

Investigation of IT system for Point of Care Testing



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Abstract

Investigation of IT system for Point of Care Testing

This report is the result of a project performed at the Department of Clinical Chemistry at the Malmö University Hospital UMAS. To reduce the load at the surgery, the possibilities to let patients treated with anticoagulant drugs test themselves using self-service terminals will be investigated. The testing of these patients is currently performed by the personnel.

The goal of this project is to investigate how terminals for self-testing should be designed with the help of a new model of test instrument. It is also of interest that the technology could be used for other types of tests and testing in the home.

This report includes investigations of the benefits of self testing, how patients manage to handle the test instruments and how the instruments can communicate with a computer system.

The main benefits of self testing are fast access to test results which makes prescribing possible immediately after the testing. From an economic point of view, personnel costs would be considerably reduced. In this case however, the high maintenance cost of the test instruments implies that the cost per test is not lower compared with the current situation.

Utilization of the advantages of the self-service terminals requires the patients to some extent be guided by the computer terminal in the case of problems during the testing. This is done by acquiring information from the test instruments through their computer interface. The design of these however, especially because of the use of infrared communication, complicates the interaction with the instruments considerably.

Keywords: self-testing, medical instruments, user interaction, serial communication, C#.

Sammanfattning

Förstudie om IT-system för patientnära testning

Denna rapport är resultatet av ett projekt utfört på avdelningen för klinisk kemi på Malmö Universitetssjukhuset UMAS. För att minska belastningen på mottagningen vill man utreda möjligheterna att låta patienter som behandlas med antikoagulativa läkemedel testa sig själva med hjälp av självbetjäningsterminaler. Testningen av dessa patienter utförs i nuläget av personalen.

Målet med projektet är att undersöka hur terminaler för självtestning bör designas med hjälp av en ny modell av testinstrument. Det är också av intresse att tekniken skulle kunna användas även för andra typer av tester och testning i hemmet.

Det som utreds i rapporten är bland annat vinsterna med självtestningen, hur patienterna klarar av att hantera testinstrumenten och hur instrumenten kan kommunicera med ett datorsystem.

De största fördelarna med självtestningen är att snabb åtkomst av testresultatet vilket medför att ordination av läkemedel kan ske omedelbart efter testningen. Ur ekonomisk synvinkel skulle personalkostnaderna sjunka betydligt. I detta fall gör dock testinstrumentens stora driftkostnader att kostnaderna per test inte blir lägre jämfört med nuläget.

För att kunna utnyttja fördelarna med självbetjäningsterminalerna krävs att patienterna till viss del kan guidas av terminalens dator om det skulle uppstå problem under testningen. Detta görs genom att hämta information från testinstrumenten via deras datorgränssnitt. Designen av dessa, i synnerhet beroende på användandet av IR-kommunikation, försvårar dock interaktionen med instrumenten betydligt.

Nyckelord: självtestning, medicinska instrument, användarinteraktion, seriekommunikation, C#.

Foreword

This report is the result of a project performed 2009 at the request of the department of Clinical Chemistry at UMAS in Malmö. The work has also been carried out at the department.

I want to thank my supervisor Magnus Cinthio and my examiner Christin Lindholm. I also want to thank the staff at the department of Clinical Chemistry, especially Francesco Palmisano, Rolf Thämlitz, Göran Pegert and Leif Persson, for supporting my work there.

Mats Risberg

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1 Introduction

This project is based on a problem at the department of Clinical Chemistry at the university hospital UMAS in Malmö. Simply described, the increasing number of patients tested for blood coagulation analysis puts pressure on the surgery and the laboratory. The proposed solution is to introduce new tests methods at the surgery. The new methods involves that the patients who are tested for blood coagulation should be given the opportunity to test themselves with a kind of self-service terminals. This measure is expected to increase the capacity of the surgery with low need of personnel. The self-service terminals will be equipped with a new type of POCT instrument that perform the analysis.

The concept of POCT (Point of Care Testing) refers to diagnostic testing performed close to the patient. Unlike traditional laboratory testing POCT is performed with portable devices with fast access to the results. [11]

In order to use the POC-devices in an efficient way, there have to be a method to transfer the collected result data to the hospital data system.

Most devices have some possibility to transfer data to a computer system, but the design of these interfaces differs between the models and manufactures. To use the interface, also software for the computer system is required.

These systems are rarely developed to suit the data systems and working routines that are used at the hospitals. This could be both because the developers lack knowledge about the hospitals and that different data systems is used among the hospitals. In some cases it would be more efficient to write down the result and insert it in the data system manually instead of using the computer interface.

A system that is customized for the hospital's requirements and that makes it possible to transfer the measured data directly to the hospital computer system could make the procedure both faster and more secure.

2 Aim

The primary goal of the project is to investigate an appropriate software design for the before-mentioned self-service terminals. This includes identifying patient and/or operator, reading test result from the POC-device and to forward the result to the hospital data system.

There are also of interest to develop a similar system that could be used to transmit test result from POC-devices used during house calls. Software used for home testing should support the same sub processes as that for the self-service terminals, but under different conditions.

In addition to coagulation measurement there are a number of other tests that also can be performed with POC-devices. The system should, if possible, not be bound to a single device but be enough flexible to support different types of devices and thus different types of tests.

2.1 Questions to Investigate

As guidance for the project the following questions have been taken into consideration:

- What would the benefits be from introducing self testing at the surgery? Before self testing could be practised it is important to know if it's beneficial or not.

- Is it easy enough for the patient to learn and use the POC-devices? Since the patients are supposed to use the instruments themselves it has to be investigated how advanced they are to use. If the patients are unable to use the instruments by themselves, alternative solutions also have to be investigated.

- Are there any standards for data communication between POC-devices and computer systems and are those followed?

When programming software to interact with the POC-devices, it is desirable to work in a general point of view. If there are common standards for the communication for several POC-devices the software would have a greater field of application and.

3 Methods

The first stage in the project was to investigate how the work was performed at the hospital. A thorough surveying of the present test process was performed to be able to compare it with the planned new methods. The information was mostly obtained through practical studies and interviews with personnel. To be able to perform a comparison in respect of time and economy a time study were carried out. In this the time for test and analysis were measured for a number of patients.

Next step was to develop a design for the self-service terminals. Before this task was started, basic theory for interaction between user and computer were studied. The two POC-devices that where available for use in the terminals were also studied thoroughly to decide which of them would be the most suited one to use. Parts of the documentation for those devices were however not available until late in the project or not at all. The devices were instead mostly studied through testing. This also gave useful experience of how the devices worked in practice.

Finally it was also investigated how the software for the self-service terminals could be implemented. A prototype were implemented which includes interface to the hospital's data system and interface to POC-device for glucose measurement. The knowledge required for this where acquired from studying documentation and interview experts at the hospital. To find out a method to communicate with the two POC-devices for coagulation measurement some experimenting with interface hardware were also performed.

4 Present situation

This chapter describes the theory behind medication with anticoagulant and how the testing is performed and followed up at the hospital. It also includes a time study performed at the test surgery at UMAS, in which time consumption for each step in the test process are recorded.

4.1 Treatment with Waran

Waran is a medicine based on the active component Warfarin, which reduces the blood's ability to coagulate. It is mostly used to treat patients with thrombosis. The problem with Warfarin is that it interacts with many other medicines as well as some foods, making it harder to doze. Also, if the doze is too strong, it could cause side effects like dangerous bleedings.

To ensure safety for the patients and that the medication have the desired effects, regular tests of the patients must be performed. The tests give the coagulation time of the blood and can be used to decide the doze.

Measuring of coagulation time for blood is called "Protrombin Time" (PT). The unit used is International Normalized Ratio (INR), which is a ratio of standard coagulation time to the coagulation time of the patient. The measured coagulation time differs between every test instrument so the INR value is altered by an instrument specific correction factor. [9]

When a treatment with Waran is started the INR value for the patient usually fluctuate somewhat. The patient is called for testing about once each week this first period. The Waran doze and also the coagulation time can in most cases be more balanced over time. The intervals between the tests can then be increased. [2]

The test method currently used in Malmö and rest of the Nordic Countries is called Orwen. This method requires either a venous or a capillary blood sample mixed with a special solution. [9] In both cases the sample can be taken only with help of the personal.

There are fully 3000 patients treated with Waran in the Region of Malmö. That results in around 1000 PT-tests each week. About 60% of the tests are performed at the test surgery at UMAS or at the surgery of Slottsstaden (another test surgery in Malmö), 30-35% at care centres and 5-10% at the patient's homes. [2]

4.2 Testing at Surgery

When a patient arrives to the test surgery, he first prints out a queue ticket and waits to be served in the reception. The patient needs to bring his identification, his patient's card and the prescription letter with him. A mechanical machine is used to copy the information from the patient's card to a referral. At the same time also an ordering code is copied to the referral. If the patient hasn't brought his patient's card it is still possible to enter that information manually. The referral is then handed to the patient who proceeds to the waiting room.

In some cases, additional PT-tests have to be performed outside the prescribed time. This is necessary e.g. before operations or dental hygienic surgeries. When an additional test is needed, the patient first contacts a nurse at the coagulation surgery who faxes an order to the reception. The fax machine is not placed at the reception but in an adjacent room, so the faxed orders must be collected regularly. The time spent at the reception is usually longer for these patients. Some of these tests can also be acute. If so, this is marked at the referral and the receptionist set the queue system to let the patient in question first in queue for the testing.

Other duties at the reception is for instance to prepare referrals at the beginning of the day and to order transportation service for patients which are going home. In addition to PT a number of other tests are carried out on the test surgery. These are also attended at the reception.

It is recommended that the patient is still for 15 minutes before a blood sample is taken, this is for the circulatory system to reach balance. With the queue system it is difficult to ensure that patients always wait that time. Often, however, the waiting time for the sampling is of a similar magnitude.

The patients are tested in a number of consulting rooms where a nurse or a Medical Laboratory Scientist (MLS) performs the test. There are a total of eight such rooms staffed according to requirements. The same queue ticket is used for the consulting rooms and the reception.

The blood samples for PT tests are primarily taken through venipuncture. A band is then first stretched around the patient's upper arm to increase the amount of blood in the veins. This also makes the superficial veins become more apparent. To acquire the blood a cannula is used, which is equipped with a socket where a tube can be connected. Blood are drawn from a vein at the inside of the elbow and collected in a test tube. The tube has vacuum pressure and aspirates in that way the blood when it is connected to the cannula. The tube also contains citrate, which prevents the blood from coagulating during transport to the laboratory. The cannula is discarded after use.

For some patients, it is difficult to take venous samples. It is then possible to instead take a capillary sample. For these samples a lancet is used to take blood from the patient's fingertip. The blood is collected with a pipette and then placed in another type of test tube.

The referral, which since the reception is marked with the patient's identity and which type of test that should be done, is completed with the tester's signature and time for the sampling. Before the sampling the patient is asked to repeat his personal identity number, to make sure the referrals not have been confused. On the backside of the referral there are a number of self-adhesive labels for various types of tests. The label corresponding PT test is affixed to the test tube before it is ready to be sent to the laboratory for analysis.

The patient gets a plaster or a compress to stop the bleeding before he leaves the consulting room.

Once every half hour all samples and referrals from the reception rooms are collected and transported to the laboratory which is located in the same building. In the laboratory the referrals are first electronically read and information from them inputted in the laboratory data system Declab. Declab is used locally in the laboratory to mediate information between the instruments.

The test tubes that should be tested for PT are sorted out. The tubes have different colours of the caps depending on which test they are meant for and can be easily identified. The laboratory is equipped with two instruments manufactured by "Sysmex" for measurement of Prothrombin time. These are also connected to Declab where the results are automatically transferred when the analysis is complete. If the results are within normal range, it is validated and sent to the patient record automatically. If any sample shows an abnormal PT-value, the personnel are informed about this via a terminal computer. An extra analysis is manually triggered for these samples after which the results are validated by the personnel. The instruments uses only part of the blood of the test tube for the analysis, multiple tests can thus be performed without need of taking a new blood sample from the patient. The validation can however in most cases be done automatically.

4.3 Home Testing

Not all patients have the possibility to visit the test surgery. If a patient is prevented from visit the surgery by disease, the testing is done by the patient in the home. The blood sample is taken by a nurse in the same way as in the surgery so the sample and the referral have to be transported to the laboratory.

The patients who are tested in their home are usually old people treated with other medicines in addition to Waran. This makes the Waran harder to dose and thus require more regular tests.

4.4 Administration of result

The system for patient records at the hospital is called the “Melior”. However to manage the dosage of Waran another system called “Auricula” is used.

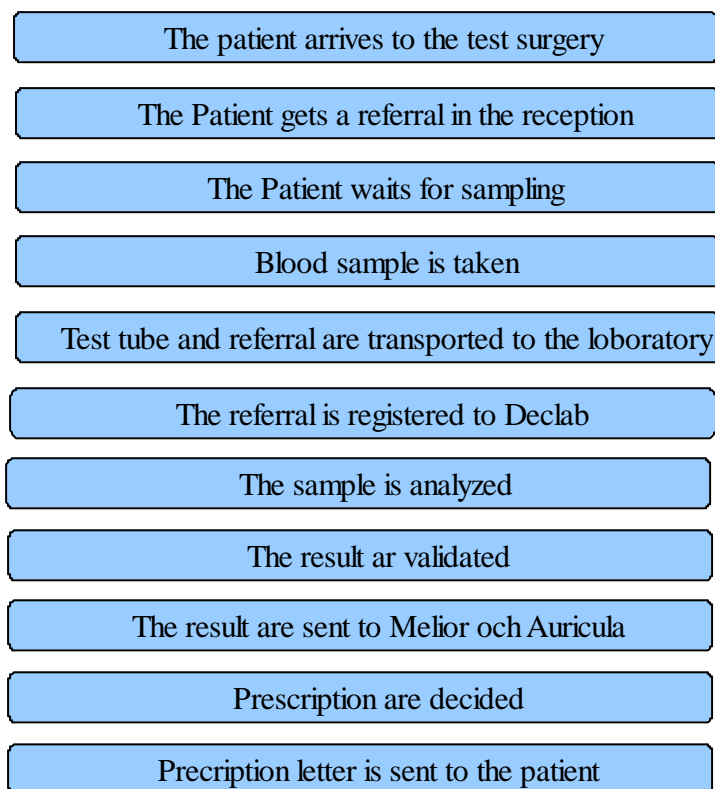
Auricula is a national database of patient records for patients treated with anticoagulants. It can be used for management of patients and dosage of medication. Today Auricula is used by UMAS and Uppsala Akademiska Sjukhus (UAS), but more hospitals and care centres have plans to start using it. [1]

The system is located in the UAS and has a web interface which can be accessed on the Internet via an HTTPS connection. Accessing and logging on to the system requires the web browser "Internet Explorer" version 6 or 7 and also a specific smart card connected to the client computer.

The results from Declab automatically become available for management in Auricula when they have been validated at the laboratory. When a new test results becomes available a nurse at the coagulation surgery decides whether the Waran dose should be altered, and how soon the patient needs to be tested again. Auricula has a function that calculates and suggests a new dose by using previous results. However, next time the patient called for testing is decided by the nurse alone. [2]

Patients are notified about the new prescription by mail. Auricula has built-in templates for letters, and can send them via email. To get the letters on paper as a traditional letter, “Posten”'s “e-Brev”-service are used. This service receives e-mails containing the letter in PDF format along with the address. The PDF-file is printed, put into envelope and sent to the attached address. [2]

In Auricula's user interface the functions of prescribing and e-mail distribution are separated. The easiest way to work with it is to create a new prescription when test results become available and then send out letters in batches a couple times a day. In most cases, the patient receives the prescription letter the next working day.



*Figure 1:
The process for PT-testing
at the test surgery.*

4.5 Time Study at the Test Surgery

To get an idea of how long time the process of PT-testing takes, and what the potential benefits of self-testing would be, a time study at the test surgery was performed. Since only a small number (10) of instances of the test procedure were included in the study, the outcome cannot be expected to be completely reliable. By taking into account other known factors affecting the time consumption when interpreting the result, it could still be useful.

4.5.1 Performance

The study was carried out by following a number of patients in the test surgery and recording the point of time for different steps in the process. Some time stamps were obtained from the data logs afterwards, while others could only be established through observation.

The first time stamp was recorded when the patient arrived at the test surgery. This was obtained from the patient's queue ticket, so actually it is the time when the patient prints out his ticket.

As mentioned before not all patients visiting the test surgery is there for the purpose of PT testing. In the reception it is found out whether that is the case or not. The patients which should be tested for PT were inquired if they were willing to participate in the study. For the participating patient the time stamp when the he leaves the reception, the number of the queue ticket and the id

number of the referral were recorded. The referral's id number is required to be able to find information about the sample in Declab later in the process.

Two more time stamps have to be determined through observation: When the patient is called for sampling and when the sampling has been completed. After this the patient leaves the surgery and the timing could start for a new patient.

After the observation was completed Declab was searched for additional time stamps using the referral's id numbers. The time stamps that could be obtained this way were when the referral was recorded into Declab, when the analysis of a sample were initiated and when test results was validated.

The time study was performed with only one observer. Because of this the timing for a new patient could not be started until the sampling for the previous patient was finished. This left no opportunity to effectively make measurements for a larger number of patients.

The flow of patients and thus also the time for the test procedure varies depending on the time of the day and the day of the week. The time study was performed a Tuesday between 08:00 and 12:00.

4.5.2 Result

All measured times stamps are shown in table 2, each column represents one patient.

Queue ticket number	869	884	905	939	946	957	970	989	11	32
Arrival at surgery	07:50	08:05	08:27	09:16	09:25	09:40	09:59	10:14	10:43	11:16
Referral handed out	07:55	08:15	08:35	09:17	09:26	09:41	10:01	10:19	10:43	11:18
Sampling started	08:10	08:23	08:50	09:21	09:32	09:48	10:08	10:32	11:04	11:32
Sampling finished	08:14	08:30	08:54	09:23	09:36	09:52	10:13	10:37	11:06	11:35
Transport to Laboratory	08:25	08:55	08:55	09:25	09:55	09:55	10:25	10:55	11:25	11:55
Referral read	08:33	08:59	09:02	09:33	10:00	10:01	10:43	11:00	11:37	12:03
Analysis started	08:52	09:47	09:51	09:48	10:23	10:22	11:03	11:15	11:51	12:46
Validation finished	08:57	09:52	09:55	09:53	10:28	10:27	11:08	11:20	11:56	12:51

*Table 2:
Measured time stamps for different stages in the test process*

By calculating the difference between the measured time stamps, the time consumption for seven different steps of the testing process was acquired. Table 3 shows the calculated times and Figure 4 shows a graphical representation. The

wide, black bars show the mean times for each step. The thin, grey bars show all the calculated times and thus gives a view of the distribution of the results.

Queue ticket number	869	884	905	939	946	957	970	989	11	32	Mean:
Wait for reception	00:05	00:10	00:08	00:01	00:01	00:01	00:02	00:05	00:00	00:02	00:03
Wait for blood sampling	00:15	00:08	00:15	00:04	00:06	00:07	00:07	00:13	00:21	00:14	00:11
Sampling	00:04	00:07	00:04	00:02	00:04	00:04	00:05	00:05	00:02	00:03	00:04
Wait for transport	00:11	00:25	00:01	00:02	00:19	00:03	00:12	00:18	00:19	00:20	00:13
Transport to Laboratory	00:08	00:04	00:07	00:08	00:05	00:06	00:18	00:05	00:12	00:08	00:08
Wait for analysis	00:19	00:48	00:49	00:15	00:23	00:21	00:20	00:15	00:14	00:43	00:26
Analysis	00:05	00:05	00:04	00:05	00:05	00:05	00:05	00:05	00:05	00:05	00:04
Time Total	01:07	01:47	01:28	00:37	01:03	00:47	01:09	01:06	01:13	01:35	01:11

Table 3:

Calculated times and mean for different moments in the test process.

The times is specified in hours and minutes

- Wait for reception

This is the time between when the patient prints his queue ticket until he has received a referral from the reception. The service time at the reception is also included in this step. This time, however, is mostly less than a minute and therefore has no significant influence on the result. Figure 4 shows that the waiting time during the study in most cases is no longer than a few minutes, but have a relatively large variance. This time is however dependant of the load at the surgery. The flow of patient is rather irregular, but has some pattern. It is for instance a large flow of patients at 07:00 when the test surgery opens, probably because many want to finish the testing before their jobs starts. It is also more patients who visit the test surgery at the beginning of the week than at the end.

- Wait for blood sampling

This time is measured starting when the patient leaves the reception until the sampling starts. This time has a large variance and also depends mostly on the flow of patients. The time is also increased if not enough consulting rooms are staffed.

- Sampling

This is the time from when the patient enters the reception room to when the sample has been taken and the patient can leave the test surgery. The measured times has a low variance and has an average of around 4 minutes. Since essentially the same procedures are carried out for each test, the time depends mostly on how hard it is to draw blood from the patient.

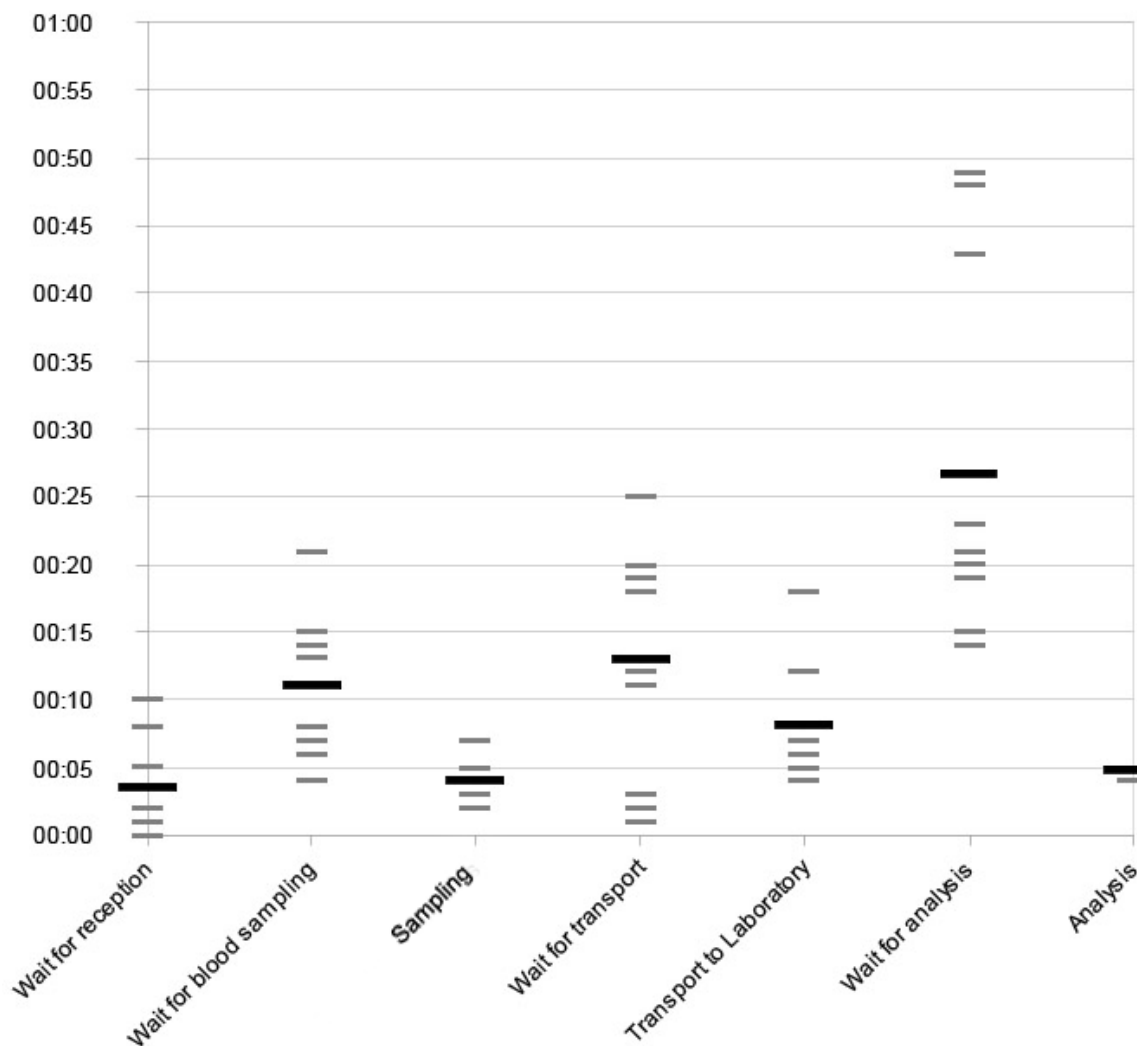


Figure 4:
Calculated times for different moments in the test process. The Y-axis represents the time specified in hours and minutes. The narrow grey bars represent the different measurements. The wide black ones represent the mean.

- Wait for transport to laboratory

This is the time from when the blood sample is drawn in the consulting room until it is collected and transported to the laboratory. The time when the blood samples are collected has not been established by observation, but by the fact that samples are collected every half hour.

The time study cannot provide more information about this operation than what is already known. The measured times is uniformly distributed between 0 and 30 minutes. The average time for this moment are calculated to 13 minutes, but would be approach 15 minutes if a larger number of patients were observed.

- Time for transport and registration at the laboratory

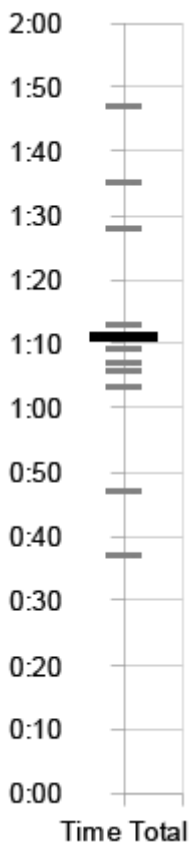
This period includes both transport to the laboratory, and any waiting period before the referral is registered into Declab. Judging from the recorded times, the transportation take around 5 minutes, after which all referrals are registered in one succession. However, it may take a while from that the referrals are delivered to the laboratory before they are registered, which increases the average time.

- Wait for analysis

This is the time from when the referral is read until the test tube is registered in the analytical instrument. This is the most time consuming moment in the study. The measured time shows that the analysis is run in sets with many samples simultaneously. The average time is around 30 minutes.

- Time for analysis

This is the time from when the analysis instrument registers the test tube until the results are validated. If the PT-value is within the normal range, the result is automatically validated immediately after the result has been measured by the instrument. All measured times for the analysis is around 5 minutes. This suggests that all of the samples were validated automatically. If manual validation would have been required, another analysis would be needed. This would have caused a time at least a twice as long.



*Figure 5:
Calculated times for the total time of the test process.
The narrow grey bars represent the different measurements. The wide black ones represent the mean.*

- Total time

The total time for the test process is illustrated in Figure 5. The average time among the different samples is around 70 minutes, but as seen in the figure there is a very large variance between the different measurements.

Factors which may cause the results to be unreliable are partly that the waiting time for the sampling varies widely between different times of day and week. Partly due to the load on the laboratory are also likely to vary and affect the time needed there. Also, the study did not include any acute tests, which would have been processed faster, or any tests that required manual validation, which takes longer time.

5 Coagulation testing with POC-devices

The PT analysis performed at the laboratory is currently done with the “Orwen” method. Earlier POC-devices for PT analysis uses a method called “Quick”, this method is standard for PT analysis outside the Nordic countries. Analyses performed with Quick however show a systematic mean difference to analyses done with Orwen, making them unsuitable to replace the current methods. Recently new POC-devices have been released that uses a different test method. These devices have been tested and have shown sufficiently good agreement with the Orwen method. [9]

The new POC-devices have been investigated to find out how they could be used for this project. This chapter gives the result of that investigation and a description of how the self-service terminals could be designed. The present test methods are also compared to how it could be performed with the self-service terminals.

5.1 Instruments for self testing

The POC-devices that are available for the planned self-service terminals are the instruments called “CoaguChek”, manufactured by Roche. The models that have been investigated are “CoaguChek XS” and “CoaguChek XS Plus”. Both of the instruments perform the measurements in the same way, but their interfaces have different design.

When a test should be done, capillary blood is applied on a special type of test strip which is inserted in the instrument. The chemicals in the test strips can only be used one time, so it has to be discarded after the test is done.

When the test strips is produced, their properties differs somewhat between each batch. To generate an exact result, a batch specific adjusting factor is therefore required. The adjusting factor is supplied to the instrument by a code chip that is delivered with the test strips.

To ensure that the code chip and the test strip match, there is a batch number for each package of test strips. The number is printed on the package, on the label of the code chip and also digitally stored on the code chip. There is no way to manually determine the batch number for a test strip. Although there is a matrix code printed on the stick, which is assumed to contain the batch number.

5.1.1 Model XS Plus

The XS Plus model is larger, has more functions than the XS Model and is intended to be used by personnel of a clinic. The user interaction is handled by a touch sensitive, graphic LCD display, a power button and sound signals.



Figure 6:
CoaguChek XS Plus

Except performing coagulation tests, the instrument also have functions to manage user accounts and patient lists. The user accounts can be used by the personnel to protect the instrument from unauthorized usage. A personal password is then required to use the device. To the user accounts it is also possible to enable a function that forces the user to perform regular quality controls.

The patient list makes it possible to bind the test results to specific patients. The patient is then selected from the list before the test is done. Configuration of user- and patient list can be done manually on the instrument or by using its computer interface. The instrument can also be used with both of these functions deactivated.

The XS Plus model also has a function to save the information from the code chip that is used. This makes testing easier if test strips from different batches are used. Before the test is started, the instrument first reads the batch number from the test strip. If information from the required code chip already is stored in the instrument, it automatically switches to the next step. If the information lacks, the batch number of the required code chip is showed on the display. When the correct code chip is inserted its information is stored. There are however no way to store information from a code chip in advance, it can only be done during a progressive test.

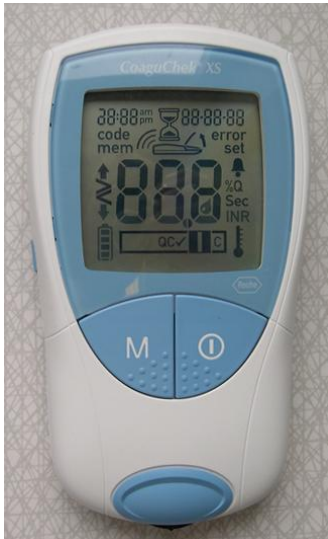
CouguChek XS Plus can communicate with a computer system by placing it in a stationary docking unit by Roche called “Handheld Base Unit”. The Communication between the instrument and the docking unit is done by IR through the communication protocol ICI.

The docking unit can communicate with a computer system by either USB or TCP/IP, in both cases it is the protocol POCT1A that are used. The communication protocols will be described later on.

5.1.2 Model XS

Model XS is intended as a private instrument, used by a single patient. It has a more simple design and has in the main the only function to perform coagulation tests. The user interaction is handled by a segmented LCD-display, three buttons and sound signals. Since the user is supposed to test himself, also the test strip may be defined as a user interface.

Unlike the XS Plus model, the XS model is unable to store information from the code chip or identify the batch number of the test strips. The reason for this are



*Figure 7:
CoaguChek XS*

supposed to be because the batch number is identified by reading the matrix code printed on the test strip. To be able to do this an optical reader is required. It has been confirmed that the XS model not is equipped with such a unit.

The XS model can communicate with a PC by using a USB adapter called “CoaguChek XS Connect”. The communication between the instrument and the USB adapter is done with an IR interface with the same communication protocol as model XS Plus. The Instrument cannot be fixed to the adapter but have to positioned manually in order for the communication to work.

The transmission between the adapter and a computer differs entirely from the XS Plus model. When the adapter is connected to the computer, a mass storage device is mounted and accessible in the computer's file system. When results from a test are downloaded from the device, they are printed in an xml-file at the mass storage device. The transmission from the meter is assumed to be started by java-script which triggers some hard ware function in the adapter.

5.2 Design of self-service terminals

The purpose of the self-service terminal is to make it possible for a patient to test himself without guidance from the personnel. The result from the test should automatically be inserted into Declab and forwarded for further use in Auricula. The self-service terminal should however be supervised by a nurse (PT-host) who can help the patient when problem occurs.

In order to bind each test result to the correct patient, the patient must in some way identify before the test. As mentioned before, the CoaguChek XS Plus has a system for managing patient lists, but this function is hard to make use of. The first problem is that the patient is selected by browsing through the patient list manually. Taking into account the number of patients using the system, this would mean browsing through a list with several hundreds of personal identity numbers. This is of course inconceivable. Even if there were a function to simplify the browsing, the instrument has still not capacity to list all patients that visits the surgery. The only solution to that would be to regularly change the patient list on the instrument to always contain the next patients that are called for testing.

A better alternative would be to instead identify with help of a computer application. In that case the identity of the patient can be verified by direct

contact to Declab. To make it as easy as possible for the patient to register themselves, the best way would be to use an identity card with the personal identity number available for mechanical input. The simplest alternative would be to use the patient's driving licence, which most of the patient posses. Driving licences have the personal identity number printed as a bar-code, which can be read with a bar-code scanner. It would also be possible to use identity cards equipped with RFID tag or magnetic stripe combined with an appropriate reading device. RFID is a technique to read information using radio waves.

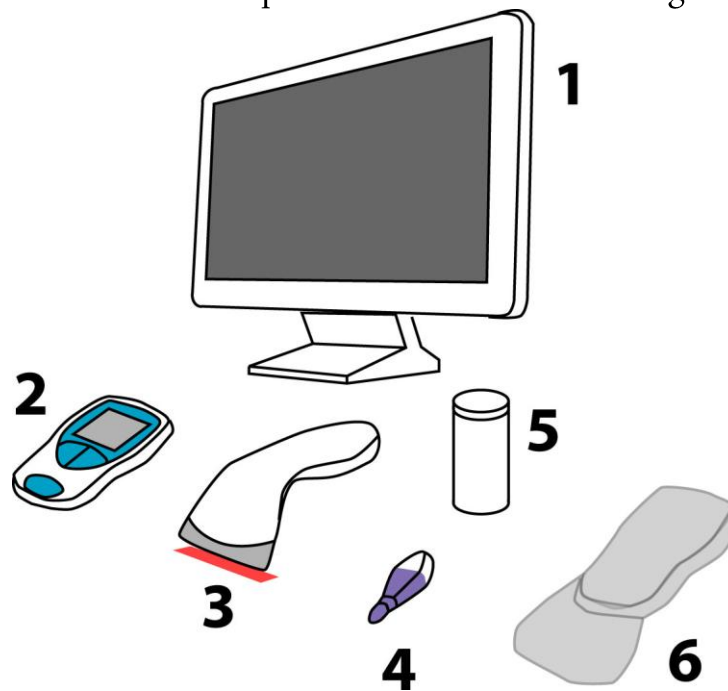


Figure 8:

The proposed equipment for the self-service terminals:

1: Touch Screen to guide the patient through the test process.

2: POC-device for PT-measurement

3: Bar-code reader to read the personal identity number from the patient's driving licence.

4: Disposable lancet.

5: Package of test strips.

6: Disposable protection to avoid contamination of the POC-device.

The alternative to use a keyboard to input the patient's personal identity number would not be a good choice. It would imply more steps, increase the chance of errors at input and furthermore be inferior in hygienic aspects. To avoid the need of keyboard and mouse also for the rest of the interaction with the computer, a touch screen could be used. In addition to being easier to keep clean it is easier to use for an inexperienced user if used in the correct way. It is also possible to draw an interactive keyboard on the screen if needed. This could for instance be if the patient has forgotten the identity card.

A disadvantage with a touch screen is that there is no response in the finger when pressing on it. When for instance pressing a key on a keyboard it is very easy to feel when the key is depressed. This can partially be compensated by adding sound and animation to the buttons on the screen.

For the test result to be compatible with the format that is used in Declab, it is also required to register an operator for the test. When the patient tests himself, he is also assigned as operator. This can be done in the same moment as he registers himself as user with the personal identity number. If the patient needs help with the testing it will instead be the PT-host that is registered as operator.

5.3 The Test Process

If the test process is structured from the patient's point of view, it could be divided in ten steps. This is however a simplified process that presupposes that the patient does not make any errors or have critical PT-value.

5.3.1 Step 1: Identifying

The identifying is, as mentioned before, performed by that the patient is scanning his personal identity number from the driving licence or any other identity card with a bar-code. If the patient for some reason lacks such a document, it must be possible to input the personal identity number through a keyboard on the screen.

5.3.2 Step 2: Verifying

The purpose of this step is to verify the identity of the patient. The patient's name along with the patient's personal identity number are displayed on the screen. The name is acquired by sending an inquiry to Declab. If the information is correct the patient moves on to the next step, otherwise he cancels the process and starts over from step 1. If the identifying fails several times, it could also be advisable that the patient is instructed to ask the PT-host for help.

5.3.3 Step 3: Information

In this step the patient is instructed to turn on the POC-device and begin the test. A suggestion is to also display a guide about how the instrument is used. Even if all patients using the self-service terminals have been trained to use them first, it must be taken into account that the patient may forget some of the moments. How the information should be displayed on the screen is a topic for further discussion. A problem will be that one screen probably couldn't hold all the information. The best would be if there was a way to determine which state the POC-device were in and change screen according to that. For instance the screen could start with displaying an instruction how to insert the test strip. After the stick has been inserted, it could switch screen and instead display an

instruction how to apply the blood. If it is possible to get any information about the state of the POC-device through the computer interface have to be tested.

5.3.4 Step 4: Starting the Instrument

The patient can start the instrument by pressing the power button. Problems could of course arise if the meter is defective or if the batteries are exhausted. This is preferably controlled by PT-host in advance, so the patients don't have to encounter it.

If the XS model used, there is also the risk that the patient accidentally starts the meter with the wrong button. In this case, the meter starts in either memory or set-up mode and the patient may need the help from PT-host to get the meter it in the correct mode again.

If instead the model XS Plus is used, the patient must after the meter is started select "Patient Test" in a menu. This could also cause the patient to accidentally press the wrong button and needs help to solve it.

After this step the instrument shows that the test strip should be inserted. How this is showed in the display differs a somewhat between the models.

In this step it is also recommended that the patient gets a lancet ready since the following steps are limited in time.

As an alternative to using power button, the meters can also be started by inserting a test strip. On the XS model, this is recommended because it will automatically start in the right mode. In this case step 4 and 5 becomes a common step in the process.

5.3.5 Step 5: Inserting Test Strip

The patient inserts a test strip in the instrument. If the test strips are kept in a container at the self-service terminals or if they are handed out to the patient before the test can be decided later. If they are kept at the self-service terminal, it is important that the patient closes the container after taking the test strip.

Otherwise the remaining test strips could to be damaged.

When the test strip is correctly inserted into the instrument, it is confirmed by a sound signal. If the test strip is too old or in any other way defect, an error message is display and it have to be replaced with a new one. This is a problem that the patient could resolve by himself if new test strips are available at the self-service terminal. But to do that the patient must be able to interpret the error message, which is not that easy to understand.

5.3.6 Step 6: Confirmation of Batch Number

This step is only needed for the XS model. Since this instrument is unable to read the batch number of the test strip, the code chip's batch number is showed in the display. If this matches the batch number of the test strip the patient proceeds by pressing the meter's M-button. Otherwise the code chip has to be replaced.

As mentioned before, the patient has no way of determine the batch number of a test strip. The number can only be found on the package in which the test strip is delivered. It may be better that the personnel ensure that test strips corresponding to the current code chip always are available at the self-service terminal. This avoids laying the responsibility of using the correct test strip on the patients. In this case the patient can just press the M-button and proceed. The best would of course be if the patient didn't have to press the button at all, but that would require reprogramming of the instrument's operative system.

Model XS Plus does not normally need this step, but if the required code chip is not available in the instrument's memory, the instrument shows which code chip is needed and wait until it is inserted. If the personnel ensure that the correct code chip always has been inserted, this will not be a problem.

5.3.7 Step 7: Heating of Test Strip

After the test strip is properly inserted and accepted by the instrument, it will be heated before the test can be performed. This takes about ten seconds.

5.3.8 Step 8: Applying Blood

When the test strip has been heated the instrument gives off a sound signal and begins to count down time. The patient has to apply blood on the test strip within 120 seconds. If the patient fails to apply enough blood in that time, an error message is displayed. When enough blood has been applied, the meter gives off a sound signal and changes the screen. After this, no more blood must be applied, as this may cause an incorrect result. The time limit for applying blood is considered to be sufficient for the patients. However some patient may experience the displaying of time counting down as stressful.

To achieve this step some training are required for the patient. The hard part in the moment is to get the right amount of blood from a finger. If you have too little blood the instrument cannot carry out the analysis. If you have too much, there is a risk that the drop of blood flows off the finger. The risk of spilling the blood also increases when the patient has decreased viscosity of blood due to medication with Warfarin. Spilled blood involves a risk of infection and also gives an unpleasant impression.

In order to avoid blood spillage some sort of disposable plastic protection could be used on the instrument. The protection should cover the instrument and the

table in front of it and be of sufficiently thick plastic to be shaped to fit around the instrument. It must also have a hole so the test strip can be inserted and be designed so that blood does not flow off from it.

5.3.9 Step 9: Result

The time required to analyse the blood sample varies according to PT value, but it will take a maximum of 30 seconds. When the analysis is complete, the result shows up on the instrument's display, but in order to acquire the result for further management, it must also be sent over to the self-service terminal's computer. The instruments do not automatically send the results through the computer interface when the measurement is complete. To guarantee that the result is transferred to Declab either the patient have to confirm that the test is finished or the computer have to determine it in some way.

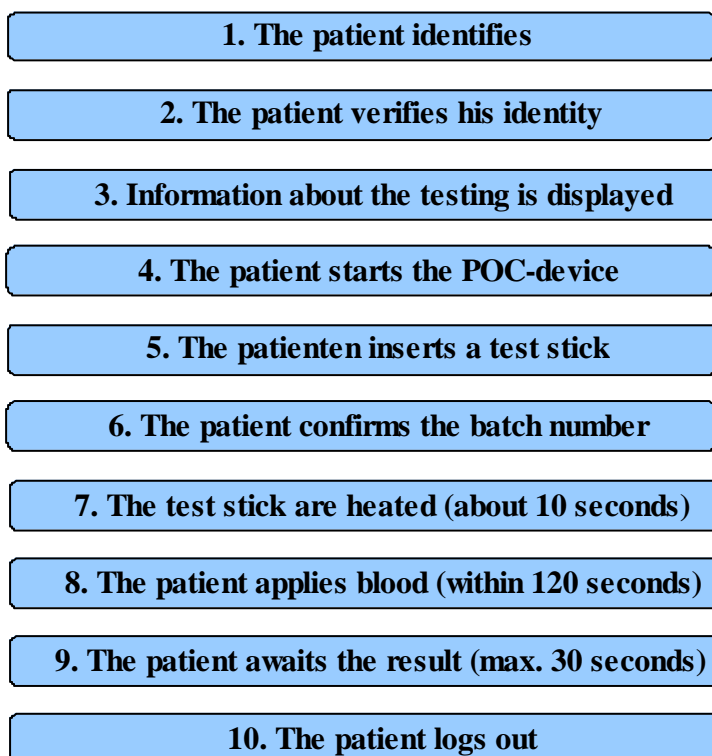
The risk that the patient forgets to confirm the results is significant. The patient will most likely consider to be informed about the result to be the goal of the test, not to insert the results in Declab. This makes it easy to forget any steps after the result is shown. [10] If the image on the touch screen also has been unchanged since step 3, the patient probably have focus on the instrument instead of the touch screen.

It would be better if the computer could check when the result is available. The only way of doing this is to set the computer to repeatedly inquire the instrument about new results. It has to be tested that this does not affect the operation of the instrument in any way.

If the results from testing would prove to be abnormally high or low, a re-testing is done. The computer application could determine which values are abnormal if this doesn't need to take into account previous PT values for the patient. The patient could then get instructions from the screen to do another test, i.e., start from step 3.

5.3.10 Step 10: Logout

When the patient gets the test result accepted by the computer application the testing is completed. In connection with that the patient signs out, it is advisable to instruct him to dispose the used equipment, i.e. the lancet, the protection for meter and test strip.



*Figure 9:
A model of the test
process for the self-
service terminals*

The most important problem with the self-service terminals is when the test instrument gets into wrong operation mode or in a state of error. Error messages consist of small icons and numbers that the patient cannot be expected to be able to interpret. Depending on which type of error there are, different kind of measures are required to solve it. In some cases it is sufficient to insert a new test strip, while other cases require assistance of PT-host. As long as the patient is unable to interpret the errors by himself, the PT-host is always needed.

If it is possible for the computer application to get information on when an error occurs, it could interpret the error, provide an explanation of the error in plain text and also inform about what action was required. This would make self-service terminals more effective because patients would not have to wait for help from the PT-host as often.

5.4 Choice of instrument

Neither of the two CoaguChek models are really designed for the type of self-testing that is described. However, both instruments could be used and have different advantages and disadvantages.

5.4.1 Usability

The user interface is different for the most part with respect to the display, where the XS Plus model with its larger, graphical display can show plainer pictures. The most important phase in the testing process is when the patient is to apply blood to the test strip, since the time for this is limited, and when the patient should stop applying blood, as continued blood supply gives an incorrect result.

In Figures 10 and 11 it is showed how the display change during these moments for each instrument.

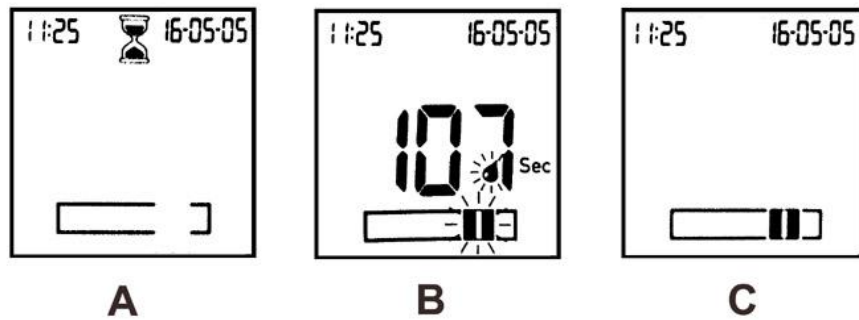


Figure 10: Display pictures from CoaguChek XS

A: The instrument is heating the test strip

B: The instrument awaits supplying of blood (radial strokes marks flashing segments)

C: A sufficient amount of blood has been supplied

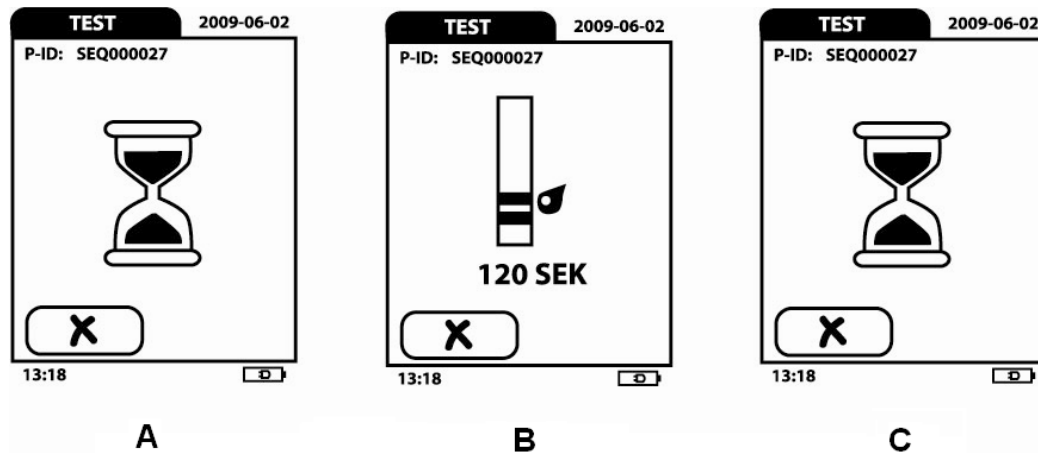


Figure 11: Display pictures from CoaguChek XS Plus

A: The instrument is heating the test strip

B: The instrument awaits supplying of blood

C: A sufficient amount of blood has been supplied

As you can see the model XS Plus has more distinct display images. The layout of the screen, however, still requires that the patient can interpret the icons. The most important are however to note when the screen changes, which is also indicated by a sound signal on both models.

It should also be noted that the XS Plus model is remarkably slower at booting and starting a test.

5.4.2 Recoverability

Both instruments have one phase in which there is a risk that the patient accidentally presses the wrong button. On the XS model, it is when the batch number of the test strip must be confirmed. If the patient presses the wrong

button this meter turns off instead of proceeding. This could easily be done because there is no logical reason that it is the button marked "M" that should be used. If that happens it is resolved by remove test strip and insert it again. For model XS Plus, it is when the instrument has been booted. The patient must then press the "PATIENT TEST" button in the main menu on the instrument. The risk of pressing the wrong button here are less likely because the button is placed on top of the screen and should be the most logical choice. If the patient would press the wrong button it is resolved by pressing the button to go back to the main menu. In both those cases, patients must realize that they have done something wrong and then also know how to solve it. It cannot be assumed that the patient is able to do that without help.

When applying the blood, there is also a risk that problems will arise. The most common error is assumed to be that the patient does not provide enough blood to test strip in time. In this case the test must be redone with a new test strip.

The XS Plus model is a bit clearer to show that an error has occurred, but the patient still needs to know how to solve the error.

5.4.3 Maintenance

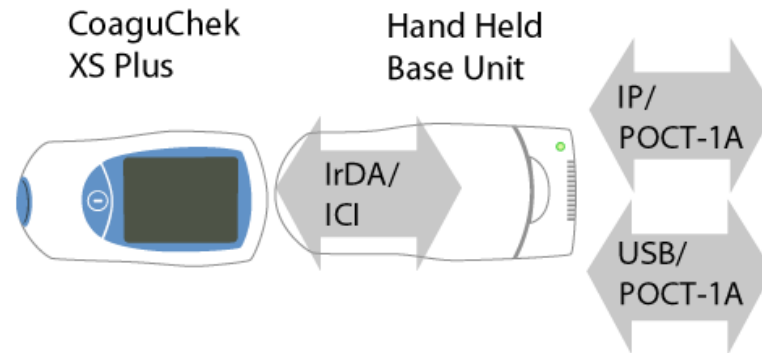
Both instruments require that the test strips are available and that the corresponding code chip are inserted in the instrument. Model XS Plus has the advantage that it automatically checks that the test strip and the code chip are from the same batch, it also saves the batch number in the test results. If the test strips from different batches for some reason are confused, there is no risk that this could cause incorrect results.

To get the same security with the XS model it is required to have proper routines for the handling of test strips. The easiest way is to only have test strips from a single batch at the self-service terminal at the same time and have the corresponding code chip connected to the instrument. When the test strips from a new batch is used, the code chip is replaced along with all the test strips. This could be taken care of by the PT-host.

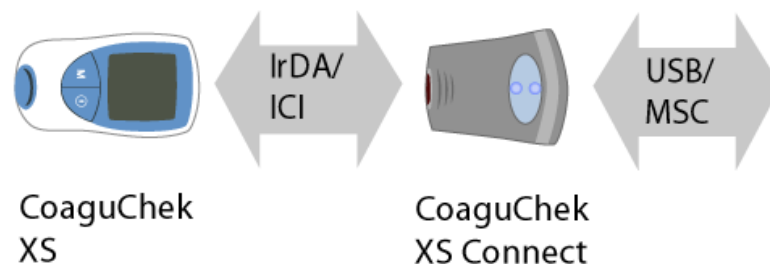
If better control of the self-service terminals and the test strips are required, the PT-host could be provided with a computer to monitor the self-service terminals via the network. If the PT-host registers when new test strips are added to a self-service terminal, the computer can show a reminder when the test strips have run out somewhere. By checking the amount of test strips each self-service terminal has used, it is also to a certain extent possible to detect if the test strips have been mixed. The computer could also show when an error has occurred at any of the instruments, presupposed that this information can be obtained through the instrument's computer interfaces.

When using the XS model, the batteries must be changed periodically. According to the user manual, about 60 measurements can be done with one set of batteries. If this model is to be used in the self-service terminals, it is recommended to replace the batteries with a battery eliminator. If using the XS Plus model, it may instead be placed into the docking unit and supplied with mains voltage.

5.4.4 Computer Interface



*Figure 12: The Computer interface of CoaguChek XS Plus
The connection between the instrument and the Handheld Base Unit is made through the ICI protocol.
The interface between the Handheld Base Unit and the computer supports only POCT-1A.*



*Figure 13: The Computer interface of CoaguChek XS
Also here are the ICI protocol cannot be reached from the computer.*

Both of the CoaguChek models have their computer interfaces physically separated in two steps. (Figure 12 and 13) The direct signal from the instruments is passed with IR communication through the ICI protocol. The signal is then converted with an adapter before it reaches the computer. The POCT1-A protocol, which is used by the XS Plus Model, is designed as a more general protocol which could be used also by other instruments. The possibility of controlling specific functions for the CoaguChek XS Plus is thereby not supported by it. [4]

Documentation of the CoaguChek XS Connect adapter for the XS model has not been available for the investigation. By studying its capability it can however be assumed that it only can use two of the functions of the ICI protocol: To receive data and to turn the instrument off.

As mentioned earlier, one important function for the self-service terminals is to be able to detect when errors have occurred on the instruments. To do this it must be able to use the full potential of the computer interface and communicating with the instrument through the ICI Protocol.

The operations that are desired by the computer interface and how they could be handled are listed below. The ICI protocol differs somewhat between the two models.

- Read the latest test result

This is a basic function supported by both instruments even when using the standard adapters.

- Determine in which state the instrument are.

This is required to change the information on the computer's touch screen during the test.

There are no documented functions for this for any of the devices. It may however be possible to get some information about the state by reading other data from the device, but this has to be confirmed through testing.

- Find out when an error has occurred

Model XS has a well developed system for recording errors. Reading error information from the instrument must however be initiated by the computer application. The easiest method of detecting an error in real time is to let the computer application reading the error information regularly and check if any new error has occurred. If this method can be used without affecting the test process in any way have to be examined.

Model XS Plus has no documented function of recording or reading errors.

- Find out when the instrument have performed a test properly

As with the error information, the instruments do not inform by automation when a test has been completed. This could be detected in the same way as described for the error information.

- Clear old test results from the memory

This function is also supported by both instruments.

Communication with the instruments through the ICI-protocol requires an adapter that converts the IR signal to a cable-transferred serial signal which can be interpreted by the computer. The IR-adapters that are available on the market can be separated in two groups depending on how they are treated by the computer's operative system. The first type is connected to the computers serial

port and can then be accessed directly through the corresponding COM-port in the OS. A COM-port is a software interface for serial ports integrated in Windows systems. The disadvantage with these adapters is that the production of them has been ceased. This is probably because they are considered as outdated. It also requires that the computer that is used is equipped with an rs-232 compatible serial port.

The second type is either integrated with the system or connected with USB. In newer Windows systems the API for these adapters are integrated with the OS and can only be used for file transfers. Sending raw serial data via the IrCOMM-protocol, which are required to use the ICI-protocol, are thus not possible. There have been uncommercial attempts of implementing IrCOMM also for newer Windows versions. [12] These drivers are however not fully stable and reliable.

Taking these facts into account none of the known adapters can be used for the self-service terminals. The alternatives are to either develop a customized adapter or modify the instruments so they can communicate through another medium.

A possible replacement for the IR-interface is to use Bluetooth. Bluetooth contains the RFCOMM-protocol which, similar to IrCOMM for IrDA, emulates a virtual rs-232 connection. [12][13] As long as Windows have an API for the RFCOMM protocol, it could be used for ICI.

Since Bluetooth uses radio waves for communication it is not blocked by solid objects as the IR-signal. This can also be to disadvantage if the communication is disturbed by other nearby Bluetooth devices. If Bluetooth are going to be used, it is thus important to secure the communication and don't use higher signal strength than required. Bluetooth is supported by practically all newer cell phones and portable computers. This is to great advantage if the testing with POC-devices should be utilized also at house calls during home-testing.

Implementation of Bluetooth for an electric device is usually done by equipping it with an interface circuit that converts the radio signals to electric signals and vice versa. If a Bluetooth interface is designed for the CoaguChek as an external adapter, this adapter has to be equipped with both interface circuits for IrDA and Bluetooth. The adapter also needs its own power supply.

If the CoaguChek device could be redesigned, it could be possible to remove its IrDA interface circuit and equip it with a Bluetooth interface circuit instead. Redesigning the instruments will probably also require it to be re-approved as a medical instrument.

5.4.5 Price

The XS Plus model is considerably more expensive than the XS model, around 10000 SEK, compared with 5000 SEK. Several of the features on the model XS Plus are also not useful in self-service terminals.

For the XS model there will also be a recurring cost for new batteries if they could not be replaced.

5.4.6 Conclusions

None of the instruments are optimized to be used by patients for testing at a hospital, but both can be used, at least for the standard procedure. To be used along with the planned self-service terminals, more operations than just reading the test result are required from the computer interface. This means that the communication has to be done through the IR interface. The greatest difference between the instrument's computer interfaces is that the XS Plus does not support error handling, which makes it unsuitable to use with the self-service terminal.

Also when taking the planned home testing into consideration the XS model is a better choice owing to its smaller size and weight. Avoiding different models at the self-testing and the home-testing would decrease the need of education.

Before the CoaguChek XS can be used its computer interface must be supplemented. Bluetooth seems at present to be the best alternative, but more investigation is required in this area.

5.5 Self Testing Compared with Present Routines

To install a self-service terminal at the test surgery would act in a similar as manning an extra adjacent room. The overall capacity of the surgery would increase. Unlike an adjacent room the self-service terminal can only be used by patients that should be tested for PT. This makes it harder to integrate them to the existing queue system. If a self-service terminal should be linked up to the queue, it must have information about which numbers belongs to patient who will be tested for PT. The best would be if the receptionist could set the numbers for the intended patient in the queue system.

One of the major advantages with the self testing is that the result is available immediately. For the patient to be able to receive a prescription however, a nurse must be in place. It could be possible that the same person is responsible as both PT-host and prescribing nurse. It may however be stressful to have to interrupt the prescriptions to help a patient.

Figure 14 shows an assessment of the resources required for PT-tests performed with the present routines at the test surgery. The values are calculated per test and

suggest that the cost for each PT-test is 32 SEK. The largest separate costs are the postage of the prescription letter and the salary for the assisting nurse.

A shortcoming of calculation of the salary is however that it assumes the personnel to work 100% of the time. Since this is impossible (and unethical) in practice, the salary cost will be somewhat higher than calculated.

A small increase of the cost will also arise for the analysis due to the samples which have to be validated manually. This is however only a small fraction of tests which would provide no significant impact to the final cost.

Moment:	Time:	Resources:	Price (SEK):	Note:
Wait for reception	2 min			
Registration in reception	0,5 min	Referral (1) Receptionist (0,5 min)	1,0 1,4	1
Wait for sampling	15 min			
Sampling	4 min	Cannula (1) Gloves (1) Vaccum tube (1) Nurse/BMA (4 min)	2,0 0,6 1,0 15,1	2
Wait for transport to lab	15 min			
Ttransport to lab	5 min	Personel (0,5 min)	1,9	2
Analysis	35 min	BMA (0,5 min) Maintenance of instruments Lost interest for instruments	1,9 1,0 0,3	2 3 4
Wait for ordination				
Prescription decided	0,5 min	Nurse (0,5 min)	1,9	2
Prescription sent to patient	12-24 h	Postage of letter (1)	4,0	
Total:	77 min + 12-24 h		32,1	

Figure 14:

An assessment of the resources required for the current test routines. All prices are calculated for one test.

Notes:

- 1) The cost for a receptionist is estimated to be 300000 for one year with 220 working days. [1]*
- 2) The cost for a nurse or MLS is estimated to be 400000 for one year with 220 working days. [1]*
- 3) The analysis is performed on two Sysmex instruments. The service for each of them is 70000/year. 145000 tests are run every year on the instruments, where 105000 (72%) of them are PT. [1]*
- 4) This cost the theoretical lost interest due to the investment in the test instrument instead of saving the money. The price for the instruments is 400000 each and the interest estimated to 5%. Also here it is taken into account that not all the tests are for PT.*

The estimated initial and current cost for self testing are displayed in figure 15 and 16. Since the self-service terminals are not implemented or tested, the values are still rather uncertain.

The assessment assumes there are 5 self-service terminals and that it will take in average 3 minutes for a patient to perform a test. According to this the maximum capacity for the self-service terminals are nearly two patients per minute. At that rate it could be hard for a single PT-host to keep up, if some problem occurs with the testing. Most of the time the patient flow will however not be that high.

	<u>Price (SEK):</u>	<u>Note:</u>
Hardware:		
Coaguchek XS	5 * 5000	
Touchscreen	5 * 8000	
PC	5 * 5000	
Barcode reader	5 * 3000	
Bluetooth adapter	5 * 2000	
Software:		
Application for testing	50000	1
Education:		
Patients:	159000	2
Personnel:	2270	3
Total:	306270	

*Figure 15:
Estimated price for purchase and installation of 5 self-service terminals.*

Notes:

1) Assumed that the application can be implemented by one full-time employee in two month.

2) There are planned to be two lessons for the patient, each 10 minutes. There are 3500 patients that are tested for PT of which 60% are assumed to be capable of self testing. [1]

A running cost for educating new patient will also appear.

3) The education for the personnel is calculated for one hour education with 1 instructor and 9 participants.

The highest cost for a PT-test performed with a self-service terminal is undoubtedly the test strip. The total cost for the test compared to the current method is slightly higher, but if the patient needs redo the test the cost is nearly doubled. The test has to be redone both if the result proves to be abnormal and if the patient fails to supply blood to the test strip.

The greatest benefits with self testing are for the patients. A capillary blood sample which requires less blood will be less unpleasant. The prescription will be available soon after the test is done and the waiting time for the sampling will also be decreased due to increased capacity at the surgery. Although the patient loses the social contact during the test he has instead the possibility to talk to the PT-host during the prescription.

Moment:	Time:	Resources:	Price (SEK):	Note:
Wait for reception	2 min			
Registration in reception	0,5 min	Referral (1)	1,5	
		Receptionist (0,5 min)	1,4	
Wait for sampling	15 min			
Sampling	3 min	Test strip (1)	30,0	
		Maintanance of instruments	1,0	1
		Lost interest for instruments	0,5	2
Prescription	0,5 min	Nurse (0,5 min)	1,9	3
Total:	21 min		36,3	

Figure 16:

An assessment of the resources required for the self-service terminals. All prices are calculated for one test.

Notes:

1) Maintenance for the self-service terminals and related equipment are estimated to be 10% of the hardware's value per year. That value is taken for 5 self-service terminals and 31200 tests/year. The number of tests per year is 60% of 1000 tests each week.

2) Same as note 4 in figure 14. The value is calculated with the total purchase and installation costs, 5% interest and 31200 tests/year.

3) A time which is not included in the figure is the time form when the result is sent to Declab until they are available in Auricula. This time are not known, but are assumed to not be long enough to have any significant influence on the total time.

6 Implementation

The software needed for the self-service terminals can be grouped into three parts: user interface, interface to the POC-device and interface to Declab. The implementation has focused on serial communication. A prototype application has been implemented which includes interface to Declab and interface to a POC-device called Contour. The Contour measures the glucose content in blood and are one of the most common device for that purpose in the region. In addition to that it is also interesting because its communication protocol is very similar to that of Declab. Performing glucose tests with self-service terminals is not requested from the hospital, the interface to the Contour could yet be applicable within home testing.

Since the documentation for the computer interfaces of the CoaguCheck devices were not available until a later stage of the project and much time were required for investigation of the IR communication, these could not be included in the prototype. The devices are however still of great importance for the project. How interaction with the devices can be performed through IR is summarized in section 6.3.

The prototype application is intended as a framework that could be expanded with user interface and support for more types of POC-devices.

6.1 C# Programming

As programming environment for the project, Visual Studio 2008 and C# was chosen. Applications written in C# can be compiled as intermediate code and executed by the .net run time system. .net is supported by newer Windows system and can thus be used on PCs, most PDAs, and some cell phones. A PDA is a type of compact, portable computer. Execution of .net application on PDAs and cell phones are done through a compact version of the runtime system with a decreased number of libraries and functions.

An alternative to C# could have been Java. Java uses a similar system with intermediate code and is supported by more different platforms than .net. An advantage with C# is that the Visual Studio environment makes the application development easy. Many libraries are included and have their documentation integrated. Graphical interfaces can also be designed without need of external tools.

6.1.1 Serial Communication

One important part of the programming is the serial communication. This is required both for the interface to a POC-device and for the interface to Declab. The .net framework includes two methods for this: serial ports and sockets.

The SerialPort class is an interface to the physical or virtual COM-ports of the system. When using a SerialPort object, a COM-port is assigned by stating its name. It can however only be assigned to a port which are unused by other applications.

The Socket library contains a number of classes to interface with the TCP sockets of the system. The socket is connected to a remote network unit by stating its IP number and the port that should be used. An incoming connection from another computer must also be accepted by the host before data can be transferred.

The communication through a SerialPort object is handled by an underlying Stream class. Since the TCP interface also could be controlled through a Stream object, using this is a good choice for implementing a protocol. When the protocol works with a stream the same methods can be used for both serial ports and TCP-connections. It makes also testing of the protocol easier.

The most basic methods of the Stream Class are read and write for receiving and transmitting data. When calling these methods the calling thread will be blocked until there are data to read, respectively when the data can be sent. A time-out can also be enabled causing the method to throw an exception if it cannot complete in the specified time.

6.1.2 User Interface

Programming of user interfaces is a bit different for the self-service terminals compared to a regular PC application. In general most of the input from the user is done through a mouse and a keyboard, which none of them is devices that the self-service terminals are equipped with. The equivalent devices for the self-service terminal would be the touch screen and the bar-code reader.

The touch screen similar function as a computer mouse, but it lacks some of the functionality of the mouse. It cannot identify more than one button, which means the scroll wheel and other buttons then the left one cannot be used. It is also impossible to detect if a button is pressed when moving the cursor over the screen. Finally, the touch screen has less precision than a mouse. The objects on the screen can thus not be too small or placed too close to each other.

For an application programmed in C#, the mouse and the touch screen are handled in the same way. It is thereby possible to use the mouse to test the application during the development.

A bar-code reader works like a keyboard in the way the information from it is handled by the computer. The software for interpreting the code are build into the reader, so the information sent to the computer are the bar-code in plain

numbers. The computer handle it as it were typed in on a numeric keyboard. In that way a keyboard can be used as a substitute for the bar-code reader during the development.

6.2 Interface to Bayer Contour Glucometer

The Contour is a small portable device supposed to be used by patients with diabetes. It is manufactured by Bayer. Many diabetics have their own device, but it is also used by nurses during house calls. The instrument is very small, only around 8 x 6 cm, and useful for that purpose.

Like the CoaguChek instruments, the Contour performs the analysis on capillary blood applied on a test strip. A batch dependant correction factor is also needed for an accurate analysis. This factor is stored on each test strip. Code chips or calibration of the device is thus not needed for different batches. The test strip is disposable and is discarded after the test is finished.

When the device has completed an analysis, the result is displayed at the screen and stored in the memory. The memory is limited to a maximum of 480 records.



*Figure 14:
The Contour POC-
device*

6.2.1 Computer Interface

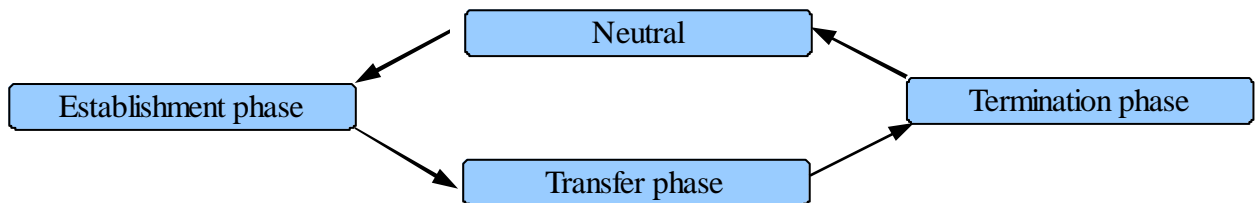
The computer interface of the Contour is build with a 3.5 mm RS-232 compatible serial connector. The instrument is delivered with an adapter cable, which is connected via USB to the computer. The cable contains interface circuits for the USB and mounts a virtual COM-port when connected and installed on a PC. The adapter cable maintains the same signal that are sent from the instrument, as if it were connected to a physical COM-port.

A computer application called “WinGlucofacts Professional” is also delivered with the instrument to receiving and managing the test result from the instrument. The application can read and erase the records on the Contour and also access the configuration settings. When reading test results from the Contour, the only choice is to receive all records simultaneously. The records are then treated as if they all were for the same patient. Along with the records also the meters model name and serial number are sent.

On the computer the records will be stored in a database file, formatted for the WinGlucofacts application. There is no useful way to copy the measured values for further use in other applications or to insert the value in Declab.

6.2.2 Communication Protocol

The communication between the Contour and a computer follows standards of communication between medical instruments and computer systems [8] to a large extent. This standard is based on four phases: neutral, establishment, transfer and termination, Figure 15. The standard is designed for half duplex and both systems must enter and leave a specific phase simultaneously. A number of rules and the use of special control characters ensure this, Figure 16.



*Figure 15:
The phases of the transmission session.*

Signal:	Code:	Description:
ACK	0x06	Acknowledgement
CR	0x0D	Carriage Return
ENQ	0x05	Enquiry
EOT	0x04	End of Transmission
ETB	0x17	End of Transmission Block
ETX	0x03	End of Text
LF	0x0A	Line Feed
NAK	0x15	Negative Acknowledgement
STX	0x02	Start of Text

*Figure 16:
Control Characters used for the communication protocol.
The hexadecimal code represents the ASCII-encoding of the character.*

A transmission session is started when one of the systems requests to send data. This is done by sending an enquiry character. If the other system is ready to receive, it responds with an acknowledgement character and both systems enter the transmission phase.

The data are sent in frames (Figure 17), which each contains a sequence number and a checksum. Each frame is confirmed by the receiver by sending an acknowledgement or negative acknowledgement character, depending on if the frame is correct or not. The frames are validated through their checksum, and are re-sent if they are defect. When all frame have been transferred, the systems enters the termination phase and then return to neutral state. The data is sent as 7-bit characters according to the ASCII character coding. The control characters are not allowed to be used for the information data.

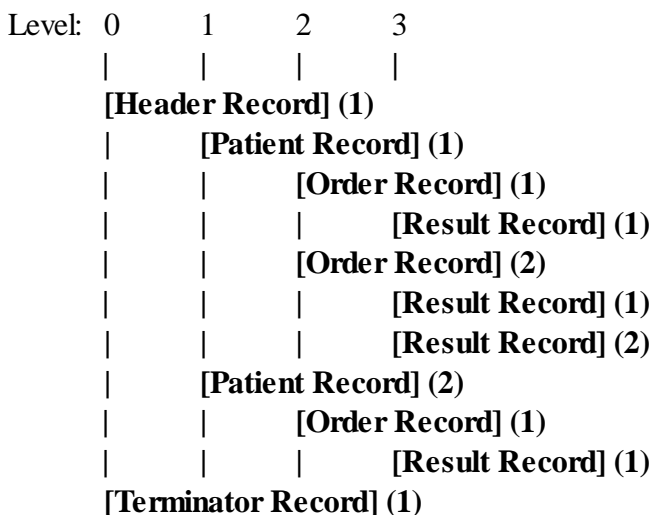
Description:	Length:	Explanation:
Start of Text	1	STX character (0x02).
Frame number	1	The ascii code for a number (0-7). The frame number are increased by 1 (modulo 8) when a new frame is sent.
Data	x	Any number of bytes containing the actual data.
Carriage Return	1	CR character (0x0D).
End of text/End of transmission block	1	ETX (0x03) if it's the last block of a transmission, otherwise ETB (0x17).
Checksum	2	The ascii representation of a 8-bit hexadecimal number. This is the 8 most significant bits of the sum of all previous characters in the block, except the initial STX.
Carriage Return	1	CR character (0x0D).
Line Feed	1	LF character (0x0A).

*Figure 17:
The structure for a data frame.*

The information is structured in a message consisting of a number of different records. A message always begins with a header record which contains a section with definitions of the delimiter characters that will be used in the rest of the message. Each record type has a number of specific fields separated by delimiter characters according to the definition. When the message is transferred all records are sent after one other, each starting in a new data frame.

The records in a message have a hierarchical system, showed in Figure 18, with each record type at a specified level. The records at level 0 are the header record and the terminator record, which ends all messages. At level 1 patient records and also scientific records and query records are included. Order records and result records are at level 2 respectively level 3. There are also comment records and manufacturer information records which can appear at any level. When the message is sent a record always belongs to the previous record of lower level.

The Contour uses the described message structure to send messages with measured result. It will constantly request to send information as long as the serial interface is active, i.e. when a cable is connected to its serial port.



*Figure 18:
An example of the message structure.
The numbers in parents is a sequence number used to distinguish between multiple consecutive records of the same type. They are thus specific for this example.*

Because of the limited size of the Contour's input buffer, it does not support receiving data according to the frame structure. When it receives a request to receive data, it instead enters a remote command mode (RCM). The RCM allows the computer system to read and make changes in the Contour's configurations. It is also possible to clear the memory. The commands consist of three parts separated by delimiter characters: address code, action code and data. The address code states which configuration that should be accessed and the action code whether it should read or write. The data is used for commands that write to the configuration memory. For commands that read data, this is returned in raw form and is not enclosed by a frame.

6.3 Interface to CoaguChek POC-devices

As mentioned in chapter 5.4.4 the communication with the CoaguChek devices has to be done through IrDA. Since there currently are no useful IR-adapters that could be used for the self-service terminals, the IR-interface has been investigated for the purpose of testing. To be able to communicate with the CoaguChek using a C#-application, the signal must be transferred to a COM-port or network connection in the computer.

As shown in figure 19 the optical IrDA signal differs from a standard RS-232 signal. The pulse width is much narrower for the IrDA and need to be a specific value. [5] Building an own IR-adapter would probably require a micro controller or an interface circuit to alter the pulse width.

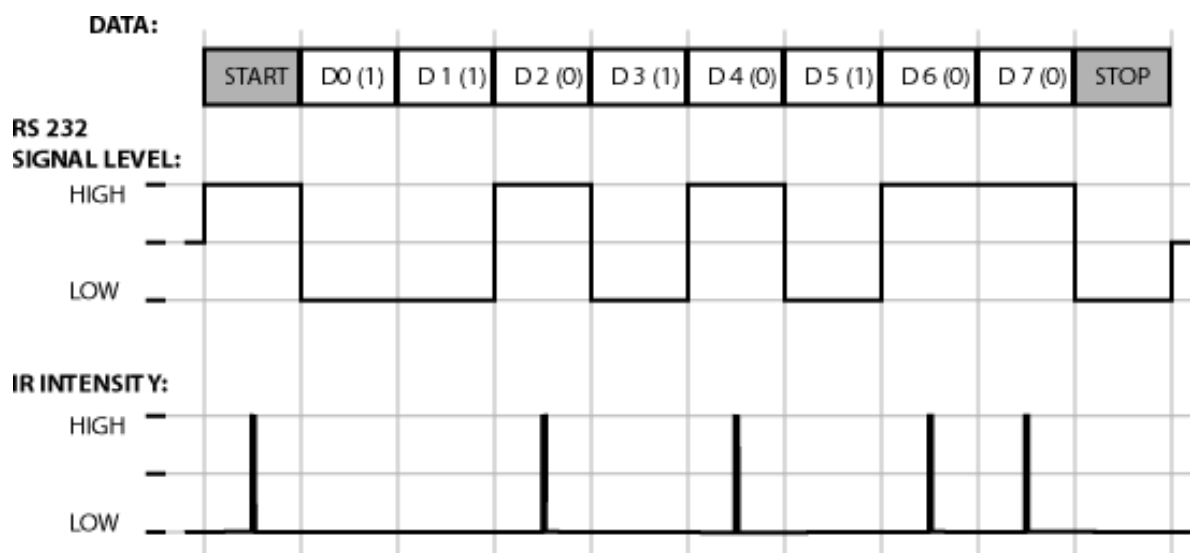


Figure 19:
The signal graph for a byte sent with serial RS-232 and by IrDA

In spite of the fact that the outdated IR/RS-232-adapters are hard to obtain, two of them were available for the investigation. The adapters are of different models and manufacturer, but appears to be technically equivalent. They have no

internal power source, but instead draw power from the serial port it is connected to. To be able to do this one or both of the serial port's DTR and RTS pins must be set to high. The combination also determines which baud rate the adapter operates at. [6]

For the application to be able to read the COM-port, it is also important to not allow the system install drivers for the adapter. Otherwise the COM-port resource will be blocked by the system.

The documentation of the ICI protocol that should be used to communicate with the CoaguChek instruments is licensed by Roche and cannot be described in this document.

6.4 Interface to Patient Record

As mentioned, there are two systems for patient records: Auricula, for PT-tests and Melior for general use. The result is transferred via Declab to those systems. For a self-service terminal at the test surgery, it would be best to transfer the test results directly to Declab in the same way as the instruments at the laboratory. Declab can be accessed via the local network from the entire hospital and also via a private network from other hospitals in the region. Accessing Declab from within the hospital does not require a login sequence, which makes the implementation easy.

If the system is expanded to also include home testing it is a bit more complicated. The idea is to send the test results via the 3G network using a PDA or cell phone. That would require a web server to communicate with at UMAS or any other hospital connected to the private network. That server would handle the communication with the PDA's for home testing and be connected to Declab to store the test results.

Another alternative is to instead connect the PDA's directly to the Auricula server. It is however not known if Auricula has any useful application interface that can be accessed via 3G. Auricula could also not be used if the system is going to be expanded to other tests, for instance glucose or hemoglobin, later on.

Either the test result is sent to UMAS or directly to Auricula, the application on the PDA has to access the private network at the hospital. This access is protected and the application has to implement the required security protocol. It may also be a good idea to control the access for each PDA from the server at the hospital. In that way a specific PDA can be completely blocked from the server if it gets lost or stolen.

6.4.1 Communication Protocol

The application interface to Declab uses the protocol similar to that described in chapter 6.2.2, but with a few differences. All data are sent in raw format without use of data frames. Since the communication is done through TCP/IP error detection are already included.

Sending a test result to Declab is performed by format it into a result record and send it along with the other records required for the message structure. If the message is correctly formatted the data will be inserted in Declab, otherwise it will be ignored. [3]

Data can also be acquired from the system by sending a message with a query record. The only information which can be obtained that way are however patient information. [3]

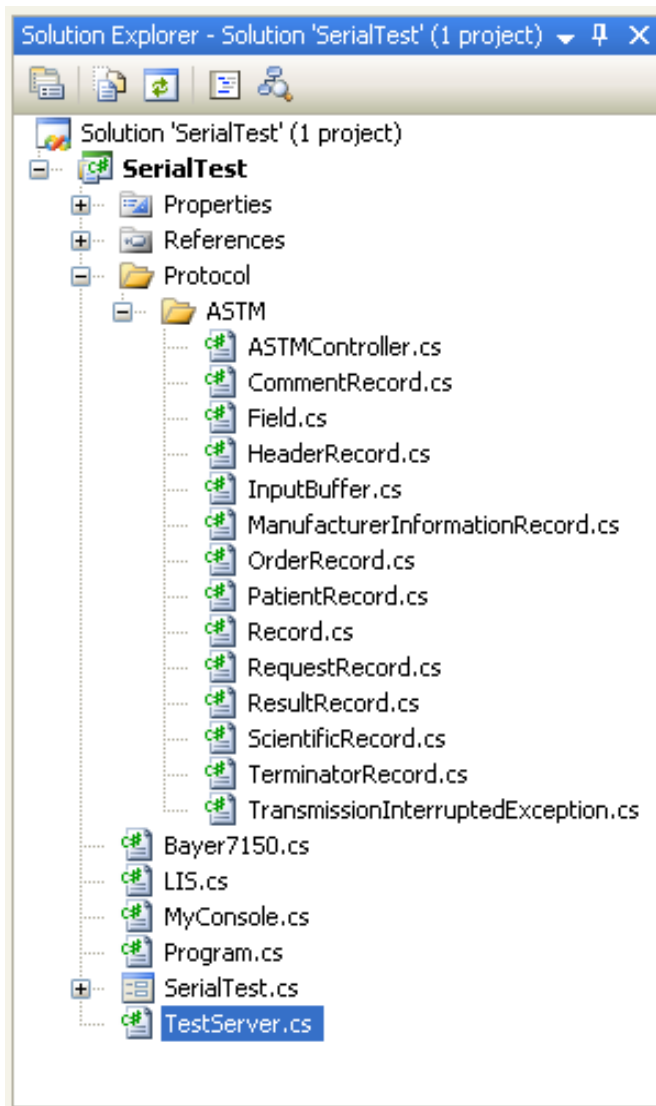
6.5 Prototype Implementation

A prototype application was implemented to test communication through serial ports and TCP. The prototype includes an implementation of the protocol, called ASTM, used by the Contour and Declab.

6.5.1 Structure

The ASTM implementation is based on the ASTMController class which includes methods for sending and receiving information. These methods are executed asynchronously and execute a callback function when a result is available or an error has occurred. The callback functions are stated as delegate type arguments when an ASTMController object is created. Delegate is a variable type that acts as a function pointer in C#. The InputBuffer are used as a help class for ASTMController for receiving data. It validates the incoming data frames and generates appropriate responses.

The Record classes are used for creating a data structure for the ASTM message. All of them are subclasses of the Record Class and their main difference is what fields they contain. The records are stored in the same hierarchical order as shown in figure 18 with the exception of the terminator record which also is stored at level 1. All messages are thus stored as a tree structure where each record have a list of references for each type of child records it can hold.



*Figure 20:
The classes of the prototype
application*

To create the records structure from a text message the Record class has a static parse method which scans through the message and returns the structure. Similarly there are an encode method which returns a record structure in the form of a text message. This method is recursive and will include the current record and all of its child records.

The actual data in the Records are stored in a list of Field objects. The data fields in an ASTM message may consist of different sets of component, so the Field class is based on a two dimensional list of Strings.

The classes LIS and Bayer7150 are device interfaces to Declab and the Contour. They implement methods for sending and receiving data by using the ASTM classes. The Bayer7150 also includes methods for the Remote Command Mode which is not a part of ASTM.

The class TestServer emulates some of the functions of Declab, making it possible to test the LIS class without access to the real one.

Expansion of the application is planned to be implemented with the same structure. Implementing support for the CoaguChek instruments would result in two device classes for the XS and XS Plus models and a new protocol name space for ICI. If the application should be used for home testing it would also require a new device class for Declab since the current supposes that the application is run within the hospitals network.

7 Result

According to the time study the time spent for a patient who is tested for PT at the surgery is between 10 and 30 minutes. The time study were performed at a time with a normal flow of patients, so the waiting time are expected to be longer than this in occasions with higher patient flow. Such occasions are for example at the beginning of the day when the surgery opens. The waiting time is also increased when the absence of personnel is high and the consulting rooms cannot be staffed properly.

The total time for testing and analysis is between 30 and 120 minutes. Also the time consumption at the laboratory varies depending on the load. This load is also affected by other factors because much work is performed there in addition to PT analyses. This is however not noticeable for the patients since the prescription letter doesn't reaches them until the next day.

Introducing of self-service terminals at the surgery would as expected increase the capacity in relation to personnel needed since one PT-host can supervise several terminals. How many terminals the PT-host can handle are however hard to decide without practical experiences.

For the patient the waiting time between reception and testing could be decreased. The load at the reception will however not be affected by the self testing, but since the patients have to wait 15 minutes before they can be tested anyway it is irrelevant if it's before or after the reception. The load at the laboratory would also be decreased since the self-service terminals do not generate any samples that should be analysed there.

Other benefits for the patients are immediate prescription and lesser need of blood for the sampling. If it's experienced as negative or positive to be assisted by a computer terminal instead of a human can however be discussed.

The self-testing is not shown to be more economically efficient compared to the present routines. This is exclusively because of the high maintenance cost of the POC-device, i.e. the test strips, which also is doubled if the patient needs to redo a test.

Most patients should be able to use the POC-device by themselves after some training. The hardest moment is to supply enough blood to the test strip. One problem is expected to be when the instrument gets into wrong operation mode or in a state of error. The patient then requires assistance from the personnel to resolve the error. The self-service terminals are most advantageous when the load at the surgery is high. At that time also more errors occur and thus the personnel

are more frequently needed. If the patients have to wait for help the self testing would be less effective. The solution is to let the self-service terminal's computer access the instrument's error information. It can in that way in most cases guide the patient to resolve the problem without need of personnel.

Of the two POC-devices that were studied only one of them, the CoaguChek XS, supported access to the error information. A disadvantage with this model is however that the management of the code chips for calibration is not as secure as for the XS Plus model. It therefore requires a more rigid management of code chips and test strips.

The computer interface to the CoaguChek instruments proved to be problematic. The instruments can be accessed either through an adequate protocol via IR or through restricted protocols via USB or TCP. Since there currently are no useful adapters for communication through IR, either the devices have to be redesigned or a new type of adapter has to be developed. Bluetooth are considered as appropriate replacement for the IR communication as long as it can be secured. Bluetooth are also useful during home testing where it allows the POC-device can be connected to a PDA or cell phone.

During the investigation of communication protocol of POC-devices a document of standards for such communication was studied ([8]). It proved to be mostly in accordance with the communication protocol of Declab and Bayer Contour. The CoaguChek instruments however use other communication protocols which are specific for these instrument, with exception of POCT1-A for the XS Plus model. Both the ASTM protocol used by Bayer Contour and POCT1-A are standard protocols that can be used by different types of POC-devices. It is however not known how widely used these are, for the CoaguChek devices the manufacturer Roche seems to have spent more effort on their own ICI protocol.

The ideal instrument for a self-service terminal would instead of having a user interface be completely controlled by the terminal computer. This would make it possible to design the user interface according to the situation in which it should be used. The CoaguChek instruments seem in some aspects have been developed for such purpose. The computer interface is relatively well developed although it does not allow complete control of the instrument. The user is still required to press buttons in order to perform a test. Roche are also licensing out the documentation of the computer interface to be used by external parties. It is however questionable why IR was chosen for the communication, since this considerably complicates implementation of systems interacting with the devices.

The implementation of the prototype application was performed in Visual Studio using C#. The language and development environment made it easy to implement the desired functionality. Support for communication through

network and serial ports are integrated in the framework and it were also possible to let a single protocol class communicate using both methods. The .net run time environment allows the application to be executed at PDA's and cell phones with .net support, which could be utilized if using the application for home testing. Visual Studio also includes useful tools for implementation of a graphical user interface.

The prototype application in its current state cannot be used for other purposes then testing. The classes implemented so far can however still be used after further completion of the application. There are currently three applications in which it is possible to use a completed version of the prototype. Except for the self-service terminals for PT-tests it is also possible to use it in home testing for PT or glucose tests. Using the system for home testing has been of interest by the hospital, but has not been further investigated in all aspects. There is however no sense of letting patients test themselves since personnel always are present. This creates different conditions for example, how the user interface should be designed. A major problem arising with the home testing is to access the hospital's network from outside in an adequate way.

Self testing with POC-devices in the respect investigated in this report could also be applied in other cases with similar clinical testing. Depending on the maintenance cost for the device needed it could also be economically beneficial. Even though the investigation focuses on details regarding the specific situation at clinical chemistry at UMAS the outcome could be of value for companies developing POC-devices and other hospitals.

8 Terminology

PT

Protrombin Time (PT) is a measure of how fast blood coagulates.

INR

International Normalized Ratio (INR) is a unit used when measuring PT.

Warfarin

A substance that reduces the blood's ability to coagulate.

Waran

A medicine based on Warfarin.

Declab

Declab is the name of a computer system used at the department of clinical chemistry at Malmö University Hospital. Declab is used to mediate and store information from the laboratory instruments.

HTTPS

Hyper Text Transfer Protocol Secure (HTTPS) is a protocol for transferring data for web pages over Internet. The protocol provides secure identification of the server and encryption of the transferred data.

Matrix Code

A two-dimensional bar code. The information is coded in a matrix of pixels instead of the bars as in the normal one-dimensional bar code.

POCT

Point of Care Testing (POCT) is diagnostic testing performed close to the patient. Unlike traditional laboratory testing POCT is performed with portable devices with fast access to the results.

POC-device

A medical device used for Point of Care Testing.

Self-service terminal

A machine where the user can perform a task without interaction with human actors. In this report it mainly refers to the self-service terminals that are planned for coagulation tests.

PT-host

The personnel who supervises the self-service terminals.

RFID

Radio Frequency Identification (RFID) is a technique to read information from electronic circuits using radio waves. The circuit, or RFID tag, can draw power from the radio waves when read and thus doesn't need any own power supply.

RS-232

RS-232 is a standard for serial communications. RS-232 is used for the PC's serial port, but are partly also used for low layer communication by IrDA and Bluetooth.

COM-port

A COM-port is the software representation for a serial port in Windows systems. COM-ports are not always connected to a physical port, but can also be virtual ports created for example by Bluetooth.

IrDA

Infrared Data Association (IrDA) is a standard for data transmission through Infrared light. IrDA were earlier used for wire-less connection of portable device to the PC, but are now almost completely replaced by Bluetooth.

IrCOMM

IrCOMM is a part of the IrDA standard which can emulate a virtual RS-232 connection.

RFCOMM

RFCOMM is a part of the Bluetooth standard which can emulate a virtual RS-232 connection.

PDA

Personal Digital Assistant (PDA) is a type of compact portable computer. PDAs are usually equipped with touch screen as primary user interface.

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