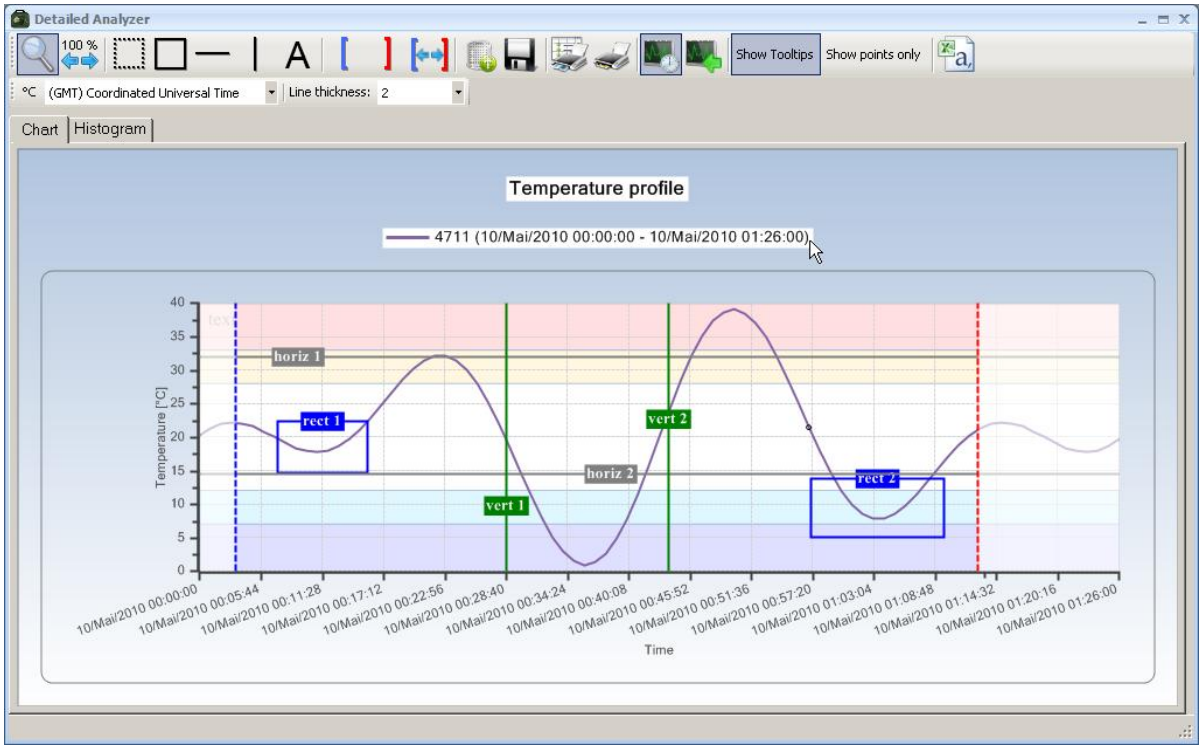
Quick Analyser

This shows the recorded values as graph. The values are taken from the TRD.



Detailed Analyser

The user is able to analyse previously saved measurements. The user can select the measurements out of a set of records where the user has access. A graph is shown where additional information can be added to the (unchangeable) temperature data. The graph can be saved again to the database.



You can open as much temperature curves as you want to be show in one graph.

New

This function allows the user to add a new text file to the TRD.

Open

The command opens a text file which is saved on the device.

Save on Tag

Copies text-files to the device

Save on Disk

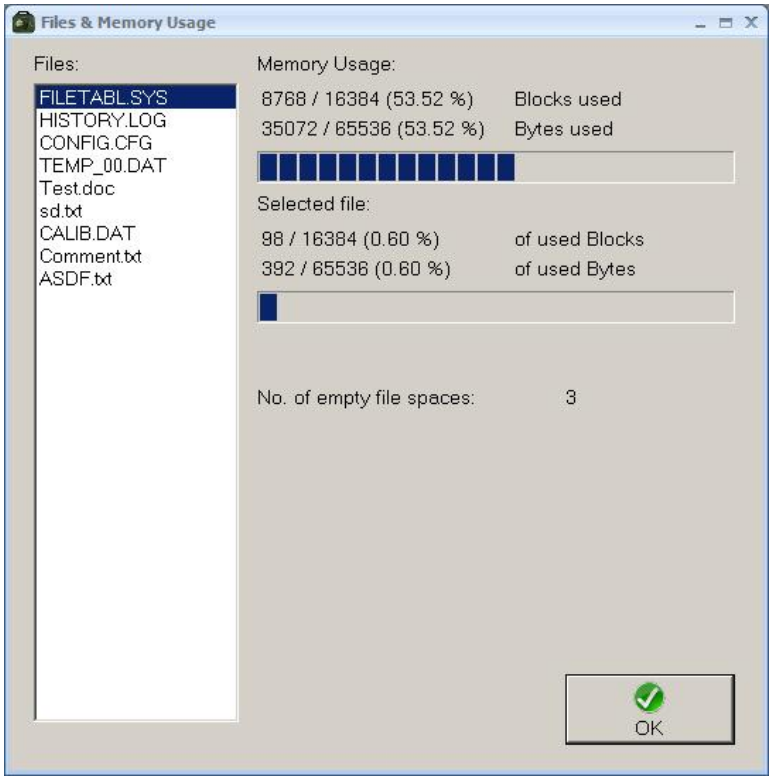
Copies text files from the TRD to some disk drive on the computer.

Delete

This deletes a text file from the TRD's memory. For deleting all data from the device you have to choose the >Initialization> function.

Memory State

This function opens the directory of the logger. All files saved on the TRD are shown, as well as their length and their total effect to the memory space.



Import

One or more temperature records can be exported to transfer them e.g. via emails. This export is done in a special format. With help of the import function those records are loaded and saved into the database. If a record already exists in the database, it will be rejected. At the end of the import procedure the user will be informed how many recordings have passed and how many are declined.

Export

This function allows the user to pack one or more temperature records into one file. The data will be encrypted and saved in a special file format. This export - file may now be sent to another user e.g. via email.

Open Windows

In case more than one menu has been opened, the user can choose one to bring it in front. This is a standard Microsoft Windows function.

Tile / Cascade

The user is able arrange the opened menus on the screen. This is a standard Microsoft Windows function.