

Integration And Implementation Of Medical-Data-Interchange- Standards In Clinical Laboratories

Informative Abstract

STIWA Fertigungstechnik Sticht Ges.m.b.H. is one of the leading companies in Europe in the field of intelligent high performance automation. STIWA manufactures production and assembly machines using modern technologies, which enable high availability and the shortest possible cycle periods. Now STIWA expands this experience to a new branch of business - laboratory automation. The development of a prototype machine for laboratory automation will provide an entry in that market.

The machine will cover the field of *specimen-sorting* and *specimen-identification* in laboratory diagnostics. The area of *laboratory diagnostics* is currently dominated by many manual work steps. These would be optimized and speeded up by the above machine.

In the last years many different *standards* in the field of *medical informatics* were developed. Many of them are specialized in a certain domain of medical care, only some of these standards are generally used. One standard has to be chosen for the integration of the machine in the existing laboratory-infrastructure. The four most important standards in industry are:

- **UN/EDIFACT:** This standard defines messages to pass detailed information on persons from one system to another in order to verify, add, change or delete person related data in information systems. The message may also indicate the action that should be taken by the receiving party either to add, change, delete or verify the person information.
- **Health Level Seven (HL7):** Health Level Seven (HL7) is both the name of the standards developing organization and the collection of protocols which are the HL7-Standard. HL7 addresses one main issue, the exchange of data, by compiling the data into messages. The format of the messages is defined by HL7's encoding rules. The timing of the message exchange is determined by trigger events.
- **CORBAMed:** CORBAMed is comprised of specifications that relate to the healthcare industry. The primary mission of CORBAMed is to improve the quality of care and reduce costs by use of CORBA technologies. CORBAMed defines standardized object-oriented interfaces between healthcare related services and functions. These interfaces serve to promote interoperability between a variety of platforms, operating systems, languages and applications.
- **xDT:** xDT is a specialized standard for the domain of blood-analysis laboratories and the communication between doctors, laboratories and health insurances. The xDT-standard was defined by German authorities for this application. Other fields of medical-data-exchange aren't covered by this standard.

The concept behind the standards, the communication model, the structure of the messages, the covered fields in medical informatics and special features of the standards are described. Following the standards are compared against with the *value benefit analysis*. After this evaluation the standard for the implementation in the machine was chosen, it is HL7. Because HL7 is widely used in the U.S. and it is the most flexible standard in medical informatics. After

the detailed discussion of the four mentioned standards other important standard developing organizations and companies are mentioned in an overview table.

Following the selection of the implemented standards, this thesis covers the *requirements specification* for the software of the machine. The most important requirements are:

- an improvement of the quality standard in the laboratory,
- a low error rate and
- an increase of the throughput of the laboratory.

The next chapter covers the design of the software in depth. The design is developed by using the *Unified Modeling Language*. Design is done iterative, by first developing different Use-Cases, out of this Use-Cases a Deployment-Diagram was generated. Next the design for the implementation of the HL7-Standard and the interface to the laboratory-information-system is described. Another important part in design is the detailed specification for the communication with the machine's *Programmable Logic Controller*. The handshakes for the uninterruptible operation of the machine are also defined. The whole design is summed up by a Class-Diagram..

After the design of the software some implementation details are described in this thesis. Another important part of the thesis is the test and evaluation of the developed software. The results of this tests promises that the developed software would work well in the prototype-laboratory.